PI: **JENSEN, ROY A.**	Title: Cancer Center Support Grant	
Received: 09/21/2016	FOA: PAR13-386	Council: 05/2017
Competition ID: FORMS-D	FOA Title: CANCER CENTER SUPPORT GRANTS (CCSGS) FOR NCI-DESIGNATED CANCER CENTERS (P30)	
2 P30 CA168524-06	Dual:	Accession Number: 3971271
IPF: 1484303	Organization: UNIVERSITY OF KANSAS MEDICAL CENTER	
Former Number:	Department: Pathology & Lab Medicine	
IRG/SRG: ZCA1 SRC (99)	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 6: 1,539,999 Year 7: 1,539,998 Year 8: 1,539,997 Year 9: 1,539,998 Year 10: 1,539,999	Animals: Y Humans: Y Clinical Trial: N Current HS Code: 20 HESC: N	New Investigator: N Early Stage Investigator: N
Senior/Key Personnel:	*Organization:*	*Role Category:*
Roy Jensen MD	University of Kansas Medical Center	PD/PI

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	**State Application Identifier**

1. TYPE OF SUBMISSION*

❍ Pre-application ● Application ❍ Changed/Corrected Application

4.a. Federal Identifier
CA168524

b. Agency Routing Number

2. DATE SUBMITTED
2016-09-21

Application Identifier

c. Previous Grants.gov Tracking Number

5. APPLICANT INFORMATION **Organizational DUNS*:** 016060860

Legal Name*: University of Kansas Medical Center Research Institute, Inc.
Department:
Division:
Street1*: MSN 1039, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937

Person to be contacted on matters involving this application
Prefix: First Name*: Deborah Middle Name: Last Name*: Maloney Suffix: MSM
Position/Title: Director, Sponsored Programs Administration
Street1*: 3901 Rainbow Boulevard
Street2: Mail Stop 1039
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937
Phone Number*: 913-588-1261 Fax Number: 913-588-3225 Email: spa@kumc.edu

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 1-481108830-A3

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofit Organization
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*

❍ New ❍ Resubmission
● Renewal ❍ Continuation ❍ Revision

If Revision, mark appropriate box(es).
❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration
❍ D. Decrease Duration ❍ E. Other *(specify)* :

Is this application being submitted to other agencies?* ❍Yes ●No What other Agencies?

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Cancer Center Support Grant

12. PROPOSED PROJECT
Start Date* Ending Date*
07/01/2017 06/30/2022

13. CONGRESSIONAL DISTRICTS OF APPLICANT
KS-003

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name*: Roy Middle Name: A Last Name*: Jensen Suffix: MD

Position/Title: Professor
Organization Name*: University of Kansas Medical Center
Department: Pathology & Lab Medicine
Division: School of Medicine
Street1*: MS 3045, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66160-0000
Phone Number*: 913-588-4700 Fax Number: 913-588-4701 Email*: RJENSEN@kumc.edu

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	$11,783,197.00
b. Total Non-Federal Funds*	$0.00
c. Total Federal & Non-Federal Funds*	$11,783,197.00
d. Estimated Program Income*	$0.00

16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

a. YES ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR

○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: First Name*: Jamie Middle Name: Last Name*: Caldwell Suffix: MBA

Position/Title*: Assoc Vice Chancellor for Research Admin
Organization Name*: University of Kansas Medical Center Research Institute, Inc.
Department: Administration
Division: KUMC Research Institute
Street1*: 3901 Rainbow Blvd MSN 1039
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937
Phone Number*: 913-588-1261 Fax Number: 913-588-3225 Email*: spa@kumc.edu

Signature of Authorized Representative*
Jamie Caldwell

Date Signed*
09/21/2016

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:

424 R&R and PHS-398 Specific Table Of Contents

Component Summary

Components	Component Project Title	Organization Name	Contact PD/PI Name or Project Lead Name
Overall	Cancer Center Support Grant	University of Kansas Medical Center Research Institute, Inc.	Jensen, Roy A
Admin-Core-001 (001)	Cancer Center Administration & Senior Leadership Core	University of Kansas Medical Center Research Institute, Inc.	Christenson, Teresa
Core-001 (002)	Planning and Evaluation	University of Kansas Medical Center Research Institute, Inc.	Jensen, Roy A
Core-002 (003)	Developmental Funds	University of Kansas Medical Center Research Institute, Inc.	Jensen, Roy A
Core-003 (004)	Biospecimen Shared Resource	University of Kansas Medical Center Research Institute, Inc.	Godwin, Andrew
Core-004 (005)	Biostatistics & Informatics Shared Resource	University of Kansas Medical Center Research Institute, Inc.	Fridley, Brooke L.
Core-005 (006)	Clinical Pharmacology Shared Resource	University of Kansas Medical Center Research Institute, Inc.	Reed, Gregory A
Core-006 (007)	Lead Development & Optimization Shared Resource	University of Kansas Center for Research, Inc.	Baltezor, Michael J
Core-007 (008)	Transgenic & Gene-Targeting Shared Resource	University of Kansas Medical Center Research Institute, Inc.	Vivian, Jay L
Core-008 (009)	Clinical Protocol and Data Management	University of Kansas Medical Center Research Institute, Inc.	Williamson, Stephen
Core-009 (010)	Protocol Review and Monitoring System	University of Kansas Medical Center Research Institute, Inc.	Khan, Qamar Jamal
Core-010 (011)	Early Phase Clinical Research Support	University of Kansas Medical Center Research Institute, Inc.	Jensen, Roy A
Project-001 (012)	Cancer Biology Research Program	University of Kansas Center for Research, Inc.	Neufeld, Kristi
Project-002 (013)	Cancer Control & Population Health Research Program	University of Kansas Medical Center Research Institute, Inc.	Ellerbeck, Edward F
Project-003 (014)	CPS-Cancer Prevention & Survivorship Research Program	University of Kansas Medical Center Research Institute, Inc.	Dixon, Dan A.
Project-004 (015)	Drug Discovery, Delivery, & Experimental Therapeutics Research Program	University of Kansas Medical Center Research Institute, Inc,	Weir, Scott James

Project/Performance
Site Location(s) Summary

Applicant Organization	City	State/Province	Country
University of Kansas Medical Center Research Institute, Inc.	Kansas City	KS	UNITED STATES

Organization Name	City	State/Province	Country	Component
The Children's Mercy Hospital	Kansas City	MO	UNITED STATES	Project-004 (015)
University of Kansas Center for Research, Inc.	Lawrence	KS	UNITED STATES	Core-006 (007)
University of Kansas Center for Research, Inc.	Lawrence	KS	UNITED STATES	Project-001 (012)
University of Kansas Medical Center	Kansas City	KS	UNITED STATES	Admin-Core-001 (001)
University of Kansas Medical Center	Kansas City	KS	UNITED STATES	Core-001 (002)
University of Kansas Medical Center	Kansas City	KS	UNITED STATES	Core-002 (003)
University of Kansas Medical Center	Kansas City	KS	UNITED STATES	Core-003 (004)
University of Kansas Medical Center	Kansas City	KS	UNITED STATES	Core-004 (005)
University of Kansas Medical Center	Kansas City	KS	UNITED STATES	Core-005 (006)
University of Kansas Medical Center	Kansas City	KS	UNITED STATES	Core-007 (008)
University of Kansas Medical Center	Westwood	KS	UNITED STATES	Core-008 (009)
University of Kansas Medical Center	Kansas City	KS	UNITED STATES	Core-009 (010)
University of Kansas Medical Center	Kansas City	KS	UNITED STATES	Core-010 (011)
University of Kansas Medical Center	Kansas City	KS	UNITED STATES	Overall
University of Kansas Medical Center	Kansas City	KS	UNITED STATES	Project-002 (013)
University of Kansas Medical Center	Kansas City	KS	UNITED STATES	Project-003 (014)

University of Kansas Medical Center	Kansas City	KS	UNITED STATES	Project-004 (015)

Human Subjects
Clinical Trial
Human Embryonic Stem Cells
Vertebrate Animals
Summary

Components	Human Subjects	Clinical Trial	HESC Involved	Vertebrate Animals
Overall	Y	N	N	Y
Admin-Core-001 (001)	N		N	N
Core-001 (002)	N		N	N
Core-002 (003)	Y	N	N	Y
Core-003 (004)	Y	N	N	N
Core-004 (005)	Y	N	N	Y
Core-005 (006)	Y	N	N	N
Core-006 (007)	N		N	Y
Core-007 (008)	N		N	Y
Core-008 (009)	Y	N	N	N
Core-009 (010)	Y	N	N	N
Core-010 (011)	Y	N	N	N
Project-001 (012)	N		N	N
Project-002 (013)	N		N	N
Project-003 (014)	N		N	N
Project-004 (015)	N		N	N

Senior/Key Personnel
Summary

Name	Organization	Role on Project	Components
Jensen, Roy A	University of Kansas Medical Center	PD/PI(Contact)	Overall
Al-Rajabi, Raed	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Anant, Shrikant	University of Kansas Medical Center	Other: AD Prevention & Control	Admin-Core-001 (001)
Anant, Shrikant	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
August, Amanda	The Children's Mercy Hospital	Other: PRMC Committee	Core-009 (010)
August, Keith	The Children's Mercy Hospital	Other: PRMC Committee	Core-009 (010)
Baccaray, Stella	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Baltezor, Michael J	University of Kansas Center for Research, Inc.	Other: Core Lead	Core-006 (007)
Befort Cardador, Christie Ann	University of Kansas Medical Center	Other: Project Lead	Project-002 (013)
Behbod, Fariba	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Bivona, Cory	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Chalise, Prabhakar	University of Kansas Medical Center	Other: Biostatistician	Core-004 (005)
Chapman, Julia A	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Christenson, Teresa	University of Kansas Medical Center	Other: Core Lead	Admin-Core-001 (001)
Coster, James	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Coulter, James	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Diaz, Francisco J.	University of Kansas Medical Center	Other: Biostatistician	Core-004 (005)
Diaz, Francisco J.	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Dixon, Dan A.	University of Kansas Medical Center	Other: Project Lead	Project-003 (014)
Ellerbeck, Edward F	University of Kansas Medical Center	Other: Project Lead	Project-002 (013)
Fabian, Carol J	University of Kansas Medical Center	Other: AD Clinical Research	Admin-Core-001 (001)
Fridley, Brooke L.	University of Kansas Medical Center	Other: Core Lead	Core-004 (005)
Gajewski, Byron J	University of Kansas Medical Center	Other: Biostatistician	Core-004 (005)
Gamis, Alan	The Children's Mercy Hospital	Other: Project Lead	Project-004 (015)
Ginn, Kevin Fate	The Children's Mercy Hospital	Other: PRMC Committee	Core-009 (010)
Godwin, Andrew	University of Kansas Medical Center	Other: Deputy Director	Admin-Core-001 (001)
Godwin, Andrew	University of Kansas Medical Center	Other: Core Lead	Core-003 (004)
He, Jianghua	University of Kansas Medical Center	Other: Biostatistician	Core-004 (005)

He, Jianghua	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Hoelscher, Diana	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Jensen, Roy A	University of Kansas Medical Center	Other: Director	Admin-Core-001 (001)
Jensen, Roy A	University of Kansas Medical Center	Other: Core Lead	Core-001 (002)
Jensen, Roy A	University of Kansas Medical Center	Other: Core Lead	Core-002 (003)
Jensen, Roy A	University of Kansas Medical Center	Other: Core Lead	Core-010 (011)
Jewell, William R	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Khan, Qamar Jamal	University of Kansas Medical Center	Other: Core Lead	Core-009 (010)
Kimler, Bruce F	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Klemp, Jennifer Rose	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Klemp, Jennifer Rose	University of Kansas Medical Center	Other: Project Lead	Project-003 (014)
Koestler, Devin	University of Kansas Medical Center	Other: Biostatistician	Core-004 (005)
Larson, Melissa Anne	University of Kansas Medical Center	Other: Manager	Core-007 (008)
Lewis, Sharon	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Li, Linheng	Stowers Institute for Medical Research	Other: Project Lead	Project-001 (012)
Lominska, Chris	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Madan, Rashna	University of Kansas Medical Center	Other: Co-Director	Core-003 (004)
Mahnken, Jonathan David	University of Kansas Medical Center	Other: Biostatistician	Core-004 (005)
Maliski, Sally L	University of Kansas Medical Center Research Institute, Inc.	Other: AD Health Communications	Admin-Core-001 (001)
Mammen, Joshua M	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Mayo, Matthew Stuart	University of Kansas Medical Center	Other: AD Shared Resources	Admin-Core-001 (001)
Mirza, Moben	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Neufeld, Kristi	University of Kansas	Other: Project Lead	Project-001 (012)
Neupane, Prakash Chandra	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Ogle, Nikki	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Phadnis, Milind	University of Kansas Medical Center	Other: Biostatistician	Core-004 (005)
Reed, Gregory A	University of Kansas Medical Center	Other: Core Lead	Core-005 (006)
Reene, Jeff	University of Kansas Medical Center	Other: COO	Admin-Core-001 (001)
Roy, Anuradha	University of Kansas	Other: HTC Manager	Core-006 (007)
Ryan, Robin	The Children's Mercy Hospital	Other: PRMC Committee	Core-009 (010)
Schoenen, Frank J.	University of Kansas	Other: Mgr Med Chem	Core-006 (007)
Shune, Leyla	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)

Skikne, Barry	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Sullivan, Debra Kay	University of Kansas Medical Center	Other: PRMC committee	Core-009 (010)
Vivian, Jay L	University of Kansas Medical Center	Other: Core Lead	Core-007 (008)
Wang, Fen	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Ward, Jan	University of Kansas Medical Center	Other: PRMC Committee	Core-009 (010)
Weir, Scott James	University of Kansas Medical Center	Other: AD Trans Research	Admin-Core-001 (001)
Weir, Scott James	University of Kansas Medical Center	Other: Project Lead	Project-004 (015)
Welch, Danny	University of Kansas Medical Center	Other: AD Basic Science	Admin-Core-001 (001)
Wick, Jo Adrianne	University of Kansas Medical Center	Other: Biostatistician	Core-004 (005)
Williamson, Stephen	University of Kansas Medical Center	Other: Core Lead	Core-008 (009)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Roy A. Jensen, MD**

eRA COMMONS USER NAME (credential, e.g., agency login): jensenra

POSITION TITLE: Professor; Director of The University of Kansas Cancer Center

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Neosho Co. Community College, Chanute, KS	A.A.	1978	Biology/Chemistry
Pittsburg State University, Pittsburgh, KS	B.S.	1980	Biology/Chemistry
Vanderbilt University, Nashville, TN	M.D.	1984	Medicine
Vanderbilt University, Nashville, TN	Residency	1987	Anatomic Pathology
Vanderbilt University, Nashville, TN	Fellowship	1988	Surgical Pathology
National Cancer Institute, Bethesda, MD	Fellowship	1991	Biotechnology Training

A. Personal Statement

I was appointed director of The University of Kansas Cancer Center and the Kansas Masonic Cancer Research Institute (KMCRI) in 2004. I serve as Professor of Pathology and Laboratory Medicine, Professor of Anatomy and Cell Biology, Professor of Cancer Biology, Professor of Biomedical Engineering, and Adjunct Professor of Molecular Biosciences at the University of Kansas and was appointed the William R. Jewell Kansas Masonic Distinguished Professor of Cancer Research in 2005. As director of the Cancer Center, I oversee all aspects of the cancer program at the university including coordination, planning, analysis, administration, budget development, space and resource allocation, program development, recruiting, oversight of the clinical program, promotion of basic, clinical, transdisciplinary and translational research, and all cancer-related fundraising activities. Prior to accepting this position, I was an investigator at the Vanderbilt-Ingram Cancer Center, director of the Human Tissue Acquisition and Pathology Shared Resource, and was an Associate Professor of Pathology, Cell Biology, and Cancer Biology at Vanderbilt University. For the last twenty years, my research has focused on the molecular and cellular biology of breast cancer with a particular interest in BRCA1 and the characterization of premalignant breast disease.

My current research interests are centered on understanding the critical role of BRCA1 expression/function/dysfunction in normal and neoplastic breast epithelium. I am an active member of the Cancer Prevention and Survivorship program and the Breast Disease Working Group and have established a number of inter- and intra- programmatic collaborations focused on the role of BRCA1 in breast epithelial stem cells (Behbod, Anant, Harlan-Williams), BRCA1 miRNA regulatory mechanisms (Kumaraswamy), and molecular mechanisms of natural products in cancer prevention (Anant).

I also take an active interest in mentoring scientists on all professional levels. I serve as the primary mentor to graduate students and postdoctoral fellows in my laboratory and co-mentor for young investigators in other departments, and have recently graduated two M.D/Ph.D students from my laboratory (Shane Stecklein and Wenja Wang).

B. Positions and Honors

Positions and Employment:

1991-1996 Assistant Professor of Pathology, Vanderbilt U. Medical Center, Nashville, TN
1991-1996 Assistant Professor of Cell Biology, Vanderbilt U. Medical Center, Nashville, TN
1993-2002 Manager, Human Tissue Acquisition and Pathology Shared Resource, Vanderbilt-Ingram Cancer Center, Nashville, TN
1996-pres Associate Professor of Pathology, Vanderbilt U. Medical Center, Nashville, TN
1996-pres Associate Professor of Cell Biology, Vanderbilt U. Medical Center, Nashville, TN

2004-pres Professor of Pathology, University of Kansas Medical Center, Kansas City, Kansas
2004-pres Professor of Anatomy and Cell Biology, University of Kansas Medical Center, Kansas City, KS
2004-pres Director, Kansas Masonic Cancer Research Institute, University of Kansas Cancer Center, Kansas City, KS

Other Professional Experience:
1994 (July) Member (ad hoc), Medical Biochemistry Study Section, National Institutes of Health,
1995 (August) Member, National Action Plan on Breast Cancer-Special Review Committee, NIH
1997-1999 Grant Review Panel, Susan G. Komen Breast Cancer Foundation, Dallas, TX
1997 Member, Molecular Genetics Study Section, Department of Defense, Breast Cancer Research Program, Fort Detrick, MD
1997 Participant, National Cancer Institute, Breast Cancer Progress Review Group, Baltimore, MD
2000 Study Section Member (ad hoc), Reproductive Endocrinology Study Section, NIH
2002-2003 Panel Member (ad hoc), Department of Defense, Breast Cancer Research Integration Panel
2003-2006 Member, Breast Health Advisory Board, Susan G. Komen Breast Cancer Fdn. Dallas, TX
2003 (Oct) Member (ad hoc), Clinical Trials Study Section (H), NIH, Bethesda, MD
2007 (Sept) Member (ad hoc), SPORE Review Study Section**,** NCI, Bethesda, MD
2009 (Sept) Member (ad hoc), Cancer Genetics Study Section, NIH, Bethesda, MD
2009 (Oct) Member (ad hoc), Subcommittee A Cancer Centers Study Section, NIH, Bethesda, MD
2010 (Feb) Member (ad hoc), SPORE Review Study Section**,** NCI, Bethesda, MD
2011 (Feb) Member (ad hoc), SPORE Review Study Section**,** NCI, Bethesda, MD
2011 (Oct) Member (ad hoc), Subcommittee A Cancer Centers Study Section, NCI, Bethesda, MD
2014 (Oct) Member (ad hoc), Subcommittee A Cancer Centers Study Section, NCI, Bethesda, MD
2015- Member (regular), Subcommittee A Cancer Centers Study Section, NCI, Bethesda, MD

Honors, Awards and Professional Organizations:
1984 University of Arkansas, Midwest Student Medical Research Forum XV, First Place Award.
1984 John L. Shapiro Award for Excellence in Pathology, Vanderbilt University School of Medicine
2008 Gary J. Miller Memorial Award, American Association for Cancer Research.
2008 Outstanding Meritorious Alumnus, Pittsburg State University.
2009 Kansas Bioscience Big Thinker Award
2011 *Ingram's* Magazine, 50 Kansans You Should Know
2012 KC Magazine, 100 People Who Make Life Better
2013- Best Doctors in America
2013 American Association of Cancer Institutes, Board of Directors
2015 Kansas City Business Journal, Power 100-Movers and Shakers in Kansas City

C. Contributions to Science

1. **Characterization of BRCA1 as a tumor suppressor.** My laboratory in conjunction with the laboratory of Dr. Jeffrey Holt published a number of seminal papers characterizing the BRCA1 protein and provided the first direct *in vitro* and *in vivo* evidence that BRCA1 functions as a tumor suppressor. In addition, our laboratories demonstrated that abnormalities in BRCA1 are not limited to cases involving germline mutation of BRCA1, and that as many as 20 to 30% of sporadic breast cancers show decreased expression of BRCA1. In retrospect, it is clear that this fraction of sporadic breast cancers corresponded to the molecular subcategory of tumors now known as triple negative breast cancer. Our 1995 paper published in Nature Genetics thus represents one of the first molecular characterizations of this critically important type of breast cancer.
   a) Thompson ME, **Jensen** RA, Obermiller PS, Page DL, Holt JT. Decreased expression of BRCA1 accelerates growth and is often present during sporadic breast cancer progression. Nat Genet. 1995;9(4):444-50. PMID: 7795653.
   b) Holt JT, Thompson ME, Szabo C, Robinson-Benion C, Arteaga CL, King MC, **Jensen** RA. Growth retardation and tumour inhibition by BRCA1. Nat Genet. 1996;12(3):298-302. PMID: 8589721.
   c) **Jensen** RA, Thompson ME, Jetton TL, Szabo CI, van der Meer R, Helou B, Tronick SR, Page DL, King MC, Holt JT. BRCA1 is secreted and exhibits properties of a granin. Nat Genet. 1996;12(3):303-8. PMID: 8589722.
   d) Hoshino A, Yee CJ, Campbell M, Woltjer RL, Townsend RL, van der Meer R, Shyr Y, Holt JT, Moses HL, **Jensen** RA. Effects of BRCA1 transgene expression on murine mammary gland development and mutagen-induced mammary neoplasia. Int J Biol Sci. 2007;3(5):281-91. PMCID: PMC1865089.

2. **Characterization of BRCA1 as a multifunctional protein.** Following the discovery that BRCA1 was critically important in the homologous recombination DNA repair pathway, it is been determined that BRCA1 participates in a wide variety of critical cellular functions. My laboratory has made a number of discoveries regarding new functions of BRCA1. In conjunction with the laboratory of Edison Liu we determined that the growth arrest observed following expression of BRCA1 is critically dependent upon the presence of the retinoblastoma protein. We also demonstrated that BRCA1 binds the retinoblastoma protein and that this is critical for the growth arrest function of BRCA1.
   In addition, my laboratory in conjunction with Jeffrey Holt's laboratory demonstrated that restoration of BRCA1 expression in BRCA1 defective tumor cells is capable of fully restoring the DNA repair capability that is inherently absent in cells with mutated BRCA1. Subsequently it has been shown by a number of investigators that BRCA1 function can be restored following a second mutation in BRCA1 and that this mediates a restoration of DNA repair capability in tumors. This phenomenon has been most commonly observed in ovarian cancer and our 2012 publication in PNAS demonstrated that HSP 90 inhibitors can block expression of BRCA1 and eliminate the tumor's ability to repair DNA. We also demonstrated that BRCA1 is an HSP 90 client protein. This finding suggests that platinum resistance in ovarian cancers can be overcome by treatment with HSP 90 inhibitors. If this proves to be correct, this would represent a critically important therapeutic advance.
   Finally, recent work in our laboratory has demonstrated that BRCA1 is an important regulatory molecule that controls the expression of numerous microRNAs. In our 2014 Oncogene paper we specifically demonstrated that BRCA1 controls the expression of epidermal growth factor receptor through transcriptional regulation of microRNA-146a. This work helps to explain the longstanding observation that epidermal growth factor receptor is frequently overexpressed in triple negative breast cancers that lack expression of BRCA1 and suggests a molecular mechanism by which triple negative breast cancers might be targeted.
   a) Aprelikova ON, Fang BS, Meissner EG, Cotter S, Campbell M, Kuthiala A, Bessho M, **Jensen** RA, Liu ET. BRCA1-associated growth arrest is RB-dependent. Proceedings of the National Academy of Sciences of the United States of America. 1999;96(21):11866-71. PMCID: PMC18378.
   b) Abbott DW, Thompson ME, Robinson-Benion C, Tomlinson G, **Jensen** RA, Holt JT. BRCA1 expression restores radiation resistance in BRCA1-defective cancer cells through enhancement of transcription-coupled DNA repair. J Biol Chem. 1999;274(26):18808-12. PMID: 10373498.
   c) Stecklein SR, Kumaraswamy E, Behbod F, Wang W, Chaguturu V, Harlan-Williams LM, **Jensen** RA. BRCA1 and HSP90 cooperate in homologous and non-homologous DNA double-strand-break repair and G2/M checkpoint activation. Proceedings of the National Academy of Sciences of the United States of America. 2012;109(34):13650-5. PMCID: PMC3427093.
   d) Kumaraswamy E, Wendt KL, Augustine LA, Stecklein SR, Sibala EC, Li D, Gunewardena S, **Jensen** RA. BRCA1 regulation of epidermal growth factor receptor (EGFR) expression in human breast cancer cells involves microRNA-146a and is critical for its tumor suppressor function. Oncogene. 2015 Aug 13;34(33):4333-46. PMID: 25417703, PMCID: PMC4739738.

3. **Pathology of Premalignant Breast Disease.** In collaboration with David Page, William DuPont, Jean Simpson, and Lowell Rogers, I was an integral member of the Vanderbilt Breast Pathology group, which played a critical role in the characterization of premalignant breast disease and has essentially helped define the breast cancer risk inherent in a wide variety of histologic lesions of the breast. This group has provided seminal data regarding the relative risks for the subsequent development of invasive breast carcinoma from ductal carcinoma in situ, lobular carcinoma in situ, atypical ductal hyperplasia, atypical lobular hyperplasia, usual hyperplasia, intraductal papilloma's, sclerosing adenosis, papillary apocrine change, fibroadenomas, and a wide variety of other histologic lesions of the breast. I have also was a key participant in the NCI sponsored workshop on the characterization of mammary lesions in genetically engineered mice and was one of them primary authors for the definitive paper which described the first comprehensive assessment and classification for mouse mammary tumors in genetically engineered mice.
   a) **Jensen** RA, Page DL, Dupont WD, Rogers LW. Invasive breast cancer risk in women with sclerosing adenosis. Cancer. 1989;64(10):1977-83. PMID: 2804888.
   b) Page DL, Dupont WD, Rogers LW, **Jensen** RA, Schuyler PA. Continued local recurrence of carcinoma 15-25 years after a diagnosis of low grade ductal carcinoma in situ of the breast treated only by biopsy. Cancer. 1995;76(7):1197-200. PMID: 8630897.
   c) Cardiff RD, Anver MR, Gusterson BA, Hennighausen L, **Jensen** RA, Merino MJ, Rehm S, Russo J,

Tavassoli FA, Wakefield LM, Ward JM, Green JE. The mammary pathology of genetically engineered mice: the consensus report and recommendations from the Annapolis meeting. Oncogene. 2000;19(8):968-88. PMID: 10713680.

d) Page DL, Schuyler PA, Dupont WD, **Jensen** RA, Plummer WD, Jr., Simpson JF. Atypical lobular hyperplasia as a unilateral predictor of breast cancer risk: a retrospective cohort study. Lancet. 2003;361(9352):125-9. PMID: 12531579.

4. **Molecular Characterization of Breast Neoplasia.** My laboratory has also been involved in the molecular characterization of human and rodent mammary carcinoma and premalignant breast lesions. The PNAS paper published in 1994 described one of the first techniques for microdissection of specific histologic lesions in the mammary gland that would enable subsequent molecular characterization. In addition, my laboratory in conjunction with Dr. Richard Caprioli's laboratory was the first to apply scanning mass spectrometry for the proteomic analysis of pathologic lesions in human tissues. These techniques and immunohistochemical analysis were then applied to characterize a wide variety of premalignant breast lesions. A representative sample of the studies is shown below, but a complete listing is found in the URL at the end of this section.

a) **Jensen** RA, Page DL, Holt JT. Identification of genes expressed in premalignant breast disease by microscopy-directed cloning. Proceedings of the National Academy of Sciences of the United States of America. 1994;91(20):9257-61. PMCID: PMC44791.

b) Heppner KJ, Matrisian LM, **Jensen** RA, Rodgers WH. Expression of most matrix metalloproteinase family members in breast cancer represents a tumor-induced host response. Am J Pathol. 1996; 149(1):273-82. Epub 1996/07/01. PMCID: PMC1865221.

c) Chaurand P, Sanders ME, **Jensen** RA, Caprioli RM. Proteomics in diagnostic pathology: profiling and imaging proteins directly in tissue sections. Am J Pathol. 2004;165(4):1057-68. PMID: 15466373.

d) Gobbi H, Arteaga CL, **Jensen** RA, Simpson JF, Dupont WD, Olson SJ, Schuyler PA, Plummer WD, Jr., Page DL. Loss of expression of transforming growth factor beta type II receptor correlates with high tumour grade in human breast in-situ and invasive carcinomas. Histopathology. 2000;36(2):168-77. PMID: 10672063.

5. **Characterization of Human S100 Protein.** S100 was initially identified in extracts of central nervous system tissues as a calcium binding protein with a classic EF hand structural motif similar to calmodulin. Its function was not known at the time, but it appeared to be a useful marker of cells from the neural crest. My work in the Watterson and Van Eldik laboratories provided the initial characterization of the S100 protein family in human brain including the amino acid sequence of S100β, the major component of the S100 fraction. Subsequently, we developed and characterized the first monoclonal antibodies specific for S100β and utilized these monoclonals in an immunohistochemical assay, which I developed to establish the initial expression profile of S100β in a series of central and peripheral nervous system tumors. The three papers listed below were foundational in terms of characterizing the expression of S100β in human tissues of neural crest origin and in demonstrating the utility of S100 antibodies as a diagnostic agent.

a) **Jensen** R, Marshak DR, Anderson C, Lukas TJ, Watterson DM. Characterization of human brain S100 protein fraction: amino acid sequence of S100 beta. Journal of neurochemistry. 1985;45(3):700-5. PMID: 4031854.

b) Van Eldik LJ, Ehrenfried B, **Jensen** RA. Production and characterization of monoclonal antibodies with specificity for the S100 beta polypeptide of brain S100 fractions. Proceedings of the National Academy of Sciences of the United States of America. 1984;81(19):6034-8. PMCID: PMC391853.

c) Van Eldik LJ, **Jensen** RA, Ehrenfried BA, Whetsell WO, Jr. Immunohistochemical localization of S100 beta in human nervous system tumors by using monoclonal antibodies with specificity for the S100 beta polypeptide. J Histochem Cytochem. 1986;34(8):977-82. PMID: 3734419.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/roy.jensen.1/bibliograpahy/45795373/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

P30 CA168524 Jensen (PI) 07/01/2012 - 06/30/2017

Cancer Center Support Grant (CCSG)
Major Goals: The University of Kansas Cancer Center is a growing matrix organization that aims to leverage unique scientific assets to build a nationally significant cancer research and treatment center that will become the leading academic institution in the world for transforming discoveries in the laboratory into new therapeutic power one part one approaches.

P30 CA168524 – suppl. Jensen (PI), Cupertino(Project PI) 07/01/2015 - 06/30/2017
NIH
CCSG Suppl: E-Decidete: Mobile Cessation Support for Latino Smokers in Mexico
Major Goals: To develop a text-message system to supplement and support the 'Vive sin taboco...!Decidete!' tablet-based smoking cessation software in Mexico.

Completed Support (selected):

CCR13261859 Cheng (PI) 08/16/2013 - 08/15/2016
Susan Komen Foundation
Molecular Switching of DCIS to invasive carcinomas by CCR2 Chemokine Receptors
Major Goals: The objectives are to characterize the mechanisms through which CCL2/CCR2 signaling in breast cancer cells regulate ductal carcinoma progression and determine an association between CCL2/CCR2 signaling in DCIS and development of IDC.
Role: Mentor

F30 DK094532 Venugopal (PI) 09/01/2011 - 08/31/2016
NIH
RNA Binding Proteins and Intestinal Stem Cells
Major Goals: To reveal a mechanism by which RBM3 increases a stem-like phenotype within a heterogenous cell population and how RBM3 induced stem cell phenotype generates resistance to radiation.
Role: Mentor

P30 CA168524 – suppl. Jensen (PI) 07/01/2013 - 06/30/2015
NIH
CCSG Suppl: To support the Clinical Trial Reporting Program Admin. Suppl.
CTRP funds will be used to facilitate the transition of CTRP reporting into ongoing Cancer Center activities by supporting additional data entry, quality assurance and technical enhancements pertaining to our clinical trials management system.

R03 MH093215 Harlan-Williams (PI) 12/06/2010 - 11/30/2013
NIH
HTS Assay to Identify Small Molecule Activators of BRCA1 Expression
Goals: Primary screen - BRCA1 promoter-driven Firefly luciferase reporter construct stably expressed in MCF7 cells Counterscreen - BRCA1 promoter-driven Renilla luciferase reporter construct stably expressed in MCF7 cells and Luciferase inhibitor screen performed by Doug Auld, PhD and colleagues at NCGC, Secondary screen - Western blot analysis for BRCA1 protein expression
Role: Co-investigator

BC100441 Stecklein (PI) 11/01/2010 – 11/30/2012
Department of Defense
Predoctoral Traineeship Award
Role of BRCA1 in Regulating EMT and Cancer Stem Cell Fate in Basal-like Breast Cancer
Role: Mentor

BC060196 David (PI) 01/01/2007 - 12/31/2010
DOD-BCRP IDEA award
A Method for Identifying Targets of E3 Ubiquitin Ligases
Role: Co-investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Raed Al-Rajabi, MD**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Assistant Professor of Internal Medicine

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Jordan, Amman, Jordan	M.B.B.S.	06/1998	Medicine
Al Bashir Hospital, Amman, Jordan	Internship	06/1999	Internal Medicine
Pediatrics, Jordan University Hospital, Amman, Jordan	Resident	06/2000	Pediatrics
Internal Medicine, Case Western Reserve University (St. Vincent Charity/St. Luke's Medical Center) Program, Cleveland, OH	Resident	06/2003	Internal Medicine
Case Western Reserve University (St. Vincent Charity/ St. Luke's Medical Center) Program, Cleveland, OH	Chief Medical Resident	06/2003	Internal Medicine
University of Texas Health Science Center, San Antonio, TX	Fellowship	06/2013	Hematology/Oncology

A. Personal Statement

I have been involved in clinical trials research since my oncology fellowship in 2013. I have been actively involved in clinical trial development locally and nationally through the Southwest Oncology Group. I have also been active in the early therapeutics and rare cancers Committees of the Southwest Oncology Group since 2014. I am the local PI on several multi-institutional pharmaceutical trials conducted at KU. I chair the GI Cancer disease working groups and help in developing investigator initiated clinical trials.

B. Positions and Honors

Positions and Employment:

2003 – 2006 Internal Medicine Physician, Physician In-Home Services, PC, Flint, MI
2006 – 2009 Internal Medicine Residency Clinic Preceptor, The Family Ambulatory Clinic, Hurley Medical Center, Flint, MI
2006 – 2009 Core Internal Medicine Residency Faculty, Hurley Medical Center, Flint, MI
2007 – 2008 Clinical Instructor, State University College of Human Medicine, Department of Internal Medicine, Lansing, MI
2007 – 2009 Physician Advisor for Hospital Utilization Review, Hurley Medical Center, Flint, MI
2008 – 2009 Advanced Medicine 4th Year Medical Student Clerkship Director, State University College of Human Medicine, Department of Internal Medicine, Lansing, MI
2008 – 2009 Assistant Professor of Medicine, Michigan State University College of Human Medicine, Department of Internal Medicine, Lansing, MI
2009 – 2010 Assistant Professor, Hospitalist, University of Texas Health Science Center, Division of Hospital Medicine, San Antonio, TX
2013 – Pres. Assistant Professor of Medicine, University of Kansas Medical Center, Kansas City, KS
2014 – Pres. Medical Director Advanced Clinical Information System (ACIS), University of Kansas Medical Center, Kansas City, KS

Honors and Awards:

1993 – 1998	Full scholarship from The University of Jordan for Bachelor's Degree in Medicine
2003	St. Luke's Medical Center Resident of The Year, KCMO
2003	St. Vincent Charity Hospital Aadel Askari Memorial Award
2007	Hurley Medical Center Golden Apple Award
2008	Hurley Medical Center Ronald E. Esterling Award for outstanding teaching skills and dedication to Internal Medicine

Other Professional Activities:

2000 – 2009	The American Medical Association, Associate Member, National
2006 – 2009	Michigan State Medical Society, Regional
2006 – 2009	Genesee County Medical Society, Local
2011 – Pres.	American Society of Hematology, National
2011 – Pres.	American Society of Clinical Oncology, National

C. Contributions to Science:

As a practicing physician, I've been involved in oncological studies and co-authored several publications.

1. I was a co-investigator in a prospective trial looking at the risk factors of chemotherapy induced nausea vomiting, assisting in the study protocol and enrolling patients.

    a. Sarhill N, Al-Shahed A, Christie R, Naqvi S, **Al-Rajabi R**. Are there any risk factors for chemotherapy-induced nausea, vomiting, early satiety, and retching? American Society of Clinical Oncology, May 18-21, 2002

2. I was a co-Investigator in a retrospective clinical trial looking at a population in south southern Texas with hepatocellular carcinoma. In this project, I assisted in building an ongoing database of patients with hepatocellular carcinoma, who were treated at the cancer therapy and research Center San Antonio Texas.

    a. **Al-Rajabi R,** Ketchum N, Dierschke N, Lu T, Pollock B, Mahalingam D. Comparative efficacy and safety analysis of Sorafenieb in patients with advanced Hepatocellular Cancer (HCC) with varying liver dysfunction: A South Texas institutional analysis. J Clin Oncol 31, 2013 (suppl; abstr e15171) (PMC# not required; not NIH funded)
    b. **Al-Rajabi R,** Patel S, Ketchum NS, Jaime NA, Lu TW, Pollock BH, Mahalingam D. Comparative dosing and efficacy of sorafenib in hepatocellular cancer patients with varying liver dysfunction. J Gastrointest Oncol. 2015 Jun;6(3):259-67. PMC4397242.
    c. Hines RB, **Al-Rajabi R.** Reply to the letter to the editor 'A randomized trial of intensive versus minimal surveillance of patients with reseted Dukes B2-C colorectal carcinoma' by Rosati et al. Ann Oncol. 2016 May;27(5):957-8. PMID: 26811349

Link to complete list of publications:
http://www-ncbi-nlm-nih-gov.proxy.kumc.edu:2048/sites/myncbi/1lqdkMeavmdAj/collections/49590694/public/

D. Research Support:

Ongoing Research Support:
N/A

Completed Research Support:
N/A

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Shrikant Anant, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): SANANT3

POSITION TITLE: Professor of Molecular and Integrative Physiology
Associate Director of Prevention and Cancer Control, NCI-designated University of Kansas Cancer Center

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Madras, India	B.S.	1978-1981	Zoology
University of Madras, India	M.S.	1981-1984	Medical Microbiology
Michigan State University, East Lansing, MI	M.S.	1984-1986	Microbiology
University of Illinois at Chicago, IL	Ph.D.	1987-1993	Molecular Genetics

A. Personal Statement

I am the Associate Director of Cancer Prevention and Control for The University of Kansas Cancer Center at The University of Kansas Medical Center (KUMC). I started at KUMC in July 2010. As the Associate Director, I am in charge of overseeing the program and working with the program leaders Dan Dixon and Jennifer Klemp (both from the CP program) in further developing and testing prevention interventions likely to be used by high and moderate risk individuals and cancer survivors. I am also responsible with being the liaison between Edward Ellerbeck and Christie Befort and the CCPH program and the senior leadership of the Cancer Center. In this role, I meet with Ellerbeck and Befort on a regular basis to discuss the work being performed by the program members. I have been actively working with Ellerbeck in identifying areas of research related to screening studies in the Native American and rural population. I am discussing developing such programs with Allen Greiner about his funded project related to colon cancer screening of native populations. There is a mutual interest in developing a program related to cancer stem cell markers, which can be utilized in the rural population. In addition to these roles and responsibilities, I am tasked with developing additional disease sights. In this regard, I have started a program in colorectal cancer prevention and am in the process of developing programs in bladder cancers. Moreover, I am a member of the Protocol Review and Monitoring Committee (PRMC), a committee that establishes a mechanism of scientific review and oversight of that research and gives authority to that mechanism. In this committee, I am tasked with ensuring scientific excellence with the protocols, and establish their relative priority to the mission if the cancer center.

I received my Ph.D. in Molecular Genetics from the University of Illinois at Chicago in 1994. Prior to joining the cancer center, I led the gastrointestinal cancers program at the University of Oklahoma Cancer Institute. I also served as director of gastroenterology research at the University of Oklahoma Health Science Center. In this capacity, I met with members of the state legislature and helped pass a bill for funding screening the Native American population of the state. Among many achievements during my career, my research team and I have discovered the protooncogene RBM3. This is the first RNA binding protein to be identified to be a protooncogene, which when overexpressed converts a normal cell to a cancer cell. Inhibiting the expression of this protein in cancer cells using specific silencer RNA caused the cells to undergo mitotic catastrophe. In addition, my team and I discovered the first tumor suppressor RNA-binding protein CELF2. The protein is ubiquitously expressed but is significantly downregulated in cancers, thereby protecting the cells from mitotic catastrophe. Another significant area of research in Anant's group is in understanding the mechanisms by which chemopreventive agents inhibit the growth and development of chemopreventive agents. I have been instrumental in demonstrating that the natural chemopreventive agent curcumin, an active ingredient in the spice turmeric, inhibits cyclooxygenase-2 and vascular endothelial growth factor expression by inhibiting the translation of their mRNA. I was also the first to demonstrate that the compound not only affects gene

transcription but also affects the translation of pro-oncogenic and anti-apoptotic encoding mRNAs. In addition to this, I have purified a novel compound that I termed marmelin from the fruit of Aegle marmelos (stone apple). An interesting observation with this compound is that it induces apoptosis through the death receptor pathway without affecting NF-kB activity. The laboratory has also identified a novel stem cell marker in colon and colon cancer cells. The laboratory at KUMC now focuses on various aspects of cancer biology at the molecular level. Specific areas of interest at the KUMC lab include: regulation of gene expression at the levels of mRNA stability and translation, cancer stem cells, and mechanism of chemoprevention by dietary factors and its novel derivatives. The cores that Anant's group is extensively using since coming to the medical center are the Flow Cytometry, the Biorepository and the Biotechnology Innovation & Optimization cores. The group also uses members of the biostatistics and the imaging core for their studies, and the Drug Discovery & Development Project Management and High Throughput Screening cores for development of novel chemoprevention agents that target the colon cancer stem cells. Anant's group collaborates with Animesh Dhar, Dan Dixon and Roy Jensen (from the CP program), Joshua Mammen and Scott Weir (from D3ET program), and Sufi Thomas, Kristi Neufeld (CB). Manuscripts are currently under preparation for publication with Animesh Dhar, Joshua Mammen, Sufi Thomas and Scott Weir. In addition, three manuscript in collaboration with Roy Jensen are in preparation.

I have been a member of multiple study sections. I was the Chair of the Complementary and Alternative Medicine Basic Science Panel of NIH from July 2008 to June 2009. In addition, I am a regular member of the Chemo-Dietary Prevention Study Section (2010-2014). I was also a regular member from 2007-2010 in the Veterans Administration Oncology Merit Review Panel, and Chair of the Gastroenterology Merit Review Panel from 2013-2016. I have also served in the Molecular Oncogenesis and Cancer Etiology Study Sections in NIH and as a member of the NCI committee reviewing SPORE grants in gastrointestinal, pancreatic, skin and prostate cancers.

B. Positions and Honors.

Positions and Employment:

1993-1995	Post-Doctoral Research Fellow, Departments of Biochemistry and Molecular Biology and Medicine, University of Chicago, Chicago, IL
1995-1998	Research Associate-Instructor, Department of Medicine, University of Chicago, Chicago, IL
1998-2006	Research Assistant Professor of Medicine (1998-2002), Assistant Professor of Medicine, and of Molecular Biology and Pharmacology (2002-2006), Member, NCI-designated Siteman Cancer Center (1998-2006), Washington University School of Medicine, St. Louis, MO
2006-2010	Professor (2010), Associate Professor of Medicine, and of Cell Biology with Tenure (2006-2010), Director, Gastroenterology Research, Program Leader, GI Cancer, OU Cancer Institute, University of Oklahoma Health Sciences Center (OUHSC), Oklahoma City, OK OUHSC
2010-pres	Tom and Teresa Walsh Professor of Cancer Prevention, Eminent Scholar, Kansas Bioscience Authority, Tenured Professor, Department of Molecular and Integrative Physiology, Cancer Biology, Medicine, and General Surgery University of Kansas Medical Center, Kansas City, KS
2010-2015	Associate Dean for Research, University of Kansas Medical Center, Kansas City, KS
2010-pres	Associate Director of Prevention and Cancer Control, NCI-designated KU Cancer Center

Other Experience and Professional Memberships:

2000-2003	Member, PhD,MD/PhD,DVM Comm, American Gastroenterology Association (AGA)
2004-2007	Member, Task Force on Gastroenterology Research, AGA
2005-2010	VA Oncology A Merit Review Study Section
2005, 2007, 2008	NIH DIG F10 CSR Fellowship Section (Regular and Minority)
2005-2009	Ad-hoc Member, NIH Cancer Etiology (2005-2006), GMPB Study Section (2007-2009), MONC Study Section (2008-2009)
2006-2011	Member, NCCAM Basic Sciences Special Emphasis Panel (Chair 2009-2011)
2006-	Director of Gastroenterology Research, University of Oklahoma HSC.
2006	Ad-hoc Member, NIH IPOD Study Section
2007-2014	Member, NIH Chemo/Dietary Prevention (CDP) Study Section (Regular 2010-2014)
2009	Chair, Abstract Review Committee-Tumor Cell Biology, GI Oncology Section, Digestive Disease Week
2009-2011	Member, Fellowships in Digestive Diseases and Nutrition
2009 Oct	Chair, Chemoprevention SEP Panel
2010-	Member, NCI SPORE review panels (2012 Oct- Discussion Leader, GI SPORE)

2011-	Member, Fellowships Panel, Complementary and Alternative Medicine
2011	VA Gastroenterology Merit Review Study Section (Chair, 2014-2016)
2013 Jan	Chair, NCCAM Program Projects Study Section
2014-	Associate Editor, Molecular Carcinogenesis, European Journal of Clinical Investigation Editorial Board Member, Gastroenterology, Amer J Physiol-GI and Liver, Intl. Journal of Cancer, Evidence Based Complementary and Alternative Medicine, Cancer Research

C. Contribution to Science

My laboratory is focused on various aspects of cancer biology at the molecular level. Specific research areas include: (1) Novel Tumor in a Dish Method, (2) Novel therapeutic targeting for Bladder Cancers, (3) Regulation of gene expression at the levels of mRNA stability and translation, (4) Cancer Stem Cells, and (5) Mechanism(s) of chemoprevention by dietary factors and its novel derivatives.

(1) Novel tumor in a dish method to study tumor metastasis: This is a new area of investigation, which has resulted in the development of a novel in vitro method to grow patient derived tumors in a dish and study their ability metastasize and induce angiogenesis. Here, primary cancer cells from patients are cultured in a miniature lung organoid grown in a dish in the laboratory. Then the cancer cells are grown in a three-dimensional culture that includes normal epithelial cells, fibroblasts and endothelial cells. The model creates an *in vivo*-like tumor microenvironment that provides the necessary cell-cell contact, 3D-architecture, and the influence of different cell types. The novel technology allows us to study how cancer stem cells behave in a native environment. In addition, we look for selective killing of cancer cells in this system to demonstrate that the newly developed compounds are highly specific and have good potency.

(Patent) **Anant, S**, Ramalingam, S, Ramamoorthy, P and Sittampalam, S. Patent 20130316392 titled "*In Vitro* Tumor in a Dish Kit and Method" addendum filed: September 2015

(2) Novel therapeutic targeting for Bladder Cancers: This is another new area of investigation. Bladder cancer is the fifth most common cancer diagnosis in the US, with a high recurrence rate. As a result, bladder cancer is now considered the most expensive cancer to treat on a per patient lifetime basis [www.cancer.gov/cancertopics/types/bladder]. It is a spectrum of two diseases, non-muscle invasive bladder cancer (NMIBC) that is treatable with endoscopic resection and intravesical therapies, and the second, muscle invasive bladder cancer (MIBC) that requires more aggressive intervention. We recently developed a novel prodrug formulation of an old anti-fungal molecule 6-cyclohexyl-1-hydroxy-4-methylpyridin-2(1H)-one, also known as Ciclopirox (CPX), because of low bioavailability of this compound. The prodrug overcomes limitations with the formulation and/or delivery route of ciclopirox or other forms of ciclopirox, resulting in increased systemic and urinary tract exposure. We have further determined that the drug is effective against bladder cancers. Currently, we are in the final stages of preclinical studies required for getting FDA approval for clinical trials in early 2016.

(Patent) Weir, S, and **Anant, S.** "Methods of Bladder Cancer Treatment with Ciclopirox, Ciclopirox Olamine, or a Ciclopirox Prodrug" Application filed March 18, 2015.

(3) Regulation of Gene Expression: A major focus of the laboratory has been in the role of RNA binding proteins in posttranscriptional control of gene expression at the posttranscriptional levels of mRNA stability and translation. We discovered the first RNA binding protein tumor suppressor gene (CELF2/CUGBP2) and the first RNA binding protein protooncogene (RBM3). Both proteins interact with AU-rich sequences in the 3'untranslated region of rapidly degraded RNAs. While CUGBP2 is a translation suppressor, RBM3 is a translation enhancer. We are currently characterizing the mechanisms by which these proteins interact with the mRNA to regulate its stability and translation, and on stem cells and its signaling pathways.

(Patent) **Anant, S,** Houchen, C, Sureban, S.M, Ramalingam, S, Subramaniam, D and Ramanujam R.P. Patent number: 7956044 Compositions comprising inhibitors of RNA binding proteins and methods of producing and using same, June 7, 2011

a) Mukhopadhyay D, Houchen CW, Kennedy S, Dieckgraefe BK, **Anant S.** Coupled mRNA stabilization and translational silencing of cyclooxygenase-2 by a novel RNA binding protein, CUGBP2. Mol Cell. 2003 Jan; 11(1):113-26. PMID: 12535526
b) Murmu N, Jung J, Mukhopadhyay D, Houchen CW, Riehl TE, Stenson WF, Morrison AR, Arumugam T, Dieckgraefe BK, **Anant S.** Dynamic antagonism between RNA-binding protein CUGBP2 and cyclooxygenase-2-mediated prostaglandin E2 in radiation damage. Proc Natl Acad Sci U S A. 2004 Sep

21;101(38):13873-8. PMC518846

c) Sureban SM, Murmu N, Rodriguez P, May R, Maheshwari R, Dieckgraefe BK, Houchen CW, **Anant S**. Functional antagonism between RNA binding proteins HuR and CUGBP2 determines the fate of COX-2 mRNA translation. Gastroenterology. 2007 Mar;132(3):1055-65. PMID: 17383427

d) Sureban SM, Ramalingam S, Natarajan G, May R, Subramaniam D, Bishnupuri KS, Morrison AR, Dieckgraefe BK, Brackett DJ, Postier RG, Houchen CW, **Anant S**. Translation regulatory factor RBM3 is a proto-oncogene that prevents mitotic catastrophe. Oncogene. 2008 Jul 31;27(33):4544-56. PMC2677646

(4) Cancer Stem Cells (CSC): Stem cell research provides a foundation for therapeutic advancement in oncology, and identification and characterization of CSCs is the top priority in this field. We have identified and characterized the stem cell marker, DCLK1 as being expressed in rare, quiescent, label retaining cells within tumors of colon, pancreatic and breast cancer tissues. Recently, our studies have been validated by articles in Nature Genetics (PMID: 23202126), Gastroenterology (PMC3910427) and J Clin Invest (PMC3934168). These studies also validated our previous claim that there is a significant potential for developing a therapy for various cancers based on targeting DCLK1+ cancer stem cells. We have currently developed a novel Marmelin derivative THB (further discussed below) that interacts with the kinase domain, and inhibits DCLK1 kinase activity. Moreover, THB is able to inhibit the growth of colon and pancreatic cancer stem cells.

(Patent) **Anant, S,** Houchen, C, May, R, and Sureban, S.M. Patent number: 8198255 siRNA-Mediated Inhibition Of Doublecortin And Ca2+/Calmodulin-Dependent Kinase-Like-1, June 12, 2012

(Patent) **Anant, S,** Houchen, C, Ramalingam, S., Ramanujam, RP, and Subramaniam, D. Patent number: 8936941. Compositions useful for cancer detection and treatment, a cancer stem cell model, and methods of production and use thereof, January 20, 2015

a) May R, Riehl TE, Hunt C, Sureban SM, **Anant S,** Houchen CW. Identification of a novel putative gastrointestinal stem cell and adenoma stem cell marker, doublecortin and CaM kinase-like-1, following radiation injury and in adenomatous polyposis coli/multiple intestinal neoplasia mice. Stem Cells. 2008 Mar;26(3):630-7. PMID: 18055444.

b) Sureban, M.S., May, R., Ramalingam. S., Subramaniam, D., Natarajan, G., **Anant, S.**, and Houchen, C.W. Selective blockade of DCAMKL-1 results in tumor growth arrest by a Let-7a microRNA dependent mechanism. Gastroenterology. 2009;137(4): 649-659. PMC2775069

c) May R, Sureban SM, Lightfoot SA, Hoskins AB, Brackett DJ, Postier RG, Ramanujam R, Rao CV, Wyche JH, **Anant S,** Houchen CW. Identification of a novel putative pancreatic stem/progenitor cell marker DCAMKL-1 in normal mouse pancreas. Am J Physiol Gastrointest Liver Physiol. 2010 Aug;299(2):G303-10. PMC2928534

d) Sureban SM, May R, Lightfoot SA, Hoskins AB, Lerner M, Brackett DJ, Postier RG, Ramanujam R, Mohammed A, Rao CV, Wyche JH, **Anant S,** Houchen CW. DCAMKL-1 regulates epithelial-mesenchymal transition in human pancreatic cells through a miR-200a-dependent mechanism. Cancer Res. 2011 Mar 15;71(6):2328-38. PMC3072762

(5) Dietary Chemoprevention and Novel Therapeutics: Another major focus of the laboratory has been to determine mechanisms by which progression of a normal cell to a cancer cell can be prevented. We are particularly interested in determining mechanisms by which dietary phytochemicals such as curcumin and marmelin regulate gene expression in colorectal, breast and pancreatic tumors. My lab has been instrumental in the discovery of a novel compound marmelin. In addition, we have performed extensive studies on Charantin (Bitter melon) and honokiol (Magnolia) and as well as three natural HSP90 inhibitors. We have also developed analogs of these compounds and are determining their effect on cancer stem cells *in vitro* and in animal models. More recently, we have focused our studies on honokiol because it is a natural compound that can target DCLK1+ cancer stem cells. Moreover, we have now developed novel derivatives of marmelin and honokiol and are performing preclinical studies with the aim of getting them to the clinic.

(Patent) Ramanujam, RP, and Anant, S. 20100009395. Luminescence Assay Utilizing A Genetically Modified Cell Line. Patent Issued: January 14, 2010

(Patent) **Anant, S,** Subramaniam, D., Padhye, S. Marmelin Analogs And Methods of Use in Cancer Treatment, Application filed June 2015

a) Subramaniam, D., May, R., Sureban, S.M., Lee, K.B., George R., Kuppusamy, P., Ramanujam, R.P., Hideg, K., Dieckgraefe, B.K., Houchen, C.W and **Anant, S.** Diphenyl difluroketone (EF24): A curcumin derivative with potent in vitro and in vivo anti-cancer activity. Cancer Res. 2008;68(6): 1962-9. PMID: 18339878.

b) Subramaniam, D., Giridharan, P., Murmu, N., Shankarnarayanan, N.P., May, R., Houchen, C.W., Ramanujam, R.P., Balakrishnan, A., Vishwakarma, R.A. and **Anant, S.** Activation of apoptosis by 1-hydroxy-5, 7-dimethoxy-2-napthalene-carboxaldehyde, a novel compound from *Aegle marmelos*. Cancer Res. 2008; 68(20):1-9. PMC2692325.
c) Ponnurangam, S., Mammen, J.M.V., Ramalingam, S., He, Z., Zhang, Y., Umar, S., Subramaniam, D, and **Anant, S**. Honokiol in combination with radiation targets Notch signaling to inhibit colon cancer stem cells. Mol Cancer Ther. 2012 Apr;11(4):963-72. PMC3324630
d) Kaushik, G., Venugopal, A., Ramamoorthy, P., Standing, D., Subramaniam, D, Umar, S., Jensen, R.A., **Anant, S.** and Mammen, J.M.V. Honokiol inhibits Melanoma stem cells by targeting Notch Signaling. Mol Carcinogenesis. 2015 Dec;54(12):1710-21. PMC4776032

Complete List of Published Work in MyBibliography: http://www.ncbi.nlm.nih.gov/pubmed/?term=anant+s

D. Research Support

Ongoing Research Support:

R01CA182872 (Anant) 01/01/2014 - 12/31/2018
NIH
Novel dual Notch/PXR targeting for colon cancer Therapy
Major goals: to determine how the novel drug MRLTHB and combination with 5FU affects Notch signaling and PXR expression in colon cancer growth.

R01CA190291 (Anant) 08/01/2014 - 07/31/2019
NIH
Bitter Melon Component and colon cancer prevention
Major goals: to further develop Charantin, an active ingredient in bitter melon extracts as a dietary preventive agent against colon cancers.

P30 CA168524 (Jensen) 07/11/2012 - 06/30/2017
NIH
Cancer Center Support Grant
Dr. Anant is the Associate Director of the Cancer Center, and in this capacity he has purview over two cancer center programs- Cancer Prevention and Cancer Control and Population Health.

Completed Research Support:

F30DK094532 (Venugopal) 12/01/2011 - 05/31/2016
NIH
RNA binding proteins and intestinal stem cells
Major goals: to investigate the ability of the RNA binding protein RBM3 to induce a stem like phenotype within colon cancer cells.
Role: Mentor.

R01 CA109269 (Anant) 04/01/2004 - 03/31/2014
NIH
Dietary Prevention of Cancer
Major goals: to determine how curcumin regulates signaling and gene expression in driving a colon cancer cell to apoptosis.

R01 CA135559 (Anant) 01/02/2009 - 01/31/2014
NIH
Posttranscriptional control in tumorigenesis
Major goals: to determine the mechanism by which the newly discovered protooncogene regulates gene expression in colon cancers.

R01 CA151727 (Dhar) 09/26/2011 - 07/31/2014
NIH
Pancreatic Cancer: Crocetin as a Novel Therapeutic Approach
Major goals: to develop therapy using commercial crocetin in pancreatic cancer models.
Role: Co-investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Margaret Amanda August, Pharm.D.**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Clinical Pharmacist, Pharmacy Team Leader

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Brenau University, Gainesville, Georgia	n/a	1998	Pre-pharmacy
University of Georgia College of Pharmacy, Athens, GA	Pharm.D.	2002	Pharmacy

A. Personal Statement

My training, expertise, and clinical experience give me the skills necessary to effectively serve as a protocol review committee member. As a pharmacist, I have expertise in the areas of pharmacology, pharmacokinetics, drug interactions, and drug administration which are integral and often complex components to any medication related research protocols. I have > 10 years of clinical experience as a pharmacist caring for pediatric oncology patients enrolled on cooperative group or other clinical trials. I have served as co-investigator on several retrospective research projects with my involvement including project design, budgeting, data collection, feasibility and research logistics and manuscript preparation. I serve as protocol pharmacist on three separate Children's Oncology Group protocol committees. As a result of these experiences, I am well suited to review protocols from a medication and from a logistical /feasibility standpoint as well as identify barriers that may impede study success.

B. Positions and Honors

Positions and Employment:

2002-2005 Pharmacist, Medical College of Georgia, August, GA
2005-2010 Hematology Oncology Clinical Pharmacist, Children's Healthcare of Atlanta, Atlanta, GA
2010-current Hematology Oncology Clinical Pharmacist and Hematology Oncology Pharmacy Team Leader, Children's Mercy Hospital, Kansas City, MO

Other Experience and Professional Memberships:

2010- Member, American Society of Health-System Pharmacists
2005- Member, Children's Oncology Group Pharmacy Committee

Honors:

2002 Rho Chi National Pharmaceutical Honor Society

C. Contribution to Science (I have previously published under name "Dalton A"):

1. Nausea and vomiting is a common and distressing side effect of chemotherapy. There are limited options for pediatric patients experiencing refractory nausea and vomiting. Olanzapine is an antiemetic agent with demonstrated efficacy in adult oncology patients and a track record of safe pediatric use. The positive experience in adult cancer patients and the fact that many children experience chemotherapy-induced nausea and vomiting despite antiemetic prophylaxis has prompted pediatric clinicians to prescribe olanzapine despite lack of published descriptions. We published a multi-center retrospective chart review of patients who were treated with olanzapine for the purpose of chemotherapy induced nausea and vomiting

describing our experience including the indication, dose, control of vomiting and adverse effects possibly associated with its use. This publication found that olanzapine may be an important option to improve CIV control in children and provided evidence that prospective evaluation of olanzapine for CINV in children is warranted. I served as co-investigator and site specific primary investigator.

a) Flank J, Thackray J, Nielson D, **August A**, Schechter T, Alexander S, Sung L, Dupuis LL. Olanzapine for treatment and prevention of acute chemotherapy-induced vomiting in children: a retrospective, multi-center review. Pediatr Blood Cancer. 2015;62(3):496-501. PMID: 25328089 (PMC# not required; not NIH funded)

2. Pegaspargase (PEG-asparaginase) is a critical component of pediatric acute lymphoblastic leukemia therapy. The traditional route of administration is intramuscular (IM) injection due to concerns for hypersensitivity reactions after intravenous (IV) administration of native E. coli L-asparaginase when compared with IM route of the same agent. The majority of clinical studies with pegaspargase in children had utilized the IM route. We undertook a retrospective chart review to describe our experience with administering pegaspargase by the IV route particularly in regards to clinically hypersensitivity reactions. The findings suggested pegaspargase by the IV route to be well tolerated and did not result in a significant incrase in the incidence of hypersensitivity reactions in children. Administration by the IV route reduces patient pain and anxiety making this route appealing to patients and families.

a) August KJ, Miller WP, **Dalton A**, Shinnick S. Comparison of hypersensitivity reactions to PEG-asparaginase in children after intravenous and intramuscular administration. J Pediatr Hematol Oncol. 2013;35(7):e283-6. PMID: 23619117 (not NIH funded)

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1VqEsSgqn8ak7/bibliograpahy/50088302/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

No number (PI: Gary Jones) 10/12/2014 – current
The Children's Mercy Hospital
The Use of Propofol for the Management of Chemotherapy-Induced Nausea and Vomiting in an Academic Pediatric Institution
The primary objective of this study is to describe the use and efficacy of propofol as an antiemetic among pediatric hematology/oncology patients in the management of chemotherapy-induced nausea and vomiting. Data collection complete, currently preparing manuscript for submission.
Role: Co-investigator

Completed Support:
N/A

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Keith August, MD**

eRA COMMONS USER NAME (credential, e.g., agency login): KJAUGUST

POSITION TITLE: Assistant Professor of Pediatrics

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Oklahoma, Norman OK	B.Sc.	1998	Chemical Engineering
University of Oklahoma, Oklahoma City, OK	M.D.	2002	Medicine
University of Louisville, Louisville, KY	Residency	2005	Pediatrics
Emory University, Atlanta, GA	M.S.	2008	Clinical Research
Emory University, Atlanta, GA	Fellowship	2008	Hematology/Oncology

A. Personal Statement

I am a practicing pediatric hematologist/oncologist with a clinical and research focus in pediatric cancer. I have received formal training in clinical research and clinical trial design. I am actively involved in clinical research and serve as the institutional principal investigator for a number of early phase trials in pediatric oncology. I am currently a member of the study committee for two COG trials, AALL1231 and ACCL1034. My institutional roles at Children's Mercy Hospital in Kansas City, Missouri include acting as the Director of both the Leukemia and Lymphoma Program and the Experimental Therapeutics in Pediatric Cancer Program. Research interests include pediatric clinical trials, the clinical pharmacology of leukemia therapy, late effects of ALL therapy including obesity, and supportive care in children receiving treatment for hematologic malignancies.

B. Positions and Honors

Positions and Employment:

2006-2008 St. Baldrick's Fellow Award
2008-2009 Instructor of Pediatrics, Emory University, Atlanta GA
2009-present Assistant Professor of Pediatrics, University of Missouri-Kansas City and Children's Mercy Hospital, Kansas City, MO

Other Professional Experience:

2010-2015 Associate Director of Experimental Therapeutics, Children's Mercy Hospital, Kansas City, MO
2015-present Interim Director of Experimental Therapeutics, Children's Mercy Hospital, Kansas City, MO
2011-present Director, Pediatric Leukemia and Lymphoma Program, Children's Mercy Hospital, Kansas City
2011 Katherine B. Richardson Endowment Award -- $25,000 grant over two years for the study "Effects of Intrathecal Methotrexate on Folate Metabolism in the Cerebrospinal Fluid of Children with Acute Lymphoblastic Leukemia."
2011 William Randolph Hearst Foundation Award – additional support awarded to the most outstanding application for Katherine B. Richardson Endowment Award

Professional Memberships:

American Society of Pediatric Hematology-Oncology
American Society of Clinical Oncology
American Society of Hematology
Children's Oncology Group

C. Contributions to Science

1. Role of inflammatory biomarkers in prediction and diagnosis of acute graft-versus-host disease in allogeneic hematopoietic stem cell transplant patients

During fellowship training, I led several projects evaluating easily detectable biomarkers of inflammation to determine their role in the development of acute graft-versus-host disease (AGVHD) in the immediate post-transplantation period. The results of these studies have broadened our understanding of the underlying immune processes that contribute to AGVHD and have identified biomarkers with the potential to predict this clinical syndrome prior to the onset of symptoms.

a) **August KJ**, Chiang KY, Bostick RM, Flanders WD, Waller EK, Langston A, Worthington-White D, Rowland P, Moore KF, Khoury HJ, Horan JT. Biomarkers of Immune Activation to Screen for Severe, Acute GVHD. Bone Marrow Transplantation. 2011; 46(4): 601-604. PMID: 20622904 (PMC# not required; not NIH funded)
b) Qayed M, Langston A, Chiang KY, **August KJ**, Hilinski JA, Cole CR, Rogatko A, Bostick RM, Horan JT. Rifaximin for Preventing Acute Graft-Versus-Host Disease: Impact on Plasma Markers of Inflammation and T-cell Activation. Journal of Pediatric Hematology and Oncology. 2013 May;35(4):e149-52. PMID: 23274384 (not NIH funded).
c) **August KJ**, Chiang KY, Qayed M, Dulson A, Worthington-White D, Cole CR, Horan JT. Relative Defects in Mucosal Immunity Predict Acute Graft-Versus-Host Disease. Biology of Blood and Marrow Transplantation. 2014 20(7): 1056-1059. PMID: 24641826 (PMC# not required; not NIH funded).

2. Understand the side effects associated with cancer chemotherapy

I have been involved with several projects looking at the impact that chemotherapy has on children. This has included looking at acute effects of therapy and potential late effects of treatment. Additional work is ongoing including the evaluation of bleeding and thrombosis risk of children treated with asparaginase and the risk of obesity as a long term side effect of leukemia therapy. This work has added helpful information to our knowledge of what to expect in children treated with chemotherapy and has improved our ability to monitor for toxicity and provided anticipatory guidance to patient and families.

a) Fulbright JM, Raman S, McClellan WS, **August, KJ**. Late Effects of Childhood Leukemia Therapy. Current Hematologic Malignancy Reports. 2011 6(3):195-205. PMID: 21695425 (not NIH funded)
b) **August KJ**, Miller WP, Dalton A, Shinnick S. Comparison of Hypersensitivity Reactions to PEG-Asparaginase in Children After Intravenous and Intramuscular Administration. Journal of Pediatric Hematology and Oncology. 2013; 35(7):e283-286. PMID: 23619117 (not NIH funded)
c) Held K, Ryan R, Champion JM, **August KJ**, Radhi MA. Caregiver Survey Results Related to Handling of Oral Chemotherapy for Pediatric Patients With Acute Lymphoblastic Leukemia. Journal of Pediatric Hematology and Oncology. 2013 Aug;35(6):e249-53. PMID: 23274379 (not NIH funded)
d) Tabassum N, **August K**, Kalpatthi R, Hongying D, Carpenter SL, Wicklund B. “Thromboelastography Testing in Children with ALL Treated with PEG-Asparaginase”, poster presentation, 2015 American Society of Pediatric Hematology/Oncology Meeting, Phoenix, AZ (May 2015)

3. Study novel approaches to cancer therapy

As Associate Director of Experimental Therapeutics in Pediatric Cancer at Children’s Mercy Hospital, I have served as the principal investigator of a number of clinical, early phase trials in pediatric cancer. Through a number of multi-institutional clinical trial consortiums, I have participated in the development and execution of several trials evaluating novel treatments in children with cancer.

a) **August KJ**, Dalton A, Katzenstein HM, George B, Olson TA, Wasileweski-Masker K, Rapkin LB. The Use of Zoledronic Acid in Pediatric Cancer Patients. Pediatric Blood and Cancer. 2011; 56:610-614. PMID: 21298747 (not NIH funded)
b) **August KJ**, Narendran A, Neville KA. Pediatric Relapsed or Refractory Leukemia: New Pharmaco-therapeutic Developments and Future Directions. Drugs. 2013; 73(5):439-461. PMID: 23568274 (not NIH funded).
c) Cunningham HD, Eldar K, **August K**, Vines CM. “Novel Single Chain Antibodies to Inhibit CCR7 Mediated-Entry of Pediatric T-Cell Acute Lymphoblastic Leukemia Into the CNS”, poster presentation, 2014 European Society of Medical Oncology, Madrid, Spain (September 2014)

d) Cooper TM, Baker SD, Direnzo J, Trippett TM, Gore L, Narendran A, **August KJ**, Absalon MJ, Boklan J, Pllard J, Magoon D, Sison EAR, Brown P. “Chemosensitization and Mobilization of AML/ALL/MDS With Plerixafor (AMD3100), a CXCR4 Antagonist: A Phase I Study of Plerixafor + Cytarabine and Etoposide in Pediatric Patients With Acute Leukemia and MDS”, poster presentation, 2013 American Society of Hematology Meeting, New Orleans, LA (December 2013)

Complete List of Published Work in “my bibliography” can be found in this link:
http://www.ncbi.nlm.nih.gov/pubmed/?term=august+kj

D. Research Support

Ongoing Research Support:
None

Completed Research Support:

Baldrick’s Foundation 08/01/2013 - 07/31/2015
Televideo Lifestyle Health Coaching for Families of Children with Acute Lymphoblastic Leukemia
The purpose of this study is to develop and evaluate a program to educate and improve diet and physical activity for children diagnosed with acute lymphoblastic leukemia in the maintenance phase of therapy.
Role: Co-Principal Investigator

Children’s Mercy Cancer Center (PI: August) 01/01/2013 - 12/31/2014
Thromboelastography Testing in Children with Acute Lymphoblastic Leukemia treated with PEG-Asparaginase
The purpose of this study is do evaluate thromboelastography testing as a marker for bleeding and/or thrombosis risk after administration of PEG-asparaginase in children with acute lymphoblastic leukemia.

Katherine B. Richardson Foundation (PI: August) 07/01/2011 - 06/30/2014
Effects of Intrathecal Methotrexate on Folate Metabolism in the Cerebrospinal Fluid of Children with Acute Lymphoblastic Leukemia
The purpose of this study is to measure folate metabolites in the cerebrospinal fluid of children treated with intrathecal methotrexate as a biomarker of increased risk for neurotoxicity.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Stella A. Baccaray, BSN, MSN**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Clinical Research Nurse

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Akron, OH	BSN	05/1990	Nursing
Albany Medical College, NY	MSN	05/1996	Nursing

A. Personal Statement

In the role of Clinical Research Nurse, I work with multidisciplinary teams directing patient care in a clinical research environment. I am involved in new or unique clinical research protocols, utilizing advanced assessment skills to identify patient care problems, formulate patient care plans and continually revise plans to adjust to changes according to the clinical research protocol. As a Clinical Research Nurse, I have professional knowledge of a wide range of nursing concepts, principles, and practices to perform highly specialized nursing assignments as well as knowledge of anatomy, physiology, pathology and pharmacology.

B. Positions and Honors

Positions and Employment:

1990 – 1991 ICU staff nurse, Ohio State University Hospitals, Columbus, OH
1991 – 1993 ICU staff nurse, Grant Medical Center, Columbus, OH
1997 – 1997 Staff nurse anesthetist, Mayfield Anesthesia Associates, Mayfield, OH
1997 – 1998 Staff nurse anesthetist, North Shore Anesthesia Associates, Manhasset, NY
1998 – 2000 Staff nurse anesthetist, Atlantic Anesthesia Associates, Oceanside, NY
2001 – 2006 Staff nurse anesthetist, Anesthesia Associates of Northern Ohio, Lorain, OH
2007 – 2011 Clinical research nurse, Cleveland Clinic, Cleveland, OH
2011 – Pres. Clinical research nurse, KU Cancer Center, Univ. of Kansas Medical Center, Westwood, KS

C. Contribution to Science

1. I have written 2 book chapters when working as a clinical research nurse in the Sleep Disorders Department at Cleveland Clinic.

a) **Baccaray, S**, Andrews, N Folvary-Schaefer, N. (2011). *Ahhh…the Comforts of Home*. Book chapter about portable monitoring and sleep apnea in A Case a Week: Sleep Disorders from the Cleveland Clinic. Oxford University Press (PMC# not required; not NIH funded)

b) **Baccaray, S**, Foldvary-Schaefer, N. (2001). *The Midnight Raider*. Book chapter about sleep eating in A Case a Week: Sleep Disorders from the Cleveland Clinic. Oxford University Press (not NIH funded)

2. I have coordinated 3 breast cancer clinical trials:

a) Neoadjuvant Chemotherapy plus Trastuzumab in Stage II/III Breast Cancer with Low HER2 Expression. http://meetinglibrary.asco.org/content/150436-156

Background: Adjuvant trials have demonstrated that addition of trastuzumab (T) to chemotherapy reduces risk of recurrence and death in women with HER2 overexpressed or gene amplified early breast cancer (BC). Central testing of specimens from patients in NSABP B-31 demonstrated that ~ 10% of patients without overexpression/gene amplification of HER2 had similar benefit from adjuvant T. Aim of this study was to assess pathologic complete response (pCR) when T is added to neo-adjuvant (NA) chemotherapy in women not exhibiting HER2 FISH amplification but had low level of protein (IHC) expression (1+ or 2+).

Conclusions: Neo-adjuvant T/nab-paclitaxel followed by AC in HER2 negative, ER + BC resulted in pCR rates higher than expected for this population. Among patients with positive axillary nodes, a very high (53%) complete response rate was noted in axilla.

b) Lapatinib in Women with Metastatic Breast Cancer Who Have Failed Prior Antihormone Therapy.

Introduction: A significant proportion of breast cancer (BC) patients show primary or acquired resistance to endocrine therapy (ET). The cross-talk between estrogen receptor and other growth factor receptor (GFR) families is suggested to play a crucial role in the development of endocrine resistance and dual targeting of these pathways can potentially reverse endocrine resistance. Lapatinib (Lap) is an oral, dual inhibitor of EGFR/HER2 and preclinical studies have demonstrated combination of Lap and ET to be effective in setting of endocrine resistance. Aims: 1) To evaluate if Lap can restore efficacy of aromatase inhibitor (AI) or fulvestrant(F) in metastatic BC, 2) Study blood/tissue response biomarkers.

Conclusion: Addition of Lap restored sensitivity to ET (AI/Fulvestrant) in 25% of patients with HER 2 negative BC. Response was independent of HER 2 positive CTC and HER2/ECD levels. Genomic profiling suggests a relationship between *PIK3CA* mutation and benefit from this approach. NGS of the entire study cohort is in process and will be reported. HER2-negative breast cancers harboring *PI3KCA* mutations may rely more on GFR/PI3K signaling than on estrogen for growth; thus, blocking GFR signaling with lap might restore hormonal sensitivity. A randomized study of lap + ET in selected patients with HER2 negative BC is warranted and biomarker results from this study may help identify subgroups that should be targeted in a larger study.

c) Lapatinib and RAD-001 for HER2 Positive Metastatic Breast Cancer.

Background: A small molecule inhibitor of HER2, lapatinib is clinically active in women with advanced HER2-positive breast cancer who have progressed on trastuzumab treatment. However, the effectiveness of this class of agents is limited by either primary resistance or acquired resistance. Using an unbiased genetic approach, Eichhorn et al performed a genome wide loss-of-function short hairpin RNA screen to identify novel modulators of resistance to lapatinib. Tumor suppressor PTEN was identified as a modulator of lapatinib sensitivity in vitro and in vivo. In addition, they show that two dominant activating mutations in PI3K pathway which are prevalent in breast cancer, also confer resistance to lapatinib. They also showed that PI3K-induced lapatinib resistance could be abrogated through the use of NVP-BEZ235, a dual inhibitor of PI3K/mTOR. This suggests that deregulation of the PI3K pathway leads to lapatinib resistance, which can be effectively reversed by inhibition of PI3K/mTOR pathway.

In summary, the combination of Everolimus and lapatinib needs to be studied in women with metastatic breast cancer who have progressed on at least one prior anti-HER2 therapy. If RAD-001 is able to overcome resistance to anti-HER2 therapies, a very desirable response rate and prolongation in TTP can be expected. Moreover, both lapatinib and Everolimus appear to be able to cross the blood brain barrier, and this combination may prove to be effective in controlling CNS metastases in this population. The investigators hypothesize that combining mTOR inhibitor Everolimus with lapatinib will be an effective strategy for patients who have progressed on a prior anti-HER2 therapy, both systemically and within the CNS.

D. Research Support

Ongoing Research Support:

The following are 3 ongoing clinical trials that I am responsible for coordinating, which includes patient screening, treatment, and follow up phases.

1. Randomized Open Label Phase II Trial of Neoadjuvant Carboplatin plus Docetaxel or Carboplatin plus Paclitaxel followed by Doxorubicin plus Cyclophosphamide in Stage I-III Triple-negative Breast Cancer.

   Primary Objective: To evaluate the pathological complete response rates with two neoadjuvant chemotherapy regimens in patients with stage I-III TNBC.

2. Femara (Letrozole) Plus Ribociclib (LEE011) or Placebo as Neo-adjuvant Endocrine Therapy for Women with ER-positive, HER2-negative Early Breast Cancer.

   Primary Objective: To determine if ribociclib in combination with letrozole for 24 weeks as neoadjuvant endocrine therapy increases the proportion of women with PEPI score of 0 at surgery compared to patients treated with letrozole alone therefore allowing more patients excellent outcomes without chemotherapy.

3. Randomized Open-label Trial of Dose-dense, Fixed-dose Capecitabine Compared to Standard-dose Capecitabine in Metastatic Breast Cancer and Advanced/Metastatic GI Cancers.

   Primary Objective: To compare the efficacy and tolerability of fixed-dose capecitabine on a 7-7 schedule (1500 mg BID, 7 days on and 7 days off) to the FDA recommended dose and schedule (1250 mg/m^2 BID, 14 days on and 7 days off) in the specified patient population.

Completed Research Support:

None (not applicable).

OMB No. 0925-0001/0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Michael J Baltezor, PhD

eRA COMMONS USER NAME (credential, e.g., agency login): MBALTEZOR

POSITION TITLE: Director, Biotechnology Innovation and Optimization Center; Director, Lead Development and Optimization Shared Resource; Deputy Director, Institute for Advancing Medical Innovation

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Missouri Western University	BS	05/1972	Chemistry
University of Kansas	MS	06/1975	Pharmaceutics and Pharmaceutical Chemistry
University of Kansas	Ph.D.	06/1977	Pharmaceutics and Pharmaceutical Chemistry

A. Personal Statement

The Biotechnology Innovation and Optimization Center (BIOC) is uniquely positioned to optimize the bioavailability and pharmacokinetics of new drug candidates prior to moving into animal or human proof of concept. The expertise of the BIOC scientific team includes drug delivery / pharmaceutics, analytical and bio-analytical chemistry and animal pharmacokinetics / pharmacodynamics. This team is able to move quickly to evaluate solubility, stability and delivery of new drug candidates and assess the outcomes in animal studies. The scientists in the BIOC have numerous years of experience in both academic and pharmaceutical industry laboratories. This provides both the scientific and regulatory expertise for the testing and decisions which are necessary to move drug candidates into animal or human proof of concept studies and to develop formulated dosage forms for use in human clinical trials. The BIOC is a component of the Lead Development and Optimization Center which is part of the KU Cancer Center Support Grant (CCSG). I serve as Director of the LDOSR. Approximately 70% of our capacity is used for cancer related projects. The BIO Center has been very active working with the physicians at Children's Mercy Hospital to develop formulations designed specifically for pediatric use. My own expertise started during my graduate studies which were focused on the delivery of new oncology drugs that were both poorly soluble and unstable. This continued during my 30+ years of pharmaceutical development experience in the pharmaceutical, contract development and medical products industries. All of my roles throughout my career have dealt with drug delivery, new product formulations and leading teams of scientists.

B. Positions and Honors

Positions and Employment

1976-1977 Pharmaceutical Scientist, Sandoz (Dorsey Laboratories)
1978-1986 Manager/Director of Pharmaceutical Research, Sandoz (Dorsey Laboratories)
1986-1988 Manager of Product Development, Marion Laboratories
1988 Director of Analytical Chemistry, Marion Laboratories
1988-1989 Vice President of OTC Research, Sandoz Consumer Products
1989-1992 Director of Pharmaceutical Sciences, Marion Merrell Dow
1992-1995 Sr. Director of Pharmaceutical Chemistry, Marion Merrell Dow

1995-1997	Sr. Director, Analytics, Hoechst Marion Roussel
1997-1998	Vice President and Global Head, Analytics, Hoechst Marion Roussel
1999	Vice President, Preclinical and Pharmaceutical Sciences, Quintiles
2000-2002	Chief Operating Officer, Global Pharmaceutical Sciences, Quintiles
2002-2003	Global Coordinator, Pharmaceutical Sciences, Quintiles
2002-2003	General Manager, Early Development Laboratory Services, Kansas City, Quintiles
2002-2005	Site Head, Kansas City, Quintiles
2003-2005	Senior Vice President & General Manager, EDLS North America, Quintiles
2005	President, Pharmaceutical Sciences, Aptuit
2006-2008	Chief Scientific Officer, Medi-Flex / Enturia
2008-2010	Vice President of R&D, Infection Prevention, Cardinal Health / CareFusion
2010-Present	Deputy Director, Institute for Advancing Medical Innovation, University of Kansas
2010-Present	Director, Biotechnology Innovation and Optimization Center, University of Kansas
2011-Present	Director, Lead Development and Optimization Shared Resource
2014-Present	Chief Scientific Officer, CritiTech, Inc.

Other Experience and Professional Memberships

Honors

1992	Distinguished Alumni Award from Missouri Western State University
2005	Missouri Western State University, Honorary Ph.D.

C. Contributions to Science

1. The majority of my career (34 years) was spent in the pharmaceutical industry (Sandoz Pharmaceuticals, Marion Laboratories, Quintiles, MediFlex/Cardinal Health). The vast majority of my work was focused on formulation, pre-formulation and analytical chemistry activities. I contributed to the development and commercialization of over 35 products. During my time at Quintiles, I managed a large development group of approximately 1200 people supporting hundreds of projects from over 500 different customers. The scope of the projects ranged from early preclinical and preformulation projects through large Phase III clinical studies and regulatory activities. The following 2 patents are included as very significant in that they were based on the non-linear absorption kinetics and metabolism of diltiazem to design and formulate a once daily coated beads in a capsule. These patents successfully withstood legal challenges on 5 separate occasions.

a) U.S. Patent No. 5,386,497, Diltiazem Formulation, D. Hendrickson, D. Dimmit, M. Williams, P. Skultety and M. Baltezor (1994).
b) U.S. Patent No. 5,439,689, Diltiazem Formulations, D. Hendrickson, D. Dimmit, M. Williams, P. Skultety and M. Baltezor (1995).

2. My 4 years of graduate studies at the University of Kansas were spent as a research associate on a NCI grant under Professors Arnold Repta and Takeru Higuchi. My first project involved the resolution of ICRF159 to prepare the more soluble enantiomer ICRF187. This drug is currently prescribed as Zinecard as a cardioprotective when co-administered with anthracyclines. My thesis work involved the complexation of polycyclic aromatic compounds and the improvement of solubility and stability. References to this work is provided below:

a) Utilization of an Enantiomer as a Solution to a Pharmaceutical Problem. Application to the solubilization of 1,2-di(4-piperazine-2,6-dione)propane. A.J. Repta, M.J. Baltezor and P.C. Bansal, J. Pharm. Sci.,65, 238 (1976). PMID: 1255455
b) Preparation and Evaluation of Bis-(3-Carboxy-4-Hydroxy-1-Naphthyl)Alkanones as Novel Complexing Agents. Complexation with some Quaternary Polycyclic Aromatic Compounds, Ph.D. Dissertation, University of Kansas, Lawrence, Kansas (1976).

3. For the past 5 years I have managed an experienced group of 8 scientists in the BIOC at the University of Kansas. This group functions as a core laboratory to help other researchers move early stage compounds into animal proof of concept and human proof of concept studies. The BIOC provides expert support for early pharmacology, chemistry, formulation and animal pharmacokinetic studies. Many of our compounds are intended for oncology indications. Our pre-formulation and drug delivery expertise is utilized by approximately

50 different researchers at KU and other academic institutions each year. In addition to our work with early stage compounds, we have been actively involved with the formulation and novel dosage forms for pediatric drug delivery. We address both the unique needs for dose adjustability but also the selection of formulation excipients that are suitable for use in young patients. Lastly, I am working with a startup company, CritiTech, that is actively developing a KU technology for the use of nanoparticles administered to provide prolonged, depot drug release based on the dissolution of poorly soluble drugs from small particles which provide increased surface area. Following are 3 publications for reference.

a) Early Drug Discovery and Development Guidelines: For Academic Researchers, Collaborators, and Start-up Companies. Hughes M, Inglese J, Kurtz A, Andalibi A, Patton L, Austin C, Baltezor M, Beckloff M, Sittampalam S, Weingarten M, Weir S, Sittampalam GS, Gal-Edd N, Arkin M, Auld D, Austin C, Bejcek B, Glicksman M, Inglese J, Lemmon V, Li Z, McGee J, McManus O, Minor L, Napper A, Riss T, Trask OJ, Weidner J, editors. Assay Guidance Manual [Internet]. Bethesda (MD): Eli Lilly & Company and the National Center for Advancing Translational Sciences; (2004-2012 May 01 [updated 2012 Oct 01]). PMID: 22553881, Not NIH funded.
b) A report from the pediatric formulations task force: perspectives on the state of child-friendly oral dosage forms. Zajicek A, Fossler MJ, Barrett JS, Worthington JH, Ternik R, Charkoftaki G, Lum S, Breitkreutz J, Baltezor M, Macheras P, Khan M, Agharkar S, MacLaren DD. AAPS J. (2013 Oct);15(4):1072-81. PMID: 23907486, PMCID: PMC3787237.
c) A phase I study of intraperitoneal nanoparticulate paclitaxel (Nanotax(®)) in patients with peritoneal malignancies. Williamson SK, Johnson GA, Maulhardt HA, Moore KM, McMeekin DS, Schulz TK, Reed GA, Roby KF, Mackay CB, Smith HJ, Weir SJ, Wick JA, Markman M, diZerega GS, Baltezor MJ, Espinosa J, Decedue CJ. Cancer Chemother Pharmacol. 2015 May;75(5):1075-87. doi: 10.1007/s00280-015-2737-4. Epub 2015 Apr 23. PMID:25898813, PMCID: PMC4506131.

Please also provide a URL to a full list of your published work as found in a publicly available digital database such as PubMed or My Bibliography, which are maintained by the US National Library of Medicine.
http://www.ncbi.nlm.nih.gov/pubmed/?term=Baltezor

D. Research Support

Ongoing Support:

P30CA168524 Jensen (PI) 07/11/2012 – 06/30/2017
NCI
Cancer Center Support Grant (CCSG) for NCI-designated Cancer Centers
Major goals: The University of Kansas Cancer Center (KUCC) is a matrix organization that leverages unique scientific assets to build a nationally significant cancer research and treatment center that will become a leading academic institution in the world in transforming discoveries in the laboratory into new therapeutic approaches.
Role: Key Personnel (Director – Lead Development and Optimization Shared Resource)

R01CA182872 Anant (PI) 01/01/2014 – 12/31/2018
NCI
Novel dual Notch/PXR "Targeting for Colon Cancer Therapy
Major Goals: We have now developed a novel drug, THB, which targets Notch signaling and inhibits PXR. The goal of the current project is to determine in vitro and in vivo proof of principle for this agent as an oral therapeutic for colon cancer, the third leading cause of cancer related deaths in both men and women.
Role: Co-Investigator

Completed Support:

Grant #QW853791 – KU Lawrence Subaward 05/14/2012 - 05/13/2014
KU Medical Center /NCI thru SAiC-Frederick
Pharmacokinetic and metabolism studies of auranofin as a treatment for relapsed chronic lymphocytic leukemia

Major Goals: Investigate the pharmacokinetics of auranofin in mice from various formulation variants with the goal of improving the oral bioavailability and reducing the variability of absorption.
Role: PI (University of Kansas)

U54RR031295 Barohn (PI) 07/01/2011 - 06/30/2012
NIH
Institutional Clinical and Translational Science Award (U54)
Major goals: Create a new academic home with training programs for clinical and translational investigators, provide an enhanced coordinated translational research infrastructure and actively engage the community in developing, testing and disseminating translational research.
Role: Key Personnel

N/A Baltezor (PI) 07/22/2009 –11/30/2011
Kansas Bioscience Authority Collaborative Cancer Research Initiative
Preclinical Development of CC-1065 Pro-drugs for Breast and Prostate Cancer Research
The overall goal of the proposed research program is to evaluate and advance novel CBI-indole2 analogs and pro-drugs for the treatment of leukemia and solid tumor cancers as breast and prostate cancer.
Role: Co-investigator

Grant #KAN0067229 Baltezor (PI) 04/01/2010 – 10/30/2011
University of Kansas Medical Center, Department of Biochemistry and Molecular Biology
HSP90 Inhibition for PKD Therapy
The overall goal of the proposed research program is to complete bioanalytical evaluation of a plasma assay for HSP90 drugs to be used for the treatment of Polycystic Kidney Disease.
Role: Collaborator

Grant #KAN0065449 Baltezor (PI) 07/01/10 – 12/31/11
Kansas Technology Enterprise Corporation
Biotechnology Innovation & Optimization Center; Center of Excellence Award
The overall goal of the proposed research program involves applied research and development in the general area of drug delivery research.
Role: Principal Investigator

OMB No. 0925-0001/0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

NAME: Christie A. Befort, PhD

eRA COMMONS USER NAME (credential, e.g., agency login): cbefort

POSITION TITLE: Associate Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Texas at Austin, Austin, TX	B.S.	05/97	Exercise Science
Arizona State University, Tempe, AZ	M.A.	05/20	Counseling Psychology
Colorado State University, Ft. Collins, CO	Ph.D.	08/04	Counseling Psychology
Palo Alto VA Health Care System, Palo Alto, CA	Internship	08/04	Clinical Psychology
University of Kansas Medical Center, Kansas City, KS	Fellowship	05/06	Obesity & Public Health

A. Personal Statement

I am a behavioral scientist with clinical and research experience in lifestyle intervention among underserved populations, particularly rural residents and minority groups. My research program focuses on cancer control and survivorship through weight loss and physical activity. I have conducted several trials as PI with funding from NCI, ACS, Komen, and PCORI with a focus on examining strategies for delivering weight loss interventions tailored to survivorship and primary care needs in rural settings. I have built an implementation research infrastructure in primary care for conducting pragmatic trials throughout are catchment area. Through the MCA and KPPEPR, I have worked with numerous communities and healthcare systems and providers throughout the Midwestern region. As a Co-Leader of Cancer Control and Population Health (CCPH) for the KU Cancer Center, I lead efforts to enhance translating cancer control into practices and communities. I co-lead our program's Implementation Science Workgroup and bring investigators together across campuses and programs with our consortium to facilitate new collaborations. In my own research, I collaborate closely with investigators in Cancer Prevention and Survivorship. I have mentored a multidisciplinary group of numerous graduate students, postdoctoral fellows, and junior faculty who have successfully obtained NIH funding. In my role as CCPH Co-leader, I enjoy promoting team science, novel multi-disciplinary collaborations, and pragmatic cancer control research.

B. Positions and Honors

Positions

2000-2003 College Instructor & Graduate Research Assistant, Colorado State University, Ft. Collins, CO
2001-2002 Psychology Extern, Hematology/Oncology Associates, Fort Collins, CO
2002-2003 Neuropsychological Technician, Rehabilitation Associates, Fort Collins, CO
2003-2004 Clinical Psychology Internship, Behavioral Medicine Track, VA Palo Alto Health System, Palo Alto, CA
2004-2006 Postdoctoral Fellow, Department of Preventive Medicine, University of Kansas Medical Center (KUMC), Kansas City, KS
2006-2007 Research Assistant Professor, Department of Preventive Medicine, KUMC, Kansas City, KS
2007-2012 Assistant Professor, Department of Preventive Medicine, KUMC, Kansas City, KS
2008-present Co-Director, Breast Cancer Survivorship Center, University of Kansas Cancer Center

2012-present Associate Professor, Department of Preventive Medicine, KUMC, Kansas City, KS
2012-present Associate Professor (Courtesy Appointment), Clinical Psychology Department, University of Kansas, Lawrence, KS
2015-present Co-Leader, Cancer Control and Population Health Program, KU Cancer Center, Kansas City, KS

Honors and Professional Activities

1997 Suma Cum Laude, Graduate with Highest Honors, University of Texas
2004-2007 NIH K30 Research Fellow, University of Kansas Medical Center
2005 NIH NCMHD Loan Repayment Program Recipient and Health Disparities Scholar
2005 Fellow, NIH Summer Institute on Randomized Clinical Trials Involving Behavioral Interventions
2007 Junior Investigator Award, University of Kansas Cancer Center Research Symposium
2015-present NIH Study Section Member, Psychosocial Risk and Disease Prevention
2015-2016 President, Women in Medicine and Science, KUMC Chapter
2016 Scholarly Achievement Award, University of Kansas

C. Contributions to Science

1. **Obesity treatment in rural primary care.** Primary care remains an underutilized resource within the healthcare system for treating obesity, especially in the rural setting where obesity prevalence is higher and weight control programs and resources are lacking. We examined perceived barriers among rural primary care physicians and identified a disconnect between physicians and their patients in perceptions of motivation to lose weight. We are currently conducting an implementation trial comparing three existing models of care (fee-for-service, patient centered medical home, and disease management) for treating obesity in rural primary care practices throughout the rural Midwest.

a) Befort CA, Greiner KA, Hall S, Pulvers KM, Nollen NL, Charbonneau A, Kaur H, Ahluwalia JS. (2006). Weight-related perceptions and expectations among patients and physicians: how well do physicians judge patients' motivation to lose weight? *Journal of General Internal Medicine, 21(10),* 1086-1090. PMCID: PMC1831634.
b) Ely AC, Banitt A, Befort C, Hou Q, Rhode PC, Grund C, Greiner A, Jeffries S, Ellerbeck E. (2008). Kansas primary care weighs in: a pilot randomized trial of a chronic care model program for obesity in three rural Kansas primary care practices. *Journal of Rural Health, 24(2),* 125-132. Not NIH funded.
c) Pulvers KM, Kaur H, Nollen, NL, Greiner KA, Befort CA, Hall S, Born W, Fitzgibbon ML, Ahluwalia JS. (2008). Comparison of body perceptions between obese primary care patients and physicians: implications for practice. *Patient Education and Counseling, 73(1),* 73-81. PMCID: PMC3864616.
d) Befort, CA, VanWormer, J.J., DeSouza, C., Ellerbeck, E.F., Kimminau, K.S., Greiner, A., Gajewski, B., Huang, T., Perri, M.G., Fazzino, T.L., Christifano, D., Eiland, L., Drincic, A. (2016). Protocol for the Rural Engagement in Primary Care for Optimizing Weight Reduction (RE-POWER) Trial: Comparing three obesity treatment models in rural primary care. *Contemporary Clinical Trials, 47,* 304-314. PMID: 26898748, Not NIH funded.

2. **Weight loss interventions for minority and rural populations.** Effectively reaching and treating populations with higher prevalence of obesity and associated chronic conditions remains a major public health challenge. We have worked collaboratively in underserved community settings to develop and test evidence-based tailored weight loss interventions. We demonstrated that motivational interviewing is no more effective than health education in improving adherence to a weight loss intervention among African American women. This study contributed to a growing literature on the appropriateness of motivational interviewing in different settings and populations. We also identified unique weight control needs of rural women, and found that group phone visits are more effective than individual phone visits for weight loss among rural women. This study contributes to a growing literature on the benefits of group phone-based treatment particularly in the rural setting.

a) Befort CA, Thomas JL, Daley CM, Rhode PC, Ahluwalia JS. (2008). Perceptions and beliefs about body size, weight, and weight loss among obese African American women: a qualitative inquiry. *Health Education and Behavior, 35(3),* 410-426. Not NIH funded.
b) Befort CA, Nollen N, Ellerbeck EF, Sullivan DK, Thomas JL, Ahluwalia JS. (2008). Motivational interviewing fails to improve outcomes of a behavioral weight loss program for obese African American women: a pilot randomized trial. *Journal of Behavioral Medicine, 31(5),* 367-377. Not NIH funded.

c) Ely A, Befort C, Banitt A, Gibson C, Sullivan D. (2009). A qualitative assessment of weight control among rural Kansas women. *Journal of Nutrition, Education, and Behavior, 41(3),* 207-211. PMCID: PMC2703188.
d) Befort CA, Donnelly JE, Sullivan DK, Ellerbeck EF, Perri MG. (2010, April). Group versus individual phone-based obesity treatment for rural women. *Eating Behaviors, 11(1),* 11-17. PMCID: PMC2823259.

3. **Weight control among breast cancer survivors.** Obesity and physical inactivity are risk factors for breast cancer recurrence. Much of the research on weight loss interventions for cancer survivors has been conducted with patients treated at academic cancer centers. We developed and implemented the only trial to date targeting weight loss and sustained weight loss maintenance among breast cancer survivors residing in distant rural communities including some of the most isolated frontier areas. Successful recruitment was accomplished through collaborations with local cancer centers throughout a 3 state region of the rural Midwest. This work contributes to the literature on how to effectively engage, recruit, and treat cancer survivors entirely from a distance with evidence-based weight loss interventions.

a) Befort CA, Austin H, Klemp JR. (2011, Oct). Weight control needs and experiences among rural breast cancer survivors. *Psycho-Oncology, 20(10),* 1069-1075. PMCID: PMC3319375.
b) Befort CA, Klemp JR, Austin HL, Perri MG, Schmitz KH, Sullivan DK, Fabian CJ. (2012). Outcomes of a weight loss intervention among rural breast cancer survivors. *Breast Cancer Research and Treatment*, *132(2),* 631-639. PMCID: PMC3314288.
c) Befort, C., Bennett, L, Christifano, D., Klemp, J., & Krebill, H. (2015, April) Effective recruitment of rural breast cancer survivors into a lifestyle intervention. *Psycho-Oncology, 24(4),* 487-490. PMCID: PMC4272910.
d) Befort, C.A., Klemp, J.R.,Sullivan, D., Shireman, T., Diaz, F., Schmitz, K., Perri, M., Fabian, C. (in press) Weight loss maintenance strategies among rural breast cancer survivors: The Rural Women Connecting for Better Health Trial. *Obesity*

4. **Factors associated with adherence and response to lifestyle intervention.** Delivering the right type and intensity of lifestyle interventions requires understanding factors that predict who will adhere and successfully adopt new lifestyle behaviors. Much of my work as a co-investigator has focused on these types of questions. For example, we have on-going trials examining brain activation around food motivation and impulsivity as predictors of adherence and response to weight loss and exercise interventions, respectively.

a) Nollen N, Befort C, Pulvers K, James AS, Kaur H, Mayo MS, Hou Q, Ahluwalia JS. (2008). Demographic and psychosocial factors associated with increased fruit and vegetable consumption among smokers in public housing enrolled in a randomized trial. *Health Psychology, 27(3),* S252-259. Accepted Prior to April 2008 .
b) Befort CA, Stewart EE, Smith BK, Gibson CA, Sullivan DK, Donnelly JE. (2008). Weight maintenance, behaviors, and barriers among previous participants of a university-based weight control program. *International Journal of Obesity*, *32(3),* 519-526. Published March 2008.
c) Hermann, S.D., Martin, L., Breslin, F., Honas J.J., Willis, E.A., Powel, J., Gibson, C., Befort, C., Lambourne, K., Burns, J., Smith, B., Sullivan, D., Washburn, RA., Yeh, H., Donnelly, J.E., Savage, C. (2014). Neuroimaging studies of factors related to exercise adherence: Rationale and design of a 9 month trial. *Contemporary Clinical Trials, 37(1),* 58-68. PMCID: PMC3946871.
d) Szabo-Reed, A., Breslin, R., Lynch, T., Patrician, T., Martin, L., Lepping R., Powell, J., Yeh, H., Befort, C., Sullivan, D., Gibson, C., Washburn, R., & Donnelly, J. (2015). Brain function predictors and outcomes of weight loss and weight loss maintenance. *Contemporary Clinical Trials, 40,* 218-231. PMCID: PMC4314339.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/christie.befort.1/bibliography/45725936/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

P30 AG035982	Watts (PI)	07/1/2016 – 06/30/2017

KU Alzheimer's Disease Center Pilot Grants
Intervention to Reduce Sitting Time in Mild Cognitive Impairment (ReST-MCI)
Single arm pilot trial to develop and test a 12 week home and telephone based intervention results in reduced total sitting time and shorter bouts of sitting in older adults with mild cognitive impairment.
Role: Co-Investigator

No Number Daley (PI) 07/1/2015 – 06/30/2018
SG Komen Breast Cancer Foundation
Continuing an American Indian Breast Cancer Disparities Training Program
Training program for American Indian students to obtain a Master of Public Health degree focusing on an aspect of breast cancer disparities research.
Role: Co-Investigator

PCORI OTO-1402-09413 Befort (PI) 01/1/2015 – 12/31/2019
Patient-Centered Outcomes Research Institutes/
Midwestern Collaborative for Treating Obesity in Rural Primary Care
Multi-site cluster randomized trial in 36 rural primary care practices comparing three models of care delivery: fee-for-service, patient centered medical home, and disease management.

R01 CA155014 Befort (PI) 08/1/2011 – 05/31/2017
NIH
Group Phone-Based Weight Control among Rural Breast Cancer Survivors
Behavioral RCT comparing impact of group phone-based lifestyle intervention to mail-only intervention on weight loss maintenance, quality of life, and breast cancer biomarkers among rural breast cancer survivors.

R18 HL122720 Perri (PI) 08/1/2013 – 04/30/2018
NIH
Rural Lifestyle Eating and Activity Program
Randomized controlled "effectiveness" trial in obese adults (N=540) to evaluate the effects of extended-care programs delivered via INDIVIDUAL or GROUP telephone counseling, compared to a health education control (CTRL) condition, on long-term (22 month) changes in body weight.
Role: Co-Investigator/PI of subaward

Select Completed Support:

R01 DK085605 Savage, C (PI) 04/1/2010 – 01/31/2016
NIH
Neuroimaging Studies of Reward, Impulsivity, and Adherence to an Exercise Program
Prospective study to identify impulsivity characteristics and related brain activation as predictors of adherence to a supervised exercise intervention among obese adults.
Role: Co-Investigator

UL1 TR000001 Befort (PI) 03/1/2013 – 02/28/2014
NIH
Frontiers Heartland Institute for Clinical and Translational Research, Clinical and Translational Science Award
Reducing sedentary behavior to prevent weight regain among breast cancer survivors
Pilot RCT comparing standard weight loss maintenance intervention to the same intervention plus an additional sedentary behavior change component with device-based real time feedback on weight and insulin changes among breast cancer survivors.

No Number Befort/ Daley(Co-PIs) 06/1/2011 – 05/31/2013
University of Kansas Cancer Center Pilot Grants
Culturally Tailored Weight Loss Program for American Indians
Community-based participatory research project examining feasibility and preliminary impact of a weight control intervention tailored for American Indians.
Role: Co-PI

K12 HD052027 Klemp (Project PI) 10/1/2008 – 12/31/2012
NIH Thomas(Program PI)
Building Interdisciplinary Research Careers in Women's Health Program (BIRCWH)
Breast Cancer Risk Biomarkers and Energy Balance in Post-Menopausal Breast Cancer Survivors
Pilot project to evaluate feasibility of a 6-month diet/exercise/behavioral intervention in overweight breast cancer survivors and estimate impact on weight, breast cancer biomarkers and measure of overall health.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. ***DO NOT EXCEED FIVE PAGES.***

NAME: **Fariba Behbod, Pharm.D., Ph.D.**

eRA COMMONS USER NAME (credential, e.g., agency login): FBEHBOD

POSITION TITLE: Associate Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Texas, Austin, TX	B.S.	08/1987	Pharmacy
Memorial-Herman Hospital, Houston, TX	Residency	08/1988	Pharmacy
University of Texas at Austin and San Antonio, Health Science Center, San Antonio, TX	Pharm. D.	08/1991	Clinical Pharmacology
University of Texas Houston and M.D. Anderson Cancer Center, Houston, TX	Ph.D.	12/2001	Integrative Biology & Pharmacology
Baylor College of Medicine, Houston, TX	Post-doc.	08/2006	Mammary Gland Biology and Tumorigenesis

A. Personal Statement

Research in our laboratory is focused on investigating the cellular and molecular factors in ductal carcinoma in situ (DCIS) and their surrounding microenvironment that promote a transition to invasive ductal carcinoma (IDC). DCIS progression is difficult to study due to the paucity of good models. We have established 2 complementary models to investigate this critical problem. The first is the tandem DCIS/IDC model, which uses samples from patients afflicted with both DCIS and IDC in the same breast and the second model is the MIND (mouse-intraductal model). MIND is a novel animal model we developed that utilizes intraductal (ID) injection of primary human DCIS cells and cell lines into the mammary ducts of immunocompromised mice. This model represents the first *in vivo* DCIS progression model. The MIND models are particularly innovative because 1) the models mimic the natural progression of human DCIS beginning from in situ lesions inside the mammary ducts followed by invasion as they bypass the myoepithelial cells and the basement membrane and, 2) the cells are derived from patient samples, so they mimic the heterogeneity of human disease. We have assembled a team and infrastructure that gives us access to a large number of patient biopsy and surgical samples. This infrastructure also facilitated the development of the DCIS MIND model. Since the approval of our IRB protocol in mid-2009, we have received ~650 tissue samples from patients, 127 of which have received a confirmed diagnosis of DCIS. Using these unique resources, we hope to investigate the natural evolution of human DCIS and the molecular mechanisms that drive the progression of some DCIS to invasion.

B. Positions and Honors

Positions and Employment:

1991-1997 Clinical Manager/Specialist, Department of Pharmacy, Hermann Hospital, Houston, TX
1991-2002 Adjunct Faculty, University of Houston College of Pharmacy, Houston, TX
1997-1998 Research Pharmacist, Organ Transplantation, U. of Texas Medical School, Houston, TX
1997-1998 Visiting Assistant Professor, College of Pharmacy, University of Houston, Houston, TX
2006-2008 Instructor, Baylor College of Medicine, Dept. of Molecular & Cellular Biology, Houston, TX
2008-2014 Assistant Professor, Department of Pathology and Laboratory Medicine, University of Kansas Medical Center (KUMC), Kansas City, KS
2014-pres. Associate Professor, Department of Pathology & Laboratory Medicine, KUMC, Kansas City, KS

Other Experience and Professional Memberships:

2002-	Associate Member, American Association for Cancer Research
1992-2008	Member, American College of Clinical Pharmacy
2008-2009	Member, KUMC Interdisciplinary Grad. Program In Biomedical Sciences, Admission Committee
2008-	Full Member; The University of Kansas Cancer Center (KUCC)
2008-	Co-Leader; KUCC Cancer Prevention Program, Stem Cell Biology and Biomarkers
2009-	KUMC M.D./Ph.D. Admission Committee
2009-	Full Member; Institute for Reproductive Health and Regenerative Medicine
2010-	Scientific Review Panel Member; Ladies Auxiliary to the Veterans of Foreign Wars
2010-	Scientific Review Panel Member; American Cancer Society Institutional Research Grant
2013-	Scientific Review Panel Member; Protocol Review and Monitoring Committee; KUMC
2011	Scientific Review Panel Member; CDMRP Review Panel, Department of Defense
2012	Guest Editor, Journal of Mammary Gland Biology and Neoplasia, March 2012
2012	Scientific Review Panel Member; SRB/NIEHS/NIH
2012	Scientific Review Panel Member; NIH/NCI Career Development
2013	Scientific Review Panel Member; NIH/NCI/ZCA1 GRB-I
2014	Scientific Review Panel Member; NIH/NCI Career Development
2014	Scientific Review Panel Member; CDMRP Review Panel, Department of Defense

Honors and Awards (selected):

1999	John P. McGovern Award; Graduate Student Poster Presentation, First Place
2000	John P. McGovern Award, Graduate Student Poster Presentation, Second Place
1999-2001	Schissler Foundation Pre-doctoral Fellowship
2001	Cell and Regulatory Biology Student Achievement Award, 1st Place
2003-2006	NCI/NIH NRSA; Post-doctoral fellowship
2003	Edward A. Smuckler Memorial Pathobiology of Cancer Workshop, Keystone, CO
2007	Novartis Oncology Basic Science Scholar Award, San Antonio Breast Cancer Symposium, San Antonio, TX
2014	Breast Cancer Research Foundation-American Association for Cancer Research Translational Breast Cancer Research Award

C. Contribution to Science

1. My research vision to aid women diagnosed with DCIS is to: **1**) improve the *in vivo* DCIS models by mimicking DCIS inter- and intra-tumoral heterogeneity and natural progression, **2**) identify the molecular and cellular basis for the invasive phenotype in human DCIS. The ultimate goal of our studies is to find clinically useful biomarkers that will help stratify those women that will or will not benefit from invasive surgical procedures and/or adjuvant therapies and discover molecular targets for prevention of DCIS invasive progression.

Improving models of human DCIS progression: To begin to address the complexities and challenges in today's treatment and diagnosis of DCIS, while a post-doctoral fellow at Baylor College of Medicine, I joined the research efforts of Drs. Medina and Allred, both long-term collaborators of my mentor, Dr. Jeffrey M. Rosen, and renowned scientists in the field of human breast premalignancy. I applied for an NIH sponsored career development award (K99/R00) for which Drs. Allred, Medina and Rosen served as co-mentors. The successful funding of our project led to the development of the first orthotopic DCIS model known as mouse-intraductal (MIND). Using the DCIS cell line MIND models, which mimicked some of the diversity of human noninvasive breast cancers, we demonstrated for the first time that subtypes of human DCIS contained distinct subpopulations of tumor-initiating cells. Our manuscript in *Breast Cancer Research* in 2009 received the status of, "highly accessed". Since then, the MIND model has gained worldwide recognition. After my arrival to The University of Kansas Medical Center (KUMC) in 2008, I aimed to establish the MIND model using primary human cells. With the help of the clinicians at KUMC, we established procedures for obtaining primary DCIS surgical and biopsy samples. This was a major accomplishment since establishing human protocols for receiving tissue has always been challenging in DCIS research compared to invasive ductal carcinoma (IDC). Being aware of this important clinical issue we worked with the patients and our radiologists to obtain one extra adjacent biopsy core. This led to the first demonstration of reproducible growth of primary DCIS cells by our MIND model. Since the approval of our IRB protocol in mid-2009, we have received >500 tissue samples from patients. Using these unique resources, we are investigating the natural evolution of human DCIS and the

molecular mechanisms that drive their progression to invasion. These studies using DCIS cell lines have led to the identification of BCL9 and our current hypothesis that BCL9 may promote DCIS invasive progression by activating the STAT3 and the canonical Wnt signaling. The following manuscripts introduced the MIND model and demonstrated its utility in studying the molecular and cellular mechanism of human DCIS progression.

a) **Behbod F**, Kittrell FS, LaMarca H, Edwards D, Kerbawy S, Heestand JC, Young E, Mukhopadhyay P, Yeh H, Allred DC, Hu M, Polyak K, Rosen JM, Medina D. An intra-ductal human-in-mouse (HIM) transplantation model mimics the subtypes of ductal carcinoma in situ. *Breast Cancer Research* 2009; 11(5):R66. PMC2790841.
b) Valdez KE, Fan F, Smith W, Allred DC, Medina D, **Behbod F**: Human primary ductal carcinoma in situ (DCIS) subtype-specific pathology is preserved in a mouse intraductal (MIND) xenograft model. *J Pathology* 2011 Dec;225(4):565-573. PMC3496769.
c) Hanan S. Elsarraj, Yan Hong, Kelli E. Valdez, Whitney Michaels, Marcus Hook, William Smith, Jeremy Chien, Jason Herschkowitz, Melissa Troester, Moriah Beck, Marc Inciardi, Jason Gatewood, Lisa May, Therese Cusick, Marilee McGinness, Lawrence Ricci, Fang Fan, Ossama Tawfik, Jeffrey R Marks, Jennifer Knapp, Hung-Wen Yeh, Patricia Thomas, Carrasco, Timothy A. Fields, Andrew K. Godwin , **Fariba Behbod**. Expression profiling of *in vivo* ductal carcinoma in situ progression models identified B cell lymphoma-9 as a molecular driver of breast cancer invasion. *Breast Cancer Research*. 2015 September 17;17:128. PMC4574212.
d) Frances Kittrell, Kelli Valdez, Hanan Elsarraj, Yan Hong, Daniel Medina, **Fariba Behbod.** Mouse Mammary Intraductal (MIND) method for transplantation of patient derived primary DCIS cells and cell lines. *Bioprotocol.* 2016 Mar 5;6(5). PMC4950990

2. Other accomplishments include the identification and characterization of mammary gland normal and cancer stem cells. For these studies, I was awarded two post-doctoral fellowships, a Department of Defense (DOD) and a National Research Service Award (NRSA). I accepted the NRSA. Before I began my studies, a previous post-doctoral fellow had shown that similar to the bone marrow, the mammary gland contained a distinct population of Hoechst-effluxing side population cells, referred to as mammary gland side population cells (MG-SPs). To better characterize MG-SPs, I performed limiting dilution transplantation studies as well as microarray gene profiling. These studies indicated that MG-SPs compared to the MG-NSPs did not possess a higher mammary regenerative potential. However, microarray gene profiling suggested that MG-SPs were a lineage-deficient mammary gland subpopulation expressing key genes involved in cell cycle regulation, development, and angiogenesis. Our studies also indicated that MG-SPs were a mixed population of epithelial and endothelial cells enriched in the expression of a unique surface marker known as endothelial cell selective adhesion molecule (ESAM). Further studies revealed that ESAM positive cells resided at the base of the mammary epithelial cells and ESAM provided a surface adhesion molecule through which mammary epithelial and endothelial cells communicated. The following manuscripts demonstrate our contribution to the field of mammary gland stem cell biology and cancer stem cells:

a) **Behbod F**, Xian W, Shaw CA, Hilsenbeck SG, Tsimelzon A, Rosen JM. Transcriptional profiling of mammary gland side population cells. *Stem Cells* 2006 Apr; 24(4): 1065-74. PMID: 16282442.
b) Woodward WA, Chen MS, **Behbod F**, Alfaro MP, Buchholz TA, Rosen JM. WNT/betacatenin mediates radiation resistance of mouse mammary progenitor cells. *Proc Natl Acad Sci USA.* 2007 Jan 9;104(2):618-23. PMC1766434.
c) Zhang M, **Behbod F**, Atkinson RL, Landis MD, Kittrell F, Edwards D, Medina D, Tsimelzon A, Hilsenbeck S, Green JE, Michalowska AM, Rosen JM. Identification of Tumor-initiating Cells in a p53 Null Mouse Model of Breast Cancer. *Cancer Research*. 2008 June 15;68(12):4674-82. PMC2459340.
d) Behbod F, Vivanco MD. Side population. Methods Mol Biol. 2015;1293:73-81. PMID: 26040682 (PMC# not required; not NIH funded).

3. In further pursuit of identifying mammary gland stem and progenitor cells, we also utilized single-cell cloning of a cell line generated in the laboratory of Dr. Medina known as COMMA-D (CD). The CD cells line exhibits normal *in vivo* morphogenesis; however, due to their immortalized nature, the mammary structures eventually become hyperplastic and form tumors. By single cell cloning of cells derived from each SP and NSP, a total of nine clones were identified, four of which possessed *in vivo* mammary outgrowth potential. Two of the clones formed mammary lobuloalveolar structures that contained both ducts and alveoli and were termed multi-potent. Two of the clones generated either ductal-only or alveolar-only structures and were referred to as ductal-limited

or alveolar-limited, respectively. We also showed that the ductal-limited and alveolar-limited progenitor clones maintained their faith over several transplant generations. The CD derived progenitor clones have provided valuable resources for the scientific community interested in studying the cellular and molecular mechanisms of self-renewal and differentiation in the distinct ductal and alveolar progenitors. For example, Bussard KM and colleagues demonstrated that the CD derived progenitor cells contain label-retaining cells that asymmetrically divide and retain their template DNA. The following manuscripts demonstrate our contribution to the field of mammary gland stem cell biology by the generation of distinct CD derived progenitor and multipotent clones:

a) Bussard KM, Boulanger CA, Kittrell FS, Behbod F, Medina D, and Smith GH. Immortalized, pre-malignant epithelial cell populations contain long-lived, label-retaining cells that asymmetrically divide and retain their template DNA. *Breast Cancer Research* 2010, Oct 21;12(5):R86. PMC3096979.
b) Kittrell FS, Carletti MZ, Kerbawy S, Heestand J, Xian W, Zhang M, LaMarca HL, Sonnenberg A, Rosen JM, Medina D, **Behbod F**. Prospective isolation and characterization of committed and multipotent progenitors from immortalized mouse mammary epithelial cells with morphogenic potential. *Breast Cancer research*, April 2011, 13:R41. PMC3219204.

4. We utilized the progenitors clones derived from the CD cell line to study the differential expression of microRNAs in the distinct mammary stem/progenitor cells. These studies led to the identification of microRNA-146b and demonstrated that microRNA-146b played a critical role in the maintenance of pregnancy-derived mammary luminal alveolar progenitors through the regulation of STAT3. I also served as the guest editor for an issue of the Journal of Mammary Gland Biology and Neoplasia focused on the role of non-coding RNAs in mammary gland development and breast cancer. The following manuscripts demonstrate our contribution to the field of non-coding RNAs in mammary gland biology and breast cancer:

a) Elsarraj HS, Stecklein SR, Valdez K, **Behbod F**. Emerging Functions of microRNA-146a/b in Development and Breast Cancer: MicroRNA-146a/b in Development and Breast Cancer. *J Mammary Gland Biol Neoplasia*. 2012 Mar;17(1):79-87. PMID: 22350993 (not NIH funded).
b) **Behbod F**, Rosen JM. (Editorial): Mammary Gland Development and Breast Cancer; Connecting the dots by non-coding RNAs. *J Mammary Gland Biology and Neoplasia*. 2012 Mar;17(1):1-2. PMID: 22402939 (not NIH funded).
c) Hanan S. Elsarraj, Yan Hong, Kelli Valdez, Martha Carletti, Sally M. Salah, Monica Raimo, Daniela Taverna, Philippe Prochasson, Uddalak Bharadwaj, David J. Tweardy, Lane K. Christenson, and **Fariba Behbod**. A novel role of MicroRNA146b in the maintenance of mammary alveolar progenitor cells. Journal of Cell Science. 2013 Jun 1;126(Pt 11):2446-58. PMC3679487.

Complete list of Published Work in My Bibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1HYEd6RnXpJAm/bibliography/40506900/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support:

P30 GM11076102 (PI: Hanzlik) 08/01/2014 - 06/30/2019
NIH/National Institute of General Medical Sciences
Project: *Center of Biomedical Research Excellence in Protein Structure and Function*

R01CA172764 (multi-PI: Cheng/Behbod) 09/01/2013 - 09/01/2018
NIH/NCI
Progression of DCIS to invasive breast cancer through CCR2 chemokine signaling
Major Goals: To elucidate the role of CCR2/CCL2 signaling in DCIS progression to invasive breast cancer.

Completed Research Support:

R21CA187890 (Behbod) 08/26/2014 - 08/25/2016
NIH/NCI
Elucidating cellular heterogeneity among cancer stem cells by Raman Spectroscopy
Major Goals: To utilize Raman spectroscopy combined with flow cytometry in order to perform intracellular molecular profiling of cancer stem cells.

No number (Behbod) 08/01/2014 - 07/30/2016
Breast Cancer Research Foundation - AACR Translational Breast Cancer Research
Essential Role of BCL9 in Promotion of Human DCIS to Invasive Ductal Carcinoma
Major Goals: 1) Evaluate BCL9 as a biomarker for DCIS with high risk of progression; 2) Evaluate the role of BCL9 in DCIS progression to invasion in animal models of disease; 3) Assess effects of pharmacologic inhibition of BCL9/β-catenin interaction on DCIS progression to IDC.

No Number (Pilot Project PI: Behbod) 07/01/2015 – 06/30/2016
Subproject: *Crystal Structure determination of STAT3/BCL9 Complex*
Major Goals: to characterize binding interactions between BCL9 and STAT3 by x-ray crystallography and then use fragment screening to identify chemical compounds to interfere with this binding. The long-term goal is to find therapeutic strategies for prevention of breast cancer non-invasive to invasive progression.
Role: Pilot Project Principal Investigator

R21CA185460 (Behbod) 05/01/2014 - 04/30/2016
NIH/NCI
Essential Role of BCL9 in Promotion of Human DCIS to Invasive Ductal Carcinoma
Major Goals: To evaluate the role of nuclear vs. cytoplasmic BCL9 in promotion of DCIS invasive progression and in the formation of a DCIS pro-invasive stromal microenvironment by recruitment of macrophages.

K22CA160587 (Valdez) 07/01/2012 – 06/31/2015
NIH/NCI
Stem cells and their aberrant self-renewal pathways in DCIS malignant progression
Major Goals: To identify hormonal regulation of cancer stem cells in human ductal carcinoma in situ and to identify population of cancer stem cells that promotes DCIS invasive regulation under the influence of estrogen and progesterone.
Role: Mentor

BC103299 (Behbod) 03/15/2011 - 04/14/2013
Department of Defense
Raman Tweezer Spectroscopy for the identification of mouse mammary tumor initiating cells
To evaluate the use of intracellular molecular profiling by Laser Raman Tweezer Spectroscopy in order to identify and characterize mouse mammary tumor initiating cells.

R00 CA127462 (Behbod) 06/01/2007 - 05/31/2013
NIH/NCI
Role of Cancer Stem Cells in Malignant Progression of Human DCIS
Major Goals: to test whether premalignant cell lines, SUM225, MCF10ATDCIS.com, and subtypes of human DCIS contain distinct cancer stem cell subpopulations which exhibit unique cancer stem cell properties.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Cory Robert Bivona, Pharm.D.**

eRA COMMONS USER NAME (credential, e.g., agency login): cbivona

POSITION TITLE: Clinical Investigational Pharmacist

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Oklahoma, Norman, OK	Pharm.D.	06/2010	Pharmacy
University of Kansas Hospital, Kansas City, KS	Residency	06/2012	Pharmacy
Board of Pharmaceutical Sciences		11/2013	Board Certified Oncology Pharmacist

A. Personal Statement

I have specific training in oncology, hematology, BMT and investigational medicine all of which in both the inpatient and outpatient environment. I have been involved in teaching of students, resident pharmacists and medical staff in training. This involves not only didactic teaching, but precepting and facilitation in retrospective research. In my current role in investigational drug services I work with physician groups on protocol writing and implementation. I also serve as a liaison with the community sites as a pharmacy resource for all cancer studies.

B. Positions and Honors

Positions and Employment:

2012 – 2015 Inpatient/Outpatient Clinical Pharmacist, Hematology/Oncology/Blood & Marrow Transplantation, University of Kansas Hospital, Kansas City, KS
2013 – pres. Adjunct Clinical Assistant Professor, University of Kansas, School of Pharmacy, Lawrence, KS
2015 – pres. Cancer Care Investigation Pharmacist, University of Kansas Cancer Center, Kansas City, KS

Other Professional Activities:

2013 – pres. Protocol Review and Monitoring Committee, KUMC, Kansas City, KS
2014 – pres. PGY-1 Residency Advisory Steering Council - Scholarly & Research Subcommittee Chair
2015 – pres. Research Abstract Reviewers Workgroup Hematology/Oncology Pharmacy Association
2015 – pres. BCOP Field Testing Workgroup Subcommittee Hematology/Oncology Pharmacy Association

C. Contribution to Science

Published work in the area of cancer therapies:

a) Bray WM, **Bivona C**, Rockey M, et al. Outcomes for newly diagnosed patients with acute myeloid leukemia dosed on actual or adjusted body weight. Cancer Chemother Pharmacol. 2015;76(4): 691-7. PMC4725583
b) Borders, EB, **Bivona C**, Medina PJ. Mammalian target of rapamycin: biological function and target for novel anticancer agents. Am J Health Syst Pharm. 2010;67(24):2095-106. PMID: 21116000 (PMC# not required; not NIH funded)

D. Research Support

Ongoing Research Support:
None

Completed Research Support:
None

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

NAME: Prabhakar Chalise, PhD

eRA COMMONS USER NAME: PCHALISE

POSITION TITLE: Research Assistant Professor of Biostatistics

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Tribhuvan University, Kathmandu, Nepal	MSc	12/98	Statistics, Mathematics
University of Arkansas, Fayetteville, AR	MS	08/05	Statistics
Florida State University, Tallahassee, FL	PhD	12/09	Biostatistics
Mayo Clinic, Rochester, MN	Postdoctoral	10/11	Statistical Genetics

A. Personal Statement

High-throughput 'omic data, such as, gene expression, DNA methylation, DNA copy number, has played instrumental role in furthering our understanding of the molecular basis in states of human health and disease. As cells with similar morphological characteristics can exhibit entirely different molecular profiles and because of the potential that these discrepancies might further our understanding of patient-level variability in clinical outcomes, there is significant interest in the use of high-throughput 'omic data for the identification of novel molecular subtypes of a disease. To this end, my primary research interest is in the development and application of integrative statistical methods using the multilevel 'omics data to identify the subtypes of cancer.

I joined University of Kansas Medical Center in 2011 as a research assistant professor. I have had very good experience in working in cancer research. I have collaborated in several internally and externally funded projects including NIH funded projects. Through these studies and other ongoing collaborations, I have had extensive experience in working with multiple types of epigenomic, genomic and proteomic data including the data generated by both microarray and sequencing technology. Most of these studies are focused on analyzing and developing new integrative approaches for the disease risk association studies using both molecular data such as SNP, mRNA expression, DNA methylation and clinical data.

My role in the Cancer Center Support Grant (CCSG) is to support the researchers with the various aspects of statistical analysis needs. Examples of my contributions are writing the statistical analysis plan for research proposals, designing the experiments, analyzing the collected data and interpretation of the results in the context of study and preparation of manuscript out of the research findings.

B. Positions and Honors

Positions and Employment

1999-2003 Assistant Professor and Researcher, Tribhuvan University, Nepal
2003-2005 Graduate Teaching Assistant, University of Arkansas, Fayetteville, AR
2005-2009 Graduate Teaching and Research Assistant, Florida State University, FL
2009-2011 Post Doctoral Research Fellow, Mayo Clinic, Rochester, MN
2011- Research Assistant Professor, University of Kansas Medical Center, Kansas City, KS

Other Experience and Professional Memberships

1998- Member, Statistical Association of Nepal
2005- Member, American Statistical Association
2009- Member, International *Biometric* Society, ENAR
2009- Member, International Genetic Epidemiology Society
2014- Member, University of Kansas Cancer Center

Honors

1997 Best First Year Student, Tribhuvan University, Nepal
2002 Best Lecturer, Pashupati Multiple Campus, Tribhuvan University, Nepal

C. Contribution to Science

1. **Integrative analysis approach of several genotypic and phenotypic data sets:** The recent development of high throughput genomic technologies has generated several types of genomic datasets on same set of patient samples e.g. mRNA gene expression, DNA methylation, DNA copy number etc. The interaction of biological processes manifesting in different data types measured by such genomic assays can have important implications for disease development and progression. Therefore, it is very important to take into account the multiple datasets together in order to optimize strength of biological information across multiple assays relevant to the disease of interest. I am actively involved in both the methods development and application aspects of such integrative data analyses which have helped in understanding the integrative framework of disease-biomarker association.

a) **Chalise P** and Fridley B. Comparison of performances of various penalty functions on Sparse Canonical Correlation Analysis. *Computational Statistics and Data Analysis, 56: 245-254, 2012.* PMCID: PMC3185379
b) **Chalise P**, Fridley B, Batzler Anthony and Liewei Wang. Simultaneous analysis of multiple data types in pharmacogenomic studies using weighted sparse canonical correlation analysis. *OMICS: A Journal of Integrative Biology, 16(7-8):363-373, July/August 2012.* PMCID: PMC3394856
c) Koestler DC, **Chalise P**, Cicek MS, Cunningham JM, Armasu S, Larson MC, Chien J, Block M, Kalli KL, Sellers TA, Fridley BL and Goode EL. Integrative genomic analysis identifies epigenetic marks that mediate genetic risk for epithelial ovarian cancer. *BMC Medical Genomics 7(1)8, 2014.* PMCID: PMC3916313
d) **Chalise P**, Koestler DC, Bimali M, Yu Q and Fridley BL. Integrative Clustering methods for High-Dimensional Molecular Data. *Translational Cancer Research,3(3), 202-216, 2014.* PMCID: PMC4166480

2. **Association analysis of Copy number variation and survival of Ovarian Cancer:** Copy number variants (CNVs) occur commonly in the genome and have been implicated in risk of complex diseases including prostate cancer, neuroblastoma, and schizophrenia. A few studies have shown the association of the CNVs with the survival of the patients. My collaborative work on the association of CNVs with the ovarian cancer survival has helped in understanding strength of such association further. Also, we have been able to propose improvements on the analysis approach.

a) Breheny P, **Chalise P**, Batzler A, Wang L and Fridley B. Genetic Association studies of copy number variation: should assignment of copy number states precede testing? *PLoS ONE 7(4): e34262. doi:10.1371/journal.pone.0034262, 2012.* PMCID: PMC3320903
b) Fridley BL*, **Chalise P***, Tsai Y-Y, Sun Z, Vierkant RA, Larson MC, Cunningham JM, Iversen ES, Fenstermacher D, Barnholtz-Sloan J, Asmann Y, Risch HA, Schildkraut JM, Phelan CM, Sutphen R, Sellers TA and Goode EL. Germline copy number variation and ovarian cancer survival. *Frontiers in Cancer Genetics, 3:142. doi:10.3389/fgene.2012.00142, 2012.* PMCID: PMC3413872

*Signifies shared first-authorship

3. **Assessment of time scales in Cox proportional hazards Model:** The Cox proportional hazards model is widely used for analyzing associations between risk factors and occurrences of events. One of the essential requirements of defining Cox proportional hazards model is the choice of a unique and well-defined time scale. Two time scales are generally used in epidemiological studies: time-on-study and chronological age. The former is the most frequently used time scale both in clinical studies and longitudinal observation studies. However, there is no general consensus on which time scale is the most appropriate for a given question or study. My work on this topic has helped in understanding the role of time scales in modeling the survival data and has helped in deciding what time scale to choose in the context of the study.

a) **Chalise P**, Chicken E and McGee D. Baseline Age Effect on Parameter Estimates in Cox Model. *Journal of Statistical Computation and Simulation, 82(12):1767-1774, 2012.*Not NIH funded
b) **Chalise P**, Chicken E and McGee D. Performance and Prediction for Varying Survival Time Scales. C*ommunications in Statistics –Simulation and Computation, 42(3): 636-649, 2013.* Not NIH funded
c) **Chalise P**, Chicken E and McGee D. Time scales in epidemiological analysis: an empirical analysis. *International Journal of Statistics and Probability*, 5(3): 91-101, 2016. Not NIH funded

4. **Study design and analysis for some collaborative projects including diet and nutrition:** One of my very important areas of research is in the design of study and the association analyses of the outcomes. There are numerous projects I am working on to this end. Results of such on-going projects have been shared with other researchers in national and international conferences.

a) Hamilton-Reeves J, Bechtel M, Hand Lauren, Schleper A, Yankee T M, **Chalise P**, Lee E K, Mirza M, Wyre H, Griffin J and Holzbeierlein J. Effects of immunonutrition for cystectomy on immune response and infection rates: a pilot randomized controlled clinical trial. *European Urology*. 69, 389-392, 2016. PMCID:PMC4793712
b) Cappendijk SLT, Carrier N., Miller GF**, Chalise P**, Pirvan DF, Santos AA, Hallquist M, James JR. In vivo nicotine exposure in the zebra finch; a promising innovative animal model to use in neurodegenerative disorders related research. *Pharmacology, Biochemistry and Behavior, 96: 152-159, 2010*. PMID:20471408
c) Chicken, E., **Chalise P**., and Loper, D. Conduit prevalence in the Woodville Karst Plain. *ASCE 327: 303-312, doi:10.1061/41003(327)29, 2008*. Not NIH funded
d) Upadyayula S, Ramaswamy M, **Chalise P**, Daniels J and Freudenberg N. The Association of Ethnic Pride with Health and Social Outcomes among Young Black and Latino Men after Release from Jail. *Youth and Society doi: 10.1177/0044118X15576736, 2015.* Not NIH funded

Complete List of Published Work

My bibliography page on NCBI:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1Rgf3_xLoJck2/bibliography/48693604/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

R01 HD076450 Chennathukuzhi (PI) 08/12/2013 - 04/30/2018
NIH
The Role of REST in the Pathogenesis of Uterine Fibroids
The goal of this project is to understand the molecular pathogenesis of uterine fibroids so that safe and efficacious therapies could be developed to treat this disease in the future. The project in vitro and in vivo experimental models to elucidate the role of REST and its target genes in the development of uterine fibroids.
Role: Co-Investigator

P30CA168524 Jensen (PI) 07/11/2012-06/30/2017
NIH/NCI
Cancer Center Support Grant

The University of Kansas Cancer Center Grant is a growing matrix organization that aims to leverage unique scientific assets to build a nationally significant cancer research and treatment center that will become the leading academic institution in the world for transforming discoveries in the laboratory into new therapeutic approaches.
Role: Statistician

Completed Support:

UL1TR000001/TR000119/TR000120 Barohn (PI) 06/01/2011 - 02/29/2016
NIH
Heartland Institute for Clinical and Translational Research
Create a new academic home with training programs for clinical and translational investigators, provide an enhanced coordinated translational research infrastructure and actively engage the community in developing, testing and disseminating translational research.
Role: Co-Investigator

R21 CA182715 Fridley (PI) 12/01/2013 - 11/30/2015
NIH/NCI
Bayesian Integrative Clustering for Determining Molecular Based Cancer Subtypes
To develop and apply a novel statistical model for determining molecular subtypes and to validate an ovarian cancer profile in two independent studies
Role: Co-Investigator

R21 CA140879 Fridley (PI) 08/01/2009 – 07/31/2011
NIH/NCI
Integrative Genomic Models for Pharmacogenomic Studies
The goal of this research is to combine various sources information collected into Bayesian models to aid in the understanding of the complex relationship between the genome and drug response.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Julia A. Chapman, MD**

eRA COMMONS USER NAME (credential, e.g., agency login): jchapman2

POSITION TITLE: Associate Professor, Director of Gynecologic Oncology

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of California, Los Angeles, CA	B.S.	1980	
University of California, Irvine, CA	M.D.	1985	Medicine
University of California, Irvine, CA	Residency	1989	Ob/Gyn
Union Memorial Hospital, Baltimore, MD	Training	1990	Pelvic Surgery
University of California, Irvine, CA	Fellow	1994	Gynecologic Oncology

A. Personal Statement

I have the clinical expertise, training, and motivation to carry out the proposed research project for the Cancer Program at the University of Kansas. I have over 20 years of both clinical experience in the treatment of women with gynecologic malignancies, as well as in the initiation and maintenance of GOG trials here at the University of Kansas Medical Center. While my role has been predominately clinical, I had maintained the division as the sole provider for over 7 years and have been a constant motivator to ensure the success of the division, despite the flux in personnel. This has included not only attracting 2 new Gynecologic Oncologists, one in 2015 and another to arrive August 2016, both of whom have a strong interest and will be able to focus on research, but also have the ability to now focus on Investigator Initiated trials. Furthermore, we have been able to continue with our Disease Working Group and involvement in NRG/GOG, promote the Phase 1 clinical trials in our patient population, and have now expanded our clinical focus into the Clinical Research Center. All of these efforts have increased our focus and promotion of clinical research in our patient population. Furthermore, our division has maintained an active relationship with Dr. A. Godwin and his Laboratory over the past 5 years; we are currently involved with both Tumor Tissue Banking (Biomarkers HSC 5929), as well as BioDepository/Tampon Trial.

1. IIT-2016-AJ-GYN-HIPEC-Ovarian: Heated Intraperitoneal Chemotherapy (HIPEC) in primary ovarian cancer patients. First IIT; Awaiting draft protocol.
2. Awaiting final draft on HIPEC Chemotherapy in Recurrent Ovarian Cancer, Jewell, A. and Chapman, J.
3. BioDepository/Tampon Trial

B. Positions and Honors

Positions and Employment:

1994 – 2002 Assistant Professor, Dept. of Gynecologic Oncology, University of Kansas Medical Center (KUMC), Kansas City, KS
2002 – pres Associate Professor, Dept. of Gynecologic Oncology, KUMC, Kansas City, KS
2003 – pres Director of Gynecologic Oncology, KUMC, Kansas City, KS
2012 – pres Medical Director, Gynecologic Oncology, KUMC, Kansas City, KS

Professional Memberships:

1995 – pres Member, Society of Gynecologic Oncologists
1995 – pres Member, Gynecologic Oncology Group
1999 – pres Member, American Society of Clinical Oncology

Honors:

1985 James H. McClure Award, University of California Irvine
1999 Resident Teacher of the Year, CREOG
2000 Outstanding professor of the Year, ACOG District VII

C. Contribution to Science:

1. One of my earliest publications concerned the impact of integrative medicine into the care of women with cancer, showing that alternative therapies had no negative impact in the care of my patients. Although this was only a small trial, it helped address a major issue that patients with cancer have-that of integrating lifestyle changes and nutritional therapies into their care.

a) Drisko JA, Chapman J, Hunter VJ. The use of antioxidant therapies during chemotherapy. Gynecol Oncol 2003 Mar;88(3). PMID: 12672707
b) Ma Y, Chapman J, Levine M, Polireddy K, Drisko J, Chen Q. High-dose parenteral ascorbate enhanced chemosensitivity of ovarian cancer and reduced toxicity of chemotherapy. Sci Transl Med 2014 Feb 5;6 (222). PMID: 24500406 (PMC# not required; not NIH funded)

2. After being on Medical Leave for 9-1/2 months, with collaboration with Surgical Oncology, we initiated and completed an approximately 20 patient experience of HIPEC in patients with recurrent colon as well as in women with recurrent ovarian cancer. Due to the smaller size and short follow-up, we are currently evaluating our outcomes. However, based upon this initial experience, with one of my new colleagues, we are in the process of initiating a clinical trial using HIPEC therapy in the upfront setting. This will be our first IIT.

3. Maintained over the past 4-5 years a collaborative involvement with Dr. Andrew Godwin and Dr. Ossama Tawfik (pathology) in developing and expanding a tumor biorepository. This collaborative involvement also extended into the maternal-fetal division with completion of a blood/tissue collection evaluation of miRNA.

a) Abstract – Small Nucleolar RNA U14 Promote Cell Cycle Progression in Ovarian Cancer. Dong Y, Mason C, Weiner C, Chapman J, Reynolds E, Johnson, G. Oral presentation at the Society of Reproductive Investigation's 63rd Annual Scientific Meeting. March 19, 2016

D. Research Support

Ongoing Research Support:

Active clinical trials:

GOG 0252 A Phase III Clinical Trial of Bevacizumab with IV versus IP Chemotherapy in Ovarian, Fallopian Tube and Primary Peritoneal Carcinoma NCI-Supplied Agent(s): Bevacizumab (NSC #704865, IND #7921)

GOG 0262 A Randomized Phase III Trial Of Every-3-Weeks Paclitaxel Versus Dose Dense Weekly Paclitaxel In Combination With Carboplatin With Or Without Concurrent And Consolidation Bevacizumab (Nsc #704865, Ind #113912) In The Treatment Of Primary Stage Iii Or Iv Epithelial Ovarian,Peritoneal Or Fallopian Tube Cancer

GOG 3001 (through Amgen) A Phase 3 Randomized, Double-blind, Placebo-controlled, Multicenter Study of AMG 386 With Paclitaxel and Carboplatin as First-line Treatment of Subjects With FIGO Stage III-IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancers

GOG 3003 A Randomized, Double-Blind, Placebo-Controlled Phase Ii Study Of Vtx 2337 In Combination With Pegylated Liposomal Doxorubicin (Pld) In Patients With Recurrent Or Persistent Epithelial Ovarian, Fallopian Tube Or Primary Peritoneal Cancer

GOG 0225 Can Diet and Physical Activity Modulate Ovarian, Fallopian Tube and Primary Peritoneal Cancer Progression-Free Survival?

GOG 0261 A Randomized Phase III Trial of Paclitaxel Plus Carboplatin Versus Ifosfamide Plus Paclitaxel in Chemotherapy- Naive Patients with Newly Diagnosed Stage I-IV, Persistent or Recurrent Carcinosarcoma (Mixed Mesodermal Tumors) of the Uterus, Fallopian Tube, Peritoneum or Ovary

GOG 3005 Veliparib With Carboplatin & Paclitaxel & as Continuation Maintenance Therapy in Subjects With Newly Diagnosed Stage III or IV, High Grade Serous, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

IMGN853-0401 First-in-Human Study to Evaluate IMGN853 in Adults With Ovarian Cancer and Other FOLR1-Positive Solid Tumors

NRG-GY004 Olaparib or Cediranib Maleate and Olaparib Compared With Standard Platinum-Based Chemo in Treating Patients With Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

GOG 0209 – Randomized Phase III Trial of Doxorubicin/Cisplatin/Paclitaxel and G-CSF versus Carboplatin/ Paclitaxel in patients with Stafe III and IV or Recurrent Endometrial Cancer

GOG 0219 A Phase III, Randomized Trial Of Weekly Cisplatin And Radiation Versus Cisplatin And Tirapazamine (Ind #46525) And Radiation In Stage Ib2, Iia, Iib, Iiib And Iva Cervical Carcinoma Limited To The Pelvis

GOG 0240 A Randomized Phase III Trial Of Cisplatin Plus Paclitaxel With And Without Nci-Supplied Bevacizumab (Nsc #704865, Ind #7921) Versus The Non-Platinum Doublet, Topotecan Plus Paclitaxel, With And Without Nci-Supplied Bevacizumab, In Stage Ivb, Recurrent Or Persistent Carcinoma Of The Cervix.

GPG 0086P A Three Arm Randomized Phase II Study of Paclitaxel/Carboplatin/Bevacizumab (NSC#704865, IND#7921), Paclitaxel/Carboplatin/Temsirolimus(NSC#683864, IND#61010) and Ixabepilone (NSC#710428, IND#59699)/Carboplatin/Bevacizumab as Initial Therapy for Measurable Stage III OR IVA, Stage IVB, or Recurrent Endometrial Cancer

GOG 0249 A Phase III Trial Of Pelvic Radiation Therapy Versus Vaginal Cuff Brachytherapy Followed By Paclitaxel/Carboplatin Chemotherapy In Patients With High Risk, Early Stage Endometrial Carcinoma

GOG 0274 – Outback A Phase III Trial Of Adjuvant Chemotherapy As Primary Treatment For Locally Advanced Cervical Cancer Compared To Chemoradiation Alone: The Outback Trial

GOG 0270 GROningen INternational Study on Sentinel Nodes in Vulvar Cancer (GROINSS-V)II: An Observational Study

RTOG 1203 A Randomized Phase III Study Of Standard Vs. IMRT Pelvic Radiation For Post-Operative Treatment Of Endometrial And Cervical Cancer (TIME-C)

GOG 0263 Randomized Phase III Clinical Trial Of Adjuvant Radiation Versus Chemoradiation In Intermediate Risk, Stage I/Iia Cervical Cancer Treated With Initial Radical Hysterectomy And Pelvic Lymphadenectomy

GOG 0265 Vaccine Therapy in Treating Patients With Persistent or Recurrent Cervical Cancer

TREG-001-00-V2-1209 A Registry of Caris Target Now Test Results (Biomarker Expression Patterns) for Evaluation of Correlation With Clinical Outcomes for Cancer

Recently Completed Research Support: None

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Teresa J. Christenson

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Associate Director for Administration

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Nebraska, Lincoln	BS	05/1988	Actuarial Science

A. Personal Statement

As the Associate Director for Administration since 2006, my role involves providing administrative support to efficiently meet KUCC's goals. My responsibilities include cancer grant support services, cancer grant administration, human resource functions, communications strategies, fiscal management of the Cancer Center and its shared resources, facilities management, planning and evaluation processes, general administrative functions and Information Technology services.

I have 22 years of management experience in business development, product development, and project management in the financial services industry.

B. Positions and Honors

Positions and Employment

1988-1996 Associate Actuary, ING Groep NV, Des Moines, IA
1996-1999 Vice President and Actuary, Product Development, ING Group NV, West Chester, PA
1999-2004 Vice President, Software Quality Assurance and Testing, West Chester, PA
2005 Management Analyst, School of Medicine, University of Kansas Medical Center, Kansas City, KS
2006 Director of Finance, The University of Kansas Cancer Center, University of Kansas Medical Center, Kansas City, KS
2006 Associate Director of Administration, The University of Kansas Cancer Center, University of Kansas Medical Center, Kansas City, KS

Other Experience and Professional Memberships

1988 Member, Society of Actuaries
1990 Associate, Society of Actuaries

C. Contribution to Science

N/A

D. Research Support

Ongoing Support:

P30 CA168524 Jensen (PI) 07/01/2012 - 06/30/2017
Cancer Center Support Grant (CCSG)
Major Goals: The University of Kansas Cancer Center is a growing matrix organization that aims to leverage unique scientific assets to build a nationally significant cancer research and treatment center that will become the leading academic institution in the world for transforming discoveries in the laboratory into new therapeutic power one part one approaches.
Role: Associate Director for Administration

Completed Support:

N/A

BIOGRAPHICAL SKETCH

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NAME: **James Coster, MD**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Assistant Professor, Department of Radiation Oncology

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Illinois, Urbana-Champaign, IL	BS	07/1984	Biology
University of Illinois, Champaign/Chicago	MD	06/1988	Medicine
Mayo Graduate School of Medicine, Rochester, MN	Residency	06/1993	Radiation oncology
Mayo Graduate School of Medicine, Rochester, MN	Fellowship	06/1992	Radiation oncology

A. Personal Statement

I have served on the Protocol Review and Monitoring Committee at the University of Kansas for three years. I have been actively involved in clinical cancer research for the past 28 years, initially as a trainee and fellow at the Mayo Clinic-Rochester, MN, then as a member of Radiation Oncology Associates of Kansas City and U.S. Oncology. During that time I was a principal investigator for both phase II and phase III trials and remained an active member of several national cooperative research groups. I have published a number of abstracts, journal articles and text book chapters highlighting aspects of that research over the past three decades.
The Radiation Oncology Department at the University of Kansas has been one of the most active and productive in the United States in clinical trial participation in recent years, particularly in the RTOG/NRG arena, generating a large number of publications each year.

B. Positions and Honors

Positions and Employment:

1992 – 1993 Instructor, Mayo Graduate School of Medicine, Rochester, MN
1993 – 2005 Medical Director, Johnson County Radiation Therapy
2005 – 2011 Executive Board, Kansas City Cancer Centers
2011 – pres. Assistant Professor, Radiation Oncology, University of Kansas Medical Center, Kansas City, KS

Other Professional Activities:

1993 – 2010 Cancer Committee, Overland Park Regional Medical Center, St. Joseph Health Center, Shawnee Mission Medical Center

Honors and Awards:

1987 – 1988 Simon Kramer clinical research scholarship via Thomas Jefferson University

C. Contribution to Science

1. It has long been recognized that radiation therapy negatively impacts dentition but whether or not this is due to direct effects, indirect effects or a combination thereof has been unclear. Animal models have not been useful in clarifying these issues. In an extensive collaboration with experts at the University of Missouri-Kansas City School of Dentistry, via careful subsection analysis of more than 1800 teeth which were in, adjacent to or beyond radiation portals, we were able to construct curves defining the relationship between radiation dose and dental breakdown clarifying the relative impact of indirect effects (loss salivary flow) and direct effects. These data represent the first human data analyzing this issue.

a) Walker MP, Wichman B, Cheng AL, **Coster J**, “Impact of Radiotherapy Dose on Dentition Breakdown in Head and neck Cancer Patients”, Pract Radiat Oncol. 2011;1: 142-148. PMC3156461

2. Since the advent of megavoltage radiation therapy units, postoperative radiation therapy has been a component of standard management for patients with metastatic squamous cell carcinoma of unknown origin arising within the head/neck. Whether or not favorable subsets of patients might be able to avoid postoperative radiotherapy without compromising tumor control was unclear until my colleagues and I analyzed a large series of patients at the Mayo Clinic-Rochester among whom postoperative radiation therapy had been withheld. A surgery-only approach was a unique institutional policy at the Mayo Clinic. In analyzing and comparing patterns of recurrence stratified by risk profile, we were able to identify risk thresholds below which radiation therapy could be safely withheld. This was a practice-changing analysis.

a) **Coster JR**, Foote RL, et al, “Cervical Nodal Metastasis of Squamous Cell Carcinoma of Unknown Origin: Indications for Witholding Radiation Therapy”, Int J Radiat Oncol Biol Phys. 1992;23: 743-749. PMID: 1618667

3. During the first several years of my career I was involved in both laboratory and human research on the combined effects of hyperthermia and external beam radiation therapy on both normal tissues and tumor cells. I was involved in the earliest detailed work involving in vivo combined hyperthermia and radiation therapy at Thomas Jefferson University in collaboration with Dr. Leslie Tupchong as parameters and toxicity criteria were being defined which hopefully lead to standard of care for application of hyperthermia in humans. I later carried this work forward to the Mayo Clinic-Rochester where I performed animal studies to define toxicity parameters for application of intraoperative hyperthermia.
As part of a national phase II trial, we recently demonstrated the efficacy of adding docetaxel to traditional adjuvant treatment for men with locally aggressive prostate cancer status post prostatectomy.

a) Kumar P, VanVeldhuizen P, Thompson, M, Shen X, **Coster J**, et al, “Preliminary updated results of a phase I/II trial using trimodality therapy in patients with post-prostatectomy high-risk pathologic (p) T2-3N0M0 prostate cancer”, J Clin Onc. 2014;32, e16084 (not NIH funded).

4. In an effort to streamline a nationwide network of oncology practices in the United States with over 1200 practicing oncologists, I chaired and authored the pathway algorithms for breast cancer radiotherapy. This was a key component of the first nationwide pathway program in the United States. This pathway program was ultimately a critical part of the Value Pathways and Quality Initiatives program adopted by McKesson Health.

D. Research Support

Ongoing Research Support:
N/A

Completed Research Support:
N/A

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **James W. Coulter, BSN**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Midwest Cancer Alliance Clinical Trials Director

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Missouri at Kansas City, MO	B.Sc.	05/1972	Biology
Rockhurst University, Kansas City, MO	BSN	12/1994	Nursing

A. Personal Statement

I have the education and experience to manage and support clinical trial activities at the University of Kansas Cancer Center and the Midwest Cancer Alliance. I have worked as a research nurse on Phase I clinical trials and as a research nurse and monitor/manager of Phase II - III oncology clinical trials. I am familiar with the regulatory requirements, human subject protections and nursing support necessary to manage enrollments, eligibility, treatment decisions and assessments needed for successful clinical trials.

B. Positions and Honors

Positions and Employment:

1995 – 1996 Staff Nurse, Research Medical Center, Kansas City, MO
1996 – 2009 Health Law Analyst, Shughart, Thompson & Kilroy, Kansas City, MO
1997 – 2010 Phase I Research Nurse (PRN), Quintiles, Overland Park, KS
2009 – 2010 Research Nurse Manager, KU Cancer Center, University of Kansas Medical Center, Kansas City, KS
2010 – Pres. Clinical Trials Director, Midwest Cancer Alliance, KU Cancer Center, University of Kansas Medical Center, Kansas City, KS

C. Contributions to Science

Not applicable.

D. Research Support

Ongoing Research Support:
None

Completed Research Support:
None

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Francisco J. Diaz, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): fjdiaz

POSITION TITLE: Associate Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
National University of Colombia, Medellin, Colombia	B.S.	1993	Mathematics
National University of Colombia, Medellin, Colombia.	M.S.	1996	Statistics
University of Kentucky, Lexington, USA	Ph.D.	2002	Statistics

A. Personal Statement

I am an experienced biostatistician who has participated in a substantial number of collaborative research projects concerning physiologic, medical and pharmacological issues, and the author or co-author of more than 90 articles published in prestigious medical or pharmacological journals. Thus, my extensive methodological expertise, and my experience in the application of statistical methods to a wide range of medical and pharmacological research will guarantee appropriate data analysis and effective contribution to study design and sample size computation.

As a biostatistician of the BISR of the University of Kansas Medical Center, I will provide collaborative support on study design/trial design, data quality control, statistical analysis, interpretation of results, data coordination, power and sample size of studies conducted by University of Kansas Cancer Center Members. This includes but is not limited to phase I, phase II and phase I/II clinical trials and animal studies. In the Protocol Review and Monitoring Committee (PRMC) I will statistically review human subject cancer or cancer-related protocols to help establish their relative priority to the institutional mission, by assessing the appropriateness of their statistical plans and sample sizes.

B. Positions and Honors

Positions and Employment:

1992-1993 Teaching assistant in statistics, Department of Mathematics, National University of Colombia, Medellin, Colombia.
1994 Instructor in statistics, Department of Mathematics, National University of Colombia, Medellin, Colombia.
1995 Teaching assistant in statistics, Department of Mathematics, National University of Colombia, Medellin, Colombia.
1996-2002 Associate Instructor in statistics, Department of Mathematics, National University of Colombia, Medellin, Colombia.
1998 Teaching assistant in statistics, Department of Statistics, University of Kentucky, Lexington, KY.
1999-2001 Statistician, Mental Health Research Center, University of Kentucky, Lexington, KY.
2002-2009 Statistics consultant, Mental Health Research Center, University of Kentucky, Lexington, KY.
2003-2006 Assistant professor, Department of Statistics, Universidad Nacional de Colombia, Medellin, Colombia.
2003-2006 Director of Undergraduate and Graduate Studies, Department of Statistics, National University of Colombia, Medellin, Colombia.

2007-2009	Associate Professor, Department of Statistics, National University of Colombia, Medellin, Colombia.
2009-present	Associate Professor, Department of Biostatistics, University of Kansas Medical Center, Kansas City, KS.

Honors:

1996	"Meritorious M.S. Thesis". Award given by the School of Sciences of the Universidad Nacional de Colombia to my M.S. thesis.
1999	"Graduate School Fellowship". Awarded by the Graduate School of the University of Kentucky, Lexington, USA.
2000	"Graduate School Fellowship". Awarded by the Graduate School of the University of Kentucky.
2000-2001	"Raymond W. Rishel Prize for Best Student in Applied Probability". Awarded by the Department of Statistics of the University of Kentucky.
2005-present	Editorial Board, Colombian Journal of Statistics (Revista Colombiana de Estadistica).
2006-2008	"Significantly Superior Faculty". Distinction awarded by the Faculty of Sciences of the National University of Colombia at Medellin, Colombia.
2007	Juror of the "Third National Award for Rheumatology Research". I was part of the committee that awarded the prize for the best research poster presented to the "XI Colombian Meeting on Rheumatology", Medellin, Colombia.
2010-present	Biostatistical Reviewer for the Clinical & Integrative Cardiovascular Science (CICS) Study Section of the National Institutes of Health (NIH) (in years 2010, 2011, 2013, 2014).
2011-2013	Editorial Advisory Board, Current Pharmacogenomics and Personalized Medicine.
2014	Biostatistical Reviewer for the NASA Crew Health, Teamwork, Behavior and Sleep Panel. Washington D.C.(two times: March 3-4, and August 27, 2014).
2015	Reviewer for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) Study Section of the National Institutes of Health (NIH). Washington DC., October 27-28, 2015.

C. Contributions to Science

1. **As a result of my collaborative work in the High Throughput Screening (HTS) laboratory of the University of Kansas, I developed statistical methods for testing toxic and dose-response effects of chemical compounds using cell based assays.** This work was motivated by the need of statistical methods for selecting effective compounds from big libraries of chemicals in order to support both drug repurposing and combinatorial chemistry research, and ultimately to expedite the finding of pharmacological cures. Part of this work (Diaz et al. 2013) was featured in the August, 2013 issue of Global Medical Discovery. These methods are published in:

a) **Diaz, F.J.,** McDonald, P.R., Roy, A., Taylor, B., Price, A., Hall, J., Blagg, B.S.J., Chaguturu, R. (2013) Compound ranking based on a new mathematical measure of effectiveness using time course data from cell-based assays. *Combinatorial Chemistry & High Throughput Screening,* 16:168-179. PMC3655799.
b) **Diaz, F.J.,** McDonald, P.R., Pinter, A., Chaguturu, R. (2015) Measuring and statistically testing the size of the effect of a chemical compound on a continuous in-vitro pharmacological response through a new statistical model of response detection limit. *Journal of Biopharmaceutical Statistics,* 25: 757-780. PMID: 24905187, PMC in process.

2. **My methodological research has been published in highly regarded statistical journals** including *Statistics in Medicine, Journal of Biopharmaceutical Statistics, and Journal of Computational and Graphical Statistics*, as well as in prestigious pharmacological journals including *Clinical Pharmacokinetics, Therapeutic Drug Monitoring, Pharmacopsychiatry,* and *Combinatorial Chemistry & High Throughput Screening.* In particular, I have developed applications of random effects linear models to drug dose individualization and personalized medicine. My research demonstrates that these models may provide more accurate predictions of blood drug levels than the models traditionally used in therapeutic drug monitoring. I believe that random effects linear models will revolutionize the mathematical theory and practical applications of pharmacology and personalized medicine. Examples of publications:

a) **Diaz, F.J.,** Berg, M.J., Krebill, R., Welty, T., Gidal, B.E., Alloway, R., Privitera, M. (2013). Random-effects linear modeling and sample size tables for two special cross-over designs of average bioequivalence studies: the 4-period, 2-sequence, 2-formulation and 6-period, 3-sequence, 3-formulation designs. *Clinical Pharmacokinetics*, 52:1033–1043. PMID: 24085600 (PMC# not required; not NIH funded)
b) **Diaz, F.J.,** Yeh, H-W., de Leon, J. (2012). Role of statistical random-effects linear models in personalized medicine. *Current Pharmacogenomics and Personalized Medicine*, 10, 22-32. PMCID: PMC3580802.
c) **Diaz, F.J.,** Cogollo, M., Spina, E., Santoro, V., Rendon, D.M., de Leon, J. (2012). Drug Dosage Individualization Based on a Random-Effects Linear Model. *Journal of Biopharmaceutical Statistics*, 22, 463-484. PMID: 22416835 (not NIH funded)
d) **Diaz, F.J**. (2016) Measuring the individual benefit of a medical or behavioral treatment using generalized linear mixed effects models. *Statistics in Medicine*, 2016 Jun 20. Doi:10.1002/sim.7005. PMID: 27323698 (not NIH funded)

3. **I have authored or co-authored a significant number of articles investigating the pharmacokinetics and side effects of psychotropic drugs.** As a first author, my collaborative research has made substantial contributions to the literature on clozapine and valproic acid metabolism. Also, I conducted the statistical analyses of eight studies investigating different aspects of the metabolic syndrome in psychiatric patients, including studies of the effects of antipsychotics on lipid levels; all these studies have been successfully published in prestigious journals. My participation in pharmacological research has allowed me to develop collaborations with worldwide experts in psychopharmacology at the University of Messina, Italy, Lausanne University, Switzerland, and the University of Kentucky at Lexington. Some examples from this work are:

a) **Diaz, F.J.,** Eap, C.B., Ansermot, N., Crettol, S., Spina, E., de Leon, J. (2014) Can valproic acid be an inducer of clozapine metabolism? Pharmacopsychiatry, 47, 89-96. PMC4229130.
b) **Diaz, F.J.,** Perez-Iglesias, R. Mata, I. Martínez-Garcia, O. Vázquez-Barquero, J.L., de Leon, J., Crespo-Facorro, B. (2011). Using structural equations to test for a direct effect of some antipsychotics on triglyceride levels in drug-naïve first-episode psychosis patients. *Schizophrenia Research*, *131*, 82-89. PMID: 21726981 (not NIH funded)
c) **Diaz, F.J.,** Santoro, V., Spina, E., Cogollo, M., Rivera, T.E., Botts, S., de Leon, J. (2008). Estimating the size of the effects of co-medications on plasma clozapine concentrations using a model that controls for clozapine doses and confounding variables. *Pharmacopsychiatry,* 41, 81-91. PMID: 1848454 (not NIH funded)
d) **Diaz, F. J.,** de Leon, J. (2002). Excessive Antipsychotic Dosing in 2 U.S. State Hospitals. *Journal of Clinical Psychiatry,* 63, 998-1002. PMID: 12444813.

4. **A substantial part of my collaborative research career has been dedicated to the study of addictions, including legal and illegal substance abuse, and their relationship with the occurrence and symptoms of psychiatric illnesses.** In particular, I have conducted the statistical analyses of more than 20 published studies investigating different aspects of smoking behavior and nicotine addiction in mentally ill patients and/or the general population, including the psychometric problems involved in measuring nicotine addiction. One of the most important articles in this area is a meta-analysis demonstrating that the association between schizophrenia and smoking is consistent all over the world (*Schizophrenia Research 2005;76:135-157*); this article has already been cited 401 times in the medical literature according to the Web of Science Core Collections. All this research demonstrates the need of understanding the socio-biological vulnerability of mentally ill people for developing addictions, and the need of developing anti-addiction therapies specific for this population. Examples of publications:

a) **Diaz, F.J.,** James, D., Botts, S., Maw, L., Susce, M.T., de Leon, J. (2009). Tobacco Smoking Behaviors in Bipolar Disorder: A Comparison of the General Population, Schizophrenia and Major Depression. *Bipolar Disorders,* 11, 154-165. PMID: 19267698 (not NIH funded)
b) **Diaz, F.J.**, Velásquez, D.M., Susce, M.T., de Leon, J. (2008). The association between schizophrenia and smoking: Unexplained by either the illness or the prodromal period. *Schizophrenia Research,* 104, 214-219. PMID: 18650069 (not NIH funded)

c) **Diaz, F. J.,** Jané, M., Saltó, E., Pardell, H., Salleras, Ll., Pinet, C., de Leon, J. (2005). A Brief Measure of High Nicotine Dependence for Busy Clinicians and Large Epidemiological Surveys. *Australian and New Zealand Journal of Psychiatry,* 39, 161-168. PMID: 15701065.
d) de Leon, J., **Diaz, F.J.** (2012) Genetics of schizophrenia and smoking: An approach to studying their comorbidity based on epidemiological findings. *Human Genetics* 131, 877-901. PMC3536540.

The following URL has a full list of my published work:

http://www.ncbi.nlm.nih.gov/sites/myncbi/francisco.diaz.1/bibliography/47794695/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support:

P30CA168524 Jensen (PI) 07/11/2012 - 06/30/2017
NIH/NCI
Cancer Center Support Grant
The University of Kansas Cancer Center is a growing matrix organization that aims to leverage unique scientific assets to build a nationally significant cancer research and treatment center that will become the leading academic institution in the world for transforming discoveries in the laboratory into new therapeutic approaches.
Role: Co-investigator

R01HD069043 Nothnick (PI) 03/06/2012 - 01/31/2017
NIH
The Role of miR-451 in Endometriosis Pathophysiology and Treatment
Major Goals: To demonstrate that miR-451plays a functional role in endometriosis growth, evaluate if miR-451 add-back can be used as a treatment for the disease, and determine if miR-451 serum levels are correlated with presence and severity of endometriosis.
Role: Co-Investigator

R01CA174735 Iwakuma (PI) 05/01/2014 - 04/30/2019
The role of MDM2-MTBP axis in Cancer Metastasis
Major Goals: To determine the roles of MTBP and its functional association with MDM2 in cancer metastasis
Role: Co-Investigator

R21DC015038 Chertoff (PI) 06/01/2016 - 06/01/2018
Developing a Biomarker for Auditory Nerve Survival
Develop a diagnostic test of auditory nerve survival that allows identifying and quantifying the limited nerve population in patients with hearing loss. This could lead to identifying the targets for genetic and stem cell treatment to cure hearing loss, predicting which patients will be good hearing aid users, predicting candidacy for a cochlear implant (which requires auditory nerve survival), and diagnosing the patient with “Hidden Hearing Loss” so that counseling regarding noise hazards can be implemented.
Role: Co-investigator.

DOD. TriService Nursing Research Program Pierce (PI) 01/01/2015 - 12/31/2016
Reducing cellular damage in traumatic brain injury using ubiquinol
Major Goals: The goal of this study is to determine if administering ubiquinol (reduced form of Coenzyme Q10) before and after traumatic brain injury (TBI) in rats would reduce cellular damage. Specifically, we plan to determine if ubiquinol attenuates brain (cortex) apoptosis, decreases mitochondrial brain damage, and alters varius brain neurochemicals and biomarkers.
Role: Co-Investigator

Recently Completed Support:

R01CA155014 Befort (PI) 08/01/2011 - 05/31/2016
NIH
Group Phone-Based Weight Control among Rural Breast Cancer Survivors
Determine cost-effective phone-based strategy for producing significant long-term weight control in rural BrCa survivors. Examine impact of weight loss and weight regain on BrCa risk biomarkers.
Role: Statistician

UL1TR000001/TR000119/TR000120 Barohn (PI) 06/01/2011 - 02/29/2016
NIH
Institutional Clinical and Translational Science Award
Create a new academic home with training programs for clinical and translational investigators, provide an enhanced coordinated translational research infrastructure and actively engage the community in developing, testing and disseminating translational research.
Role: Co-Investigator

N11-C02 Pierce (PI) 08/01/2011 - 07/31/2014
DOD. TriService Nursing Research Program
Coenzyme Q10: A New Treatment for Hemorrhagic Shock
This study is to examine Coenzyme Q10 as a potential therapy to reduce cellular and microcirculation damage following hemorrhagic shock. Production of reactive oxygen species, apoptosis, leukocyte adherence, and mast cell degranulation following hemorrhagic shock with or without administration of Coenzyme Q10 will be measured.
Role: Statistician

SUB#007808 Privitera, Berg (PIs) 04/01/2012 - 03/31/2014
Food and Drug Administration
Single-Dose Bioequivalence Study of Generics of Lamotrigine.
A comparison of lamotrigine brand product with two generics with single doses in a cross-over trial.
Role: Statistician, Principal Investigator at the Data Analysis and Management Center (KUMC)

PO#4500063997 Privitera, Berg (PI) 04/01/2012 - 03/31/2014
Food and Drug Administration
Chronic-Dose Bioequivalence Study of Generics of Lamotrigine
A comparison of two generics of lamotrigine in a cross-over trial using chronic doses.
Role: Statistician, Principal Investigator at the Data Analysis and Management Center (KUMC)

R33DC011096 Chertoff (PI) 06/15/2010 - 05/31/2015
NIH
Diagnosing Outer Hair Cell Health Along the Cochlear Partition
The aim of the R21 phase is to determine if the cochlear microphonic (CM), in response to a low-frequency tone embedded in high-pass noise, can be used to quantify the location of missing outer hair cells along the cochlear partition.
Role: Statistician

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

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NAME: Dan Alan Dixon, PhD

eRA COMMONS USER NAME (credential, e.g., agency login): DIXON00

POSITION TITLE: Co-Leader Cancer Prevention & Survivorship Program

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Augustana Unversity, Sioux Falls, SD	B.A.	05/1987	Biology & Chemistry
Northwestern University, Evanston, IL	Ph.D.	01/1994	Molecular Biology & Biochemistry
University of Utah, Salt Lake City, UT	Postdoctoral	09/1998	Molecular Biology

A. Personal Statement

I am a basic cancer researcher with specific training in protein/nucleic acid interactions and expertise in cancer biology and inflammation research primarily in the area of colorectal tumorigenesis. My research area is focused on understanding post-transcriptional regulation in cancer. Our efforts have focused on the oncogenic and tumor-suppressive effects of specific RNA-binding proteins and microRNAs and have established the critical role these post-transcriptional factors play in regulating oncogenic gene expression during tumorigenesis. Our current work has extended into demonstrating that RNA-binding proteins and microRNAs can serve as risk and response biomarkers, along with being effective new cancer prevention targets for controlling oncogenic gene expression through post-transcriptional mechanisms.

My leadership roles as the Associate Director of the NIH/COBRE-funded Center for Colon Cancer Research (University of South Carolina) and Co-Leader of the NCI-designated University of Kansas Cancer Center Cancer Prevention and Survivorship (CPS) Program have allowed me to develop and lead working groups in gastrointestinal cancer prevention, utilizing member strengths in molecular biomarker identification and development of novel therapeutics. As a result of these experiences, I am aware of the importance of developing collaborative projects among program members with the goal of producing peer-reviewed publications and competitive proposal applications. Together with Dr. Jennifer Klemp, we will lead the CPS program, which is responsible for (a) interrogation of precancerous biology for the purpose of identifying targets and potential agents/interventions for prevention of cancer, and development of risk and response biomarkers for prevention interventions, and (b) performance of early phase prevention and survivorship translational trials that will facilitate discovery and benefit the KUCC translational efforts as a whole. We are also responsible for identifying developing fields and making recommendations to the CPS program members. As a means to promote intra- and inter-programmatic collaborations, we are responsible for coordinating working group sessions, seminars, retreats and programmatic funding. I will be responsible for coordinating and facilitating activities within Theme I (Pre-Cancerous Biology and Risk Biomarkers) with Dr. Fariba Behbod in the CPS Program.

B. Positions and Honors

Positions and Employment

1987-1991 Graduate Research Assistant, Dept. of Mol. Biology and Biochemistry, Northwestern Univ.
1991-1993 Graduate Research Assistant, Department of Microbiology, University of California, Davis
1994-1998 Postdoctoral Fellow, Program in Human Molecular Biology and Genetics, University of Utah
1998-2001 Instructor, Department of Oncological Sciences, University of Utah
2001-2003 Research Assistant Professor, Dept. of Surgery, Vanderbilt University Medical Center

2004-2010 Assistant Professor, Dept. of Biological Sciences, University of South Carolina
2010-2012 Associate Professor, Dept. of Biological Sciences, University of South Carolina
2010-2012 Associate Director, Center for Colon Cancer Research, University of South Carolina
2012- Associate Professor, Department of Cancer Biology, University of Kansas Medical Center
2013- Co-Leader, Cancer Prevention and Survivorship Program, University of Kansas Cancer Center

Professional Memberships

1986 Member, *Beta Beta Beta* Biological Society, Augustana University
1987 Member, Blue Key National Honor Fraternity, Augustana University
1999-present Member, American Heart Assoc. Council on Arteriosclerosis, Thrombosis, and Vascular Biology
2002-present Member, American Gastroenterological Association
2002-present Member, American Association for Cancer Research

Study Sections and Other Professional Activities (selected)

NIH
NCI Subcommittee J - Career Development Panel, regular member (2016-2018)
Small Business (SBIR) Special Emphasis Panel in Digestive Sciences (2015)
Molecular Genetics B (MGB) Study Section, *ad hoc* member (2014)
NIEHS Committee Member on Promotions, *ad hoc* member (2011)
NIAID Special Emphasis Panel, Program Project Grant Reviewer (2009)

DOD
USAMRMC Peer Reviewed Cancer Research Program Programmatic Panel (2014-2017)
Chairman, Peer Reviewed Cancer Research Program Colorectal Cancer Study Section (2013)
CDMRP Discovery Award Colorectal Cancer Peer Review Panel (D-CC-2) (2011)
CDMRP Colorectal Cancer Peer Review Panel (PRCRP CC) (2010)

AGA
AGA Institute Research Awards Panel member (2014-2017)
Chair, DDW Tumor & Cell Biology Abstract Review Committee (2014-2016)
AGA Institute Councillor for the Gastrointestinal Oncology (GIONC) Section (2014-2017)
Digestive Disease Week, Abstract Reviewer (2008-present)

AACR
AACR Colon Cancer Research Fellowships Scientific Review Committee (2015-2017)
Abstract Review Committee, Frontiers in Cancer Prevention Conference (2014)
Scientific Program Committee Co-Chair, Frontiers in Cancer Prevention Conference (2013)

AHA
Basic Cell, Genetics and Epigenetics Peer Review Group-2, standing member (2012-present)
Basic Cell & Molecular Biology Peer Review Group-1, standing member (2002-2005)

2014-present Editorial Board, *Cancer Research* (American Association of Cancer Research)
2016-present Editorial Board, *npj Precision Oncology* (Nature Publishing Group)
2016 Co-Editor, *Gastroenterology Clinics* issue on Gastrointestinal Neoplasia (Elsevier)
2012-present Editorial Board, *Frontiers in Gastrointestinal Cancers* (Frontiers in Science)
2010-present Associate Editor, *Frontiers in Pharmacotherapy of Inflammation* (Frontiers in Science)

2015-present Fight Colorectal Cancer Medical Advisory Board Member
2012-present Fight Colorectal Cancer National Research Advocates Training Scientific Advisor
2012-2014 Faculty Leadership Academy, University of Kansas Medical Center
2007-2010 American Cancer Society Greater Midlands Leadership Council Member
2002-2004 Leadership Development in Biomedical Research Trainee, Vanderbilt University

Honors and Awards

1987 Outstanding Biology Student Award, Augustana College
1987 *Magna Cum Laude*, Augustana College
1991 *Sigma Xi* Award in Biochemistry, Northwestern University
2000 American Heart Association Young Investigator Award
2006 American Gastroenterological Association Annual Meeting Basic Science Plenary speaker
2012 Keynote speaker, 2nd World Congress on Cancer Science & Therapy, OMICS Group
2014 Chief Guest, 2nd International Conference on Herbal and Synthetic Drug Studies (HSDS-2014), ISTRA, Pune, India.
2015 Andrew Giusti Memorial Award for Research Advocacy (Fight Colorectal Cancer Foundation)

C. Contribution to Science

1. **Biochemistry of Genetic Recombination:** My early research investigated the mechanisms of homologous recombination in the main pathway of genetic recombination in *E. coli*, the RecA/RecBCD pathway, and focused on determining the biochemical role of the RecBCD enzyme in the recombination process through its DNA nuclease and helicase activities. This seminal work demonstrated homologous DNA pairing through the concerted actions of RecBCD, SSB (single-stranded DNA binding protein), and RecA proteins and this exchange of genetic information was stimulated at recombination hotspots, known as χ sites. Further analysis identified that χ is a regulatory DNA sequence that acts to attenuate the destructive nuclease activity of RecBCD enzyme allowing it to maintain its recombination-promoting DNA helicase activity through a mechanism of functional subunit inactivation of the RecBCD holoenzyme. My efforts have resulted in a new paradigm for the molecular behavior of recombination hotspots and have contributed to understanding the process of homologous recombination.
    a) **Dixon, D.A.** and Kowalczykowski, S.C. (1991). Homologous Pairing *In Vitro* Stimulated by the Recombination Hotspot, Chi. Cell *66*: 361-371.
    b) **Dixon, D.A.** and Kowalczykowski, S.C. (1993). The Recombination Hotspot, Chi, is a Regulatory Sequence that Acts by Attenuating the Nuclease Activity of the *Escherichia coli* RecBCD Enzyme. Cell *73*: 87-96.
    c) **Dixon, D.A.**, Churchill, J.J. and Kowalczykowski, S.C. (1994). Reversible Inactivation of the *Escherichia coli* RecBCD Enzyme by the Recombination Hotspot, Chi, is Due to Functional Inactivation or Loss of the RecD Subunit. Proc. Natl. Acad. Sci. USA *91*: 2980-2984. PMCID: PMC43498
    d) **Dixon, D.A.** and Kowalczykowski, S.C. (1995). Role of the *Escherichia coli* Recombination Hotspot, χ, In RecABCD-Dependent Homologous Pairing. J. Biol. Chem. *27*: 16360-16370.

2. **Regulation of COX-2 Expression:** As a postdoctoral fellow, I initiated a project examining the regulation of the inducible isoform of cyclooxygenase COX-2. Prior to my efforts, it was known that elevated prostaglandins were a contributing factor in chronic inflammation and various cancers. I identified that the COX-2 mRNA is targeted for rapid degradation and translational suppression through contains AU-rich sequence elements (AREs). My work has shown this 3'UTR mRNA element to be the target of post-transcriptional regulation that dictates the fate of the COX-2 transcript. These publications established the fundamental role post-transcriptional regulation has in controlling COX-2 expression in physiological and pathological states.
    a) **Dixon, D.A.**, Tolley, N.D., King, P.H., Nabors, L.B., McIntyre, T.M., Zimmerman, G.A., and Prescott, S.M. (2001) Altered Expression of the mRNA Stability Factor HuR Promotes Cyclooxygenase-2 Expression in Colon Cancer Cells. J. Clin. Invest. *108*:1657-1665. PMCID: PMC200983
    b) **Dixon, D.A.**, Balch G.C., Kedersha N., Anderson, P., Zimmerman, G.A., Beauchamp, R.D., and Prescott, S.M. (2003) Regulation of Cyclooxygenase-2 Expression by the Translational Silencer TIA-1. J. Exp. Med. *198*: 475-481. PMCID: PMC2194089
    c) **Dixon, D.A.**, Tolley, N.D., Bemis-Standoli, K., Martinez, M.L., Weyrich, A.S, Morrow, J.D., Prescott, S.M., Zimmerman, G.A. (2006) Expression of COX-2 in Platelet-Monocyte Interactions Occurs via Combinatorial Regulation Involving Adhesion and Cytokine Signaling. J. Clin. Invest. *116*:2727–2738. PMCID: PMC1570372
    d) Aguado, A., Rodríguez, C., Martínez-Revelles, S., Avendaño, M.S., Zhenyukh, O., Orriols, M., Martínez-González, J., Alonso, M.J., Briones, A.M., ***Dixon, D.A.**, *Salaices, M. (2015) HuR mediates the synergistic effects of angiotensin II and interleukin 1β on vascular COX-2 expression and cell migration. Br. J. Pharmacol. *172*:3028-3042. *Co-corresponding authors. PMCID: PMC4459021.

3. **Post-Transcriptional Regulation in Cancer:** Various cancers exhibit enhanced expression of inflammatory mediators, angiogenic growth factors and oncogenes resulting from defective post-transcriptional regulation. Efforts from my laboratory and collaborations have identified the mechanisms allowing for pathogenic mRNA stabilization. These publications (and those above) show that oncogenic signaling directly influences the enhanced expression of the RNA-stability factor HuR and loss of the RNA-

decay factor TTP. My efforts have established that these RNA-binding proteins can serve as novel tumor-promoting and tumor-suppressing factors, along with developing a new paradigm for understanding altered gene expression during tumor development.

a) Young, L.E., Sanduja, S., Bemis-Standoli, K., Pena, E.A., Price, R.L., **Dixon, D.A.** (2009) The mRNA Binding Proteins HuR and Tristetraprolin Regulate Cyclooxygenase 2 Expression During Colon Carcinogenesis. Gastroenterology *136*:1669-1679. PMCID: PMC3742387

b) Sanduja, S., Kaza, V., **Dixon, D.A**. (2009) The mRNA Decay Factor Tristetraprolin (TTP) Induces Senescence in Human Papillomavirus-Transformed Cervical Cancer Cells by Targeting E6-AP Ubiquitin Ligase. Aging, *1*:803-817. PMCID: PMC2815738

c) Rounbehler, R.J., Fallahi, M., Yang, C., Steeves, M.A., Li, W., Doherty, J.R., Schaub, F.X., Sanduja, S., **Dixon, D.A.**, Blackshear, P.J. and Cleveland, J.L. (2012) Tristetraprolin is a Tumor Suppressor that Impairs Myc-Induced Lymphoma and Abolishes the Malignant State. Cell, *150*:563-574. PMCID: PMC3422762

d) Blanco, F.F, Preet, R., Aguado, A., Vyas, A. Padhye, S., Weir, S.J., Anant, S., Meisner-Kober, N., Brody, J.R. and **Dixon, D.A.** (2016) Impact of HuR inhibition by the small molecule MS-444 on colorectal cancer cell tumorigenesis. Oncotarget, *in press*.

4. **RNA-Binding Proteins and MicroRNAs in Cancer:** My work demonstrating loss of rapid mRNA decay to be a contributing factor during colorectal tumorigenesis has advanced toward understanding the dynamics between RNA-binding proteins and microRNAs. I have shown that targeting of AU-rich mRNA elements is a competition between these *trans*-acting factors, where tumor cells alter the balance to promote RNA stabilization. I uncovered a novel growth-inhibitory property of TGF-β, where TGF-β facilitates delivery of mRNAs to cytoplasmic centers of RNA decay (P-bodies) though the tristetraprolin (TTP) protein. Additionally, a genetic approach was taken to identify single nucleotide polymorphisms (SNPs) in COX-2 and RNA-binding proteins as a means to understand their expression in cancer. My current efforts are now determining the role of RNA-binding proteins in promoting extracellular vesicle release from tumors and their feasibility as tumor-specific biomarkers, along with identifying novel compounds that can selectively inhibit this process.

a) Young, L.E., Moore, A.E., Sokol, L., Meisner-Kober, N. and **Dixon, D.A.** (2012) The mRNA Stability Factor HuR Inhibits MicroRNA-16 Targeting of Cyclooxygenase-2. Mol. Cancer Res. *10:*167-180. PMCID: PMC3262080 ***Selected as top cited research article in Mol. Cancer Res. (AACR Journals).***

b) Moore, A.E., Young, L.E. and **Dixon, D.A.** (2012) A Common Single-Nucleotide Polymorphism in Cyclooxygenase-2 Disrupts MicroRNA-Mediated Regulation. Oncogene, *31*:1592-1598. PMCID: PMC3454533

c) Upadhyay, R., Sanduja, S., Kaza, V. and **Dixon, D.A.** (2013) Genetic Polymorphisms in RNA Binding Proteins Contribute to Breast Cancer Survival. Int. J. Cancer, *132*:E128-E138. PMCID: PMC3508313

d) Blanco, F.F., Sanduja, S., Deane, N.G., Blackshear, P.J. and **Dixon, D.A.** (2014) TGF-β regulates P-body formation through induction of the mRNA decay factor tristetraprolin (TTP). Mol. Cell. Biol. *34*:180-195. PMCID: PMC3911289

Complete List of Published Work in My Bibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1Nq5uubggnpQz/bibliograpahy/44033258/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

R01 CA191785 Xu and Aubé (MPIs) 06/01/2015 - 05/31/2020
NIH/NCI
Molecular cancer therapy targeting HuR-ARE interaction
The major goal of this proposal is to obtain small molecule inhibitors as chemical probes that potently bind to

HuR and modulate its functions, and ultimately select 1-2 most drug-like lead compounds for further development as a new class of molecular cancer therapy that inhibit cancer with HuR overexpression.
Role: Co-Investigator

R21 CA185831 Chen (PI) 07/01/2016 - 06/30/2018
NIH/NCI
New HuR inhibitor against pancreatic cancer EMT and CSCs
To study a new inhibitor of HuR on its activity and mechanism in inhibiting pancreatic cancer EMT and cancer stem cells.
Role: Co-Investigator

P30 CA168524 Jensen (PI) 07/01/2012 - 06/30/2017
NIH/NCI
Cancer Center Support Grant
The University of Kansas Cancer Center (KUCC) is a matrix organization that leverages unique scientific assets to build a nationally significant cancer research and treatment center that will become a leading academic institution in the world in transforming discoveries in the laboratory into new therapeutic approaches.
Role: Co-Leader of the Cancer Prevention Program.

R01 CA212600 Brody (PI) 09/01/2016 - 08/31/2021
NIH/NCI
Targeting HuR to improve a synthetic lethal therapy for pancreatic cancer
The goal of this proposal is to determine the role of HuR in promoting a resistance mechanism for pancreatic adenocarcinoma exposed to PARP inhibitors.
Role: Co-Investigator (*Scored in the 8th percentile*)

No Grant Number Dixon (PI) 07/01/2016-06/30/2017
AACR-Bayer Innovation and Discovery Grant
Targeting HuR in Colorectal Cancer

Completed Support:

R01 CA134609 Dixon (PI) 09/21/2009 - 07/31/2015
NIH/NCI
Post-Transcriptional Regulation in Colorectal Cancer
The studies in this grant assess the role of post-transcriptional gene regulation and RNA-binding proteins in the etiology of colorectal cancer.

P30 GM103495 Timmerman (PI) 09/01/2010 - 05/31/2015
National Institutes of Health COBRE
Center for Cancer Experimental Therapeutics
The goal of this project is the establishment of the Center for Cancer Experimental Therapeutics (CCET) in the State of Kansas. High Throughput Screening and Medicinal Chemistry Core facilities will be further developed to identify novel bioactive compounds that will be useful basic biomedical research tools, and potential therapeutic agents.
Role: Pilot Project PI

OMB No. 0925-0001/0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

NAME: **Edward F. Ellerbeck, MD, MPH**

eRA COMMONS USER NAME (credential, e.g., agency login): EELLERBECK

POSITION TITLE: Professor of Medicine; Chair, Dept. of Preventive Medicine and Public Health

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Missouri at KC; Kansas City, MO	BA	12/79	Biology
University of Missouri at KC; Kansas City, MO	MD	05/82	Medicine
Johns Hopkins University; Baltimore, MD	MPH	05/87	Epidemiology

A. Personal Statement

I am chair of the Department of Preventive Medicine & Public Health and Professor of Internal Medicine at the University of Kansas Medical Center. I have over 20 years of experience in measuring and improving the quality of medical care. I developed, implemented and tested a 'chronic care model' for smoking cessation, demonstrating that smokers are willing to make repeated cessation attempts over a 2-year period of follow-up. I have conducted direct observation of smoking cessation interventions in physician offices and serve as Medical Director of "U Kan Quit" at KUMC hospital. I have provided direction in the design, implementation, analysis, and safety monitoring of multiple NIH-funded smoking cessation trials. I have a strong record of community and provider engagement. I pioneered NIH-funded research within our KPEPR practice-based research network (Kansas Physicians Engaged in Prevention Research). I lead the Cancer Control and Population Health program within our cancer center, a program that, over the past 5 years, has engaged more than 10,000 participants from under-represented communities into cancer research studies. I have mentored nine faculty on grants that subsequently led to independent NIH funding. In 2012, I received the KUMC Excellence in Mentoring Junior Faculty Award and in 2013 received the Chancellor's Distinguished Teaching Award. In this grant, I will continue my role as co-leader of the CCPH program, working with Dr. Befort to advance cancer control research in the area, with a particular emphasis on tobacco control and implementation research in rural communities.

B. Positions and Honors

Positions and Employment

1982-1985 Resident (Internal Medicine), UMKC Affiliated Hospitals, Kansas City, MO
1985-1986 Chief Resident (Internal Medicine), UMKC Affiliated Hospitals, Kansas City, MO
1986-1987 Assistant Professor of Medicine, University of Missouri at KC, Kansas City, MO
1987-1989 Resident (Preventive Medicine), Johns Hopkins University, Baltimore, MD
1989-1990 Research Associate, Center for Immunization Research, Johns Hopkins University, Baltimore, MD
1990-1992 Research Fellow, (General Internal Medicine), Johns Hopkins University, Baltimore, MD
1992-1995 Medical Officer, Health Care Financing Administration, Office of Peer Review, Baltimore, MD
1995-1997 Medical Officer, Health Care Financing Administration, Health Standards and Quality, KCMO
1997-2009 Associate Professor, Preventive Medicine; Internal Medicine, University of Kansas Medical Center, Kansas City, KS
2000-2009 Associate Professor, School of Nursing, University of Kansas Medical Center, Kansas City, KS
2005-present Chair, Department of Preventive Medicine, University of Kansas Medical Center
2008-present Sosland Family Endowed Chair in Preventive Medicine and Public Health

2009-present Professor, Departments of Preventive Medicine and Public Health and Internal Medicine, University of Kansas Medical Center, Kansas City, KS

Professional Activities

2008 – Deputy Editor, Journal of General Internal Medicine
2010 – Board of Directors, Association for Prevention Teaching and Research, treasurer 2012-14
2012 – Board of Directors, American Journal of Preventive Medicine, president 2014 - present
2014 – NIH Dissemination and Implementation Research in Health Study Section, member

Honors

2012 KUMC Excellence in Mentoring Junior Faculty Award
2013 Chancellor's Distinguished Teaching Award

C. Contributions to Science (mentees indicated with *)

1. **Addressing smoking as a chronic illness.** Smoking has many characteristics in common with other chronic diseases, but characteristically has been treated with short term interventions. We developed and tested a program based on the chronic care model that provided repeated offers of smoking cessation over two years. We showed that patients were willing to make repeated quit attempts over time and moreover that the impact of treatment did not diminish over time, even in the absence of multiple prior quit attempts. We procured a diversity supplement for Dr. Cupertino to work on this project, experience that she used to get her K award.
   a) Cupertino AP*, Mahnken JD, Richter K, Cox LS, Casey G, Resnicow K, Ellerbeck EF. Long-term engagement in smoking cessation counseling among rural smokers. J Health Care Poor Underserved. 2007 Nov; 18(4 Suppl):39-51.
   b) Ellerbeck EF, Mahnken JD, Cupertino AP, Cox LS, Greiner KA, Mussulman LM, Nazir N, Shireman TI, Resnicow K, Ahluwalia JS. Impact of varying levels of disease management on smoking cessation: a randomized trial. Ann Intern Med. 2009; 150(7):437-46. PMCID: PMC2825176
   c) Cupertino AP*, Wick JA, Richter KP, Mussulman L, Nazir N, Ellerbeck EF. The impact of repeated cycles of pharmacotherapy on smoking cessation: a longitudinal cohort study. Arch Intern Med. 2009 Nov 9; 169(20)1928-30. PMCID: PMC2826277
   d) Hui AS*, Nazir N, Faseru B, Ellerbeck EF. Ongoing self-engagement in quit attempts and cessation outcomes among rural smokers who were unable to quit after 2 years of repeated interventions. *Journal of Rural Health. 2013 Winter; 29(1):106-12.* PMCID: PMC3539219

2. **Improving smoking cessation for hospitalized patients.** I worked with the Health Care Financing Administration (CMS) and the Kansas Foundation for Medical Care, to measure quality of care in hospitals and implement quality improvement activities. As I became more involved with smoking cessation interventions, we used some of the lessons learned from those activities to design and test better ways to deliver consistent tobacco treatment for hospitalized patients. We identified increased uptake of telephone counseling with 'warm handoffs' for smoking cessation, and the critical role of insurance on uptake of smoking cessation therapy after hospital discharge.
   a) Tague C*, Richter KP, Cox LS, Keighley J, Hutcheson T, Fitzgerald SA, **Ellerbeck EF**. Impact of Telephone-Based Care Coordination on Use of Cessation Medications Post-Hospital Discharge: A Randomized Controlled Trial. Nicotine Tob Res. 2016 May 18. pii: ntw138. [Epub ahead of print] PMID: 27194545, Not NIH funded.
   b) Faseru B, Yeh HW, **Ellerbeck EF,** Befort C, Richter KP. Prevalence and predictors of tobacco treatment in an academic medical center. JT Comm J Qual Patient Saf. 2009 Nov; 35(11):551-7. PMCID: PMC2796192
   c) Faseru B, Turner M, Casey G, Ruder C, Befort CA, **Ellerbeck EF**, Richter KP. Evaluation of a hospital-based tobacco treatment services: Outcomes and lessons learned. Journal of Hospital Medicine. 2011 Apr;6(4):211-218. Epub 2010 Nov 24. PMCID: PMC3081657
   d) Richter KP, Faseru B, Mussulman LM, **Ellerbeck EF**, Shireman TI, Hunt JJ, Carlini BH, Ayars CL, Cook DJ, Preacher KJ. Using "warm handoffs" to link hospitalized smokers with tobacco treatment after discharge: Study protocol of a randomized controlled trial. Trials. 2012 Aug 1;13(1):127. (Epub ahead of print). PMCID: PMC3495904

3. **E-health to improve delivery of preventive services.** As we have worked on improving the quality of primary care treatment, it has become more and more obvious that e-health is going to play a critical role in the future of chronic care treatment. We showed that a smoking cessation decision support tool led to high uptake of cessation pharmacotherapy, that racial and ethnic minority girls responded positively to an e-health intervention to increase fruit and vegetables and reduce sugar-sweetened beverages when this intervention was linked to 'music download rewards', that an e-health intervention focused on implementation intentions could increase delivery of CRC services, and that office-based telemedicine for smoking cessation in rural communities was comparable to telephone counseling.
   a) Cupertino AP*, Richter K, Cox LS, Garrett S, Ramirez R, Mujica F, Ellerbeck EF. Feasibility of a Spanish/English computerized decision aid to facilitate smoking cessation efforts in underserved communities. J Health Care Poor Underserved. 2010; 21(2):504-17. PMID 20453353. Not NIH Funded
   b) Greiner KA, Daley CM, Epp A, James A, Yeh HW, Geana M, Born W, Engelman KK, Shellhorn J, Hester CM, LeMaster J, Buckles DC, Ellerbeck EF. Implementation intentions and colorectal screening: a randomized trial in safety-net clinics. Am J Prev Med. 2014 Dec; 47(6):703-14. doi: 10.1016/j.amepre.2014.08.005. Epub 2014 Nov 18. PMID: 25455115; PMCID: PMC4311575.
   c) Nollen NL*, Mayo MS, Carlson SE, Rapoff MA, Goggin KJ, Ellerbeck EF. Mobile technology for obesity prevention: a randomized pilot study in racial- and ethnic-minority girls. Am J Prev Med. 2014 Apr; 46(4):404-8. PMCID: PMC3962588
   d) Richter KP, Shireman TI, Ellerbeck EF, Cupertino AP, Catley D, Cox LS, Preacher KJ, Spaulding R, Mussulman LM, Nazir N, Hunt JJ, Lambart L. Comparative and cost effectiveness of telemedicine versus telephone counseling for smoking cessation. Journal of medical Internet research. 2015; 7(5):e113. PMID: 25956257, PMCID: PMC4468596

4. **Communicating with smokers.** During the conduct of our smoking cessation studies we have identified a number of critical issues that can inform efforts to smoking cessation interventions. We showed that 'novelty' was positively associated with using a new pharmacotherapy agent and that improving self-efficacy was more important than improving motivation to promote cessation. We showed that health education outperformed motivational interviewing for unmotivated smokers (again highlighting the role of self-efficacy) and in an invited editorial to Addiction, pointed out how treatment defaults may inadvertently reduce the number of smokers receiving evidence-based treatment.
   a) Cupertino AP*, Richter KP, Cox LS, Nazir N, Greiner KA, Ahluwalia JS, Ellerbeck EF. Smoking cessation pharmacotherapy preferences in rural primary care. Nicotine & Tobacco Research. 2008;10(2):301. PMCID: PMC2821185
   b) Cupertino AP*, Berg CJ, Gajewski B, Hui SA, Richter K, Catley D, Ellerbeck E. Change in self-efficacy, autonomous and controlled motivation predicting smoking. Journal of Health Psychology. 2012 Jul;17(5):640-52. Epub 2011 Nov 10 PMCID: PMC3549683
   c) Catley D, Goggin K, Harris KJ, Richter KP, Williams K, Patten C, Resnicow K, Ellerbeck EF, Bradley-Ewing A, Lee HS, Moreno JL, Grobe JE. A Randomized Trial of Motivational Interviewing: Cessation Induction Among Smokers With Low Desire to Quit. Am J Prev Med. 2016 May;50(5):573-83. doi: 10.1016/j.amepre.2015.10.013. Epub 2015 Dec 23. PMID: 26711164; PPMCID: PMC4841713.
   d) Richter KP, Ellerbeck EF. It's time to change the default for tobacco treatment. Addiction. 2014 Oct 16.(Epub ahead of print) doi: 10.1111/add.12734 Not NIH funded.

5. **Advancing cancer control in underserved communities.** In 1999, I directed the first, multi-practice study in what was to become the KPEPR practice-based research network (Kansas Physicians and Patients Engaged in Prevention Research). This began with observational studies of smoking cessation and other cancer control activities that led to four peer-reviewed publications describing variations in delivery of smoking cessation, cancer screening, and nutrition and exercise counseling. Our team showed the impact of office systems on delivery of mammography services and smoking cessation in rural primary care practices. We have also conducted qualitative research, speaking directly with patients about the impact of local culture and their relationship with their physician as it relates to smoking cessation.
   a) Ellerbeck EF, Ahluwalia JS, Jolicoeur DG, Gladden J, Mosier MC. Direct observation of smoking cessation activities in primary care practice. J Fam Pract. 2001; 50(8):688-93.

b) Engelman* KK, Ellerbeck EF, Perpich D, Nazir N, McCarter K, Ahluwalia JS. Office systems and their influence on mammography use in rural and urban primary care. J Rural Health. 2004 Winter; 20(1):36-42.
c) Hutcheson* TD, Greiner KA, Ellerbeck EF, Jeffries SK, Mussulman LM, Casey GN. Understanding smoking cessation in rural communities. J Rural Health 2008 Spring; 24(2):116-24. PMID 18397444 Published 4 APR 2008 – prior to NIH policy of 7 APR 2008
d) Befort CA, VanWormer JJ, DeSouza C, Ellerbeck EF, Kimminau KS, Greiner A, Gajewski B, Huang T, Perri MG, Fazzino TL, Christifano D, Eiland L, Drincic A. Protocol for the Rural Engagement in Primary Care for Optimizing Weight Reduction (RE-POWER) Trial: Comparing three obesity treatment models in rural primary care. Contemporary clinical trials. 2016; 47:304-14. PMID: 26898748, Not NIH funded.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1TSB0_kul68QX/bibliography/43229940/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

CER-1306002901 Ellerbeck (PI) 03/24/2014 - 06/29/2017
Patient-Centered Outcomes Research Institute
Smoking Cessation versus Long-term Nicotine Replacement Among High-risk Smokers
Compare the benefits of traditional smoking cessation versus guided maintenance with nicotine replacement for smokers with COPD.

R01 DA035796 Cox (PI) 06/01/2014 - 03/31/2019
National Institutes of Health
Advancing Tobacco Use Treatment for African American Smokers
This study will evaluate the efficacy of varenicline treatment to improve quit rates in African American daily smokers of all smoking levels, with the goal of reducing tobacco-related disparities.
Role: Co-Investigator

UL1TR000001/TR000119/TR000120 Barohn (PI) 06/01/2011 – 02/29/2017
NIH
Institutional Clinical and Translational Science Award (U54)
The major goals are to create a new academic home with training programs for clinical and translational investigators, provide an enhanced coordinated translational research infrastructure and actively engage the community in developing, testing and disseminating translational research.
Role: Director of Research Training Core

P30 CA168524 Jensen (PI) 07/01/2012 - 06/30/2017
NIH
Cancer Center Support Grant
The University of Kansas Cancer Center is a growing matrix organization that aims to leverage unique scientific assets to build a nationally significant cancer research and treatment center that will become the leading academic institution in the world for transforming discoveries in the laboratory into new therapeutic approaches.
Role: Co-director CCPH

P30 CA1685424-04S1 Jensen (PI) 07/01/2015 – 06/30/2017
NIH
Cancer Center Support Grant Suppl: E-Decidete: Mobile Cessation Support for Latino Smokers in Mexico
Our major goal is to develop a text-message system to supplement and support the “vive sin taboco…!Decidete!’ tablet-based smoking cessation software in Mexico.
Role: Co-Investigator - Supplement

AD-1310-08709 Nollen (PI) 10/01/2014 – 09/30/2017
Patient-Centered Outcomes Research Institute
Informing Tobacco-Treatment Guidelines for African American Non-Daily Smokers
The long-term objective of our research is to inform evidence-based guidelines for treating tobacco dependence among non-daily smokers. The objective of this study is to see if NRT is an effective treatment option for AA non-daily smokers
Role: Co-Investigator

OB-1402-09413 Befort (PI) 01/01/2015 – 12/31/2019
Patient-Centered Outcomes Research Institute
Midwestern Collaborative for Treating Obesity in Rural Primary Care
Obesity rates are higher among rural residents, and it may be especially difficult to treat for rural primary care providers (PCPs) who often serve as front-line providers for a wider range of presenting concerns.
Role: Co-Investigator

R01 HL131512 Richter (PI) 02/01/2016 – 01/31/2021
NHLBI
Changing the Default for Tobacco Treatment
This study will examine the impact of opt-in versus opt-out approaches for offering smoking cessation services to smokers during hospitalization and after discharge.
Role: Co-Investigator

Completed Support:

R41 MD010318 Ellerbeck (PI) 08/01/2015 – 07/31/2016
NIH/Agile Health
Kick Butts: Mobile Engagement and Cessation Support for Latino Smokers
Kick Butts is a unique and innovative offering that provides high touch smoking cessation support through low cost technology channels.
Role: PI of subaward with Agile Health

R01 CA101963 Ellerbeck (PI) 07/09/2003 - 01/31/2015
National Cancer Institute
Disease Management for Smokers in Rural Primary Care/Centralized Disease Management for Rural Hospitalized Smokers
This grant examines new modalities for enhancing the reach and effectiveness of smoking cessation efforts in rural health delivery systems, including primary care physicians' offices and rural hospitals.

R03 HD081730 Gibbs (PI) 08/01/2014 – 07/31/2016
NIH
Adaptation and Validation of a Nutrition Literacy Assessment Instrument
The goal of this research is to produce a valid and reliable tool for measuring nutrition literacy in a chronic disease population and identify the associations between nutrition literacy and diet quality in this population.
Role: Co-Investigator

U01 HL105232 Richter (PI) 09/20/2010 - 05/31/2014
NIH
Increasing Post-discharge Follow Up among Hospitalized Smokers
Our objective in this application is to determine the relative effectiveness, and cost-effectiveness, of warm handoff versus fax referral in linking hospitalized smokers with quitline services at discharge. Outcomes include enrollment in quitline services, cessation outcomes, and cost-effectiveness.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Carol J. Fabian, MD**

eRA COMMONS USER NAME (credential, e.g., agency login): cfabian

POSITION TITLE: Professor of Medicine

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date	FIELD OF STUDY
University of Kansas, Lawrence, KS	B.A.	6/1968	Psychology
University of Kansas, Lawrence, KS	M.D.	6/1972	Medicine
Wesley Medical Center, Wichita, KS	Residency	6/1975	Internal Medicine

A. Personal Statement

I will serve as the Associate Director for Clinical Research for the Cancer Center. My primary goal is to increase the quantity and quality of clinical investigator initiated research and increase accrual on high priority clinical interventional trials. In this capacity I will work closely with the co-leaders of programs where clinical research is conducted (D3ET, CPS, CCPH), the head of the Protocol Review Monitoring Committee (PRMC), the head of the Clinical Trial Office, disease working group co-leaders, investigators, leaders of the shared resources, and the Cancer Center Director and Deputy Director to assure that investigators have the necessary support, resources, and training to successfully conduct clinical and translational research. This includes support and resources for clinical interventional trials for cancer treatment as well as prevention and survivorship. I will chair the monthly clinical and translational research group meetings, attend each disease working group meeting at least once yearly, attend program meetings where clinical research is conducted at least once yearly, serve on the IIT steering committee, and meet with other special groups as appropriate including community physician faculty, and members of the MCA. I will work with the Center Director to suggest appropriate disease working group leaders as needed and with working group and program leaders to suggest needed resources.

My qualifications include a 38 year history as a clinical/translational researcher in breast clinical oncology treatment, prevention, and survivorship. I have been the PI of multiple clinical and translational trials in cancer treatment and breast cancer prevention and survivorship, most of which received funding through peer reviewed mechanisms and am currently the contact PI for a large multi-PI, multi-institutional Komen Promise Grant. I co-chair the SWOG Survivorship Committee, where our emphasis is promoting investigations towards reducing morbidity associated with obesity, physical inactivity and cancer treatment by young investigators. I have served on Study Sections dealing with biomarkers and energy balance, advisory committees for key large trials in Breast Cancer Prevention, and Guideline Committees for various aspects of prevention and treatment. I have previously co-led the Cancer Prevention and Survivorship Program from its' inception until April of 2016 and am familiar with issues affecting program leaders. My long tenure at the University of Kansas in clinical, research, and administrative capacities ensures familiarity with a large number of faculty from diverse background, as well as issues important to the immediate community, and catchment area.

B. Positions and Honors

Positions and Employment:

1976-1980 Special Assistant to the Group Chairman; Southwest Oncology Group, Kansas City, KS
1977-1981 Assistant Professor of Medicine; Division of Clinical Oncology, University of Kansas Medical Center, Kansas City, KS
1981-1987 Associate Professor of Medicine; Division of Clinical Oncology, KU Medical Center
1987-pres Professor of Medicine; Division of Clinical Oncology, KU Medical Center

1992-1999	Medical Director, University of Kansas Cancer Center
1999-pres	Director, Breast Cancer Prevention Center, University of Kansas Medical Center
1999-2005	Leader, Breast Research Program, Kansas Masonic Cancer Research Institute
2005-2007	Leader, Cancer Risk Assessment, Prevention and Control Program
2004-2011	Kansas Masonic Cancer Research Endowed Chair
2007-pres	Leader, Cancer Prevention and Survivorship Program, University of Kansas Cancer Center (co-leader with Dan Dixon starting 2012)
2007- pres	Director, Breast Cancer Prevention and Survivorship Research Center
2009- pres	Co-Chair Southwest Oncology Group Cancer Survivorship Committee
2011- pres	Morris Family Endowed Chair in Cancer Prevention
2011-pres	University Distinguished Professor
2011-2012	Chair ASCO Prevention Committee
2012-pres	Chair ASCO Prevention Workforce Pipeline Workgroup

C. Contribution to Science My 5 most important contributions to Science over the last 38 years are as follows:

1. **Served as PI, or on the steering Committee of Several Phase III Co-operative Group Trials**
   a) **Fabian** CJ, Mansfield CM, Dahlberg S, Jones SE, Miller TP, Van Slyck E, Grozea PN, Morrison FS, Coltman CA Jr, and Fisher RI: Low-dose involved field radiation after chemotherapy in advanced Hodgkin disease: A Southwest Oncology Group Randomized Study. Ann Intern Med 120:903-912, 1994. PMID: 8172436 ***Demonstrated that low dose involved field radiation consolidation following chemotherapy in Stage III and IV Hodgkin's Disease reduces relapse*.**
   b) Goss PE, Ingle JN, Alés-Martínez JE, Cheung AM, Chlebowski RT, Wactawski-Wende J, McTiernan A, Robbins J, Johnson KC, Martin LW, Winquist E, Sarto GE, Garber JE, **Fabian CJ,** Pujol P, Maunsell E, Farmer P, Gelmon KA, Tu D, Richardson H; NCIC CTG MAP.3 Study Investigators. Exemestane for breast-cancer prevention in postmenopausal women. N Engl J Med. 2011; 364:2381-91. PMID: 21639806, Not NIH funded. ***Exemestane reduced breast cancer incidence by 65% compared to placebo***.
   c) Powles TJ, Diem SJ, ***Fabian*** CJ, Neven P, Wickerham DL, Cox DA, Muram D, Agnusdei D, Dowsett SA, Amewou-Atisso M, Cummings SR. Breast cancer incidence in postmenopausal women with osteoporosis or low bone mass using arzoxifene. Breast Cancer Res Treat. 2012; 134:299-306. PMID: 22484799, Not NIH funded. ***Demonstrated reduced breast cancer incidence with a SERM***.
   d) Moore HC, Unger JM, Phillips KA, Boyle F, Hitre E, Porter D, Francis PA, Goldstein LJ, Gomez HL, Vallejos CS, Partridge AH, Dakhil SR, Garcia AA, Gralow J, Lombard JM, Forbes JF, Martino S, Barlow WE, **Fabian CJ,** Minasian L, Meyskens FL Jr, Gelber RD, Hortobagyi GN, Albain KS; POEMS/S0230 Investigators. Goserelin for ovarian protection during breast-cancer adjuvant chemotherapy N Engl J Med. 2015; 372:923-32. PMID: 25738668, PMCID: PMC4405231. ***Demonstrated better ovarian function protection and reduced recurrence of ER negative cancer with a GNRH agonist/ antagonist***

2. Developed Random Peri-Areolar Fine Needle Aspiration (RPFNA) as effective minimally invasive method of serial tissue sampling for biomarkers for women under 60 at increased risk for breast cancer. Demonstrated that a cytologic pattern of hyperplasia with atypia produced a 5 fold increase in short term risk compared to those without this pattern and stratified short term risk based on the Gail Model. These observations paved the way for use of benign breast tissue sampling to obtain biomarkers for use in response assessment in Phase I and II Chemoprevention Trials (see points 3 and 4).
   a) **Fabian** CJ, Kimler BF, Zalles CM, Klemp JR, Kamel S, Zeiger S, and Mayo MS: Short-term breast cancer prediction by random Fabian CJ, Kimler BF, Zalles CM, Klemp JR, Kamel S, Zeiger S, and Mayo MS: Short-term breast cancer prediction by random periareolar fine-needle aspiration cytology and the Gail risk model. J Natl Cancer Inst 92:1217-27, 2000. PMID: 10922407lar fine-needle aspiration cytology and the Gail risk model. J Natl Cancer Inst 92:1217-27, 2000. PMID: 10922407
   b) Phillips TA, **Fabian CJ**, Kimler BF, Petroff BK. Assessment of RNA in human breast tissue sampled by random periareolar fine needle aspiration and ductal lavage and processed as fixed or frozen specimens. Reprod Biol 2013;13: 75-81. PMID: 23522074, Not NIH funded.

c) Hidaka BH, Li S, Harvey KE, Carlson SE, Sullivan DK, Kimler BF, Zalles CM, **Fabian C**J. Omega-3 and omega-6 Fatty acids in blood and breast tissue of high-risk women and association with atypical cytomorphology. Cancer Prev Res (Phila). 2015 May;8(5):359-64. CAPR-14-0351. Epub 2015 Feb 23. PMID: 25712053, Not NIH funded.

3. Used benign tissue biomarkers many of which we adapted for cytology specimens (morphology, Ki-67, mRNA and proteomics) to evaluate the effectiveness of a prevention intervention in pilot, phase I and phase II primary prevention trials.
   a) **Fabian CJ**, Kimler BF, Zalles CM, Klemp JR, Petroff BK, Khan QJ, Sharma P, Setchell KD, Zhao X, Phillips TA, Metheny T, Hughes JR, Yeh HW, Johnson KA. Reduction in Ki-67 in benign breast tissue of high risk women with the lignan Secoisolariciresinol Diglycoside (SDG). Cancer Prev Res (Phila). 2010;3: 1342-50. PMC2955777.
   b) **Fabian CJ**, Kimler BF, Donnelly JE, Sullivan DK, Klemp JR, Petroff BK, Phillips TA, Metheny T, Aversman S, Yeh HW, Zalles CM, Mills GB, Hursting SD. Favorable modulation of benign breast tissue and serum risk biomarkers is associated with >10 % weight loss in postmenopausal women. Breast Cancer Res Treat 2013;142: 119-132. PMC3921968.
   c) **Fabian** CJ, Kimler BF, Zalles CM, Phillips TA, Metheny T, Petroff BK, Havighurst TC, Kim KM, Bailey HH, Heckman-Stoddard BM: Clinical trial of acolbifene in premenopausal women at high risk for breast cancer. Cancer Prev Res Published Online First September 21, 2015; doi:10.1158/1940-6207.CAPR-15-0109. PMC4670810.
   d) **Fabian** CJ, Kimler BF, Phillips TA, Box JA, Kreutzjans AL, Carlson SE, Hidaka BH, Metheny T, Zalles CM, Mills GB, Powers KR, Sullivan DK, Petroff BK, Hensing WL, Fridley BL, Hursting SD Modulation of Breast Cancer Risk Biomarkers by High-Dose Omega-3 Fatty Acids: Phase II Pilot Study in Premenopausal Women. Cancer Prev Res (Phila). 2015 Oct;8(10):912-21. PMID: 26438592, PMC in process.

4. Worked with basic scientists to define mechanism of action and develop translational Phase IIB trial models for prevention where animals and humans are given the same relative dose of the intervention compared to control and the same biomarkers are used in parallel clinical trials but as opposed to the human trial which is carried out for only 6-12 months with biomarker modulation as a primary endpoint, a portion of the animals are allowed to go on to cancer development and then it is determined if biomarker modulation is associated with reduction in cancer incidence.
   a) Delman DM, **Fabian CJ**, Kimler BF, Yeh H, Petroff BK. Effects of Flaxseed Lignan Secoisolariciresinol Diglucosideon Pre-neoplastic Biomarkers of Cancer Progression in a Model of Simultaneous Breast and Ovarian Cancer Development. Nutr Cancer. 2015 Jul;67(5):857-64. Epub 2015 May 26. PMID: 26010915, PMC in process.
   b) Ford NA, Rossi EL, Barnett K, Yang P, Bowers LW, Hideka B, Kimler BF, Carlson SE, Shureiqi I, deGraffenried LA, **Fabian CJ**, Hursting SD.Omega-3-Acid Ethyl Esters Block the Pro-tumorigenic Effects of Obesity in Mouse Models of Postmenopausal Basal-Like and Claudin Low Breast Cancer. Cancer Prev Res (Phila). 2015 Jun 22. [Epub ahead of print] PMID: 26100521, PMC in process
   c) Chen CH, **Fabian C**, Hursting S, deGraffenried LA. Breast Cancer Genetic and Molecular Subtype Impacts Response to Omega-3 Fatty Acid Ethyl Esters.utr Cancer. 2016 Jul 1:1-13. [Epub ahead of print] PMID: 27367296, Not NIH funded.
   d) **Fabian CJ**, Kimler BF, Hursting SD Omega-3 fatty acids for breast cancer prevention and survivorship. Breast Cancer Res. 2015 May 4;17:62. PMC4418048.

5. Translating positive findings into practice change takes not only randomized clinical trials but consensus building and adoption into guidelines and training the next generation. I have authored reviews and co-authored guidelines in breast cancer prevention and survivorship. I have also been involved in investigating the likelihood that in the coming years fewer oncologists are likely to be engaged in prevention or prevention research and was primary author of a paper reporting an ASCO sponsored survey of trainees and training directors in which reasons for reluctance to enter a research career in academic medicine in general and prevention in particular are detailed including uncertain career and economic pathway, lack of clinical mentors and training are highlighted.
   a) Visvanathan K, Hurley P, Bantug E, Brown P, Col NF, Cuzick J, Davidson NE, Decensi A, **Fabian C**, Ford L, Garber J, Katapodi M, Kramer B, Morrow M, Parker B, Runowicz C, Vogel VG 3rd, Wade JL,

Lippman SM. Use of pharmacologic interventions for breast cancer risk reduction: American Society of Clinical Oncology clinical practice guideline. J Clin Oncol. 2013; 31:2942-62. PMID: 23835710, Not NIH funded.

b) Ligibel JA, Alfano CM, Courneya KS, Demark-Wahnefried W, Burger RA, Chlebowski RT, **Fabian CJ**, Gucalp A, Hershman DL, Hudson MM, Jones LW, Kakarala M, Ness KK, Merrill JK, Wollins DS, Hudis CA. American Society of Clinical Oncology position statement on obesity and cancer. J Clin Oncol. 2014; 32:3568-74. PMID: 25273035, Not NIH funded.

c) Irwin M**, Fabian C**, McTiernan A. Risk Reduction from Weight Management and Physical Activity Interventions in Improving Outcomes for Breast Cancer Survivors Adv Exp Med Biol. Biol 2015;862;193-212. PMID: 26059937, Not NIH funded.

d) **Fabian** CJ, Kimler BF, Hursting SD. Omega-3 fatty acids for breast cancer prevention and survivorship. Breast Cancer Res. 2015; 17:62 Review PMID: 25936773, PMCID: PMC4418048.

A complete list of publications is available in MyBibliography:
http://www.ncbi.nlm.nih.gov/myncbi/browse/collection/47845155/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support:

R01 CA155014 Befort (PI) 08/01/2011 – 05/31/2017
NIH / NCI: *Group Phone-based Weight Control among Rural Breast Cancer Survivors*
The objectives of this project are to determine a cost-effective phone-based strategy for producing significant long-term weight control in rural breast cancer survivors and to examine impact of weight loss and weight regain on breast cancer risk biomarkers.
Role: Co-Investigator, subject recruitment, help assess adverse events, biomarker assays. Initial Trial Design Befort CA, Contemp Clin Trials 2014; 37:261-271. PMID: 24486636

KG101039 Fabian (PI) 09/24/2010-09/23/2016
Komen for the Cure: *Flaxseed Lignan as a Prevention Strategy for Pre-Menopausal Women at High Risk for Development of Breast Cancer.*
The objective of this study is to conduct a randomized, placebo-controlled Phase II breast cancer trial of the flaxseed lignan Secoisolariciresinol glycoside (SDG) in pre-menopausal women who are at high risk of development of breast cancer; and to demonstrate modulation of biomarkers (primary endpoint is decrease in proliferation via Ki-67 immunocytochemistry) in breast epithelial cells acquired by RPFNA. Tumor model studies in rats and mice also conducted to inform the clinical trial.
Role: PI, direct protocol, coordinate clinical trial, perform RPFNAs, and write manuscripts. Initial animal model publication Delman DM Nutr Cancer. 2015 Jul;67(5):857-64. Epub 2015 May 26. PMID: 26010915

No Number Fabian (PI) 05/01/2015-05/01/2017 (NCE)
Frontiers Pilot and Collaborative Studies Funding Program
Risk Biomarker Modulation by Duavee in Women at Moderate Risk for Breast Cancer.
The objective of this pilot trial is to determine the effect of Duavee (combination of bazedoxifene and estrogen) on proliferation in the benign breast tissue of peri- and postmenopausal women with hot flashes and increased risk for breast cancer. Role: PI, direct protocol development, coordinate clinical trial, perform RPFNAs, and write manuscripts (Accrual initiated 5-2016)

P30-CA168524 Jensen (PI) 07/11/2012 - 06/30/2017
NIH/NCI *Cancer Center Support Grant*
Role: Key Personnel: Cancer Prevention and Survivorship Program Co-Leader until 7-1-2016 and now AD Clinical Research

U10CA32102 Blanke (PI) 08/01/2014 -07/31/2017
NIH/NCI *SWOG NCORP Research Base*
Role: PI subcontract Cancer Survivorship Committee Co-Chair

No Number Fabian (PI) 10/01/2014 - 09/30/2016
Breast Cancer Research Foundation:
Will the Omega-3 Fatty Acid DHA Prevent Development of Cognitive Dysfunction Due to Chemotherapy?
The objective of this study is to examine the effects of omega-3 fatty acid supplementation on cognitive function in women diagnosed with breast cancer and undergoing neo-adjuvant cytotoxic chemotherapy. Role: PI, direct protocol development, coordinate clinical trial, and write manuscripts. Accrual initiated 10-2015

Completed Research Support:

SAC110051 Fabian (PI) 07/01/2010 - 09/21/2015
Komen for the Cure: *Development of Biomarkers of Response to Prevention Interventions with Lignans*
The objective of this study is to develop new biomarkers of response using modern molecular techniques that will allow assessment at the gene and protein expression level. Role: PI, direct development, coordinate clinical activities, and write manuscripts. Fabian CJ, Kimler BF: Incorporating biomarkers in studies of chemoprevention. In: Novel Biomarkers in the Continuum of Breast Cancer. Ed: V Stearns. Springer Publications. 2016

No Number Fabian (PI) 06/01/2010 - 05/31/2014
Kansas Bioscience Authority
Omega 3 Fatty Acids for Prevention of Breast Cancer in Pre-menopausal Women
Conduct a pilot clinical trial to determine the effect of Lovaza on breast cancer risk biomarkers in pre-menopausal women at high risk for development of breast cancer. Role: PI, direct protocol development, coordinate clinical trial, perform RPFNAs, and write manuscripts. Fabian et al Cancer Prev Res (Phila). 2015 Oct;8(10):912-21. PMID: 26438592

No Number Fabian (PI) 10/01/2012 - 09/30/2014
Breast Cancer Research Foundation
High Dose Omega-3 Fatty Acids and Weight Loss for Breast Cancer Prevention
The objective of this study was to establish and utilize biomarkers to quantify response to a prevention intervention of omega-3 fatty acid supplementation and weight loss in post-menopausal women at high risk for the development of breast cancer. Cells and fluids from RPFNA samples of breast tissue assessed. Role: PI, direct protocol development, coordinate clinical trial, perform RPFNAs, and write manuscripts.

OMB No. 0925-0001/0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
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NAME: Brooke L. Fridley, PhD

eRA COMMONS USER NAME (credential, e.g., agency login): FRIDLEY1

POSITION TITLE: Associate Professor of Biostatistics (Tenured)

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Truman State University, Kirksville, MO	B.S.	12/1997	Mathematics
Iowa State University, Ames, IA	M.S.	5/2000	Statistics
Iowa State University, Ames, IA	Ph.D.	12/2003	Statistics

A. Personal Statement

My role on the CCSG renewal will be to oversee and provide scientific leadership for the Biostatistics and Informatics Shared Resource (BISR) for the University of Kansas Cancer Center (KUCC). I joined the University of Kansas Medical Center (KUMC) in the fall of 2012 as an Associate Professor of Biostatistics to Director the BISR for the newly NCI designated KUCC. I am also the Site Director for the Kansas-INBRE Bioinformatics Core. My research focus is in the areas of statistical genomics, cancer genomics, and pharmacogenomics. I have extensive experience in the design and analysis of 'omic studies conducted with both microarray and high-throughput sequencing technologies, for which I have been awarded 3 NIH grants to develop statistical methods for high-dimensional genomic studies. I have over 200 publications, of which I was first author on 24 manuscripts and senior author on 15 publications. This includes a co-first authored paper published in *Nature Communications* and an invited editorial for *The Journal of the National Cancer Institute*. In addition to the extensive research experience I have gained during my career, I also have mentored 7 post-doctoral fellows in statistical genomics, along with the mentoring numerous KL2 scholars and pre-doctorial students. Within my current roles at KUMC as the Director of two NIH funded cores/shared resources, I am providing leadership and input into KUMC's initiative to expand the bioinformatics and statistical genomics capabilities, resources and educational opportunities.

B. Positions and Honors

Positions and Employment

1998 Lab Instructor, Stat101, Iowa State University
1999 Biostatistics Intern, Quintiles
1998-2002 Instructor, Stat101, Iowa State University
2001-2002 Biostatistics Intern, Mayo Clinic
2002-2003 Statistical Consultant, College of Family & Consumer Science, Iowa State University
2003-2006 Assistant Professor, University of Wisconsin, La Crosse
2006-2008 Research Associate, Mayo Clinic
2006-2010 Assistant Professor of Biostatistics, Mayo Clinic
2008-2012 Associate Consultant, Mayo Clinic
2009-2012 Adjunct Assistant Professor of Biostatistics, School of Public Health, University of Minnesota
2010-2012 Associate Professor of Biostatistics, Mayo Clinic
2012-Present Associate Professor of Biostatistics, University of Kansas Medical Center
2012-Present Director, Biostatistics and Informatics Share Resource, University of Kansas Cancer Center
2012-Present Site Director, K-INBRE Bioinformatics Core, University of Kansas Medical Center
2016 Awarded Tenure, University of Kansas Medical Center.

Other Experience and Professional Memberships

2009 Study section member for NIH ARRA grants

2013 Study section member for: NIH/NCI Member Conflicts EPIC grants; NIH/NIEHS K99 applications
2013-Present Editorial board for *Journal of the National Cancer Institute* (statistical editor)
2014 Study section member for: NIH/NCI R01; NIH R15
2014-Present Standing study section member for Cancer Prevention Research Institute of Texas (CPRIT)
2015 Study Section member for: NIH/NIMH R01; NIH/NIGMS R01
2015-2016 Member, KUMC School of Medicine Research Committee
2016 Study section member for: NIH/NIMH R01

Honors

1993-1997 President's Combined Ability Scholarship, Truman State University
1997 Magnum Cum Laude, Truman State University
1999-2000 Vera David Graduate Fellowship, Statistics Department, Iowa State University
2000-2001 Rebecca Klemm Fellowship, Statistics Department, Iowa State University
2000-2001 Holly & Beth Fryer Fellowship, Statistics Department, Iowa State University
2001-2003 NSF VIGRE Fellowship, Statistics Department, Iowa State University
2009 Highly Rated Paper at 100th Annual AACR Meeting, AACR
2014 Invited to attend National Academy of Sciences Kavli Frontiers of Sciences Symposium

C. Contribution to Science

1. **Genetic and environmental architecture of Epithelial Ovarian Cancer risk.** Over the course of the last decade, I have contributed to some of the largest genetic epidemiology studies of ovarian cancer conducted in the world through the Ovarian Cancer Association Consortium (OCAC). My contribution to these studies has primarily been in the statistical analysis of high-dimensional 'omic data, included custom candidate gene and SNP arrays. Through these studies we have determined around 20 novel risk loci for ovarian cancer.
   a) Shen*, H, **Fridley*, BL**, Song, H, Lawrenson, K, et al. (2013). Epigenetic analysis leads to identification of HNF1B as a subtype-specific susceptibility gene for ovarian cancer. *Nat Commun, 4*, 1628. PMID: 23535649, PMCID: PMC3848248
   b) Pharoah, PD, Tsai, YY, Ramus, SJ, Phelan, CM, Goode, EL, Lawrenson, K, Buckley, M, **Fridley, BL**, et al. (2013). GWAS meta-analysis and replication identifies three new susceptibility loci for ovarian cancer. *Nat Genet, 45*(4), 362-370, 370e361-362. PMID: 23535730, PMCID: PMC3693183
   c) White, KL, Schildkraut, JM, Palmieri, RT, Iversen, ES, Jr., Berchuck, A, Vierkant, RA, Rider, DN, Charbonneau, B, Cicek, MS, Sutphen, R, Birrer, MJ, Pharoah, PP, Song, H, Tyrer, J, Gayther, SA, Ramus, SJ, Wentzensen, N, Yang, HP, Garcia-Closas, M, Phelan, CM, Cunningham, JM, **Fridley, BL**, Sellers, TA, Goode, EL, & Ovarian Cancer Association, C. (2012). Ovarian cancer risk associated with inherited inflammation-related variants. *Cancer Res, 72*(5), 1064-1069. PMID: 22282663, PMCID: PMC3293997
   d) Usset, J, Raghavan, R, …, Goode, EL, **Fridley, BL.** (2016). Assessment of multifactor gene-environment interactions and ovarian cancer risk: candidate genes, obesity, and hormone-related risk factors. *Cancer Epidemiol Biomarkers Prev.* (Epub ahead of print). PMID: 26976855, PMCID: In process

2. **Tumor and Germline studies of Epithelial Ovarian Cancer Survival.** In additional to my role within OCAC for the statistical analysis for genetic variation associated with outcome, I am an active member of the Ovarian Tumor Tissue Analysis Consortium (OTTA) and lead many of the analyses related to IHC data from TMAs and association with clinical outcome and/or histology. I also have been the statistical lead for numerous tumor studies involving DNA methylation array data, Agilent gene expression arrays, and recently RNA-seq studies for the rare histologies of ovarian cancer.
   a) **Fridley, BL**, Armasu, SM, Cicek, MS, Larson, MC, Wang, C, Winham, SJ, Kalli, KR, Koestler, DC, Rider, DN, Shridhar, V, Olson, JE, Cunningham, JM, & Goode, EL. (2014). Methylation of leukocyte DNA and ovarian cancer: relationships with disease status and outcome. *BMC Med Genomics, 7*, 21. PMID: 24774302, PMCID: PMC4102255
   b) Wang, C, Cicek, MS, Charbonneau, B, Kalli, KR, Armasu, SM, Larson, MC, Konecny, GE, Winterhoff, B, Fan, JB, Bibikova, M, Chien, J, Shridhar, V, Block, MS, Hartmann, LC, Visscher, DW, Cunningham, JM, Knutson, KL, **Fridley, BL**, & Goode, EL. (2014). Tumor hypomethylation at 6p21.3 associates with longer time to recurrence of high-grade serous epithelial ovarian cancer. *Cancer Res, 74*(11), 3084-3091. PMID: 24728075, PMCID: PMC4054691

c) Goode, EL, Maurer, MJ, Sellers, TA, Phelan, CM, Kalli, KR, **Fridley, BL**, Vierkant, RA, Armasu, SM, White, KL, Keeney, GL, Cliby, WA, Rider, DN, Kelemen, LE, Jones, MB, Peethambaram, PP, Lancaster, JM, Olson, JE, Schildkraut, JM, Cunningham, JM, & Hartmann, LC. (2010). Inherited determinants of ovarian cancer survival. *Clin Cancer Res, 16*(3), 995-1007. PMID: 20103664, PMCID: PMC2818685

d) Wang, C, Winterhoff, B, Kalli, K, Block, M, Armasu, S, Larson, M, Chen, H, Keeney, G, Hartmann, L, Shridhar, V, Konecny, GE, Goode, EL, **Fridley, BL.** (2016). Expression signature distinguishing two tumor transcriptome classes associated with progression free survival among rare histological types of epithelial ovarian cancer. *British Journal of Cancer,* 114(12):1412-20. PMID: 27253175, PMCID: Pending.

3. **Pharmacogenomic studies using model systems.** In additional to my role on multiple ovarian cancer studies, I have been a member of the Pharmacogenomics Research Network (PGRN), a NIGMS funded network, where I supported the statistical analyses of multiple phenotype-genotype from a liver bank samples and cell lines studies. I am currently involved in multiple pharmacogenomics studies involving pediatric patients being conducted at Children's Mercy Hospital (Kansas City, MO), for which RNA-seq, SNP genotypes genome-wide, DNA methylation, and metabolite information, in addition to some enzymes activity levels from pediatric liver samples (ages 0 – 12) have been collected. The goal of these studies is to determine the ontogeny of drug response in pediatric patients.
   a) **Fridley, BL**, Batzler, A, Li, L, Li, F, Matimba, A, Jenkins, GD, Ji, Y, Wang, L, & Weinshilboum, RM. (2011). Gene set analysis of purine and pyrimidine antimetabolites cancer therapies. *Pharmacogenet Genomics*. PMID: 21869733, PMCID: PMC3192305
   b) Pei, H, Li, L, **Fridley, BL**, Jenkins, GD, Kalari, KR, Lingle, W, Petersen, G, Lou, Z, & Wang, L. (2009). FKBP51 affects cancer cell response to chemotherapy by negatively regulating Akt. *Cancer Cell, 16*(3), 259-266. PMID: 19732725, PMCID: PMC2755578
   c) Li, L, **Fridley, B**, Kalari, K, Jenkins, G, Batzler, A, Safgren, S, Hildebrandt, M, Ames, M, Schaid, D, & Wang, L. (2008). Gemcitabine and Cytosine Arabinoside Cytotoxicity: Association with Lymphoblastoid Cell Expression. *Cancer Res, 68*(17), 7050-7058. PMID: 18757419, PMCID: PMC2562356
   d) Niu, N, Qin, Y, **Fridley, BL**, Hou, J, Kalari, KR, Zhu, M, Wu, TY, Jenkins, GD, Batzler, A, & Wang, L. (2010). Radiation pharmacogenomics: a genome-wide association approach to identify radiation response biomarkers using human lymphoblastoid cell lines. *Genome Res, 20*(11), 1482-1492. PMID: 20923822, PMCID: PMC2963812

4. **Clinical pharmacogenomic studies.** In addition to studies involving model systems (liver banks, cell lines, mouse models), I have also contributed to the study of pharmacogenomics translational studies involving clinical patient information.
   a) Liu, M, Ingle, JN, **Fridley, BL**, Buzdar, AU, Robson, ME, Kubo, M, Wang, L, Batzler, A, Jenkins, GD, Pietrzak, TL, Carlson, EE, Goetz, MP, Northfelt, DW, Perez, EA, Williard, CV, Schaid, DJ, Nakamura, Y, & Weinshilboum, RM. (2013). TSPYL5 SNPs: association with plasma estradiol concentrations and aromatase expression. *Mol Endocrinol, 27*(4), 657-670. PMID: 23518928, PMCID: PMC3607698
   b) Lamba, JK, **Fridley, BL**, Ghosh, TM, Yu, Q, Mehta, G, & Gupta, P. (2014). Genetic variation in platinating agent and taxane pathway genes as predictors of outcome and toxicity in advanced non-small-cell lung cancer. *Pharmacogenomics, 15*(12), 1565-1574. PMID: 25340731, PMCID: PMC4450105.
   c) Tan, XL, Moyer, AM, **Fridley, BL**, Schaid, DJ, Niu, N, Batzler, AJ, Jenkins, GD, Abo, RP, Li, L, Cunningham, JM, Sun, Z, Yang, P, & Wang, L. (2011). Genetic variation predicting cisplatin cytotoxicity associated with overall survival in lung cancer patients receiving platinum-based chemotherapy. *Clinical cancer research, 17*(17), 5801-5811. PMID: 21775533, PMCID: PMC3167019
   d) Matimba, A, Li, F, Livshits, A, Cartwright, CS, Scully, S, **Fridley, BL**, Jenkins, G, Batzler, A, Wang, L, Weinshilboum, R, & Lennard, L. (2014). Thiopurine pharmacogenomics: association of SNPs with clinical response and functional validation of candidate genes. *Pharmacogenomics, 15*(4), 433-447. PMID: 24624911, PMCID: PMC4027966

5. **Bayesian Statistical Methods for genomic studies.** Through my collaborations as a Co-Investigator on multiple NIH funded research projects, I often observed the need for novel sophisticated statistical methods to address the proposed research question. Therefore, my statistical research program is closely aligned with my collaborative research activities. One focus of my research is in the area of new Bayesian statistical methods for 'omic data, including methods for gene set / pathway analyses, genomic clustering,

and integrative analysis methods, for which I have been awarded three NIH grants. These methods have since been used in many of my collaborative research projects.

a) **Fridley, BL**, Lund, S, Jenkins, GD, & Wang, L. (2012). A Bayesian integrative genomic model for pathway analysis of complex traits. *Genet Epidemiol, 36*(4), 352-359. PMID: 22460780, PMCID: PMC3894829
b) **Fridley, BL**, Jenkins, G, Schaid, DJ, & Wang, L. (2009). A Bayesian hierarchical nonlinear model for assessing the association between genetic variation and drug cytotoxicity. *Stat Med, 28*(21), 2709-2722. PMID: 19572260, PMCID: PMC2755562
c) Larson, NB, & **Fridley, BL**. (2013). PurBayes: estimating tumor cellularity and subclonality in next-generation sequencing data. *Bioinformatics, 29*(15), 1888-1889. PMID: 23749958, PMCID: PMC3712213

Complete List of Published Work: http://www.ncbi.nlm.nih.gov/pubmed/?term=((Fridley B) OR Fridley BL) AND ("1997/01/01"[Date - Publication] : "3000"[Date - Publication])

D. Research Support

Ongoing Support:

RSG-14-067-01-TBE — Chien (PI) — 07/01/2014 - 06/30/2018
Am Cancer Society
Mechanism of Carboplatin Resistance in Ovarian Cancer
Major Goals: To characterize molecular mechanisms contributing to carboplatin resistance in ovarian cancer
Role: Co-Investigator

P30 CA168524 — Jensen (PI) — 07/11/2012 – 6/30/2017
NIH/NCI
Cancer Center Support Grant
Major Goals: The University of Kansas Cancer Center is a growing matrix organization that aims to leverage unique scientific assets to build a nationally significant cancer research and treatment center that will become the leading academic institution in the world for transforming discoveries into new therapeutic approaches.
Role: Director of Biostatistics and Informatics Shared Resource

P20 GM103418 — Wright (PI) — 05/15/2014 - 04/30/2019
NIH/NIGMS
Kansas IDeA Network of Biomedical Research Excellence
Major Goals: Establish a multi-disciplinary research network with a thematic scientific focus that will build, strengthen, and integrate research in cell and developmental biology in the State of Kansas
Role: KUMC Bioinformatics Satellite Director

<No Number> — Hagan (PI) — 10/01/2015 - 09/30/2017
The V Foundation
Progesterone Receptor Promotes Inflammation in Breast Cancer
Major Goal: to determine how ck2-dependent phosphorylation on PR affects inflammatory functions in the breast (via STAT5), particularly through modulating the anti-inflammatory functions of NF-kB.
Role: Statistician

<NONE> — Hagan (PI) — 07/15/2016 - 07/14/2019
DEPARTMENT OF DEFENSE
Novel Pro-Inflammatory Progesterone Receptor/STAT5 Gene Programs in Breast Cancer
Major Goals: The objective of the experiments outlined in this proposal is to determine if progesterone receptor contributes to breast cancer growth and progression by promoting a pro-inflammatory microenvironment
Role: Co-Investigator

Completed Support:

P20 GM103418 — Wright (PI) — 05/01/2012-04/30/2014
NIH/NIGMS
Kansas IDeA Network of Biomedical Research Excellence
Goal: Establish a multi-disciplinary research network with a thematic scientific focus that will build, strengthen, and integrate research in cell and developmental biology in the State of Kansas.

Role: KUMC Bioinformatics Satellite Director

R21 GM86689 Fridley (PI) 08/01/2011 – 07/30/2013
NIH/NIGMS
Bayesian hierarchical nonlinear models for pharmacogenomic cytotoxicity studies.
Goal: To develop Bayesian models to assess the relationship between *in vitro* phenotypes and genomic data.
Role: Principal Investigator

R21 CA140879 Fridley (PI) 08/01/2009 – 07/31/2011
NIH/NCI
Integrative Genomic Models for Pharmacogenomic Studies
The goal of this research is to combine various sources information collected into Bayesian models to aid in the understanding of the complex relationship between the genome and drug response.
Role: Principal Investigator

U19 CA148112 Goode (PI) 07/02/2010-06/30/2014
NIH/NCI
Follow-up of Ovarian Cancer genetic association and Interaction studies (FOCI)
Goal: To discover loci associated with ovarian cancer risk and survival and to functional follow-up of these loci.
Role: Co-Investigator

U19/U01 GM61388 Weinshilboum (PI) 07/01/2010 – 06/30/2015
NIH/NIGMS 07/12/2005 – 06/30/2010
Pharmacogenetics of Phase II Drug Metabolizing Enzymes
The major goals of this project are to investigate the genomic structures of phase-II drug metabolizing enzymes and the pharmacogenetics of major depression and breast cancer treatment.
Role: Co-Investigator

R21 CA182715 Fridley (PI) 12/01/2013 - 11/30/2015
NIH/NCI
Bayesian Integrative Clustering for Determining Molecular Based Cancer Subtypes
Goal: To develop and apply a novel statistical model for determining molecular subtypes and to validate an ovarian cancer profile in two independent studies
Role: Principal Investigator

DEPARTMENT OF DEFENSE Chien (PI) 08/01/2013-06/16/2015
Integrated Genomics and Proteomics to Uncover Novel Mechanisms of Resistance to Chemotherapy in Ovarian Cancer
Goal: To identify the novel molecular mechanism of chemotherapy resistance in ovarian cancer.
Role: Co-Investigator

R01 CA138461 Wang (PI) 04/01/2009 – 03/31/2014
NCI
Pharmacogenomics and Mechanism of Cytidine Analogues
The goal of this research is to determine the mechanisms by which FKBP5 regulates AKT activation, followed by testing the role of FKBP5 in gemcitabine response using nude mice models and tumor samples from pancreatic patients who have been treated with gemcitabine.
Role: Co-Investigator

R01 CA132780 Weinshilboum (PI) 04/01/2008 – 03/31/2013
NCI
Pharmacogenomics of cytosine arabinoside (Ara-C) and acute myelogenous leukemia
We propose to study the pharmacogenomics of Ara-C. The results of these studies will increase our understanding of the contribution of inheritance to individual variation in Ara-C efficacy and toxicity, and will help us to move toward the goal of “individualized” therapy for the treatment of AML.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Byron J. Gajewski, PhD**

eRA COMMONS USER NAME: bgajewski

POSITION TITLE: Professor of Biostatistics

EDUCATION/TRAINING: (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Marquette University, Milwaukee, WI	BS	1993	Civil Engineering, Mathematics
Marquette University, Milwaukee, WI	MS	1995	Mathematics
Texas A&M University, College Station, TX	PhD	2000	Statistics

A. Personal Statement

For almost 14 years, I have obtained specific education and expertise in Bayesian biostatistics, clinical trials, and the development and validation of measures of patient reported outcomes (PROs), key research areas for this **Cancer Center Support Grant (CCSG)**. I have been a full member of the University of Kansas Cancer Center (KUCC) in **Cancer Control and Population Health (CCPH)** since 2009 and I am part of the **Biostatistics and Informatics Shared Resource (BISR).** I have expertise in the design and implementation of clinical trials. I have published new clinical trials designs and methodology in top tier biostatistics journal (e.g. *Statistics in Medicine*), of which one was quoted in NHLBI's RFA-HL-08-013. I have also published several papers showcasing novel Bayesian predictors of clinical trials accrual stemming from a University of Kansas Cancer Center pilot grant.

My methodological and applied work has been stemmed from a funded R03 (1R03NR013236) that developed novel methods for the development of new patient reported outcome (PRO) measures. My methodological work has also been very useful in designing funded cancer clinical trials. Two funded studies showcase novel Bayesian clinical trials one of which is colorectal cancer screening (1RO1 CA188898) and the other on smoking cessation (1R01HL131512). My work on this **CCSG** renewal will continue to foster the development of new applications of patient reported outcomes and design novel adaptive clinical trials in cancer and cancer related studies.

a) **Gajewski, B.J**., Mayo, M.S. (2006), "Bayesian Sample Size Calculations in Phase II Clinical Trials using a Mixture of Informative Priors," *Statistics in Medicine,* 25(15), 2554-2566.
b) **Gajewski, BJ**, Berry, SM, Quintana, M, Pasnoor, M, Dimachkie, M, Herbelin, L, and Barohn, R (2015), "Building Efficient Comparative Effectiveness Trials through Adaptive Designs, Utility Functions, and Accrual Rate Optimization: Finding the Sweet Spot," *Statistics in Medicine,* 34(7), 1134-1149 (PMCID: PMC4355191).
c) **Gajewski, B**, Berry, S, Barsan, W, Silbergleit, R, Meurer, W, Martin, R, Rockswold, G (in press) "Hyperbaric Oxygen Brain Injury Treatment (HOBIT) Trial: A Novel Multi-factor Design with Response Adaptive Randomization and Longitudinal Modeling," *Pharmaceutical Statistics* (not NIH Sponsored Research).

B. Position and Honors

Positions and Employment:

2000−2002 Statistical Consultant to University of Florida School of Medicine
2000−2002 Assistant Professor of Statistics, St. Cloud State University

2002−2008 Assistant Professor, University of Kansas Schools Nursing and Allied Health
2008-2012 Associate Professor of Biostatistics, University of Kansas School of Medicine
2012-pres Professor of Biostatistics, University of Kansas School of Medicine

Other Experience and Professional Memberships:

1996-Pres American Statistical Association
2004-2008 Council, American Statistical Association, Kansas – Western Missouri Chapter
2002-Pres Eastern North American Region, International Biometrics Society
2006-Pres Reviewer *Statistics in Medicine*
2004-2009 Protocol Review and Monitoring Committee (PRMC) of the University of Kansas Cancer Center
2009-2011 Reviewer, American Cancer Society IRG Grant Program
2007-Pres Full Member, University of Kansas Cancer Center (2009-present, "Cancer Control & Population Health")
2009-2010 NIH Peer Review Committee, Clinical Hematology Special Emphasis Panel, reviewer
2014-Pres Patient Centered Outcomes Research Institute (PCORI) Scientific Reviewer
2013-Pres PStat® Accredited Professional Statistician, American Statistical Association

Honors:

1997 Kosciusko Foundation Fellowship
2008 Gajewski & Mayo (2006) study quoted in NHLBI's RFA-HL-08-013
2013 Director's Award: Faculty from the American Indian Health Research and Education Alliance

C. Contribution to Science (Selected from 150 peer-reviewed publications)

My statistical methodological and collaborative research focuses on Bayesian data analysis specifically in the design and modeling of clinical trials, psychometrics and patient reported outcomes (PROs) modeling, and health care services. My collaborative work spans cancer, medicine, nursing, health professions, and other related fields.

1. **Clinical Trials**
   a) Mayo, M.S., and **Gajewski, B.J**. (2004), "Bayesian sample size calculations in phase II clinical trials using informative conjugate priors," *Controlled Clinical Trials*, 25, 157-167.
   b) **Gajewski, B**, Simon, S, and Carlson, S (2008), "Predicting accrual in clinical trials with Bayesian posterior predictive distributions," *Statistics in Medicine*, 27(13)**,** 2328-2340**.** (accepted before April 7, 2008, no PMCID needed)
   c) Jiang, Y, Simon, S, Mayo, MS, & **Gajewski, BJ** (2015), "Modeling and Validating Bayesian Accrual Models on Clinical Data and Simulations Using Adaptive priors," *Statistics in Medicine,* 34(4), 613-629. PMCID: PMC4314351.
   d) Wick, J, Berry, SM, Yeh, H, Choi, W, Pacheco, CM, Daley, C, **Gajewski, BJ** (in press), "A Novel Evaluation of Optimality for Randomized Controlled Trials," *Journal of Biopharmaceutical Statistics.* PMCID: in process.

2. **Psychometrics/Patient Reported Outcomes**
   a) **Gajewski, B.J**., Hart, S, Bergquist, S, & Dunton, N (2007), "Inter-rater Reliability of Pressure Ulcer Staging: Ordinal Probit Bayesian Hierarchical Model that allows for Uncertain Rater Response," *Statistics in Medicine*, 26(25), 4602-4618.
   b) Jiang, Y, Boyle, DK, Bott, MJ, Wick, JA, Yu, Q, **Gajewski, BJ** (2014), "Expediting Clinical and Translational Research via Bayesian Instrument Development," *Applied Psychological Measurement*, 38(4), 296-310. PMCID: PMC4034393.
   c) Garrard, L, Price, L, Bott, M **Gajewski, B** (in press), "A novel method for expediting the development of patient-reported outcome measures and an evaluation across several populations," *Applied Psychological Measurement* (PMCID pending).
   d) Gibbs, H, Ellerbeck, E, Befort, C, **Gajewski, B**, Kennett, AR, Yu, Q, Christifano, D, Sullivan, DK (in press), "Measuring Nutrition Literacy in Breast Cancer Patients: Development of a Novel Instrument," *Journal of Cancer Education* (PMCID pending).

3. **Health care services**
   a) **Gajewski, B.J.,** Lee, R, Thompson, S, Dunton, N, Becker, A, Wells, V (2006), "Non-Normal Path Analysis in the Presence of Measurement Error and Missing Data: A Bayesian Analysis of Nursing Homes' Structure and Outcomes," *Statistics in Medicine*, 25(21), 3632-3647.
   b) **Gajewski, B.J**., Nicholson, N. and Widen, J.E. (2009), "Predicting Hearing Threshold in Non-Responsive Subjects Using a Log-Normal Bayesian Linear Model in the Presence of Left Censored Covariates," *Statistics in Biopharmaceutical Research*, 1(2), 137–148. Not NIH funded.
   c) **Gajewski, B.J**., Lee, R, Dunton, N (2012), "Data Envelopment Analysis in the Presence of Measurement Error: Case Study from the National Database of Nursing Quality Indicators® (NDNQI®)," *Journal of Applied Statistics*, 39 (12), 2639-2653. PMCID: PMC3544524.
   d) **Gajewski, B.J.** & Dunton, N (2013), "Identifying Individual Changes in Performance with Composite Quality Indicators while Accounting for Regression-to-the Mean," *Medical Decision Making, 33(3), 396-406.* PMCID: PMC3538092.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/pubmed/?term=gajewski+byron

D. Research Support

Ongoing Research Support:

P30 CA168524 Jensen (PI) 07/11/2012 – 6/30/2017
NCI
Cancer Center Support Grant
The University of Kansas Cancer Center is a growing matrix organization that aims to leverage unique scientific assets to build a nationally significant cancer research and treatment center that will become the leading academic institution in the world for transforming discoveries in the laboratory into new therapeutic approaches.
Role: Statistician

RO1 CA188898 Greiner (PI) 07/1/2016 – 6/30/2021
NCI
AIMSS: Adaptive Intervention to Maximize Colorectal Screening in Safety Net Populations
Although Colorectal Cancer (CRC) screening is now used by more of the age eligible population than in prior decades, many low-income and uninsured individuals remain unscreened. This project will test an adaptive and sequential intervention approach to maximize rates of screening among a safety-net clinic population suffering from high rates of CRC disparities. It will target a diverse sample of patients including low-income African Americans, Latinos, refugees, and Whites. We will use a Bayesian adaptive design to test the impact of one or two doses of an "implementation intentions" informed behavioral intervention versus generic health education on CRC screening. Study outcomes will be measured from fecal immunochemical test or colonoscopy reports from the study testing center.
Role: Co-Investigator

R01HL131512 Richter (PI) 02/01/2016-01/31/2021
National Institutes of Health
Changing the Default for Tobacco Treatment
The purpose of this Bayesian adaptive clinical trial is to determine the population impact of changing the default for tobacco cessation treatment. The main hypothesis is that more patients presented in an OPT OUT to smoking cessation will participate in counseling, use cessation medications, and be abstinent from smoking at 1 month post randomization compared to those presented to OPT IN.
Role: Co-Investigator

R03HD081730 Gibbs (PI) 08/01/2014-07/31/2016
National Institutes of Health
Adaptation and Validation of a Nutrition Literacy Assessment Instrument

The goal of this research is to produce a valid and reliable tool for measuring nutrition literacy in a chronic disease population and identify the associations between nutrition literacy and diet quality in this population.
Role: Key Personnel

OB-1402-09413 Befort (PI) 01/01/2015 - 12/31/2019
Patient-Centered Outcomes Research Institute
Midwestern Collaborative for Treating Obesity in Rural Primary Care
Obesity rates are higher among rural residents, and it may be especially difficult to treat for rural primary care providers (PCPs) who often serve as front-line providers for a wider range of presenting concerns.
Role: Co-Investigator

R01HD083292 Gajewski/Carlson/ Valentine (PI) 01/19/2016-12/31/2021
National Institutes of Health
Assessment of DHA Supplementation in Pregnancy to Reduce Early Preterm Birth (ADORE)
To determine if a supplement of 1000 mg DHA /day compared to 200 mg DHA/day during the last two trimesters of pregnancy can reduce ePTB (*primary efficacy analysis*). We employ a novel Bayesian response adaptive randomization design that assigns more subjects to the “winning” group.

CER-1306-02496 Barohn (PI) 04/01/2014-3/31/2017
Patient Centered Outcomes Research Institute (PCORI)
PAIN-CONTROLS
Determine which drug is most effective in producing pain relief and improving quality of life in patients with CSPN. We will perform a prospective randomized comparative effectiveness Bayesian adaptive design study with those who do not have diabetes and for whom no other cause has been found. The four drugs we will use are nortriptyline, duloxetine, pregabalin and mexiletine.
Role: Co-Investigator

R01 HD047315 Carlson (PI) 04/04/2006-01/31/2016 (renewal)
National Institutes of Health
DHA Supplementation and Pregnancy Outcomes
To determine whether maternal RBC PL DHA can be significantly increased by supplementation, assess the effect of DHA supplementation on duration of gestation, evaluate adverse events in women and infants in the treated and placebo groups, evaluate the effect of maternal DHA supplementation on visual evoked potential acuity in infancy, and evaluate the effect of DHA supplementation on the development of fundamental measures of cognitive function in infancy.
Role: Co-Investigator

<NONE> Mayo (PI) 01/01/2013-12/31/2016
NuFactor
Data Coordinating Center for NuFACTOR IG Treatment Outcomes Assessment and Clinical Guidelines Study
This is a quality assessment/improvement study to evaluate treatment outcomes associated with disease-specific IG prescribing regimens in NuFACTOR IG patients.
Role: Co-Investigator

Completed Research Support:

R03 NR013236 Gajewski (PI) 05/21/2014 - 05/20/2016
National Institutes of Health
A Novel Method for Expediting the Development of Patient Reported Outcome Measures
The specific aims for this proposed study are to: 1) Test Ordinal Bayesian Instrument Development (OBID) by comparing its performance (i.e., stability and development time differences) to classical instrument development using simulation date 2) Beta test OBID across settings of patient and family caregiver populations 3) Disseminate OBID software for evaluation by investigators in varied research communication.

No Number Gajewski (PI) 06/01/2013-6/01/2014
NCI (The KUCC)
The KUCC Pilot of Bayesian Prediction for Interim Review of Studies with Slow Accrual
The aims of this research study are to develop and test a software program for accrual (Aim #1) and develop a hierarchical extension to the accrual model (Aim #2). In Aim #1, we will develop a web-based applet that will provide a simple and easy to use interface that will encourage use of Bayesian models by a broader range of researchers. In Aim #2, the research team will develop a hierarchical accrual model. These extensions would provide modeling of individual strata in a stratified randomized study.

CTSA Pilot Gajewski/Carlson (PIs) 03/01/2015 - 02/28/2016
NIH
DHA Supplementation in Pregnancy to Reduce Early Preterm Birth: A Pilot
DHA is nutrient that is low in the diet of US women. Early preterm, i.e. births before 34 weeks gestation, affects 3.4 % of US pregnancies and results in births with the highest overall infant mortality and morbidity. The current project seeks to determine if prenatal nutritional supplementation with 1 gram per day of DHA can reduce early preterm birth. A positive finding would have enormous implications for the formulation of public policy on prenatal nutrition.

UL1RR033179 Barohn & Aaronson (PI) 04/01/2011-3/31/2014
National Institutes of Health
Frontiers: Heartland Institute for Clinical and Translational Research
The University of Kansas Heartland Institute for Clinical and Translational Research is an academic home for clinical and translational research, providing support to scientists and involving the community, so that discoveries and research findings wi|l be brought more rapidly to the point of care, thus improving the health of all Kansans.
Role: Biostatistician

P20 MD004805 Daley & Greiner (PI) 04/01/2010-3/31/2015
National Institutes of Health
Center for American Indian Community Health (CAICH)
The CAICH addresses health disparities among American Indians, who face some of the greatest health disparities of any racial/ethnic group in the US and who have not historically been well represented in medical research or education in the health professions. The center addresses a variety of health issues and focuses on two major health issues among American Indians, smoking and mammography. American Indians have the highest rates of smoking and rising incidence and disproportionate mortality for breast cancer.
Role: Methods Core Director

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Alan S Gamis, MD, MPH**

eRA COMMONS USER NAME (credential, e.g., agency login): AGAMIS1

POSITION TITLE: Chief, Section of Oncology, Children's Mercy Hospital Kansas City

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Drake University, Des Moines, IA	BA	1980	Biology
University of Illinois, Chicago, IL	MD	1984	Medicine
University of Minnesota, Minneapolis MN	MPH	1991	Epidemiology
Children's Mercy Hospital, KC, MO	Resident	1987	General Pediatrics
University of Minnesota, Minneapolis MN	Fellow	1991	Pediatric Oncology & Bone Marrow Transplant

A. Personal Statement.

My research expertise is in the design and development of multi-institutional clinical trials in childhood cancer, specifically in AML. I am a board certified Pediatric Hematologist/Oncologist and continue to care for patients with cancer in a large children's cancer center. I am also trained as an Epidemiologist receiving an MPH in 1991 as a foundation for clinical trial development. I have been active in AML research activities in the Children's Oncology Group since 1993, first serving on several COG clinical trial committees (AML, Neuroblastoma, Hodgkins, Stem Cell Transplant, Epidemiology, & Supportive Care/Nursing), then chairing two large clinical trials. The first was the phase III trial COG A2971 - Treatment of Children with Down's Syndrome and AML, MDS, and Transient Myeloproliferative Disorder, from 1996-2004.This was followed by a second national Phase III trial, COG-AAML0531- Phase III Randomized Trial of Gemtuzumab Combined with Conventional Chemotherapy for de novo Acute Myeloid Leukemia in Children, from 2004 until the present. I have served as a member of the COG Myeloid Scientific Disease Committee since 1996 and served as Chair of the committee from 2007-2013 overseeing all aspects of Myeloid Leukemia research (design, implementation, analysis, and strategic planning) during which time we designed and developed numerous clinical trials in childhood AML. I have also served on the COG Epidemiology Steering Committee from 1992-1995 and the COG Stem Cell Transplant Steering Committee from 2002 to 2010. I was a founding member of the Pediatric Blood and Marrow Transplant Consortium beginning in 1992 ultimately serving as its Chair from 1999-2004 during which time I led the successful attainment of the UO1 NHLBI grant as an original PI of a clinical core center of the Bone Marrow Transplant Clinical Trials Network (BMT CTN). During this time I successfully joined the PBMTC with the COG through the NIH grant BAA-RM-04-23 grant, Re-engineering the Clinical Research Enterprise: Feasibility of Integrating and Expanding Clinical Research Networks, from 2004-2008.Locally, as the Director of the Children's Mercy Cancer Center, I oversee all clinical and research activities related to cancer care and successfully oversaw the program's expansion, program development and ultimately consortium institutional partnership with the NCI-designated University of Kansas Cancer Center. I will serve as the Co-Program Leader of the D3ET Program.

B. Positions and Honors.

Professional Experience:

Jul 91-present	Staff Physician, Hematology/Oncology, The Children's Mercy Hospital, Kansas City, MO
2003-present	Chief, Section of Oncology, The Children's Mercy Hospital, Kansas City, MO
Jul 91-Aug 99	Assistant Professor, Pediatrics, University of Missouri-Kansas City, KC, MO
Sep 99-Jul 08	Associate Professor, Pediatrics, UMKC School of Medicine, KC, MO

Jul 08-present	Professor, Pediatrics, UMKC School of Medicine, KC, MO
Jul 12-present	Adjunct Professor, University of Kansas (KU) School of Medicine, KC, KS
Jul 12-present	Member/Co-Program Leader, KU NCI-designated Cancer Center, Drug Discovery Program

Other Experience and Professional Memberships:

2004-2011	American Academy of Pediatrics, Fellow- Executive Committee, Member-at-large, Subsection of Hematology/Oncology
2007-present	Cancer.net, American Society of Clinical Oncology website for patients. Editor for Pediatric Acute Myeloid Leukemia section,
2015-present	PDQ (Physician Data Query) - National Cancer Institute's Cancer Information Editorial Board. Member of Pediatric Treatment Editorial Board.

Selected Honors and Awards:

1996-2016	Best Doctors in America, for subspecialty, Pediatric H/O and BMT
2007-2016	Kansas City Super Doctor, *KC Magazine*, (region's top 10% of Oncology physicians (peer-selected), Hall of Fame honoree
2010	American Pediatric Society, elected to this research honor society.
2015	Golden Apple Fellow Mentor Award, Children's Mercy
2015	Ingram's Top Doctor Award 2015 (top 10 physicians in Kansas City), Ingram's Magazine

C. Contribution to Science (focus on myeloid leukemia research)

1. My early work in myeloid leukemias focused on improving supportive care for patients receiving intensive AML therapy, and the therapeutic options for relapsed AML patients. These efforts resulted in the greater awareness and the clarification that those at risk for overwhelming sepsis with alpha-hemolytic streptococcal infections were those receiving high dose cytarabine infusions. In relapse patients, I participated in the design of the CCG-2951 trial and the determination that the sequential administration of cytarabine (an S phase specific agent) followed by mitoxantrone would be the method of choice which has been the basis of its use in relapse and de novo serial COG protocols since. The following are representative manuscripts of these efforts:
   a) **Gamis A,** Howell B, DeSwarte J, Feusner J, Woods W. (2000) "Incidence and impact of alpha streptococcal infections in a prospective childhood AML trial, CCG 2891 - A report from the Childrens Cancer Group", Journal of Clinical Oncology, 18:1845-1855.
   b) Wells, R, Adams M, Alonzo T, Arceci R, Buckley J, Buxton A, Dusenbery K, **Gamis A**, Masterson M, Vik T, Warkentin P, Whitlock J. (2003) "Mitoxantrone and Cytarabine Induction, High Dose Cytarabine and Etoposide Intensification for Pediatric Patients with Relapsed or Refractory Acute Myeloid Leukemia: Children's Cancer Group Study 2951", Journal of Clinical Oncology, 21(15):2940-47.
   c) Sung L, **Gamis A**, Alonzo T, Buxton A, Britton K, DeSwarte-Wallace J, Woods W (2009). Infections and association with different intensity of chemotherapy in children with acute myeloid leukemia, Cancer, 115:1100-8. PMC2677372

2. Subsequent focus of research in myeloid leukemias was directed to the unique aspects of AML in children with Down Syndrome. This spanned retrospective data analysis of the experience on the Phase III AML trial, CCG-2891 which included all children with AML including those with Down Syndrome, continuing on as the study chair of the COG trial, A2971, Treatment of Children with Down's Syndrome and AML, MDS, and Transient Myeloproliferative Disorder, then the Myeloid Disease Scientific Chair overseeing the development of the trials, AAML0431 - The Treatment of Down Syndrome Children with Acute Myeloid Leukemia and Myelodysplastic Syndrome under the Age of 4 Years, and the COG trial, AAML08B1 - Biology of Transient Myeloproliferative Disorder in Down Syndrome Infants. I have subsequently participated in the development of the just opened COGtrial, AAML1531: Risk Stratified Therapy for Acute Myeloid Leukemia in Down Syndrome, as a study committee member. The CCG-2891 analysis resulted in the first description that age significantly impacted and defined myeloid leukemia in Down Syndrome children. The COG A2971 trial was the first COG and the largest trial in the world to that date that focused on Myeloid Leukemias in Down Syndrome and saw improvement in survival for those diagnosed with AML and defined the disorder Transient Myeloproliferative Disorder of Down Syndrome which continues to serve as the basis of current risk-based treatment stratification of this disorder. COG

AAML0431 recently had its data released and presented showing further improvement in overall survival for those with AML with alterations in the chemotherapy backbone and identified those at high risk for relapse. COG AAML1531 builds upon this knowledge and now stratifies therapy for Down Syndrome children diagnosed with AML based upon the risk factors identified in COG AAML0431. These trials also served to improve the epidemiologic understanding of this disorder. The following are selected representative manuscripts of these efforts:

a) **Gamis A**, Woods W, Alonzo T, Buxton A, Lange B, Barnard D, Gold S, Smith F (2003) "Increased Age at Diagnosis Has a Significantly Negative Effect on Outcome in Children with Down Syndrome and Acute Myeloid Leukemia—A Report from the Children's Cancer Group Study, CCG-2891", Journal of Clinical Oncology, 21(18):3415-3422.
b) Sorrell A, Gerbing R, Kumar M, Alonzo T, Hilden J, Smith F, **Gamis A** (2012). "Favorable Survival rates Maintained in Down syndrome children with acute myeloid leukemia/myelodysplasia (AML/MDS) treated with reduced dose chemotherapy on the Children's Oncology Group trial, COG A2971", Cancer 118(19):48-6-4814. PMC3879144
c) Wen Q, Goldenson B, Silver S, Schenone M, Huang Z, An WF, Lewis T, Dancik V, Thiollier C, Wang L, Diebold L, Bliss-Moreau M, VerPlank L, Moore C,Vokes M, Bray M, Scherer C, Carpenter A, Tolliday N, Clemons P, Mishra R, Vemula S, Shi J, Wei L, Kapur R, Lopez C, Gerby B,Ballerini P,Pflumio F, Gilliland DG, Goldberg L, Birger Y, Izraeli S, **Gamis A,** Smith F, Woods W, Goh B, Root D, Carr S, Gould R, Mercher T, Bradner J, Schreiber S, Stern A, Crispino J (2012). "Identification of regulators of polyploidization presents therapeutic targets for treatment of AMKL." Cell, 150(3):575-589. PMC3613864
d) Malinge, S., Chlon, T., Dore, L.C., Ketterling, R.P., Tallman, M.S., Paietta, E., **Gamis, A.S.**, Taub, J.W., Chou, S.T., Weiss, M.J., Crispino, J.D., Figueroa, M.E. (2013). "Development of Acute Megakaryoblastic Leukemia in Down Syndrome Is Associated with Sequential Epigenetic Changes", Blood, 122(14):e33-43. PMC3790517

3. With these areas of foundational research, I then assumed the study chair position of the COG Phase III trial for children, adolescents and young adults with *de novo* AML, specifically COG AAML0531. This trial was designed to test the antibody-conjugate agent, gemtuzumabozogamicin (GO), in order to improve EFS and OS without further increasing traditional chemotherapy intensity. This trial identified that GO improved EFS through the reduction in relapse risk in specific subsets of patients. Further analyses are ongoing to better identify those will benefit from this new agent. As a result of this and several adult trials of GO, the company is working to bring this agent back to market as it is the only new agent in many years to improve outcomes in AML patients. We also designed the trial to be the first COG AML trial with a stratified treatment assignment of intensification based on relapse risk. This trial further incorporated real-time central pathologic, cytogenetic, and immunophenotypic review of all diagnostic specimens for the first time in COG AML trials in order to ensure proper therapy stratification and accuracy of risk factors for response and treatment outcome. This trial also developed a highly annotated leukemic cell bank for biologic correlates including more in depth leukemic mutation analyses and host polymorphism impact. This opened the opportunity to establish the NCI/COG AML TARGET project that has successfully obtained 200 leukemia trios (diagnosis, remission, relapse) and an additional 50 duo's from patients with refractory AML for whole genome, exome, RNA, and methylome sequencing. This large biology trial as well as numerous biologic investigations is ongoing. The following are selected representative manuscripts of these efforts:
   a) Ho P, Kuhn J, Gerbing R, Pollard J, Zeng R, Miller K, Heerema N, Raimondi S, Hirsch B, Franklin J, Lange B, **Gamis A,** Alonzo T, Meshinchi S (2011). The *WT1 s*ynonymous SNP rs16754 correlates with higher mRNA expression and predicts significantly improved outcome in favorable-risk pediatric AML: a report from the Children's Oncology Group. Journal of Clinical Oncology*,* 29(6):704-711. PMC3056655
   b) Mortland, L., Alonzo, T.A., Walter, R., Gerbing, R.B., Mitra, A., Pollard, J., Loken, M., Hirsch, B., Raimondi, S., Franklin, J., Pounds, S., Cao, X., Rubnitz, J., Ribeiro, R., **Gamis, A**., Meshinchi, S., Lamba, J. (2013) "Clinical significance of CD33 non-synonymous single nucleotide polymorphisms (SNPS) in pediatric patients with acute myeloid leukemia treated with gemtuzumab-ozogamicin-containing chemotherapy", Clin Cancer Res 19:1620–1627. PMC3602123
   c) **Gamis, A.S**., Alonzo, T.A., Meshinchi, S., Sung, L., Gerbing, R.B., Raimondi, S.C., Hirsch, B.A., Kahwash, S.B., Heerema-McKenney, A., Winter, L., Glick, K., Davies, S.M., Byron, P., Smith, F.O., Aplenc R. (2014) "Gemtuzumab Ozogamicin in children with *de novo* acute myeloid leukemia (AML) improves event-free survival by reducing relapse risk – Results from the randomized Phase III

Children's Oncology Group trial, AAML0531", Journal of Clinical Oncology, 32:3021-3032. PMC4162498

d) Tarlock, K., Alonzo, T.A., Gerbing, R.B., Raimondi, S.C., Hirsch, B., Sung, L., Pollard, J.A., Aplenc, R., Loken, M., **Gamis, A.S.,** Meshinchi, S. (2016) "Gemtuzumab Ozogamicin Reduces Relapse Risk in *FLT3*/ITD Acute Myeloid Leukemia: A Report from The Children's Oncology Group", Clinical Cancer Research, 1078-0432.CCR-15-1349: February 2016. PMC4834220

4. A focused and strategic approach to the development of clinical and translational research in the childhood myeloid leukemias is critical for the most efficient and productive advancements in their understanding and their treatment. Building upon my prior international consortium leadership experience in developing and eventually chairing the Pediatric Blood and Marrow Transplant Consortium (PBMTC) and my successful grant award to be one of the original PI's for the NHLBI's Bone Marrow Transplant Clinical Trials Network (BMT CTN) coupled with my accumulating expertise in childhood AML, I assumed the Chairmanship of the COG Myeloid Disease Scientific committee, a position held from 2007-2013. The focus of this effort was to improve therapy stratification coupled with new agent evaluation while establishing a robust translational research mechanism utilizing the many leukemic and host specimens obtained from the many patients consented for this research. This research was biologically delineated for the *de novo* patients into 3 approaches for myeloid leukemia of Down Syndrome, acute promyelocytic leukemia, and all others with newly diagnosed AML (which itself was further delineated by biology and response). The second focus was upon those patients who were refractory or had relapsed on upfront therapies, either those being tested in COG and in standard of care approaches for patients not previously enrolled. Working with multiple specialties we collaborated to evaluate the efficacy of novel approaches, new agents, improved diagnostics, improved response precision, and improved supportive care in numerous trials developed during this time and which laid the foundation for current trials enrolling patients and those in design phase of development. The following are selected representative manuscripts of these efforts:
   a) **Gamis AS**, Alonzo TA, Perentesis JP, Meshinchi S (2013). "Children's Oncology Group's 2013 blueprint for research: Acute myeloid leukemia", Pediatr Blood Cancer 60(6):964-971. PMC4605815
   b) Canner J, Alonzo T, Franklin J, Freyer D, **Gamis A**, Gerbing R, Lange B, Meshinchi S, Woods W, Perentesis J, Horan J (2013). "Differences in Outcomes of Newly Diagnosed Acute Myeloid Leukemia for Adolescent/Young Adult and Younger Patients: A Report from the Children's Oncology Group", Cancer, 119(23): 4162-4169. PMC4398142
   c) Horton, T.M., Perentesis, J.P., **Gamis, A.S**., Alonzo, T.A., Gerbing, R.B., Ballard, J., Adlard, K., Howard, D.S., Smith, F.O., Jenkins, G., Kelder, A., Schuurhuis, G.J., Moscow, J.A. (2014) "A Phase 2 Study of Bortezomib Combined With Either Idarubicin/Cytarabine or Cytarabine/Etoposide in Children with Relapsed, Refractory or Secondary Acute Myeloid Leukemia: A Report from the Children's Oncology Group",Pediatr Blood Cancer, 61(10):1754-60. PMC4247259
   d) Cooper, T., Alonzo, T.A., Gerbing, R.B., Perentesis, J., Whitlock, J., Taub, J.W., Horton, T.M., **Gamis, A**., Meshinchi, S., Loken, M.R., Razzouk, B.I. (2014). "AAML0523: A report from the Children's Oncology Group on the efficacy of clofarabine in combination with cytarabine in pediatric patients with relapsed acute myeloid leukemia", Cancer, 120:2482-2489. PMC4126862

D. Research Support

Ongoing Research Support:
None

Completed Research Support:
U01 HL69254 Gamis (PI) 09/01/2001 - 09/28/2006
NIH
Pediatric Blood and Marrow Transplant Consortium, Clinical Core Center for the NHLBI/NCI Blood and Bone Marrow Transplant Clinical Research Network
Role: Site Principal Investigator

U10 CA98543, subcontract 11802 Gamis (PI) 07/07/2003 – 08/31/2015
NIH
Children's Oncology Group Chair's Grant

COG Study Chair support
Role: COG Myeloid Disease Steering Committee Chair

R01 CA111778 Parentesis (PI) 01/01/2005-12/31/2010
NIH
Molecular Studies of Down Syndrome Leukemia
Role: Co-Investigator

Leukemia & Lymphoma Society (SCOR grant) 10/01/2007- 09/30/2012
Specialized Center of Research in Targeted Therapies for Infant Leukemias
Subcontract as Core C (Biologic Correlates and Clinical Integration Core)
Role: Key Personnel

U10 Supplemental Grant 01/01/2008-12/31/2009
NIH-National Cancer Institute (NCI)
Biomarker, Imaging, and Quality of Life Supplemental Funding Program (BIQSFP)
COG-AAML0531 Biomarkers for risk identification and risk-based therapy in pediatric AML
(Renewable for duration of AAML0531 – 2010).
Role: Unfunded Consultant / Senior Advisor to grant that supports biologic correlate research specifically in AAML0531.

BAA-RM-04-23 01/01/2004-12/31/2007
NIH
Re-engineering the Clinical Research Enterprise: Feasibility of Integrating and Expanding Clinical Research Networks
Joint COG and PBMTC 3 year Contract with NHLBI
Role: Unfunded contract author & Steering Committee Member

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Kevin Fate Ginn, MD**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Assistant Professor Hem/Onc, Director Neuro-Oncology Program

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Clemson University, Clemson, SC		12/1996	Biochemistry
Presbyterian College, Clinton, SC	B.S.	05/1999	Biology
Medical University of South Carolina, Charleston, SC	M.D.	06/2005	Medicine
Louisiana State University, New Orleans, LA	Residency	06/2008	Pediatrics
University of Missouri Kansas City-Children's Mercy	Fellowship	06/2011	Hematology/Oncology
St. Jude Children's Research Hospital, Memphis, TN	Fellowship	06/2012	Neuro-Oncology

A. Personal Statement

Improvement in the survival of pediatric patients with cancer has been significant over the last few decades primarily due to strong collaborative groups performing well planned clinical trials. The safety of those trials and the integrity of the data collected are of utmost importance to the success of this work. My previous experience as a study member and now as institutional principle investigator for several clinical trials prepares me well for a role on the Protocol Review and Monitoring Committee of the University of Kansas Cancer Center. I act as a representative of Children's Mercy and have an expertise in Pediatric Neuro-Oncology.

B. Positions and Honors

Positions and Employment:

2012 – Pres. Assistant Professor, Division of Hematology/Oncology, Children's Mercy Hospital and Clinics, Kansas City, MO
2012 – Pres. Director Neuro-Oncology Program, Children's Mercy Hospital and Clinics, Kansas City, MO
2013 – Pres. Clinical Assistant Professor of Pediatric Hematology/Oncology, University of Kansas Medical Center, Kansas City, KS

C. Contribution to Science:

1. **Publications:** I have contributed with clinical expertise in studies related to malignancies in children.
   a) **Ginn KF** and Gajjar A (2012) Atypical teratoid rhabdoid tumor: current therapy and future directions. Front. Oncol. 2:114. doi: 10.3389/fonc.2012.00114. PMC3439631
   b) Butler DF, **Ginn KF**, Daniel JF, Bloomer JR, Kats A, Shreve N, Myers GD (2015). Bone marrow transplant for X-linked protoporphyria with severe hepatic fibrosis. Pediatr Transplant. Jun;19(4):E106-10. PMID: 25856424 (PMC# not required; not NIH funded)
   c) Zaky W, Dhall G, Khatua S, Brown RJ, **Ginn KF**, Gardner SL, Yildiz VO, Yankelevich, Finlay JL (2015). Choroid plexus carcinoma in children: The Head Start experience. Pediatr Blood Cancer. May;62(5): 784-9. PMID: 25662896

d) Radhi M, Fulbright JM, **Ginn KF** and Guest EM (2015). Childhood cancer for the primary care physician. Primary Care: Clinics in Office Practice. Mar;42(1):43-55. PMID: 25634704 (not NIH funded)

2. Poster presentations:

a) **Kevin F. Ginn MD**, Amanda Wise BS, Faris Farassati. Ral signaling in medulloblastoma: biological and therapeutic outcome. 2010 Children's Oncology Group Fall Meeting, Young Investigator Poster Session. Dallas, Texas. October 2010.

b) **Kevin F. Ginn MD**, Amanda Wise BS, Faris Farassati. Ral signaling in medulloblastoma: biological and therapeutic outcome. 2010 Society for Neuro-Oncology Scientific Meeting and Education Day. Montreal, Canada. November 2010.

c) Sasmita Das, Boumediene Bouzahzah, **Kevin F. Ginn MD**, Bhaskar C. Das. Design and Synthesis of Boron containing potential therapeutic agents for treatment of Atypical Teratoid Rhabdoid Tumor (ATRT). The International Chemical Congress of Pacific Basin Societies Meeting. Honolulu, Hawaii December 2015.

d) Brain Carter, Kirstin Hirni, Jenni Linebarger, Lynne Covitz, **Kevin Ginn**. Medical non-treatment decisions can be rational in adolescents. American Society for Bioethics and Humanities Annual Meeting. Houston, Texas October 2015.

3. Oral presentations:

a) Bhaskar C. Das, **Kevin F. Ginn**, Akiva Mintz. Design and synthesis of boron containing retinoid based potential PET Imaging agent for glioblastoma. The International Chemical Congress of Pacific Basin Societies Meeting. Honolulu, Hawaii December 2015.

b) **Kevin F. Ginn** and Bhaskar C. Das. Retinoid based potential theranostic agents for the treatment of atypical teratoid rhabdoid tumor. The International Chemical Congress of Pacific Basin Societies Meeting. Honolulu, Hawaii December 2015.

D. Research Support

Ongoing Research Support:

No number (PIs: Ginn & Das) 2015 – 2017
Midwest Cancer Alliance, Partners Advisory Board Funding
Title: *Investigating MAGMAS inhibitors in adult and pediatric glioblastoma*

Recently Completed Research Support: None

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Andrew K. Godwin

eRA COMMONS USER NAME: AKGODWIN

POSITION TITLE: Professor & Director, Molecular Oncology, Deputy Director, KU Cancer Center; Chancellor's Distinguished Chair in Biomedical Sciences

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Kansas	BS	05/1982	Cellular Biology
University of Pennsylvania, Philadelphia, PA	PhD	12/1989	Molecular Biology

A. Personal Statement

I am a Professor and the Director of Molecular Oncology in the Department of Pathology and Laboratory Medicine at KUMC. I am leading the Personalized Cancer Medicine initiative for the KU Cancer Center, which supports enhanced biobanking and data warehousing efforts, the growth of an early phase clinical trial infrastructure, and the development a state-of-the-art clinical translational biomarker discovery laboratory. I was named a Kansas Bioscience Authority Eminent Scholar in 2010 and the Chancellor's Distinguished Chair in Biomedical Sciences Endowed Professor in 2012 and my contributions towards education and training was recognized with the KUMC School of Medicine Achievement Award for Mentoring Post-Docs in 2014 and the KU Medical Center's Faculty Investigator Research Award in 2015. My research program continues to focus on various aspects of both basic and translational research, with an emphasis on early detection of cancer, predictive and prognostic biomarkers, liquid biopsies based on extracellular vesicles, molecular therapeutics, companion diagnostics, clinical trials, and biosample ascertainment. For this CCSG renewal, I will serve in the capacity of the Deputy Director for our NCI-designated Cancer Center and as the Director of the Biospecimen Shared Resource.

B. Positions and Honors

1990-1991 Postdoctoral Associate, Division of Medical Sciences, Fox Chase Cancer Center, PA
1991-1992 Research Associate, Division of Medical Sciences, Fox Chase Cancer Center, PA
1992-1995 Assistant Member, Division of Medical Sciences, Fox Chase Cancer Center, PA
1995-2001 Associate Member, Division of Medical Sciences, Fox Chase Cancer Center, PA
1995-2010 Director of the Clinical Molecular Genetics Laboratory, Fox Chase Cancer Center, PA
1997-2010 Adjunct Professor, Department of Chemistry, Lehigh University, Bethlehem, PA
1999-2010 Director of the Biosample Repository Core Facility, Fox Chase Cancer Center, PA
2001-2009 Member (with tenure), Division of Medical Sciences, Fox Chase Cancer Center, PA
2003-2004 Chief Scientific Officer, Alteris Therapeutics, Inc., Malvern, PA
2006-present Adjunct Professor, Dept. of Biochemistry, Drexel Univ. College of Medicine, Philadelphia, PA
2008-2009 Program Leader, Ovarian Cancer, Fox Chase Cancer Center, PA
2008-2010 Co-PI of The Fox Chase Cancer Center/University of Pennsylvania Ovarian Cancer SPORE
2009-2010 Co-Leader, Women's Cancer Program, Fox Chase Cancer Center, PA
2009-2010 Senior Member (Professor), Division of Medical Sciences, Fox Chase Cancer Center
2010-present Adjunct Professor, Fox Chase Cancer Center, Philadelphia, PA
2010-present Professor, Department of Pathology & Laboratory Medicine, University of Kansas Medical Center (KUMC), Kansas City, KS
2010 Kansas Bioscience Authority Eminent Scholar
2010-2013 Associate Director for Translation Research, University of Kansas Cancer Ctr, Kansas City, KS
2010-present Director, Molecular Oncology, University of Kansas Medical Center, Kansas City, KS
2011-present Director, Biospecimen Shared Resource, University of Kansas Cancer Center, Kansas City, KS
2011-present Biorepository Coordinator for the Frontiers Translational Technologies Resource Center
2012-present Chancellors Distinguished Chair in Biomedical Sciences endowed Professor, Kansas City, KS
2013-present Deputy Director, University of Kansas Cancer Center, Kansas City, KS
2014 Achievement Award for Mentoring Post-Docs, University of Kansas School of Medicine
2015 Faculty Investigator Research Award, University of Kansas Medical Center

2015-present Member, Children's Mercy Cancer Center, Kansas City, MO
2015-present Member, Children's Mercy Cancer Center Genomics Program, Kansas City, MO

Other Experience, Reviews and Professional Memberships (selected):
99,02,04,05,06 Review committee for U.S. Army Medical Research and Materiel Command: Ovarian Cancer
2000-2016 Associate Editor for *Cancer Research*
2001-present Ad-hoc reviewer for the Special Emphasis Panels
2001-2003 Review committee for NCI: Pathology C (renamed to Molecular Cancer Pathobiology)
2003-2007 Review committee for NCI: Charter Member for Cancer Genetics
03,04,06,07,10 Review committee for U.S. Army Medical Research and Materiel Command: Breast Cancer
2004-present Editorial Board for *Current Cancer Therapy Reviews*
2005, 2010 Review committee for NCI: Ovarian Cancer & GYN SPOREs
2008-present Associate Editor for *Human Genomics and Proteomics*
2008-present Editorial Board for *Future Medicine*
2008-2009 Steering Committee Member, The Cancer Genome Atlas Project
2009-2010 Co-Leader, Women's Cancer Program, Fox Chase Cancer Center, Philadelphia, PA
2009-2012 Ovarian Cancer Working Group Member, The Cancer Genome Atlas project
2010 Scientific Review Group 2010/5 ZCA1 RPRB-M (M1) P-SPOREs in GYN, Breast, Skin Cancers
2010-present Pharmacogenomics Advisory Group, Coriell Institute for Medical Research, Camden, NJ
2011-present Medical and Scientific Advisory Board for the National Ovarian Cancer Coalition
2012-2014 Scientific Advisory Board for the Research Advocacy Network (Tissue Think Tank)
2012-present Chair, Scientific Advisory Board for the Basser Research Center for BRCA
2013-present Board of Director, Vicki Welsh Fund for Ovarian Cancer Awareness
2013-present Cervical Cancer Working Group Member, The Cancer Genome Atlas project
2013-present Kidney Papillary Cancer Working Group Member, The Cancer Genome Atlas project
2014-present Sarcoma Cancer Working Group Member, The Cancer Genome Atlas project
2015 Outstanding Investigator Award (OIA)-2 Review Panel
2015-present PanCanAtlas Working Group Member (multiple groups), The Cancer Genome Atlas project

C. Contributions to Science

1. **Ovarian Oncogenesis.** I became interested early in my career in the field of ovarian cancer through early studies of cancer genetics and multi-drug resistance. My career has spanned over 25 years and contributed to over 180 ovarian cancer-related publications. I served as a co-PI for an ovarian cancer SPORE program while at Fox Chase Cancer Center (FCCC) and have participated on many ovarian cancer clinical trials. I established the first *in vitro* model of incessant ovulation, derived the first human ovarian surface epithelial cell cultures from BRCA1 and BRCA2 mutation carriers (in collaboration with Dr. Henry Lynch), cloned the human glutathione S-transferase gene (in collaboration with Alton Meister) and demonstrated the role of glutathione synthesis in resistance to cisplatin using human ovarian cancer cells that I derived (in collaboration with Drs. Thomas Hamilton & Robert Ozols) and have been used by countless researchers around the globe. I participated in the first study that identified AKT2 (in collaboration with Dr. Joseph Testa) and demonstrated its role in ovarian cancer oncogenesis. I was the first to study and establish a role for γ-synuclein in the pathogenesis of breast and ovarian cancer (and now many solid tumors). I mapped and cloned several candidate tumor suppressor genes, reported the utility of monitoring circulating tumor cells in ovarian cancer clinical trials, and performed the first genomic siRNA screen to identify points of molecular vulnerability that are now being used in drug discovery efforts for novel therapies. Our most recent studies have uncovered an important role of TGF-β/SMAD signaling in platinum resistance, which will lead to investigator initiated trials to re-awake tumors to this therapy.

a) Godwin, A.K., Testa, J.R., Handel, L.M., Liu, Z., Vanderveer, L.A., Tracey, P.A., and Hamilton, T.C. Spontaneous transformation of rat ovarian surface epithelial cells: association with cytogenetic changes and implications of repeated ovulation in the etiology of ovarian cancer. J Natl Cancer Inst. 1992 Apr 15;84(8):592-601 (PMID: 1556770).
b) Godwin, A.K., Meister, A., O'Dwyer, P.J., Huang, C.S., Hamilton, T.C., and Anderson, M.E. High resistance to cisplatin in human ovarian cancer cell lines is associated with marked increase of glutathione synthesis. Proc Natl Acad. Sci USA 1992 Apr 1;89(7):3070-3074 (PMID: 1348364) PMCID: PMC48805.
c) Cheng, J.Q., Godwin, A.K., Bellacosa, A., Taguchi, T., Franke, T.F., Hamilton, T.C., Tsichlis, P.N., and Testa, J.R. AKT2, a putative oncogene encoding a member of a subfamily of protein-serine/threonine kinases, is amplified in human ovarian carcinomas. Proc Natl Acad Sci USA 1992 Oct 1;89(19):9267-9271 (PMID: 1409633) PMCID: PMC50107.

d) Schultz, D.C., Vanderveer, L., Berman, D.B., Hamilton, T.C., Wong, A.J., and Godwin, A.K. Identification of two candidate tumor suppressor genes on chromosome 17p13.3. Cancer Res 1996 May 1;56(9):1997-2002 (PMID: 8616839).

2**. Translational Research and Biospecimens.** Most people do not realize or appreciate the time, resources, and effort needed to establish highly annotated biobanks of human biospecimens and clinical data to support translational research. I have been a leader in this field, and have established biobanks spanning multiple institutes and tens of thousands of participants. I have contributed to NIH initiatives and have been listed as a source for the NCI Tissue Expediter since it beginnings. My efforts at FCCC were acknowledged in RAND as one of the top biosample repositories. I have been a tissue source site for both The Cancer Genome Atlas (TCGA) and Clinical Proteomic Tumor Analysis Consortium (CPTAC). I was a member of the TCGA steering committee and several disease working groups as well as an active participant in the Early Detection Research Network (EDRN) since 2005. I established the Family Risk Assessment Program (FRAP) biosample repository (in collaboration with Dr. Mary Daly) at FCCC prior to the discovery of *BRCA1* and *BRCA2* to support the identification of inherited factors, which included >7,000 cancer-prone families. I also developed some of the earlier clinical tests (CLIA/CAP accredited) to screen women and men for mutations in *BRCA1* and *BRCA2* (prior to the suppression by Myriad's patent). This resource contributed to the better understanding of the role of *BRCA* mutations in hereditary breast and ovarian cancer. We were also the first to show that loss of expression of *BRCA1* via non-sense mediated decay and/or allele-specific expression was associated with breast cancer risk. Based on my past research and the valuable clinical resources I helped assemble at FCCC and the Triple Negative Breast Cancer Registry we are actively developing at KUMC, I served as a core member of the Consortium of Investigators of Modifiers of *BRCA1*/2 (CIMBA), an international consortium that has assembled and is evaluating large cohorts (>45,000) of *BRCA1* and *BRCA2* mutation carriers for genetic modifiers of breast cancer risk. This collective has published over 40 seminal articles since its formation regarding the role of *BRCA* and *BRCA*-related gene in breast and ovarian cancer.

a) Holgado-Madruga, M., Emlet, D.R., Moscatello, D.K., Godwin, A.K., and Wong, A.J. A Grb2-associated docking protein in EGF- and insulin-receptor signalling. Nature*,* 1996 Feb 8;379(6565):560-564 (PMID: 8596638).
b) Rebbeck, T.R., Levin, A.M., Eisen, A., Snyder, C., Watson, P. Cannon-Albright, L., Isaacs, C., Olopade, O., Garber, J.E., Godwin, A.K., Daly, M.B., Narod, S.A., Neuhausen, S., Lynch, H.T., and Weber, B.L. Breast cancer risk after bilateral prophylactic oophorectomy in *BRCA1* mutation carriers. J Natl Cancer Inst, 1999 Sep 1;91(17):1475-1479 (PMID: 10469748).
c) Chen, X., Weaver, J., Bove, B.A., Vanderveer, L., Weil, S.C., Miron, A., Daly, M.B. Godwin, A.K. Allelic imbalance in *BRCA1* and *BRCA2* gene expression is associated with an increased breast cancer risk. Hum Mol Genet, 2008 May 1;17(9):1336-1348. Paper accepted prior to April 7, 2008. (PMID 18204050).
d) The Cancer Genome Atlas Research Network. Integrated genomic analyses of ovarian carcinoma. Nature, 2011 Jun 29;474(7353):609-615 (PMID: 21720365) PMCID: PMC3163504.

3. **Molecular Therapeutics in Cancers.** I served as the Translational Science Co-chair and/or translational scientist for multiple Gynecologic Oncology Group (GOG) and Eastern Cooperative Oncology Group (ECOG) clinical trials evaluating molecularly targeted agents, such as AMG102, AMG386, AMG479, AMG706, cetuximab, dasatinib, everolimus, enzastaurin, gefitinib, lapatinib, RAD001, sorafenib, temsirolimus, and VEGF-TRAP and I am currently a member of the Early Therapeutics & Rare Cancers & Breast Committees for the Southwest Oncology Group (SWOG). In collaboration with scientists at Bristol Myers-Squibb we were the first group to demonstrate, in a Phase II clinical trial of advanced colon cancer, that patients with tumors expressing high gene levels of epiregulin and amphiregulin were more likely to have disease control on cetuximab treatment. Embedded in this study were important finding by my group indicating that the *KRAS* mutational status was highly informative of likely response to EGFR-targeted therapy. Our mutation study ultimately led to numerous other confirmatory studies and a Provisional Clinical Opinion statement by the American Society of Clinical Oncology that all patients with metastatic colorectal cancer who are candidates for anti-EFGR therapy (*i.e.,* cetuximab and panitumumab) have their tumors tested for *KRAS* mutations. My clinical research efforts continue to explore and expand the use of molecular pathology in personalizing patient care and I direct a CLIA/CAP accredited clinical molecular oncology laboratory, which helps guide patient care on a daily basis.

a) Schilder, R., Sill, M.W., Chen, X., Darcy, K.M., Decesare, S.L., Lewandowski, G., Lee, R.B., Arciero, C.A., Wu, H., Godwin, A.K. Phase II study of gefitinib in patients with relapsed or persistent ovarian or primary peritoneal carcinoma and evaluation of epidermal growth factor receptor mutations and

immunohistochemical expression: a Gynecologic Oncology Group Study. Clin Cancer Res, 2005 Aug 1;11(15):5539-5548 (PMID: 16061871).

b) Khambata-Ford, S., Garrett, C.R., Meropol, N.J., Basik, M., Harbison, C.T., Wu, S., Wong, T.W., Huang, X., Takimoto, C.H., Godwin, A.K., Tan, B.R., Krishnamurthi, S.S., Burris, H.A. 3rd, Poplin, E.A., Hidalgo, M., Baselga, J., Clark, E.A., Mauro, D.J. Expression of epiregulin and amphiregulin and K-ras mutation status predict disease control in metastatic colorectal cancer patients treated with cetuximab. J Clin Oncol, 2007 Aug 1;25(22):3230-3237 (PMID: 17664471).

c) Usha, L., Sill, M.W., Darcy, K.M., Benbrook, D., Hurteau, J., Michelin, D.P., Mannel, R.S., Hanjani, P., DeGeest, K., Godwin, A.K. A Gynecologic Oncology Group phase II trial of the protein kinase C-beta inhibitor, enzastaurin and evaluation of markers with potential predictive and prognostic value in persistent or recurrent epithelial ovarian and primary peritoneal malignancies. Gynecol Oncol, 2011 Jun 1;121(3):455-461 (March 15, 2011 [Epub ahead of print]) (PMID: 21414654) PMCID: PMC3100412.

d) Kwon, Y., Smith, B.D., Zhou, Y., Kaufman, M.D., Godwin, A.K. Effective inhibition of c-MET-mediated signaling, growth and migration of ovarian cancer cells is influenced by the ovarian tissue microenvironment. Oncogene, 2015 Jan 8;34(2):144-153 (Dec. 23, 2013 [Epub ahead of print]) (PMID: 24362531) PMCID: PMC4067476.

4. **The pathogenesis of gastrointestinal stromal tumor (GIST)**. My interest in GIST began in the early 2000's. Using patient samples from the CSTI571-B2222 Phase II trial, we were the first group to report genetic markers that could predict the response of patients with metastatic/recurrent GIST to imatinib mesylate (also known as Gleevec™), an oral 2-phenylaminopyrimidine derivative that acts as a selective inhibitor against several receptor tyrosine kinases including KIT, PDGFRA, and BCR-ABL (selected as "**The Best of MCT-10 Years**" in November, 2011). Our subsequent studies uncovered that imatinib has therapeutic benefit for GIST via KIT inhibition, but potentially independent of AKT activity and glucose deprivation. To expand the original profiling studies, my group directly assessed pre-treatment biopsy samples from a prospective neoadjuvant phase II trial (RTOG 0132) and identified an expanded 38-gene signature that included 18 *KRAB-ZNF 91* subfamily members, 10 of which mapped to a single locus on chromosome 19p. We were also the first to report a role of IGF-1R in the pathogenesis of GIST, especially in tumors that lacked kinase mutations. These so called "wild-type" tumors are clinically more resistant to imatinib-based therapies and have few gross genomic alterations. We and other have now clearly shown that mutations in the *SDH* gene family inversely correlate with IGF-1R expression. Our studies led to the first clinical trials of wild-type pediatric and young adult GIST patients with an anti-IGF-1R targeted therapy. We are also the first to report a drug repurposing screen for GIST.

a) a. Frolov, A., Chahwan, S., Ochs, M., Arnoletti, J.P., Pan, Z-Z., Favorova, O., Fletcher, J., von Mehren, M., Eisenberg, B., and Godwin, A.K. Response markers and the molecular mechanisms of action of Gleevec in gastrointestinal stromal tumors (GISTs). Mol Cancer Ther, 2003 Aug;2(8):699-709(PMID: 12939459).

b) b. Tarn, C., Skorobogatko, Y. V., Taguchi, T., Eisenberg, B., von Mehren, M., Godwin, A.K. Therapeutic effect of imatinib in gastrointestinal stromal tumors: AKT signaling dependent and independent mechanisms. Cancer Res, 2006 May 15;66(10):5477-5486 (PMID: 16707477)

c) c. Tarn, C., Rink, L., Merkel, E, Flieder, D., Pathak, H., Koumbi, D., Testa, J., Eisenberg, B., von Mehren, M., Godwin, A.K. Insulin-like growth factor 1 receptor is a potential therapeutic target for gastrointestinal stromal tumors. Proc Natl Acad Sci USA, 2008 Jun 17;105(24):8387-8392 (PMID: 18550829) PMCID: PMC2448846.

d) d Ochs, M.F., Rink, L., Tarn, C., Mburu, S., Taguchi, T., Eisenberg, B., Godwin, A.K. Detection of treatment-induced changes in signaling pathways in gastrointestinal stromal tumors using transcriptomic data. Cancer Res, 2009 Dec 1;69(23):9125-9132 (Nov 10, 2009 [Epub ahead of print]) (PMID: 19903850) PMCID: PMC2789202.

5. **Exosomes in Cancer.** For the past several years our lab has been exploring the role of the exosomes in cancer initiation and progression and as biomarkers for early detection and response to therapy. We report the first evidence that GIST cells invade the interstitial stroma through the release of oncogenic KIT-containing exosomes, which triggers the phenotypic conversion of progenitor smooth muscle cells to tumor-promoting cells. Our study indicated that exosome release and subsequent MMP1 induction created a positive feedback-loop mechanism established between tumor and stromal cells which drives GIST development and offers new insights for potential therapeutic strategies to block GIST progression and metastatic spread. More generally, we sought to exploit exosomes as potential biomarkers to detect and monitor disease states. We therefore fabricated the first microfluidic platform (lab-on-a-chip) to streamline and expedite the exosome analysis

pipeline by integrating specific immunoisolation and targeted protein analysis of circulating exosomes. We foresee that the microfluidic exosome analysis platform will form the basis for critically needed infrastructures for advancing the biology and clinical utilization of exosomes in the diagnosis and monitoring of disease during therapy.

a) Atay, S., Banskota, S., Crow, J., Sethi, G., Rink, L., Godwin, A.K. Oncogene KIT-containing exosomes increase gastrointestinal stromal tumor cell invasion. Proc Natl Acad Sci USA, 2014 Jan 14;111(2):711-716. (Dec. 30, 2013 [Epub ahead of print]) (PMID: 24379393) PMCID: PMC3896203.
b) He, M., Crow, J., Roth, M., Zeng, Y., Godwin, A.K. Integrated immunoisolation and protein analysis of circulating exosomes using microfluidic technology. Lab Chip, 2014 Oct 7;14(19):3773-3780 (August 6, 2014 [Epub ahead of print]) (PMID: 25099143) PMCID: PMC4161194.
c) US Patent number 14KU036M (Application Numbers 61/953,109 and 62/025,151, entitled, "Microfluidic Exosome Molecular Profiling Device", 03/14/2014 and 07/16/2014.

A complete list of Dr. Godwin's publications (including **316** research articles, **41** book chapters and review articles, and **4** invited editorials, which have yielded ~30,000 citations) can be found at the links below. Dr. Godwin's current *h*-index is 92. http://scholar.google.com/citations?user=fXDESs0AAAAJ&hl=en&authuser=1
http://www.ncbi.nlm.nih.gov/sites/myncbi/andrew.godwin.1/bibliography/41140450/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

RSG-14-067-01-TBE Chien (PI) 07/01/2014 - 06/30/2018
American Cancer Society
Functional Genetics to Identify Carboplatin Resistant Genes in Ovarian Cancer.
Major goals: To identify drug resistant genes associated with carboplatin resistance in ovarian cancer.
Role: Co-Investigator

R21CA186846 Zeng (PI) 08/01/2014 - 07/30/2017
NIH
Integrated Microfluidic Exosome Profiling for Early Detection of Cancer
Major goals: To yield a transformative platform for exosome research and cancer diagnosis, which could confer new capabilities for elucidating the biological functions of exosomes and for developing reliable biomarkers and clinical tests for early detection of cancer.
Role: Co-Investigator

P30 CA168524 Jensen (PI) 07/01/2012-06/30/2017
NIH
Cancer Center Support Grant
Major goals: The University of Kansas Cancer Center is a growing matrix organization that aims to leverage unique scientific assets to build a nationally significant cancer research and treatment center that will become the leading academic institution in the world for transforming discoveries in the laboratory into new therapeutic approaches.
Role: Deputy Director & Director, Biospecimen Repository

U01CA168870 Abbott (PI) 07/01/2015 – 06/30/2017
NIH
Glycomic Analysis of Exosomes Present in the Ascites and Plasma of Ovarian Cancer
Major goals: To isolate exosomes from the ascites and plasma of ovarian cancer patients and identify the glycoproteins present using nano-ESI-RPLC-MS/MS analysis.
Role: Subcontract Principal Investigator

Completed Support:

U01CA113916 Engstrom (PI) 08/13/2005 - 06/30/2016
Fox Chase Cancer Center (NCI)
Fox Chase Clinical Epidemiology and Validation Center
Major goals: to identify a reliable panel of biomarkers that would allow clinicians and pathologists to discern which individuals are at increased risk for developing invasive breast cancer.
Role: Subcontract Principal Investigator.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES**

NAME: **Jianghua He, Ph.D.**

eRA COMMONS USER NAME (credential, e.g., agency login): hejiang

POSITION TITLE: Associate Professor

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Science and Technology of China	B.S.	1997	Information Management
University of Science and Technology of China	M.S.	2000	Management Science
Bowling Green State University, Bowling Green, OH	M.A.	2001	Statistics
Florida State University, Tallahassee, Florida	Ph.D.	2007	Statistics

A. Personal Statement

With over 10 years of education/training and research experience in Statistical and medical fields, I am well-prepared to fulfill my role on the PRMC committee of the University of Kansas Cancer Center. I have been closely involved with clinical research since I joined the University of Kansas Medical Center (KUMC) in 2007. As a Biostatistician of the General Clinic Research Center for three years, I reviewed various clinical studies and helped PIs with study design and data analysis. I also reviewed grants for NIH study sections several times over the years. As a co-investigator, I worked on multiple NIH/FDA funded research grants of R01, R03, and R21. Some related publications are listed here.

1. Vidoni ED, Sciver AV, Johnson DK, **He J**, Honea R, et al. A community-based approach to a trial of aerobic exercise in Alzheimer's disease. Contemporary Clinical Trials. 2012, 33:1105–1116. PMC3468654. (*The author name was spelled wrong as Jinghua He instead of Jianghua He.)*
2. Pasnoor M, **He J**, Herbelin L, Dimachkie M, Barohn RJ, Muscle Study Group. Phase II Trial of Methotrexate in Myasthenia Gravis. Annals of the New York Academy of Sciences. 2012, 1275 (2012) 23–28. PMC3564221.
3. Pasnoor M, **He J**, Herbelin L, Burns T, Nations S, Bril V, Wang AK, Kissel J, Saperstein D, Rosenfeld J, Shaibani A, Jackson C, Swenson A, Howard JF Jr, Goyal N, Wicklund M, Pulley M, Miller J, Mozaffar T, Dimachkie M, Statland JM, Barohn RJ, and the MSG methotrexate Sutdy MG Group. A randomized controlled trial of methotrexate for patients with generalized myasthenia gravis. Neurology. 2016 Jul 5;87(1):57-64. PMC4932232.
4. Davis AM, Dean K, Mousa J, Edwards S, Cocjin J, Almadhoun O, **He J**, Bruce A, Hyman P. A randomized controlled trial of an outpatient protocol for transitioning children from tube to oral feeding: No need for amitriptyline. The Journal of Pediatrics. 2016. 172:136-141. PMC4846510.

B. Positions and Honors

Positions and Employment:

2001 Teaching Assistant for College Algebra, Bowling Green State University, Bowling Green, OH
2003 – 2005 Teaching Assistant for Statistics through Examples and Business Statistics, Florida State University, Tallahassee, FL
2005 – 2007 Research Assistant, College of Medicine, Florida State University, Tallahassee, FL
2006 Research Assistant, Department of Statistics, Florida State University, Tallahassee, FL
2007 – 2013 Assistant Professor, Department of Biostatistics, University of Kansas Medical Center, Kansas City, KS
2013 – Pres. Associate Professor, Department of Biostatistics, University of Kansas Medical Center, Kansas City, KS

Other Experience and Professional Memberships:

2004 – Pres. Member, American Statistical Association (ASA)
2007 – 2010 Member, International Biometric Society Eastern North American Region (ENAR)
2007 – 2013 Member, Center for Biostatistics and Advanced Informatics, University of Kansas Medical Center (KUMC), Kansas City, Kansas
2007 – Pres. Member, Kansas Masonic Cancer Research Institute, KUMC

Honors and Awards:

08/2003 Teaching Fellowship, Florida State University, Tallahassee, FL
08/2004 Book award, Statistics Department, Florida State University, Tallahassee, FL
12/2004 Best First-year Student in Theoretical Statistics, Florida State University, Tallahassee, FL
03/2006 Student Paper Award, ASA Chapter Meeting of Florida, Jacksonville, FL
05/2006 Winner of the Yongyuan and Anna Li Student Presentation, Florida State University, Tallahassee
03/2010 Faculty Travel Award, University of Kansas Medical Center
04/2012 Faculty Travel Award, University of Kansas Medical Center
12/2013 WIMS (The University of Kansas Women in Medicine & Science Organization) scholarship to attend the AAMC Mid-Career Women Faculty Professional Development Seminar 2013.

C. Contribution to Science

1. Survival Analysis for Medical Research (Statistical Methodology)

Survival analysis is my major methodologic research field. My focus is on non-proportional hazards models, which are different from the most commonly used Cox model. Based on an empirical Bayesian Dynamic Survival Models, I proposed an approach to identify the appropriate values for smoothing parameters. For interim analysis using survival analysis, I also proposed an approach to adjust for censoring when the Cox model was used under non-proportional hazards situations. I have also collaborated with other researchers as well as supervised students to do research in related fields.

a) **He J**, McGee D, and Niu X: Application of the Bayesian Dynamic Survival Model in Medicine. Statistics in Medicine. 2010, 29:347--360. PMID: 20014356 (PMC# not required; not NIH funded)
b) **He J**, Mayo M: Adjusted Interim Survival Analysis under non-proportional Hazards, Communications in Statistics: Simulation and Computation, 2012; 41:1, 111-124 (not NIH funded)
c) Mahnken JD, **He J**, Yeh H, Nazir N, Jianas LL, Engelman KK. Survival analysis applied to proportion data: comparing mammography visits in high and low repeat rate facilities. Health Services and Outcomes Research Methodology. 2013, 13(1):68-83 (not NIH funded)
d) Bimali M, **He J**. Association between Obesity and Cancer: An Analysis Using the Competing Risk Regression Approach. Advances in Epidemiology. 2015 (Accepted).

2. Epidemiology research on obesity and mortality

Based on my expertise in statistics, I conducted innovative research on an important topic: obesity and mortality. In epidemiology research, different or event opposite results have been reported in the literature about the association of obesity and mortality. Using non-proportional hazards models, I was able to demonstrate that part of the controversy may be due the fact that traditional fixed effect models were used to describe a changing relationship (2.a and 2.b). In 2011, I won a pilot grant to verify the findings from a previous study based on a single cohort data using multiple studies and was able to show that the changing associations exist in multiple studies (2.c). This finding not only explains part of the controversy in the literature but also reveals that traditional statistical methods may be inadequate for capturing the association of body weight and mortality.

a) **He J**, McGee D, and Niu X: Application of the Bayesian Dynamic Survival Model in Medicine. Statistics in Medicine. 2010, 29:347--360. PMID: 20014356. (not NIH funded)
b) **He J**: Modeling the Dynamic Association of BMI and Mortality in the Framingham Heart Study. Annals of Epidemiology. 2011, 21(7):517-25. PMID: 21641526. (not NIH funded)
c) **He J**, Yu Q, Zhang H, Mahnken JD. The dynamic association of body mass index and all-cause mortality in multiple cohorts and its impacts. Emerging Themes in Epidemiology. 2014 11:17. PMC4211318.

3. Innovative research in quality and safety of patient care
I worked with the research team of the National Database of Nursing Quality Indicators for over 5 years and gained deep knowledge about research in patient care. Besides helping other researchers in their study, I also led some important research on trend and seasonality of patient outcomes, among which the seasonality was reported for the first time for these outcomes. I also led a study on risk adjustment impact on research findings based on a large database of VA hospitals, the finding of which suggested that counter-intuitive results about nurse staffing and patient outcomes in the literature may be due to inadequate risk adjustment.

a) **He J**, Dunton N, Staggs V. Unit-level time trends in inpatient fall rates of U.S. hospitals. Medical Care, 2012, 50(9):801-7. PMID: 22889804. (not NIH funded)
b) **He J,** Staggs V, Bergquist-Beringer S, Dunton N. Unit-level time trends and seasonality in the rate of hospital-acquired pressure ulcers in US acute care hospitals. Research in Nursing and Health. 2013, 36(2):171-80. PMID: 23408376. (not NIH funded)
c) **He J**, Li Y, Sales A, Almenoff P, Keighley J. The impact of risk adjustment at patient level on the association of Nurse staffing and 30-day mortality. Nursing Research, 2013, 62(4): 226-232. PMID: 23817280. (not NIH funded)
d) Staggs V, **He J**. Recent trends in hospital nurse staffing in the United States. The Journal of Nursing Administration. 2013; 43(7-8):388-93. (not NIH funded)

Complete List of Published Work in MyBibliography (four publications are not available in pubmed):
http://www.ncbi.nlm.nih.gov/sites/myncbi/1lEX9vvJ6z9A5/bibliography/48216494/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support:

CONTRACT #HHSM-500-2013-130061 (PI: Dunton) 09/30/2014 - 09/29/2016
Econometrica Inc
Development, Implementation and Maintenance of Quality Measures for the Program of All-Inclusive Care for the Elderly (PACE)
Major Goals: To develop measures of healthcare service quality for persons participating in the PACE program. The developed measures would assess patient safety, quality of care, and functional status of PACE participants.
Role: Statistician

R56 AG047590 (Collins) 09/30/2015 - 08/31/2017
NIH
Text Messaging to Promote Walking in Latinos with Peripheral Arterial Disease
Major Goals: Our central hypothesis is that interventions that promote walking will successfully improve walking ability and achieve our long term goal of reducing PAD progression and disability among this high-risk population. Use of short-message services (SMS) or test messages to promote walking is a novel approach. Text messaging permeates all ages, cultures, and socioeconomic backgrounds. The percent of US Latino adults who utilize text messages is 83% compared to 68% of non-Hispanic whites. Thus, the delivery of a behavior change intervention using text messaging is a viable option for Latino adults.
Role: Statistician

P30 CA168524(Jensen) 07/11/2012 - 06/30/2017
NIH
Cancer Center Support Grant
Major Goals: The University of Kansas Cancer Center is a growing matrix organization that aims to leverage unique scientific assets to build a nationally significant cancer research and treatment center that will become the leading academic institution in the world for transforming discoveries in the laboratory into new therapeutic approaches.
Role: Statistician

R21 CA191158 (Daley) 04/01/2015 - 03/31/2017
NIH
Development of a Tobacco Health Literacy Instrument
Major Goals: To develop a health literacy instrument that is specific to tobacco use among American Indian populations through the use of community-based participatory research methods, where a team of experts will estimate content validity and factor analysis on participants' responses to estimate instrument's dimension and reliability.
Role: Co-Investigator

Recently Completed Research Support:

R01 HL098909(Collins) 04/15/2012 - 05/31/2016
NIH
Promoting Walking in African Americans with Peripheral Arterial Disease
Major Goals: Determine efficacy motivational interviewing increase walking distance in African Americans with peripheral arterial disease. Achieve 3 arm randomized trial using PACE PIs PACE and face to face visits and phone contacts. Home based walking program.
Role: Key Personnel

UL1 TR000001 (Barohn) 06/01/2011 - 02/29/2016
NIH
Institutional Clinical and Translational Science Award (U54)
Major Goals: Create a new academic home with training programs for clinical and translational investigators, provide an enhanced coordinated translational research infrastructure and actively engage the community in developing, testing and disseminating translational research.
Role: Biostatistician

CDRN-1306-04631 (Waitman) 03/06/2014 - 09/05/2015
Patient Centered Outcomes Research Institute (PCORI)
Greater Plains Collaborative Clinical Data Research Network
Establishment of Greater Plains Collaborative (GPC) Clinical Data Research Network with 10 institutions for standardizing data across i2b2 platforms and creating common infrastructure/methodologies to conduct comparative effectiveness research in future phases. Focus is on three patient cohorts: ALS, breast cancer, obesity.
Role: Key Personnel

American Nurses Association (Dunton) 01/1/2008 - 12/31/2014
National Database of Nursing Quality Indicators
The National Database of Nursing Quality Indicators is established and maintained to: (1) provide benchmarking information on nursing-sensitive indicators to acute care hospitals for use in their quality improvement initiatives; and (2) monitor local and national trends in hospital nurse staffing to facilitate the American Nurses Associations Patient Safety, Nursing Quality initiative.
Role: Biostatistician

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Diana Hoelscher, Pharm.D., BCPS, BCOP**

eRA COMMONS USER NAME (credential, e.g., agency login): dsvoboda

POSITION TITLE: Clinical Pharmacist

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
The University of Wisconsin School of Pharmacy, Madison, WI	Pharm.D.	05/2007	Pharmacy

A. Personal Statement

I am well-suited to serve on PRMC due to my background as a clinical pharmacist specializing in hematology and oncology. I have completed a hematology/oncology pharmacy residency and also obtained board certification in this specialty. During my residency, I completed a clinical research project, so I became familiar with the process of getting a study approved. The study was discontinued early due to low accrual and I did not publish beyond presenting a poster at the Hematology Oncology Pharmacists Association (HOPA) annual meeting, but it was still a valuable learning experience. As a pharmacist, I review studies on PRMC with a different perspective than the medical oncologists, surgeons, nurses, study coordinators, etc.

B. Positions and Honors

Positions and Employment:

2007 – 2008 PGY1 Pharmacy Residency, Saint Luke's Hospital in Kansas City, MO
2008 – 2009 Clinical Pharmacist, Saint Luke's East in Lee's Summit, MO
2009 – 2010 PGY2 Hematology/Oncology Pharmacy Residency at the University of Kansas Hospital in Kansas City, KS
2011 – pres. Clinical Pharmacist at the University of Kansas Health System in Kansas City, KS

Other Professional Activities:

Greater Kansas City Society of Health System Pharmacists	Member, 2007 – present Secretary, 2011 – 2012 President, 2013 – 2015
Missouri Society of Health System Pharmacists	Member, 2007 – present GKCSHP liaison, 2014
Kansas Council of Health System Pharmacists	Member, 2013 – present
Hematology Oncology Pharmacists Association	Member, 2009 – present

C. Contribution to Science

No publications.

D. Research Support:

Ongoing Research Support: None
Completed Research Support: None

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **William R. Jewell, MD**

eRA COMMONS USER NAME (credential, e.g., agency login): WJEWELL1

POSITION TITLE: Professor of Surgery, (retired), Co-Director, Grant Development Core, KU Cancer Ctr

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Blackburn College, Carlinville, IL	B.A.	1953-1957	Chemistry
University of Illinois	B.S.	1957-1959	Medicine
University of Illinois, College of Medicine	M.D.	1959-1961	Medicine
University of Illinois, Research and Educational Hospital, Chicago, IL	Residency	1961-1966	Surgical Residency

A. Personal Statement

After practicing Surgery and Surgical Oncology for 40 years, 2 years in the United States Air Force, 3 years at the University of Kentucky and 35 years at the University of Kansas, I retired from surgical practice in December 2006. I remain at the university as an emeritus professor of surgery and consultant to the Kansas University Cancer Center. The title of Co-Director of the Grant Development Core. Supported by my Co-Director and by a research grant development specialist our core provides infrastructure support for all aspects of research grant development for all 150 members of the cancer center program. We are particularly interested helping all new junior faculty members, both clinical and basic science to be properly mentored to develop their research careers. I also served as a consultant and Medical Director for Oncimmune, LLC, a small company based in Nottingham, UK and DeSoto, Kansas which developed a blood test for the early detection of lung cancer. Their product, EarlyCDT-Lung is currently available as a CLIA laboratory approved test. During my tenure at the University of Kansas I have served in several administrative roles (see below). My most important position was as the Director of the University of Kansas Cancer Center (known at that time as the Kansas Masonic Cancer Research Institute) from 1995 through 2004. I have always had a major interest in the early diagnosis of cancer dating back to 1971 with my participation in the Breast Cancer Demonstration Project sponsored by the American Cancer Society.

B. Positions and Honors

Positions and Employment:

1962-1965 Assistant in Surgery, University of Illinois, College of Medicine
1965-1966 Instructor in Surgery, University of Illinois, College of Medicine
1968-1971 Assistant Professor of Surgery, University of Kentucky Medical Center
1969-1971 Director, Surgical Oncology, University of Kentucky Medical Center
1971-1974 Associate Professor of Surgery, University of Kansas Medical Center, Kansas City, KS
1974-present Professor of Surgery, University of Kansas Medical Center, Kansas City, KS
1971-1978 Chief, Section of Surgical Oncology University of Kansas Medical Center (KUMC)
1977-1978 Associate Dean, College of Medicine University of Kansas Medical Center
1977-1978 Associate Chairman, Department of Surgery University of Kansas Medical Center
1978-1997 Chief, Section of General, Thoracic and Oncologic Surgery University of Kansas Medical Center, Kansas City, KS
1992-1998 Principal Investigator, NSABP Contract STAR Trial.
1994-1996 Associate Director for Clinical Research, University of Kansas Cancer Center (KUMC)

1995-2004 Director, Kansas Masonic Cancer Research Institute, University of Kansas Medical Center
12/97-10/98 Interim Chairman, Department of Pathology & Laboratory Medicine University of Kansas Medical Center, Kansas City, KS
2004-2007 Vice Chairman, Department of Surgery, University of Kansas Medical Center
2007-2010 Associate Director for Education, University of Kansas Cancer Center, KUMC
2010-present Co-Director of University of Kansas Cancer Center Grant Development Core
2007-2010 Medical Director of Oncimmune, LLC, De Soto, KS.

Advisory Committees:

SWOG
1978-1979 Chairman, Surgery Quality Control and Education Committee
1989-1992 Vice Chairman, Melanoma Committee
1992-1995 Executive Committee, Southwest Oncology Group

National Cancer Institute
1980-1986 Review Committee, Clinical Cancer Program Project
1982-1985 Consultant, Clinical Cancer Program Project Review Committee
1985-1986 Chairman, Clinical Cancer Program Project Committee
1988-1993 Clinical Cancer Support Grant Review Committee, Subcommittee A
1995-2001 Program Project, Subcommittee D
1997 Department of Defense Breast Reviewer
1999-present SPORE Reviewer on multiple occasions
1999-2001 Chairman, Subcommittee D
2002-2006 Member, Subcommittee H
2008 Member Komen Foundation Review

American Cancer Society
1982 Kansas Division, Vice President
1981-1982 Kansas Division, Chairman, Public Education Committee
1981-1984 Kansas Division, Scientific Committee
1981-1985 Advisory Committee on Immunology and Immunotherapy (national ACS)

American College of Surgeons
1983-1990 Cancer Management Course Committee Metropolitan Kansas City on Applicants

Honors and Service:
Alpha Omega Alpha
American College of Surgeons, Fellow
American Association for Cancer Research
Warren H. Cole Society - President 1988-1989
The Society of Head and Neck Surgeons
Society of Surgical Oncology (James Ewing), Resident Fellow Award Committee
Student Voice Award for Excellence in Teaching, 1997-2000
William R. Jewell Kansas Masonic Chair of Cancer Research, University of Kansas, established 2006
William R. Jewell Lectureship in Translational research, University of Kansas, established 2006

C. Contribution to Science:

1. As a junior faculty member I had a major interest in cancer metabolism. Along with my co-workers we were the first in this country to demonstrate an increase in serum albumin catabolism in rats bearing Walker 256 tumors. We did this by demonstrating an increase in turnover in I-131 labelled serum albumin. We further showed that this effect could be abrogated by bilateral adrenalectomy. In addition we further observed that there was apparent cellular ingress of albumin leading to the hypothesis that tumors could cause increased breakdown of albumin to provide amino acids for tumor growth (see two publications below):

a) Jewell, W.R and Hunter, L. The effect of adrenalectomy and high protein diet on tumor altered albumin metabolism. Cancer Research; 1971 Mar;31(3):257-9. PMID: 5547212
b) Jewell W.R., Krishnan E.C., and Schloerb P.R. Apparent cellular ingress albumin in Walker 256 tumor and rat muscle. Cancer Research. 1975 Feb;35(2):405-8. PMID: 1109805

2. As an Associate Professor of Surgery, I was involved in early clinical trials in cancer immunotherapy. We had a major program at the University of Kansas in active specific and adoptive immunotherapy. We had several very interesting but also very inconsistent results. In our basic science trials in the B-16 melanoma model we demonstrated that it was possible to essentially cure mice with growing melanomas with adoptive immunotherapy e.g. transfer factor of Lawrence and immune RNA. Unfortunately, human melanoma did not have similar responses.

a) Jewell,W.R., Thomas, J.H.,Morris,P.A. and Humphrey, L.J. Critical analysis of treatment of stage II and stage III melanoma patients with immunotherapy. Ann. Of Surgery. May;183(5):543-9. PMC1344342
b) Jewell, W.R.,Thomas J.H.,Morse, P.A. and Humphrey, L.J. Comparison of allogenic tumor vaccine with leukocyte transfer and transfer factor treatment of human cancers. Ann. N.Y. Academy of Science 1976;277(00):516-21. PMID: 1069560

3. In mid-career I was active in clinical investigations. I was an active participant in the Southwest Oncology Group. I served as a member of the executive committee, Chair of the Surgical Committee and Vice-Chair of the melanoma committee. It was during this time that I was an active reviewer on several NIH, DOD and ACS committees (see above).

a) Rivkin, S.E. Green,S. Metch, B. Abeloff, Jewell W.R., Constanzi, J.J., et al. (1994) Adjuvant CMFVP versus Tamoxifen for postmenopausal node positive and ER positive breast cancer. A Southwest Oncology Group Study. J. Clin. Oncol. 1996 Jan;14(1):46-51. PMID: 8558219
b) Balch, C.M., Soong, S.J. …Jewell, W.R., et al. Efficacy of an elective regional node dissection of 1 to 4 mm thick melanoma for patients 60 years of age and younger: A Southwest Oncology Group Study. Ann Surg. 1996 Sep;224(3):255-63; discussion 263-6. PMC1235362

4. In the early 1970`s along with Dr. Carl Mansfield and others we developed the first comprehensive program for managing invasive breast cancer with lumpectomy and radiation therapy as opposed to mastectomy. This led to several publications (see below). We also worked with several of our patients to champion the effort leading to enactment of a state law in Kansas that mandated that patients receive full disclosure of this form of treatment before consenting to a mastectomy.

a) Jewell, W.R.,Krishnan L., Reddy, E.K. and Mansfield , C.M.(1987) Intraoperative implantation radiation therapy plus lumpectomy for carcinoma of the breast. Arch Surg. 1987 Jun;122(6):687-90. PMID: 3034194
b) Krishnan, L.,Mansfield, C.M. Jewell,W.R., Reddy, E.K.,Thomas J.H. and Krishnan, E.C. Breast conservation treatment with perioperative interstitial irradiation. Am. J. Clin. Oncology. 1987 Oct;10(5):383-6. PMID: 3661490

5. From 1995 until 2004 I served as the Director of the University of Kansas Cancer Center. This came about because of my six year experience on Subcommittee A. During my tenure on this committee I had the privilege of reviewing about half of all the existing NCI Cancer Centers at that time. Throughout my tenure in this position we began to develop the infrastructure and institutional support to begin the process required to become an NCI designated cancer center. Subsequently, under the direction of Dr. Roy Jensen this has become a reality.

D. Research Support

Ongoing Support:
None

Completed Support:
Clinical Trial to Evaluate the Worth of Tamoxifen in Conjunction with; lumpectomy and Breast Irradiation for the Treatment of Noninvasive Intraductal Breast Cancer. KUMC KSC #5578-92. PI-NSABP B-24.

A Clinical Trial to Evaluate the Effect of Dose Intensification and Increased Cumulative Dose of Postoperative Adriamycin-cyclophosphamide (AC) Therapy with G-CSF on the Disease-Free Survival and Survival of Patients with Primary Breast Cancer and Positive Axillary Nodes. KUMC KSC #5648-92. PI-NSABP B-23.

A Clinical Trial Comparing Short, Intensive AC q Tamoxifen with Conventional CMF q Tamoxifen in Node-Negative Breast Cancer Patients with ER-Negative Tumors. KUMC KSC #5649-92. PI-NSABP B-23.

A Clinical Trial to Determine the Worth of Tamoxifen in the Management of Patients with Node-Negative, Occult, Invasive Breast Cancer Treated by Lumpectomy. KUMC KSC #5649-92. PI-NSABP B-21.

A Clinical Trial to Determine the Worth of Chemotherapy and Tamoxifen over Tamoxifen alone in the Management of Patients with Primary Invasive Breast Cancer, Negative Axillary Nodes and Estrogen Receptor Positive Tumors. KUMC KSC #5651-92. PI-NSABP B-20.

A Protocol to Compare Short, Intensive, Preoperative Systemic Adriamycin Cyclosphamide Therapy with Similar Therapy Administered in Conventional Postoperative Fashion. KUMC KSC #5652-92. PI-NSABP B-18.

A Clinical Trial to Assess the Relative Efficacy of 5-FU + Leucovorin with or without Interferon Alpa-2a in Patients with Dukes' B and C Carcinoma of the Colon. KUMC KSC #5808-93. PI-NSABP CO-5

A Randomized Trial in Patients with Metastatic or Locally Advanced Breast Cancer Comparing the Effect of 3-Hour vs. 24-Hour Infusion of High-Dose Taxol. KUMC KSC #6349-95. PI-NSABP B-26
Immunotherapy of Metastatic Melanoma. NIH Grant HD30802. Co-Investigator.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. ***DO NOT EXCEED FIVE PAGES****.*

NAME: **Qamar Jamal Khan, MD**

eRA COMMONS USER NAME (credential, e.g., agency login): QJKHAN

POSITION TITLE: Associate Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
King Edward Medical College, Pakistan	M.B.B.S.	04/1986	Medicine
Bridgeport Hospital – Yale University, Bridgeport, CT	Resident	03/1997	Internal Medicine
University of Kansas Medical Center, Kansas City, KS	Fellow	12/2004	Hematology/Oncology

A. Personal Statement

I am an Associate Professor of medicine at the University Of Kansas School Of Medicine. I am a breast oncologist, and therapy for breast cancer is the focus of my research interest. Since joining as a faculty member in the Division of Hematology and Oncology at the University, I have been very involved in the design and conduct of clinical trials, especially IITs. Initially, the focus of my research was breast cancer prevention and I was able to publish in prestigious peer review journals such as breast cancer research and cancer epidemiology biomarkers and prevention (CEBP) as the primary author.

I designed and completed a pilot phase II trial (IIT funded by pharma) to study the effect of vitamin D supplementation on joint pain and fatigue in women with breast cancer receiving an adjuvant aromatase inhibitor. Based on the results of this trial, I designed a randomized trial (The VITAL trial) which was recently completed via a successful collaboration between KU and Wichita CCOP and presented as an oral presentation at 2012 ASCO annual meeting. This presentation was also selected as a BEST of ASCO trial. We were able to accrue 160 women in 12 months for this trial.
More recently, the focus of my research has shifted to the treatment of breast cancer therapeutic trials, especially neo-adjuvant treatment. I have designed and have received funding for seven investigator-initiated trials including:

- Abraxane and trastuzumab followed by dose dense doxorubicin and cyclophosphamide as neo-adjuvant therapy in invasive breast cancer with low HER2 expression' was completed and presented at the annual meeting of ASCO in 2015.
- Combined Fulvestrant and Anastrozole as neo-adjuvant endocrine therapy in postmenopausal women with hormone receptor positive invasive breast cancer is another IIT that I designed and completed. 42 patients were enrolled. In this trial, women with stage I-III receptor positive breast cancer have OncotypeDx performed on core biopsy specimen. If the RS is less than 25, they receive 4 months of combined endocrine therapy. Primary endpoint is change in Ki67 and PCR. We have blood and tissue stored for analyses which will be used to study biomarkers of endocrine resistance.

Based on the design of this trial, I have initiated a multi-center IIT funded by Novartis ($ 3 million): "A randomized trial of letrozole +/- LEE011 as neo-adjuvant endocrine therapy for breast cancer: The FELINE trial." Subsites include 6 other academic centers including City of Hope, MGH, University of Miami, University of Arkansas, among others. KU is the lead site.

I serve as the Chair of the KU Protocol Review and Monitoring Committee (PRMC). PRMC conducts independent scientific reviews and bio statistical reviews of all trials being initiated at the cancer center, is

responsible for prioritization of new trials to ensure the availability of adequate patient numbers and resources and conducts monitoring of activated protocols for their continued scientific relevance and accrual. As the chair of the PRMC, I provide leadership and direction for the committee meetings by attending all these meetings (twice a month), appoint members to the committee, and review expedited protocols for approval.

B. Positions and Honors

Positions and Employment:

1986 – 1987 Intern Mayo Hospital, Lahore, Pakistan
1987 – 1993 Medical Officer Pakistan Institute of Medical Services, Islamabad, Pakistan
1993 – 1994 Medical Intern Bridgeport Hospital, Yale University, Bridgeport CT
1994 – 1996 Medical Resident Bridgeport Hospital, Yale University, Bridgeport CT
1996 – 1997 Chief Medical Resident Bridgeport Hospital- Yale University, Bridgeport CT
2002 – 2004 Fellow in Hematology and Oncology Division of Hematology/Oncology, University of Kansas Medical Center
1997 – 2000 Staff Physician Beaufort Jasper Comprehensive Health services, Ridgeland, SC
2000 – 2002 Instructor Division of Hematology/Oncology, University of Kansas Medical Center
2002 – Pres. Student Voice Award, KU School of Medicine.
2005 – 2011 Assistant Professor Division of Hematology/Oncology, University of Kansas Medical Center
2005 – 2012 Member Cancer Research Fellowship Review Committee for Ladies Auxiliary of Veterans of foreign wars of the United States
2011 – Pres. Associate Professor Division of Hematology/Oncology, University of Kansas Medical Center, Kansas City, KS
2008 – 2013 Chair Breast Disease Working Group, University of Kansas Cancer, Center, Kansas City, KS
2013 – Pres. Chair Protocol review and Monitoring Committee, Research Institute, University of Kansas Medical Center, Kansas City, KS

Professional Certifications:

2005 American Board of Internal Medicine Hematology
2005 American Board of Internal Medicine Oncology

Professional Societies and Affiliations:

2002 – pres. American Society of Clinical Oncology

Honors and Awards (selected):

2001 – 2002 Student Voice Award- University of Kansas School of Medicine
2001 Top Doc Award, University of Kansas School of Medicine
2004 Top Doc Award, University of Kansas School of Medicine
2009 Heart of Gold Oncologist Finalist – Cancer Action

C. Contribution to Science

1. My early research was focused on breast cancer prevention. Specifically, I developed expertise in risk assessment and study of biomarkers of risk and response in breast cancer prevention. I showed that Ki-67 expression in benign breast cells obtained via random periareolar fine needle aspiration (RPFNA), correlates with cytology and may be used as a response biomarker for prevention intervention trials. Also, I showed that Ki67 expression does not correlate with mammographic density, which is another biomarker and may be used as an independent biomarker of response.

a) **Khan QJ**, Kimler BF, Clark J, Metheny T, Zalles CM, Fabian CJ. Ki-67 Expression in benign breast ductal cells obtained by random periareolar fine needle aspiration. Cancer Epidemiol Biomarkers Prevention 14:786-789, 2005.
b) **Khan QJ**, Kimler BF, O'Dea AP. Sharma P, Fabian CJ. Mammographic density does not correlate with Ki-67 expression or cytomorphology in benign breast cells obtained by Random Periareolar Fine Needle

Aspiration from women at high risk of breast cancer. Breast Cancer Research 9:R35 (30 May), 2007.

c) Fabian CJ, Kimler BF, Zalles CM, **Khan QJ**, Mayo MS, Phillips TA, Simonsen M, Metheny T, Petroff BK. Reduction in proliferation with six months of letrozole in women on hormone replacement therapy. Breast Cancer Research and Treatment 106(1):75-84, 2007. PMID: 17221152 (not NIH funded).

2. My next contribution is enhancing the knowledge of correlation between vitamin D and breast cancer treatment side effects. Specifically, I designed and completed a pilot phase II trial (IIT funded by pharma) to study the effect of vitamin D supplementation on joint pain and fatigue in women with breast cancer receiving an adjuvant aromatase inhibitor. Based on the results of this trial, I designed a randomized trial (The VITAL trial) which was completed via a successful collaboration between KU and Wichita CCOP and presented as an oral presentation at 2012 ASCO annual meeting. This presentation was also selected as a BEST of ASCO trial. These trials suggested a benefit oif vitamin D in reducing arthralgia from aromatase inhibitors.

a) **Khan QJ,** Reddy PS, Kimler BF, Baxa SE, Sharma P, Fabian CJ. A prospective study to determine the prevalence of hypovitaminosis D in women with early stage breast cancer treated with an aromatase inhibitor and the benefit of vitamin D supplementation on musculoskeletal symptoms. Breast Cancer Res and Treat 106(1):75-84, 2007 (not NIH funded)

b) **Khan QJ,** Reddy PS, Kimler BF, et al. Effect of vitamin D supplementation on serum 25-hydroxy vitamin D levels, joint pain, and fatigue in women starting adjuvant letrozole treatment for breast cancer. Breast Cancer Res Treat 119:111-118, 2010. PMC4182952

c) **Khan QJ,** Kimler BF, Reddy PS, Sharma P, Klemp JR, Fabian CJ. Randomized trial of vitamin D3 to prevent worsening of musculoskeletal symptoms and fatigue in women with breast cancer starting adjuvant letrozole: The VITAL trial. Oral Abstract Session, Patient and Survivor Care Abstract Number: 9000; J Clin Oncol 30, 2012 (suppl; abstr 9000) (PMC# not required; not NIH funded)

3. The more recent focus of my research has been neo-adjuvant treatment of breast cancer. I have designed and have received funding for several investigator-initiated trials including and presented findings in two national meetings. I have shown that Herceptin may be effective in patients with HER2 negative luminal B, ER positive, early breast cancer, achieving a pathologic CR of 25% in this population. – 'Abraxane and trastuzumab followed by dose dense doxorubicin and cyclophosphamide as neo-adjuvant therapy in invasive breast cancer with low HER2 expression' was completed and presented at the annual meeting of ASCO in 2015. Biomarkers of response are being investigated.

Combined Fulvestrant and Anastrazole as neo-adjuvant endocrine therapy in postmenopausal women with hormone receptor positive invasive breast cancer is another IIT that I designed and completed. 42 patients were enrolled. In this trial, women with stage I-III receptor positive breast cancer have OncotypeDx performed on core biopsy specimen. If the RS is less than 25, they receive 4 months of combined endocrine therapy. Primary endpoint is change in Ki67 and PCR. We have blood and tissue stored for analyses which will be used to study biomarkers of endocrine resistance. I presented this trial after completion at SABCS. Dramatic KI(-67 responses were observed suggesting complete cell cycle arrest with this combination. Biomarkers of response are being investigated.

Based on the design of this trial, I have initiated a multi-center IIT funded by Novartis ($ 3 million): "A randomized trial of letrozole +/- LEE011 as neo-adjuvant endocrine therapy for breast cancer: The FELINE trial. Subsites include 6 other academic centers including City of Hope, MGH, University of Miami, University of Arkansas, among others. KU is the lead site.

a) **Khan QJ**, O'Dea AP, Fabian CJ, Sharma P. Neoadjuvant chemotherapy plus trastuzumab in stage II/III breast cancer with low HER2 expression. 2015 ASCO Annual Meeting: J Clin Oncol 33, 2015 (suppl; abstr 1039). (PMC# not required; not NIH funded).

b) **Khan QJ**, Barr JA, Britt AS, Kimler BF, Connor CS, McGinness M, Mammen JMV, Wagner JL, Amin A, Springer M, Baccaray S, Fabian CJ, Sing AP, Sharma P. Fulvestrant plus anastrozole as neoadjuvant therapy in postmenopausal women with hormone receptor positive early breast cancer. 2015 SABCS Annual Meeting, P5-13-03 (PMC# not required; not NIH funded).

Link to my complete list of publications:
http://www.ncbi.nlm.nih.gov/pubmed/?term=khan+qj

D. Research Support

Ongoing Research Support:

CLEE011XUS10T (FELINE) trial (PI: Khan) 10/15/2015 - 10/14/2017
The goal of this study is to study the effectiveness of Ribociclib (LEE011) or Placebo when combined to letrozole as Neo-adjuvant Endocrine Therapy for Women with ER-positive, HER2-negative Early Breast Cancer.

X-7/7 Trial (KU Cancer Center Grant) (PI: Khan) 04/20/2015 - 04/20/2017
The goal of this study is to compare 2 doses and schedules of oral capecitabine in breast cancer and GI cancers.

Completed Research Support:

Novartis Pharmaceuticals Corp (PI: Khan) 11/14/2008 - 12/31/2015
The goal of this study was to evaluate benefit of High Dose Vitamin D3 on Letrozole associated musculoskeletal Symptoms and fatigue (VITAL)

Genomic Health, Inc. (PI: Khan) 04/28/2009 - 12/31/2015
The goal of this study was to study the effect of combined Fulvestrant and Anastrazole as neo-adjuvant endocrine therapy in postmenopausal women with hormone receptor positive invasive breast cancer

Abraxis BioScience, LLC (PI: Khan) 03/03/2009 - 12/31/2015
The goal of this study was to study the effect of Abraxane and trastuzumab followed by dose dense doxorubicin and cyclophosphamide as neoadjuvant therapy in invasive breast cancer with low HER2 expression.

PFED23-KAN-01 05/25/1999 - 12/31/2011
NSABP Foundation Inc (NIH)
Study of Tamoxifen and Raloxifene (STAR) for the Prevention of Breast Cancer
Role: Co-investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. ***DO NOT EXCEED FIVE PAGES.***

NAME: **Bruce F. Kimler, Ph.D.**

eRA COMMONS USER NAME (credential, e.g., agency login): bkimler

POSITION TITLE: Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Texas, Austin, TX	B.A.	05/1970	Zoology
University of Texas, Austin, TX	M.A.	05/1971	Zoology
University of Texas, Austin, TX	Ph.D.	05/1973	Radiation Biology

A. Personal Statement

Since 1980, I have been involved with the design, conduct, analysis, audit, and review of clinical trials that span the gamut from cancer prevention to treatment to survivorship. I am well-versed in regulatory requirements, including IRBs, FDA, and specifically NCI/NIH mandates. Starting in 2004 with its implementation, I have served on the University of Kansas Cancer Center Protocol Review and Monitoring Committee as a member, co-chair, and chair. I am intimately familiar with the responsibilities and activities of the PRMC.

The following recent publications are of specific relevance to my clinical trial background:

1. Fabian CJ, **Kimler BF**, Donnelly JE, Sullivan DK, Klemp JR, Petroff BK, Phillips TA, Metheny T, Aversman S, Yeh H, Zalles CM, Mills GB, Hursting SD. Favorable modulation of benign breast tissue and serum risk biomarkers is associated with >10% weight loss in postmenopausal women. Breast Cancer Res Treat 142:119-32, 2013. PMC3921968
2. Connor CS, **Kimler BF**, Mammen JMW, McGinness MK, Wagner JL,Alsop S, Ward C, Fabian CJ, Khan QK, Sharma P: Impact of neoadjuvant chemotherapy on axillary nodal involvement in patients with clinically node negative triple negative breast cancer. Journal of Surgical Oncology 2014 Sep 29. doi: 10.1002/jso.23790. PMID: 25266871 (PMC# not required; not NIH funded).
3. Fabian CJ, **Kimler BF**, Phillips TA, Nydegger JL, Kreutzjans AL, Carlson SE, Hidaka BH, Metheny T, Zalles CM, Mills GB, Powers KR, Sullivan DK, Petroff BK, Hensing WL, Fridley BL, Hursting SD: Modulation of breast cancer risk biomarkers by high dose omega-3 fatty acids: Phase II pilot study in post-menopausal women. Cancer Prev Res 8:922-931, 2015. PMC4596784
4. Fabian CJ, **Kimler BF**, Zalles CM, Phillips TA, Metheny T, Petroff BK, Havighurst TC, Kim KM, Bailey HH, Heckman-Stoddard BM: Clinical trial of acolbifene in premenopausal women at high risk for breast cancer. Cancer Prev Res 8:1146-1155, 2015. PMC4670810

B. Positions and Honors

Positions and Employment:

1973-75 Post-Doctoral Appointee; Division of Biological and Medical Research, Argonne National Laboratory, Argonne, IL

1975-77 Post-Doctoral Fellow; Department of Radiation Therapy and Nuclear Medicine, Thomas Jefferson University Hospital, Philadelphia, PA

1977-80 Assistant Professor; Department of Radiation Therapy, University of Kansas Medical Center, Kansas City, KS

1977-85 Member, Graduate Faculty; Department of Radiation Biophysics, University of Kansas, Lawrence, KS

1980-84 Associate Professor; Department of Radiation Therapy, University of Kansas Medical Center
1984-97 Professor of the International Molecular Cytology Program of the Instituto de Investigaciones Citologicas, Valencia, Spain
1984-present Professor, Dept. of Radiation Oncology, University of Kansas Medical Center, Kansas City, KS

C. Contribution to Science

Over the past 41 years I have published some 196 research articles; full list available at:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1too9PhsIOHQ1/bibliography/46183803/public/?sort=date&direction=ascending
The list includes five areas that encompass 30 of the 35 publications that have been cited at least 35 times (H-index = 35). These five define my five most important contributions to science. For each area, examples are provided by a) the most cited article, b) the earliest article, and c) the most recent publication (not necessarily in the H-index).

1. In a collaboration since 1989 with Carol Fabian, we have developed, validated, and disseminated the breast tissue sampling technique of random peri-areolar fine needle aspiration (RPFNA) as a means to acquire epithelial cells for cytologic and biochemical analyses. Cytologic evidence of hyperplasia with atypia conveys a 5-fold increase in short term risk of developing breast cancer (a). This also provides cells for biomarker analyses used in early phase breast cancer chemoprevention clinical trials (Areas 2). On all projects I was involved in concept design, was responsible for database management and integrity, provided primary statistical analysis, and wrote or co-wrote all manuscripts.

a) Fabian CJ, **Kimler BF**, Zalles CM, Klemp JR, Kamel S, Zeiger S, and Mayo MS: Short-term breast cancer prediction by random periareolar fine-needle aspiration cytology and the Gail risk model. J Natl Cancer Inst 92:1217-27, 2000. PMID: 10922407
b) Zalles C, **Kimler BF**, Kamel S, McKittrick R, Fabian CJ: Cytology patterns in random aspirates from women at high and low risk for breast cancer. The Breast Journal 1:343-349, 1995
c) Fabian CJ, **Kimler BF**: Incorporating biomarkers in studies of chemoprevention. Adv Exp Med Biol 882:69-94, 2016. PMID: 26987531 (not NIH funded)

2. Based on the RPFNA model (area 1), used benign tissue biomarkers, many of which we adapted for cytology specimens (morphology, Ki-67, mRNA and proteomics), to evaluate the effectiveness of intervention in pilot, phase I and phase II clinical trials of breast cancer chemoprevention. These tissue acquisition trials employed surrogate endpoint biomarkers to monitor efficacy of novel approaches which would then predict the likelihood of translating to a reduction in risk for breast cancer development. On all projects I was involved in concept design, was responsible for database management and integrity, provided primary statistical analysis and wrote or co-wrote all manuscripts. I was either Co-PI or Co-I with responsibility for all financial, administrative, and regulatory aspects on funded projects that totaled more than $27 million.

a) Fabian CJ, **Kimler BF**, Elledge RM, Grizzle WE, Beenken SW, Ward JH: Models for early chemoprevention trials in breast cancer. Hematology/Oncology Clinics of North America 12:993-1017, 1998. PMID: 9888018
b) Fabian CJ, **Kimler BF**, Brady DA, Mayo MS, Chang CHJ, Ferraro JA, Zalles CM, Stanton AL, Masood S, Grizzle WE, Boyd NF, Arneson DW, and Johnson KA: A phase II breast cancer chemoprevention trial of oral α-difluoromethylornithine: breast tissue, imaging, and serum and urine biomarkers. Clin Cancer Res 8:3105-3117, 2002. PMID: 12374678
c) Fabian CJ, **Kimler BF**, Zalles CM, Phillips TA, Metheny T, Petroff BK, Havighurst TC, Kim KM, Bailey HH, Heckman-Stoddard BM: Clinical trial of acolbifene in premenopausal women at high risk for breast cancer. Cancer Prev Res Published OnlineFirst September 21, 2015; doi:10.1158/1940-6207. PMC4670810

3. Numerous projects have addressed a variety of clinical cancer management aspects. These have ranged from clinical trials to explore new therapeutic or supportive (a) concepts, to retrospective analyses to identify prognostic and predictive factors for patient outcome and/or response to therapy (c). (b) provided the first successful example of personalized medicine – years before the term was coined – with examination of the patient's hematopoetic stem cells via a clonogenic assay (see area 5) to predict an exquisite inherent radiation

sensitivity and thus modify the patient's radiation treatment plan. On most projects I was involved in writing the funding applications. On all projects I was involved in concept design, was responsible for database management and integrity, provided primary statistical analysis and wrote or co-wrote all manuscripts.

a) Hart RM, **Kimler BF**, Evans RG, Park CH: Radiotherapeutic management of medulloblastoma in a pediatric patient with ataxia telangiectasia. Int J Radiat Oncol Biol Phys 13:1237-1240, 1987. PMID: 3610711
b) Khan QJ, Reddy PS, **Kimler BF**, Sharma P, Baxa SE, O'Dea AP, Klemp JR, Fabian CF: Effect of vitamin D supplementation on serum 25-hydroxy vitamin D levels, joint pain, and fatigue in women starting adjuvant letrozole treatment for breast cancer. Breast Cancer Res Treat 119:111-118, 2009. PMC4182952
c) Rao D, **Kimler BF**, Nothnick WB, Davis M, Fan F, Ossama Tawfik O: Transgelin: A potentially useful diagnostic marker differentially expressed in triple-negative and non-triple negative breast cancers. Human Pathol 2015 Mar 10. pii: S0046-8177(15)00081-7. doi: 10.1016/j.humpath.2015.02.015. PMC4426210

4. Developed and/or utilized a variety of animal models to investigate the interaction of tissues with ionizing radiation. For pre-clinical cancer therapeutic development this involved both tumor models and normal tissue damage measures in rodents (rats and mice). Much of the work focused on combinations of radiation and chemotherapy that could be translated to the clinic. Another area was examination of structural and functional deficits in brain resulting from in utero irradiation of rats. I provided the radiobiological expertise on all studies. On most projects I wrote the funding applications and administered the grants. On most projects I provided primary statistical analysis; and wrote or co-wrote all manuscripts.

a) Henderson SD, **Kimler BF**, Morantz RA: Radiation therapy of 9L rat brain tumors. Int J Radiat Oncol Biol Phys 7:497-502, 1981. PMID: 7251420
b) **Kimler BF**: Prenatal irradiation: a major concern for the developing brain. Int J Radiat Biol 73:423-434, 1998. PMID: 9587081
c) Aljitawi O, Yinghua Xiao Y, Eskew J, Parelkar N, Swink M; Radel J, Lin TL, **Kimler BF**, Mahnken JD, McGuirk JP, Broxmeyer HE, Vielhauer G: Hyperbaric oxygen improves engraftment of ex-vivo expanded and gene transduced human CD44 cells in a murine model of umbilical cord blood transplantation. Blood Cells Mol Dis. 2013 52:59-67, 2014. PMC4075130

5. In collaboration with Chan Park utilized an agar culture system to assess clonogenic survival of stem cells from leukemic patients and normal individuals. Used this to determine response to ionizing radiation, chemotherapy, and a unique growth modulating effect of L-ascorbic acid (LAA); and correlate with clinical outcomes. I provided the radiobiological expertise on studies involving ionizing radiation. On all projects I provided primary statistical analysis and co-wrote all manuscripts.

a) **Kimler BF**, Park CH, Yakar D, Mies R: Radiation response of human hematopoietic cells (normal and leukemic) assayed by in vitro colony formation. Int J Radiat Oncol Biol Phys 11:809-816, 1985. PMID: 3980276
b) Han S-S, Kim K, Hahm E-R, Park CH, **Kimler BF**, Lee SJ, Lee S-H, Kim WS, Jung CW, Park K, Kim J, Yoon S-S, Park S: Arsenic trioxide represses constitutive activation of NF-kB and COX-2 expression in human acute myeloid leukemia, HL-60. J Cell Biochem 94:695-707, 2005. PMID: 15547942
c) Park CH*, **Kimler BF***, Yi SY, Park SH, Kim K, Jung CW, Kim SH, Lee ER, Rha M, Kim S, Park HK, Lee SJ, Park HK, Lee MH, Yoon SS, Min YH, Kim BS, Kim J-A, Kim WS*: Depletion of L-ascorbic acid alternating with its supplementation in the treatment of patients with acute myeloid leukemia or myelodysplastic syndromes. European J Haematology 83:108-118, 2009. *These authors contributed equally. PMID: 19284416 (PMC# not required; not NIH funded)

D. Research Support

Ongoing Research Support:

IRG-09-062-04 PI: Kimler 01/01/2013 – 12/31/2016
American Cancer Society: Institutional Research Grant

Provide pilot project funds to assist junior faculty in the development of academic careers in cancer-related research.
Role: PI and Chair of the Institutional Research Grant Review Committee

No Number PI: Fabian 10/01/2014 - 09/30/2016
Breast Cancer Research Foundation
Will the Omega-3 Fatty Acid DHA Prevent Development of Cognitive Dysfunction Due to Chemotherapy?
The objective of this study is to examine the effects of omega-3 fatty acid supplementation on cognitive function in women newly diagnosed with breast cancer and undergoing neoadjuvant chemotherapy.
Role: Co-Investigator

No Number PI: Kimler/Co-PI: Fabian 07/01/2006 – no end date
Hearst Foundation
TransIllumination Breast Spectroscopy as a Risk Assessment Tool for Breast Cancer
The major goal of this project is to explore the utility of TIBS for risk prediction, in combination with cytomorphology of cells acquired by RPFNA from young premenopausal high risk women.
Role: PI, directs protocol development, coordinates clinical trials

No Number PI: Fabian/Co-PI: Kimler 04/01/2005 – no end date
Intergenetics, Inc.
Correlation of SNP Patterns in High Risk Postmenopausal Women on HRT
The major goal of this project is to correlate oligogenotype patterns of single nucleotide polymorphisms with cytomorphology of specimens obtained by RPFNA in post-menopausal high risk women.
Role: Co-PI

Completed Research Support:

KG101039 PI: Fabian 06/01/2010 - 09/23/2016
Komen for the Cure Promise Grant
Flaxseed Lignan as a Prevention Strategy for Pre-Menopausal Women at High Risk for Development of Breast Cancer
The objective of this study is to conduct a randomized, placebo-controlled Phase II breast cancer chemoprevention trial of the flaxseed lignan Secoisolariciresinol diglycoside (SDG) in pre-menopausal women who are at high risk of development of breast cancer; and to demonstrate modulation of biomarkers (primary endpoint is decrease in proliferation via Ki-67 immunocytochemistry) in breast epithelial cells acquired by random periareolar fine needle aspiration (RPFNA). Tumor model studies in rats and mice will also be conducted to inform the clinical trial.
Role: Co-PI

SAC110051 PI: Fabian 07/01/2010 - 03/31/2016
Komen For the Cure
Development of Biomarkers of Response to Prevention Interventions with Lignans
The objective of this study is develop new biomarkers of response using modern molecular techniques that will allow assessment at the gene and protein expression level. The newly available TaqMan Arrays and reverse phase proteomics arrays will be added to existing RTqPCR and western assays. Validate biomarkers using specimens from studies using animal models of carcinogenesis.
Role: Co-Investigator

No Number PI: Fabian 10/01/2012 - 09/30/2014
Breast Cancer Research Foundation
High Dose Omega-3 Fatty Acids and Weight Loss for Breast Cancer Prevention
The objective of this study was to conduct a pilot feasibility study of omega-3 fatty acids (EPA+DHA) in obese or overweight peri- or post-menopausal women who are at high risk of development of breast cancer who are enrolled in a diet-exercise-behavioral modification intervention to lose weight. The primary endpoints are evaluation of modulation of biomarkers in serum and in breast epithelial cells acquired by RPFNA.
Role: Co-Investigator

No Number PI: Fabian 06/01/2010 - 05/31/2014
Kansas Bioscience Authority
Omega 3 Fatty Acids for Prevention of Breast Cancer in Premenopausal Women
The objective of this study is to conduct a pilot feasibility study of omega-3 fatty acids (Lovaza) in pre-menopausal women who are at high risk of development of breast cancer; and to evaluate modulation of biomarkers in serum and in breast epithelial cells acquired by RPFNA. Tumor model studies in mice will also be conducted to inform the clinical trial.
Role: Co-PI

R01 CA122577 PI: Fabian 09/20/2007 - 07/31/2013
NIH/NCI
Breast Cancer Prevention by Letrozole in High Risk Women
The major goal of this project is to conduct a randomized, placebo-controlled trial of letrozole in postmenopausal women who are taking hormone replacement therapy and are at high risk of development of breast cancer, using RPFNA to acquire epithelial cells for tissue-based surrogate endpoint biomarkers.
Role: Co-PI

CFEM345DUS45 PI: Fabian/Co-PI: Kimler 11/01/2006 – 12/31/2013
Novartis Pharmaceutical Company
Breast Cancer Prevention by Letrozole in High Risk Women
Funding and study agent provided for clinical trial described above. Same role and responsibilities.
Role: Co-PI

N01-CN-35153 PI: Fabian/Co-PI: Kimler 02/16/2006 – 09/30/2012
NIH/NCI Subcontract from University of Wisconsin Cancer Chemoprevention Consortium
Phase II Study of Acolbifene in Premenopausal Women at High Risk for Breast Cancer.
The major goal of this project is to conduct a Phase II clinical chemoprevention trial of the SERM acolbifene and examine reduction in proliferation in breast epithelial cells acquired by RPFNA.
Role: Co-PI

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Jennifer R. Klemp, Ph.D.**

eRA COMMONS USER NAME (credential, e.g., agency login): jklemp

POSITION TITLE: Associate Professor of Internal Medicine, Clinical Oncology; Founder/CEO, Cancer Survivorship Training, Inc.; Co-Leader, Cancer Prevention, KU Cancer Center

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Kansas, Lawrence, Kansas	B.A.	05/1994	Biology
University of Kansas Medical Center, Kansas City, Kansas	M.P.H.	051999	Public Health
University of Kansas, Lawrence, Kansas	M.A.	05/2003	Clinical Psychology
Rush University Medical Center, Chicago, Illinois	Internship	07/2007	Behavioral Science
University of Kansas, Lawrence, Kansas	Ph.D.	08/2007	Clinical Psychology

A. Personal Statement

I have extensive experience over the past 18 years working in primary and secondary breast cancer prevention. As the Director of Cancer Survivorship at the University of Kansas Cancer Center and across the State of Kansas, I coordinate a multi-disciplinary program that serves breast cancer survivors from the greater Kansas City area and across the state. My clinical practice is focused on cancer genetics and my clinical research has focused on quality of life, quality improvement and technology, cancer genetics, and behavioral interventions in primary and secondary prevention populations. Most recently, I have evaluated cardiovascular risk factors, both co-morbid and breast cancer treatment related, and exploring methods to assess and modify these risk factors. In my research, I implemented an NIH BIRCWH K-12 pilot study of a diet, exercise, and behavior modification program to overweight breast cancer survivors. Recently, completed a pilot study building on this initial work exploring the use of home based exercise (cardio + resistance training): increased intensity interval training versus standard exercise in breast cancer survivors participating in a group based weight loss program to modify cardiopulmonary fitness. Currently, I have a corporative group protocol underdevelopment within the Southwest Oncology Group incorporating a behavioral weight control intervention and measures of cardiovascular fitness within cancer survivors. I have also been a PI on a DOD study prospectively monitoring quality of life and cognitive function in pre-menopausal women newly diagnosed with breast cancer. I am also a Co-I for an NCI RO1, Rural Women Connecting for Better Health (PI, Befort) evaluating methods for weight maintenance in a group of rural breast cancer survivors. I have been a Co-I for several breast cancer prevention trials, including a R21 pilot study (PI, Fabian) of a weight loss intervention for high-risk post-menopausal women (some of whom were breast cancer survivors), an institutionally supported study of a light walking intervention for women newly diagnosed with breast or uterine cancer, an American Cancer Society and Susan G. Komen (PI, Befort) supported study too develop novel and cost-effective strategies for improving successful weight control among rural breast cancer survivors and to examine the impact of successful weight loss on breast cancer biomarkers, and a Susan G. Komen Promise grant (PI, Fabian) examining flaxseed for primary breast cancer prevention. I have recently been asked to serve as a member on the NCI Community Oncology COPTRG Community Oncology Cardiotoxicity Task Force. I have also recently been invited to serve on the Academy of Oncology Nurse & Patient Navigators (AONN+) Leadership Council to provide insight and advice to AONN+ concerning educational needs relating to oncology nurse and patient navigators. I am the Founder and CEO of Cancer Survivorship Training, Inc., an eLearning solutions company accelerating education and training to healthcare providers.

B. Positions and Honors

Positions and Employment:

1996-2000	Program Coordinator	University of Kansas Medical Center, Kansas City, Kansas
2000-2001	Program Manager	University of California- San Francisco, Ca.
2000-2006	Research Instructor	University of Kansas Medical Center, Kansas City, Kansas
2007-2008	Internship	Rush University Medical Center, Chicago, Ill
2007-2014	Assistant Professor of Medicine	University of Kansas Medical Center, Kansas City, Kansas
	Associate Director	Breast Cancer Survivorship Center, Westwood, Kansas
2008-Present	Full Member- Cancer Prevention	University of Kansas Cancer Center, Westwood, Kansas
2009-Present	Affiliate Professor of Nursing	University of Kansas Medical Center, Kansas City, Kansas
2010-Present	Affiliate Professor of Psychology	University of Kansas, Lawrence, Kansas
2011-Present	Survivorship & Navigation Group	National Cancer Survivorship Resource Ctr
2011-Present	Founder/CEO	Cancer Survivorship Training, Inc.
2012-Present	Director, Cancer Survivorship	University of Kansas Cancer Center, Westwood, Kansas
2014-Present	Associate Professor of Medicine	University of Kansas Medical Center, Westwood, Kansas
2016-Present	Co-Leader, Cancer Prevention & Survivorship Program	University of Kansas Cancer Center, Kansas City Kansas

Society Memberships, Offices and Honors:

2006-2007	B. Kent Houston Awards for Excellence in Health Psychology
1997-1998	W.S. Sutton Scholarship in Genetic Research, KU Medical Center
1999- Present	Associate Member, American Association of Clinical Oncology (ASCO)
2000- Present	Advisory Board Member, Facing our Risk Empowered (FORCE)
2007- Present	Full Member (Cancer Prevention program), The University of Kansas Cancer Center
2009-2012	Westwood Hills, Kansas, City Council Member
2010- Present	SWOG Member
2011- Present	Survivorship Programs & Navigation Workgroup: National Cancer Survivorship Resource Ctr
2011 Present	Kansas City Business Magazine, Honored as a “Rising Star”
2011	SWOG Young Investigator Training Course
2012- Present	Society of Behavioral Medicine
2013- Present	NCI Community Oncology COPTRG Community Oncology Cardiotoxicity Task Force
2013- Present	Advisory Board Member, Academy of Oncology Nurse and Patient Navigators and Survivorship

C. Contribution to Science

1. My clinical practice and research interest in cancer genetics is fueled by desire to deliver point of service access to cancer risk counseling and testing, risk stratify patients in order to provide evidence-based screening, prevention, and management. The current problem is that there are a limited number of genetic experts and personalized medicine is becoming more main-stream. In order to address the challenges with identification and risk assessment, access to genetic testing, and understanding subsets (ie., triple negative breast cancer), I have participated and led research to address these challenges and opportunities. From this research we have found that delivery of genetic testing results by phone is acceptable to high risk women, that there is a higher incidence of BRCA1 and BRCA2 mutations in women with triple negative breast cancer, and

the prospective follow-up via a triple-negative registry has provided insight on treatment response and characteristics of this very high risk group of breast cancer survivors.

a) **Klemp, J.,** Brady, D., Frank, T.S., Kimler, B.F., & Fabian, C.J. (2000). Incidence of BRCA1/2 germ line alterations in a high risk cohort participating in a phase II (biomarker) chemoprevention trial. European Journal of Cancer, 36:1209-1214. PMID: 10882858.
b) **Klemp, J.R.,** O'Dea, A., Chamberlain, C., & Fabian, C.J. (2005). Patient satisfaction of BRCA 1/2 genetic testing by women at high risk for breast cancer participating in a prevention trial. Familial Cancer, 4(4): 279-284. PMID: 16341803.
c) Sharma P, **Klemp JR**, Kimler BF, Mahnken JD, Fabian CJ, Geier L, Khan QJ, Elia M, Connor CS, McGinness MK, Mammen JMW, Ward CE, Ranallo L, Knight C, Stecklein SR, Jensen RA, Godwin AK. Germline BRCA Mutation Evaluation in a Prospective Triple-Negative Breast Cancer Registry: Implications for Hereditary Breast and/or Ovarian Cancer Syndrome Testing. Breast Cancer Res Treat. May 7, 2014. [Epub ahead of print]. PMC4171847.
d) Couch FJ, Hart SN, Sharma P, Toland AE, Wang X, Miron P, Olson JE, Godwin AK, Pankratz VS, Olswold C, Slettedahl S, Hallberg E, Guidugli L, Davila JI, Beckmann MW, Janni W, Rack B, Ekici AB, Slamon DJ, Konstantopoulou I, ……, **Klemp JR**, et al. Inherited Mutations in 17 Breast Cancer Susceptibility Gene Among a Large Triple-Negative Breast Cancer Cohort Unselected for Family History of Breast Cancer. J Clin Oncol, 2015 Feb 1;33(4):304-11. PMC4302212

2. Breast cancer prevention is vital in the cancer control continuum. My work has focused on improved methods to assess risk, provide informed shared decision making, and implementation of primary, secondary, and tertiary breast cancer prevention area focus. Clinical research focused on tissue based risk and response markers as well as tools for communication have been a focus of research since the beginning of my career. Steps to improve communication and implement prevention strategies across the cancer control continuum are an ongoing area of my clinical research.

a) Fabian, C.J., Kimler, B.F., Zalles, C.M., **Klemp, J.R.,** Kamel, S., Zeiger, S., & Mayo, M.S. (2000). Short-term prediction of breast cancer by random periareolar fine-needle aspiration cytology and the Gail Risk Model. Journal of the National Cancer Institute, 92(15):1217-1227. PMID: 10922407.
b) Ozanne, E.M., **Klemp, J.R**., & Esserman, L.J. (2006). Breast cancer risk assessment and prevention: A framework for shared decision-making consultations. The Breast Journal, 12(2):103-113. PMID: 16509834.
c) Fabian CJ, Kimler BF, Zalles CM, **Klemp JR**, Petroff BK, Khan QJ, Sharma P, Setchell KD, Zhao X, Phillips TA, Metheny T, Hughes JR, Yeh HW, Johnson KA. Reduction in Ki-67 in benign breast tissue of high risk women with the lignan Secoisolariciresinol Diglycoside (SDG). *Cancer Prev Res* 2010 Aug 19;[Epub ahead of print]. PMC2955777
d) **Klemp JR.** (2015). Breast Cancer Prevention Across the Cancer Care Continuum. Seminars in Oncology Nursing. Vol 31(1), 67-72, 2015. PMID: 25951738 (PMC# not required; not NIH funded).

3. Breast cancer survivorship includes managing the effects of the diagnosis and treatment, including a focus on symptom management, issues related to menopausal status, urban vs. rural differences, loss or impaired fertility, and the perceived cognitive impairment in breast cancer survivors. This focus on the quality of life of breast cancer survivors was integral in my pre-doctoral training and continues mid-career.

a) Khan, Q.J., Reddy, P.S., Kimler, B.F., Sharma, P., Baxa, S.E., O'Dea, A.P., **Klemp, J.R**., & Fabian, C.J. (2010). Effect of vitamin D supplementation on Serum 25-hydroxy vitamin D levels, joint pain, and fatigue in women starting Adjuvant Letrozole treatment for breast cancer. Breast Cancer Research and Treatment, 119:111-118. PMC4182952.
b) Befort, C.C. & **Klemp, J.R.** (2011). Sequelae of breast cancer and the influence of menopausal status at diagnosis among rural breast cancer survivors. Journal of Women's Health,20(9):1307-1313. PMC3168971
c) **Klemp, J.R.** & Kim, S.S. (2012). Fertility preservation in young women with breast cancer. Journal of Assisted Reproduction and Genetics, 29(6): 469-472. PMC3370052.
d) Myers JS, Wick JA, **Klemp JR**. Potential factors associated with perceived cognitive impairment in breast cancer survivors. Support Care Cancer. 2015 Nov;23(11):3219-28. PMC4586297

4. Developing survivorship programming has become integral in the delivery of care to survivors and their families from the time of diagnosis through the lifespan. Work focused on understanding the current status of care delivery in both adults and survivors of childhood cancers has been a focus of survey and clinical delivery. My role has been to better understand and delivery comprehensive survivorship care and work with practices across the country to implement survivorship care and measure patient and organizational outcomes.

a) **Klemp, J.R.** & Frazier, L.M., Glennon, C., Trunececk, J., & Irwin, M. (2011). Improving cancer survivorship care: Oncology nurses' educational needs and preferred methods of learning. Journal of Cancer Education, 26(2): 234-242. PMC4183224.
b) McClellan, W., **Klemp, J.R.,** Krebill, H., Ryan, R., Nelson, E.L., Panicker, J., Sharma, M., & Stegenga, K. (2013). Understanding the functional late effects and informational needs of adult survivors of childhood cancer. Oncology Nursing Forum, 40(3): 254-262. PMC4164344.
c) **Klemp, J.R.,** Knight, C.J., Ranallo, L.B., & Fabian, C.J. (2013). The demands of cancer survivorship: The who, what, when, where, why, and how. Community Oncology, 10(9): 266-271 (not NIH funded)
d) **Klemp, J.R.** (2015). Survivorship care planning: One size does not fit all. Seminars in Oncology Nursing. Vol 31(1), 67-72, 2015. PMID: 25636397 (not NIH funded)

5. Weight control is a key focus for cancer prevention and survivorship clinical research. Developing delivery models, both in person and using tele-medicine has been a central focus of our work. In addition, obtaining and understanding the impact of biomarker change has been a target as we work towards a prescription for diet and exercise.

a) Befort, C.A., **Klemp, J.R.**, Austin, H.L., Perri, M.G., Schmitz, K.H., Sullivan, D.K., & Fabian, C.J. (2012). Outcomes of a weight loss intervention among rural breast cancer survivors. Breast Cancer Research and Treatment,132(2):631-639. PMC3314288.
b) Fabian CJ, Kimler BF, Phillips TA, Donnelly JE, Sullivan DK, Petroff BK, Zalles CM, Metheny T, Aversman S, **Klemp JR**, Mills GB, Hursting SD. Favorable Modulation of Benign Breast Tissue and Serum Risk Biomarkers Is Associated with >10% Weight Loss in Postmenopausal Women. Breast Cancer Res Treat. Nov;142(1):119-32, 2013. PMC3921968.
c) Burnett, D., Kluding, P., Porter, C., Fabian, C., & **Klemp, J.R**. (2013). Cardiorespiratory fitness in breast cancer survivors. SpringerPlus, 2(1): 68. PMC3606517.
d) Befort C, Bennett L, Christifiano D, Krebill H, **Klemp JR.** Effective Recruitment of Rural Breast Cancer Survivors into a Lifestyle Intervention. *Psychooncology*. Jun 21, 2014. PMC4272910.

Link to my complete list of publications:
http://www.ncbi.nlm.nih.gov/pubmed/?term=klemp+j

D. Research Support

Ongoing Research Support:

CDC15-1501 10/01/2015 - 09/30/2018
Kansas Department of Health and Environment (Center for Disease Control)
Kansas Survivor Care Quality Initiative (KSCQI)
Major Goals: Increase the quality of life of cancer survivors including physical and mental health and to increase the number of state and regional cancer center that work together to develop a comprehensive care summary and follow-up to promote physical and mental health after completing cancer treatment.
Role: Co-PI

KG101039 Fabian CJ (PI) 09/24/2010 - 09/23/2016
Komen Promise Grant
Flaxseed Lignan as a Prevention Strategy for Pre-Menopausal Women at High Risk for Development of Breast Cancer.

Goals: Conduct a randomized, placebo-controlled Phase II breast cancer chemoprevention trial of the flaxseed lignan SDG in pre-menopausal women who are at high risk of development of breast cancer; and to demonstrate modulation of risk biomarkers including Ki-67 in breast epithelial cells acquired by RPFNA.
Role: Co-Investigator

R01CA155014 Befort (PI) 08/01/2011 - 05/31/2017
NIH/NCI
Group Phone-Based Weight Control among Rural Breast Cancer Survivors
RCT comparing impact of group phone intervention to mail-based intervention for weight loss maintenance, quality of life, and breast cancer risk biomarkers at 18 months among rural breast cancer survivors.
Role: Co-Investigator

No number Daley (PI) 08/13/2015 - 08/12/2018
SG Komen Breast Cancer Foundation
Continuing an American Indian Breast Cancer Disparities Training Program
Major Goals: The goal of this proposal is to continue a training program for American Indian students to obtain a Master of Public Health degree focusing on an aspect of breast cancer disparities research
Role: Co-Investigator

Completed Research Support:

CDRN-1306-04631 Waitman (PI) 03/01/2014 - 09/01/2015
Patient Centered Outcomes Research Institute
The Greater Plains Collaborative: a PCORNet Clinical Data Research Network
Major Goals: to facilitate more efficient comparative effectiveness research that could significantly increase the amount of information available to healthcare decision makers and the speed at which it is generated in breast.
Role: Site Breast PI

No Number Klemp (PI) 11/2010-11/2015
National Breast Cancer Foundation, Inc.
Supporting a primary and secondary breast cancer prevention navigator.
Goals: This position will assist patients through screening, breast cancer education and risk assessment, and recruitment into breast cancer prevention trials.

Back in the Swing Klemp (PI) 07/2008-06/2015
Breast Cancer Survivorship Center
Goals: The major goal of this project is to provide on-going clinical research via data collection, clinical trials, and program development within the Breast Cancer Survivorship Center.

No Number Waitman (PI) 09/2013-08/2015
PCORI
The Greater Plains Collaborative; a PCORNet Clinical Data Research Network (GPC Breast Cancer).
The GPC is a new network of 10 leading medical centers in seven states committed to a shared vision of improving healthcare delivery through ongoing learning, adoption of evidence-based practices, and active research dissemination.
Role: Co-Investigator

K12 HD052027 Klemp (Project PI) Thomas (Program PI) 10/2010-02/2013
NIH/NCI
Internal career development award designed to bridge transition to external funding
Goals: Pilot project to evaluate breast cancer biomarkers and measure of overall health following a 6-month diet/exercise/behavioral intervention in overweight breast cancer survivors.
Role: Project PI

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Devin Charles Koestler, PhD**

eRA COMMONS USER NAME: DKOESTLER

POSITION TITLE: Assistant Professor of Biostatistics

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Rochester Institute of Technology	B.S.	05/07	Applied Mathematics
Brown University	Ph.D.	05/12	Biostatistics
Dartmouth College	Postdoctoral	07/13	Molecular Epidemiology and Biostatistics
Stanford University	Graduate Certificate	Present	Bioinformatics

A. Personal Statement

Throughout my career, my number one priority has been to utilize my training in biostatistics and background in the quantitative sciences to understand the biology of living systems. As a doctoral student in biostatistics at Brown University, I was fortunate to have the opportunity to work in a multidisciplinary environment that involved the application of my quantitative training as a means toward understanding the role of epigenetics in states of human disease, including cancer. This multidisciplinary research experience provided many important lessons, not the least of which was that the size and complexity of the typical 'omic data set represents a major bottleneck in the translation of raw 'omic data into clinically and biologically important information. This realization has been the driving force behind my research program, which involves the development and application of novel bioinformatics/statistical methodologies for identifying biologically and clinically relevant patterns in high-throughput 'omic' data.

After joining University of Kansas Medical Center as an Assistant Professor of Biostatistics in the fall of 2013, I was awarded a Frontiers Junior Faculty Career Development Award (project 1KL2TR000119) to develop and apply novel statistical methods for integrating multiple different 'omic data types to better understand ovarian cancer risk and prognosis, as well as pilot funding to develop prognostic models for predicting bladder cancer recurrence-risk using clinical, epidemiologic, and molecular biomarkers (supported by the University of Kansas Cancer Center Support Grant (CCSG)). Through these projects, my ongoing and past collaborations, and my previous involvement in a cross-disciplinary post-doctoral training program at Dartmouth College, I have acquired extensive experience working with numerous different types of 'omic data, i.e., genotypic, DNA methylation, microbiome, mRNA expression, miRNA expression, and next-gen sequencing data. These experiences and my continued collaboration with other KUCC investigators underscore my role in the Biostatistics and Informatics Shared Resource (BISR) and ongoing commitment to the CCSG.

B. Positions and Honors

Positions and Employment

2008-2009 Research Assistant, Department of Pediatrics, Women and Infants Hospital, Providence RI

2009-2011 Research Assistant, Departments of Biostatistics and Pathology and Laboratory Medicine, Brown University, Providence RI
2011-2013 Postdoctoral Research Fellow, Section for Biostatistics and Epidemiology, Dartmouth College, Hanover, NH
2013- Assistant Professor, Department of Biostatistics, University of Kansas Medical Center, Kansas City, KS

Other Experience and Professional Memberships

2011- Member, International Biometric Society
2011- Member, American Society for Human Genetics
2011- Review Editor, Frontiers in Toxicogenomics
2012- Associate Member, American Academy for Cancer Research
2013- Member, Epigenome Wide Association Consortium (EWAC)
2013- Associate Editor, PLOS ONE

Honors

2010 Superfund Research Program (SRP) Training Core Appointment, Brown University
2010 International Affairs Travel Award, Brown University
2011 Eastern North American Region (ENAR) Distinguished Student Paper Award
2011 Ruth L. Kirschstein National Research Service Awardee
2013 Kansas INBRE Recruitment Award
2015 Outstanding Faculty Award, University of Kansas Medical Center, Department of Biostatistics
2015 Top performers (team Jayhawks), DREAM 9.5, Prostate Cancer DREAM Challenge.

C. Contribution to Science

1. Rapid technological breakthroughs in high-throughput technologies for assessing the genome, transcriptome, epigenome, etc. together with with an ever evolving understanding of these mechanisms, has necessitated the development of novel statistical/analytical approaches that pace with such advancements. My earliest publications concern the development of novel unsupervised clustering methodologies for identifying biologically meaningful signal(s) in the analysis of high-throughput 'omic data. Clustering refers to the grouping of subjects and/or genomic features based on their similarity. Due in large part to the fact that clustering analysis represents efficient tool for understanding molecular variation across subjects/genomic features and because of its promise for identifying previously undocumented molecular subtypes, unsupervised clustering analysis has emerged one of the most popular tools in the analysis of high-throughput 'omic data. Yet, the unique features of different 'omic data types, interest in identifying clinically/biologically meaningful molecular subtypes, and an increasing sophistication in study designs, have demanded the development of new statistical tools for clustering analysis. My research in this area as attempted to meet these demands; specifically my most significant contributions to the scientific community include:

   a) **Koestler DC**, Marsit CJ, Christensen BC, Karagas MR, Bueno R, Sugarbaker DJ, Kelsey KT, Houseman EA. Semi-supervised recursively partitioned mixture models for identifying cancer subtypes. Bioinformatics. 2010;26(20):2578-85. doi: 10.1093/bioinformatics/btq470. PMID: 20834038; PMCID: PMC2951086.
   b) **Koestler DC**, Christensen BC, Marsit CJ, Kelsey KT, Houseman EA. Recursively partitioned mixture model clustering of DNA methylation data using biologically informed correlation structures. Statistical applications in genetics and molecular biology. 2013;12(2):225-40. doi: 10.1515/sagmb-2012-0068. PMID: 23468465, PMCID: PMC4007267.
   c) **Koestler DC**, Marsit CJ, Christensen BC, Kelsey KT, Houseman EA. A recursively partitioned mixture model for clustering time-course gene expression data. Translational cancer research. 2014;3(3):217-32. PMID: 25346887, PMCID: PMC4208690.
   d) **Koestler DC**. Statistical Diagnostics for Cancer: Analyzing High Dimensional Data. Semisupervised methods for analyzing high-dimensional genomic data. Ed. 1, Wiley-Blackwell. 93-106. 2013. Not NIH funded.

2. Owing to the tissue-specificity of DNA methylation, a formidable and well-recognized challenge in the analysis DNA methylation data is the potential for confounding due to the underlying cell composition of the biospecimen(s) used for its assessment. Failure to appropriately adjust for cell composition in the statistical analysis of DNA methylation data can lead to misleading and/or misinterpreted associations. Together with my collaborators, we were one of the first groups to formalize the importance of cell heterogeneity in the analysis of DNA methylation data and more importantly, pioneered the development of a novel statistical framework that enables researchers to control for the potential confounding effects of cell composition in DNA methylation array analyses. This body of research has received substantial recognition within the epigenomics research community, including over 200 citations of our methodology since its publication in 2012, editorial and cover highlight of our contributions in the August 2012 issue of Cancer Epidemiology Biomarker's and Prevention, and several feature stories in regional and national periodicals. My most significant contributions in this area include:

    a) Houseman EA, Accomando WP, **Koestler DC**, Christensen BC, Marsit CJ, Nelson HH, Wiencke JK, Kelsey KT. DNA methylation arrays as surrogate measures of cell mixture distribution. BMC bioinformatics. 2012;13:86. doi: 10.1186/1471-2105-13-86. PMID: 22568884; PMCID: PMC3532182.
    b) **Koestler DC**, Marsit CJ, Christensen BC, Accomando W, Langevin SM, Houseman EA, Nelson HH, Karagas MR, Wiencke JK, Kelsey KT. Peripheral blood immune cell methylation profiles are associated with nonhematopoietic cancers. Cancer epidemiology, biomarkers & prevention : a publication of the American Association for Cancer Research, cosponsored by the American Society of Preventive Oncology. 2012;21(8):1293-302. doi: 10.1158/1055-9965.EPI-12-0361.PMID: 22714737; PMCID: PMC3415587.
    c) **Koestler DC***, Christensen B*, Karagas MR, Marsit CJ, Langevin SM, Kelsey KT, Wiencke JK, Houseman EA. Blood-based profiles of DNA methylation predict the underlying distribution of cell types: a validation analysis. Epigenetics : official journal of the DNA Methylation Society. 2013;8(8):816-26. doi: 10.4161/epi.25430. PMID: 23903776; PMCID: PMC3883785
    d) **Koestler DC**, Jones MJ, Usset J, Christensen BC, Butler RA, Kobor MS, Wiencke JK, Kelsey KT. Improving cell mixture deconvolution by identifying optimal DNA methylation libraries (IDOL). BMC bioinformatics. 2016;17(1):120. doi: 10.1186/s12859-016-0943-7. PMID: 26956433; PMCID: PMC4782368.

3. As with other 'omic data types the technologies and techniques for high-throughput assessment of DNA methylation are ever advancing and continuously changing; an aspect which has driven the development of a wealth of statistical/analytical tools for the preprocessing, statistical analysis, and interpretation of results generated from such data. A common experience among researchers new to this area is a feeling of being overwhelmed by the breadth of available tools/methods and a general confusion about the steps involved in a proper and defensible DNA methylation array analysis. Together with my collaborators, I have attempted to lead the way in development of research material aimed at assisting the epigenomics research by distilling the latest developments in this field as a means toward streamlining DNA methylation array analyses. My efforts to achieve this objective include a publicly available tutorial on DNA methylation array preprocessing and analysis, which has generated nearly 100 requests from researchers around the world, invited contributions for book chapters on DNA methylation array analysis, as well as other scientific material aimed at assisting researchers. Specific highlights exemplifying my contributions in this are include:

    a) Wilhelm-Benartzi CS*, **Koestler DC***, Karagas MR, Flanagan JM, Christensen BC, Kelsey KT, Marsit CJ, Houseman EA, Brown R. Review of processing and analysis methods for DNA methylation array data. British journal of cancer. 2013;109(6):1394-402. doi: 10.1038/bjc.2013.496. PubMed PMID: 23982603; PubMed Central PMCID: PMC3777004.
    b) **Koestler DC**, Jones M, Kobor M. The era of integrative genomics: more data or better methods? Epigenomics. 2014;6(5):463-7. doi: 10.2217/epi.14.44. PubMed PMID: 25431938.

c) **Koestler DC.** **The Nuts and Bolts of DNA methylation Array Preprocessing and Analysis.** Tutorial on the proper handling of array-based DNA methylation data, with a specific emphasis on the Illumina Infinium HumanMethylation450 array.
d) **Koestler DC** and Houseman EA. Computational and Statistical Epigenomics. Model based clustering analysis of DNA methylation array data. Ed. 1, Springer (Statistics series). Edited by: Andrew Teschendorff. June 2015.

4. Work on the "fetal origins" or Developmental Origins and Health and Disease (DOHaD) hypothesis has demonstrated that infant growth, itself linked to antenatal environmental factors, such as: diet, xenobiotic exposures, stress, and lifestyle factors, is a significant risk factor for long-term chronic disease. The vulnerability of the fetus to environmental insults together with the DOHaD hypothesis have served to motivate my work on understanding the impact of in-utero exposure to environmental toxicants and downstream health outcomes. Beginning during my post-doctoral training at Dartmouth College and continuing to the present, I have utilized my background in DNA methylation and 'omic analyses to characterize the relationship between in-utero exposure to trace-metals (at common levels of exposure) and the placental/infant epigenome, and more recently, the extent to which changes confer downstream health risks. Some of my most significant contributions to the emerging area of developmental epigenomics include:

a) **Koestler DC**, Avissar-Whiting M, Houseman EA, Karagas MR, Marsit CJ. Differential DNA methylation in umbilical cord blood of infants exposed to low levels of arsenic in utero. Environmental health perspectives. 2013;121(8):971-7. doi: 10.1289/ehp.1205925. PubMed PMID: 23757598; PubMed Central PMCID: PMC3733676.
b) Fei DL*, **Koestler DC***, Li Z, Giambelli C, Sanchez-Mejias A, Gosse JA, Marsit CJ, Karagas MR, Robbins DJ. Association between In Utero arsenic exposure, placental gene expression, and infant birth weight: a US birth cohort study. Environmental health : a global access science source. 2013;12:58. doi: 10.1186/1476-069X-12-58. PubMed PMID: 23866971; PubMed Central PMCID: PMC3733767.
c) Maccani JZ, **Koestler DC**, Houseman EA, Marsit CJ, Kelsey KT. Placental DNA methylation alterations associated with maternal tobacco smoking at the RUNX3 gene are also associated with gestational age. Epigenomics. 2013;5(6):619-30. doi: 10.2217/epi.13.63. PubMed PMID: 24283877.
d) Maccani JZ, **Koestler DC**, Lester B, Houseman EA, Armstrong DA, Kelsey KT, et al. Placental DNA Methylation Related to Both Infant Toenail Mercury and Adverse Neurobehavioral Outcomes. Environmental health perspectives. 2015. doi: 10.1289/ehp.1408561. PubMed PMID: 25748564.

- Signifies shared first-authorship

Complete List of Published Work in MyBibliography:

http://www.ncbi.nlm.nih.gov/sites/myncbi/1N1samnT9scQJ/bibliography/41517057/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

R01ES025145 Marsit, Carmen and Koestler, Devin (PIs) 02/01/2016 - 01/31/2020
NIH National Institute of Environmental Health Sciences
MicroRNA, Environmental Exposures and Newborn Outcomes
This research aims to identify the mechanistic role of microRNA, which can effect the function of the placenta, in mediating the impact of environmental exposures on children's growth neurodevelopment. Such findings may have significant clinical and public health impact, providing an opportunity for early interventions for at-risk

children, and potentially identifying novel paths for prevention and treatment.
Role: Co-Principal Investigator

R01CA166150 Michaud, Dominque (PI) 07/01/2014 - 06/30/2017
NIH National Cancer Institute
Microbiomes in Human Pancreatic Cancer
In the US, pancreatic cancer is the fourth leading cause of cancer-related death, and as most pancreatic cancers are diagnosed late in the progression of the disease, only 5% of patients are alive 5 years after initial diagnosis. Unfortunately, the causes of pancreatic cancer are largely unknown, but new studies support the role of bacteria. The goals of this research include: (1) measurement of microbiota in patients with pancreatic cancer, and in subjects who did not have cancer using a combination of state-of-the-art molecular techniques; (2) examine possible routes of bacteria dissemination from the mouth to the pancreas.
Role: Co-Investigator

KL2TR000119 Barohn, Richard J and Aaronson, Lauren S (PIs) 03/01/2014-02/28/2017
NIH National Center for Advancing Translational Science
Integrative Genomics for Understanding Ovarian Cancer Risk and Progression
The goal of this project to integrate multiple 'omic data types in combination with the application of novel bioinformatics and statistical methodologies for understanding the relationship between genetics, epigenetics, and mRNA expression on ovarian cancer risk and progression.
Role: KL2 Scholar and project Principal Investigator

Completed Support:

Pilot Program Koestler (PI) 12/01/2013-12/01/2014
University of Kansas Cancer Center (KUCC)
Development of Prediction Models for Bladder Cancer Recurrence Using Clinical, Pathological, and Molecular Data
The goal of this project is to develop and evaluate prognostic nomograms for predicting short-term risk of recurrence among non-muscle invasive bladder cancer cases. We will additionally examine the extent to which the addition of molecular biomarkers, specifically blood-derived DNA methylation biomarkers, improve the prediction performance of nomograms that use clinical and pathological data only.
Role: Principal Investigator

R25 CA134286 Karagas, Margaet, Moore, Jason, and Tosteson, Tor (PIs) 09/01/2011-08/31/2013
Training Program for Quantitative Population Sciences in Cancer
The overarching goal of the Training Program for Quantitative Population Sciences in Cancer is to improve the resources available for future cancer research by providing innovative interdisciplinary training for postdoctoral fellows. This program will be designed to provide early career researchers with opportunities to integrate specialized research knowledge and methodologies within the fields of bioinformatics, biostatistics and epidemiology
Role: Trainee

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Melissa A. Larson, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): MLARSON2

POSITION TITLE: Research Assistant Professor, Molecular and Integrative Physiology; Technical Director, Transgenic and Gene-Targeting Facility

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Cornell University, Ithaca, NY	B.S.	05/1989	Animal Science
Virginia Tech, Blacksburg, VA	M.S.	05/1993	Reproductive Physiology
University of Missouri, Columbia, MO	Ph.D.	12/2000	Reproductive Physiology

A. Personal Statement

In my position as the Technical Director of the Transgenic and Gene-Targeting Facility at the University of Kansas Medical Center, I am poised to directly facilitate the animal research models proposed in this application. I have 25 years of experience in the field of transgenic animals, having begun in 1991 by making pigs transgenic for human protein C. I then served as the Research Specialist in the Transgenic Core Facility at the University of Missouri for the duration of my doctoral program. My dissertation explored the expression of microinjected transgenes in murine, porcine and bovine embryos, as well as the expression of interferon-tau in bovine blastocysts. I have been responsible for the oversight and functional operation of an institutional core facility at each of the following locations: the Stowers Institute for Medical Research, the University of Missouri-Kansas City and KUMC. My work experiences at these locations have included the generation of transgenic mice by pronuclear injection, the generation of chimeric mice by blastocyst injection, gene-targeting of embryonic stem cells and support services including sperm and embryo cryopreservation, rederivation and in vitro fertilization. In addition, our facility has continued to evolve over time and implement new technologies as they become available, such as the generation of gene-targeted mice by pronuclear injection and the generation of gene-modified mice with the genome editing tools CRISPR/Cas9, TALENs and ZFNs. I have also successfully addressed investigator requests for new services, including embryo bisection and nuclear transfer, as well as staying current with training in the latest protocols for embryo and sperm cryopreservation and subsequent in vitro fertilization.

1. **Larson MA**, Bronshteyn I, Vivian CJ, Welch DR, Vivian JL. Nuclear Transfer between Strains of Inbred Mice. Trans Res. 2016;16(2):203-204. PMC in process.

B. Positions and Honors

Positions and Employment:

1993-1999 Research Specialist, Transgenic Animal Core Facility, University of Missouri, Columbia, MO
1993-2000 Graduate Research Assistant, Animal Sciences Department, University of Missouri, Columbia
2001-2001 Research Specialist, Stowers Institute for Medical Research, Kansas City, MO
2002-2003 Managing Director, Embryonic Stem Cell Facility, Stowers Institute for Medical Research, Kansas City, MO
2003-2004 Manager, Reproductive Biology Group, Laboratory Animal Services Facility, Stowers Institute for Medical Research, Kansas City, MO
2004-2005 Transgenic Facility Manager, Laboratory Animal Ctr., University of Missouri, Kansas City, MO
2005-2005 Manager, Laboratory Animal Center, University of Missouri, Kansas City, MO

2005-2006 Director, Laboratory Animal Centers, University of Missouri, Kansas City, MO
2006-2009 Director, Transgenic and Gene-Targeting Institutional Facility, University of Kansas Medical Center, Kansas City, KS
2006-pres. Research Assistant Professor, Department of Molecular and Integrative Physiology, University of Kansas Medical Center, Kansas City, KS
2010-pres. Technical Director, Transgenic and Gene-Targeting Institutional Facility, University of Kansas Medical Center, Kansas City, KS

Honors:

2009-2010 Kansas Technology Enterprise Corporation Scholar Award
2016 International Society for Transgenic Technologies Registration Award to 13th Transgenic Technology Meeting, March 20-23, 2016, Prague, Czech Republic.
2016 International Society for Transgenic Technologies Travel Award to 13th Transgenic Technology Meeting, March 20-23, 2016, Prague, Czech Republic.

C. Contribution to Science

1. My dissertation research focused in part on the in vitro expression of transgenes injected in murine, porcine and bovine embryos. I found that the percentage of blastomeres expressing the reporter transgene in each species was inversely proportional to the timing of zygotic genome activation, which led to our hypothesis that transgene integration was occurring with the onset of zygotic transcription.

a) **Larson MA**, Kubisch HM, Funahashi H, Hernandez-Ledezma JJ, Day BN, Roberts RM (1995). Comparative expression patterns of two transgenes in murine, porcine and bovine embryos. Theriogenology 43:262.

2. In addition to these transgene expression studies, my dissertation work largely involved study of the expression of interferon-tau by bovine blastocysts. I found that in vitro, female bovine embryos are less able to make the transition to the expanded blastocyst stage of development, while producing far greater amounts of interferon-tau. This is likely due to an increased sensitivity to high glucose levels, and it may help to explain the in vivo skewing in sex ratio observed in some species.

a) **Larson MA,** Kimura K, Kubisch HM, Roberts RM (2001). Sexual dimorphism among bovine embryos in their ability to make the transition to expanded blastocyst and in the expression of the signaling molecule IFN-□ Proc Natl Acad Sci 98:9677-9682.

3. As the Technical Director of the Transgenic and Gene-Targeting Facility, I have been responsible for producing gene-modified mice for investigators at the University of Kansas Medical Center for 10 years. I have also been responsible for producing gene-modified rats following injection of ZFNs by performing the embryo collection, pronuclear injection and embryo transfer surgeries into recipient female rats.

a) Karim Rumi MA, Dhakal P, Kubota K, Chakraborty D, Lei T, **Larson MA**, Wolfe MW, Roby KF, Vivian JL, Soares MJ (2014). Generation of Esr1 knockout rats using zinc finger nuclease-mediated genome editing. Endocrinology. 155(5):1991-1999. PMID: 24506075

4. I have also established new services in the Transgenic Facility to meet the needs of KUMC investigators. In one case, I designed a tool and procedure to physically cut mouse blastocysts in half, effectively separating the inner cell mass from the trophectoderm in order to study expression of genes involved in development.

a) Saha B, Home P, Ray S, **Larson M**, Paul A, Rajendran G, Behr B, Paul S (2013). EED and KDM6B Coordinate First Mammalian Cell Lineage Commitment to Ensure Embryo Implantation. Mol Cell Biol 33(14):2691-705. PMC3700131

D. Research Support

Ongoing Research Support:

Kansas-Idea Network of Biomedical Research Excellence (K-INBRE) 05/01/2016 - 04/30/2017
K-INBRE Institutional Core Facility Support Proposal
LabStamp Tattoo Systems for Mouse Identification Services
Role: Co-PI

Center of Biomedical Research Excellence (COBRE) (PI: Abrahamson) 09/01/2012 – 06/30/2017
Institutional Development Award (IDeA), National Center for Research Resources, NIH
Molecular Regulation of Cell Development and Differentiation
Role: PI for Core B: Transgenic Facility

Completed Research Support:

Kansas-Idea Network of Biomedical Research Excellence (K-INBRE) 05/01/2015 - 04/30/2016
K-INBRE Institutional Core Facility Support
Completion of a Dedicated Surgical Suite for Embryo Transfer Surgeries with Refined Anesthesia Delivery Apparatus
Role: subproject PI

Kansas-Idea Network of Biomedical Research Excellence (K-INBRE) 05/01/2014 - 04/30/2015
K-INBRE Institutional Core Facility Support
Upgrades for a Dedicated Surgical Suite for Genetic Modification Procedures
Role: subproject PI

Kansas-Idea Network of Biomedical Research Excellence (K-INBRE) 05/01/2012 - 04/30/2013
K-INBRE Institutional Core Facility Support
KUMC Transgenic Facility Procurement and Optimization of a PhiC31-Mediated Platform for Rapid in Vivo Transgenesis in the Mouse
Role: subproject PI

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Sharon M. Lewis, BSN, MSN**

eRA COMMONS USER NAME (credential, e.g., agency login): slewis

POSITION TITLE: Nurse Practitioner

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Newman University, Wichita, KS	BSN	12/1993	Nursing
University of Kansas Medical Center (KUMC), Kansas City, KS	MSN	12/1998	Nurse Practitioner
University of Kansas Medical Center, Kansas City, KS	DNP	12/2013	Adult-Geriatric

A. Personal Statement

I have been with the University of Kansas Clinical Research Center since it opened in January, 2012. I have been the full-time Nurse Practitioner and am a Sub-Investigator on all Early Phase Oncology and Hematology Clinical Trials at this facility. I perform all bone marrow procedures as required per protocol. I co-facilitated getting the healthy cooking classes started for cancer patients, caregivers and survivors. I am also the manager of the hospital nurses and medical assistants at this facility. I am also on the Executive Resourcing Committee and Protocol Review Monitoring Committee.

B. Positions and Honors

Positions and Employment:

1999 – 2000 Nurse Practitioner at Wichita Clinic, Bluestem – Eureka, KS
2000 - 2008 Nurse Practitioner at Coffey County Hospital, Burlington, KS
2008 – 2012 Nurse Practitioner at the University of Kansas Cancer Center, Primary brain tumors and hematology, KUMC, Westwood, KS
2013 – 2015 Adjunct facility at St. Mary University, Overland Park, KS
2012 – pres. Nurse Practitioner, University of Kansas Clinical Research Center, KUMC, Fairway, KS

Professional Membership:

2008 – pres. Oncology Nursing Society member

C. Contribution to Science

No publications.

D. Research Support:

Ongoing Research Support: None

Completed Research Support: None

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

DO NOT EXCEED FIVE PAGES.

NAME: Linheng Li, PhD

eRA COMMONS USER NAME (credential, e.g., agency login): LINHENGL

POSITION TITLE: Investigator/Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Fudan University, Shanghai, P.R. China	B.S.	1985	Biology
Fudan University, Shanghai, P.R. China	M.S.	1988	Genetics
New York University, Medical Center, New York	M.S.	1993	Molecular & Cellular Biol.
New York University, Medical Center, New York	Ph.D.	1995	Molecular & Cellular Biol.
University of Washington Medical Center, Seattle WA	postdoc	2000	Molecular Biotechnology

A. Personal Statement

I have a broad background in molecular, cellular, genetic, and developmental biology, with specific training and expertise in hematopoietic and intestinal stem cell systems. My research includes investigation of roles of niche(s) in maintaining and regulating hematopoietic or intestinal stem cells; key niche signals that support stem cell renewal; targeting cancer stem cells via understanding the drug-resistant nature; and intrinsic regulation of stem cells by imprinting genes and Hox gene cluster. As PI or co-Investigator on internal and NIH-funded grants, I have experience developing systems and establishing collaborations to conduct studies as those proposed for the University of Kansas Cancer Center (KUCC NCI-CC). I have successfully managed projects (e.g. staffing, research protections, budget), collaborated with other investigators, and produced several peer-reviewed publications from each endeavor. As a result of these previous experiences, I am aware of the importance of frequent communications among parties involved and of constructing a realistic research plan, timeline, and budget. I have the training, motivation, expertise, and capabilities required to serve as co-leader of the KUCC NCI-CC Cancer Biology program.

B. Positions and Honors

Professional Positions

2000–05	Assistant Investigator, Stowers Institute for Medical Research, Kansas City, MO
2001-06	Affiliate Assistant Professor, Dept. of Pathology, University of Kansas Medical Center, Kansas City, KS
2006-2008	Associate Investigator, Stowers Institute for Medical Research
2006-2009	Affiliate Associate Professor, Dept. of Pathology, University of Kansas Medical Center
May 2008-present	Investigator, Stowers Institute for Medical Research
July 2009-present	Affiliate Professor, Dept. of Pathology, University of Kansas Medical Center
2010-present	Co-Leader, Cancer Biology, University of Kansas Cancer Center (NCI-CC)

Honors

Fellow of the American Gastroenterological Association (AGA) 2013
Fellow of the American Association for the Advancement of Science (AAAS) 2011
Hudson Prize for excellence in basic biomedical research, M.R. and Evelyn Hudson Foundation 2004
Excellence in Life Sciences Award in Basic Research, Missouri Biotechnology Association 2003

Advisory Panels and Service

University of Kansas Cancer Center Leadership Council Member, Co-Leader Cancer Biology	National Institutes of Health ad hoc Reviewer Hematopoiesis Study Section
The Institute for Stem Cell and Regenerative Medicine University of Washington; SAB (2011-2015)	Chinese Biological Investigators Society Board of Directors (President 2011-2013)
International Society for Stem Cell Research Membership Committee	Faculty of 1000 Medicine Contributing Faculty

C. Contributions to Science

My laboratory uses mouse models of the hematopoietic and intestinal systems to focus on fundamental questions in adult stem cell biology: (1) what are the roles of microenvironment(s) or niche(s) in maintaining and regulating hematopoietic or intestinal stem cells (HSCs or ISCs) and (2) which key niche signals support stem cell renewal and the related molecular mechanisms underlying self-renewal, and (3) how to target cancer stem cells via understanding the drug-resistant nature.

1. **Identification of hematologic stem cell (HSC) niches**. For decades, studies of HSC behavior focused mainly on defining intrinsic regulatory programs controlling HSC functions, leading to deterministic or stochastic models of cell renewal and differentiation. However, in 1978 Ray Schofield proposed that in vivo HSCs reside in a specialized microenvironment, termed the “niche”. Since then, scientists have searched for the location and types of cells in bone marrow that might function as a niche for the HSC. My group identified in 2003, and later confirmed in 2009 using real-time imaging, a subset of bone-lining cells located mainly in the endosteal region of trabecular bone capable of supporting HSCs. In 2014 we identified that megakaryocytes, progeny derived from HSCs, can function as a niche to support HSCs. These findings, along with data from several other groups, redefined the traditional view of HSCs and led to the appreciation that homeostasis in HSCs is a tightly regulated balance between intrinsic and extrinsic cues. This discovery has spawned identification of various stromal cell types in bone marrow that have functional roles as components of a niche. Together, these findings demonstrate that in vivo functional niches in mammalian systems are far more intricate and diverse than previously anticipated, and that the existence of multiple inputs or niches may be responsible in great part for the robustness of the HSC system in both physiological homeostasis and stress.
   a) Zhang, J., C. Niu, L. Ye, H. Huang, X. He, W. G. Tong, J. Ross, J. Haug, T. Johnson, J. Q. Feng, S. Harris, L. M. Wiedemann, Y. Mishina, and L. Li. Identification of the haematopoietic stem cell niche and control of the niche size. Nature 2003 Oct 23; 425:836-841. PMID: 14574412
   b) Xie, Y., T. Yin, W. Wiegraebe, X. C. He, D. Miller, D. Stark, K. Perko, R. Alexander, J. Schwartz, J. C. Grindley, J. Park, J. S. Haug, J. P. Wunderlich, H. Li, S. Zhang, T. Johnson, R. A. Feldman, and L. Li. Detection of functional haematopoietic stem cell niche using real-time imaging. Nature 2009 Jan 1; 457:97-101. PMID: 19052548, Not NIH funded.
   c) Zhao, M., Perry, J.M., Marshall, H., Venkatraman, a., Qian, P., He, X.C., Ahamed, J., & Li, L., Megakaryocytes maintain homeostatic quiescence and promote post-injury regeneration of hematopoietic stem cells. Nature Medicine 2014 Oct 19; 20:1321-26. PMID: 25326798, Not NIH funded.

2. **Characterization of key signaling pathways that regulate HSC and control HSC self-renewal and ex vivo expansion of HSCs.** My research program has played a significant role in our current understanding of how stem cell niches function. Using genomic and genetic approaches, we have identified cells that function as niche components, as well as signals emanating from these niches that contribute to the regulation of the quiescent and active states of stem cells. Additionally, our discoveries have improved our understanding of the roles of major developmental signaling pathways (Notch, BMP, Wnt, FGF, PTEN controlled PI3K-Akt, IGF) in the maintenance and regulation of adult stem cells. During postdoctoral training, I identified the human homolog of the Notch ligand, Jagged1, and demonstrated that Jagged1-Notch signaling inhibits hematopoietic stem and progenitor cell differentiation (16). More recently, we demonstrated that BMP and Wnt signaling act in a reciprocal manner to control stem cell self-renewal, and

that FGF signaling is mainly required for post-injury recovery of bone marrow by promoting HSC expansion and mobilization. We have also helped clarify the role of Wnt signaling in HSC regulation. We have distinguished between the roles of noncanonical and canonical Wnt signaling, respectively, in maintaining HSC quiescence and in promoting HSC activation and expansion. Regarding self-renewal, we demonstrated in mice that cooperation between Wnt-β-catenin and PI3K-Akt signaling facilitates HSC self-renewal in vivo and that pharmacological manipulation of these two pathways facilitates HSC expansion in vitro. We are translating this mouse study into expanding HSCs from human umbilical cord blood and have so far made remarkable progress, thus opening up new avenues for future treatment of blood disorders, including leukemia and cancer.

a) Zhang, J., J. C. Grindley, T. Yin, S. Jayasinghe, X. C. He, J. T. Ross, J. S. Haug, D. Rupp, K. S. Porter-Westpfahl, L. M. Wiedemann, H. Wu, and L. Li. PTEN maintains haematopoietic stem cells and acts in lineage choice and leukaemia prevention. Nature 2006 May 25; 441:518-22. PMID: 16633340
b) Zhao, M., J. T. Ross, T. Itkin, J. M. Perry, A. Venkatraman, J. S. Haug, M. J. Hembree, C. X. Deng, T. Lapidot, X. C. He, and L. Li. FGF signaling facilitates post-injury recovery of mouse hematopoietic system. Blood 2012 Aug 30; 120:1831-1842. PMID: 22802336; PMCID: PMC3433089
c) Perry, J. M., X. C. He, R. Sugimura, J. C. Grindley, J. S. Haug, S. Ding, and L. Li. 2011. Cooperation between both Wnt/{beta}-catenin and PTEN/PI3K/Akt signaling promotes primitive hematopoietic stem cell self-renewal and expansion. Genes & Development 2011 Sep 15; 25:1928-1942. PMID: 21890648, PMCID: PMC3185965.
d) Sugimura, R., X. C. He, A. Venkatraman, F. Arai, A. Box, C. Semerad, J. S. Haug, L. Peng, X. B. Zhong, T. Suda, and L. Li. Noncanonical Wnt signaling maintains hematopoietic stem cells in the niche. Cell 2012 Jul 20; 150:351-365. PMID: 22817897; PMCID: PMC4492542

3. **Proposing the coexistence of quiescent and active stem cell subpopulations, which provides insight to Investigating drug-resistant cancer cells and developing related targeting strategies.** Elegant studies in Drosophila and C. elegans previously suggested that a single dominant stem cell niche modulates the balance between self-renewal and differentiation. Yet, in recent years, evidence from my laboratory and others indicates that rapidly regenerating mammalian tissues contain at least two subpopulations of stem cells. A quiescent group undergoes only occasional cell division and functions as a reserve pool, and an active group undergoes relatively frequent cell division and supports ongoing tissue generation. The active stem cells are different from transit amplifying (TA) cells, as the former undergo self-renewal and support homeostatic tissue generation while the latter represent rapidly cycling progenitor cells. Multiple stem cell populations are not unique to HSCs; quiescent reserve stem cells have been demonstrated in the intestine by genetic ablation or radiation-induced loss of active ($Lgr5^{+}$) stem cells. Moreover, recent observations have revealed that the reserve pool of stem cells can also be derived from reprograming of progenitors under stress conditions. In contrast to flies and nematodes, it appears that mammals have evolved multiple stem and progenitor cell populations within a tissue to handle the demands of a much longer life span and larger body size.
    a) Haug, J. S., X. C. He, J. C. Grindley, J. P. Wunderlich, K. Gaudenz, J. T. Ross, A. Paulson, K. P. Wagner, Y. Xie, R. Zhu, T. Yin, J. M. Perry, M. J. Hembree, E. P. Redenbaugh, G. L. Radice, C. Seidel, and L. Li. N-cadherin expression level distinguishes reserved versus primed states of hematopoietic stem cells. Cell Stem Cell 2008 Apr 10; 2:367-379. PMID: 18397756, Not NIH funded
    b) Li, L., and H. Clevers. 2010. Coexistence of quiescent and active adult stem cells in mammals. Science 2010 Jan 29; 327:542-545. PMID: 20110496; PMCID: PMC4105182

4. **Determining a critical role of imprinting genes in maintaining the most primitive HSCs via suppressing Igf2 signaling and mTOR pathways.** Dormant HSCs are currently defined by their quiescent state. We tested a hypothesis that metabolic state determines the state of dormant (or reserve) versus active (or primed) HSCs. We studied the molecular mechanism that controls the metabolic state of this specific subpopulation. To distinguish reserve HSCs from primed HSCs, we conducted RNA-seq analysis, and to our surprise, the imprinting genes were predominantly expressed in reserve HSCs, including H19 and Gtl2 loci. We conducted genetic KO study and showed that H19 plays a crucial role in maintaining reserve HSCs via suppressing Igf2 signaling.

a) Venkatraman, A., X. C. He, J. L. Thorvaldsen, R. Sugimura, J. M. Perry, F. Tao, M. Zhao, M. K. Christenson, R. Sanchez, J. Y. Yu, L. Peng, J. S. Haug, A. Paulson, H. Li, X. B. Zhong, T. L. Clemens, M. S. Bartolomei, and L. Li. Maternal imprinting at the H19-Igf2 locus maintains adult haematopoietic stem cell quiescence. Nature 2013 Aug 15; 500(7462):345-9. PMID: 23863936; PMCID: PMC3896866
b) Qian P., He X., Paulson A., Li Z., Tao F., Perry JM, Guo F., Zhao M., Zhi L., Venkatraman A., Haug JS, Parmely T., Li H., Dobrowsky RT, Ding W-X, Kono T., Ferguson-Smith AC., Li L. The *Dlk1-Gtl2* Locus Preserves LT-HSC Function by Inhibiting the P13K-mTOR Pathway to Restrict Mitochondrial Metabolism. Cell Stem Cell. 2016 Feb 4; (18):214-228. PMID: 26627594, PMC in process.

5. **Identification, isolation, and in vitro culture of intestinal stem cells.** Wnt signaling is known to regulate intestinal stem cell (ISC) proliferation and self-renewal. We identified that BMP signaling antagonizes Wnt signaling to maintain quiescent ISCs and inhibits ISC self-renewal. We further showed that PTEN controlled PI3K-Akt signaling mediated a cross talk between BMP and Wnt signaling pathways. Identification of intestinal stem cells (ISCs) has relied heavily on the use of transgenic reporters in mice, but this approach is limited by mosaic expression patterns and difficult to apply directly to human tissues. We developed reliable surface markers, $CD44^{+}CD24^{lo}CD166^{+}$, $GRP78^{lo/-}$ and $c\text{-}Kit^{-}$, that facilitated identification of putative stem cells from the mouse small intestine and colon respectively. $CD44^{+}CD24^{-/lo}CD166^{+}$ also identified putative human ISCs. We also established a robust functional assay to characterize ISCs from mouse and human tissues.
   a) He, X. C., J. Zhang, W. G. Tong, O. Tawfik, J. Ross, D. H. Scoville, Q. Tian, X. Zeng, X. He, L. M. Wiedemann, Y. Mishina, and L. Li. 2004. BMP signaling inhibits intestinal stem cell self-renewal through suppression of Wnt-beta-catenin signaling. Nature Genetics. 2004 Oct; 36:1117-1121. PMID: 15378062
   b) Wang F, Scoville D, He XC, Mahe M, Box A, Perry J, Smith NR, Lei Nanye N, Davies PS, Fuller MK, Haug JS, McClain M, Gracz AD, Ding S, Stelzner M, Dunn JC, Magness ST, Wong MH, Martin M, Helmrath M, Li L. Isolation and Characterization of Intestinal Stem Cells Based on Surface Marker Combinations and Colony-Formation Assay. Gastroenterology. 2013 Aug; 145(2):383-395.e21. PMID: 23644405; PMCID: PMC3781924
   c) Xi C He, Tong Yin, Justin C Grindley, Qiang Tian, Toshiro Sato, W Andy Tao, Ramanarao Dirisina, Kimberly S Porter-Westpfahl, Mark Hembree, Teri Johnson, Leanne M Wiedemann, Terrence A Barrett, Leroy Hood, Hong Wu, and Linheng Li. PTEN-deficient intestinal stem cells initiate intestinal polyposis. Nature Genetics. 2007 Feb; 39(2):189-98. PMID: 17237784; PMCID: PMC4681524

Link to publications from PubMed in MyBibliography

D. Research Support

Ongoing Support:

SIMR 1004 Linheng Li (PI) 1/1/2000 – 12/31/2021
Stowers Institute for Medical Research
Investigation of micro environmental regulatory signals for stem cell development
Investigation of molecular and genetic pathways controlling adult stem cell development in the hematopoietic and intestinal systems using transgenic and gene targeting animal model approaches. This funding is not associated with a specific project.

U01 DK085507 Linheng Li (PI) 09/01/2009 – 08/31/2019
National Institutes of Health,
Isolation and Characterization of Intestinal Stem Cells
Identification, isolation, and characterization of intestinal stem cells and their niche cells to provide a better understanding of intestinal stem cell properties and their role in intestinal regeneration, and to open new avenues for studying intestinal stem cell behavior in vitro and possible clinical implications in stem cell transplantation and stem cell based replacement therapy for gastrointestinal diseases.

KU Endowment Association Jensen (PI) 7/1/2013 – 6/30/2017
Promote collaboration to enhance discovery of mechanisms that underlie tumor development, progression and malignant behavior; leverage basic science discoveries to inspire pre-clinical and clinical development of novel cancer therapies.
Role: Co-Leader Cancer Biology, University of Kansas Cancer Center (NCI-CC)

Completed Support:

Hall Family Foundation 1/1/2013 – 12/31/2014
Major Goals: Investigation of hematologic malignancies, specifically to determine targets and efficacy of therapeutic agents for acute leukemia.
Role: Co-Investigator

U01 DK085507 Linheng Li (PI) 09/01/2013 – 08/31/2014
National Institutes of Health
Supplement to the existing NIH-funded project
Isolation and Characterization of Human ISC Populations
Build a network of regulatory signals emanating from different niche components under homeostatic and stressed conditions and provide comprehensive understanding of the microenvironmental and regulation and stress influence of intestinal stem cell state and fate.

U01 DK085507-04S1 Linheng Li (PI) 09/01/2012 – 08/31/2013
National Institutes of Health
Supplement to the existing NIH-funded project
Isolation and Characterization of Human ISC Populations
Isolate and propagate active and quiescent intestinal stem cell populations from human small intestine, and assess expression profiles under homeostatic and various pathologic conditions, while establishing reliable antibodies and other markers of the small bowel stem cell niche.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Christopher E. Lominska, MD**

eRA COMMONS USER NAME (credential, e.g., agency login): clominska

POSITION TITLE: Assistant Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Kansas, Lawrence, KS	B.A.	05/1999	Biology
Columbia University College of Physicians and Surgeons, New York, NY	M.D.	05/2005	Medicine
St. Luke's-Roosevelt Hospital Center, New York, NY	Internship	06/2006	Internal Medicine
Georgetown University Hospital, Washington, DC	Residency	07/2010	Radiation Oncology

A. Personal Statement

I am Assistant Professor in the Department of Radiation Oncology at the University of Kansas Medical Center, an NCI designated Cancer Center, and my responsibilities include a subspecialty clinical practice in head and neck cancer. I serve as the Associate residency program director and direct student electives and research activities within our department. My clinical and research activities are focused on improving patient outcomes through novel radiation technologies, investigating combinations of radiation with systemic therapy, and reducing late toxicities of radiation and understanding their underlying mechanisms.

I co-chair our head and neck disease working group and participate actively in clinical trials through our national group, the Radiation Therapy Oncology Group (RTOG), which is now a member of NRG Oncology. My department was the top academic accruer to RTOG clinical trials in 2014, and I was the top enroller within my department. I have also served as institutional PI on pharmaceutical-sponsored trial. I have published on re-irradiation of head and neck cancers and novel radiation technologies (stereotactic radiosurgery and stereotactic body radiation therapy. The current Cummings Otolaryngology, the premier textbook of head and neck surgery, contains my chapter on radiation techniques for larynx cancer.

I collaborate with basic and translational scientists at the University of Kansas Medical Center, working on clinical manifestations of lymphedema and fibrosis after radiotherapy and head and neck cancer, as well as with the University of Missouri Kansas City, where I am a co-investigator on a grant elucidating the mechanisms of radiation induced dental disease.

B. Positions and Honors

Positions and Employment:

2010 – Present Assistant Professor, Department of Radiation Oncology, University of Kansas Medical Center, Kansas City, Kansas

2014 – Present Adjunct Faculty Member, Department of Hearing and Speech, University of Kansas Medical Center, Kansas City, Kansas

Other Professional Experience:

2011 – Present Director of Student Research and Electives, Department of Radiation Oncology, University of Kansas Medical Center, Kansas City, Kansas

2013 – Present Associate Residency Program Director, Department of Radiation Oncology, University of Kansas Medical Center, Kansas City, Kansas

Professional Memberships:

2005 – Present	Member, American Society of Radiation Oncology
2013	Ad hoc reviewer, Journal of Gastrointestinal Oncology
2015	Reviewer, Ladies Auxiliary VFW Postdoctoral Cancer Research Fellowship

Honors and Awards:

1998	Undergraduate Research Award, University of Kansas, Lawrence, KS
2002	Simon Rifkind Fellow, Center for the Study of Society and Medicine, Columbia University, New York, NY
2009	Radiation Research Society Scholars-In-Training Travel Award
2012	Highest enrollment of patients on clinical trials, Department of Radiation Oncology, University of Kansas Medical Center
2014	Highest enrollment of patients on clinical trials, Department of Radiation Oncology, University of Kansas Medical Center

C. Contribution to science

1) Although radiation provides curative therapy for many patients with head and neck cancers, older treatment techniques expose large volumes of normal tissue to radiotherapy with the potential for late side effects. Treatment options for recurrent disease are limited. Utilizing novel radiotherapy techniques in head and neck cancer. I have explored the potential novel radiotherapy techniques for patients with head and neck cancer including the use of stereotactic body radiation therapy (SBRT), a technology that reduces treatment duration and dose to normal tissues. I have investigated these techniques for patients with recurrent cancers and with radiation resistant histologies.

a) Unger K, **Lominska CE**, Deeken J, Davidson B, Newkirk K, Gagnon G, Hwang J, Slack R, Noone A, Harter KW. Fractionated Stereotactic Radiosurgery for Reirradiation of Head and Neck Cancer. Int J Radiat Oncol Biol Phys. 2010 Aug 1:77(5):1411-9. PMID: 20056341 (PMC# not required; not NIH funded)
b) Karam SD, Snider JW, Wang H, Wooster M, **Lominska CE**, Deeken J, Newkirk K, Davidson B, Harter KW. Survival outcomes of patients treated with hypofractionated stereotactic body radiation therapy for parotid gland tumors: a retrospective analysis. Front Oncol. 2:55, May 2012. PMC3364484
c) Karam SD, Snider JW, Wang H, Wooster M, **Lominska CE**, Deeken J, Newkirk K, Davidson B, Harter KW. Reirradiation of recurrent salivary gland malignancies with fractionated stereotactic body radiation therapy. J Radiat Oncol. 2012 Jun; 1(2):147-153. PMC3573714
d) Pokhrel D, McClinton C, Sood S, Badkul R, Saleh H, Jiang H, **Lominska C**. Monte Carlo evaluation of tissue heterogeneities corrections in the treatment of head and neck cancer patients using stereotactic radiotherapy. J Appl Clin Med Phys. 2016 Mar 8;17 (2): 6055. PMID: 27074489 (PMC# not required; not NIH funded)

2) In addition to novel applications of radiotherapy technology, I am interested in understanding the mechanisms and reducing the late toxicities of treatment. Application of radiotherapy to the head and neck is associated with long term side effects which include damage to the pharynx and larynx (aspiration and feeding tube dependence), tooth decay and gum disease, and lymphedema and fibrosis of the soft tissues of the neck and face. My work on lymphedema and lymphedema therapy after radiotherapy for head and neck cancers has been presented at national meetings and I am collaborating with other investigators to characterize the links between radiotherapy, lymphedema and fibrosis, as well as the potential mechanisms ability of fibroblasts associated with radiation induced fibrosis to increase risk of cancer relapse. I am also collaborating with dental investigators to characterize the mechanisms underlying radiotherapy effects on the dentition. I am a co-investigator on an NIH funded RO1 on this project.

a. **Lominska CE**, Kumar P. Radiation Therapy for the Larynx and Hypopharynx. In Cummings CW et al: Otolaryngology-Head and Neck Surgery, 6th edition. Philadelphia, Elsevier, Volume 2, Chapter 111, pp. 1714-1731, 2015. (not NIH funded)
b. K. Doke, L. Bowman, Y. Shnayder, P. Neupane, H. Yeh, L. Brown, C. **Lominska CE**. Lymphedema Therapy Improves Neck Circumference, Range of Motion and Pain Scores in Head and Neck Radiotherapy

Patients. Presented at: 56th Annual American Society of Therapeutic Radiation Oncology Meeting; 2014 Sept. 14-17; San Francisco, CA. (not NIH funded)

c. Straub JM, New J, Hamilton CD, **Lominska C**, Shnayder Y, Thomas SM. Radiation-induced fibrosis: mechanisms and implications for therapy. J Cancer Res Clin Oncol. 2015 Nov;141(11):1985-94. PMC4573901

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/chris.lominska.1/bibliography/48151535/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support:

R01 DE021462 (PI: Walker, M.) 09/01/2015 - 08/31/2020
University of Missouri Kansas City (NIH)
Understanding the Mechanism of Radiotherapy-Induced Dentition Breakdown
The proposed study outcomes should identify mechanism(s) responsible for the radiotherapy effects on the dentition and the altered structure/function characteristic of radiated teeth leading to improved preventive and restorative treatments for oral cancer-patents post-radiation.
Role: Co-investigator

Completed Research Support:

RSNA President's Circle Research Resident Grant (PI: Lominska) 07/01/2009 – 06/30/2010
An investigation of EphB1 as a mediator of the AT phenotype
Investigating new molecular mediators of the Ataxia-Telangiectasia (AT) syndrome causing radiation sensitivity and abnormal brain development

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Rashna Madan, M.B.B.S.**

eRA COMMONS USER NAME (credential, e.g., agency login): rmadan

POSITION TITLE: Associate Professor; Assistant Director Biospecimen Repository Core Facility

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Kasturba Medical College, India	M.B.B.S.	1997	Medicine
Montefiore Medical Center/Albert Einstein College of Medicine, Bronx, NY	Residency	2005	Pathology; Neuropathology
Memorial Sloan-Kettering Cancer Center, New York, NY	Fellowship	2008	Oncologic Pathology
Montefiore Medical Center/Albert Einstein College of Medicine, Bronx, NY	Fellowship	2008	Cytopathology

A. Personal Statement

I am an American Board of Pathology certified anatomic and cytopathologist who has been practicing at Kansas University Medical Center for over 6 years where I provide clinically relevant, up-to-date and accurate diagnoses in keeping with the current contributions of molecular research to pathology. I received my pathology training at Montefiore Medical Center/Albert Einstein College of Medicine, Bronx, New York where I earned the Outstanding House Officer in 2005, a very rare distinction for pathology residents. I also trained in Oncologic Pathology at Memorial Sloan-Kettering Cancer Center, New York, New York where I gained broad experience in diagnosing diverse neoplasms and was exposed to intensive biobanking practices. At the University of Kansas Medical Center in addition to my clinical and teaching responsibilities (I am the director of the Post-Sophomore fellowship in pathology and a member of Resident Education Committee), I was appointed Assistant Director of the Biospecimen Repository Core Facility (BRCF) in 2011. I provide diagnostic and administrative skills, supporting the efforts of the BRCF director, Andrew Godwin Ph.D, in expanding and transforming the BRCF. Our Biorepository has contributed to The Cancer Genome Atlas (TCGA). Additionally, I am the representative pathologist for the weekly multidisciplinary pulmonary and gastrointestinal tumor boards.

Throughout my career I have been involved in several clinical and translational research projects both in a primary as well as contributory role (please see URL provided for My Bibliography for a complete list). I will provide comprehensive pathology support for this initiative as well.

B. Positions and Honors

Positions and Employment:

2007-2013 Assistant Professor, Department of Pathology, University of Kansas Medical Center (KUMC), Kansas City, Kansas
2013-present Associate Professor, Department of Pathology, KUMC, Kansas City, Kansas
2008-present Director of Post-Sophomore Year Fellowship, Department of Pathology, KUMC, Kansas City, Kansas
2011-present Assistant Director, Biospecimen Repository Core Facility, University of Kansas Cancer Center, KUMC, Kansas City, Kansas

Certifications:

2000 Educational Commission for Foreign Medical Graduates
2005 Diplomate, American Board of Pathology, Anatomic Pathology/Clinical Pathology

2007 Diplomate, American Board of Pathology Subspecialty in Cytology

Honors and Awards:

2005 Outstanding House Officer - Montefiore Medical Center, Bronx, New York
2005 Outstanding Achievement in the Teaching of Medical Students – Leo M. Davidoff Society, Albert Einstein College of Medicine of Yeshiva University, Bronx, New York

C. Contributions to Science:

Given my interest in oncologic pathology I have been involved in several translational and clinical research projects where I have provided diagnostic support for tumor identification and categorization as well as tissue microarray construction and immunohistochemical evaluation. Some of these have been in the following areas:

1. **Ovarian carcinomas:**

   a) Zhang X, Cheng L, Minn K, **Madan R**, Godwin AK, et al. Targeting of mutant p53-induced FoxM1 with thiostrepton induces cytotoxicity and enhances carboplatin sensitivity in cancer cells. Oncotarget. 2014; 5(22):11365-80. PMCID: PMC4294351

   b) Sethi G, Kwon Y, Burkhalter RJ, Pathak HB, **Madan R**, et al. PTN signaling: Components and mechanistic insights in human ovarian cancer. Molecular carcinogenesis. PMCID: PMC4456343

2. **Breast carcinomas:**

   a) **Madan R**, Smolkin MB, Cocker R, Fayyad R, Oktay MH. Focal adhesion proteins as markers of malignant transformation and prognostic indicators in breast carcinoma. Hum Pathol. 2006 Jan; 37(1):9-15. PMID: 16360410

   b) O'Neil M, **Madan R**, Tawfik OW, Thomas PA, Fan F. Lobular carcinoma in situ/atypical lobular hyperplasia on breast needle biopsies: does it warrant surgical excisional biopsy? A study of 27 cases. Ann Diagn Pathol. 2010 Aug;14(4):251-5. PMID: 20637429, not NIH funded.

   c) St. Romain PE, **Madan R**, Tawfik OW, Damjanov I, Fan F. Organotropism and Prognostic Marker Discordance in Distant Metastases of Breast Carcinoma: Fact or Fiction? A Clinicopathologic Analysis. Hum Pathol. 2012 Mar;43(3):398-404. PMID: 21840040, not NIH funded.

   d) Shatat L, Gloyeske N, **Madan R**, Tawfik O, Fan F. Microinvasive breast carcinoma carries an excellent prognosis regardless of the tumor characteristics. Hum Pathol. 2013 Dec;44(12):2684-9. PMID: 24071019, not NIH funded.

3. **Book Chapters:**
   a) **Madan R**. Chapter 4 - The Digestive System. St. Romain P, Madan R, Damjanov I. Chapter 2 – The Respiratory System. Madan R, Damjanov I. Chapter 6 – Pancreas. In the Atlas of Histopathology, Damjanov I, JayPee (JP) Medical Publishers 2011.
   b) **Madan R**. Chapter 7 – Thyroid. In Cytopathology Review, Fan F and Damjanov I, JayPee (JP) Medical Publishers 2012.
   c) Baranda J, **Madan R**, Godwin AK. Chapter 9 - Gastrointestinal Stromal Tumors (GISTs): From Molecular Pathogenesis To Therapy. In the Handbook of Therapeutic Biomarkers in Cancer (edited by G. Patrinos and W. Ansorge), Pan Stanford Publishing, 2013.

Complete List of Published Work in "my bibliography" can be found in this link:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1hQWyGISRSvQv/bibliograpahy/48156308/public/?sort=date&direction=descending

D. Research Support

Ongoing Support:

P30 CA168524 Jensen (PI) 07/11/2012 - 06/30/2017
NCI
Cancer Center Support Grant
Biospecimen Shared Resource as part of the Cancer Center Support Grant at The University of Kansas Medical Center
The University of Kansas Cancer Center is a growing matrix organization that aims to leverage unique scientific assets to build a nationally significant cancer research and treatment center that will become the leading academic institution in the world for transforming discoveries in the laboratory into new therapeutic approaches.
Role: Assistant Director of the BSR/BRCF

Completed Research Support:

No number Tawfik (PI) 04/01/2010 – 03/31/2011
Institute for Advancing Medical Innovation (IAMI)
Evaluation of the Potential Impact of Telecytology [Tele"PAP"ologyTM] of Cell Block Preparations from Pap Smears
To evaluate the feasibility of evaluating cell blocks from Pap smears for the detection of precancerous and cancerous lesions of the cervix using imaging technology to overcome current limitations with digitizing cytologic specimens.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Jonathan D. Mahnken, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): jmahnken

POSITION TITLE: Associate Professor of Biostatistics

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Concordia University, NE	B.A.	05/1996	Mathematics
University of Nebraska, Lincoln, NE			Biometry
University of Texas Medical Branch, Galveston, TX	M.S.	05/2000	Preventive Medicine
University of Texas - Health Science Center, Houston, TX	Ph.D.	12/2003	Biometry

A. Personal Statement

I have special interest and expertise in study design and data analysis. I am an Accredited Professional Statistician™ (PStat®), having received this accreditation from the American Statistical Association in 2010. I also have experience leading statistical and data management personnel. For example, I am the Director of the Data Management and Statistics Core for The University of Kansas Alzheimer's Disease Center (KU ADC). My role as Co-Investigator on this project is to provide statistical support for cancer and cancer-related projects. I have provided this type of support for many investigators at my institution, and have provided significant input into the design of many studies, in particular studies which have been funded by the NIH, and helped draft and edit the text describing the statistical analysis plans and statistical analyses performed for published studies. I have been a faculty biostatistician at The University of Kansas Medical Center since 2004, I have gained years of collaborative experience with basic, clinical, translational, and epidemiologic investigators. A subset of my publications relevant to my contributions as a statistical scientist on this proposal is listed below.

1. **Mahnken JD**: "Power and Sample Size Calculations for Models from Unknown Distributions Using Quasi-likelihood Methods." *Statistics in Biopharmaceutical Research*. 1(3):328-336, 2009. Not NIH funded.
2. Ambrosius W, **Mahnken JD**: "Power for Studies with Random Group Sizes." *Statistics in Medicine*. 29:1137-1144, 2010. PMCID: PMC2936967.
3. Vidoni ED, Mattlage A, **Mahnken J**, Burns JM, McDonough J, Billinger SA: "Validity of the Step Test for Exercise Prescription: No Extension to a Larger Age Range." *Journal of Aging and Physical Activity*. 21:444-454, 2013. Not NIH funded.
4. **Mahnken JD**, He J, Yeh HW, Nazir N, Jianas LL, Engelman KK: "Survival Analysis Applied to Proportion Data: Comparing Mammography Visits in High and Low Repeat Rate Facilities." *Health Services and Outcomes Research Methodology*. 13(1):68-83, 2013. Not NIH funded.

B. Positions and Honors

Positions and Employment:

2000-2001 Research Assistant, Office of Biostatistics, University of Texas Medical Branch (UTMB), Galveston, Texas
2001-2004 Research Associate, Office of Biostatistics, UTMB, Galveston, Texas
2004-2007 Assistant Professor, Department of Preventive Medicine and Public Health, The University of Kansas Medical Center (KUMC), Kansas City, Kansas

2007-2010	Assistant Professor, Department of Biostatistics, KUMC, Kansas City, Kansas
2008-2010	Scientific Director, Biostatistics and Informatics Shared Resource, The University of Kansas Cancer Center
2010-Present	Associate Professor with tenure, Department of Biostatistics, KUMC, Kansas City, Kansas
2011-Present	Director, Data Management and Statistics Core, The University of Kansas Alzheimer's Disease Center

Other Experience and Professional Memberships:

1999-Present	Member, American Statistical Association
2003-Present	Member, International Biometric Society Eastern North American Region
2004-Present	Chair, MS in Clinical Research program Admissions Committee, KUMC
2004-2009	Assistant Director, MS in Clinical Research program Executive Committee, KUMC
2005-Present	Member, Kansas Masonic Cancer Research Institute, KUMC
2006-2008	Member, Protocol Review and Monitoring Committee, University of Kansas Cancer Center
2006-2012, 2015	Clinical and Integrative Cardiovascular Science Study Section, NIH (3/06, 7/06, 2/07, 10/07, 02/09, 02/10, 02/12, 10/12, 02/15, 06/15)
2006-2008	Special Emphasis Panels and Study Sections, NIDCR, NIH (11/06, 5/07, 8/07, 10/07, 2/08, 3/08, 3/08, 3/08)
2008-2010	Member, Data Safety and Monitoring Board, The University of Kansas Cancer Center
2008	Special Emphasis Panel, Clinical Hematology, NIH (10/08)
2009	Special Emphasis Panel, NINR, NIH (02/09)
2010, 2014	Developmental Therapeutics Study Section, NIH (09/10, 03/14)
2010-2016	Accredited Professional Statistician™ (PStat®), American Statistical Association
2011-Present	Member, Executive Committee, The University of Kansas Alzheimer's Disease Center
2011-2014	Scientific Review Committee, National Alzheimer's Coordinating Center
2013, 2015, 2016	Biobehavioral and Behavioral Processes Integrated Review Group, NIH (02/13, 11/13, 03/15, 03/16)
2015	Special Emphasis Panel, NIDDK, NIH (11/15)

Honors:

2004	Delta Omega Honorary Society in Public Health
2005-2010	National Institutes of Health Loan Repayment Project Award
2006	Kansas Masonic Cancer Research Institute Pilot Award, KUMC
2007	Excellence in Public Health Teaching Award, MPH Program, KUMC
2008, 2009	Faculty Domestic Travel Award

C. Contribution to Science

1. I have statistical research interests focused in two areas: 1) study design, including power and sample size calculations; and 2) maximum likelihood estimation for censored data. Reviewing and designing studies requiring covariate adjustment motivated me to develop a new method for calculating power for data when the underlying distribution is not known. Not knowing the true underlying distribution is a common problem for calculating power and sample size, and often covariate adjustment may be required in the planned statistical protocol. My method, which allows for covariate adjustment, presents a generalizable tool for use in the justification or determination of study sample sizes. Other work in this area of statistics includes my collaborative work for determining the optimal sample size for phase II studies with multiple constraints. Though not a first author, my contribution to this manuscript was substantial, including the development of all lemmas in the appendix and writing the code for all of the programs in SAS. The effort that I led to develop a milestone algorithm for a large U54 cooperative agreement (funded by the NIH) resulted in a manuscript that also fits within my body of work in study design. Another manuscript published in *Statistics in Medicine* presents methods for calculating power for designs with random group sizes.

a) **Mahnken JD**: "Power and Sample Size Calculations for Models from Unknown Distributions Using Quasi-likelihood Methods." *Statistics in Biopharmaceutical Research*. 1(3):328-336, 2009. Not NIH funded.

b) Mayo MS, **Mahnken JD**, Soong S: "Optimal Designs for Two-Arm, Phase II Clinical Trial Design with Multiple Constraints." *Journal of Biopharmaceutical Statistics*. 20(1):106-124, 2010. PMID: 20077252, Not NIH funded.
c) **Mahnken JD**, Mayo MS, Nudo RJ: "A Decision Algorithm for Translating Preclinical Trial Results to Enhance Recovery after Stroke." *Journal of Biopharmaceutical Statistics*, 19(1):204-216, 2009. PMCID: PMC2700836.
d) Ambrosius W, **Mahnken JD**: "Power for Studies with Random Group Sizes." *Statistics in Medicine*. 29:1137-1144, 2010. PMCID: PMC2936967.

2. In my other focus area, analyzing censored data, I have extended the traditional maximum likelihood techniques for univariate survival data and have applied this approach in public health research involving screening data (i.e., screening mammography for breast cancer). This work has been published in *Statistical Methods in Medical Research*. I am also lead author on a manuscript analyzing censored proportions as part of my collaborative effort on a grant funded by the American Cancer Society.

a) **Mahnken JD**, Chan W, Freeman DH, Freeman JL: "Reducing the Effects of Lead-Time Bias, Length Bias, and Over-Detection in Evaluating Screening Mammography: A Censored Bivariate Data Approach." *Statistical Methods in Medical Research*, 17:643-663, 2008. PMID: 18445697.
b) **Mahnken JD**, He J, Yeh HW, Nazir N, Jianas LL, Engelman KK: "Survival Analysis Applied to Proportion Data: Comparing Mammography Visits in High and Low Repeat Rate Facilities." *Health Services and Outcomes Research Methodology*. 13(1):68-83, 2013. Not NIH funded.

3. On a more applied level, I have research interests and expertise in secondary data analysis. My pilot award from the Kansas Masonic Cancer Research Institute and my R03 (NIH/NIDCR) allowed me to evaluate the utility of using Medicare claims to identify incident oral and pharyngeal cancer cases. These efforts have led to the following publications.

a) **Mahnken JD**, Keighley JD, Cumming CG, Girod DA, Mayo MS: "Evaluating the Completeness of the SEER-Medicare Linked Database for Oral and Pharyngeal Cancer." *Journal of Registry Management*, 35(4):145-148, 2008. PMCID: PMC2950706.
b) **Mahnken JD**, Keighley JD, Girod DA, Chen X, Mayo MS: "Identifying Incident Oral and Pharyngeal Cancer Cases Using Medicare Claims." *BMC Oral Health*. 13:1 (9 pages), 2013. PMID: 23280327, PMCID: PMC3538504.

4. Beyond my own research interests, I am currently a co-investigator on large, externally funded grants from the NIH. This includes my role as Director of the Data Management and Statistics Core for The University of Kansas Alzheimer's Disease Center. My contributions to the research at this institution include grant development, study design, data analysis, interpretation of the results, and dissemination of the study findings to the scientific community. This role as biostatistical collaborator was to be the primary focus of my hire as Assistant Professor back in 2004, and remains my primary role as a faculty biostatistician today. Since joining the faculty at KUMC, I have aided in the development and attainment of numerous large-scale grant and contract applications. I believe the importance of my role as a collaborating scientist has been valued by many of the investigators with whom I work, as evidenced by my position as second and as senior author on numerous manuscripts derived from our collaborations. Examples of biomedical research journals in which I have collaborative publications includes *Annals of Internal Medicine*, *Medical Care*, *Chest*, *Cancer*, *American Journal of Kidney Diseases*, *Kidney International*, *Journal of the American Geriatric Society*, *Annals of Epidemiology*, *Journal of the American Society of Nephrology*, *Clinical Journal of the American Society of Nephrology*, and *Proceedings of the National Academy of Sciences*. Four of these publications are listed below.

a) Guggenmos DJ, Azin M, Barbay S, **Mahnken JD**, Dunham C, Mohseni P, Nudo RJ: "Restoration of Function after Brain Damage Using a Neural Prosthesis." *Proceedings of the National Academy of Sciences of the U.S.A*. 110(52):21177-21182, 2013. PMCID: PMC3876197.
b) Ellerbeck EF, **Mahnken JD**, Cupertino AP, Sanderson Cox L, Greiner KA, Mussulman LM, Nazir N, Shireman T, Resnicow K, Ahluwalia JS: "Effect of Varying Levels of Disease Management on Smoking Cessation: A Randomized Trial." *Annals of Internal Medicine*, 150(7):437-446, 2009. PMCID: PMC2825176.
c) Wetmore JB, Ellerbeck EF, **Mahnken JD**, Phadnis M, Rigler SK, Spertus JA, Zhou X, Mukhopadhyay P, Shireman TI: "Stroke and the 'Stroke Belt' in Dialysis: Contribution of Patient Characteristics to

Ischemic Stroke Rate and Its Geographic Variation." *Journal of the American Society of Nephrology*. 24(12):2053-2061, 2013. PMCID: PMC3839545.

d) Shireman TI, **Mahnken JD**, Howard PA, Kresowik TF, Ellerbeck EF, Hou Q: "Development of a Contemporary Bleeding Risk Model for Elderly Warfarin Recipients." *Chest*, 130(5):1390-1396, 2006.

Complete List of Published Work can be found in this link:
https://scholar.google.com/citations?user=5aWyyU8AAAAJ&hl=en&oi=ao

D. Research Support

Ongoing Research Support:

P30 CA168524 Jensen (PI) 07/11/2012 - 06/30/2017
NIH/NCI
Cancer Center Support Grant
The University of Kansas Cancer Center is a growing matrix organization that aims to leverage unique scientific assets to build a nationally significant cancer research and treatment center that will become the leading academic institution in the world for transforming discoveries in the laboratory into new therapeutic approaches.
Role: Statistician

P30 AG035982 Swerdlow (PI) 08/15/2011-06/30/2017
NIH/NIA
University of Kansas Alzheimer's Disease Core Center
The purpose of this center is to provide well-organized cores resources to advance the knowledge of Alzheimer's disease and aging.
Role: Core Leader

U01 AG016976 Swerdlow (sub-contract PI) 07/01/2011 - 06/30/2019
University of Washington (NIH)
National Alzheimer's Coordinating Center (NACC)
The purpose of this sub-contract is to continue to provide to NACC designated common data which form the basic level of participation required of all NIA-funded Alzheimer's Disease Centers.
Role: Sub-contract Core Leader, Data Management and Statistics Core

R01 AG043962 Burns (PI) 07/01/2013-06/30/2018
NIH/NIA
Effect of Aerobic Exercise on Alzheimer's Pathophysiology in Preclinical AD
The major goal of this research is to assess the effect of exercising on preclinical Alzheimer's Disease using an exercise intervention program.
Role: Co-Investigator

Completed Research Support:

No Number Aljitawi (PI) 10/01/2013-09/30/2015
SWOG
Exploring the Use of Hyperbaric Oxygen in Umbilical Cord Blood Transplantation
The purpose of this trial is to assess the safety of the use of hyperbaric oxygen treatment prior to umbilical cord blood transplantation.
Role: Biostatistician

R03 TW008723 Cupertino and Richter (PIs) 07/01/2010-06/30/2013
NIH
Optimizing Treatment for Brazilian Smokers through Community-based Primary Care

The purpose of this project is to enhance access to tobacco treatment for Brazilian smokers and build a research collaboration between the U.S. and Brazil.
Role: Collaborator/Guest Faculty at the Universidade Federal de Juiz de Fora

R01 AG033673 Burns (PI) 02/01/2010-01/31/2013
NIH/NIA
Aerobic Fitness in Slowing the Progression of Alzheimer's Disease
The major goal of this research is to assess the effect of exercising on Alzheimer's Disease using an exercise intervention program.
Role: Co-Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Sally L. Maliski, RN. PhD, FAAN**

eRA COMMONS USER NAME (credential, e.g., agency login): Maliski2

POSITION TITLE: Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Sate University of New York, Albany, NY	BS	05/1976	Nursing
Russell Sage College, Troy, NY	MS	05/1980	Nursing
University of North Carolina at Chapel Hill, Chapel Hill, NC	PhD	12/1997	Nursing
University of California at Los Angeles, Los Angeles, CA			Quality of Life Postdoctoral Fellowship

A. Personal Statement

I have over 15 years of experience conducting research with underserved men treated for prostate cancer and their families. My work has also included playing a key role in the development of the nurse case manage model for IMPACT (Improving Access, Counseling and Treatment for Californians with prostate cancer), a program that provides free prostate cancer treatment for uninsured men with incomes under 200% FPL. Our work has centered on quality of life and cancer treatment-related symptom management among underserved populations. I have been PI of 2 Department of Defense funded studies and 3 NIH funded studies. Clinically, I was a patient care coordinator for a hospice in upstate New York. Additionally, I have a strong academic administrative background, previously as Associate Director for Academic and Student Affairs and now as Dean. Thus, I bring to this position a solid background of research among underserved populations and a strong commitment to improving cancer screening, treatment, survivorship, and palliative care to reduce cancer-related health disparities.

B. Positions and Honors

Positions and Employment

1976-1980 Staff and Head Nurse, Veterans Administration Medical Center, Albany, NY
1979-1984 91C Medical Corpsmen Course Director, Army Reserve Nurse Corps, 364th General Hospital, Albany NY
1980-1981 Assistant Professor, Columbia Memorial Hospital School of Nursing, Hudson, NY
1981-1985 Patient Care Coordinator, Hospice of Schenectady, Schenectady, NY
1985-1987 Assistant Professor, Columbia Memorial Hospital School of Nursing, Hudson, NY
1987-1988 Co-Owner, Health Care Review Associates, Schodack Landing, NY
1989-1996 Research Assistant, University of North Carolina, Chapel Hill, NC
1996-1997 Instructor, University of North Carolina, Greensboro, NC
1997 Assistant Professor, Rutgers University, Newark, NJ
1998-1999 Research Associate, University of Pennsylvania, Philadelphia, PA

2001-2004 Assistant Researcher, University of California, Los Angeles, CA
2004-2011 Clinic Coordinator, Westminster Free Clinic, Thousand Oaks, CA
2005-2011 Assistant Professor, University of California, Los Angeles, CA
2011-2016 Associate Professor, University of California School of Nursing and David Geffen School of Medicine, Department of Urology, Los Angeles, CA
2012-2016 Associate Dean for Academic and Student Affairs, University of California, Los Angeles, CA
2016-present Dean and Professor, University of Kansas Medical Center School of Nursing, Kansas City, KS
2016-present Associate Director, Population Health and Health Disparities, University of Kansas Cancer Center, Kansas City, KS

Other Experience and Professional Memberships

1976-present Sigma Theta Tau
1980-present Oncology Nursing Society
2003-2004 Prostate Cancer Workgroup Member, California Dialogue on Cancer
2003 Reviewer, ONS/Schering Excellence in Cancer Nursing Award
2003-present Peer reviewer, Nursing Research, Patient Education and Counseling, Psycho-Oncology, Supportive Care in Cancer, Cancer Nursing, European Journal of Clinical Care, Health Risk and Society, and Oncology Nursing Forum
2004 Reviewer, 8th National Conference on Cancer Nursing Research
2004-2005 ONS National Survey Project Team on Nursing Research Priorities
2006-2009 Reviewer, ONS Small Grants Program
2007-2009 Member, APHA
2008-2009 Reviewer: Oncology Nursing Society Foundation Small Grants Program, NIHR Innovation Grant, Social Sciences and Humanities Research Council of Canada Grant
2009-present Member, Board of Directions for California IMPACT program
2011 Ad Hoc reviewer Department of Defense Prostate Cancer Research Program
2011 External Reviewer, University of Colorado, College of Nursing
2011 Member, Yale-China Association
2016 Member, University of Kansas Hospital Authority Board of Directors

Honors

1987-1989 Merit Assistantship, University of Nursing Carolina, Chapel Hill
2001 Recipient, ONS/Schering Excellence in Cancer Nursing Research Award
2005 Nominee, ONS/Schering Excellence in Cancer Nursing Research Award
2010 Fellow in the American Academy of Nursing
2014 Daisy Award Educator recipient

C. Contribution to Science

1. **I have over 15 years of experience conducting research with underserved men treated for prostate cancer and their families.** My work has also included playing a key role in the development of the nurse case management model for IMPACT (Improving Access, Counseling and Treatment for Californians with prostate cancer), a program that provides free prostate cancer treatment for uninsured men with incomes under 200% FPL.

   a) Maliski SL, Husain M, Connor SE, Litwin MS. Alliance of support for low-income Latino men with prostate cancer: God, doctor, and self. Journal of religion and health. 2012;51(3):752-62. doi: 10.1007/s10943-010- 9369-0. PMID: 20625832; PMCID: PMC3444699

   b) Oduro C, Connor SE, Litwin MS, Maliski SL. Barriers to prostate cancer care: affordable care is not enough. Qualitative health research. 2013;23(3):375-84. doi: 10.1177/1049732312467852. PMID: 23202482. Not NIH funded.

c) Sevilla C, Maliski SL, Kwan L, Connor SE, Litwin MS. Long-term quality of life in disadvantaged men with prostate cancer on androgen-deprivation therapy. Prostate cancer and prostatic diseases. 2012;15(3):237-43. doi: 10.1038/pcan.2011.71. PMID: 22289781. Not NIH funded.

d) Maliski SL, Connor SE, Litwin MS. Purposeful interaction: ways Latino men communicate about prostate cancer. Oncology nursing forum. 2012;39(6):603-8. doi: 10.1188/12.ONF.603-608. PMID: 23107854, PMCID: PMC3686632.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/sally.maliski.1/bibliography/44072472/public/?sort=date&direction=descending

D. Research Support

Ongoing Support:

R01NR014518 Maliski (PI) 9/23/2014-7/31/2019
NIH/NINR
Staying Strong and Healthy during Androgen Deprivation Therapy for Latino Men
This mixed methods study will compare cardiovascular and metabolic risk measures, HRQOL, and depression among Latino men receiving the Stay Strong and Health intervention with men in a usual care with attention group within and between groups. A subsample with be interviewed with transcripts being analyzed using grounded theory techniques to develop explanatory models of decision-making relative to nutrition and activity in the intervention and usual care groups for comparison of process and perceptions of the intervention.

Completed Support:

R21NR2786 Maliski (PI) 6/1/2011-5/31/2013
NIH/NINR
Underserved Men's Understanding of Androgen Deprivation Therapy Related Risks
This qualitative study will develop an explanatory framework for processes used by Latino men to understand and manage androgen deprivation therapy symptoms and risks.

No Number Maliski (PI) 5/1/2011-4/30/2014
UCLA School of Nursing Intramural Grant
Staying Strong and Healthy
This pilot study is testing a nurse-directed telephone-based intervention to minimize the cardiovascular risks associated with androgen deprivation therapy among Latino men.

R21NR010383 Maliski (PI) 9/26/2008-9/25/2011
NIH/NINR
Prostate Cancer Clinical Decision-Making by Diagnosed and High Risk Latino Men
This study focuses on Mexican/Mexican American men. Using qualitative methods we seek to understand prostate cancer treatment, disclosure, and screening decision processes from the perspectives of Mexican/Mexican-American men who have made prostate cancer treatment and disclosure decisions and high risk brothers and sons of Mexican/Mexican-American men who are deciding on screening.

PC060612 Maliski (PI) 1/1/2007-12/31/2010
DoD
The Impact of Prostate Cancer Treatment-Related Symptoms on Low-Income Latino Couples.
Given the dearth of research on the effect of prostate cancer and its treatment on low-income Latino couples, the purpose of this study is to describe, using mixed qualitative and quantitative methods, the experience and impact on the relationship of prostate cancer treatment-related symptoms from the perspective of low-income Latino men and their partners.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Joshua Mammen, MD, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): jmammen13

POSITION TITLE: Associate Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Boston University, Boston, MA	B.A.	1995	Biology/Chemistry
Boston University, Boston, MA	M.D.	1999	Biology/Chemistry
University of Cincinnati, Cincinnati, OH	M.B.A.	2005	Management and Marketing
University of Cincinnati, Cincinnati, OH	Residency	2007	General Surgery
University of Texas MD Anderson Cancer Center, Houston, TX	Fellowship	2009	Surgical Oncology
University of Cincinnati, Cincinnati, OH	Ph.D.	2009	Molecular and Cellular Physiology

A. Personal Statement

I am a Surgeon-Scientist with interests in understanding mechanisms of malignancy and therapeutic targeting. Clinically, I specialize in surgical oncology. My training has been in Gastrointestinal, Pancreatic, Melanoma and Breast cancers. My current areas of interest include colorectal, melanoma, breast cancer, and sarcoma. My overall goal is to create a responsive and collaborative environment to partner with patients to treat their malignancy. While at the University of Cincinnati, I trained under Dr. Jeffrey Matthews. My research involved determining the role of PKC isoforms in ischemic injury in the gut. I moved to University of Kansas in part because at the time of my move, Dr. Anant was being recruited to the University as the Associate Director for the Cancer Center and Associate Dean for Research in the School of Medicine. Within 6 months of his joining the university, I knew I had made the perfect decision related to my scientific career. Dr. Anant has built an excellent program surrounding chemoprevention and honokiol. At the same time, he has been instrumental in identifying the colon cancer stem cells, especially the marker DCLK1, which he first published on in 2007. While others in the field had not jumped in enthusiastically, a recent manuscript and the accompanying editorial in Nature Genetics (Nat Genet. 2012 Dec 16;45(1):98-103. doi: 10.1038/ng.2481. Epub 2012 Dec 2. and 2012 Dec 16;45(1):7-9. doi: 10.1038/ng.2502) has validated the approach of targeting DCLK1. D. Anant continued pushing forward and has been working on identifying compounds that would inhibit DCLK1 kinase activity. Dr. Anant developed an in vitro kinase assay. Using homology modeling he identified honokiol as a compound that can interact with DCLK1. We were independently working on honokiol as an agent that targets melanoma and breast cancers cells, especially stem cells. Since Dr. Anant's arrival, we have been actively collaborating in the project. We have developed or acquired reagents related to various stem cell signaling pathways, including the hippo signaling pathway. I will share these reagents with his group. In addition, I personally spend time working on the bench. I helped Dr. Subramaniam with some of the experiments, and will continue helping the group with their studies. I am also particularly interested in moving the compound forward from the bench to the bed side. In this regard, Dr. Anant, Dr. Michael Baltezor and I have been meeting on a regular basis to develop an oral formulation for delivery into humans. The compound as such has excellent bioavailability, and we do not expect any problems to arise with our formulation. I will actively work to get FSA approval for the compound and also with the IRB to get a protocol accepted for a pilot clinical trial in patients with colorectal and melanoma cancers (to begin with). Upon approval of the protocol with the various agencies/review boards, I will initiate a pilot clinical trial with an aim to prevention, using DCLK1 and hippo signaling proteins as biomarkers.

B. Positions and Honors

Positions and Employment:

2001-2004 Postdoctoral Research Fellowship, Department of Surgery, University of Cincinnati, OH
2005-2007 Clinical Instructor, Department of Surgery, University of Cincinnati, OH
2009-2014 Assistant Professor, Department of Surgery, University of Kansas Medical Center (KUMC), Kansas City, KS
2009-present Assistant Professor, Department of Molecular and Integrative Physiology, KUMC
2010-present Associate Program Director, General Surgery Residency, KUMC
2012-present Vice-Chair for Research for the Department of Surgery, KUMC
2014-present Associate Professor, Department of Surgery, Univ. of Kansas Medical Center, Kansas City, KS
2014-present Division Chief for Surgical Oncology for the Department of Surgery, University of Kansas Medical Center, Kansas City, KS

Medical License # 0433909, State of KS.

Professional Memberships:

2005-present Alpha Omega Alpha
1999-present American College of Surgeons
Governing Council, Young Fellows Association (2013-present)
Resident and Associate Society Executive Committee (RAS) (2005-2011)
Chair of the Resident and Associate Society (2009-2010)
2003-present American Physiological Society
2006-present American Society of Breast Surgeons
2007-present Society of Surgical Oncology
2007-present American Society of Clinical Oncology
2007-present American Association for Cancer Research
2011-present Commission on Cancer
State Chair for Kansas (2011-present)
Education Committee (2013-present)

Honors:

1999 Phi Beta Kappa, Boston University College of Arts and Sciences, Boston, Massachusetts
2003 Jeffrey B. Doane Award (best graduate student as voted on by the faculty), Department of Molecular and Cellular Physiology, University of Cincinnati, Cincinnati, Ohio
2004 First Place, Basic Science, Resident Research Forum, Ohio Chapter of the American College of Surgeons, Columbus, Ohio May
2004 First Place, Clinical Science Division, Ohio Committee on Trauma Resident Essay Contest, Columbus, Ohio
2005 Alpha Omega Alpha, University of Cincinnati College of Medicine, Cincinnati, Ohio
2007 Max Zinniger Award (best resident as voted on by the faculty), Department of Surgery, University of Cincinnati, Cincinnati, Ohio, 2007
2013 Top Doctors (Kansas City's Finest Doctors), 435 South Magazine, January 2013 issue
2014 Central Surgical Association Foundation Enrichment Award
2014 Finalist, Rainbow Teaching Award, University of Kansas

C. Contributions to Science

1. As a faculty member in the Division of Surgical Oncology, my basic science, translational and basic science focus has been on malignancies, mostly breast cancer and melanoma.
   a. Sharma P, Klemp JR, Kimler BF, Mahnken JD, Geier LJ, Khan QJ, Elia M, Connor CS, McGinness MK, **Mammen JM,** Wagner JL, Ward C, Ranallo L, Knight CJ, Stecklein SR, Jensen RA, Fabian CJ, Godwin AK. Germline BRCA mutation evaluation in a prospective triple-negative breast cancer registry: implications for hereditary breast and/or ovarian cancer syndrome testing. Breast Cancer Res Treat. 2014 Jun;145(3):707-14. PMC4171847 Connor CS, Kimler BF, Mammen JM, McGinness MK, Wagner

JL, Alsop SM, Ward C, Fabian CJ, Khan QJ, Sharma P. Impact of neoadjuvant chemotherapy on axillary nodal involvement in patients with clinically node negative triple negative breast cancer. 2015; 111(2):198-202. PMID: 25266871 (PMC# not required; not NIH funded).

b. Kaushik G, Kwatra D, Subramaniam D, Jensen RA, Anant S, Mammen JM. Honokiol affects melanoma cell growth by targeting the AMP-activated protein kinase signaling pathway. Am J Surg. 2014 Oct 2;208(6):995-1002. PMC4433539

c. Kaushik G, Venugopal A, Ramamoorthy P, Standing D, Subramaniam D, Umar S, Jensen RA, Anant S, Mammen JM. Honokiol inhibits melanoma stem cells by targeting notch signaling. Mol Carcinog. 54(12):1710-21. PMC4776032

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1tA8SICq3Yrk4/bibliography/45126197/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support:

No number Mammen (PI) 10/01/2015 – 09/30/2016
Menorah Legacy Foundation
Center of Excellence for Regional Chemotherapy at the University of Kansas
The grant provides funds to establish a Center for Regional Chemotherapy which includes the infrastructure to recruit for clinical trials as well as perform translational research.

Completed Research Support:

No number Mammen (PI) 2014 - 2015
Central Surgical Association Foundation
Targeting Notch in Melanoma Stem Cells
The goal of the study is explore the role of Notch in modulating melanoma stem cell survival with the ultimate goal of reducing the risk of melanoma recurrences.

No Number Mammen (PI) 2009 - 2013
University of Kansas Medical Center
Ischemia/Reperfusion Injury in the Intestine: Important Roles for PKC, MAPK, and Adenosine
The goal of the study is to explore the signaling in intestinal epithelial cells following ischemic insult. In vitro results reveal roles for PKC, MAPKs, and Adenosine. The study moves the research to the *in vivo* setting.

No Number Mammen (PI) 2009 - 2013
University of Kansas Medical Center
The Signaling of Melanoma Cells during Ischemic Limb Perfusion/Infusion
The goal of the study is to explore the signaling in melanoma cells during limb perfusion or isolated limb perfusion, concentrating on the signaling related to ischemia. Both *in vitro* and *in vivo* methods are used.

OMB No. 0925-0001/0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Matthew S. Mayo, PhD, MBA**

eRA COMMONS USER NAME (credential, e.g., agency login): MATTMAYO

POSITION TITLE: Professor and Chair

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Missouri, Columbia, MO	B. A.	1986	Statistics
University of Missouri, Columbia, MO	M. A.	1990	Statistics
University of Alabama, Tuscaloosa, AL	Ph.D.	1995	Applied Statistics
Baker University, Baldwin, KS	M.B.A.	2004	Management

A. Personal Statement

I have two decades of experience in biostatistics and data management in a medical research setting. Much of my collaborative research experience has been in the realm of cancer, cancer prevention, exercise and obesity and smoking cessation. I have created numerous cores/shared resources and have been the Associate Director for Shared Resources for KUCC since 2008. I have worked with KUCC leadership for nearly a decade and will continue to do so. For this application I will oversee the shared resources and represent them at KUCC leadership meetings and work to facilitate their operations, use and evaluate each on an ongoing basis and examine the need for new shared resources.

B. Positions and Honors

Positions and Employment:

1996 – 1998 Research Assistant Professor, Medical Statistics Section, Division of Hematology/Oncology, University of Alabama at Birmingham, Birmingham, AL
1998 – 2008 Director of Biostatistics/Informatics, KU Cancer Center, University of Kansas Medical Center (KUMC), Kansas City, KS
2010 – 2012 Director of Biostatistics/Informatics, KU Cancer Center, University of Kansas Medical Center (KUMC), Kansas City, KS
1998 – 2003 Assistant Professor, Dept. of Preventive Medicine and Public Health, KUMC, Kansas City, KS
2002 – 2005 Director, Medical Statistics and Research Design Unit, Department of Preventive Medicine and Public Health, KUMC, Kansas City, KS
2003 – 2006 Associate Professor, Dept. of Preventive Medicine and Public Health, KUMC, Kansas City, KS
2004 – 2010 Director, Center for Biostatistics and Advanced Informatics, KUMC, Kansas City, KS
2001 – 2006 Director of Clinical Trials Office, Kansas Cancer Institute, KUMC, Kansas City, KS
2004 – 2012 Associate Director, MS in Clinical Research degree program, KUMC, Kansas City, KS
2006 – 2007 Professor, Department of Preventive Medicine and Public Health, KUMC, Kansas City, KS
2007 – pres. Professor and Founding Chair, Department of Biostatistics, KUMC, Kansas City, KS
2008 – pres. Associate Director for Shared Resources, The University of Kansas Cancer Center, KUMC, Kansas City, KS

Honors and Awards:

1999 – 2003 Member, Epidemiology Study Section, State of California Tobacco Related-Diseases Research Program
2000 – 2001 Member, American Association of Cancer Research (AACR) Breast Cancer Subcommittee for the Intraepithelial Neoplasia (IEN) Task Force
2001 Member, Department of Defense Prostate Cancer Research Program

2002 – 2003 Member, R24 Special Emphasis Panel, National Ctr. on Minority Health and Health Disparities
2003 – 2013 Member, SPS3 Data and Safety Monitoring Board, National Institutes of Health
2004 Member, Review Panel, Transdisciplinary Tobacco Use Research Centers, NIH
2004 – 2010 Member, Cancer Biomarkers Study Section, National Institutes of Health
2004 – 2008 Distinguished Faculty Member, School of Breast Oncology
2005 – 2009 Member, CAM314 Data and Safety Monitoring Board, Genzyme
2006 – pres. Member, American Joint Commission on Cancer (AJCC) Statistical Task Force
2007 University of Kansas School of Medicine Excellence in Mentoring Award
2010 – 2012 Member, DMID Protocol Number: 07-0082, Data and Safety Monitoring Board, NIH
2011 Elected Fellow of the American Statistical Association
2011 – 2016 Member, Data Monitoring Committee, "A Phase 2, Placebo Controlled, Double-Blind, Randomized, Clinical Trial to Determine Safety, Tolerability and Efficacy of Pulsed, Inhaled Nitric Oxide (iNO) Versus Placebo as Add-on Therapy in Symptomatic Subjects with Pulmonary Arterial Hypertension [PAH]", INO Therapeutics
2011 – pres. Member, Data and Safety Monitoring Board, "Effect of Exercise and Weight Loss on Cardiovascular Health (Heart Health Study)", NHLBI
2012-1017 PStat® Accreditation, American Statistical Association
2012-2013 President-elect, Association of Clinical and Translational Statisticians
2014-2015 President, Association of Clinical and Translational Statisticians
2016-pres. Immediate past-President, Association of Clinical and Translational Statisticians
2015 – pres. Member, CREST2 DSMB, NINDS

C. Contribution to Science

1. **I have worked with numerous researchers in attaining federal funding for research related to cancer and cancer prevention** that includes basic, clinical and populations-based research and publishing these findings in high impact journals.

   a) Fabian CJ, Kimler BF, Zalles CM, Klemp JR, Kamel S, Zeiger S, and **Mayo MS**: "Short-Term Breast Cancer Prediction by Random Periareolar Fine Needle Aspiration Cytology and the Gail Risk Model". Journal of the National Cancer Institute, 92(15), 1217-1227, 2000.

   b) Fabian CJ, Kimler BF, and **Mayo MS**: "Ductal Lavage for Early Detection – What Doesn't Come Out in the Wash". Journal of the National Cancer Institute, 96(20), 1488-1489, 2004. (Invited Manuscript)

   c) Reed GA, Peterson KS, Smith HJ, Gray JC, Sullivan DK, **Mayo MS**, Crowell JA, and Hurwitz A: "A Phase I Study of Indole-3-carbinol in Women: Tolerability and Effects". Cancer Epidemiology, Biomarkers & Prevention, 14(8), 1953-1960, 2005.

   d) Huang CH, Williamson SK, Van Veldhuizen PJ, Hsueh C-T, Allen A, Tawfik O, Wick J, Smith H, Uypeckcuat AM, **Mayo M**, and Kelly K: "Potential Role of Platelet-Derived Growth Factor Receptor Inhibition Using Imatinib in Combination with Docetaxel in the Treatment of Recurrent Non-small Cell Lung Cancer". Journal of Thoracic Oncology, 6(2), 372-377, 2011. PMID: 21178640, Not NIH funded.

2. **Statistical expertise related to study and clinical trial design.** I have a long track history of federally funded research for which I have been the lead statistician and co-investigator as well as having a track record of statistical methodological research in the areas of experimental and clinical trial design.

   a) **Mayo MS** and Conerly MD: "Evaluating Overall Significance Levels in Multi-Factor ANOVA". Journal of Biopharmaceutical Statistics, 9(1), 129-143, 1999. Not NIH funded.

   b) **Mayo MS** and Gajewski B: "Bayesian Sample Size Calculations in Phase II Clinical Trials Using Informative Conjugate Priors". Controlled Clinical Trials, 25(2), 157-167, 2004. Not NIH funded.

   c) Gajewski BJ and **Mayo MS**: "Bayesian Sample Size Calculations in Phase II Clinical Trials Using a Mixture of Informative Priors". Statistics in Medicine, 25, 2554-2566, 2006. Not NIH funded.

d) **Mayo MS**, Mahnken J and Soong S-J: "Optimal Designs for Two-Arm, Phase II Clinical Trial Design with Multiple Constraints". Journal of Biopharmaceutical Statistics, 20(1), 106-124, 2010. Not NIH funded.

3. **Design and analysis of studies in exercise, nutrition and obesity**. I have worked on numerous studies and aided in the development of numerous federally peer-reviewed funded research projects in this area and publishing these finding in high impact journals.

a) Donnelly JE, Hill JO, Jacobsen DJ, Potteiger J, Sullivan DK, Johnson SL, Heelan K, Hise M, Fennessey PV, Sonko B, Sharp T, Jakicic JM, Blair SN, Tran ZV, **Mayo M**, Gibson C, and Washburn RA: "Effects of a 16-Month Randomized Controlled Exercise Trial on Body Weight and Composition in Young, Overweight Men and Women: the Midwest Exercise Trial." Archives of Internal Medicine, 163(11), 1343-1350, 2003.

b) Donnelly JE, Gibson CA, Smith B, Washburn RA, Sullivan DK, DuBose KD, **Mayo MS**, Schmelzle KH, Ryan JJ, Williams SL, and Jacobsen DJ: "Physical Activity Across the Curriculum (PAAC): A Randomized, Controlled Trial to Promote Physical Activity and Diminish Overweight and Obesity in Elementary School Children". Preventive Medicine, 49(4), 336-341, 2009. PMID: 19665037. PMCID: PMC2766439.

c) Donnelly JE, Honas JJ, Smith BK, **Mayo MS**, Gibson CA, Sullivan DK, Lee J, Herrmann SD, Lambourn K, and Washburn RA: "Aerobic Exercise Alone Results in Clinically Significant Weight Loss for Men and Women: Midwest Exercise Trial 2". Obesity (Silver Spring), 21(3), E219-228, 2013. PMCID: PMC3630467.

d) Donnelly JE, Saunders RR, Saunders M, Washburn RA, Sullivan DK, Gibson CA, Ptomey LT, Goetz JR, Honas JJ, Betts JL, Rondon MR, Smith BK, and **Mayo MS**: "Weight Management for Individuals with Intellectual and Developmental Disabilities: Rationale and Design for an 18 Month Randomized Trial". Contemporary Clinical Trials, 36(1), 116-125, 2013. PMCID: PMC4180227.

4. **Design and analysis of studies in smoking cessation with a focus in minority populations.** I have worked on numerous studies and aided in the development of numerous federally peer-reviewed funded research projects in this area and publishing these finding in high impact journals.

a) Ahluwalia JS, Richter K, **Mayo MS**, Ahluwalia HK, Choi WS, Schmelzle KH, and Resnicow K: "African American Smokers Interested and Eligible for a Smoking Cessation Clinical Trial: Predictors of not Returning for Randomization". Annals of Epidemiology, 12(3), 206-212, 2002.

b) Ahluwalia JS, Harris KJ, Catley D, Okuyemi KS, and **Mayo MS**: "Sustained-Release Bupropion for Smoking Cessation in African Americans: A Randomized Controlled Trial". Journal of the American Medical Association, 288(4), 468-474, 2002.

c) Ho MK, Faseru B, Choi WS, Nollen NL, **Mayo MS**, Thomas JL, Okuyemi KS, Ahluwalia JS, Benowitz NL, and Tyndale RF: "Utility and Relationships of Biomarkers of Smoking in African-American Light Smokers". Cancer Biomarkers, Epidemiology & Prevention, 18(12), 3426-3434, 2009. PMID: 19959692. PMCID: PMC2791893

d) Cox LS, Nollen NL, **Mayo MS**, Choi WS, Faseru B, Benowitz NL, Tyndale RF, Okuyemi KS, and Ahluwalia JS: "Bupropion for Smoking Cessation in African American Light Smokers: A Randomized Controlled Trial". Journal of the National Cancer Institute, 104(4), 2012. PMCID: PMC3283533.

My NCBI bibliography:
http://www.ncbi.nlm.nih.gov/myncbi/browse/collection/47959961/?sort=date&direction=ascending

My Google Scholar bibliography:
http://scholar.google.com/citations?hl=en&user=jmgByd8AAAAJ

D. Research Support

Ongoing Support:

R01 DA031815 Nollen (PI) 05/01/2012 - 04/30/2017
NIH
Understanding Disparities in Quitting in African American and White Smokers
This study will examine mechanisms explaining lower quit rates in African Americans relative to Whites and has the potential to significantly improve tobacco use treatment outcomes by identifying specific barriers and facilitators to quiting smoking for African Americans and for Whites.
Role: Co-Investigator

P30 CA168524 Jensen (PI) 07/11/2012 - 06/30/2017
NIH
Cancer Center Support Grant
The University of Kansas Cancer Center is a growing matrix organization that aims to leverage unique scientific assets to build a nationally significant cancer research and treatment center that will become the leading academic institution in the world for transforming discoveries in the laboratory into new therapeutic approaches.
Role: Key Personnel

R01 DK094833 Sullivan (PI) 09/25/2012 - 06/30/2017
NIH
A Virtual Reality Intervention (Second Life) to Improve Weight Maintenance
The proposed investigation explores alternative delivery systems for weight management. We propose a randomized trial to test the effectiveness of a phone based weight management program compared to a Second Life program for weight maintenance.
Role: Co-Investigator

R01 DA035796 Cox (PI) 06/01/2014 - 03/31/2019
NIH
Advancing Tobacco Use Treatment for African American Smokers
This study will evaluate the efficacy of varenicline treatment to improve quit rates in African American daily smokers of all smoking levels, with the goal of reducing tobacco-related disparities.
Role: Co-Investigator

AD-1310-08709 Nollen (PI) 10/01/2014 - 09/30/2017
Patient-Centered Outcomes Research Institute
Informing Tobacco-Treatment Guidelines for African American Non-Daily Smokers
The long-term objective of our research is to inform evidence-based guidelines for treating tobacco dependence among non-daily smokers. The objective of this study is to see if NRT is an effective treatment option for AA non-daily smokers
Role: Co-Investigator

R01HD079642 Donnelly (PI) 03/06/2015 - 02/28/2020
NIH
Weight Management for Adolescents with IDD
To compare weight loss from 0-6months between groups randomized to Face-to-Face (FTF)/Conventional Diet (CD) vs. Technology delivered (TECH)/CD and TECH/CD vs. TECH enhanced Stop Light Diet (eSLD). This design will provide comparisons of both delivery systems (FTF/CD vs. TECH/CD) and diets (TECH/CD vs TECH/eSLD).
Role: Co-Investigator

<NONE> Mayo (PI) 01/01/2013 - 12/31/2016
NuFactor
Data Coordinating Center for NuFACTOR IG Treatment Outcomes Assessment and Clinical Guidelines Study

This is a quality assessment/improvement study to evaluate treatment outcomes associated with disease-specific IG prescribing regimens in NuFACTOR IG patients.
Role: PI

Completed Support:

R01 HL111842 [NIH0067966] Donnelly (PI) 05/04/2012 - 04/30/2016
University of Kansas Center for Research
A Randomized Trial of Recommendations for Exercise to Prevent Weight Regain
Evaluate effectiveness of 3 recommended levels of exercise for the prevention of weight regain and potential gender differences in this response.
Role: Co-Investigator

R01DK083539 Donnelly (PI) 02/06/2011 - 08/31/2015
NIH
Weight Loss and Maintenance for Individuals with Intellectual Developmental Disability
Evaluate the efficacy of a system that offers individuals with IDD dietary choice within a constellation of options what can contribute to weight loss and weight maintenance and simplifies the prescription and logistics associated with participation in physical activity.
Role: Key Personnel

UL1TR000001/TR000119/TR000120 Barohn (PI) 06/01/2011 - 02/29/2016
NIH
Institutional Clinical and Translational Science Award
Create a new academic home with training programs for clinical and translational investigators, provide an enhanced coordinated translational research infrastructure and actively engage the community in developing, testing and disseminating translational research.
Role: Key Personnel

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **MOBEN MIRZA, MD**

eRA COMMONS USER NAME (credential, e.g., agency login): MMIRZA2

POSITION TITLE: ASSITANT PROFESSOR; DEPARTMENT OF UROLOGY

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Northwestern University, Evanston, IL	B.A.	06/2000	Environmental Sci/Eng
University of New Mexico, Albuquerque, NM	M.D.	05/2004	Medicine
University of New Mexico, Albuquerque, NM	Residency	06/2006	General Surgery
University of New Mexico, Albuquerque, NM	Residency	06/2009	Urology
University of Kansas, Kansas City, KS	Fellowship	06/2010	Urologic Oncology

A. Personal Statement

My clinical practice is in line with my training as a urologic oncologist. I have access to excellent mentors, a large cancer center, and a research enterprise that supports my interests. As a result, I am able to participate in a multidisciplinary environment where I have been able to help take bench ideas in to the clinical setting (see description of IIT below, section D). I have also been able to use our multidisciplinary team to help conduct research both on outcomes, enhanced pathways, and quality of life impact of our surgical treatments. We also have been able to identify unique considerations in our geriatric population (section C). Furthermore, our national presence allows me to both help in design and recruit to large cooperative group trials in all settings of urologic cancer. My goal is to take my initial work in my IIT and translate it into a larger phase II/III trial with funding from NIH or DOD.

B. Positions and Honors

Positions and Employment:

2010 – pres. Assistant Professor of Urology, University of Kansas Medical Center (KUMC), Kansas City, KS

Other Professional Activities:

2010 – pres. Director of Urological Services; Cameron Regional Medical Center
2012 – pres. Medical Student Clerkship Director
2013 – pres. Medical Director Mercy Free Health Clinic
2013 – pres. Residency Site Director; Cameron Regional Medical Center
2014 – pres. Wyandotte & Johnson Counties Care Liaison
2014 – pres. Editorial Board-Urologists in Cancer Care

Honors and Awards:

1996 – 2000 Multiple Dean's List Honors – Northwestern University
2000 Honors in Senior Thesis - "Water Management in the Rio Grande River"
2003 Pfizer Scholars in Urology Award
2006 Top 10% General Surgery Resident
2009 New Investigator Course – GU Committee; Southwest Oncology Group
2010 National Institute of Health; Fellows in Academic Careers Award
2012 Volunteer of the Year, Mercy Health Free Clinic
2012 Frontier Heartland Research Award
2013 Selected for and completed AUA Program Director Course
2012 – 2013 Selected for and completed KUMC Leadership Academy

2013 Fellow of the American College of Surgeons
2014 Selected for and completed Quality Academy- KUMC
2015 Selected for and completed Jayhawk Academy - KUMC
2016 Selected for the American Urological Association Leadership Course

Memberships in Professional Societies:

2000 – pres. American Medical Association
2005 – pres. American Urological Association, SCS of AUA
2009 – pres. Society of Urologic Oncology
2010 – pres. Southwest Oncology Group
2014 – pres. Treasurer Association of Physicians of Pakistani Descent of North America
2016 – pres. President - Kansas Urologic Association

C. Contribution to Science

1. I have been part of a very directed effort at KU urologic oncology towards outcomes, pathways, and recovery in patients undergoing treatment for muscle-invasive bladder cancer.

a) **Mirza, M**. Neutrophil-to-Lymphocyte ration as a prognostic factor in upper tract urothelial cancer. *BJU Int* 2014 Sep;114(3):316-7. PMID: 25156498 (PMC# not required; not NIH funded)
b) Hamilton Z, Parker W, Griffin J, **Mirza M**, Wyre H, Holzbeierlein J, Lee E. Alvimopan in an Enhanced Recovery Program Following Radical Cystectomy. Bladder Cancer. 2015 Oct. (1): 137-142. PMC4929338
c) Hamilton-Reeves J, Bechtel M, Hand L, Schleper A, Yankee T, Chalise P, Lee E, **Mirza M**, Wyre H, Griffin J, Holzbeierlein J. Effects of Immunonutrition for Cystectomy on Immune Response and Infection Rates; A Pilot Randomized Controlled Clinical Trial. 2016 Mar;69(3):389-92. PMC4793712
d) Murray K, Parker W, Stephany H, Redger K, **Mirza M**, Lopez-Corona E, Holzbeierlein JM, Lee EK. Venous Thromboembolism after Radical Cystectomy: Experience with Screening Ultrasonography. Arab Journal of Urology. 2016 Mar;14(1):37-43. PMC4767786

2. We have a fairly high volume prostate cancer practice especially for patients undergoing surgical treatment of prostate cancer. We are looking at techniques and factors that affect both cancer related and quality of life outcomes. My current IIT listed in the next section is an example how we are taking our bench research and applying it to our clinical practice.

a) **Mirza M**, Art K, Wineland L, Tawfik O, Thrasher JB. A Comparison of Radical Perineal, Radical Retropubic, and Robot-assisted Laparoscopic Prostatectomies in a Single Surgeon Series. *Prostate Cancer*. 2011;2011:878323. PMC3216259
b) **Mirza M**, Griebling TL. Erectile Dysfunction and Urinary Incontinence After Prostate Cancer Treatment. *Seminars in Oncology Nursing*. 2011;19(8):118-23. PMID: 22018407 (not NIH funded).
c) Murray, K, Griffin, J, Feng, Y, **Mirza, M**, Thrasher JB., Lopez-Corona, E, Duchene, DA. Modifier 22 on perioperative outcomes of robotic assisted laparoscopic prostatectomy. *Can J Urol*. 2014 Aug;21 (4): 7385-9. PMID: 25171284 (not NIH funded).
d) Eggener SE, Badani K, Barocas DA, Barrisford GW, **Mirza M,** Morgan TM, et al. Gleason 6 Prostate Cancer: Translating Biology into Population Health. *J Urol*. 2015 Sep;194(3):626-34. PMC4551510

3. We are researching cancer treatment outcomes specifically in the geriatric population and identifying unique considerations and both quality of life and risk management.

a) **Mirza M**, Griebling TL. Erectile Dysfunction and Urinary Incontinence After Prostate Cancer Treatment. *Seminars in Oncology Nursing*. 2011;19(8):118-23. PMID: 22018407 (not NIH funded)
b) **Mirza M**, Griebling TL. Screening and Management of Prostate Cancer in the Elderly. *Clinical Geriatrics* 2011;27(4):278-287 (not NIH funded).
c) **Mirza M.** Management of Small Renal Masses in the Older Adult. In: *Clin Geriatr Med.* 2015 Nov; 31 (4): 603-13. PMID: 26476119 (not NIH funded).

Link to complete list of publications:
http://www.ncbi.nlm.nih.gov/pubmed/?term=moben+mirza

D. Research Support

Ongoing Research Support:

NCT02198859 (PI: Mirza) 2014 – current
Investigator Initiated Trial Funded by Frontier Heartland Award and Department of Urology
Evaluation of Lithium and Its Effect on Clinically Localized Prostate Cancer
This study has sought to determine its effect on prostate cancer cells in human patients undergoing radical prostatectomy. In this phase I study, we are assessing the toxicity of lithium administration in patients prior to radical prostatectomy.

Completed Research Support:
None

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Kristi L. Neufeld, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): KNEUFELD

POSITION TITLE: Professor of Molecular Biosciences

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Bethel College, North Newton, KS	B.A.	05/1987	Biology
Bethel College, North Newton, KS	B.S.	05/1987	Chemistry
University of Utah, Salt Lake City, UT	Ph.D.	12/1993	Cellular, Viral, and Molecular Biology
University of Utah, Salt Lake City, UT	Postdoctoral	12/1998	Human Genetics

A. Personal Statement

I serve as a Co-Leader of the Cancer Biology Program at The University of Kansas Cancer Center and a Professor with tenure in the Department of Molecular Biosciences at The University of Kansas. As Co-Leader of the Cancer Biology program, my charge is to facilitate interaction and bridge research initiatives between campuses and represent the research interests of the KU-Lawrence campus to Cancer Center leadership. My laboratory is physically located on the KU-Lawrence campus (42 miles from KUMC) which is home to 38 cancer center members (8 in CB). Interactions between the various campuses are facilitated by live video conferencing and joint seminars. In 2006, together with Roy Jensen, Michael Soares, and Leanne Wiedeman, I developed a course, Carcinogenesis and Cancer, as a mechanism to integrate research and information from multiple campuses. Now in its ninth offering, this course, which is taught by live videoconference between KUMC, KU-Lawrence and Stowers campuses, exemplifies the use of videoconferencing technology to bridge the three campuses. I have graduated five Ph.D. and one master's students from my lab; and have mentored and trained four postdocs and 43 practicum and undergraduate students. I have served on the dissertation committee of 54 students including two from Stowers and one from KUMC. In addition to the Carcinogenesis and Cancer course, I designed and teach "Molecular Biology of Cancer", a lecture class for senior level undergraduate and graduate students. In 2008, I was awarded the University of Kansas William T. Kemper Fellowship for Teaching Excellence and in 2014, the Steeples Service to Kansans Award.

The long-range goal of my laboratory is to reveal the underlying mechanisms for growth control of normal intestinal tissue, explaining how disruption of this normal state leads to tumor formation. Using cultured colon cells and mouse models, we examine how loss of the tumor suppressor protein Adenomatous polyposis coli (APC) leads to colon carcinogenesis. The *APC* gene is conceivably the most prevalent site for selected somatic mutations, as half of the population is expected to develop colonic polyps during a normal lifespan and 80% of these tumors are initiated by mutations in both *APC* alleles. Since first identifying the large (310 kDa) tumor suppressor APC protein in the nuclei of both cultured epithelial cells and colonocytes from human tissue, I have been engaged in understanding the functions of nuclear APC.

- **K. L. Neufeld**. "Nuclear Functions of APC" published in 2008 as a chapter in the book *Adenomatous polyposis coli protein* by Landes Bioscience, Inke Näthke and Brooke McCartney editors and also published in *Adv Exp Med Biol.* 656:13-29 (2009). PMC3061301

As a new faculty member at the University of Kansas, I decided that a more complete understanding of nuclear APC functions would require expansion of my research program to include both cultured cells and a model organism. To this end, my lab generated a mouse with compromised nuclear APC localization using knock-in

technology to inactivate the Apc nuclear localization signals (mNLS). With this Apc^{mNLS} mouse model and also several mouse models with germline *Apc* mutations resembling those found in human colon cancers, I have gained an appreciation for the complex interplay between genotype and phenotype. Two large scale reviews reflect my engagement in this area:

- (2013) Zeineldin, M. & **Neufeld, K. L.** "More than two decades of Apc modeling in rodents" *BBA Reviews on Cancer 1836:80-89*; PMC3655098.
- (2013) Zeineldin, M. & **Neufeld, K. L.** "Understanding phenotypic variation in rodent models with germline Apc mutations." *Cancer Research*: 73: 2389-2399; PMC3630257.

My lab is now focused on three major downstream consequences of the APC signaling pathway: 1) We have demonstrated a role for nuclear APC in intestinal cell proliferation and differentiation, Wnt signaling, inflammation and tumor suppression using our Apc^{mNLS} mouse model and are now examining a role for APC in asymmetric cell division; 2) We are determining the mechanism by which APC regulates cell cycle progression through a novel interaction with DNA topoisomerase IIα; and 3) We are defining the role of tumor suppressor protein adenomatous polyposis coli (APC) and stem cell marker Musashi in governing homeostasis of normal intestinal stem cells. This work follows our identification of a double negative feedback loop between APC and Musashi (MSI1). As PI and co-PI for multiple R01 and P01 grants from the NIH/NCI and NSF as well as numerous regional grants, I have demonstrated the leadership qualities to administer and direct research projects, coordinating and motivating a research team to successfully accomplish the specific aims. My expertise in the molecular and cellular biology of APC proteins, combined with over 8 years of experience generating and analyzing various mouse models for intestinal neoplasia, and nearly two decades assessing APC functions in cultured cells including colon cancer cells qualify me to successfully contribute to research projects in this area.

B. Positions and Honors

Positions and Employment:

1993-1998	Postdoctoral fellowship, Laboratory of Dr. Raymond L. White, Dept. of Human Genetics, University of Utah, Salt Lake City, UT
1998-2002	Research Assistant Professor, Dept. of Oncological Sciences, Huntsman Cancer Institute, University of Utah, Salt Lake City, UT
2003-2010	Assistant Professor, Dept. of Molecular Biosciences, University of Kansas, Lawrence, KS
2004-2005	Director of Graduate Studies for Dept. of Molecular Biosciences, University of Kansas, Lawrence, KS
2010-2016	Associate Professor, Dept. of Molecular Biosciences, University of Kansas, Lawrence, KS
2013-2016	Associate Professor, Dept. of Cancer Biology, University of Kansas Medical Center, Kansas City, KS
2009-present	Co-Leader, Cancer Biology Program, NCI-Designated KU Cancer Center, KUMC.
2011-present	Co-Director, Division of Molecular, Cellular, Developmental Biology and Cancer, Higuchi Biosciences Center, University of Kansas, Lawrence, KS
2016-present	Professor, Dept. of Molecular Biosciences, University of Kansas, Lawrence, KS
2016-present	Professor, Dept. of Cancer Biology, University of Kansas Medical Center, Kansas City, KS

Other Experience and Professional Memberships:

2011 Nov	ZRG1 FO9-D (20) Oncological Sciences Fellowship Special Emphasis Panel
2011-present	KU Center for Research, Inc. Board of Trustees
2011-present	Editorial Board Member, ISRN Cell Biology
2012 June	ZRG1 FO9-P (20) Oncological Sciences Fellowship Special Emphasis Panel
2014 Nov	Defense Health Program, Department of Defense, Congressionally Directed Medical Research Programs (CDMRP), Scientist Peer Reviewer for Cancer Research Program Proposals
2015 June	NIH Cancer Molecular Pathobiology [CAMP] Study Section, Reviewer
2016 Feb	NIH Cancer Molecular Pathobiology [CAMP] Study Section, Reviewer

Awards and Scholarships:

NIH Training Grant, "Polio virus RNA replication", [T32 CA09602], 1989-1992

NIH Training Grant, "Localization of the tumor suppressor protein adenomatous polyposis coli in normal epithelial cells", [T32 CA09602], 1994-1996

USAMRDC Postdoctoral fellowship, “Potential role of the tumor suppressor adenomatous polyposis coli in polarization of breast epithelial cells”, [DAMD17-96-1-6173], 1996-1999
NIH Program Project Grant, “Molecular and Cellular Biology of the APC protein” [P01 CA073992], 2001-2002
Kansas IDeA Network of Biomedical Research Excellence Faculty Scholar Award, 2006
University of Kansas William T. Kemper Fellowship for Teaching Excellence, 2008
NIH-Center for Cancer Experimental Therapeutics, Project Award [P20 RR15563], 2003-2004
NIH “Tyloindicines: Chemistry and Biology”, Co-I [R01 CA90602], 2004-2007
NIH “Nuclear functions of the tumor suppressor protein APC”, PI [R01 CA109220], 2004-2011
NIH “Novel molecular cancer therapy targeting Musashi”, Co-I [R01 CA178831], 2014-2017
NSF “Collaborative Research: beta-catenin regulation during asymmetric stem cell divisions”, PI, 2015-2018
DoD “Microbial transplantation in prevention of colorectal cancer”, Mentor to Graduate Student (PI), 2016-2017
Steeples Service to Kansans Award, University of Kansas, 2014

C. Five Most Significant Contributions to Science [URL for a full list of my published work]
http://www.ncbi.nlm.nih.gov/myncbi/browse/collection/40794861/?sort=date&direction=ascending

1. **Determine subcellular distribution of tumor suppressor APC protein**. In the early 1990s, I was the first to identify APC in the nuclei of both cultured epithelial cells and colonocytes from human tissue. I later demonstrated that APC shuttles between the cytoplasm and nucleus and identified and characterized two nuclear localization signals (NLS) and two nuclear export signals (NES) that mediate this nucleo-cytoplasmic shuttling.
   a) **Neufeld, K. L.** and R. White. (1997) Nuclear and cytoplasmic localizations of adenomatous polyposis coli protein. *Proc. Natl. Acad. Sci. USA*. 94: 3034-3039. PMC20317
   b) Zhang, F., White, R., and **K. L. Neufeld.** (2000) Phosphorylation near nuclear localization signal regulates nuclear import of adenomatous polyposis coli protein. *Proc. Natl. Acad. Sci. USA*. 97: 12577-12582. PMC18806
   c) **Neufeld, K. L.**, Nix, D. A., Bogerd, H, Kang, Y., Beckerle, M. C., Cullen, B. R., and R. L. White. (2000) Adenomatous Polyposis Coli protein contains two nuclear export signals and shuttles between nucleus and cytoplasm. *Proc. Natl. Acad. Sci. USA.* 97: 12085-12090. PMC17298
   d) Zhang, F., White, R., and **K. L. Neufeld.** (2001) Cell density and phosphorylation control the subcellular localization of APC, *Mol. Cell Biol*. 21:8143-8156. PMC99979

2. **Describe new regulatory mechanisms for proto-oncogene β-catenin.** My research provided the first evidence that nuclear APC can modulate nuclear β-catenin activity by sequestration and thus can participate in regulation of Wnt signaling. I also identified a novel, GSK3-β-independent mechanism by which APC targets β-catenin for degradation through Siah-1.
   a) **Neufeld, K. L**., Zhang, F., Cullen, B. R. and R. L. White. (2000) APC-mediated down-regulation of β-Catenin activity involves nuclear sequestration and nuclear export. *EMBO Rep*. 6:519- 523. PMC1083789
   b) Liu, J., Stevens, J., Rote, C.A., Yost, J. H., Hu, Y. **Neufeld, K. L.**, White, R., and N. Matsunami. (2001) Siah-1 mediates a novel β -catenin degradation pathway linking p53 to the adenomatous polyposis coli protein. *Mol. Cell*. 7:927-936. PMID11389840
   c) Anderson, C, **K. L. Neufeld** and White, R. (2002) Subcellular distribution of Wnt pathway proteins in normal and neoplastic colon. *Proc. Natl. Acad. Sci. USA*. 99: 8683-8688. PMC124359

3. **Identify Topoisomerase IIα, lamin-B1 and B2 and Keratin-81 and -81 as new protein partners for nuclear APC.** Biochemical analysis of APC protein led to discovery of new protein binding partners and expanded the potential roles for APC as a tumor suppressor.
   a) Satterwhite, D.J., White, R, Matsunami, N., and **K. L. Neufeld**. (2000) Inhibition of Topoisomerase IIα Expression by Transforming Growth Factor-β1 is Abrogated by the Papillomavirus E7 Protein. *Cancer Res.* 60: 6989-94. PMID11156401
   b) Wang, Y., Azuma, Y., Moore, D., Osheroff, N., and **K. L. Neufeld.** (2008) Interaction between Tumor Suppressor APC and Topoisomerase IIα: Implications for the G2/M Transition" *Mol. Biol. Cell* 19:4076-4085. PMC2555924

c) Wang, Y., Azuma, Y., Friedman, D. B., Coffey, R., and **K. L. Neufeld**. (2009) Novel Association of APC with Intermediate Filaments Identified using a New Versatile APC Antibody. *BMC-Cell Biology* 10:75-88. PMC2774295
d) Wang, Y., Coffey, R, Osheroff, N., and **K.L. Neufeld.** (2010) Topoisomerase IIα Binding Domains of Adenomatous Polyposis Coli Influence Cell Cycle Progression and Aneuploidy. *PLoS ONE*, *5(4): e9994*. PMC2848841

4. **Develop mouse model to identify new functions for nuclear APC.** Studies of complex traits such as tumor suppression / tumorigenesis, inflammation, and tissue homeostasis require use of a model organism. Mice generated to harbor a specific genetic alteration that compromised nuclear localization of Apc displayed unexpected phenotypes, leading to identification and characterization of new Apc protein functions.
a) Ashton GH, Morton JP, Myant K, Phesse TJ, Ridgway RA, Marsh V, Wilkins JA, Athineos D, Muncan V, Kemp R, **Neufeld K**, Clevers H, Brunton V, Winton DJ, Wang X, Sears RC, Clarke AR, Frame MC, Sansom OJ. (2010) Focal adhesion kinase is required for intestinal regeneration and tumorigenesis downstream of Wnt/c-Myc signaling. *Dev. Cell,* 19(2): 259-269. PMC3291717
b) Zeineldin, M., Cunningham, J., McGuinness, W., Alltizer, P., Cowley, B., Blanchat, B, Xu, W., Pinson, D. & **Neufeld, K.L.** (2012) A knock-in mouse model reveals roles for nuclear Apc in cell proliferation, Wnt signal inhibition and tumor suppression. *Oncogene* 31: 2423-2437. PMCID 3265630
c) Zeineldin, M., Miller, M, Sullivan, R. & **Neufeld, K.L.** (2014) Nuclear adenomatous polyposis coli suppresses colitis-associated tumorigenesis in mice. *Carcinogenesis*: 35 (8): 1881-1890. PMC4123651
d) Zeineldin, M. & **Neufeld, K.L.** (2015) New insights from animal models of colon cancer: Inflammation control as a new facet on the tumor suppressor APC gem *Gastrointestinal Cancer: Targets and Therapy:* 2015:5: 39-52.

5. **Ascertain multiple ways to regulate APC levels and the phenotypic consequence of *APC* loss**. We showed that Musashi 1 is regulated by APC and also regulates APC. We provided the first biochemical evidence that Msi-1 up-regulation might be a consequence of tumor suppressor APC loss that is amenable to chemical inhibition. TGF-β can regulate APC levels and the genetic modifier Pla2g2a can function in a cell-non autonomous manner to alter tumorigenesis resulting from Apc loss or oncogenic β-catenin.
a) Satterwhite, D.J. and **K. L. Neufeld**. (2004) TGF-β targets the Wnt pathway components, APC and β-catenin, as Mv1Lu cells undergo cell cycle arrest. *Cell Cycle* 3(8):1069-73. PMID15280661
b) Spears, E & **Neufeld, K. L.** (2011) A novel double-negative feedback loop between Adenomatous Polyposis coli and musashi1 in colon epithelia. *J. Biol. Chem.* 286: 4946-4950. PMCID: 3037606
c) Zeineldin, M. Jensen, D., Paranjape, S.R., Parelkar, N. K., Jokar, I, Vielhauer, G. A. & **Neufeld, K.L.** (2014) Human Cancer Xenografts in Outbred Nude Mice Can Be Confounded by Polymorphisms in a Modifier of Tumorigenesis. *Genetics*: 197:1365-1376. PMC4125406
d) Smith, A. R., Marquez, R. T., Tsao, W. Pathak, S. Roy, A., Ping, J., Wilkerson, B., Lan, L, Meng, W. **Neufeld**, **K. L.,** Sun, X-F, and L. Xu (2015) Tumor Suppressive microRNA-137 Negatively Regulates Musashi-1 in Colorectal Cancer, in press, Oncotarget 6(14):12558-73. PMC4494958

D. Research Support

Ongoing Research Support:

R01 CA178831 (PIs: J. Aube, K. L. Neufeld, L. Xu) 09/19/2014-09/13/2017
NIH/NCI
Small molecules modulating RNA-binding protein Msi1
Goal: Structure-based rational design of novel Msi1 inhibitors based on existing lead compounds.

IOS-1456538 (PIs: K.L. Neufeld and B. Phillips) 04/15/2015-03/31/2018
NSF
Collaborative Research: beta-catenin regulation during asymmetric stem cell divisions
Goal: Decipher conservation of Wnt signaling role in asymmetric stem cell divisions in mouse and *C. elegans*.

P30 CA168524 (PI: Jensen) 07/15/2012-05/14/2017
NIH/NCI

Cancer Center Support Grant
Goal: leverage unique regional scientific assets to build a nationally significant cancer research center that will become a leading institution for transforming discoveries in the laboratory into new therapeutic approaches.
Role: Program Leader, Cancer Biology

Provost's Strategic Initiative Grant (PIs: K. L. Neufeld, L. Xu) 10/01/2013-09/30/2016
Research Investment Council, University of Kansas
Chemical Biology Team Science Approach to Cancer Drug Discovery
Goal: Develop team to discover new cancer therapeutic targets

W81XWH-16-1-0115 (PI: Gomez, C) 08/01/2016-07/31/2017
Department of Defense, FY15 Peer Review Cancer Research Program / Horizon Award
A Role for APC in Goblet Cell Function and the Unfolded Protein Response (UPR)
Goal: determine regulation and role of APC in the UPR in both in vitro models as well as in KU-32-treated mice
Role: Mentor of Graduate student (PI)

Completed Research Support (past 3 years):

Program Project Planning Grant 09/23/2013-09/22/2016
KU Cancer Center
RNA Binding Proteins in Colorectal Cancers
Goal: Develop cohesive and integrated research programs
Role: Co-PI with S. Anant, D. Dixon, L. Xu, S. Umar, J. Aube, S. Weir, P. Ramamoorthy

University of Kansas RGS/CLaS/MB (PI: K. L. Neufeld) 07/01/2012-06/30/2015
Studies of tumor suppressor APC

P30 GM103495 (PI: B.N. Timmermann) 06/01/2012-05/31/2015
NIH/NCRR COBRE, Center for Cancer Experimental Therapeutics
Novel molecular cancer therapy targeting Musashi
Goal: to identify a new class of molecular cancer therapeutics that inhibits specific protein/RNA interactions required for cancer cell survival.
Role: PI subaward

P20 RR016475 (PI: Wright, D) 07/01/2012-06/30/2013
NIH
Kansas Institutional Development Award Network of Biomedical Research Excellence (K-INBRE)
Chemoprevention of inflammation-mediated colon cancer with novel activator of heat shock response
Role: Mentor for Maged Zeineldin, Postdoctoral Fellow

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Prakash Neupane, MD**

eRA COMMONS USER NAME (credential, e.g., agency login): pneupane

POSITION TITLE: Associate Professor; Staff Physician

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Institute of Medicine, Tribhuvan University, Nepal	M.B.B.S.	1991	Medicine
Tribhuvan University Teaching Hospital, Kathmandu, Nepal	Internship	1992	Internal Medicine
St. Barnabas Hospital-Affiliated with NY Hospital/Cornell Medical Center	Residency	1998	Internal Medicine
Louisiana State University Health Sciences Center, Shreveport, Louisiana	Fellowship	2001	Hematology/Oncology

A. Personal Statement

I specialize in head and neck cancer. Areas of interest include treatment of head and neck cancer, clinical research and cancer supportive care. My goals are to provide state of the art care and to improve survival while maintaining good quality of life in head and neck cancer patients. My teaching focus is on clinical skills and disease management.

I focus on specific diseases, natural course of disease and how as a physician we can or cannot alter the natural curse of the disease. In a situation where we cannot change the curse of the disease, how can we make a patient's life better. With this philosophy, medical students are encouraged to learn and curable and incurable disease, end of life care and communication with patients with terminal illnesses. Residents and hematology oncology fellows will be able to learn curative and palliative intent of treatments, and where it is appropriate not to treat the disease, but focus on comfort care. My instructional areas are mostly in clinical setting where I teach with an example of a real patient situation.

My philosophy is to teach evidence based practice of medicine, which is cost effective and efficient. Teach students, residents and fellows in clinical setting with a practical example of cost and benefit of each tests, prescription and treatment methods. Show an example of cost effective, and equally effective evidence based practice.

B. Positions and Honors

Positions and Employment:

1993 House Officer, Tribhuvan University Teaching Hospital, Kathmandu, Nepal
2001 – 2004 Assistant Professor of Medicine, Louisiana State University Medical Center, Shreveport, LA
2004 – 2005 Medical Oncologist, Bothwell Regional Heath Center, Sedalia, MO
2005 – 2008 Medical Oncologist & Medical Director Palliative Care and SSM Hospice, St. Mary's Health Center, Jefferson City, MO
2008 – 2015 Assistant Professor of Medicine, Internal Medicine - Hematology/Oncology, University of Kansas Medical Center, Kansas City, KS
2015 – pres. Assistant Professor of Medicine, Internal Medicine - Hematology/Oncology, University of Kansas Medical Center, Kansas City, KS

Other Professional Activities:

2008 – pres. KU Cancer Center Associate Member, University of Kansas Medical Center, Kansas City, KS
2011 – 2013 ACIS, Medical Director, University of Kansas Medical Center, Kansas City, KS

2011 – pres. Head and Neck Medical Oncology, Site Specific Team Leader; Co-Chair- Head and neck disease working group, University of Kansas Medical Center, Kansas City, KS
2011 – pres. Associate Program Director, Hematology/Oncology Fellowship, University of Kansas Medical Center, Kansas City, KS

C. Contributions to Science

One of my research focuses was in the area of lung cancer, where I have co-authored several publications.

a) Dakhil CS, Wick JA, Kumar AK, Satyan MT, **Neupane P**. Extra pulmonary small cell carcinoma: The University of Kansas Experience and review of Literature. Med Oncol. 2014 Oct;31(10):187. PMC4248605
b) Huang CH, Wick JA, Sittampalam GS, Nirmalanandhan VS, Ganti AK, **Neupane PC**, Williamson SK, Godwin AK, Schmitt S, Smart NJ, Spencer S, Van Veldhuizen PJ. A multicenter pilot study examining the role of circulating tumor cells as a blood-based tumor marker in patients with extensive small-cell lung cancer. Front Oncol. 2014; 4: 271. PMC4196518
c) Komiya T, Perez RP, Yamamoto S, **Neupane P**. Primary lung mucoepidermoid carcinoma: Analysis of prognostic factors using Surveillance, Epidemiology, and End Results Program (SEER). Clin Respir J. 2015 Dec 9. PMID: 26663856
d) Huang CH, Williamson SK, **Neupane P**, Taylor SA, Allen A, Smart NJ, Uypeckcuat AM, Spencer S, Wick J, Smith H, Van Veldhuizen PJ, Kelly K. Impact Study: MK-0646 (Dalotuzumab), Insulin Growth Factor 1 Receptor Antibody Combined with Pemetrexed and Cisplatin in Stage IV Metastatic Non-squamous Lung Cancer. Front Oncol. 2016 Jan 13;5:301. PMC4710681

Link to Complete List of Publications:
http://www.ncbi.nlm.nih.gov/pubmed/?term=Neupane+P

D. Research Support

Ongoing Research Support: Active clinical trials:

A Study of Pembrolizumab (MK-3475) for First Line Treatment of Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck (MK-3475-048/KEYNOTE-048)
Role: Site PI

Phase II Non-Randomized Two Arm Trial of Induction Chemotherapy with *nab*-Paclitaxel and Cisplatin (AP: Arm 1) or single agent *nab*-paclitaxel (A: Arm 2) as Induction Therapy followed by Definitive Concurrent Chemoradiation for Locally Advanced Squamous Cell Carcinoma of the Head and Neck (HNSCC): **"**The APA Trial"
A collaborative study with Washington University School of Medicine St Louis, (Pending regulatory approval)
Role: Site PI

Phase I/II Trial of the Addition of PD 0332991 to Cetuximab in Patients with Incurable SCCHN.
A collaborative study with Washington University School of Medicine (Pending regulatory approval)
Role: Site PI

Completed Research Support: Completed clinical trials:

Randomized Phase II Trial of Everolimus versus Placebo as Adjuvant Therapy in Patients with Locally Advanced Squamous Cell Cancer of the Head and Neck (SCCHN)
Multicenter Investigator initiated trial lead by University of Chicago and Louisiana State University
Role: Site Principle Investigator

A Randomized, Double-Blind, Placebo-Controlled Study of Chemotherapy Plus Cetuximab in Combination with VTX 2337 in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck.
Role: Site PI

Cisplatin and 5FU followed by Concomitant Chemo radiotherapy to improve the Over All Survival and Progression Free Survival in Patients with Locally Advanced Squamous Cell Carcinoma of Head and Neck
Role: Site PI

A phase III randomized controlled study comparing the survival of patients with unrespectable hepatocellular carcinoma (HCC) treated with thymitaq to patients treated with doxorubicin
Role: Site PI

A randomized, double blinded placebo controlled, phase III study of oxaliplatin/ 5FU/ Leukovorin with PTK787/ZK222584 or placebo in patients with previously treated metastatic adenocarcinoma of colon or rectum
Role: Site PI

A randomized, double blinded placebo controlled, phase III study of oxaliplatin/ 5FU/ Leukovorin with PTK787/ZK222584 or placebo in patients with previously untreated metastatic adenocarcinoma of colon or rectum
Role: Site PI

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Nikki Renee Ogle, Pharm.D.**

eRA COMMONS USER NAME (credential, e.g., agency login): nogle

POSITION TITLE: Oncology Pharmacist

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Kansas, Lawrence, KS	Pharm.D.	2011	Pharmacy
Nebraska Medical Center, Omaha, NE	Residency	2012	Pharmacy
University of Kansas Medical Center, Kansas City, KS	Residency	2013	Hematology/Oncology Pharmacy

A. Personal Statement

In my current position as an oncology pharmacist at The University of Kansas Hospital, I will be serving as a committee member on the Protocol Review and Monitoring (PRMC). I will also be working with the hematology and oncology team in caring for our patients, including those enrolled in a clinical trials. In my training at the University of Kansas Medical Center as a PGY-2 hematology/oncology resident, I had the opportunity to work with a number of patients being treated per clinical trial protocol. I completed 2 research projects during my residency (please see below for details). I feel that my residency training has prepared me to assist teams in caring for our patients currently enrolled on protocols. In addition, my role at University Medical Center (Lubbock, TX 2013-2016) included actively participating in SWOG and industry studies allowing me to expand my research protocol knowledge. I also participated in clinical research during my time as a preceptor with Texas Tech Health Sciences Center.

B. Positions and Honors

Positions and Employment:

2013 – 2016 Oncology Pharmacist, Department of Pharmacy, University Medical Center, Lubbock, TX
3/2016 – pres. Clinical Oncology Pharmacist, Department of Pharmacy, University of Kansas Hospital, Kansas City, KS

Certifications:

12/2014 – pres. Board of Pharmacy Specialties Board Certified Oncology Pharmacist (BCOP)

Professional Memberships:

2010 – pres. Member, Rho Chi Honors Society
2011 – pres. Member, Hematology/Oncology Pharmacy Association (HOPA)
BCOP Field Testing Work Group Committee Member (5/2015 to current)
2014 – pres. Member, Lubbock Area Society of Health-System Pharmacists (LASHP)
Scholarship Committee Member (2014-2015)
2014 – pres. Member, Texas Society of Health-System Pharmacists (TSHP)
New Practitioner Mentor (1/2015 to current)

C. Contributions to Science

Ogle, NR. & Akkerman, SR. Guidance for the Discontinuation or Switching of Antidepressant Therapies in Adults. Journal of Pharmacy Practice. 2013 Aug;26(4):389-96. PMID: 23459282 (PMC# not required; not NIH funded).

D. Research Support

Ongoing Research Support: None

Completed Research Support: None

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. ***DO NOT EXCEED FIVE PAGES.***

NAME: **Milind Phadnis, Ph.D.**

eRA COMMONS USER NAME (credential, e.g., agency login): mphadnis

POSITION TITLE: Assistant Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Fr. Conceicao Rodrigues College of Engineering, Mumbai, India	B.S.	1998	Production Engineering
University of Alabama, Tuscaloosa, AL	M.S.	2005	Industrial Engineering
University of Alabama at Birmingham, AL	Ph.D.	2011	Biostatistics

A. Personal Statement

My primary research interest is in the development and applications of statistical methods in the biomedical and health sciences. My statistical research focus is concentrated in the area of Survival Analyses, Design and Analyses of Clinical Trials, Analyses of Longitudinal Data, and Epidemiology. My major collaborative contributions involve working with researchers in stroke, pharmaco-epidemiology, cardiovascular diseases, neuroscience, and gastroenterology.

I joined the Department of Biostatistics at The University of Kansas Medical Center in December 2011 as a Research Assistant Professor. Since then, I have collaborated with several internally and externally funded projects including NIH grants. Over the last four years, I have been working in the area of assessment of risk factors for stroke as well as in the evaluation of effectiveness of cardioprotective medications in the dialysis population. These collaborative experiences have helped me co-author seven publications in leading biomedical journals. In addition to my collaborative experience, I have been successful in publishing two novel statistical methods oriented publications geared specifically towards answering critical questions arising from my collaborative work. I have also contributed toward the Statistical section of a successfully funded PCORI grant in the area of smoking cessation research. I am also actively involved in the design and analysis of Phase I/II clinical trials in cancer conducted at my university and I am responsible for leading a team of analysts in designing the database and case report forms. In addition to these skills, I have gained experience in the design and implementation, overseeing and leading the data management and analysis of an ongoing biotherapeutics industry sponsored clinical trial in neuroscience addressing issues of randomization, non-response, and management of missing data. My research interests in this field have enabled me to successfully switch to a tenure track position starting this year.

B. Positions and Honors.

Positions and Employment:

2002 – 2004 Teaching Assistant, Dept. of Industrial Engineering, University of Alabama, Tuscaloosa, AL
2004 – 2004 Summer Internship: Quality Control Engineer, Johnson Controls Inc, Cottondale, AL
2005 – 2005 Statistical Quality Control Engineer, Recticel North America Inc, Tuscaloosa, AL
2005 – 2011 Research Assistant, Division of Gastroenterology, University of Alabama, Birmingham, AL
2011 – 2011 Research Biostatistician, Division of Gastroenterology, University of Alabama, Birmingham, AL
2011 – 2016 Research Assistant Professor, Department of Biostatistics, University of Kansas Medical Center, Kansas City, KS
7/2016 – pres. Assistant Professor, Department of Biostatistics, University of Kansas Medical Center, Kansas City, KS

Professional Certifications:

12/2004 Certified Reliability Engineer, American Society for Quality (ASQ)
12/2005 Certified Quality Engineer, American Society for Quality (ASQ)

Professional Societies and Affiliations:

2010 Member, American Statistical Association
2014 Member, University of Kansas Cancer Center

C. Contributions to Science

1. **Publications that demonstrate collaborative experience working with NIH grants:**
The following publications demonstrate my expertise in working with large databases in NIH grants. Specifically, in my collaborations with researchers in pharmaco-epidemiology, stroke, cardiovascular diseases and nephrology, I was responsible for the handling and linking of large datasets and preparing them for analyses. I was also responsible for the detailed statistical analyses as well as the implementation of novel methodological approaches in these publications.

   a) Wetmore JB, Ellerbeck EF, Mahnken JD, **Phadnis M**, Rigler SK, Mukhopadhyay P, Spertus JA, Zhou X, Hou Q, Shireman TI. Atrial fibrillation and risk of stroke in dialysis patients. (2013) *Annals of Epidemiology*, Vol 23: 112-118. Epub 2013 Jan 16. PMCID: PMC3570646
   b) Wetmore JB, **Phadnis MA**, Mahnken JD, Ellerbeck EF, Rigler SK, Zhou X, Shireman TI. Race, ethnicity, and state-by-state geographic variation in hemorrhagic stroke in dialysis patients. (2014) *Clinical Journal of the American Society of Nephrology*. Vol. 9(4): 756-763. doi: 10.2215/ CJN.06980713. PMCID: PMC3974358
   c) Shireman TI, **Phadnis MA**, Wetmore JB, Zhou X, Rigler SK, Spertus JA, Ellerbeck EF, Mahnken JD. Antihypertensive medication exposure and cardiovascular outcomes in hemodialysis patients. (2014) *American Journal of Nephrology.* Vol. 40(2): 113-122. doi: 10.1159/000365255. PMCID: PMC4175183
   d) Wetmore JB, **Phadnis MA**, Ellerbeck EF, Shireman TI, Rigler SK, Mahnken JD. Relationship between stroke and mortality in dialysis patients. (2015) *Clinical Journal of the American Society of Nephrology*. Vol. 10(1): 80-89. doi: 10.2215/CJN.02900314. PMCID: PMC4284406

2. **Publications that demonstrate first-author statistical methodology experience while working with NIH grants:**
The following publications are evidence of my statistical methodological contributions emerging from my collaborative work with biomedical researchers (see [1] above) on NIH grants. The innovative statistical approaches developed by me were a result of my collaborative work dealing with USRDS and Medicare/ Medicaid data and were aimed at answering research questions specific to areas of stroke and pharmaco-epidemiology.

   a) **Phadnis MA**, Shireman TI, Wetmore JB, Rigler SK, Zhou X, Spertus JA, Ellerbeck EF, Mahnken JD. Estimation of drug effectiveness by modeling three time-dependent covariates: An application to data on cardioprotective medications in the chronic dialysis population. (2014) *Statistics in Biopharmaceutical Research*. Vol. 6(3): 229-240. doi: 10.1080/19466315.2014.920275. PMCID: PMC4203430
   b) **Phadnis MA,** Wetmore JB, Shireman TI, Ellerbeck EF, Mahnken JD. An ensemble survival model for estimating relative residual longevity following stroke: Application to mortality data in the chronic dialysis population. (2015) *Statistical Methods in Medical Research* . doi: 10.1177/0962280215605107 PMID: 2640394, PMCID in process.

3. **Selected publications from multi-disciplinary collaborative work in nephrology, stroke and pharmacoepidemiology:**

   a) Wetmore JB, Ellerbeck EF, Mahnken JD, **Phadnis MA**, Rigler SK, Spertus JA, Zhou X, Mukhopadhyay P, Shireman TI. Stroke and the 'stroke belt' in dialysis: contribution of patient characteristics to ischemic

stroke rate and its geographic variation. (2013) *Journal of the American Society of Nephrology*. Vol. 24(12): 2053-2061. doi: 10.1681/ASN.2012111077. PMCID: PMC3839545

b) Wetmore JB, Mahnken JD**, Phadnis MA**, Ellerbeck EF, Shireman TI. Relationship between calcium channel blocker class and mortality in dialysis. (2015) *Pharmacoepidemiology and Drug Safety* (in press) doi: 10.1002/pds.3869. PMCID: PMC4715475

c) Shireman TI, Mahnken JD, **Phadnis MA**, Ellerbeck EF. Effectiveness comparison of cardio-selective to non-selective β-blockers and their association with mortality and morbidity in end-stage renal disease: a retrospective cohort study. (2016). *BMC Cardiovascular Disorders*. Vol. 16 (60). doi: 10.1186/s12872-016-0233-3. PMCID in process.

d) Sisante J, Abraham M, **Phadnis MA,** Billinger S, Mittal M. Ambulatory status protects against venous thromboembolism in acute mild ischemic stroke patients. (2016) *Accepted for publication to Journal of Stroke and Cerebrovascular Diseases*. PMCID in process.

4. Other selected publications from collaborative work in gastroenterology:

a) Mel Wilcox C, **Phadnis M**, Varadarajulu S. Biliary stent placement is associated with post-ERCP pancreatitis (2010). *Gastrointestinal Endoscopy*, 72(3):546-550. Epub 2010 Jul 14. PMID: 20633882 PMCID not required; not NIH funded.

b) Varadarajulu S, Bang JY, **Phadnis MA**, Christein JD, Mel Wilcox CM. Endoscopic transmural drainage of peripancreatic fluid collections: Outcomes and predictors of treatment success in 211 consecutive patients. (2011) *Journal of Gastrointestinal Surgery*, 15(11):2080-2088. Epub 2011 Jul 23. PMID: 21786063, not NIH funded.

c) Varadarajulu S, **Phadnis MA**, Christein JD, Wilcox CM. Multiple transluminal gateway technique for EUS-guided drainage of symptomatic walled-off pancreatic necrosis. (2011) *Gastrointestinal Endoscopy*. 74 (1):74-80. Epub 2011 May 25. PMID: 21612778, not NIH funded.

d) Ranney NR, **Phadnis M**, Trevino J, Ramesh J, Wilcox CM, , Varadarajulu S. Impact of biliary stents on EUS-guided FNA of pancreatic mass lesions. (2012) *Gastrointestinal Endoscopy*, Vol. 76(1):76-83. PMCID: PMC4163947

Complete List of Published Work:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1LAhH-ZVAaIQK/bibliography/45979820/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

CER-1306-02901 Ellerbeck (PI) 12/17/2008 - 12/16/2016
PCORI
Smoking Cessation versus Long-term Nicotine Replacement among High-risk Smokers
We intend to compare the benefits of traditional smoking cessation (SC) versus guided maintenance therapy (GMT) with NRT. Additionally, we also aim to develop estimates of patient-desired outcomes based on patient-specific characteristics and treatment choice (SC vs. GMT).
Role: Biostatistician

Completed Support:

CSL, Behring Dimachkie (PI) 04/01/2014 – 03/31/2015
Open Label study of subcutaneous immunoglobulin (SCIg) in myasthenia gravis
Goals: The primary objective is to measure the efficacy of subcutaneous immunoglobin (SCIg) in the 12-week experimental treatment phase of myasthenia gravis subjects who are stable after completing the IVIg screening phase.
Role: Biostatistician

K23 DK085378 Wetmore (PI) 04/01/2010 - 02/28/2015
NIH (NIDDK)
Factors Associated with Warfarin Administration in Hemodialysis Patients with Chronic Atrial Fibrillation

We seek to utilize a novel linkage of USRDS/Medicate and 50-State Medicaid databases to perform a large observational study in order to determine the risks and benefits of warfarin for stroke prevention in dialysis.
Role: Biostatistician

R01 DK080111 Shireman (PI) 09/15/2008 - 07/31/2013
NIH (NIDDK)
Are cardioprotective medications effective in ESRD?
The primary objective in this grant was to evaluate the role of being compliant with cardioprotective medications on mortality and morbidity benefits in patients from the ESRD population using USRDS/Medicate and 50-State Medicaid databases.
Role: Biostatistician

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Gregory A. Reed, PhD**

POSITION TITLE: Professor of Pharmacology, Toxicology, and Therapeutics

eRA COMMONS USER NAME (credential, e.g., agency login): greed52

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
DePauw University, Greencastle, IN	B.A.	05/1974	Chemistry
Wayne State University, Detroit, MI	Ph.D.	11/1981	Chemistry (Biochemistry)

A. Personal Statement

My roles are to assist in the design, performance, and interpretation of pre-clinical and clinical studies of drug disposition, and to assist and perform pharmacokinetic/pharmacodynamic modeling. I have developed, validated, and used LC-based quantitative assays for over 35 years, and have worked primarily with LC-MS/MS assays for the past 12 years. Under my guidance, my laboratory and the GLP-compliant Bioanalytical Laboratory I direct have developed and validated LC-MS/MS assays for over 35 drugs and their metabolites from human and rodent plasma and urine, for single drugs in human cerebrospinal fluid and human ascites fluid, and for ten drugs in cell lysates and tissue homogenates. These quantitative assays have generated key data for several NIH-funded studies, and also for twelve non-NIH-funded clinical studies. It is noteworthy that the clinical studies have required external monitoring and auditing for data generation and management and have been approved for each study. I have provided this support for my own NIH-funded studies and for other investigator's studies of pharmacokinetics of novel drugs and formulations, and for the characterization of drug-drug and drug-diet interactions in human subjects. These studies included those performed in three NCI-funded Phase 1 clinical trials of proposed cancer chemopreventive agents, and as part of an NCCAM-funded study of drug-botanical interactions. In summary, we have the instruments, software, experience, and protocols necessary to quickly and efficiently apply the required bioanalytical procedures, as well as provide assistance in interpretation of the data and for design of subsequent experiments.

B. Positions and Honors

Positions and Employment

1981 - 1983	Staff Fellow, Laboratory of Pulmonary Function and Toxicology, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina
1983 - 1985	Staff Fellow, Laboratory of Molecular Biophysics, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina
1985 - 1991	Assistant Professor, Department of Pharmacology, Toxicology, and Therapeutics, University of Kansas Medical Center, Kansas City, KS
1991 - 2016	Associate Professor, Department of Pharmacology, Toxicology, and Therapeutics, University of Kansas Medical Center, Kansas City, KS
2003 - 2016	Associate Professor, Department of Internal Medicine-Clinical Pharmacology, University of Kansas Medical Center, Kansas City, KS
1991 - 2016	Associate Professor, Department of Pharmacology, Toxicology, and Therapeutics, University of Kansas Medical Center, Kansas City, KS
2006 - 2016	Associate Professor, Department of Internal Medicine-Clinical Pharmacology, University of Kansas Medical Center, Kansas City, KS
2016 - Present	Professor, Department of Pharmacology, Toxicology, and Therapeutics, University of Kansas Medical Center, Kansas City, KS

2016 - Present	Professor, Department of Internal Medicine-Clinical Pharmacology, University of Kansas Medical Center, Kansas City, KS
1989 - 2005	Executive Coordinator, Environment and Occupational Health Center, University of Kansas Medical Center, Kansas City, KS
2006 - 2014	Director, Analytical Core Laboratory, Liver Center, University of Kansas Medical Center, Kansas City, KS
2012 – present	Executive Director, Clinical Pharmacology, University of Kansas Cancer Center Fairway, KS
2014 – present	Director, Pharmacokinetics/Pharmacodynamics Program, Frontiers CTSA, University of Kansas Medical Center

Other Experience and Professional Memberships

1974-Present	Member, American Chemical Society
1988-Present	Member, American Association for Cancer Research
2003	Member, FIFRA Scientific Advisory Panel (SAP), Environmental Protection Agency
2005	Member, Predictive ADME-Toxicology Special Emphasis Panel, RFA-RM-04-023, NIGMS
2006-Present	Member, International Society for the Study of Xenobiotics
2007-Present	Member, American Society for Pharmacology and Experimental Therapeutics
2006	Member, CAM at Minority or Health Disparities Research Centers, Scientific Review Group, PAR-05-152, NCCAM
2004-2008	Member, Scientific Review Group, NIEHS Superfund Hazardous Substances Basic Research and Training Grant Program
2009	Reviewer, California Tobacco-Related Disease Research Program
2010	Member, Scientific Review Group, NIEHS Superfund Hazardous Substances Basic Research and Training Grant Program

Honors

2006	John Doull Medal and Lectureship, Central States Chapter-Society of Toxicology
2007	Chancellor's Distinguished Teaching Award for Excellence in Teaching, University of Kansas

C. Contribution to Science

1. **The first half of my research career investigated the molecular mechanisms of non-cytochrome P450-dependent xenobiotic oxidations.** Initially, these were reactions coupled to the synthesis of prostaglandins and other eicosanoids. Mechanistically, we established that these were free radical oxidations. Of particular interest were those reactions that involved peroxyl radicals as direct oxidants. My work established that the initial product of the oxidation of the drug phenylbutazone was a peroxyl radical. The importance of this finding was two-fold: first, that this substrate-derived free radical was sufficiently stable to diffuse away from the enzyme and to act as a direct epoxidizing reagent, as demonstrated by the epoxidation of 7,8-dihydroxy-7,8-dihydrobenzo[a]pyrene. Second, we proved that the ability of phenylbutazone to inhibit prostaglandin H synthase, its' therapeutic target, was absolutely dependent on the generation of this free radical. This was followed by further investigations of peroxyl radicals as non-enzymatic epoxidizing reagents, most notably the peroxyl radical derivative of (bi)sulfite that is formed by either autoxidation or peroxidase-initiated oxidation.

   a) **Reed, G. A**., Brooks, E. A., and Eling, T. E.: Phenylbutazone-dependent epoxidation of 7,8-dihydroxy-7,8-dihydrobenzo(a)pyrene: A new mechanism for prostaglandin H synthase-catalyzed oxidations. *J. Biol. Chem.* **259**: 5591-5595, 1984. PMID: 6425293

   b) **Reed, G. A.,** Griffin, I. O., and Eling, T. E.: Inactivation of prostaglandin H synthase and prostacyclin synthase by phenylbutazone: Requirement for peroxidative metabolism. *Mol. Pharmacol.* **27**: 109-114, 1985. PMID: 3917545

c) **Reed, G. A.,** Curtis, J. F., Mottley, C., Mason, R. P., and Eling, T. E.: Epoxidation of (±)-7,8-dihydroxy-7,8-dihydrobenzo(a)pyrene during (bi)sulfite autoxidation: Activation of a procarcinogen by a cocarcinogen. *Proc. Natl. Acad. Sci. (USA)* **83**: 7499-7502, 1986. PMID: 3463979

d) Green, J.L. and **Reed, G.A**.: Benzo[a]pyrene bay-region sulfonates: A novel class of reactive intermediates. *Chem. Res. Toxicol.* **3**: 59-64, 1990. PMID: 2131826

2. **Under the mentorship of Aryeh Hurwitz, my research moved from molecular characterization of xenobiotic metabolism *in vitro* to pharmacokinetic/pharmacodynamic investigations in human subjects.** We developed and utilized a probe drug approach to assessing effects of xenobiotics on key CYP enzyme activities, and applied this approach to assessing drug-supplement interactions. This included Phase 1 clinical trials of two related indole compounds proposed to be cancer chemopreventive agents, supported by NCI contracts. The initial study used indole-3-carbinol (I3C), a natural product found in cruciferous vegetables. We found that in humans, orally-administered I3C is converted to its dimeric derivative 3, 3'-diindolylmethane (DIM) pre-systemically. As a result, the pharmacokinetics were determined based solely on DIM. We also found that chronic administration of I3C resulted in marked induction of CYP1A2 and a corresponding change in the ratios of urinary estrogen metabolites. These effects were consistent with what had been observed in animal models. This was followed by a similar study with oral DIM, the only detectable I3C-based compound found systemically.

a) **Reed, G.A**., Peterson, K.S., Smith, H.J., Gray, J., Sullivan, D., Mayo, M.S., Crowell, J.A., and Hurwitz, A. A phase I study of indole-3-carbinol in women: Tolerability and effects. *Cancer Epidem., Biomarkers & Prev.* **14**: 1953-1960, 2005. PMID: 16103443

b) **Reed, G.A.**, Arneson, D.W., Putnam III, W., Smith, H.J., Gray, J.C., Sullivan, D.K., Mayo, M.S., Crowell, J.A., and Hurwitz, A. Single- and Multiple-Dose Administration of Indole-3-carbinol to Women: Pharmacokinetics Based on 3,3'-Diindolylmethane. *Cancer Epidem., Biomarkers & Prev.* **15**: 2477-2481, 2006. PMID: 17164373

c) **Reed, G.A**., Sunega, J.M., Sullivan, D.K., Gray, J.C., Mayo, M.A., Crowell, J.A., and Hurwitz, A. Single-dose pharmacokinetics and tolerability of absorption-enhanced 3, 3'-diindolylmethane in healthy subjects. *Cancer Epidem Biomarkers & Prev.* **17**: 2619-2624, 2008. PMID: 18843002; PMCID: PMC2602858

3. **The knowledge and capabilities I have developed in pharmacokinetics/pharmacodynamics, and particularly my emphasis on drug-drug interactions, brought me into human studies performed by the smoking cessation group** in our Department of Preventive Medicine. We investigated the previously observed lower success rate in smoking cessation in African Americans, particularly when bupropion was employed. Since most African Americans smoke mentholated cigarettes, we tested the hypothesis that menthol from cigarettes could alter the pharmacokinetics of bupropion, thus decreasing its effects. We first developed a novel, efficient system for recruitment, retention, and data acquisition for the African American smoker population we required for the study. Then we used that design to perform the actual study. Our data did not show any significant pharmacokinetic differences for bupropion between smokers of mentholated and non-mentholated cigarettes, suggesting that our hypothesis is not correct. Additional studies of nicotine metabolites in subjects enrolled in various smoking cessation studies continue to be performed in my laboratory, and I also play an active role in the interpretation of those data.

a) Faseru, B., Cox, L.S., Bronars, C. A., Opole, I., **Reed, G. A**., Mayo, M.S,, Ahluwalia, J.S., and Okuyemi, K. .S Design, recruitment, and retention of African-American smokers in a pharmacokinetic study. *BMC Med Res Methodol*. **10**:6, 2010. PMID: 20085641; PMCID: PMC2850393

b) Okuyemi, K.S., Faseru, B., **Reed, G.A.**, Cox, L.S., Bronars, C.A., Opole, I., Whembolua, G.-L., Mayo, M.S., Ahluwalia, J.S., and Benowitz, N.L. Effects of menthol on the pharmacokinetics of bupropion among African American smokers. *Nicotine Tobacco Res*, 14(6):688-693, 2012. PMID:22318754; PMCID: PMC3356293

4. **My major research role now is to provide pharmacokinetics/pharmacodynamics guidance and support for clinical and translational studies.** This has included an ongoing study to define the pharmacokinetic and pharmacodynamic effects of an intentional drug-drug interaction, namely the inhibition of docetaxel clearance by ketoconazole, and the clinical utility of this combination. We found that docetaxel clearance was markedly inhibited by ketoconazole, allowing use of lower doses of docetaxel. The inter-individual variability in docetaxel pharmacokinetics, however, was greatly increased by ketoconazole, raising an unacceptable decrease in predictability of the dose-exposure relationship. Additional drug-drug interaction studies in cancer chemotherapy are underway. I also provide bioanalytical and clinical pharmacology components for clinical trials of new formulations or routes of administration for existing drugs and for drug repurposing studies, such as with ciclopirox olamine.

   a) Van Veldhuizen, P.J., **Reed, G**., Aggarwal, A., Baranda, J., Zulfiqar, M., and Williamson, S.: Docetaxel and ketoconazole in advanced hormone refractory prostate cancer: A phase I and pharmacokinetic study. *Cancer* 98: 1855-1862, 2003. PMID: 14584067

   b) Minden, M.D., Hogge, D.E., Weir, S.J., Kasper, J., Webster, D.A., Patton, L., Jitkova, Y., Hurren, R., Gronda, M., Goard, C.A., Rajewski, L.G., Haslam, J.L., Heppert, K.E., Schorno, K., Chang, H., Brandwein, J.M., Gupta, V.,Schuh, A.C., Trudel, S., Yee, K.W., **Reed, G.A.**, Schimmer, A.D. Oral ciclopirox olamine displays biological activity in a phase I study in patients with advanced hematologic malignancies. *Amer J Hematol* Nov 25. doi: 10.1002/ajh.23640, [Epub ahead of print], 2013. PMID: 24273151, Not NIH funded.

   c) Williamson SK, Johnson GA, Maulhardt HA, Moore KM, McMeekin DS, Schulz TK, **Reed GA**, Roby KF, Mackay CB, Smith HJ, et al. A phase I study of intraperitoneal nanoparticulate paclitaxel (Nanotax®) in patients with peritoneal malignancies. *Cancer Chemother Pharmacol.* 75:1075-87, 2015. PMID: 25898813. PMCID: PMC4506131

   d) **Reed, G**., Schiller, G., Kambhampati, S., Tallman, M., Douer, D., Minden, M., Yee, K., Gupta, V., Brandwein, J., Jitkova, Y., Gronda, M., Hurren, R., Shamas-Din, A., Schuh, A., and Schimmer, A. A Phase 1 Study of Intravenous Infusions of Tigecycline in Patients with Acute Myeloid Leukemia. Cancer Med, in press, 2016.

Complete List of Published Work in MyBibliography: (Please copy and paste link in your web browser).
http://www.ncbi.nlm.nih.gov/sites/myncbi/1bkX6Rtrkhc5u/bibliography/40316033/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

P30 CA168524 Jensen (PI) 07/01/2012 - 06/30/2017
Cancer Center Support Grant (CCSG)
Major Goals: The University of Kansas Cancer Center is a growing matrix organization that aims to leverage unique scientific assets to build a nationally significant cancer research and treatment center that will become the leading academic institution in the world for transforming discoveries in the laboratory into new therapeutic power one part one approaches.
Role: Key Personnel

Completed Support:

No Number Schimmer (PI) 07/01/2009-12/31/2013
Phase 1 study evaluating the tolerance and biological activity of oral ciclopirox olamine in patients with relapsed or refractory hematologic malignancy
This is a Phase 1 dose-escalation clinical trial, and Dr. Reed is providing bioanalytical and pharmacokinetics support.
Role: Co-investigator

No Number Williamson (PI) 07/01/2008-12/31/2013
Crititech & Institutional Funding
Phase 1 study of nanoparticulate paclitaxel in peritoneal malignancy
This is a Phase 1 dose-escalation clinical trial, and Dr. Reed is providing bioanalytical and pharmacokinetics support.
Role: Co-investigator

P20GM103549 Jaeschke (PI) 09/02/2011-06/30/2016
NIH
Nuclear Receptors in Liver Health and Disease
This multi-investigator program examines the roles of nuclear receptors in controlling both normal and pathological functions in the liver.
Role: Core laboratory director

5UL1TR000001 Barohn (PI) 06/01/2011-02/29/2016
NIH
Heartland Institute for Clinical and Translational Research
This CTSA support grant provides infrastructure and core services to foster clinical and translational research.
Role: Director, Pharmacokinetics/Pharmacodynamics Program

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Jeffrey C. Reene, MBA**

eRA COMMONS USER NAME (credential, e.g., agency login): JREENE

POSITION TITLE: Chief Operating Officer

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Illinois, Champaign-Urbana	B.A.	05/76	Finance
University of Illinois, Champaign-Urbana	M.B.A.	05/78	Business

A. Personal Statement

Mr. **Reene** is the Chief Operating Officer of The University of Kansas Cancer Center. He has served as a senior advisor to the Director since 2005. **Reene** focuses on external partnerships and relationships with the business and civic community. He also represents the cancer center on the medical center's Executive Vice Chancellor leadership group. **Reene** led the design and initial build out of the Midwest Cancer Alliance clinical trials network. He has 30 years of entrepreneurial growth company experience.

B. Positions and Honors

Positions and Employment

1978-1991 Partner, Andersen Consulting (Accenture), Houston, TX
1991-1999 Executive Vice President, Cerner Corporation, Kansas City, MO
1999-2001 President and CEO, NetSales, Inc, Overland Park, KS
2001-2003 Chief Operating Officer, GeoAccess, Lenexa, KS
2003-2005 Principal, Leadership for Growth, Leawood, KS
2005- pres Chief Operating Officer, The University of Kansas Cancer Center, Kansas City, KS

C. Contribution to Science

None

D. Research Support

Ongoing Support:

P30 CA168524 Jensen (PI) 07/11/2012 - 06/30/2017
NIH
Cancer Center Support Grant
The University of Kansas Cancer Center is a growing matrix organization that aims to leverage unique scientific assets to build a nationally significant cancer research and treatment center that will become the

leading academic institution in the world for transforming discoveries in the laboratory into new therapeutic approaches.
Role: Key Personnel

Completed Support:

None

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME **Anuradha Roy, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): ANUROY

POSITION TITLE: Director, High Throughput Screening Laboratory

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Miranda House, University of Delhi, India	B.Sc	06/1984	Zoology Honors
Jawaharlal Nehru University, New Delhi, India	M. Sc	06/1986	Life sciences
Jawaharlal Nehru University, New Delhi, India	Ph.D	05/1991	Molecular Biology/Biochemistry
Cleveland Clinic Foundation, Cleveland, Ohio	Post-Doctoral	07/2001	Post-transcriptional Gene Regulation

A. Personal Statement

I provide scientific and administrative direction to the High throughput screening lab (HTS). As part of the KUCC Lead Development and Optimization Shared Resource (LDOSR) and Target acceleration group (TAG), I work with junior and senior investigators from all academic departments at KU/KUMC and KState and help develop their target ideas into assays that can be screened for identification of chemical probes. I have more than 20 years of assay development experience in both academic and biotech environment and have managed development, optimization and execution of early drug discovery projects from target identification, biochemical and cell-based assay development for medium and high throughput screening campaigns. I specialize in adapting diverse biological systems (mammalian cancer cells, stem cells, bacteria, yeast, filamentous fungi, algae and other microbial systems) for primary HTS screening and secondary assay development. I have extensive experience in monitoring assay quality, troubleshooting issues with assay performance, analyzing large complex data sets, and routinely support medicinal chemistry efforts in hit identification and probe/hit/lead optimization. I have also provided scientific direction to drug repositioning and synergistic drug combination screens for treatment of pediatric and other cancers.

B. Positions and Honors

1995-2001 Research Associate, Cleveland Clinic Foundation, Cleveland, Ohio
2001-2007 Scientist II, PTC therapeutics Inc., South Plainfield, NJ
2007-2010 Senior Research Associate, High Throughput Screening Laboratory, University of Kansas
2010-2013 Section Editor, Combinatorial Chemistry and High Throughput Screening, Bentham Pub
2011-2012 Interim-Director, High Throughput Screening Laboratory, University of Kansas
2012-2013 Assistant-Director, High Throughput Screening Laboratory, University of Kansas
2013-present Director, High Throughput Screening Laboratory, University of Kansas

Honors

1982 Agnes Scott Award in Embryology, Dept. of Zoology, Delhi University, India
1982 Science Merit Award, Faculty of Science, Delhi University, India
1983 Science Merit Award, Faculty of Science, Delhi University, India
1986 Jawaharlal Nehru Memorial Fund award, Jawaharlal Nehru University, India
1991 Young Scientist Award, Indian National Science Academy, India
1996 Elsa Albrecht Award, Dept. of Cell Biology, Cleveland Clinic Foundation

1999 Merlin F. Bumpus Award (Basic Research), Cleveland Clinic Foundation, Cleveland
1999 Speaker**,** RNA Editing Gordon Conference, Ventura, California
2000 Speaker, RNA Society Meeting, University of Madison-Wisconsin
2004 PTC Innovation Award, PTC Therapeutics Inc., South Plainfield, NJ
2005 PTC Science Day Award, PTC Therapeutics Inc., South Plainfield, NJ
2006 PTC Recognition Award: VEGF Back-up drug candidate program, South Plainfield, NJ
2013 Invited Speaker, 7th Annual Sickle cell Disease Research and Educational Symposium and 36th National Sickle Cell Disease Scientific meeting (April 17, 2013).
2013 Invited Speaker, 2013 Western Association of Core Directors meeting, Univ of Southern California. Sept 19-20.
2014 Invited Speaker, Enabling Future Pharma Conference, 09-12 July 2014, Bloomingdale, Chicago.
2014 NIH Study section Reviewer (U01 study section)
2014 Grant Reviewer, North Carolina Biotechnology Center (Institutional Development Grant program)
2015 Invited Speaker, department of Entomology, Kansas State University, May 4.

C. Contribution to Science

1. **2007-present**: **As the Director of HTS laboratory, I have contributed to diverse assay development platforms and early screening campaigns of projects drawn from various biological systems**. In the few representative publications, I developed the assay platforms, performed high throughput screens, performed data analysis, worked with medicinal chemists for cheminformatics and early analoging.

   Examples include: Iron scavenging through siderophores was targeted for antimicrobial drug design. A High throughput screen was designed to identify compounds that inhibited the activity of isochorismate-pyruvate lyase of Pseudomonas aeruginosa, an enzyme required for the production of the siderophore pyochelin. The compounds inhibited the growth of PAO1 P. aeruginosa under iron-limiting conditions. The identified compounds also inhibited the growth and enzymatic activity of E.coli chorismate mutase, a protein of similar fold and similar chemistry, and Yersinia enterocolitica salicylate synthase, a protein of differing fold but catalyzing the same lyase reaction.

   Sickle cell disease symptoms can be alleviated through expression of fetal globin. A high throughput screen was performed using chemical inducer of dimerization (CID)-dependent bone marrow cells (BMCs) derived from human γ-globin promoter-firefly luciferase β-globin promoter-Renilla luciferase β-globin yeast artificial chromosome (γ-luc β-luc β-YAC) transgenic mice. The screen identified 232 compounds that induced γ-globin 2-fold or higher, with minimal or no β-globin induction, minimal cytotoxicity and that did not directly influence the luciferase enzyme. Some of the compounds upregulated expression of fetal globin protein in human primary erythroid progenitor cells.

   4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), one of the most prevalent and procarcinogenic compounds in tobacco, is bioactivated by respiratory cytochrome P450 (CYP) 2A13, forming DNA adducts and initiating lung cancer. CYP2A13 inhibition offers a novel strategy for chemoprevention of tobacco-associated lung cancer. I adapted a spectral shift assay (vide infra) reflecting interactions of compounds with CYP2A13 to HTS format for high throughput screening and identified 93 compounds that bound to CYP2A13 specifically compared with 94% identical CYP2A6.

   a) Meneely KM, Luo Q, Riley AP, Taylor B, **Roy A**, Stein RL, Prisinzano TE, Lamb AL. Expanding the results of a high throughput screen against an isochorismate-pyruvate lyase to enzymes of a similar scaffold or mechanism. Bioorg Med Chem. 2014 Nov 1;22(21):5961-9. PMID: 25282647, PMCID: PMC4254016

   b) A Cell-Based High-Throughput Screen for Novel Chemical Inducers of Fetal Hemoglobin for Treatment of Hemoglobinopathies (2014). Kenneth R. Peterson, Flávia C. Costa, Halyna Fedosyuk, Renee Y. Neades, Allen M. Chazelle, Lesya Zelenchuk, Andrea H. Fonteles, Parmita Dalal, **Anuradha Roy**, Rathnam Chaguturu, Biaoru Li, and Betty S. Pace. PLoS One.2014 Sep 16;9(9). PMID: 25225870, PMCID: PMC4165891

   c) Linda C. Blake, **Anuradha Roy**, David Neul, Frank J. Schoenen, Jeffrey Aubé, and Emily Scott (2013) Benzylmorpholine Analogs as Selective Inhibitors of Lung Cytochrome P450 2A13 for the

Chemoprevention of Lung Cancer in Tobacco Users. Pharmaceutical Research. 2013 Sep;30(9):2290-302 PMID: 23756756, PMCID: PMC3781598.

d) US patent 20090137592 - Morpholines as selective inhibitors of cytochrome p450 2A13. Emily Scott, **Anuradha Roy**

2. **1997-2007**: **At PTC Therapeutics, I worked on early discovery of post-transcriptional regulatory mechanisms on various targets from oncology and anti-infectives.** I discovered a unique translational read-through mechanism that overrides the inhibitory effects of short upstream open reading frames in Her-2 mRNA in Her-2 overexpressing breast cancer cells cell lines. Transcripts harboring 5' upstream open reading frames (uORFs) are often found in genes controlling cell growth including receptors, oncogenes, or growth factors. 5' upstream open reading frames uORFs can modulate translation or RNA stability and mediate inefficient translation of these potent proteins under normal conditions. In dysregulated cancer cells, where the gene product, for example Her-2 receptor, is overexpressed, post-transcriptional processes must exist that serve to override the inhibitory effects of the uORFs. Within this 3' UTR, a translational derepression element (TDE) that binds to a 38-kDa protein was identified. These results define a novel biological mechanism in which translational control of genes harboring a 5' uORF can be modulated by elements in their 3' UTRs.

a) **Anuradha Mehta**[1], Christopher Trotta and Stuart Peltz (2006) Derepression of the Her-2 uORF is mediated by a novel post-transcriptional control mechanism in cancer cells. Genes & Development, 20, 939-953. (1: Corresponding author).PMID: 16598037, PMCID: PMC1472302

b) US050048549A1 published 03/03/2005. Methods and Agents for Screening for Compounds Capable of Modulating Gene Expression (GEMSII) - Cao, L, **Mehta A**, Naryshkin N, Romfo C, Trifillis P, Trotta C. (Provisional).

3. **1994-2001: A multi-protein complex deaminates cytidine to uracil in apo-B mRNA and introduces a premature stop codon by converting CAA to UAA.** The catalytic subunit of the complex, a cytidine deaminase requires additional proteins (complementing activity) for editing in vitro. The main focus of my work was characterization of protein-protein and protein-RNA interactions required for editing, purification of native complementing protein and cloning of tits gene (ACF) required for editing, functional reconstitution of editing in vitro and structure-function analysis of Apobec-Complementing protein (ACF).

a) **Anuradha Mehta** and Donna Driscoll (2002) Identification of domains in Apobec-1 Complementation Factor required for RNA binding and apolipoprotein-B mRNA editing. RNA, 8(1), 69-82. PMID:11871661, PMCID: PMC1370230.

b) **Anuradha Mehta**, Michel T. Kinter, Nicholas Sherman and Donna M. Driscoll (2000) Mechanism of apolipoprotein B mRNA editing: Molecular cloning of Apobec-1 complementation Factor (ACF), a novel RNA-binding protein involved in the editing of Apolipoprotein-B mRNA. Molecular and Cellular Biology, 20 (9), 1846-1854. PMID: 10669759, PMCID: PMC85365.

c) **Anuradha Mehta** and Donna M. Driscoll (1998) A sequence-specific RNA-binding protein complements Apobec-1 to edit apolipoprotein-B mRNA. Molecular and Cellular Biology, 18 (8), 4426-4432. PMID: 9671452, PMCID: PMC109028.

d) **Anuradha Mehta**, Subhas Banerjee and Donna M. Driscoll (1996) Apobec-1 interacts with 65 kDa complementing protein to edit apolipoprotein-B mRNA in vitro. Journal of Biological Chemistry, 271 (45), 28294-28299. PMID: 8910449.

4. **1985-1991:** As part of a long-term program to develop transgenic plants with low oxalic acid content, I reported for the first time, the purification of oxalate decarboxylase from Collybia velutipes, the biochemical characterization of some of its properties, immunoscreening of a cDNA library with antibodies raised against the enzyme, and the isolation and characterization of immunopositive clones. Using this clone, the regulation of oxalate decarboxylase in C. velutipes was also studied.

a) **Anuradha Mehta** and Asis Datta (1991) Oxalate Decarboxylase in Collybia velutipes: Purification, Characterization and cDNA cloning. Journal of Biological Chemistry, 35, 23548-23553.PMID:1748632

b) Keswarni, M., Azam, M., Natarajan, K., **Mehta, A**. and Datta, A. (2000) Oxalate Decarboxylase from Collybia velutipes: Molecular cloning and its overexpression to confer resistance to fungal infection in transgenic tobacco and tomato. Journal of Biological Chemistry, 275 (10), 7230-7238. PMID: 10702293

c) US patent No. 05547870, relating to the enzyme Oxalate Decarboxylase and to a DNA sequence encoding same and to a method of protecting plants from the deleterious effects of oxalic acid.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1beAv-vXZgrkw/bibliography/47285195/public/?sort=date&direction=ascending.

D. Research Support

Ongoing Support:

R21 AI115187 Klebba (PI) 07/15/2015-06/30/2017
NIH/NIAID
High-throughput Fluorescence Screening for Inhibitors of TonB-dependent Iron Transport
Goals: The proposed research will use a novel fluorescence assay to screen large libraries of compounds for chemicals that inhibit Gram-negative bacterial iron acquisition, thereby thwart bacterial growth, and lead to the development of new antibiotics against bacterial pathogens.
Role: Co-Investigator

No Number Septer (PI) 09/01/2015-08/31/2017
MidWest Cancer Alliance
A Novel Approach to Developing Therapies for Familial Adenomatous Polyposis related Cancers including Colorectal Cancer and Desmoid Tumors.
Goals: The broad objective of this project is to identify natural compounds and or industry-abandoned drugs to prevent or combat the devastating manifestations of familial adenomatous polyposis (FAP), specifically colorectal adenomas which progress to colorectal cancer (CRC), and desmoid tumors (DT) which often occur in the years after total colectomy.
Role: Consultant

R01NS088059 Muma (PI) 04/01/2015-03/31/2019
NIH/NINDS
HTS to identify small molecules to disrupt abnormal huntingtin interactions in HD.
Goals: The goal of this project is to identify compounds that disrupt the binding of mhtt to CaM and do so selectively without inhibiting the function of CaM. The top compounds will further protect against both the deleterious effects of mhtt in neuronal cells and the transamidation of mhtt in neurons.
Role: Co-Principal Investigator

HHSN272201400056C-0-0-1 David (PI) 09/30/2014-9/29/2018
NIH
Adjuvants Discovery for Diptheria Toxin
Role: Co-Investigator

No Number Jensen (PI) 09/30/2012-9/29/2017
Hall Family Foundation
HTS to design and execute all projects for early discovery screening and hit evaluation.
Role: Investigator

P30 CA168524 Jensen (PI) 07/11/2012-06/30/2017
NIH/NCI
NCI Cancer Center Support Grant

Core C Lead Development and Optimization
The major goals of this award are for Dr. Roy to manage the day-today activities of the HTS core facility including the development of new technologies, execution of the high throughput screens, personnel management, and assessment of new technologies for in-house use. She has ultimate responsibility to insure quality control, and that the screens are executed to the predetermined and agreed upon standards. Dr. Roy assists investigators and provides expertise in HTS assay development, HTS, and lead optimization.
Role: Co-Investigator

Completed Support:

P30GM103495 Timmermann (PI) 09/01/2010-05/31/2015
NIH
COBRE, Center for Cancer Experimental Therapeutics (CCET)
The goal of this project is the establishment of the Center for Cancer Experimental Therapeutics (CCET) in the State of Kansas. High Throughput Screening and Medicinal Chemistry Core facilities will be further developed to identify novel bioactive compounds that will be useful basic biomedical research tools, and potential therapeutic agents.
Role: Core Leader of Core B: High Throughput Screening Core Facility

Midwest Cancer Alliance Grant Neville (PI) 10/01/2013 – 9/30/2015
HTS to identify drugs and compounds for the treatment of pediatric osteosarcoma.
Role: Consultant

R01 AI095236 Mir (PI) 08/01/2011-07/31/2014
NIH
Identification and characterization of inhibitors for hantavirus replication.
The major goals of this project are to develop an assay for the identification of inhibitors that can inhibit the interaction between the tail domain of glycoprotein Gn and nucleocapsid protein. These inhibitors should block the packaging of viral genome during virus replication in cells
Role: Co-Investigator

R21 HL106299 Qiu (PI) 07/01/2011-06/30/2012
NIH
Study of Bone Marrow Failure Caused by B19 Virus Infection
The primary goal is to reveal the molecular mechanism underlying the caspase-10-mediated apoptosis of human erythroid progenitors by B19 virus infection and particularly by the non-structural 11kDa protein.
Role: Co-Investigator

R01GM099959 Karanicolas (PI) 04/01/2012-03/31/2016
NIH/MSFD
Identifying inhibitors of protein interactions using pocket optimization
Goals: The objective of this project is to employ insights from computational methodology we have recently developed to address the distinct challenges associated with finding inhibitors of different classes of protein surface. Our central hypothesis is that exploring protein fluctuations leading to formation of surface pockets is critical for understanding the regions of chemical space in which suitable inhibitory compounds may be found.
Role: Collaborator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Robin E. Ryan, MPH**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Research Program Manager

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Union College, Schenectady, New York	B.S.	06/1982	Environmental Studies
University of Kansas Medical Center, Kansas City, Kansas	MPH	05/2007	Public Health

A. Personal Statement

During my employment at Children's Mercy Hospital, I assisted in developing the initial plan for data safety and monitoring for a multi-center consortium group. My current role managing the research program within the Division of Hematology/Oncology/Bone Marrow Transplant affords me many opportunities to know the importance of blending good clinical trial practices with good patient care. Since beginning my work in research I have had a strong interest in ethics. I pursued additional training in ethics during my Masters work, and I continue to seek on-going continuing education in this area. I believe that I well understand the patient advocacy needs and the need for quality research data management and reporting.

B. Positions and Honors

Positions and Employment:

2000 – 2001 Data Manager, Division of Hematology/Oncology, Children's Mercy, Kansas City, MO
2001 – 2003 Clinical Research Coordinator, Division of Hematology/Oncology, Children's Mercy, Kansas City, MO
2003 – 2005 Advanced Clinical Research Coordinator, Division of Hematology/Oncology, Children's Mercy, Kansas City, MO
2005 – 2014 Research Supervisor, Division of Hematology/Oncology, Children's Mercy, Kansas City, MO
2014 – pres. Research Program Manager, Div. of Hematology/Oncology, Children's Mercy, Kansas City, MO

Other Experience and Professional Memberships:

2000 – pres. Member, Children's Oncology Group
2002 – pres. Certification, Society of Clinical Research Associates
2014 – pres. Member, Kansas City NCI Community Oncology Research Program IRB
2015 – pres. Member, University of Kansas Cancer Center, PRMC

Honors:

2007 Betsy Beisecker Award for Public Health Excellence, Univ. of Kansas School of Public Health

C. Contribution to Science

I work with investigators to ensure that new trials are written to encompass rigorous data standards and oversight. My publication history reflects my work with survivors of childhood cancer and their ongoing social and medical needs.

a) Klemp K, Stegenga K, McClellan W, Krebill H, **Ryan R**, Sharma M, Panicker J,Fulbright J, Lowry B, Nelson E. Adult survivors of childhood cancer: Development of a regional transitions program. JCO Vol 31, No 31 (November 1 Supplement), 2013: 217 (not NIH funded)
b) McClellan W, Klemp JR, Krebill H, **Ryan R**, Nelson EL, Panicker J, Sharma M, Stegenga K., Understanding the functional late effects and informational needs of adult survivors of childhood cancer. Oncol Nurs Forum. 2013 May 1;40(3):254-62. doi: 10.1188/13.ONF.254-262. PMC4164344
c) McClellan, W., Fulbright, J.M., Doolittle, G.C., Alsman, K., Klemp, J.R., **Ryan, R**., Nelson, E-L., Stegenga, K., Krebill, H., Al-hihi, E. M., Schuetz, N., Heiman, A., Lowry, B. (2015). A collaborative step-wise process to implementing an innovative clinic for adult survivors of childhood cancer. Journal of Pediatric Nursing 30, p. e147-e155. PMID: 26202467

D. Research Support

Ongoing Research Support: None

Completed Research Support: None

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Frank J. Schoenen, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): FSCHOENEN

POSITION TITLE: Associate Research Professor and Medicinal Chemist

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Rockhurst College, Kansas City, MO	B.S.	05/1980	Chemistry
Xavier University, Cincinnati, OH	M.S.	05/1982	Chemistry
University of South Carolina, Columbia, SC	Ph.D.	11/1987	Chemistry
Yale University, New Haven, CT	Postdoctoral	11/1988	Chemistry
Harvard University, Cambridge, MA	Postdoctoral	05/1990	Chemistry

A. Personal Statement

Trained as a synthetic organic chemist, I had over 15 years' experience as Medicinal Chemist and Manager at GlaxoSmithKline (GSK) and as Vice President at Nuada Pharmaceuticals, working in the inflammation and cancer therapeutic areas, and in high-throughput chemistry at the early stages of drug discovery. In 2005, I joined the University of Kansas (KU) Chemical Methodologies and Library Development Center as the Associate Director for the Administrative Core and the Director for the Synthesis Core, where I was responsible for imagining, creating, and operating high-functioning compound-library construction, library design, analysis & purification, and compound management cores, and for directing the synthesis and distribution of thousands of compounds to academic, government, and private-sector biological collaborators throughout the world. This led naturally in 2008 to my position as Associate Director, Project Manager, and Chemistry Team Leader for the KU Specialized Chemistry Center, one of only two national laboratories funded by the National Institutes of Health (NIH) Molecular Libraries Probe Production Centers Network (MLPCN) to support synthesis and medicinal chemistry aspects of hit-to-probe optimization. In these roles, I provided scientific management for a diverse portfolio of over 40 MLPCN projects leading to 23 probe compounds. Currently, I am Associate Research Professor in the Higuchi Biosciences Center at the University of Kansas, and Medicinal Chemist on the Target Acceleration Group sponsored by the Drug Discovery, Delivery & Experimental Therapeutics Research Program within the University of Kansas Cancer Center. Within the oncology therapeutic area, I collaborate to study inhibitors of the AAA ATPase p97, SUMO1, class IA PI3K isoform p110β, the lineage-specific melanoma oncogene MITF, and compounds that reduce the prevalence of the perinucleolar compartment, as potential anti-tumor and anti-metastatic agents. My 26 years of experience as an independent researcher in the fields of synthesis and medicinal chemistry combined with my leadership of numerous cross-institutional, inter-disciplinary KU and MLPCN medicinal chemistry projects qualify me to contribute to the proposed project.

1. Frankowski, K., Patnaik, S., Schoenen, F., Huang, S., Norton, J., Wang, C., Titus, S., Ferrer, M., Zheng, W., Southall, N., Day, V.W., Aubé, J., & Marugan, J.J. Discovery and Development of Small Molecules That Reduce PNC Prevalence. In: Probe Reports from the NIH Molecular Libraries Program [Internet]. Bethesda (MD): National Center for Biotechnology Information (US); 2010-. Available from: http://www.ncbi.nlm.nih.gov/books/NBK143533/ PMID: 23762948
2. Faloon, P.W., Bennion, M., Weiner, W., Smith, R.A., Wurst, J., Weiwer, M., Hartland, C., Dandapani, S., Munoz, B., Schoenen, F., Palmer, M., Metkar, S., Haq, R., Fisher, D.E., Aubé, J., & Schreiber, S.L. A Small Molecule Inhibitor of the MITF Molecular Pathway. In: Probe Reports from the NIH Molecular Libraries Program. [Internet]. Bethesda (MD): National Center for Biotechnology Information (US); 2010-Available from: http://www.ncbi.nlm.nih.gov/books/NBK154496/ PMID: 24027801

3. Chou, T.F., Li, K., Frankowski, K.J., Schoenen, F.J., & Deshaies, R.J. (2013). Structure-Activity Relationship Study Reveals ML240 and ML241 as Potent and Selective Inhibitors of p97 ATPase. ChemMedChem, 8, 297-312. PMCID: PMC3662613
4. Alontaga, A.Y., Li, Y., Chen, C.-H., Ma, C.-T., Malany, S., Key, D.E., Sergienko, E., Sun, Q., Whipple, D.A., Matharu, D.S., Li, B., Vega, R., Li, Y.-J., Schoenen, F.J., Blagg, B.S.J., Chung, T.D.Y., & Chen, Y. (2015) Design of High Throughput Screening Assays and Identification of a SUMO1-Specific Small Molecule Chemotype Targeting the SUMO-Interacting Motif-Binding Surface. ACS Comb. Sci., 17, 239-246. PMCID: PMC4609574

B. Positions and Honors

Positions and Employment:

1990-1991 Senior Scientist, Glaxo Research Institute, Research Triangle Park (RTP), NC
1991-1998 Research Investigator I, Glaxo Research Institute/GlaxoWelcome, RTP, NC
1998-2001 Research Investigator II, GlaxoWelcome/GlaxoSmithKline, RTP, NC
2001-2002 Manager, Discovery Research, High Throughput Chemistry, GlaxoSmithKline, RTP, NC
2002-2005 VP, Research Chemistry & Operations, Nuada Pharmaceuticals, Durham, NC
2005- Associate Research Professor, Higuchi Bioscience Center, University of Kansas, Lawrence, KS
2005-2009 Associate Director, Administrative Core, Chemical Methodologies and Library Development Center of Excellence, University of Kansas, Lawrence, KS
2006-2009 Director, Synthesis Core, Chemical Methodologies and Library Development Center of Excellence, University of Kansas, Lawrence, KS
2007- Courtesy Associate Professor, Department of Medicinal Chemistry, University of Kansas, Lawrence, KS
2008-2015 Associate Director, Project Manager, and Chemistry Team Leader, Molecular Libraries Probe Production Centers Network Specialized Chemistry Center, University of Kansas, Lawrence, KS
2015- Medicinal Chemist, Target Acceleration Group, Drug Discovery, Delivery & Experimental Therapeutics Research Program, University of Kansas Cancer Center, Kansas City, KS

Other Experience and Professional Memberships:

1993- Member, American Chemical Society
2013- Member, External Advisory Board, NYSTEM High-Throughput Screening and Chemistry Shared Facility, Columbia University Medical Center, New York, NY
2014 Ad hoc Member, Special Emphasis Panels, NIAID ZAI1-AWA-M-J1 and NIAID ZAI1-AWA-M-J2, “Partnerships for Biodefense”

Honors:

1988-1990 National Research Service Award Postdoctoral Fellowship from NCI
2000 U.S. Research Excellence Award, Glaxo Welcome, RTP, NC
2012 KU Research Achievement Award, University of Kansas, Lawrence, KS

C. Contribution to Science

1. **Identification of TNF-α Converting Enzyme (TACE).** With an inter-disciplinary team of collaborators at GSK (I was the sole synthesis and medicinal chemist on the team), studies demonstrated that the compound GI129471, a broad-spectrum inhibitor of matrix metalloproteinases, prevented TNF-α release from monocytic cell lines. These studies provided evidence that the target for GI129471 was TNF-α-converting enzyme (TACE). TACE was purified from porcine spleen and the human monocytic cell line Mono Mac 6 using a variety of purification techniques, including an affinity purification step using a biotinylated inhibitor GW9277 (which led to a 400,000-fold increase in specific activity), an analogue of GI129471 which I designed and synthesized. The purification and cloning of TACE led to its identification as a membrane-bound disintegrin metalloproteinase and expression and production of functional recombinant TACE, which provided a ready source of enzyme to facilitate the search for small-molecule anti-inflammatory agents targeting the final processing stage of TNF-α production.

   a) McGeehan, G.M., Becherer, J.D., Bast, R.C., Boyer, C.M., Champion, B., Connolly, K.M., Conway, J., Furdon, P., Karp, S., Kidao, S., McElroy, A.B., Nichols, J., Pryzwansky, K.M., **Schoenen, F.J**., Sokut, L., Truesdale, A., Vorghese, M., Warner, J., & Ways, J.P. (1994). Regulation of Tumor Necrosis Factor-α Processing by a Metalloproteinase Inhibitor. Nature, 370, 558-560. PMID: 8052311

b) Moss, M.L., Lin, C., Becherer, J.D., Bickett, D.M., Chen, W.-J., Didsbury, J., Hassler, D., Leesnitzer, M.T., McGeehan, G., Milla, M., Moyer, M., Rocque, W., Seaton, T., **Schoenen, F.J.,** Warner, J., & Willard, D. (1997). Structural Features and Biochemical Properties of TNF-α Converting Enzyme (TACE). Journal of Neuroimmunology, 72, 127-129. PMID: 9042103

c) Moss, M.L., Jin, C., Milla, M.E., Bickett, M.D., Burkhart, W., Carter, H.L., III, Chen, W.-J., Clay, W.C., Didsbury, J.R., Hassler, D., Hoffman, C.R., Kost, T.A., Lambert, M.H., Leesnitzer, M.A., McCauley, P., McGeehan, G., Mitchell, J., Moyer, M., Pahel, G., Rouque, W., **Schoenen, F.J**., Seaton, T., Su, J.-L., Warner, J., Willard, D., & Becherer, J.D. (1997). Cloning of a Disintegrin Metalloproteinase that Processes Precursor Tumor Necrosis Factor-α to its Mature Form. Nature, 385, 733-736. PMID: 9034191

2. As the **Associate Director and Director for the University of Kansas (KU) NIH-funded Chemical Methodologies and Library Development (CMLD) Center and Synthesis Core**, respectively, I was responsible for imagining, creating, and operating high-functioning compound-library construction, library design, analysis & purification, and compound management cores, and for directing the synthesis and distribution of thousands of compounds to 18 academic, government, and private-sector biological collaborators throughout the world. In addition, I oversaw the processing (i.e., analysis, purification, packaging, creation of associated data files, implementation of MTAs, and shipping) of over 3,000 compounds for NIH-funded Pilot Scale Libraries Grants for PIs throughout the nation (Jeff Aubé, University of Kansas; Scott Gilbertson, University of Houston; Gunda Georg, University of Minnesota; Paul Hanson, University of Kansas; Richard Larock, Iowa State University; Ohyun Kwon, UCLA; and Jared Shaw, UC Davis) and their submission to the NIH Molecular Libraries Small Molecule Repository (MLSMR). Of nearly 20,000 compounds processed by the KU CMLD Center to support the above activities, approximately 12,000 passed the MLSMR compound submission criteria and nearly 7,000 were shipped by the University of Kansas to the MLSMR, making KU the most significant academic contributor, at the time, to the non-commercial compound subset of the MLSMR (7,000 of approximately 30,000 non-commercial compounds total).

   a) Vedantham, P., Guerra, J.M., **Schoenen, F.,** Huang, M., Gor, P.J., Georg, G.I., Wang, J.L., Neuenswander, B., Lushington, G.H., Mitscher, L.A., Ye, Q.-Z., & Hanson, P.R. (2008). Ionic Immobilization, Diversify and Release: Application to the Generation of a Library of Methionine Aminopeptidase Inhibitors. Journal of Combinatorial Chemistry, 10, 185-194. PMID: 18163595

   b) Rolfe, A., Young, K., Volp, K., **Schoenen, F**., Neuenswander, B., Lushington, G.H., & Hanson, P.R. (2009). One-Pot, Three-Component, Domino Heck-aza-Michael Approach to Libraries of Functionalized 1,1-Dioxido-1,2-benzisothiazoline-3-acetic Acids. Journal of Combinatorial Chemistry, 11, 732-738. PMCID: PMC2895961

   c) Painter, T.O., Bunn, J.R., **Schoenen, F.J**., Douglas, J.T., Day, V.W., & Santini, C. (2013). Skeletal Diversification via Heteroatom Linkage Control: Preparation of Bicyclic and Spirocyclic Scaffolds from N-Substituted Homopropargyl Alcohols. Journal of Organic Chemistry, 78, 3720-3730. PMCID: PMC3691958

   d) Gold, B., Smith, R., Nguyen, Q., Roberts, J., Lopez Quezeda, L., Somersan-Karakaya, S., Warrier, T., Little, D., Pingle, M., Zhang, D., Ballinger, E., Zimmermann, M., Dartois, V., Hanson, P.R., Mitscher, L.A., Porubsky, P., Rogers, S., **Schoenen F.J.,** Nathan, C.F., Aubé, J. (2016). Novel Cephalosporins Selectively Active on Non-replicating *Mycobacterium Tuberculosis*. J Med Chem. 2016 Jun 17. [Epub ahead of print]. PMID: 27144688 (PMC journal in process)

3. As the **Associate Director, Project Manager, and Chemistry Team Leader for the NIH-funded Molecular Libraries Probe Production Centers Network KU Specialized Chemistry Center**, one of only two national laboratories funded by the NIH to specifically support synthesis and medicinal chemistry aspects of hit-to-probe optimization, I provided scientific leadership and management for a diverse portfolio of 40 multi-national, cross-institutional, inter-disciplinary MLPCN projects leading to 23 probe compounds whose activity spans a variety of biological targets and therapeutic areas (CNS, infectious diseases, and oncology). The KOR agonist (ML138 and ML139) and antagonist probes (ML140 and ML190), the AAA ATPase p97 inhibitor probes (DBeQ, ML240 and ML241), the probe that modulates the prevalence of the perinucleolar compartment (ML246), and the E. coli bacterial capsule biogenesis inhibitor probes (ML317 and ML333) are particularly noteworthy, as these probes or close structural analogues have shown in vivo efficacy.

a) Frankowski, K.J., Hedrick, M.P., Gosalia, P., Li, K., Shi, S., Whipple, D., Ghosh, P., Prisinzano, T.E., **Schoenen, F.J**., Su, Y., Vasile, S., Sergienko, E., Gray, W., Hariharan, S., Milan, L., Heynen-Genel, S., Mangravita-Novo, A., Vicchiarelli, M., Smith, L.H., Streicher, J.M., Caron, M.G., Barak, L.S., Bohn, L.M., Chung, T.D.Y., & Aubé, J. (2012). Discovery of Small Molecule Kappa Opioid Receptor Agonist and Antagonist Chemotypes through a HTS and Hit Refinement Strategy. ACS Chemical Neuroscience, 3, 221-236. PMCID: PMC3378255

b) Schreiber, S.L., Kotz, J.D., Li, M., Aube´, J., Austin, C.P., Reed, J.C., Rosen, H., White, E.L., Sklar, L.A., Lindsley, C.W., Alexander, B.R., Bittker, J.A., Clemons, P.A., de Souza, A., Foley, M.F., Palmer, M., Shamji, A.F., Wawer, M.J., McManus, O., Wu, M., Zou, B., Yu, H., Golden, J.E., **Schoenen, F.J.,** […] Emmitte, K.A., & NIH Molecular Libraries Project Team. (2015). Advancing Biological Understanding and Therapeutics Discovery with Small-Molecule Probes. Cell, 161, 1252-1265. PMCID: PMC4564295

c) Roy, S., Sileikyte, J., Schiavone, M., Neuenswander, B., Argenton, F, Aubé, J., Hendrick, M.P., Chung, T.D., Forte, M.A., Bernardi, P., **Schoenen, F.J**. (2015) Discovery, Synthesis, and Optimization of Diarylisoxazole-3-carboxamides as Potent Inhibitors of the Mitochondrial Permeability Transition Pore. ChemMedChem, 10, 1655-1671. PMCID: PMC4674087

d) Arshad, M., Goeller, C.C., Pilla, D., **Schoenen, F.J**., Seed, P.C. (2015). Threading the needle: small molecule targeting of a xenobiotic receptor to ablate *Escherichia coli* polysaccharide capsule expression without altering antibiotic resistance. Journal of Infectious Diseases, 213, 1330-1339. PMCID: PMC4799666

4. **Small-molecule Inhibitors of the AAA ATPase p97 as potential therapeutics for the treatment of cancer.** The AAA ATPase p97 participates in key steps in ubiquitin-dependent protein quality control, autophagy, and numerous fundamental cell functions. p97 is overexpressed in some cancers, and how p97 and its numerous interacting proteins (cofactors) participate in tumor development is largely unknown. Collaborating with Professors Ray Deshaies and Tsui-Fen Chou, I was the lead medicinal chemist on the inter-disciplinary team that validated the p97 inhibitor high-throughput screening hit DBeQ and that optimized DBeQ to provide lead compounds ML240 and ML241. DBeQ was the first selective p97 inhibitor. Studies using ML240 argue for the possibility of tuning small molecules to specific p97 physiological functions to treat a specified pathological state as well as generating specificity in the context of malignancies. Studies using ML241 argue for the possibility to develop domain- (i.e., p97 ATPase domain), complex- (i.e., p97 cofactor complex), and disease-specific (i.e., IBMPFD/ALS-specific) p97 inhibitors. Cleave Biosciences licensed intellectual property surrounding DBeQ, ML240, and ML241. Their derivative of these probes, CB-5083, a close structural analogue, is currently in two Phase I clinical trials, one in relapsed and refractory multiple myeloma and the other in solid tumors refractory to the standard-of-care.

a) Chou, T.-F., Brown, S.J., Minond, D., Nordin, B.E., Li, K., Jones, A.C., Chase, P., Porubsky, P.R., Stoltz, B.M., **Schoenen, F.J**., Patricelli, M.P., Hodder, P., Rosen, H., & Deshaies, R.J. (2011). Reversible Inhibitor of p97, DBeQ, Impairs both Ubiquitin-dependent and Autophagic Protein Clearance Pathways. Proceedings of the National Academy of Sciences of the USA, 108, 4834-4839. PMC3064330

b) Chou, T.-F., Bulfer, S.L., Weihl, C.C., Li, K., Lis, L.G., Walters, M.A., **Schoenen, F.J**., Lin, H.J., Deshaies, R.J., & Arkin, M.R. (2014). Specific Inhibition of p97/VCP ATPase and Kinetic Analysis Demonstrate Interaction between D1 and D2 ATPase Domains. Journal of Molecular Biology, 426, 2886-2889. PMC4102644

c) Fang, C.-J., Gui, L., Zhang, X., Moen, D.R., Li, K., Frankowski, K.J., Lin, H.J., **Schoenen, F.J.,** & Chou, T.-F. (2015). Evaluating p97 Inhibitor Analogues for their Domain-selectivity and Potency Against the p97-p47 Complex. ChemMedChem, 10, 52-56. PMC4280364

d) Gui, L., Zhang, X., Li, K., Frankowski, K.J., Li, S., Wong, D.E., Moen, D.R., Porubsky, P.R., Lin, H.J., **Schoenen, F.J.**, Chou, T.F. (2016). Evaluating p97 Inhibitor Analogues for Potency Against p97-p37 and p97-Npl4-Ufd1 Complexes. ChemMedChem. 2016, 11, 953-957. PMID: 27043824 (PMC journal in process)

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/frank.schoenen.1/bibliography/48102920/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

KUCC Pilot Project — Chien (PI) — 07/01/2016 – 06/30/2017
University of Kansas Cancer Center
Exploiting vulnerabilities in ovarian cancer by targeting ER-stress pathway
Our goal is to test the hypothesis that VCP/p97 AAA-ATPase inhibitors provoke ER stress, reduce the expression of HR repair genes, and enhance the sensitivity to cisplatin and ER stress-activating agents.
Role: Co-Investigator

J.R. and Inez Jay Fund — Schoenen (PI) — 07/01/2016 – 06/30/2017
KU Higuchi Biosciences Center
Bioenergetic Manipulation for the Treatment of Alzheimer's Disease
Our primary goal is to synthesize and evaluate the biological activity for novel oxaloacetic acid (OAA) prodrug compounds, which should be more stable than OAA, systemically safe, cross the blood-brain barrier, access neurons and astrocytes, activate mitochondrial biogenesis, increase respiratory capacity, and increase glycolysis capacity.

MRA Team Science Award — Fisher, Schoenen (PIs) — 05/01/2016 – 04/30/2019
Melanoma Research Alliance
Targeting the lineage-specific melanoma oncogene MITF
The goal of this project is develop drugs that target a distinct protein called MITF, which is known to promote resistance to melanoma therapies.

Completed Support:

U54MH084689 — Aubé (PI) — 09/01/2008 – 05/31/2015
NIH
University of Kansas Specialized Chemistry Center
We propose to marshal a history of success in synthetic medicinal chemistry and NIH investments in these activities in the service of the MLPCN as a Specialized Chemistry Center (SCC). A Center-based research project is proposed to address the question of intracellular target identification for small molecule probes, an acknowledged roadblock in biomedical research.
Role: Project Manager/Associate Director

P50GM069663 — Aubé (PI) — 09/30/2003 – 07/31/2014
NIH
Center of Excellence in Chemical Methodologies and Library Development
The scientific focus of this Center of Excellence is to develop innovative high throughput synthesis.
Role: Associate Director/Senior Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Leyla Shune, MD**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Assistant Professor of Medicine

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Istanbul University, Cerrahpasa Medical Faculty, Turkey	M.D.	2004	Medicine
University of Minnesota, Minneapolis, MN	Residency	2010	Internal Medicine
University of Minnesota, Minneapolis, MN	Fellowship	2013	Hematology/Oncology
Memorial Sloan Kettering Cancer Center, New York, NY	Fellowship	2014	Bone Marrow Transplant

A. Personal Statement

I am an Assistant Professor in the division of Hematology/Oncology, with a strong interest in umbilical cord blood transplantation clinical research. My role in previous studies was to screen and enroll patients in studies, and then monitor them according to study guidelines. Due to our high volume of patients, I'm confident we'll be able contribute to the success of future studies.

B. Positions and Honors

Positions and Employment:

2014 – pres. Assistant Professor, Internal Medicine, Division of Hematology/Oncology, University of Kansas Medical Center, Kansas City, KS

Honors:

1998 – 2004 National scholarship for medical education
2009 American Society of Hematology: Research Trainee Award
2010 Jeevan Paul Humanitarian Award for Compassion

Professional Memberships:

American Society of Hematology (ASH)
American Society of Bone Marrow Transplantation (ASBMT)
American society of clinical oncology (ASCO)

C. Contributions to Science

My research interest in hematological malignancies led me to co-author several publications in this area.

a) **Shune L**, Cayci Z, Rogosheske J, Brunstein C, Ustun C. Extramedullary blastic crisis in abdominal lymph nodes in a patient with chronic myelogenous leukemia on imatinib Leuk Res. 2012 Jun; 36(6): e131-2. PMID: 22444689 (PMC# not required; not NIH funded).
b) Ustun C, Trottier BJ, Sachs Z, DeFor TE, **Shune L**, Courville E, Holtan SG, Dolan M, Weisdorf DJ, Warlick ED. Monosomal karyotype at the time of diagnosis or transplantation predicts outcomes of Allogeneic Hematopoietic Cell Transplantation in Myelodysplastic Syndrome. Biol Blood Marrow Transplant. 2015 May;21(5):866-72. PMC4790415

c) Shah GL, **Shune L**, Purtill D, Devlin S, Lauer E, Lubin M, Bhatt V, McElrath C, Kernan NA, Scaradavou A, Giralt S, Perales MA, Ponce DM, Young JW, Shah M, Papanicolaou G, Barker JN. Robust Vaccine Responses in Adult and Pediatric Cord Blood Transplantation Recipients Treated for Hematologic Malignancies. Biol Blood Marrow Transplant. 2015 Dec;21(12):2160-6. PMC4672874
d) Rinehart M, Hochard E, Rockey M, Abhyankar S, Ganguly S, Lin T, McGuirk J, **Shune L**, Singh A, Aljitawi O. Evaluation of cytomegalovirus reactivation and tolerability in seropositive umbilical cord transplant patients after implementation of an intensive prevention strategy. Hematol Oncol Stem Cell Ther. 2016 Mar 17. PMID: 27013276 (PMC journal – in process).

D. Research Support

Ongoing Research Support: None

Completed Research Support: None

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Barry Skikne, MD**

eRA COMMONS USER NAME (credential, e.g., agency login): bskikne

POSITION TITLE: Professor of Medicine

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of the Witwatersrand, Johannesburg, SA	M.B.B.Ch.	1969	Medicine
Johannesburg General Hospital, Johannesburg, South Africa	Intern	06/1970	Surgery
Johannesburg General Hospital, Johannesburg, South Africa	Intern	12/1970	Internal Medicine
Johannesburg General Hospital, Johannesburg, South Africa	Sr. Intern	1971	Internal Medicine
Johannesburg General Hospital, Johannesburg, South Africa	Resident	1974	Internal Medicine
University of Kansas Medical Center, Kansas City, Kansas	Fellow	1978	Hematology

A. Personal Statement

I have been involved with clinical research including clinical trials since 1976 when starting out as a staff member in the Department of Medicine at the Johannesburg General Hospital, University of Witwatersrand. From that time I have been extensively involved in numerous clinical trials and have had further in depth experience in the design and implementation of a number of other clinical trials initiated when I moved career to the pharmaceutical industry, at Celgene Corporation where I worked in Clinical Research and Development.

I have initiated a number of clinical trials during the time I was at the University of Kansas Medical Center, and then at Celgene. These trials were internal/institutional trials and at Celgene were both Celgene sponsored trials run within the United States of America and ongoing Global Phase III trials in the areas of acute myeloid leukemia, Chronic Myelo-monocytic leukemias and Myelodysplastic syndromes and also involving allogeneic transplantation. I have acted as the lead clinical research physician in conducting all aspects of these trials and work closely with statistics, regulatory, clinical operations, translational groups and have also had experience and interactions with the FDA and other regulatory bodies in Europe and Japan. I also have experience in running the Bone marrow/hematopoietic stem cell transplant program at the University of Kansas Medical Center for 14 years.

B. Positions and Honors

Positions and Employment

1975-1977 Consultant Specialist Physician in Internal Medicine, Hematology and Hematological Oncology, Johannesburg General Hospital and University of the Witwatersrand, Johannesburg, South Africa

1978-1979 Instructor in Internal Medicine, Division of Hematology, University of Kansas Medical Center, Kansas City, Kansas

1979-1984	Assistant Professor in Internal Medicine, Division of Hematology, University of Kansas Medical Center, Kansas City, Kansas
1984-1989	Associate Professor in Internal Medicine, Division of Hematology, University of Kansas Medical Center, Kansas City, Kansas
1989-2009	Professor of Internal Medicine, Division of Hematology, University of Kansas Medical Center, Kansas City, Kansas
1993-2007	Director, Blood & Marrow Transplant Program, Division of Hematology, University of Kansas Medical Center, Kansas City, Kansas
2009-2016	Executive Director, Clinical Research and Development, Celgene Corporation, Summit, New Jersey
2016-present	Professor of Medicine, Division of Hematologic Malignancies and Cellular Therapeutics, University of Kansas Medical Center, Kansas City, Kansas

Other Experience and Professional Memberships

American College of Physicians, Fellow
South African College of Physicians, Fellow
American Society of Hematology
National Committee for Clinical Laboratory Standards
American Federation for Clinical Research
American Society for Blood and Marrow Transplantation
Central Society for Clinical Research
Southwest Oncology Group
International Society of Laboratory Hematology
Past Secretary, Board of Trustees, Kansas University Internal Medicine Foundation.

Honors

1990-1991	Student Voice. Honors in Education. School of Medicine, University of Kansas
1987-1988	Outstanding Teacher Award. Department of Medicine Housestaff. University of Kansas
1968	Cluver Prize. Public Health. University of Witwatersrand. Fifth year medicine class

C. Contribution to Science

1. **Phase I Investigator involving CC-486 (oral azacitidine)**
   a) Garcia-Manero G, Gore SD, Cogle C, Ward R, Shi T, MacBeth KJ, Giordano H, Sakoian S, Jabbour E, Kantarjian H, **Skikne B**. A phase I study of oral azacitidine in myelodysplastic syndromes, chronic myelomonocytic leukemia and acute myeloid leukemia. J Clin Oncol 2011 29:2521-2527. PMCID: PMC3675699.
   b) Laille E, Savona MR, Scott BL, Boyd TE, Dong Q, **Skikne BS**. Pharmacokinetics of different formulations of oral azacitidine (CC-486) and the effect of food and modified gastric pH on pharmacokinetics in subjects with hematologic malignancies. J Clinical Pharmacology 2014 54(6):630-639. PMID: 24374798, Not NIH funded.
   c) Garcia-Manero G, Gore SD, Cogle CR, Jabbour EJ, Ward MR, MacBeth KJ, Laille E, Giordano H, Kantarjian HM, **Skikne BS**. Evaluation of Oral Azacitidine using extended treatment schedules: A phase I study. Blood 2010 116 21:265. Not NIH funded.
   d) Mehta J, Schuster MW, Harpel J, **Skikne B**, Shore T, Duffey S, Greenberg J, Divine C, Halvorsen Y, Cosentino C, Habne W. A phase I safety, tolerability, pharmacokinetic, and pharmacodynamic assessment of velafermin in patients with active oral mucositis. Biology of Blood and Marrow Transplantation 2006: 12:2 (Suppl):1.143-144.

2. **Designing/Implementation of Global Phase III Clinical Trials**
   a) AZA-MDS-003: A Phase 3, Multicenter, Randomized, Double-blind Study to Compare the Efficacy and Safety of Oral Azacitidine Plus Best Supportive Care Versus Placebo Plus Best Supportive Care in Subjects With Red Blood Cell Transfusion-dependent Anemia and Thrombocytopenia Due to IPSS Lower-risk Myelodysplastic Syndromes.

b) AZA-AML-001: Phase 3, Multicenter, Randomized, Open-Label, Study of Azacitidine (Vidaza®) Versus Conventional Care Regimens for the Treatment of Older Subjects With Newly Diagnosed Acute Myeloid Leukemia.
c) CC-5013-MDS-005: Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study To Compare The Efficacy And Safety of Lenalidomide (Revlimid®) Versus Placebo In Subjects With Transfusion-Dependent Anemia Due to IPSS Low Or Imtermidate-1 Risk Myelodysplastic Syndromes Without Deletion 5Q(31) And Unresponsive Or Refractory To Erythropoiesis-Stimulating Agents
d) Contributed to design of azacitidine study in AML: Dombret H, et al. International phase 3 study of azacitidine vs conventional care regimens in older patients with newly diagnosed AML with >30% blasts. Blood 2015 :blood-2015-01-621664; doi:10.1182/blood-2015-01-621664, PMCID: PMC4504945.

3. **Co-Investigator in Clinical Trials**
   a) Garcia-Manero G, Gore SD, Kambhampati S, Scott B, Tefferi A, Cogle CR, Edenfield WJ, Hetzer J, Kumar K, Laille E, Shi T, MacBeth KJ, **Skikne B**. Efficacy and safety of extended dosing schedules of CC-486 (oral azacitidine) in patients with lower-risk myelodysplastic syndromes. Leukemia. 2016 30:889-896. PMCID: PMC4832070.
   b) Mintz PD, Neff A, MacKenzie M, Goodnough LT, Hillyer C, Kessler C, McCrae K, Menitove JE, **Skikne BS**, Damon L, Lopez-Plaza I, Roualt C, Crookston KP, Benjamin RJ, George J, Lin JS, Corash L, Conlan MG. A randomized, controlled Phase III trial of therapeutic plasma exchange with fresh-frozen plasma prepared with amotosalen and ultraviolet a light compared to untreated FFP in thrombotic thrombocytopenic purpura. Transfusion 2006;46:1659-1662.
   c) Garcia-Manero G, Gore SD, Cogle C, Ward R, Shi T, MacBeth KJ, Giordano H, Sakoian S, Jabbour E, Kantarjian H, **Skikne B**. A phase I study of oral azacitidine in myelodysplastic syndromes, chronic myelomonocytic leukemia and acute myeloid leukemia. J Clin Oncol 2011 29:2521-2527. PMCID: PMC3675699.
   d) List AF, Bennett JM, Sekeres MA, **Skikne B**, Fu T, Shammo JM, Nimer SD, Knight RD, Giagounidis A. Extended survival and reduced risk of AML progression in erythroid-responsive lenalidomide-treated patients with lower-risk del(5q) MDS. Leukemia 2014 28:1033-1040. PMCID: PMC4017258.

4. **Development of Clinical Assay Systems**
   a) **Skikne BS**, Punnonen K, Caldron PH, Bennett MT, Ervasti M, Gasior GH, Chamberlin JS, Sullivan LA, Bray KR, Southwick PC. Improved differential diagnosis of anemia of chronic disease and iron deficiency anemia: A prospective multicenter evaluation of soluble transferrin receptor and the sTfR/log ferritin index. Am J Hematol 2011 86:923-927. PMID:21812017
   b) **Skikne BS**. Test of the month. Serum transferrin receptor. Am J Hematol 2008 83:872-875. PMID: 18821709.
   c) Cook JD, Flowers CH, **Skikne BS**. The quantitative assessment of body iron. Blood 2003;101:3359-3364.
   d) Cook JD, Flowers CH, **Skikne BS**. An assessment of dried blood-spot technology for identifying iron deficiency. Blood 1998;92:1807-1813.

5. **Other Clinical Contributions:**
   a) Baynes RD, Reddy GK, Shih YJ, **Skikne BS**, Cook JD. The serum form of the erythropoietin receptor identified by sequence specific peptide antibody. Blood 1993;87:2088-2095.
   b) **Skikne BS**, Ahluwalia N, Fergusson B, Chonko A, Cook JD. Effects of erythropoietin therapy on iron absorption in chronic renal failure. J Lab Clin Med 2000;135 :452 – 458.
   c) Goodnough LT, **Skikne B**, Brugnara C. Erythropoietin, iron, and erythropoiesis. Blood 2000;96:823 – 83
   d) Wesselius LJ, Nelson ME, **Skikne BS**. Increased release of ferritin and iron by iron-loaded alveolar macrophages in cigarette smokers. Am J Resp Crit Care Med 1994;150:690-695.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1RwG2P8t9f5Q1/collections/50928655/public/

D. Research Support

Ongoing Support

AZA PH US 2008 CL008 EudraCT #: N/A IND#: 74,618 3/27/2008-present
A Phase I, Dose-Ranging Study to Evaluate the Pharmacokinetics and Safety of Azacitidine Administered Subcutaneously (SC) and as Different Oral Formulations in Subjects With Myelodysplastic Syndromes (MDS), Chronic Myelomonocytic Leukemia (CMML), Acute Myelogenous Leukemia (AML), Lymphoma, and Multiple Myeloma
Role: Study investigator/ medical monitor of study/ primary responsible for the study.

CC-5013-MDS-005 EudraCT #: 2009-011513-24 IND#: unknown 9/3/2009-present
Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study To Compare The Efficacy And Safety of Lenalidomide (Revlimid®) Versus Placebo In Subjects With Transufsion-Dependent Anemia Due to IPSS Low Or Imtermidate-1 Risk Myelodysplastic Syndromes Without Deletion 5Q(31) And Unresponsive Or Refractory To Erthropoiesis-Stimulating Agents
Role: Designer / Implementation of study/ initial medical monitor

AZA-AML-001 EudraCT #: 2009-012346-23 IND#: 64,251 10/27/2009-present
A Phase 3, Multicenter, Randomized, Open-Label, Study of Azacitidine (Vidaza®) Versus Conventional Care Regimens for the Treatment of Older Subjects With Newly Diagnosed Acute Myeloid Leukemia
Role: Designer / Implementation of study / physician primarily responsible for study

CC-5013-AML-001 EudraCT #: N/A IND#: 060100; 064251 3/21/2011-present
A Phase 2, Multicenter, Randomized, Open-label, Parallel-group Study of a Lenalidomide (Revlimid®) Regimen or a Sequential Azacitidine (Vidaza®) Plus Lenalidomide (Revlimid®) Regimen Versus an Azacitidine (Vidaza®) Regimen for Therapy of Older Subjects With Newly Diagnosed Acute Myeloid Leukemia
Role: Designer / Implementation of study / physician primarily responsible for study

AZA-MDS-003 EudraCT #: 2012-002471-34 IND#: 074618 5/1/2012-present
A Phase 3, Multicenter, Randomized, Double-blind Study to Compare the Efficacy and Safety of Oral Azacitidine Plus Best Supportive Care Versus Placebo Plus Best Supportive Care in Subjects With Red Blood Cell Transfusion-dependent Anemia and Thrombocytopenia Due to IPSS Lower-risk Myelodysplastic Syndromes.
Role: Designer / Implementation / physician primarily responsible for study

T-CC-486-008 EudraCT #: 2012-002420-32 IND#: 074618 6/21/2012-present
A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Compare Efficacy and Safety of Oral Azacitidine Plus Best-supportive Care Versus Best Supportive Care as Maintenance Therapy in Subjects With Acute Myeloid Leukemia in Complete Remission
Role: Designer / Implementation of study / physician primarily responsible for study

CC-486-AML-002 EudraCT #: 2012-005805-36 IND#: 074618 1/22/2013-present
A Phase 1/2 Dose and Schedule Finding Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of Oral Azacitidine (CC-486) in Subjects With Acute Myelogenous Leukemia and Myelodysplastic Syndromes After Allogeneic Hematopoietic Stem Cell Transplantation
Role: Designer / Implementation of study / physician primarily responsible for study

CC-486-MDS-006 EudraCT #: 2014-002675-29 IND#: 074618 6/30/2014-present
A Phase 2, International, Multicenter, Randomized, Open-label, Parallel Group to Evaluate the Efficacy and Safety of Cc-486 (Oral Azacitidine) Alone in Combination With Durvalumab (MEDI4736) in Subjects With Myelodysplastic Syndromes Who Fail to Achieve an Objective Response to Treatment With Azacitidine for Injection or Decitabine
Role: Partial responsibility of design/implementation and medical monitoring

Completed Support:

CC-5013-MDS-004 EudraCT #: 2005-000454-73 IND#: unknown 2/16/2005- 6/30/2010

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, 3-Arm Study of the Efficacy and Safety of 2 Doses of Lenalidomide Versus Placebo in Red Blood Cell (RBC) Transfusion-Dependent Subjects With Low- or Intermediate-1-Risk Myelodysplastic Syndromes Associated With a Deletion (Del) 5q[31] Cytogenetic Abnormality
Role: responsible for medical monitoring at tail end of study, data assimilation and reporting

CC-5013-MDS-009 Other ID #: N/A IND#: unknown 9/28/2009-10/31/2010
Multi-center, Survival Data Collection in Subjects Previously Enrolled in Celgene Protocol CC-5013-MDS-003
Role: Designer / Implementation and primarily responsible for all aspects of the study.

AZA-MDS-004 Other ID #: T-AZA-006 IND#: unknown 2/9/2012-5/31/2015
A Phase 1, Multicenter, Open-Label Study to evaluate the pharmacokinetics and effect of food of a new tablet formulation or oral azacitidine, and to evaluate the safety and efficacy of oral azacitidine in subjects with myelodysplastic syndromes, chronic myelomonocytic leukemia or acute myeloid leukemia.
Role: Initially was investigator on this study. After joining the sponsoring company, became physician responsible of all aspects of study.

CC-486-MDS-001 Other ID #: N/A IND#: N/A 4/16/2013-7/31/2015
A Phase 1, Multicenter, Open-label, Dose-escalation Study of Oral Azacitidine (CC-486) in Japanese Subjects With Hematological Neoplasms
Role: Designer / Implementation and certain aspects of the study along with other Japanese scientist.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES**

NAME: **Debra K. Sullivan, Ph.D.**

eRA COMMONS USER NAME (credential, e.g., agency login): DKSullivan

POSITION TITLE: Professor and Chair

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Illinois at Chicago, Chicago, IL	B.S.	05/1985	Nutrition/Medical Dietetics
University of Illinois at Chicago, Chicago, IL	M.S.	05/1987	Nutrition/Medical Dietetics
University of Illinois, Urbana, IL	Ph.D.	08/1997	Nutritional Sciences

A. Personal Statement

I am the Chair of the Department of Dietetics and Nutrition at KUMC and Director of the nutrition core for the Clinical and Translational Science Unit. I have extensive experience in conducting diet and behavior modification interventions for weight management as well as measuring dietary intake. I have been a core team member of the KU Weight Control Research Team for 18 years and lead the nutrition components of all of our studies. Our team has been consistently NIH funded for 18 years. Specific to this proposal, I have experience with weight management interventions for cancer prevention and survivors.

a. Gibbs HD, Ellerbeck EF, Befort C, Gajewski B, Kennett AR, Yu Q, Christifano D, Sullivan DK. (2015) Measuring Nutrition Literacy in Breast Cancer Patients: Development of a Novel Instrument. J Cancer Educ. May 9 [Epub ahead of print]. PMC4639469
b. Hidaka BH, Li S, Harvey KE, Carlson SE, Sullivan DK, Kimler BF, Zalles CM, Fabian CJ. (2015) Omega-3 and omega-6 Fatty acids in blood and breast tissue of high-risk women and association with atypical cytomorphology. Cancer Prev Res (Phila). 8:359-364. PMID: 25712053.
c. Befort CA, Klemp JR, Fabian C, Perri MG, Sullivan DK, Schmitz KH, Diaz FJ, Shireman T. (2014) Protocol and recruitment results from a randomized controlled trial comparing group phone-based versus newsletter interventions for weight loss maintenance among rural breast cancer survivors. Contemp Clin Trials.37:261-271. PMC3992482.
d. Fabian CJ, Kimler BF, Donnelly JE, Sullivan DK, Klemp JR, Petroff BK, Phillips TA, Metheny T, Aversman S, Yeh HW, Zalles CM, Mills GB, Hursting SD. (2013). Favorable modulation of benign breast tissue and serum risk biomarkers is associated with >10 % weight loss in postmenopausal women. Breast Cancer Res Treat. 142(1):119-32. PMC3921968.

B. Positions and Honors

Positions and Employment:

1987- 1989	Clinical Dietitian, Rush-Presbyterian-St. Lukes Medical Center, Chicago, IL
1989 - 1991	Research/Metabolic Dietitian, Pediatric Genetics/Metabolism and the Center For Handicapped Children, Univ. IL at Chicago, Chicago, IL
1991- 1995	Nutrition Consultant: Pediatric Genetics/Metabolism, Univ. IL at Chicago, Chicago, IL; Hinsdale, IL; Peoria, IL; and Rockford, IL
1991-1996	Assistant Study Coordinator, Midwest Region: “Maternal PKU Collaborative Study”, (HHS-N01-2-3155) Principal Investigator: R Matalon, Dept. Human Nutrition & Dietetics, Univ. IL at Chicago, Chicago, IL
1995-1996	Nutrient Analyst, Chicago Center for Clinical Research, Chicago, IL

1997- 2003	Assistant Professor, Dept. Dietetics & Nutrition, University of Kansas Medical Center, Kansas City, KS
2003-2010	Associate Professor, Dept. Dietetics & Nutrition, University of Kansas Medical Center, Kansas City, KS
2005-2010	Chair, Dept. Dietetics & Nutrition, University of Kansas Medical Center, Kansas City, KS
2010-present	Midwest Dairy Professor of Clinical Nutrition and Chair, Department of Dietetics and Nutrition, University of Kansas Medical Center, Kansas City, KS

Honors:

2002 School of Allied Health Stata Norton Distinguished Teaching Award. University of KS Medical Center
2006 Outstanding Educator in Kansas, Kansas Dietetic Association
2007 Investigator Research Award, University of Kansas Medical Center
2008 Honorary Mentoring Award. University of Kansas School of Medicine.

C. Contribution to Science

1. My primary contribution to the science of weight management is through my expertise in dietary components of behavioral interventions. Our team's early studies focused on various diet types for weight loss and weight loss maintenance. We then began to conduct research to determine the best method of weight management for special populations such as individuals with intellectual disabilities and cancer survivors. More recently, we have begun to explore different delivery methods in order to reach a broader population such as rural individuals. I also provide dietary intervention expertise to numerous investigators beyond our core team.
   a. Befort CA, Klemp JR, Austin HL, Perri MG, Schmitz KH, **Sullivan DK**, Fabian CJ. (2012). Outcomes of a weight loss intervention among rural breast cancer survivors. Breast Cancer Res Treat. 132(2):631-9. PMC3314288.
   b. **Sullivan DK**, Goetz JR, Gibson CA, Washburn RA, Smith BK, Lee J, Gerald S, Fincham T, Donnelly JE. (2013) Improving weight maintenance using virtual reality (Second Life). J Nutr Educ Behav. 45(3):264-8. PMID: 23622351 (PMC# not required; not NIH funded)
   c. Donnelly JE, Goetz J, Gibson C, **Sullivan DK**, Lee R, Smith BK, Lambourne K, Mayo MS, Hunt S, Lee JH, Honas JJ, Washburn RA. (2013). Equivalent weight loss for weight management programs delivered by phone and clinic. Obesity (Silver Spring). 21(10):1951-9. PMC4442605
   d. Ptomey LT, **Sullivan DK**, Lee J, Goetz JR, Gibson C, Donnelly JE. (2015). The use of technology for delivering a weight loss program for adolescents with intellectual and developmental disabilities. J Acad Nutr Diet. 115:112-118. PMID: 25441960 (not NIH funded)

2. In addition to the community based weight management studies above, our team also conducts controlled feeding and supervised exercise studies in order to determine dose response changes to specific interventions. In these studies, I am responsible for development of the diet interventions, measurement of dietary intake, raining and supervision of the diet research staff, and interpretation of the dietary results.
   a. Donnelly JE, Kirk EP, Jacobsen DJ, Hill JO, **Sullivan DK**, Johnson SL. (2003). Effects of 16 mo of verified, supervised aerobic exercise on macronutrient intake in overweight men and women: the Midwest Exercise Trial. Am J Clin Nutr. 78(5):950-6. PMID: 14594781.
   b. Donnelly JE, **Sullivan DK**, Smith BK, Jacobsen DJ, Washburn RA, Johnson SL, Hill JO, Mayo MS, Spaeth KR, Gibson C.(2008) Alteration of dietary fat intake to prevent weight gain: Jayhawk Observed Eating Trial. Obesity (Silver Spring). 16(1):107-12. PMID: 18223621
   c. Donnelly JE, Honas JJ, Smith BK, Mayo MS, Gibson CA, **Sullivan DK**, Lee J, Herrmann SD, Lambourne K, Washburn RA. (2013) Aerobic exercise alone results in clinically significant weight loss for men and women: Midwest exercise trial 2. Obesity (Silver Spring). 21:E219-228. PMC3630467.
   d. Herrmann SD, Martin LE, Breslin FJ, Honas JJ, Willis EA, Lepping RJ, Gibson CA, Befort CA, Lambourne K, Burns JM, Smith BK, **Sullivan DK,** Washburn RA, Yeh HW, Donnelly JE, Savage CR. (2014). Neuroimaging studies of factors related to exercise: rationale and design of a 9 month trial. Contemp Clin Trials. 37:58-68. PMC3946871.

3. In order to better measure dietary intake of research participants, we conduct studies using new technology and validation studies of our methods. We have been successfully using digital images to collect dietary intake for over 15 years and more recently are using mobile technology to obtain images of food and beverages consumed. We consistently find that using images improves the accuracy.
   a. Hise ME, **Sullivan DK**, Jacobsen DJ, Johnson SL, Donnelly JE. (2002) Validation of energy intake measurements determined from observer-recorded food records and recall methods compared with the doubly labeled water method in overweight and obese individuals. Am J Clin Nutr.75:263-267. PMID: 11815316.
   b. Grunwald GK, **Sullivan DK**, Hise M, Donnelly JE, Jacobsen DJ, Johnson SL, Hill JO.(2003). Number of days, number of subjects, and sources of variation in longitudinal intervention or crossover feeding trials with multiple days of measurement. Br J Nutr. 90:1087-95. PMID: 14641968.
   c. Ptomey LT, Herrmann SD, Lee J, **Sullivan DK**, Rondon MF, Donnelly JE. (2013). Photo-assisted recall increases estimates of energy and macronutrient intake in adults with intellectual and developmental disabilities. J Acad Nutr Diet.Dec; 113:1704-9. PMC3834035.
   d. Ptomey LT, Willis EA, Goetz JR, Lee J, **Sullivan DK**, Donnelly JE. (2015) Digital photography improves estimates of dietary intake in adolescents with intellectual and developmental disabilities. Disabil Health J. 8:146-50. PMID: 25281035 (not NIH funded)

4. Since I have considerable expertise in design of diet interventions and measurement of dietary intake, I contribute to the research efforts of numerous investigators. In each case, I contribute substantially to development, implementation and interpretation of the nutrition data. I am able to explore new diet and health relationships.
   a. Choi IY, Lee P, Denney DR, Spaeth K, Nast O, Ptomey L, Roth AK, Lierman JA, **Sullivan DK**. (2015). Dairy intake is associated with brain glutathione concentration in older adults. Am J Clin Nutr. 101: 287-93. PMC4307202.
   b. Currie LM, Tolley EA, Thodosoff JM, Kerling EH, **Sullivan DK**, Colombo J, Carlson SE. (2015). Long chain polyunsaturated fatty acid supplementation in infancy increases length- and weight-for-age but not BMI to 6 years when controlling for effects of maternal smoking. Prostaglandins Leukot Essent Fatty Acids. 2015 98:1-6. PMC4444372.
   c. Ruisinger JF, Gibson CA, Backes JM, Smith BK, **Sullivan DK**, Moriarty PM, Kris-Etherton P. (2015). Statins and almonds to lower lipoproteins (the STALL Study). J Clin Lipidol. 9:58-64. PMID: 25670361. (not NIH funded)
   d. Luo T, Miranda-Garcia O, Adamson A, Hamilton-Reeves J, **Sullivan DK**, Kinchen JM, Shay NF. (2016) Consumption of Walnuts in Combination with Other Whole Foods Produces Physiologic, Metabolic, and Gene Expression Changes in Obese C57BL/6J High-Fat-Fed Male Mice. J Nutr. 2016 Aug 3. pii: jn234419. [Epub ahead of print] PubMed PMID: 27489005 (not NIH funded)

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/pubmed/?term=sullivan+dk

D. Research Support

Ongoing Research Support:

R01 DK108732 (PI: Donnelly) 06/01/2016 – 05/31/2021
National Institutes of Health
Weight Management in Rural Health Clinics
The goal of the project is to determine the effectiveness of different levels of care for rural adults for weight management.
Role: Co-Investigator

R01 HD086001 (Gustafson) 04/08/2016 – 02/28/2021
National Institutes of Health
Prenatal DHA and Neurofunctional Development
The goal of the clinical trial is to determine the effect of maternal DHA supplementation on fetal and infant neurodevelopment.
Role: Co-Investigator

R01 HD079642 (Donnelly) 04/01/2014 - 03/31/2019
National Institutes of Health
Weight Management for Adolescents with Intellectual and Development Disabilities
The goal is to compare weight loss from 0-6 months between groups randomized to Face-to-Face (FTF)/Conventional Diet (CD) vs. Technology Delivered (TECH)/CD and TECH/CD vs. TECH/enhanced Stop Light Diet (eSLD). This design will provide comparisons of both delivery systems (FTF/CD vs. Tech/CD) and diets (TECH/CD vs. TECH/eSLD).
Role: Co-Investigator

R01 HL111842 (Donnelly) 05/04/2012-04/30/2017
National Institutes of Health
A Randomized Trial of Recommendations for Exercise to Prevent Weight Regain
The goal of this project is to compare the effect of 3 different levels of exercise on weight loss maintenance.
Role: Co-Investigator

R01 DK094833 (Sullivan & Donnelly) 09/25/2012 – 06/30/2017
National Institutes of Health
A virtual reality intervention (Second Life) to improve weight maintenance
The goal of this project is to evaluate the use of virtual reality as a platform for weight maintenance.
Role: Co-Principal Investigator

R03 HD081730 (Gibbs) 08/01/2014 - 07/31/2017
National Institutes of Health (no-cost extension)
Adaptation and Validation of a Nutrition Literacy Assessment Instrument
Major Goals: The goal of this research is to produce a valid and reliable tool for measuring nutrition literacy in a chronic disease population and identify the associations between nutrition literacy and diet quality in this population.
Role: Co-Investigator

Selected Completed Research Support (past 3 years):

UL1 TR000001 (Barohn & Aaronsen) 06/01/2011 – 02/29/2016
NIH
Clinical and Translational Science Award (CTSA)
The goal is to speed the translation of laboratory discoveries into treatments for individuals.
Role: Nutrition Director

R01CA155014 (Befort) 08/11/2011 – 05/31/2016
NIH
Group Phone-Based Weight Control among Rural Breast Cancer Survivors
Behavioral RCT comparing impact of group phone-based lifestyle intervention to mail-only intervention on weight loss maintenance, quality of life, and breast cancer biomarkers among rural breast cancer survivors.
Role: Co-Investigator

R01DK085605 (Savage) 04/01/2010 - 01/31/2016
National Institutes of Health
Neuroimaging studies of reward, impulsivity, and adherence to an exercise program
The objective of this project is to characterize brain activation underlying reward processing and impulse control in obese and healthy weight individuals, to identify brain activation predictors of adherence and success in an exercise program, and to identify the effects of exercise and increased fitness on brain activation.

R01DK085317 (Donnelly) 04/01/2010 - 03/31/2015
National Institutes of Health
Physical Activity and Academic Achievement (A+PAAC)

The major Goal is to assess the impact of academic lessons taught through PA on the academic achievement of elementary school children.
Role: Co-Investigator

No number (Hull & Holly) 06/01/2014 - 05/31/2015
Kansas City Area Life Sciences Institute
Novel methods to prevent excessive gestational weight gain in overweight women
Major Goals: This study will assess the effectiveness of a novel behavioral lifestyle intervention to achieve appropriate gestational weight gain (GWG). The aims of this study are: 1) determine whether the intervention can encourage appropriate GWG, 2) determine whether the intervention can decrease sedentary time, 3) and perform a process analysis to determine subject satisfaction, barriers to recruitment, acceptability and adherence to the intervention and study retention.
Role: Co-Investigator

No number (Donnelly) 07/01/2010 - 08/31/2015
National Institutes of Health
Weight loss and maintenance for individuals with IDD
The goal of this project is to evaluate novel methods for weight reduction and the prevention of weight regain for individuals with intellectual and developmental disabilities.
Role: Co- Investigator

No number (Washburn) 04/01/2009 - 03/30/2013
National Institute of Health
Resistance training: energy balance and weight management
The goal of this project is to determine the impact of resistance training on body composition in overweight adults.
Role: Co-Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Jay L. Vivian, PhD**

eRA COMMONS USER NAME: jvivian

POSITION TITLE: Research Associate Professor

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Illinois at Urbana-Champaign	B.S.	06/1993	Biology-Honors
University of Texas-Houston M.D. Anderson Cancer Center	Ph.D.	06/1999	Genes & Development
Case Western Reserve University	Postdoc	1999-2000	Developmental Genetics
University of North Carolina-Chapel Hill	Postdoc	2000-2004	Developmental Genetics

A. Personal Statement

The generation and analysis of genetically modified mice are important tools for cancer biology researchers of the KU Cancer Center. Because of my recognized expertise in mouse genetics and pluripotent stem cell models, I serve as the **Scientific Director** of the **Transgenic and Gene Targeting Shared Resource** of the KU Cancer Center and the University of Kansas Medical Center. In this position oversee the staff in the KUMC Transgenic Facility to support KUCC researchers and to advance new methods related to the generation of cancer models. With extensive expertise in mouse developmental genetics and pluripotent stem cell biology, and broad experience in generation and analysis of mouse models, I am well qualified for this role, as is demonstrated by my publication record in this area. I have extensive experience in mouse experimental genetics (23+ years), and have successfully generated a number of mouse and pluripotent stem cell models via a variety of novel methods, including homologous recombination in embryonic stem cells, gene trap, chemical mutagenesis, and genome editing. I have published a variety of manuscripts directly relevant to these efforts, including novel methods for mutagenesis and gene targeting, development of screening methodologies, and molecular analysis of regulatory signaling pathways.

In my position as Scientific Director, I consult with faculty and staff on project design for transgenic and mutant mouse models and rodent and human pluripotent stem cell models. During my tenure as Scientific Director, the facility has assisted investigators in many new transgenic and stem cell models using advanced technologies, including BAC transgenesis, *in vivo* recombinase-mediated cassette exchange, genome editing pipeline for using CRISPR/Cas9 tools for germline manipulation in the mouse and rat, and reprogramming and genetic manipulation of human induced pluripotent stem cell lines.

B. Positions and Honors

Positions and Employment

1993-1999	Graduate Research Assistant, Univ. of Texas M.D. Anderson Cancer Center, Houston, TX
1999-2000	Postdoctoral fellow, Case Western Reserve University, Cleveland, OH
2000-2004	Postdoctoral fellow, University of North Carolina, Chapel Hill, NC
2004-2013	Assistant Professor, Department of Pathology and Laboratory Medicine, University of Kansas Medical Center, Kansas City, KS

2009-	Scientific Director, Transgenic and Gene Targeting Institutional Facility, University of Kansas Medical Center, Kansas City, KS
2013-	Research Associate Professor, Department of Pathology and Laboratory Medicine, University of Kansas Medical Center, Kansas City, KS

Other Experience and Professional Memberships

1995-	Member, Society for Developmental Biology
2002-2006	Member, International Mammalian Genome Society
2015-	Member, Society for Neuroscience

C. Contribution to Science

1. I have a long-standing interest in the development of novel methods for transgenesis and mutagenesis of the mammalian genome, in pluripotent stem cells and in vivo. I was involved in early studies of homologous recombination in mouse ES cells, and developed novel methods of gene targeting and transgenesis. I have also developed novel screening strategies to identify chemically mutagenized cells in genotype-directed screens. These methods in mouse ES cells have successfully been used for the generation of important mouse models. We have extended these mutagenesis studies to human pluripotent stem cell models as well. Much of our current studies, both in pluripotent stem cells and in vivo, now utilize genome editing tools such as CRISPR/Cas9, and we have published multiple studies for generating novel mutant animal models using these important reagents.
   a) **Vivian, J. L.**, Klein, W. H., and Hasty, P. (1999). Temporal, Spatial and Tissue-Specific Expression of a Myogenin-lacZ Transgene Targeted to the Hprt Locus in Mice. BioTechniques, 27, 154-62. PMID: 10407678.
   b) **Vivian, J. L**., Chen, Y., Yee, D., Schneider, E., and Magnuson, T. (2002). An allelic series of mutations in Smad2 and Smad4 identified in a genotype-based screen of N-ethyl-N-nitrosourea-mutagenized mouse embryonic stem cells. Proc. Natl. Acad. Sci. USA, 99, 15542-15547. PMCID: PMC137753.
   c) Rumi, MA, Dhajal, P., Kubota, K., Chakraborty, D., Lei, T., Larson, M.A., Wolfe M.W., Roby K.F., **Vivian, J.L.**, Soares, M.J. (2014). Generation of Esr1 knockout rats using zinc finger nuclease-mediated genome editing. Endocrinology, 155(5):1991-9. PMCID: PMC3990838.
   d) Kubota, K., Cui, W., Dhakal, P, Wolfe, M.W., Rumi, M.A., **Vivian, J.L.,** Roby, K.F., Soares, M.J. (2016). Rethinking progesterone regulation of female reproductive cyclicity. Proc Natl Acad Sci U S A. 2016. pii: 201601825. PMCID: PMC4839436.

2. The function of TGF-beta superfamily signaling is a continuing area of focus in my lab, with studies in mouse embryogenesis and functions of these pathways in pluripotency. These studies in pluripotent stem cells incorporate mutagenesis, novel inducible transgenesis methods, pharmacological manipulation, fluorescent reporters, and mathematical modeling to understand the activity of the NODAL and BMP signaling pathways in regulating the undifferentiated stem cell phenotype. Our work has uncovered a novel connectivity between the NODAL and BMP pathways. Our work has also uncovered a function for these signaling pathways in the regulation of the heterogeneous nature of stem cells in undifferentiated culture, including the control of the dynamic expression of pluripotency factors such as NANOG. These studies have important implications both for a basic understanding of pluripotency, and also avenues for modulating pluripotency and these pathways during directed differentiation for regenerative therapy studies. Our recent work have explored the roles of these pathways in neural and trophoblast differentiation of human pluripotent stem cells.
   a) Burgess-Galvin, K.E., Travis, E.D., Pierson, K.E., and **Vivian, J.L.** (2013). TGF-beta-related signaling in embryonic stem cell maintenance: self-renewal as a dynamic and regulated equilibrium. Stem Cells. 31(1):48-58. PMCID: PMC3528825.
   b) Lakatos D, Travis ED, Pierson, KE, **Vivian, JL**, Czirok, A. (2014). Autocrine FGF feedback can establish distinct states of Nanog expression in pluripotent stem cells: a computational analysis. BMC Computational Biology. 8(1), 112. PMCID: PMC4189679.
   c) Renaud SJ, Chakraborty D, Mason CW, Rumi MA, **Vivian JL**, Soares MJ. (2015). OVO-like 1 regulates progenitor cell fate in human trophoblast development. Proc Natl Acad Sci USA. 112(45):E6175-84. PMCID: PMC4653227.

d) Soares, M.J. and **Vivian, J.L.** (2016). Tipping the balance toward trophoblast development. Proc Natl Acad Sci U S A. 113(19):5144-5146. PMID 27118838, PMCID: PMC4868416.

3. Many of our studies in mutagenesis are directed toward studies of developmental genetics of the mouse, to understand the molecular basis of embryogenesis. We have generated and analyzed many mouse mutations, with a variety of developmental phenotypes. Our work has uncovered important shared functions of the myogenic regulatory transcriptional regulators in skeletal muscle differentiation. Other efforts using ENU mutagenesis of TGF-beta signaling components have uncovered a communication between the definitive endoderm and the developing vasculature, and a role for Notch signaling in the regulation of vessel diameter. We have collaborated in studies of the function of a histone methyltransferase in developmental hematopoiesis, and a role of a prolactin family member in placental development. These studies have identified gene regulatory cascades controlling these various developmental events.
   a) **Vivian, J. L**., Chen, Y., Yee, D., Schneider, E., and Magnuson, T. (2002). An allelic series of mutations in Smad2 and Smad4 identified in a genotype-based screen of N-ethyl-N-nitrosourea-mutagenized mouse embryonic stem cells. Proc. Natl. Acad. Sci. USA, 99, 15542-15547. PMCID: PMC137753.
   b) Yi Feng, Y., Yang, Y., Ortega, M.M., Copeland, J.N., Zhang, M., Jacob, J.B., Fields, T.A., **Vivian, J.L.,** Fields, P.A. (2010). Early mammalian erythropoiesis requires the Dot1L methyltransferase. Blood, 116(22):4483-91. PMCID: PMC3321824.
   c) Copeland, J.N., Feng, Y., Neradugomma, N.K., Fields, P.E., and **Vivian, J.L.** (2011). Notch signaling regulates remodeling and vessel diameter in the extraembryonic yolk sac. BMC Dev. Biol 11:12. PMCID: PMC3051915.
   d) Bu, P., Alam, S.M., Dhakal, P**.**, **Vivian, J.L**., Soares, M. (2016). A Prolactin Family Paralog Regulates Placental Adaptations to a Physiological Stressor in the Mouse. Biol Reprod. 115. 138032. PMID: 26985002, PMCID: PMC4939737.

Complete List of Published Work:
http://www.ncbi.nlm.nih.gov/pubmed/?term=vivian+jl

D. Research Support

Ongoing Support:

R21 GM11467 Smith/Vivian (PIs) 7/1/2015-6/30/2017
NIH
Role of a BHLHB9 polymorphism in the etiology of a developmental disorder
The major goals of this project are to generate and analyze mouse models and human pluripotent stem cell models of a rare neurological disorder associated with a putative mutation in the BHLHB9 locus. The resulting phenotypes will be assessed, with a focus on behavioral assessments and molecular defects.
Role: Multi-PI

No Number Newell/Vivian (PIs) 7/1/2016-6/30/2017
Patton Trust
UBQLN2 Mutations in a pediatric neurodegenerative disorder: animal and cell models
The goals of this project are to generate and analyze mouse and human pluripotent stem cell models of a rare human neurodegenerative disorder associated with a deleterious variant in the UBQLN2 locus. The resulting phenotypes will be assessed, with a focus on behavioral assessments, molecular defects, and use of the pluripotent stem cell line for differentiation and drug screening.
Role: Multi-PI

No Number McCarson (PI) 7/1/2016-6/30/2018
Tourette Association of America
Modeling a Tourette-related Human Development Disorder in Mice with Nerve Growth Factor-related Gene Mutations
The major goals of this project are to analyze a novel mouse model of a Tourette syndrome/repetitive behavioral disorder we have generated via CRISPR/Cas9 genome editing, modeling two missense variants

identified in a family. Phenotypes in this model will be assessed, with a focus on behavioral assessments and molecular defects.
Role: Co-Investigator

No Number Smith (PI) 4/15/2011-7/14/2016 NCE
Deffenbaugh Foundation
Human iPS cell models of neuronal differentiation and repair
This purpose of this work is to develop methods to generate human induced pluripotent stem cells and differentiate these cells for use in spinal cord injury models. Reporter based transgenic iPS cell models will be developed for assessing neural differentiation.
Role: Project Investigator

P20 GM104936 Abrahamson (PI) 9/1/2012-6/30/2017
NIH
Molecular Regulation of Cell Development and Differentiation
This P20 Center of Biomedical Research Excellence (COBRE) Program Project is focused on supporting research involving the molecular regulation of cell development and differentiation. I serve as the Director of Core B: Transgenic Facility. In this role I serve as the faculty member to oversee the operations of the Transgenic Facility and assist COBRE investigators in the development of mouse models.
Role: Core Director

P01 HD079363 Soares (PI) 7/24/2014-6/30/2019
NIH/NICHD
Stem Cells and Epigenetics of Trophoblast Lineage Development
The purpose of this project is to elucidate molecular mechanisms controlling development of the trophoblast lineage. The research will provide insights into understanding the etiology of early pregnancy loss.
Role: Co-investigator

R01 DK091277 Fields (PI) 4/15/2012-3/30/2017
NIH
Role of the Histone methyltrasferase Dot1l in erythropoeisis
The purpose of this work is to understand the role of Dot1l in hematopoiesis. My role will involve the generation of induced pluripotent stem cell models and to develop cellular differentiation methods for an in vitro model of Dot1l function in erythropoeisis.
Role: Co-Investigator

Completed Support:

R21 HD071880 Roby (PI) 4/1/2013-3/31/2015
NIH
Fragile X Premutation and Ovarian Insufficiency
The major Aims of this proposal are to generate and analyze a mouse model for reproductive defects associated with Fragile X Syndrome. My role on this project will be to generate a conditional transgenic model for issue-specific expression of the Fragile X expanded repeat, using a novel in vivo targeting approach. I will also work closely with the PI in the analysis of this mouse model.
Role: Co-Investigator

R21 OD010478 Soares (PI) 5/27/2013-4/30/2015
NIH
Rat Models for Sex Steroid Action
The major Aims of this proposal are to generate and analyze mutant rat models with defects in estrogen receptor and prostaglandin receptor signaling. Genome Editing strategies using Zinc Finger Nucleases will be used to develop the proposed models.
Role: Co-investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Fen Wang, MD, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): FENWANG

POSITION TITLE: Associate Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Beijing Medical University, China	Bachelor of Medicine	1984	Medicine
People's Hospital, Beijing Medical University, China	Resident	1987	Surgery
Medical School of Essen University, Germany	PhD	1991	Biomedicine
Medical Center of University of South Alabama, AL	Residency	1998	Surgery
University of Kansas Medical Center, Kansas City, KS	Residency	2002	Radiation Oncology

A. Personal Statement

I am a board certified Radiation Oncologist and have more than 10 years of experience in clinical practice and research, especially in the field of CNS malignance. I was the institutional principal investigator for RTOG from 2008 to 2012 and conducted multiple clinical trials at KUMC cancer center. I was also the institutional PI for an industry sponsored phase I clinical trial, which studied the efficacy of a PARP inhibitor with whole brain radiation on the patients with brain metastasis. The result of this clinical trial has been published in Journal of Neuro-oncology. I have a background in cancer research and drug discovery/delivery, with specific training and expertise in key research areas for this application including clinical trial, molecular cancer therapeutics, drug delivery, and drug resistance. My research has produced number of publications and has been presented at national and international meetings. I received the KUCC pilot grant award in 2014 to conduct research project studying stem cell treatment for glioblastoma multiform. In summary, I have demonstrated a record of successful and productive clinical trial and research relevant to the current proposed research project. My expertise and experience have prepared me well to support the proposed project.

B. Positions and Honors

Positions and Employment:

1991 – 1997 Research Scientist. The Elliott Mastology Center, Baton Rouge, LA.
2002 – 2004 Clinic Instructor, Dept. of Radiation Oncology, Univ. of Kansas Medical Center, Kansas City, KS
2004 – Pres. Assistant Professor, Dept. of Radiation Oncology, Univ. of Kansas Medical Center, KS
2010 – Pres. Associate Professor, Dept. of Radiation Oncology, University of Kansas Medical Center, KS

Other Experience and Professional Memberships:

1992 – 1997 American Association for Cancer Research
1998 – Pres. American Society for Therapeutic Radiology and Oncology
2003 – Pres. Southwest Oncology Group (SWOG)

2006 – Pres. Director of Residency Program, Dept. of Radiation Oncology, University of Kansas Medical Center, KS.
2007 – 2010 American Brachytherapy Society
2005 – 2006 Committee member: Cancer fellowship Review Panel for Ladies Auxiliary – Veterans of Foreign Wars.
2006 – Pres. Committee member: KMCRI Protocol Review and Monitoring Committee,
2006 – Pres. Committee member: SOM Faculty Council, University of Kansas.
2006 – Pres. Committee chair: Educational Committee, Department of Radiation Oncology,
2008 – 2012 Institution Principal Investor: Radiation Therapy Oncology Group (RTOG)
2009 – Pres. Member of Graduate Medical Education Committee (GMEC), KUMC
2011 – Pres. Member. Society of Neuro-Oncology
2008 – Pres. Member: Disease Working Group for CNS and Lung cancer
2014 – Pres. Co-chair, Disease Working Group for Lung Cancer
2015 – Pres. Committee member of institutional review board

C. Selected Peer-reviewed Publications

As a Radiation Oncologist, I've been part of oncology research teams and have co-authored several publications.

a) Minesh P. Mehta, Walter Curran, **Fen Wang** , Lawrence Kleinberg , Anthony Brade , H. Ian Robins, Aruna Turaka , Terri Leahy, Diane Medina, Hao Xiong, Nael Mostafa, Ming Zhu, Jane Qian, Kyle Holen, Vincent Giranda, Ding Wang. Veliparib in Combination with Whole Brain Radiation Therapy in Patients with Brain Metastases: Results of a Phase 1 Study. J. Neurooncol. 2015 Apr; 122(2):409-17. PMID: 25682091 (PMC# not required; not NIH funded)
b) H. Ian Robins, Peixin Zhang, Mark R. Gilbert, Arnab Chakravarti, John F. de Groot, Sean A. Grimm, **Fen Wang**, Frank S. Lieberman, Andra Krauze, Andy M. Trotti, Nimish Mohile, Andrew Y. J. Kee, Howard Colman, Robert Cavaliere, Santosh Kesari, Steven J. Chmura, Minesh Mehta. A randomized phase I/II study of ABT-888 in combination with temozolomide in recurrent temozolomide resistant glioblastoma: an NRG oncology RTOG group study. J Neurooncol 2016 Jan;126(2):309-16. PMID: 26508094 (not NIH funded).
c) Pokhrel, D, Sood, S, Lominska, C, Kumar, P, Badkul, R, Jiang H, **Wang, F**. Potential for reduced radiation-induced toxicity using intensity-modulated arc therapy for whole-brain radiotherapy with hippocampal sparing. J Appl Clin Med Phys. 2015 Sep 8; 16(5):5587. PMID: 26699321 (not NIH funded)
d) Pokhrel, D, Badkul, R, Jiang, H, Kumar, P, **Wang, F.** Technical Note: Dosimetric evaluation of Monte Carlo algorithm in iPlan for stereotactic ablative body radiotherapy (SABR) for lung cancer patients using RTOG 0813 parameters. J Appl Clin Med Phys. 2015 Jan 8; 16(1):5058. PMID: 25679161 (not NIH funded).

D. Research Support

Ongoing Research Support:
None

Completed Research Support:

KU Cancer Center - Pilot Project F. Wang (PI) 2014 - 2015
Targeting Wnt/β-catenin and PI3K/Akt pathways and inhibiting glioblastoma stem-like cells tumorigenicity in tissue culture and xenograft model using lower dose of doxorubicin.
Major Goal: The major goal of this proposal is to develop novel target agent against GMB stem cells and establish a multi-disciplinary cancer drug discovery team for stem cell treatment.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Jan Ellen Ward, LPN**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Clinical Research Coordinator

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Wichita Area Vocational Technical School, Wichita, KS	LPN	01/1994	Nursing

A. Personal Statement

I have the education and experience to manage and support clinical trial activities at the University of Kansas Cancer Center. I have worked as a research coordinator in the community and academic setting. I have experience with Phase I – IV clinical trials and am familiar with the regulatory requirements, human subject protections and nursing support necessary to manage enrollments, eligibility, treatment decisions and assessments needed for successful clinical trials.

B. Positions and Honors

2001 – 2004 Clinical Research Associate/Clinical Research Coordinator, Veterans Administration Medical Center, Kansas City, KS
2005 – pres. Clinical Research Coordinator, KU Cancer Center, University of Kansas Medical Center, Kansas City, KS

C. Contribution to Science

None (not applicable).

D. Research Support

None (not applicable).

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Scott J. Weir, PharmD, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): SJWEIR

POSITION TITLE: Professor of Pharmacology, Toxicology and Therapeutics

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Nebraska, Omaha, NE	B.Sc.	1979	Biology
University of Nebraska Medical Center, Omaha, NE	Pharm.D.	1980	Pharmacy
University of Nebraska Medical Center, Omaha, NE	Ph.D.	1986	Pharmacokinetics & Biopharmaceutics

A. Personal Statement

I hold the Frank B. Tyler Cancer Research Professorship in Therapeutic Discovery and the rank of Professor in the Department of Pharmacology, Toxicology and Therapeutics at the University of Kansas Medical Center (KUMC). I have adjunct faculty appointments in the School of Medicine, University of Missouri at Kansas City and the Department of Pharmaceutical Chemistry, School of Pharmacy, University of Kansas.

Along with Dr. Alan Gamis, MD, MPH, Associate Director, Division of Hematology, Oncology and Bone Marrow Transplant, Children's Mercy Hospital, I co-lead one of four research programs within the NCI Cancer Center at the University of Kansas Medical Center, the Drug Discovery, Delivery and Experimental Therapeutics Research Program (D3ET). Cancer research conducted by D3ET members is best described by three programmatic themes including development of novel cancer therapeutic strategies in preclinical models, discovery and delivery of novel anticancer drugs, and repurposing approved and abandoned drugs for cancer. As co-leaders, we provide leadership in areas of emphasis including pediatric oncology, high-quality cancer-focused research projects at the biology/chemistry interface, basic and clinical science collaborations resulting in clinical trials, and increasing patient accruals on experimental therapeutics trials.

My dual role at KUMC is focused on product development-focused translational science. First, I direct the Institute for Advancing Medical Innovation IAMI at KUMC. IAMI translates peer review-funded basic research into medical innovations, and using an industry approach, executes product development-focused translational research to de-risk the technologies with the intent of partnering those with promise. To date, IAMI has invested over $8.0M in 48 projects, nine of which have resulted in royalty-bearing licenses, and three, have resulted in faculty startup companies. IAMI's therapeutic areas of focus are cancer, neuroscience, and rare diseases. Drugs and diagnostics are the priority technology areas, while IAMI is opportunistic when it comes to investing in advancing medical devices. Multi-disciplinary, multi-organizational project teams are formed with IAMI leadership. Empowered project teams are guided to develop milestone-based product development-focused translational research project plans. Teams are co-led by faculty inventors and IAMI project managers, creating an outstanding training environment for young and established faculty.

Secondly, I play regional and national leadership roles in advancing translational science. I serve as Associate Director for Translational Research at the University of Kansas Cancer Center (KUCC). In this Associate Director role, I lead multi-disciplinary teams focused on translating cancer biology discoveries to new agents for the treatment and prevention of cancer, and to advance these agents to early phase clinical proof of concept trials. Over the past six years (and illustrated by the publications below), in collaboration with industry, academia, government and disease philanthropy partners, we have advanced ten new drug treatments to clinical proof of concept trials. In addition, three IND applications were successfully filed with FDA and one CTA application successfully cleared by Health Canada. I serve on the Management Committee for *The Learning Collaborative*, a unique partnership between KUCC, The Leukemia and Lymphoma Society and the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH). This

partnership brings together the unique competencies and capabilities of each partner, focused on discovering and developing new treatments for blood cancers.

I also advise NIH Director Francis Collins and NCATS Director Christopher Austin on translational science, through my roles on the NCATS Advisory Council and Cures Acceleration Network Board. In 2013-2014, I co-chaired the NCATS Advisory Council CTSA Working Group on the IOM Report that generated recommendations on how to build upon the successes of the CTSA program and realize its full potential for transforming translational science to benefit human health. The Working Group developed a set of clear recommendations to develop a "*translational science workforce that has the skills and knowledge to advance translation of discoveries*". I also serve as a scientific advisor to initiatives and programs within the NCATS intramural program such as the National Chemical Genomics Center, Therapeutics for Rare and Neglected Diseases program, Bridging Interventional Development Gap program, and New Therapeutic Uses program.

1. **Weir, SJ**, DeGennaro LJ, Austin, CP. Repurposing Approved and Abandoned Drugs for the Treatment and Prevention of Cancer through Public-Private Partnership. Cancer Res, 2012 Mar 1;72(5):1055-8. Epub 2012 Jan 13. PMID: 22246671, PMCID: PMC3341848.
2. Pessetto ZY, **Weir SJ**, Sethi G, Broward MA, Godwin AK. Drug Repurposing for Gastrointestinal Stromal Tumor. Mol Cancer Ther 2013 Jul:12(7):1299-1309. PMCID: PMC3707936.
3. Minden MD, Hogge, DE, **Weir, SJ**, Kasper, J, Webster, DA, Patton, L, Jitkova, Y, Hurren, Gronda, M, Goard, CA, Rajewski, LG, Haslam, J, Heppert, KE, Schorno, K, Chang, H, Brandwein, JM, Gupta, V, Schuh, AC, Trudel, S, Yee, KW, Reed, GA, Schimmer, AD. Oral ciclopirox olamine displays biological activity in a phase I study in patients with advanced hematologic malignancy. Am J Hematol. 2014 April; 89(4):363-368. PMID 24273151, Not NIH funded.
4. Williamson SK, Johnson GA, Maulhardt HA, Moore KM, McMeekin DS, Schulz TK, Reed GA, Roby KF, Mackay CB, Smith HJ, **Weir SJ**, Wick JA, Markman M, diZerega GS, Baltezor MJ, Espinosa J, Decedue CH. A phase I study of intraperitoneal nanoparticulate paclitaxel (Nanotax®) in patients with peritoneal malignancies. Cancer Chem Pharmacol. Epub 2015 April 23. PMID 25898813, PMCID: PMC4506131.

B. Positions and Honors

Positions and Employment:

1986-1988 Pharmacokineticist II, Clinical Pharmacology, Marion Laboratories, Inc., Kansas City, MO.
1988-1992 Team Leader, Clinical Pharmacology, Marion Laboratories, Inc., Kansas City, MO
1992-1994 Department Head, Clinical Pharmacokinetics, Marion Merrell Dow, Inc., Kansas City, MO
1994-1996 Director, Acting Vice President, Global Pharmacokinetics, Marion Merrell Dow, Inc. and Hoechst Marion Roussel, Inc., Kansas City, MO
1996-1998 Director, Global Pharmacokinetics, Hoechst Marion Roussel, Inc., Kansas City, MO
1999-2005 Vice President, Early Development and Laboratory Services, Quintiles Inc., Kansas City, MO
2005-2006 Executive Director, Preclinical Technologies, Aptuit Inc., Kansas City, MO
2006-2008 Director, Office of Therapeutics, Discovery and Development, Univ.of Kansas Medical Center, Kansas City, KS
2006-Present Associate Director, Translational Research, Univ. of Kansas Cancer Center, Kansas City, KS
2009-Present Director, Institute for Advancing Medical Innovation, University of Kansas Medical Center, Kansas City, KS
2015-Present Program Leader, Drug Discovery, Delivery & Experimental Therapeutics, Univ. of Kansas Cancer Center, Kansas City, KS

Other Experience and Professional Membership:

1983-Present Member, American Association of Pharmaceutical Scientists
2006-Present Member, American College of Clinical Pharmacology
2006-Present Program Leader, Drug Discovery and Experimental Therapeutics Program, University of Kansas Cancer Center
2006-Present Member, Leadership Committee, University of Kansas Cancer Center
2006-Present Member, CTSA Steering Committee, University of Kansas Medical Center
2009-Present Member, American Association for Cancer Research
2011-Present Management Committee, The Learning Collaborative
2012-Present Co-Chair, Screen-to-Lead Program Study Section, The Leukemia and Lymphoma Society
2012-Present Advisory Council Member, National Center for Advancing Translational Science (NCATS) National Institute of Health

2012-Present External Advisory Committee, T32 Pediatric Clinical Pharmacology Training Program, Children's Mercy Kansas City
2012-Present Advisory Board Member, Cures Acceleration Network (CAN), National Institute of Health
2013-2014 Co-Chair, NCATS Advisory Council CTSA Working Group on the IOM Report
2013-2016 Team Member, Clinical Trial Transformation Initiative Patient Engagement Working Group
2014- Present External Advisory Committee, University of Kentucky Institute for Clinical and Translational Science
2015-Present Member, IOM Working Group on Mapping the Drug Discovery and Development Process

Honors:

1984 Rho Chi Pharmaceutical Honor Society
1984 Sandoz Foundation Fellowship in Biopharmaceutics and Pharmacokinetics
1985 Joseph Noh Graduate Student Fellowship
2006 Frank B. Tyler Cancer Research Professor in Therapeutic Discovery

C. Contribution to Science

I have a proven track record in advancing new drug therapies from the bench to the bedside. Prior to joining the University of Kansas Medical Center (KUMC), I led a drug development division in the pharmaceutical industry for 20 years focused on advancing promising new drug therapies from drug discovery through human and/or clinical proof of concept. My efforts contributed to the successful development and registration of several drug products across a wide range of therapeutic areas. Since joining KUMC, we have established pharmaceutical industry best practices, recruited industry veterans, formed and reorganized supported cores and centers, and established strategic partnerships with industry, academia, government and disease philanthropy organizations, all focused on supporting the discovery, delivery and clinical evaluation of new drug therapies for the treatment and prevention of cancer and rare diseases in children, adolescents, adults and the elderly.

1**. Drug Discovery and Development in an Industry Setting.** Over the course of 20 years, I held positions of increasing responsibility in Research and Development for Marion Laboratories Inc., Marion Merrell Dow Inc., Hoechst Marion Roussel, Aventis Pharmaceuticals, Quintiles Inc, and Aptuit Inc. I was responsible for managing and integrating several departments within this drug development division including pharmacology, toxicology, drug metabolism and pharmacokinetics, bioanalytical chemistry, and clinical pharmacology. During two mergers, I co-led task forces that developed innovative early drug development strategies resulting in the acceleration of development candidates from discovery through clinical proof of concept. During the Hoechst Marion Roussel Inc merger, I led the harmonization and integration of drug metabolism and pharmacokinetics disciplines across the three companies being merged. Drug discovery and development processes developed through these efforts made direct, positive impacts on our efforts to identify failures quickly as well as accelerate winners to late stage drug development. My efforts as well as those of my division contributed to the successful registration and commercialization of several drug products that continue to benefit patients today such as Cardizem CD® and Cardizem Injectable®, Carafate®, Anzemet® Oral and Injectable, Pentasa®, Rifater®, rifapentine, and several Allegra® drug products. Publications representative of my contributions to the science supporting development of these drug products are provided below.

a) Dias VC, **Weir SJ,** and Ellenbogen KA: Pharmacokinetics and pharmacodynamics of intravenous diltiazem in patients with atrial fibrillation or atrial flutter. Circulation 1992 Nov;86(5):1421-1428. PMID: 1423955.
b) Stoltz M, Reynolds D, Elkins L, Salazar D, and **Weir S**: Pharmacokinetics and pharmacodynamics of the monoamine oxidase B inhibitor mofegiline assessed during a phase I dose tolerance trial. Clin Pharmacol Ther 1995 Sep**;**58(3):342-353. PMID: 7554709.
c) Yu DK, Morrill BS, Eichmeier LS, Lanman RC, Lanman MB, Giesing DH, and **Weir S**: Pharmacokinetics of 5-aminosalicylic acid from controlled release capsules in man. Eur J Clin Pharmacol 1995;48(3-4):273-277. PMID: 7589054.
d) Russell T, Stoltz M, and **Weir SJ**: Pharmacokinetics, pharmacodynamics, and tolerance of single- and multiple-dose fexofenadine hydrochloride in healthy male volunteers. Clin Pharmacol Ther 1998 Dec;64:612-621. PMID: 9871426.

2. **Drug Discovery and Development in Academia.** Since joining KUMC over nine years ago, I have led efforts to build an end-to-end, integrated drug discovery and development program that translates basic laboratory discoveries into medical innovations, developing and executing project plans focused on de-risking those projects, and in doing so, creating data packages that support partnering and real financing of the

innovations. The drug discovery and development program capitalizes on the University's research base, leverages R&D infrastructure available within the University, and partners with drug discovery and development service providers and collaborators external to the University, with a singular focus of advancing projects to clinical proof of concept. A two-pronged approach is routinely taken in parallel, to discover new therapeutic entities and also, to look for opportunities to repurpose existing drugs. IAMI's first drug product, Epaned™, developed in partnership with Silvergate Pharmaceutics LLC and Children's Mercy Hospital in Kansas City, MO, was approved by FDA in August 2013 and commercially launched in October 2013. The drug discovery and development program established under my leadership is a key differentiator for KUMC's CTSA center as well as its NCI designated Cancer Center. Representative publications reflecting my contributions to academic drug discovery and development are provided below.

a) Song, S, Christova, T, Perusini, S, Alizadesh, S, Bao, RY, Miller, BW, Hurren, R, Jitkova, Y, Gronda, M, Isaac, M, Joseph, B, Subramanian, R, Aman, A, Chau, A, Hogge, DE, **Weir, SJ**, Kasper, J, Schimmer, A, Al-Awar, R, Wrana, JL, Attisano, L. Wnt inhibitor screen reveals iron dependence on {beta}-catenin signaling in cancers. Cancer Res 2011 Dec 15:71(24):7628-39. Epub 2011 Oct 18. PMID: 22009536, Not NIH funded.
b) Hughes, M, Inglese, J, Kurtz, A, Andalibi, A, Patton, L, Austin, C, Baltezor, M, Beckloff, M, Sittampalam, S, Weingarten, M, **Weir, S**: Early Drug Discovery and Development Guidelines: For Academic Researchers, Collaborators, and Start-Up Companies. NCBI Bookshelf, National Library of Medicine, National Institutes of Health Bookshelf ID: NBK92015. Epub 2012 May 1. PMID 22553881, Not NIH funded.
c) Periyasamy G, Ponnurangam S, Chakrabarti D, Sugumar A, Padigaru M, **Weir SJ**, Balakrishnan A, Sharma S, Anant S. CDK-4 Inhibitor P276 Sensitizes Pancreatic Cancer Cells to Gemcitabine-Induced Apoptosis. Mol Cancer Ther 2012 Jul;11(7):1598-608. PMCID: PMC3392497.
d) **Weir SJ**, Gao Y, Henney HR. Population pharmacokinetics and pharmacodynamics of dalframpridine-ER in healthy volunteers and patients with MS. Curr Med Res Opin 2013 29(12):1627-1636. Epub 2012 Nov 16. PMID: 23157466, Not NIH funded.

3. **Discovery and Development of New Treatments for Bladder Cancer**. In addition to providing drug discovery and development leadership at KUMC, I am a co-inventor of a promising new treatment for non-muscle invasive bladder cancer (NMIBC). The patented prodrug of ciclopirox represents potentially the first systemically administered treatment for NMIBC. Following systemic administration, this agent selectively delivers ciclopirox to the entire urinary tract. In vitro and in vivo preclinical proof of principle has been established in human bladder cancer cell lines as well as a validated mouse model of invasive bladder cancer. IND-enabling activities are underway with plans to initiate clinical proof of concept studies in NMIBC patients in 2017. Issued, pending and filed patent applications supporting development of ciclopirox prodrug are provided below.

a) Issued Patent US 8,609,637. *Prodrugs of 6-cyclohexyl-1-hydroxy-4-4methylyridin-2-(1H)-one and derivatives thereof.* Tanol M and **Weir, SJ,** Issued 17 December 2013.
b) Patent Pending PCT/US2011/063070. *Prodrugs of 6-cyclohexyl-1-hydroxy-4-4methylyridin-2-(1H)-one and derivatives thereof.* Tanol M and **Weir, SJ,** Filed 02 December 2011.
c) Patent Filed 62/134,747. *Methods Of Bladder Cancer Treatment With Ciclopirox, Ciclopirox Olamine, or a Ciclopirox Prodrug*. **Weir SJ** and Anant S**,** Filed 18 March 2015.
d) Issued Certificate of Japanese Patent No. 5853028. *Prodrugs of 6-cyclohexyl-1-hydroxy-4-4methylyridin-2-(1H)-one and derivatives thereof.* Tanol M and **Weir, SJ,** Issued 11 December 2015.
e) Issued Patent US 9,243,014 B2. *Methods of Treatment with Prodrugs of 6-cyclohexyl-1-hydroxy-4-4methylyridin-2-(1H)-one and derivatives thereof.* Tanol M and **Weir, SJ,** Issued 26 January 2016.

D. Research Support

Ongoing Research Support:

R01CA190291 Anant (PI) 08/01/2014-07/31/2018
NIH/NCI
Bitter Melon and Stem Cell Signaling in Colon Cancer
The objective of *Bitter Melon and Stem Cell Signaling in Colon Cancer* is to: 1) dissect the mechanism by which bitter melon extracts and an active compound in the extracts (charantin) inhibit ROS levels in DCLK1+

stem cells; 2) determine the role of Notch signaling in regulating PXR expression, and 3) characterize the effect of DCLK1 and target proteins myosin light chain kinase and acyl CoA synthase as biomarkers for determining preclinical proof of principle in validated mouse models.
Role: Co-Investigator

R01CA182872 Anant (PI) 01/01/2014-12/31/2018
NIH/NCI
Novel Dual Notch/PXR Targeting for Colon Cancer Therapy
The objective of *Novel Dual Notch/PXR Targeting for Colon Cancer Therapy* is to evaluate novel compounds MRLTHB and MRLTHBCD as therapeutic agents for the treatment of colon cancer. This project has three aims including: 1) characterization of the preclinical pharmacokinetics and pharmacodynamics of MRLTHBCD; 2) determination of in vivo preclinical efficacy of MRLTHBCD alone and in combination with 5-fluourouracil in a validated colon cancer mouse model, and 3) evaluation of whether Notch-1 inhibition is essential for MRLTHBCD activity and its effects of overexpressing the active protein on PXR gene expression.
Role: Principal Investigator (Multi-PI)

P30CA168524 Jensen (PI) 07/11/2012 - 06/30/2017
NIH/NCI
Cancer Center Support Grant (CCSG) for NCI-designated Cancer Centers
The University of Kansas Cancer Center (KUCC) is a matrix organization that leverages unique scientific assets to build a nationally significant cancer research and treatment center that will become a leading academic institution in the world in transforming discoveries in the laboratory into new therapeutic approaches.
Role: Key Personnel (Associate Director – Translational Research, D3ET Program Leader)

No number Weir (PI) 12/20/2010-12/31/2016
The Leukemia & Lymphoma Society - Therapy Acceleration Program
The Learning Collaborative (TLC)
Funding will support new therapies for chronic lymphocytic leukemia through a trans-disciplinary collaboration team that includes regional and national partners from government, patient advocacy organizations, academia and industry.
Role: Principal Investigator

Completed Research Support (in the past 3 years):

U54RR031295 Barohn (PI) 07/01/2011 - 06/30/2016
NIH
Institutional Clinical and Translational Science Award (U54)
Create a new academic home with training programs for clinical and translational investigators provide an enhanced coordinated translational research infrastructure and actively engage the community in developing, testing and disseminating translational research.
Role: Key Personnel (Director – Novel Clinical and Translational Research Methods I)

Grant #20086282 Weir (PI) 01/01/2009-12/31/2015
Ewing Marion Kauffman Foundation Strategic Grant
Major Goal: This grant provides support to establish the Institute for Advancing Medical Innovation at the University of Kansas
Role: Principal Investigator

U13MH088095 Weir (PI) 07/01/2010 – 03/31/2014
NIH-*Annual Conference on Development of Robust Experimental Assay Methods (DREAM)*
Role: Principal Investigator

UL1TR000001 Barohn (PI) 07/15/2012 - 01/31/2014
NIH -*Drug Repurposing and Rediscovery for Gastrointestinal Stromal*
Role: Key Personnel

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Danny R. Welch, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): DWELCH

POSITION TITLE: Professor and Chair- Cancer Biology; Associate Director for Basic Research and Education; Hall Family Endowed Professor of Molecular Medicine

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of California at Irvine	BS	6/1980	Biological Sciences
University of Texas – Houston	PhD	5/1984	Biomed Sci – Tumor Bio
University of Texas- MD Anderson Cancer Center	Postdoc	8/1984	Tumor Biol- Metastasis

A. Personal Statement

I have been studying various aspects of cancer biology, tumor progression and metastasis since I was an undergraduate at UCI. I was the first graduate student in the Department of Tumor Biology at M.D. Anderson Cancer Center, where I studied phenotypic and genetic instability leading to development of heterogeneity as well as developing liposomal drug delivery methods. Following graduate school I worked my way through the ranks in the discovery programs at Upjohn and Glaxo before taking my first faculty position at Penn State Hershey Medical Center, where I was the first faculty member hired into the Jake Gittlen Cancer Research Institute. At Penn State, the focus of my research shifted to discovery of metastasis-regulatory genes. There, we cloned 2 of the now more than 30 metastasis suppressors (KISS1 and BRMS1) began to characterize their function(s). I was then recruited to UAB where we continued to define the regulatory pathways in mechanisms of action for these and additional metastasis suppressors and metastasis-regulatory microRNA. Since moving to the University of Kansas Cancer Center, my laboratory's work is increasing its translational focus and has also begun studying the roles of mitochondrial genetics in regulating complex diseases, focusing on metastasis. The major tumor types studied in my lab are melanoma, breast, pancreatic, but we also have experience in colorectal, lymphoma, ovarian, prostate and neuroblastoma.

Research Expertise: As we have characterized the metastasis suppressors, our research has taken us into the arenas of G-protein coupled receptors, phosphoinositide signaling, tumor dormancy, chromatin structure, epigenetics, microRNA regulation/function and mitochondrial genetics. We have experience in genetics, biochemistry, molecular biology, mouse models and cell biology. I am co-inventor, with Scott Ballinger, of the MNX mouse.

Leadership & Teaching Experience: I serve on the external advisory boards for numerous cancer center (CCSG) and T32 grants as well as not-for-profit research and educational foundations. I have been primary mentor for 12 graduate students and 23 postdoctoral fellows, all of whom have obtained research positions in cancer research in academia, industry and government. I have launched two graduate programs (Cancer Biology at UAB and an HHMI-funded program in translational research) and have broad managerial experience, including personnel development, budget preparation, communication, and leadership of multi-investigator programs. I have reviewed numerous NIH and HHMI graduate programs in addition to service on the Board of Directors for the Cancer Biology Training Consortium (CABTRAC) as Secretary and Treasurer. I am currently President-elect. I am currently Associate Director for Basic Sciences and Education at the NCI-designated University of Kansas Cancer Center. I am delighted to bring these experiences to bear on this CCSG application as Associate Director for Basic Sciences and Education at the KU Cancer Center.

B. Positions and Honors

1984-1988 The Upjohn Co. –
- 1984-1988 Scientist I, Cancer & Infectious Diseases Research
- 1988-1988 Scientist II, Cancer & Infectious Diseases Research

1988-1990 Glaxo Research Laboratories –
- 1988-1989 Senior Scientist III Department of Chemotherapy
- 1989-1990 Res. Investigator Department of Chemotherapy

1990-2002 Penn State University College of Medicine –
- 1990-1997 Assistant Professor of Pathology
- 1997-2003 Associate Professor of Pathology (tenured)
- 1994-2003 Associate Professor of Pharmacology
- 1991-2003 Graduate Faculty, Penn State University College of Medicine
- 1999-2002 Director - National Foundation for Cancer Research Ctr. for Metastasis Research

2002-2011 University of Alabama at Birmingham –
- 2002-2011 Leonard H Robinson Professor of Pathology
  Professor of Pharmacology & Toxicology
  Director - National Foundation for Cancer Research Ctr. for Metastasis Research
  Senior Member, UAB Comprehensive Cancer Center
  Senior Member, Center Metabolic Bone Disease
  Senior Member, Gene Therapy Center
  Senior Member, Skin Diseases Research Center
- 2004-2011 Professor of Cell Biology
- 2008-2011 Director, UAB Graduate Program in Cancer Biology
  Director's Council, UAB Comprehensive Cancer Center
- 2009-2011 Director, Howard Hughes Med-to-Grad Graduate Program

2011- pres. The University of Kansas Medical Center –
- 2011-present Professor & Chair, Department of Cancer Biology
  Hall Family Foundation Professor of Molecular Medicine
  Professor of Pathology
  Professor of Cell & Molecular Physiology
  Director - National Foundation for Cancer Research Ctr. for Metastasis Research
  Associate Director for Basic Research & Education - KU Cancer Center
- 2014-present Director, Office of Postdoctoral Affairs

C. Honors and Awards (selected):

1983 Sigma Xi
2001 American Cancer Society Chairman's Award for Outstanding Efforts in Cancer Control
2003, 2009 UAB Molecular and Cellular Pathology Graduate Student Teaching Award
2006 - 2008 President, Metastasis Research Society (Board of Directors 1998-2014)
2008 Metastasis Research Society Paget-Ewing Award for Excellence in Metastasis Research
2008 UAB Dean's Award for Excellence in Mentoring
2009-2013 Director, Howard Hughes Medical Institute Med-into-Grad Graduate Program (UAB)
2010-2017 Komen Scholar (Susan G. Komen for the Cure)
2011 Kansas Bioscience Authority Eminent Scholar

Advisory Boards (selected):

1992-2001 Medical Director At-Large, American Cancer Society Commonwealth Division
1997-2003 ACS Study Section - Carcinogenesis, Nutrition & Environment (Chair, 2003)
2000-2010 California Breast Cancer Research Program (Chair 2008-2010)
2000-2011 American Institute for Cancer Research Scientific Review Panel B
2004-2005 US Army Medical Research & Materiel Command, Breast Cancer Research Program Integration Panel

2005,2007 European Union Framework VI and VII review panels
2007-2010 Susan G. Komen for the Cure Review Panels (Chair 2007, 2009, 2010, 2011-2015)
2004-2010 NIH Cancer Genetics Study Section (Chair 2008-2010)
2010-2015 Susan G. Komen for the Cure Scientific Advisory Council
2011-2014 American Cancer Society Extramural Research Advisory Council
2014-2017 NCI-F Study Section
2015 European Commission - Research Executive Agency — 'Health, Demographic Change and Wellbeing' challenge under Horizon 2020

Editorial Boards (key leadership and present)
2004-2011 Editor-in-Chief, *Clin Exptl Metastasis*
2009-present Deputy Editor, *Cancer Research*
2011-present Deputy Editor, *Cancer Today*
2013-present Associate Editor, *Journal of Molecular Medicine*
2000-present *Clinical & Experimental Metastasis*
2001-present *Cancer & Metastasis Reviews*
2001-present *Cancer Research*
2007-present *Cancer Microenvironment*
2008-present *Journal of Ovarian Research*

D. Contributions to Science

1. **Developed and characterized many widely used metastasis models and wrote key methods review to perform metastasis assays.**

   a) Neri, A., **Welch, D.R.**, Kawaguchi, T. & Nicolson, G.L. Development and biologic properties of malignant cells and clones of a spontaneously metastasizing rat mammary adenocarcinoma. *Journal of the National Cancer Institute* (1982) 68: 507-517. PMID: 6950180
   b) **Welch, D.R.**, Bisi, J.E., Miller, B.E., Conaway, D., Seftor, E.A., Yohem, K.H., Gilmore, L.B., Seftor, R.E.B., Nakajima, M. & Hendrix, M.J.C. Characterization of a highly invasive and spontaneously metastatic human malignant melanoma cell line. *International Journal of Cancer* (1991) 47:227-237. PMID: 1671030
   c) **Welch, D.R.** Technical considerations when studying cancer metastasis in vivo. (1997) *Clinical and Experimental Metastasis* 15(3): 272-306. PMID: 9174129
   d) **Welch, D.R.**, Lobl, T.J., Seftor, E.A., Wack, P.J., Aeed, P.A., Yohem, K.H., Seftor, R.E.B. & Hendrix, M.J.C.(1989) Use of the membrane invasion culture system (MICS) as a screen for anti-invasive agents. *International Journal of Cancer* 43:449-457. PMID: 2925275

2. **First to identify the pro-metastatic role for neutrophils (similar to myeloid-derived suppressor cells) and pro-invasive/pro-metastasis effect of TGFβ.**

   a) **Welch, D.R.**, Schissel, D.J., Howrey, R.P. & Aeed, P.A. Tumor-elicited polymorphonuclear cells, in contrast to 'normal' circulating polymorphonuclear cells, stimulate invasive and metastatic potentials of rat mammary adenocarcinoma cells. *Proceedings of the National Academy of Science (USA)* (1989) 86:5859-5863. PMID: 2762301
   b) McGary, C.T., Miele, M.E., **Welch, D.R.** Highly metastatic 13762NF rat mammary adenocarcinoma clones secrete IL-3 or GM-CSF-like activity that is apparently responsible for neutrophilia response. *American Journal of Pathology* (1995) 147: 1668-1681. PMID: 7495292
   c) **Welch, D.R.**, Fabra, A. & Nakajima, M. (1990) Transforming growth factor-beta stimulates mammary adenocarcinoma cell invasion and metastatic potential. *Proceedings of the National Academy of Science (USA)* 87:7678-7682. PMID: 2217201

3**. Discovered 8 of the 30 functionally defined metastasis suppressors.**

   a) **Welch, D.R.**, Chen, P., M.E. Miele., Bower, J.M., McGary, C.T., Stanbridge, E.J. & Weissman, B.E. Microcell-mediated transfer of chromosome 6 into metastatic human C8161 melanoma cells suppresses metastasis, but not inhibit tumorigenicity. *Oncogene* (1994) 9: 255-262. PMID: 8302587
   b) Lee, J.-H., Miele, M.E., Hicks, D.J., Phillips, K.K., Trent, J.M., Weissman, B.E. and **Welch, D.R.** (1996) KiSS-1, A novel malignant melanoma metastasis-suppressor genes identified in chromosome 6-

malignant melanoma microcell hybrids. *Journal of the National Cancer Institute* 88: 1731-1737. PMID: 8944003

c) Seraj, M.J.*, Samant, R.S.*, Verderame, M.F., **Welch, D.R.** (2000) Functional evidence for a novel human breast carcinoma metastasis suppressor, BRMS1, encoded at chromosome 11q13 * Contributed equally to this work. *Cancer Research* 60: 2764-2769. PMID: 10850410

d) Bohl, C.R., Harihar, S., Denning, W.L., Sharma, R., and **Welch, D.R**. (2014) Metastasis Suppressors in Breast Cancers: Mechanistic Insights and Clinical Potential. *Journal of Molecular Medicine* 92: 13-30 (JMME-D-13-00316, doi: 10.1007/s00109-013-1109-y). PMCID: PMC3923422

4. **Defined the first molecular pathways regulating metastasis and metabolism (includes microRNA) and developed the MNX mouse to study cross-talk between mitochondrial and nuclear DNA for the study of cancer and cardiovascular disease.**

a) Feeley, K.P., Bray, A.W., Westbrook, D.G., Johnson, L.W., Kesterson, R.A., *Ballinger, S.W. ***Welch, D.R**. (2015). Mitochondrial genetics regulate breast cancer tumorigenicity and metastatic potential. Cancer Research 2015 Oct 15;75(20):4429-36. PMCID: PMC4610037. (*Co-corresponding authors)

b) Goldberg, S.F., Miele, M.E., Hatta, N., Takata, M., Paquette-Straub, C., Freedman, L.P. and **Welch, D.R.** (2003) Melanoma metastasis suppression by chromosome 6: Evidence for a pathway regulated by DRIP130/CRSP3 and VDUP1. *Cancer Research* 63: 432-440. PMID: 12543799

c) Hurst, D.R., Edmonds, M.D., Scott, G.K., Benz, C.C. and **Welch, D.R.** (2009) Breast cancer metastasis suppressor 1 BRMS1 up-regulates miR-146 that suppresses breast cancer metastasis. *Cancer Research* 69: 1279-1283 (DOI:10.1158/0008-5472.CAN-08-3559). PMCID: PMC2754225

d) Liu, W., Beck, B.H., Vaidya, K.S., Nash, K.T., Feeley, K.P. , Ballinger, S.W., Pounds, K.M., Denning, W.L., Diers, A.R., Landar, A., Dhar, A., Iwakuma, T., **Welch, D.R**., (2014) Metastasis suppressor KISS1 seems to reverse the Warburg effect by enhancing mitochondrial biogenesis. *Cancer Research* 74: 954-963 (doi: 10.1158/0008-5472.CAN-13-1183). PMCID: PMC3946400.

5. **Described how KISS1 induces dormancy of already disseminated cells.**

a) Goldberg, S.F.*, Harms, J.F.*, Quon, K. and **Welch, D.R.** (2000) Metastasis-suppressed C8161 melanoma cells arrest in lung but fail to proliferate. *Clinical and Experimental Metastasis* 17: 601-607. * Contributed equally to this work. (although dated 1999, actually submitted and published 2000) PMID: 10845559

b) Nash, K.T., Phadke, P.A., Navenot,J -M., Hurst, D.R., Accavitti-Loper, M.A., Sztul, E., Vaidya, K.S., Frost, A.R., Kappes, J.C., Peiper, S.C. and **Welch, D.R.** (2007) KISS1 metastasis suppressor secretion is required for multiple organ metastasis suppression and for the maintenance of disseminated cells in a dormant state. *Journal of the National Cancer Institute* 99: 309-321. (DOI:10.1093/jnci/djk053) PMCID: PMC1820615

Complete List of Published Work in MyBibliography: (Peer-reviewed = 197; Books/chapters = 46; Abstracts = 330)
http://www.ncbi.nlm.nih.gov/sites/myncbi/1fqEnvnZmMIkU/bibliography/43249282/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

SAC110037 Welch (PI) 07/28/2011 – 09/27/2017
Susan G. Komen for the Cure
Regulation of Metastasis by Mitochondrial DNA
Assess roles of mtDNA in metastasis
Role: PI

No Number Welch (PI) 01/01/2014 – 12/31/2016
National Foundation for Cancer Research
NFCR Center for Metastasis Research
Role: Perform pilot experiments related to metastasis genetics.

Role: PI

P30 CA168524 Jensen (PI) 07/11/2012 – 06/30/2017
PHS/NCI
Cancer Center Support Core Grant
The major goal of this project is Cancer Center core support. The core grant supports the senior leadership, programs and shared facilities of the Cancer Center, organizational framework to promote interdisciplinary research, and development and support of shared resources.
Role: Associate Director for Basic Research and Education

R01 CA174735 Iwakuma (PI) 05/01/2014 - 04/30/2019
The Role of MDM2-MTBP Axis in Cancer Metastasis
To determine the roles of MTBP and MDM2 in cancer metastasis.
Role: Co-Investigator

PDF14301553 Marquez, Xu (PIs) 08/02/2014 – 08/01/2017
Susan G. Komen for the Cure
Novel anti-MetastamiR therapy for metastatic breast cancer
Postdoctoral Fellowship to study roles of miRNA as potential therapeutics.
Role: Co-mentor

Completed Support:

R01CA134981 Welch (PI) 09/01/2009 – 05/31/2016
PHS/NCI
KISS1: Defining Mechanisms for Anti-metastatic Therapy
Determine whether KISS1 maintain disseminated tumor cells in a non-proliferating, dormant state.
Role: PI

CCR13261859 Cheng (PI) 08/16/2013 - 08/15/2016
Susan Komen Foundation
Molecular Switching of DCIS to invasive carcinomas by CCR2 Chemokine Receptors
Characterize the mechanisms through which CCL2/CCR2 signaling in breast cancer cells regulate DCIS progression.
Role: Mentor

No Number Welch (PI) 10/01/2009 - 09/30/2013
Howard Hughes Medical Institute
Howard Hughes Med-into-Grad Graduate Program
Develop multidisciplinary graduate program

KG110409 Welch (PI Subcontract UAB) 12/01/2011 – 07/17/2014
Susan G. Komen for the Cure
Gli1 in the development and persistence of micro-metastases of breast cancer
Role: Consultant

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Jo Adrianne Wick, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): jawick

POSITION TITLE: Assistant Professor/Assistant Director of Graduate Education

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Mary Hardin-Baylor, Belton, TX	BS	2003	Mathematics
Baylor University, Waco, TX	MS	2005	Statistics
Baylor University, Waco, TX	PhD	2008	Statistics

A. Personal Statement

My research focuses on issues in clinical trial design and Bayesian methodology. I have engaged in methodological research in both a clinical and pre-clinical research environment in areas including benefit-risk analysis, response-adaptive clinical trial design, Bayesian trial design, and secondary data analysis. Since starting at KUMC, I have expanded my research to include statistical applications to basic science, most notably to developing more efficient clinical trial designs and high-throughput screening methods, and to statistics education. My roles for this project will include overseeing all design and statistical analysis for the study aims and I will ensure proper interpretation of results.

B. Positions and Honors

Positions and Employment:

2004 - 2005 Teaching Assistant, Department of Statistical Science, Baylor University, Waco, Texas
2005 - 2007 Statistical Consultant, Department of Statistical Science, Baylor University, Waco, Texas
2006 Statistical Consultant, Darnall Army Community Hospital, Fort Hood, Texas
2006 - 2007 Teacher of Record, Department of Statistical Science, Baylor University, Waco, Texas
2007 Biostatistics Intern, Eli Lilly & Company, Indianapolis, Indiana
2008 - Present Assistant Professor, Department of Biostatistics, University of Kansas Medical Center, Kansas City, Kansas
2013 - Present Assistant Director, Graduate Education, Department of Biostatistics, University of Kansas Medical Center, Kansas City, Kansas

Other Experience and Professional Memberships:

2004 - Present Member, American Statistical Association
2008 - Present Member, Kansas/Western Missouri Chapter of the American Statistical Association
2008 - Present Member, Eastern North American Region/International Biometric Society
2008 - 2009 Ad-hoc Reviewer, *Statistics in Medicine*
2008 - 2013 Ad-hoc Reviewer, *Contemporary Clinical Trials*
2008 - 2011 Member, Protocol Review and Monitoring Committee, University of Kansas Cancer Center, Kansas City, Kansas
2008 - Present Member, University of Kansas Cancer Center, Kansas City, Kansas
2008 - Present Co-chair, Biostatistics Graduate Degree Program Development Committee, University of Kansas Medical Center
2008 - Present Member, Kansas Public Health Association
2009 Reviewer, National Institutes of Health Biology of Development and Aging IRG panel: Cancer Biomarkers

2009	Reviewer, Prostate Cancer Research Program, Congressionally Directed Medical Research Program, Department of Defense
2009 - 2010	Reviewer, Diagnostic and Prognostic Biomarkers-2 Peer Review Committee, Susan G. Komen for the Cure Grants Program
2009 - 2013	Member, Biostatistics Graduate Program Curriculum Committee, University of Kansas Medical Center
2009 - 2014	Reviewer, National Institutes of Health Clinical and Integrative Cardiovascular Science Study Section
2011	Reviewer, Epigenetic Alterations Peer Review Committee, Susan G. Komen for the Cure Grants Program
2011 - 2013	Ad-hoc Reviewer, *Journal of Clinical Oncology*
2013	Reviewer, National Institutes of Health Oncology 2 – Translational Clinical (OTC) Developmental Therapeutics Study Section
2013	Ad-hoc Reviewer, *The American Statistician*
2013	Ad-hoc Reviewer, *Journal of Statistics Education*
2013 - Present	Chair, Biostatistics Graduate Program Admissions Committee, University of Kansas Medical Center
2013 - Present	Chair, Biostatistics Graduate Program Curriculum Committee, University of Kansas Medical Center
2013 - Present	Member, MPH Program Executive Committee, University of Kansas Medical Center
2013 - Present	Member, MSCR Program Executive Committee, University of Kansas Medical Center
2013 - 2014	Vice President, Kansas/Western Missouri Chapter of the American Statistical Association
2014 - 2015	President, Kansas/Western Missouri Chapter of the American Statistical Association
2014 - Present	Member, MD-PhD Program Admissions Committee, University of Kansas Medical Center
2016 - Present	Biostatistics Thread Head for ACE Curriculum, Office of Medical Education, KU School of Medicine

Honors and Awards:

2005	Interdisciplinary Research and Scholarship Appointment, Baylor University, Waco, Texas
2007	Outstanding Graduate Student, Baylor University Department of Statistical Science, Waco, Texas
2008	Baylor University Graduate School Travel Award
2012	University of Kansas Medical Center, Biostatistics Teacher of the Year Award
2013	University of Kansas Medical Center, Biostatistics Teacher of the Year Award

C. Contribution to Science

1. My collaborative publications focus primarily on pre-clinical and clinical testing of interventions targeting cancer. I served as co-investigator or biostatistician in all of these studies for which my responsibilities included trial design, data analysis and visualization, and interpretation and dissemination of findings.

a) Williams, C.B., Kambhampati, S., Fiskus, W., Wick, J.A., Dutreix, C., Ganguly, S., Aljitawi, O., Reyes, R., Fleming, A., Abhyankar, S., Bhalla, K.N., McGuirk, J.P. (2013). Preclinical and Phase I Results of Decitabine in Combination with Midostaurin (PKC412) for Newly Diagnosed Elderly or Relapsed/Refractory Adult Patients with Acute Myeloid Leukemia. Pharmacotherapy, DOI: 10.1002/phar.1316. PMID: 23798029 (PMC# not required; not NIH funded)

b) Dubey, S., **Wick, J.A**., Tawfik, O., Zainfeld, D., Holzbeierlein, J., Van Veldhuizen, P.J., Thrasher, B., Karan, D. (2014). MP49-05 Applicability of Macrophage Inhibitory Cytokine-1 as a Potential Biomarker for Racial Disparity in Prostate Cancer. The Journal of Urology, DOI: 10.1016/j.juro.2014.02.1106. Not NIH funded.

c) Huang, C.H., **Wick, J.A**., Gurusingham S., Nirmalanandhan, V.S., Ganti, A.K., Neupane, P.C., Williamson, S.K., Godwin, A.K., Schmitt, S., Smart, N.J., Spencer, S., Van Veldhuizen, P.J. (2014). A Multicenter Pilot Study Examining the Role of Circulating Tumor Cells as a Blood-Based Tumor Marker in Patients with Extensive Small-Cell Lung Cancer. Frontiers in Oncology, DOI: 10.3389/fonc.2014.00271. PMC196518.

d) Williamson, S., Johnson, G., Maulhardt, H., Moore, K., McMeekin, D., Schultz, T., Reed, G., Roby, K., Mackay, C., Smith, H., Weir, S., **Wick, J**., Markman, M., diZerega, G., Espinosa, J., Decedue, C. (2015). A Phase I Study of Intraperitoneal Nanoparticulate Paclitaxel (Nanotax®) in Patients with Peritoneal Malignancies. Cancer Chemotherapy and Pharmacology, DOI: 10.1007/s00280-015-2737-4. PMC4506131.

2. I am co-investigator on several studies examining the effectiveness of various intervention models (e.g., group and/or telehealth delivery) in chronic heart failure and home parental nutrition. This research has demonstrated the importance of knowledge, social support, income adequacy and depression in improving patient clinical outcomes and quality of life.

a) Smith, C.E., Piamjariyajul, U., **Wick, J.A**., Spertus, J.A., Russell C., Dalton, K.M., Elyachar, A., Vacek, J.L., Reeder, K.M., Nazir, N., Ellerbeck, E. F. (2014). Multidisciplinary Group Clinic Appointments: The Self-Management and Care of Heart Failure (SMAC-HF) Trial. Circulation Heart Failure, DOI: 10.1161/CIRCHEARTFAILURE.113.001246. PMC4241146
b) Smith, C.E., Piamjariyakul, U., Dalton, K.M., Russell, C., **Wick, J.A**., Ellerbeck, E.F. (2015). Nurse-Led Multidisciplinary Heart Failure Group Clinic Appointments: Methods, Materials, and Outcomes Used in the Clinical Trial. Journal of Cardiovascular Nursing, DOI: 10.1097/JCN.0000000000000255. PMC4464953.

3. My methodological research revolves around clinical trial design. These methods include survey development, clinical testing of interventions and selection of the optimal design based on operating and subject-focused characteristics.

a) Mahnken, J.D., **Wick, J.A**., Gajewski, B.J., Mayo, M.S. (2010). A Study Design with Conditionally, Serially Assessed Co-Primary Endpoints: An Application to a Single-Arm, Pilot Non-Hodgkin's Lymphoma trial. Drug Development Research, DOI: 10.1002/ddr.20387. Not NIH funded.
b) Jiang, Y., Boyle, D., Bott, M., **Wick, J.A**., Yu, Qing, Gajewski, B. (2014). Expediting Clinical and Translational Research via Bayesian Instrument Development. Applied Psychological Measurement, DOI: 10.1177/0146621613517165. PMC4034393.
c) **Wick, J.A**., Berry, S.M., Yeh, H., Choi, W., Pacheco, C.M., Daley, C., Gajewski, B. (2015). A Novel Evaluation of Optimality for Randomized Controlled Trials. Journal of Biopharmaceutical Statistics (in press).

NCBI Bibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/jo.wick.1/bibliography/48518633/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support:

P30 CA168524 (Jensen, Roy) 07/11/2012 – 6/30/2017
NIH/NCI
Cancer Center Support Grant
Major Goals: The University of Kansas Cancer Center is a growing matrix organization that aims to leverage unique scientific assets to build a nationally significant cancer research and treatment center that will become the leading academic institution in the world for transforming discoveries in the laboratory into new therapeutic approaches.
Role: Statistician

R01CA185011 (Anant, Shrikant) 01/01/2014 - 12/31/2018
NIH
Novel dual Notch/PXR Targeting for Colon Cancer Therapy

Major Goals: We have now developed a novel drug, THB that targets Notch signaling and inhibits PXR. The goal of the current project is to determine in vitro and in vivo proof of principle for this agent as an oral therapeutic for colon cancer, the third leading cause of cancer related deaths in both men and women.
Role: Co-Investigator

Recently Completed Support (selected):

UL1TR000001/TR000119/TR000120 (Barohn, Richard Joel) 06/01/2011 - 02/29/2016
NIH
Heartland Institute for Clinical and Translational Research
Major Goals: Create a new academic home with training programs for clinical and translational investigators, provide an enhanced coordinated translational research infrastructure and actively engage the community in developing, testing and disseminating translational research.
Role: Statistician

R01EB015911 (Smith, Carol E) 01/01/2013 - 12/31/2015
NIH
Mobile Technologies Assisting Patients and Family Caregivers in Healthy Living
Major Goals: 1) Develop trajectories curves from existing date, 2) Test PC tablet type devices to improve family caregivers independence and health status, and 3) develop database prediction score.
Role: Co-Investigator

U54 CA154253 (Greiner Jr, Keith A) 09/17/2010 – 08/31/2016
NIH
Kansas Community Cancer Health Disparities Network
Major Goals: The Kansas Communities Cancer Disparities Network (KCCDN) will build on our existing CBPR research experience and alliances with community-based organizations to integrate existing cancer disparities research with service and technology networks across our state.
Role: Statistician

KL2 RR033177 (Wick, JA) 08/15/2011 – 08/14/2013
Frontiers: Heartland Institute for Clinical and Translational Research
KL2 Clinical and Translational Research Career Development Program
Pilot project title: *Quantitative Methods for q-HTS in Cancer Drug Discovery*
Develop and validate unique statistical tools for high-throughput screening and lead optimization work that would improve pharmacological evaluation of millions of new chemical entities that are screened against cancer-related targets.
Role: pilot project PI

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Stephen K. Williamson, M.D.**

eRA COMMONS USER NAME (credential, e.g., agency login): SWILLIAMSON

POSITION TITLE: Professor of Medicine

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Kansas Newman College, Wichita, KS	B.S.	05/1976	Chemistry
University of Kansas Medical Center, KC, KS	M.D.	06/1979	Medicine

A. Personal Statement

I have been involved in clinical trials research since my oncology fellowship, starting in 1984. This experience along with my leadership experience, educational background and training will allow me to successfully lead this research program.

I have been involved in clinical trial development locally and nationally through the Southwest Oncology Group (now known as SWOG) with active roles in the Lung, GI and Head and Neck Committees. I am an experienced principal investigator (PI) for multiple investigator initiated trials at the University of Kansas, including 2 phase I trials involving therapeutic agents developed at The University of Kansas Medical Center (references C.5.a-d below). Cooperative group experience includes serving as PI on 10 phase II trials, the PI for one national phase III clinical trial, co-PI on a phase III rectal trial, an intergroup phase III colon cancer trial and a co-investigator and contributor to over 30 trials for SWOG. I have been the local PI on over 20 multi-institutional pharmaceutical trials. I have been the Director of the Protocols office of the Kansas Cancer Institute at KUMC from 1994 to 2001 and serve on multiple regulatory committees related to monitoring and the conduct of clinical trials. In terms of leadership positions, I have served as the Hematology/Oncology Division as its Director from 1996 to 2009, was appointed the Medical Director of the Cancer Center's Clinical Trial Unit from 2009 to 2011 and again from 2013 to the present date. In September 2015 I was appointed Director of the Early Phase Program of the KU Cancer Center (KUCC). In these roles I oversee all aspects of the clinical trials support unit (regulatory, study coordination, data management, compliance, finance and contracting) as well as the early phase program of the cancer center. The primary aim of the early phase program is to accelerate scientific discovery of novel therapeutics through the conduct of innovative early phase trials in a compassionate, patient centered environment. The unit is dedicated solely to the conduct of early phase trials with superior exam and treatment space; nursing and treatment staff solely dedicated to clinical trial support; investigational pharmacy; biospecimen collection, preparation, storage and shipping; expert pharmacology/pharmacologist on site; biostatistical and data management support; and support for investigator initiated clinical trial development.

To support the acceleration of scientific discovery of novel therapeutics through the conduct of investigator-initiated clinical trials (IITs), Scott Weir (Associate Director for Translational Research) and I formed the Investigator-Initiated Trial Steering Committee. The IIT Steering Committee is a venue for basic and clinical researchers to present IIT concepts arising from laboratory and bedside discoveries. The IIT Steering Committee provides a structure for defining and refining IIT concepts prior to and following discussion. Investigators receive instant feedback from experienced clinical researchers and representatives from each of the relevant KUCC Shared Resources (i.e., Biospecimen, Lead Development and Optimization (LDO), Clinical

Trial Office (CTO), Clinical Pharmacology and Biostatistics/Data Management shared resources). The IIT Steering Committee works with KUCC members to generate pilot clinical data by conducting "affordable" pilot IITs that enable significant, impactful and fundable cancer therapeutic clinical trials. Under my (and co-Chair Weir) direction, dedicated IIT project managers work with KUCC members to shepherd IIT concepts to the IIT Steering Committee. Multidisciplinary teams support KUCC members to advance IITs from concept to clinic with the assistance of a dedicated IIT project manager and writer. This initiative has significantly increased the number of our IIT's.

B. Positions and Honors

Positions and Employment

1979-1980	Internal Medicine Internship, University of Oklahoma, Tulsa Medical College, Tulsa, OK
1980-1982	Internal Medicine Residency, University of Oklahoma, Tulsa Medical College, Tulsa, OK
1982-1983	Private Practice, General Internal Medicine, The Hertzler Clinic, Halstead, KS
1983-1984	Instructor, Department of Internal Medicine, University of Kansas School of Medicine, Wichita, KS
1983-1984	Staff Physician, Wichita Veterans Administration Medical Center, Wichita, KS
1984-1986	Fellowship in Medical Oncology, University of Kansas Medical Center, Kansas City, KS
1986-1993	Assistant Professor of Medicine, University of Kansas Medical Center, Kansas City, KS and the Kansas City Veterans Administration Medical Center, Kansas City, MO
1993-1999	Associate Professor of Medicine, University of Kansas Medical Center, Kansas City, KS and the Kansas City Veterans Administration Medical Center, Kansas City, MO
1999-present	Professor of Medicine, University of Kansas Medical Center, Kansas City, KS
2000-2002	Interim Director, Division of Hematology/Oncology, University of Kansas Medical Center, Kansas City, KS
2002-2009	Director, Division of Hematology/Oncology, University of Kansas Medical Center, Kansas City, KS
2006	Interim Deputy Director, Kansas Masonic Cancer Research Institute, KUMC
2009-2011	Medical Director, Clinical Trials Shared Resource, KUMC
2011-2013	Chair, Protocol Review and Monitoring Committee, University of Kansas Cancer Center
2013-Present	Medical Director, Clinical Trials Research Unit, University of Kansas Cancer Center
2015–	Director, University of Kansas Cancer Center Early Phase Program

Other Experience and Professional Memberships

1979-	Member, American College of Physicians, National
1985-	Member, Physicians for Social Responsibility, National
1986-	Member, American Society of Clinical Oncology, National
1986-	Member, Southwest Oncology Group, Regional
1987-	Member, International Association for the Study of Lung Cancer, National
1992-	Fellow, American College for Physicians, National
1996-	Member, Central Society for Clinical Research, Regional
1997-2006	Member, Midwest Bioethics Center, Regional
2000-2013	Member, American College of Surgeons Oncology Group, National
2002-	Member, Kansas Foundation for Medical Care, Inc., Local
2008-	Member, American College of Physicians Executives, National
2010-	Health Volunteers Overseas, International
2010-	Member, Association of American Cancer Institutes, National
2015-	Steering Committee, Association of American Cancer Institutes, Clinical Research Initiative

Honors

1981	Best Paper in Internal Medicine, Resident's Day, Convocation by University of Oklahoma, Tulsa Medical College, Tulsa, OK
1982	American Heart Association Award for Best Paper in Cardiology, Resident's Day, University of Oklahoma, Tulsa Medical College, Tulsa, OK
1997	Mother Teresa Award, Awarded to a faculty member by the Hematology and Oncology Fellows
2005	University of Kansas Top Doc Award, Awarded by the Kansas University Hospital, nominated and awarded by hospital and medical staff
2005-2016	Best Doctors in America

C. Contribution to Science

1. **Co-Investigator of Phase III Clinical Trial** that changed the standard of practice for chemotherapeutic management of metastatic colon cancer in the US, including advancing the role of surgery in treating liver metastases.
   a.) Goldberg RM, Sargent DJ, Morton RF, Fuchs CS, Ramanathan RK, **Williamson SK,** Findlay BP, Pitot HC, and Alberts SR: A randomized controlled trial of fluorouracil plus leucovorin, irinotecan, and oxaliplatin combinations in patients with previously untreated metastatic colorectal cancer. J Clin Oncol 22:23-30, 2004. PMID: 14665611
   b.) Goldberg RM, Sargent DJ, Morton RF, Fuchs CS, Ramanathan RK, **Williamson SK**, Findlay, BP, Pitot, HC, Alberts, S: A Randomized Controlled Trial of Reduced Dose Bolus Fluorouracil Plus Leucovorin and Irinotecan or Infused Fluorouracil Plus Leucovorin and Oxaliplatin in Patients With Previously Untreated Metastatic Colorectal Cancer: A North American Intergroup Trial. J Clin Oncol: 24(21):3347-53, 2006. PMID: 16849748
   c.) Ashley AC, Sargent DJ, Grothey A, Campbell ME, Morton RF, Fuchs CS, Ramanathan RD, **Williamson SK,** Findlay BP, Alberts SR, Pitot HC, Goldberg RM: An updated efficacy and toxicity analysis of Intergroup trial N9741 in first line treatment of metastatic colorectal cancer with a focus on the patients treated with irinotecan and oxaliplatin (IROX) Cancer: 110(3):670-7, 2007. PMID: 17559146
   d.) Dy GK, Krook JE, Green EM, Sargent DJ, Morton RF, Fuchs CS, Ramanathan RK, **Williamson SK,** Findlay BP, Pockaj BA, Sticca RP, Alberts SR, Pitot HC, Goldberg RM: Impact of complete response to chemotherapy on overall survival in advanced colorectal cancer: Results from Intergroup N9741. J Clin Oncol: 25(23):3469-74, 2007. PMID: 17687151

2. **Co-Investigator with Dr. Smalley in developing new treatment for rectal cancer:**
   a) Smalley SR, **Williamson SK:** The role of protracted 5-FU infusion plus radiotherapy in Rectal Cancer. J. of Infusional Chemotherapy 4:116-119, 1994.
   b) Smalley SR, Benedetti JK, **Williamson SK**, Robertson JM, Estes NC, Maher T, Fisher B, Rich TA, Martenson JA, Kugler JW, Benson AB, Haller DG, Mayer RJ, Atkins JN, Cripps C, Pederson J, Periman PO, Tanaka MS, Leichman CG, and Macdonald JS: GI Intergroup 0144 - Phase III Trial Of 5-FU Based Chemotherapy Regimens Plus Radiotherapy In Postoperative Adjuvant Rectal Cancer. J Clin Oncol: 24(22):3542-7, 2006. PMID: 16877719

3. **Clinical evaluation of tirapazamine, an agent targeting hypoxic cancer cells, in lung cancer:**
   a) Le QT, McCoy J, **Williamson S,** Ryu J, Edelman MJ, Gaspar LE, Dakhil SR, Sides SD, Crowley J, Gandara DR: Phase I study of tirapazamine plus cisplatin/etoposide and concurrent thoracic radiotherapy in limited small cell lung cancer (S0004): A Southwest Oncology Group Study. Clinical Cancer Research 10:5418-5424, 2004. PMID: 15328179
   b) Williamson SK, Crowley JJ, Lara PN, Tucker RW, Mc'Coy J, Lau DHM, Gandara DR: S0003: Paclitaxel/Carboplatin (PC) versus PC + Tirapazamine (PCT) in Advanced Non-Small Cell Lung Cancer (NSCLC). A Phase III Southwest Oncology Group (SWOG) Trial. J Clin Oncol: 23(36):9097-104, 2005. PMID: 16361616
   c) Le QT, Moon J, Redman MW, **Williamson SK,** Lara PN, Goldberg Z, Gaspar LE, Moore DF, Crowley JJ, and Gandara DR: SWOG 0222: A phase II study of Tirapazamine / Cisplatin/Etoposide and Concurrent Thoracic Radiotherapy for Limited Stage Small Cell Lung Cancer. J Clin Oncol: 27:3014-3019, 2009 PMID: 19364954, PMCID: PMC2702233.

4. **Contributor to new drug development in lung cancer:**
   a) **Williamson SK,** Crowley JJ, Livingston RB, Panella TJ, Goodwin JW: Phase II trial and cost analysis of fazarabine in advanced non-small cell carcinoma of the lung: A Southwest Oncology Group Study. Invest. New Drugs 13:67-71, 1995
   b) Hesketh PJ, Crowley JJ, Burris III HA, **Williamson SK**, Balcerzak SP, Peereboom D, Goodwin JW, Gross HM, Moore Jr. DF, Livingston RB, Gandara DR: Evaluation of docetaxel in previously untreated extensive-stage small cell lung cancer: A Southwest Oncology Group Phase II Trial. The Cancer J from Scientific Am 5:237-241, 1999.
   c) Bastasch M, Panella TJ, Kretzschmer SL, Graham D, Mayo M, **Williamson S:** Phase II trial of pyrazoloacridine in advanced non-small cell carcinoma of the lung. IND 20:339-342, 2002. PMID: 12201497

d) Mack P C, Redman M W, Chansky K, **Williamson S K**, Farneth N C, Lara Jr. P N, Wilbur A Franklin W A, Le Q-T, Crowley J J, Gandara D R: Low osteopontin plasma levels are associated with superior outcomes following platinum-based chemotherapy in advanced non-small cell lung cancer patients: Southwest Oncology Group Trial S0003. J Clin Oncol: 26(29):4771-477, 2008. PMID: 18779603, PMCID: PMC2653139.

5. **Phase I investigator:**
   a) **Williamson SK** and Slavik M: Phase I evaluation of Spirogermanium and 5 fluorouracil in colorectal carcinoma. Invest. New Drugs 9:49 52, 1991
   b) Kusumoto M, Umeda S, Ikubo A, Aoki Y, Tawfik O, Oben R, **Williamson S,** Jewell W, Suzuki T: Phase 1 clinical trial of irradiated Autologous melanoma cells adenovirally transduced with human GM-CSF gene. Cancer Immunol Immunother 50:373-381, 2001. PMID: 11676397
   c) **Williamson, Stephen**; Johnson, Gary; Maulhardt, Holly; Moore, Kathleen; McMeekin, D.; Schulz, Thomas; Reed, Gregory; Roby, Katherine; Mackay, Christine; Smith, Holly; Weir, Scott; Wick, Jo; Markman, Maurie; diZerega, Gere; Baltezor, Michael; Espinosa, Jahna; Decedue, Charles: A Phase I Study of Intraperitoneal Nanoparticulate Paclitaxel (Nanotax®) in Patients with Peritoneal Malignancies. Cancer Chemotherapy and Pharmacology Epub 23 Apr 2015. PMCID: PMC4506131.
   d) Huang CH, **Williamson SK,** Van Veldhuizen PJ, Hsueh CT, Allen A, Tawfik O, Wick J, Smith H, Uypeckcuat AM, Mayo M, Kelly K: Potential Role of Platelet – Derived Growth Factor Receptor Inhibition Using Imatinib in Combination with Docetaxel in the Treatment of Recurrent Non-small Cell Lung Cancer. J Thorac Oncol.2011 Feb;6(2):372-7. PMID: 21178640, Not NIH funded.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1vWKxkdzyDdkq/bibliography/48321238/public/?sort=date&direction=ascending

D. Research Support
Ongoing Support

No Number Williamson (PI) 06/1/2016-06/1/2018
Pharmacyclics
A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors
The purpose of this study is to evaluate the safety, tolerability, and efficacy of the combination treatment of ibrutinib with everolimus, paclitaxel, docetaxel, or cetuximab in selected advanced gastrointestinal and genitourinary tumors.
Role: PI

No Number Williamson (PI) 08/1/2012-08/1/2017
New Link Genetics
A Phase III Study of Chemotherapy and Chemoradiotherapy With or Without Algenpantucel-L (HyperAcute®-Pancreas) Immunotherapy in Subjects With Surgically Resected Pancreatic Cancer
The purpose of this study is to assess overall survival after treatment with a regimen of adjuvant therapy (Gemcitabine alone or with 5-FU chemoradiation) with or without HyperAcute®-Pancreas (algenpantucel-L) immunotherapy in subjects who have undergone surgical resection.
Role: PI

No Number Williamson (PI) 06/1/2013-03/30/2017
ArQule, Inc.
A Phase 3, Randomized, Double-Blind Study of Tivantinib (ARQ 197) in Subjects With MET Diagnostic-High Inoperable Hepatocellular Carcinoma Treated With One Prior Systemic Therapy
The purpose of this study is to determine if tivantinib (ARQ 197) is effective in treating patients with MET diagnostic-high hepatocellular carcinoma (liver cancer) who have already been treated once with another therapy.
Role: PI

No Number Williamson (PI) 11/1/2014-12/1/2016
Acceleron, Inc
A Phase 1b, Open Label Study of Dalantercept plus Sorafenib in Patients with Advanced Hepatocellular Carcinoma
The purpose of this study is to evaluate the safety and tolerability of dalantercept plus sorafenib in patients with advanced hepatocellular carcinoma (HCC) to determine the recommended dose level of dalantercept in combination with sorafenib.
Role: PI

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No Number Williamson (PI) 06/1/2015-06/1/2017
Rogosin Institute
A Phase IIb, Nonrandomized, Open-Label Trial With Mouse Renal Adenocarcinoma (RENCA) Cell Containing Agarose-Agarose Macrobeads Compared With Best Supportive Care in Patients With Treatment-Resistant, Metastatic Colorectal Carcinoma
This study is to evaluate the efficacy of renal adenocarcinoma (RENCA) macrobead implantation compared with best supportive care, as assessed by overall survival
Role: PI

P30 CA168524 Jensen (PI) 7/11/2012-06/30/2017
Cancer Center Support Grant
Role: Key Personnel

P30 CA168524 S1 Jensen (PI) 06/01/2016-05/31/2019
Cancer Center Support Administrative Supplement: ETCTN
The project will accelerate the development of NCI-IND agents in rare cancer types to improve the outcome of cancer therapy.
Role: Supplement PI

Completed Support:

No Number Huang (PI) 06/1/2005-11/1/2013
University of Chicago
A Phase III Randomized Trial of Docetaxel Based Induction Chemotherapy in Patients With N2/N3 Locally Advanced Head and Neck Cancer
The purpose of this trial is to compare the effectiveness of induction chemotherapy followed by chemoradiotherapy versus the same chemoradiotherapy alone in patients with locally advanced head and neck cancer.
Role: Co-Investigator

No Number Johnson (PI) 09/1/2008-09/1/2013
Institutional Funding & Crititech
A Phase 1 Study of Intraperitoneal Nanoparticle Paclitaxel in Patients With Peritoneal Malignancies
The purpose of this study is to evaluate the safety, pharmacokinetics and preliminary efficacy of an intraperitoneally administered suspension of nanoparticulate paclitaxel in patients with refractory malignancies principally confined to the peritoneal cavity.
Role: Co-Investigator

No Number Drisko (PI) 01/1/2010-06/30/2015
Lotte & Hecht Memorial Foundation
Intravenous Vitamin C in Combination with Chemotherapy in Pancreatic Cancer patients
The purpose of this study is to evaluate the toxicity, pharmacokinetics and preliminary activity of high dose IV Vitamin C in combination with gemcitabine in patients with pancreatic cancer.
Role: Co-Investigator

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Medical Center
Duns Number:	016060860
Street1*:	MS 3045, 3901 Rainbow Boulevard
Street2:	
City*:	Kansas City
County:	Wyandotte
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66160-0000
Project/Performance Site Congressional District*:	KS-003

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ❍ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ● **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number 00003411

2. Are Vertebrate Animals Used?* ● **Yes** ❍ **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ● Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number A3237-01

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	Overall_ProjectSummary_final1019799894.pdf
8. Project Narrative*	Overall_ProjectNarrative_final1019799893.pdf
9. Bibliography & References Cited	References_Cited1019799887.pdf
10.Facilities & Other Resources	Overall_FacilitiesResources_final1019799886.pdf
11.Equipment	
12. Other Attachments	DT11019799895.pdf DT2A1019799896.pdf DT2B1019799897.pdf DT31019799898.pdf DT41019913950.pdf DT51019913949.pdf Other_Attachments_PartII_Information_on_Consortium1019799901.pdf

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Overall – Project Summary

The University of Kansas Cancer Center (KUCC) is a matrix cancer center that includes: the University of Kansas Medical Center campuses in Kansas City, Wichita and Salina, the University of Kansas in Lawrence and via consortium agreement, the Stowers Institute for Medical Research and Children's Mercy Kansas City. In 2015, 187 members of KUCC accounted for $13.4M of NCI funding and a total of $61.2M in overall cancer-related funding, an increase of $10M during the previous funding period. Roy A. Jensen, MD, who is supported by a strong, nationally recognized leadership team, leads KUCC. Over the last four years substantial progress has been made broadening partnerships with communities throughout the KUCC catchment area, boosting recruitment of physician-scientists, augmenting clinical research and early-phase clinical trials, advancing education for the next generation of scientists and health care providers and heightening influence for KUCC researchers in the national scientific community. KUCC has established four specific aims to ensure KUCC leads in the fight against cancer:

1. Leverage unique institutional and regional assets to become a leading academic institution for transforming discoveries from the laboratory into new anticancer drug therapies;
2. Provide the optimal environment to focus the power of precision medicine, basic science inquiry, drug discovery and development, and behavioral interventions to decrease cancer incidence, morbidity and mortality;
3. Be a nationally recognized leader in partnering with key stakeholders, community advocates and regional leaders to develop, promote, and foster the adoption and implementation of research-based cancer prevention, diagnosis, treatment, control, and survivorship practices throughout the KUCC catchment area to mitigate the impact of cancer; and
4. Provide leadership in envisioning, developing and implementing a thoughtful, comprehensive strategy to educate the next generation of physician-scientists and allied investigators in cancer research, treatment, prevention and control.

To accomplish these goals KUCC has four research programs: Cancer Biology, Cancer Control and Population Health, Cancer Prevention and Survivorship, and Drug Discovery, Delivery and Experimental Therapeutics. In addition, KUCC supports the Clinical Trials Office, five established shared resources - Biospecimen, Biostatistics and Informatics, Clinical Pharmacology, Lead Development and Optimization and Transgenic and Gene-Targeting – along with three developing shared resources – Cell Authentication and Pathogen Screening, Health Communications Research and Nutrition.

Overall – Project Narrative

KUCC aims to leverage unique regional scientific assets to build a nationally significant cancer research center that will become a leading institution for transforming discoveries in the laboratory into new therapeutic approaches. KUCC will expand its depth, breadth and impact and strive to become an NCI-designated comprehensive cancer center that meets the needs of the more than 4.4M Americans who live within the 92,000 square miles of the KUCC catchment area.

Overall – Facilities and Other Resources

Physical Space

The University of Kansas Cancer Center (KUCC) is located primarily in Kansas City, Kansas. The closest other NCI-designated Cancer Center is located in Omaha, Nebraska (**Figure 1**).

Figure 1. The University of Kansas Cancer Center – Relative to other NCI-Designated Cancer Centers

KUCC is a matrix organization with two consortium partners and four campuses (**Figure 2**):

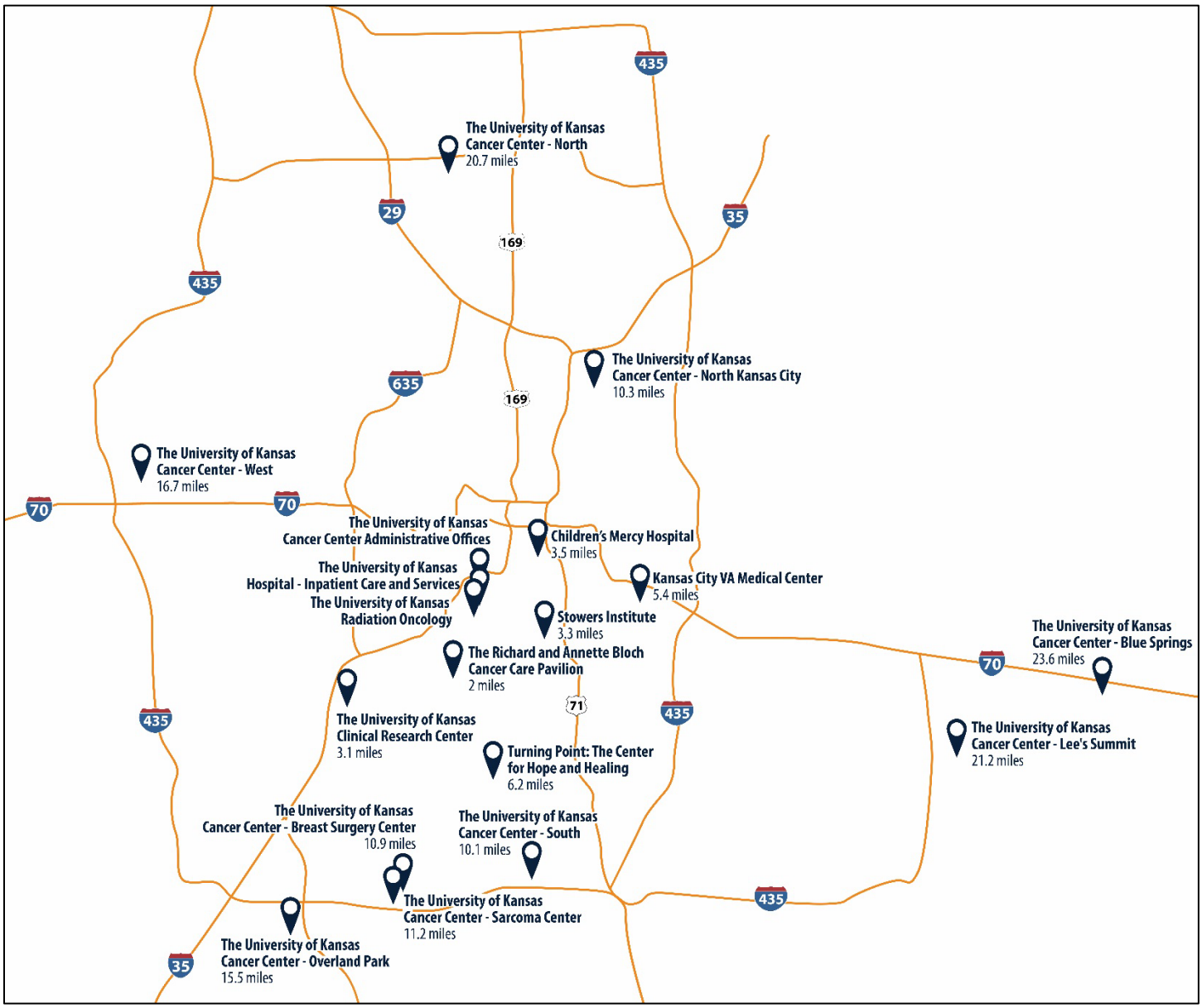
1. The University of Kansas Medical Center (KUMC) – Kansas City, Kansas
2. The University of Kansas – Lawrence (KU-Lawrence) – Lawrence, Kansas
3. Stowers Institute for Medical Research (Stowers) – Kansas City, Missouri
4. Children's Mercy – Kansas City, Missouri

Figure 2. The University of Kansas Cancer Center and Consortium Partners

KUCC has 187 members: 126 members are located at the University of Kansas Medical Center campus in Kansas City, Kansas; three members are located at the University of Kansas Medical Center campus in Wichita, Kansas; 38 members are located at the University of Kansas campus in Lawrence, Kansas; 11 members are located at the Stowers Institute for Medical Research in Kansas City, Missouri; and nine members are located at Children's Mercy in Kansas City, Missouri.

The map in **Figure 3** shows the locations of KUCC, Stowers, Children's Mercy and the KU Health System community sites (with distances between indicated).

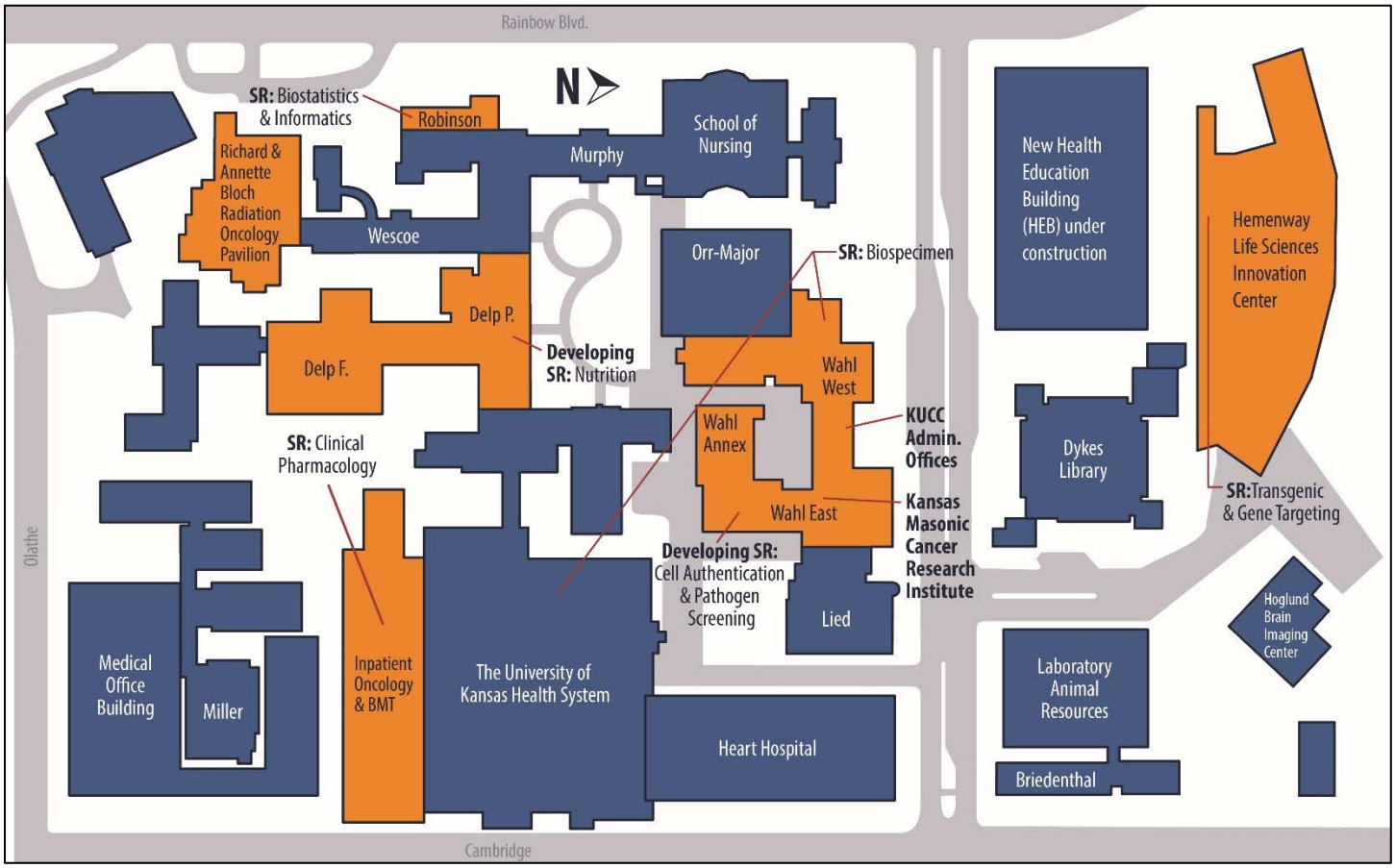
Figure 3. The University of Kansas Cancer Center – Kansas City Metro Area Locations



The main campus of The University of Kansas Medical Center (KUMC) in Kansas City, Kansas is located on 41 acres with 43 buildings containing 2.4 million sq. ft. **Figure 4** shows a map of the main KUMC campus, including The University of Kansas Health System. Golden colored buildings house KUCC members, shared resources or administration.

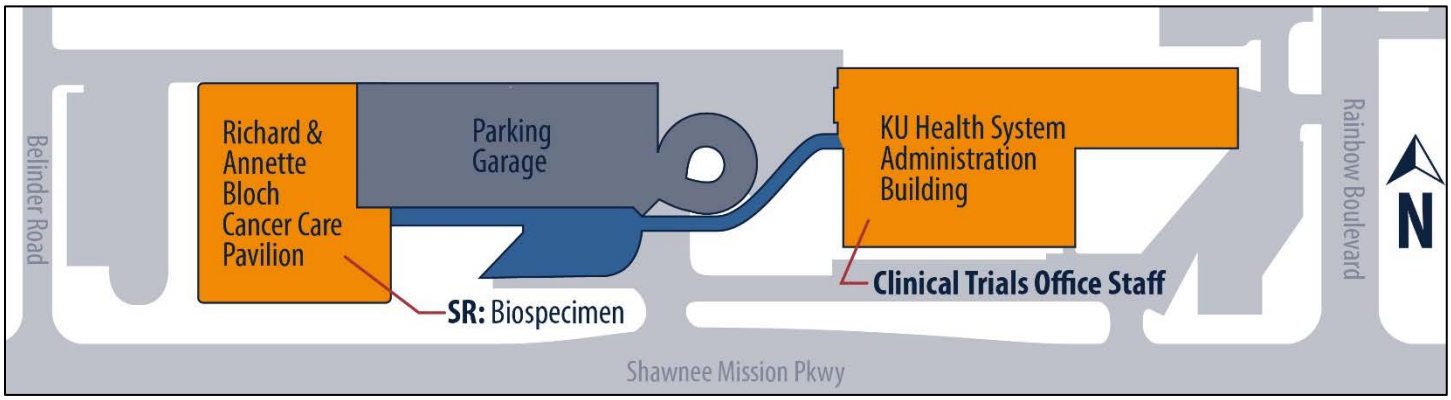
Specifically, the Biospecimen, Biostatistics and Informatics, Transgenic and Gene-Targeting and Clinical Pharmacology shared resources, along with the Nutrition and Cell Authentication & Pathogen Screening developing shared resources, are located on the main KUMC campus.

Figure 4. The University of Kansas Cancer Center – The University of Kansas Medical Center – Main Campus



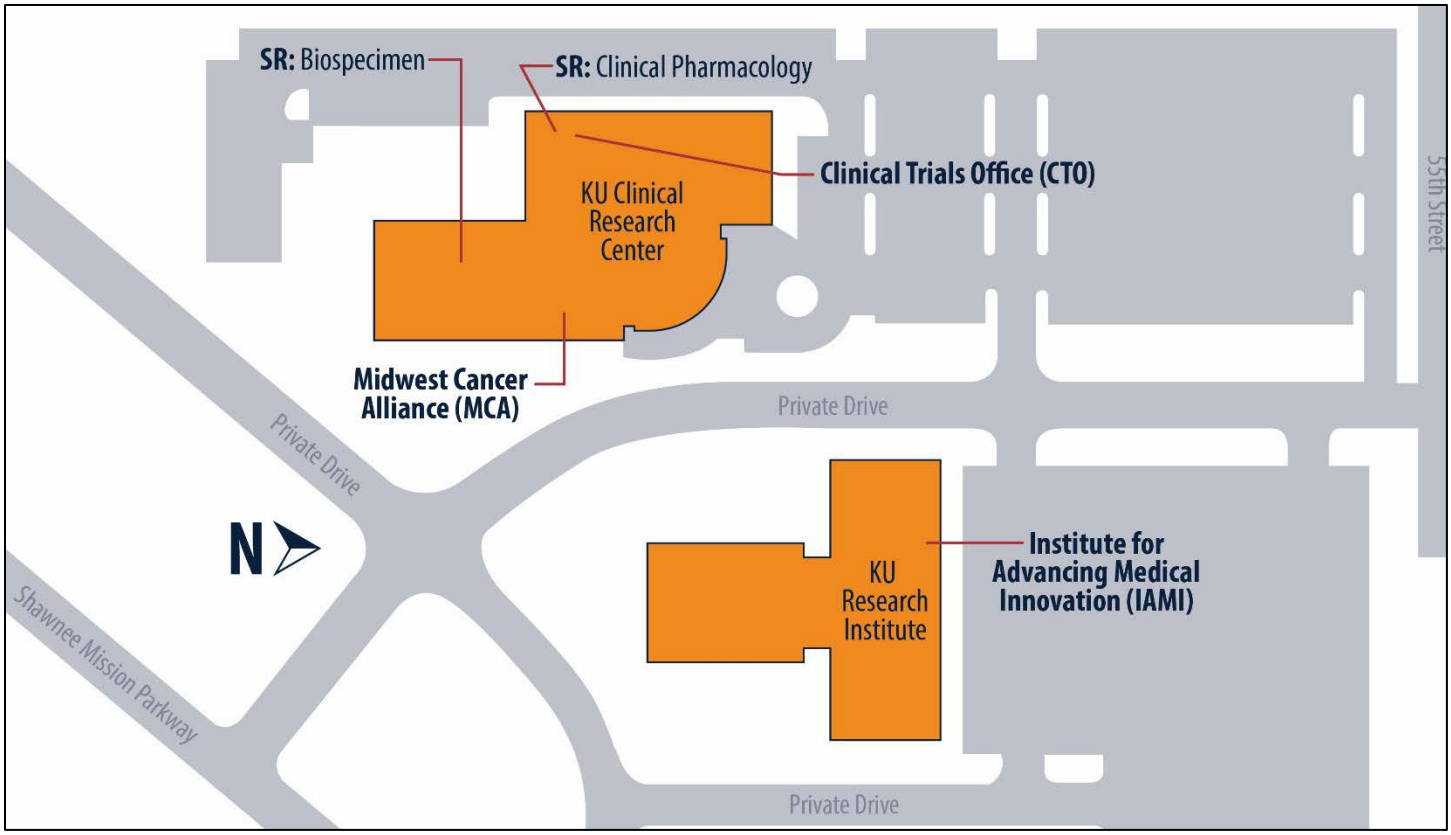
The KUCC Westwood campus is located two miles south of the main campus. The University of Kansas Health System outpatient cancer services and KUCC Clinical Trials Office space are located here (**Figure 5**).

Figure 5. The University of Kansas Cancer Center – The University of Kansas Health System – Westwood Campus



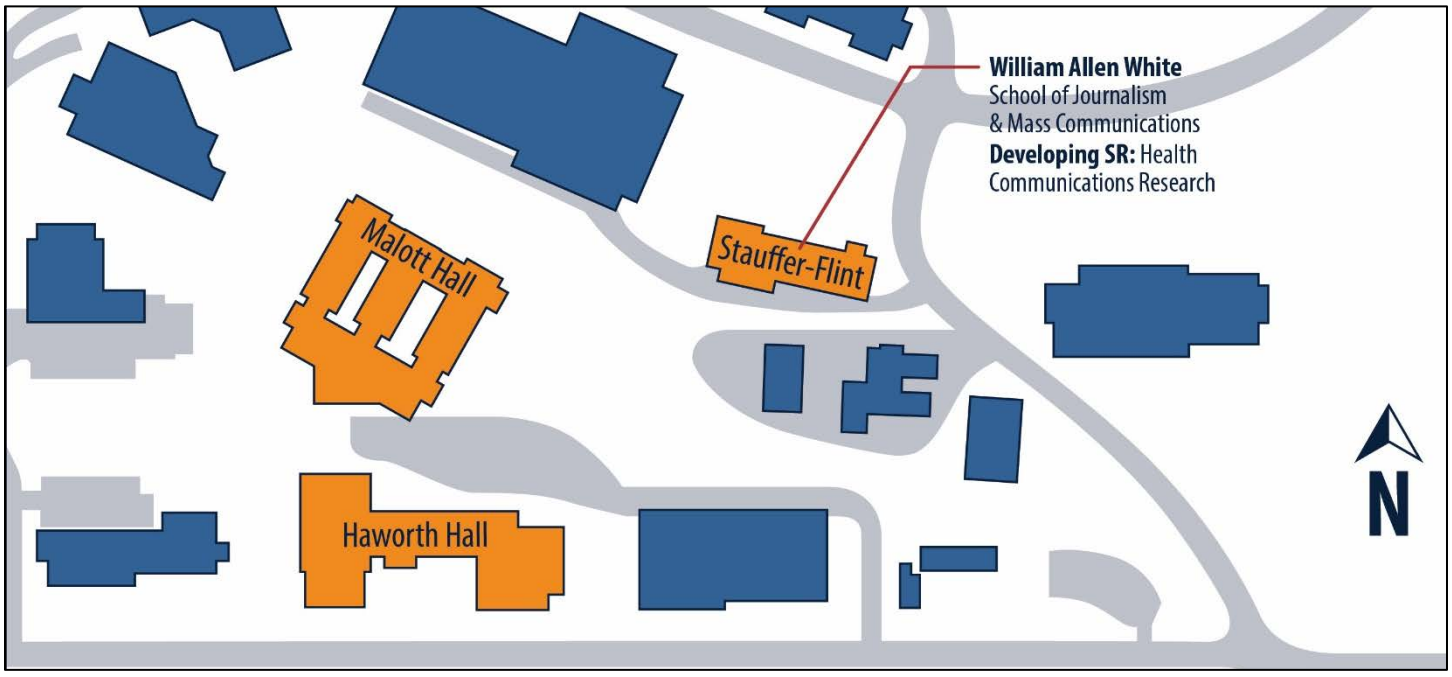
The KU Clinical Research Center is located three miles south of the main campus (**Figure 6**). The KU Clinical Research Center, a 82,000 sq. ft. building, includes an Oncology Phase I unit, longer-term observation rooms (overnight) for Phase I patients, offices for the clinical research operation, space for shared resources and the Midwest Cancer Alliance. Across the street is an administrative building that includes space for the Institute for Advancing Medical Innovation.

Figure 6. The University of Kansas Cancer Center – KU Clinical Research Center



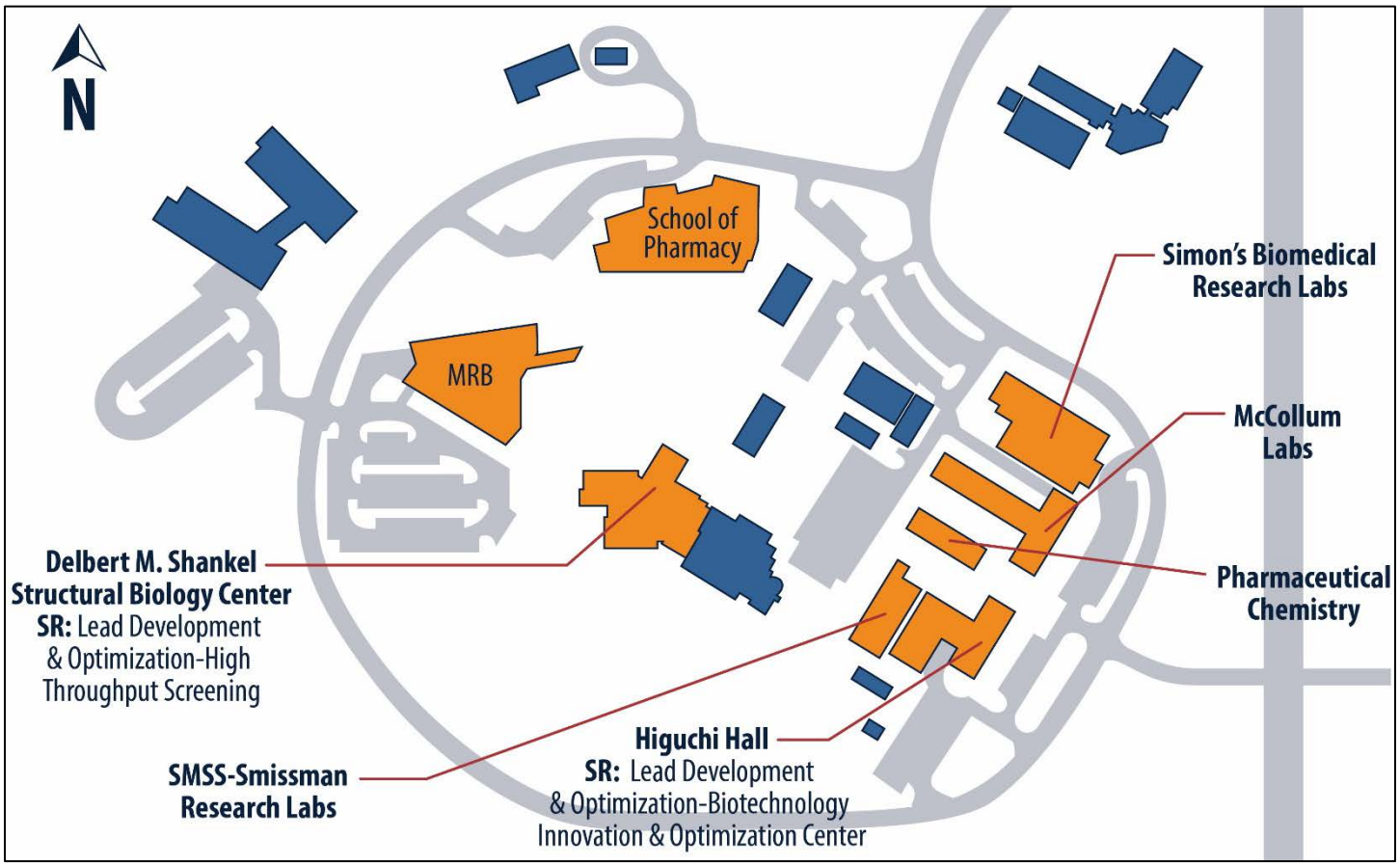
The University of Kansas in Lawrence, Kansas is located 45 minutes west of the KUMC main campus in Kansas City, Kansas (**see Figure 2**). KUCC primarily has members in Malott, Haworth and Stauffer-Flint halls (**Figure 7**). The developing Health Communications Research shared resource is located in Stauffer-Flint.

Figure 7. The University of Kansas Cancer Center – The University of Kansas – Main Campus



Less than 2 miles away from the University of Kansas main campus is the KU West Campus (**Figure 8**). The KU School of Pharmacy and the Lead Development and Optimization shared resource are located here.

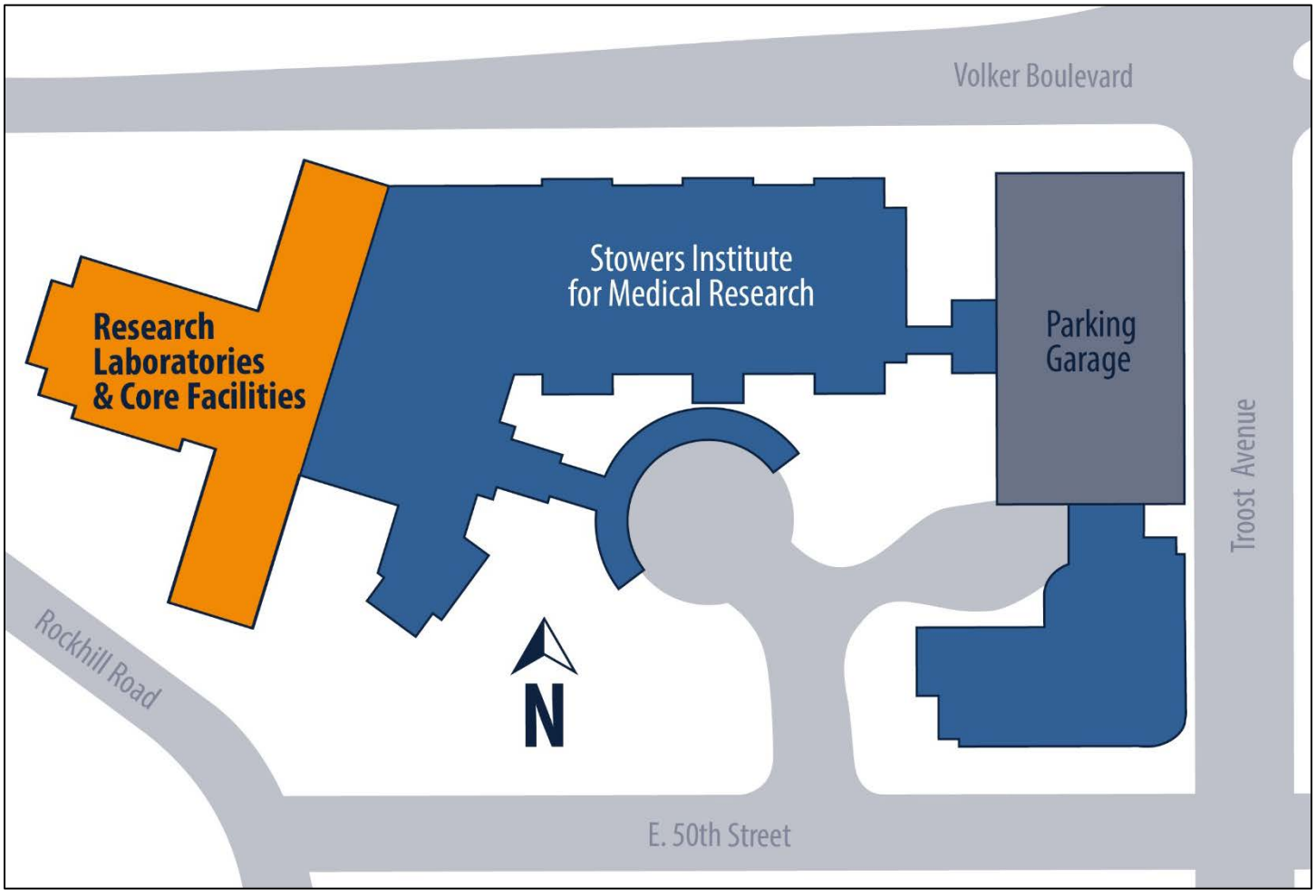
Figure 8. The University of Kansas Cancer Center – The University of Kansas – West Campus



The Stowers Institute for Medical Research is located ~3 miles from the KUMC main campus (see **Figure 2**). Situated on a 10-acre campus, Stowers buildings contain 880,000 sq. ft. of workspace including laboratories, technology centers, scientific support facilities and administrative offices (**Figure 9**). Each floor of the science building accommodates six to eight investigators. Support areas include darkrooms, tissue culture labs, shared equipment rooms and cold rooms. Technology centers and institute wide core facilities are conveniently interspersed with research labs throughout the campus to promote interactions between groups and efficient use of space.

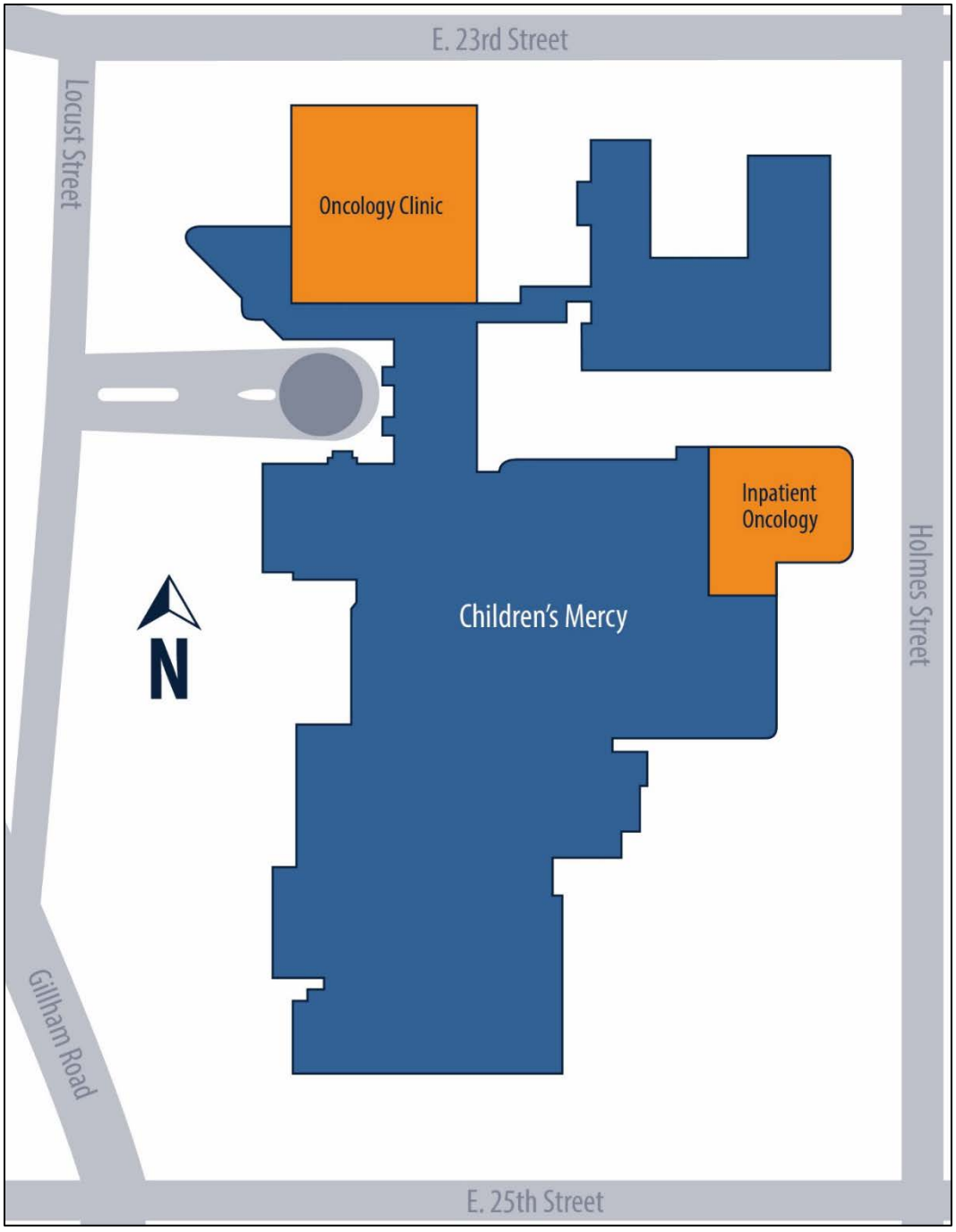
Stowers has 13 core facilities and technology centers:
1. Computational Biology
2. Cytometry
3. Electron Microscopy
4. Histology
5. Imaging
6. Laboratory Animal Services
7. Media Preparation
8. Microscopy
9. Molecular Biology
10. Proteomics
11. Reptiles and Aquatics
12. Screening
13. Tissue Culture

Figure 9. The Stowers Institute for Medical Research – a Consortium Partner with The University of Kansas Cancer Center



Children's Mercy is located ~3 miles from the KUMC main campus (see **Figure 2**). Children's Mercy has dedicated and developed resources to support both translational and clinical research. At the main campus facility, more than 48,000 sq. ft. of active research space provides an environment where clinical and basic investigators interact, discover and develop new approaches to the diagnosis and treatment of pediatric cancers (**Figure 10**). The new Center for Pediatric Genomic Medicine laboratory is located in Crown Center and occupies approximately 3,500 sq. ft. This state-of-the-art facility allows Children's Mercy to perform a far greater number of diagnostic testing and genome analyses for its patients – a new service available inside a children's hospital for the very first time. Additionally, the Pediatric Clinical Research Unit located in the hospital's Hall Tower is a state-of the art, 5,000 sq. ft. facility dedicated to the support of clinical-translational research. This unit and its staff of experienced research nurse coordinators support the activities of the Experimental Therapeutics in Pediatric Cancer program and the hospital's pivotal role as the Pediatric Clinical Pharmacology core of the NIH-funded Pediatric Trials Network.

Figure 10. Children's Mercy – a Consortium Partner with The University of Kansas Cancer Center



Institutional Commitment

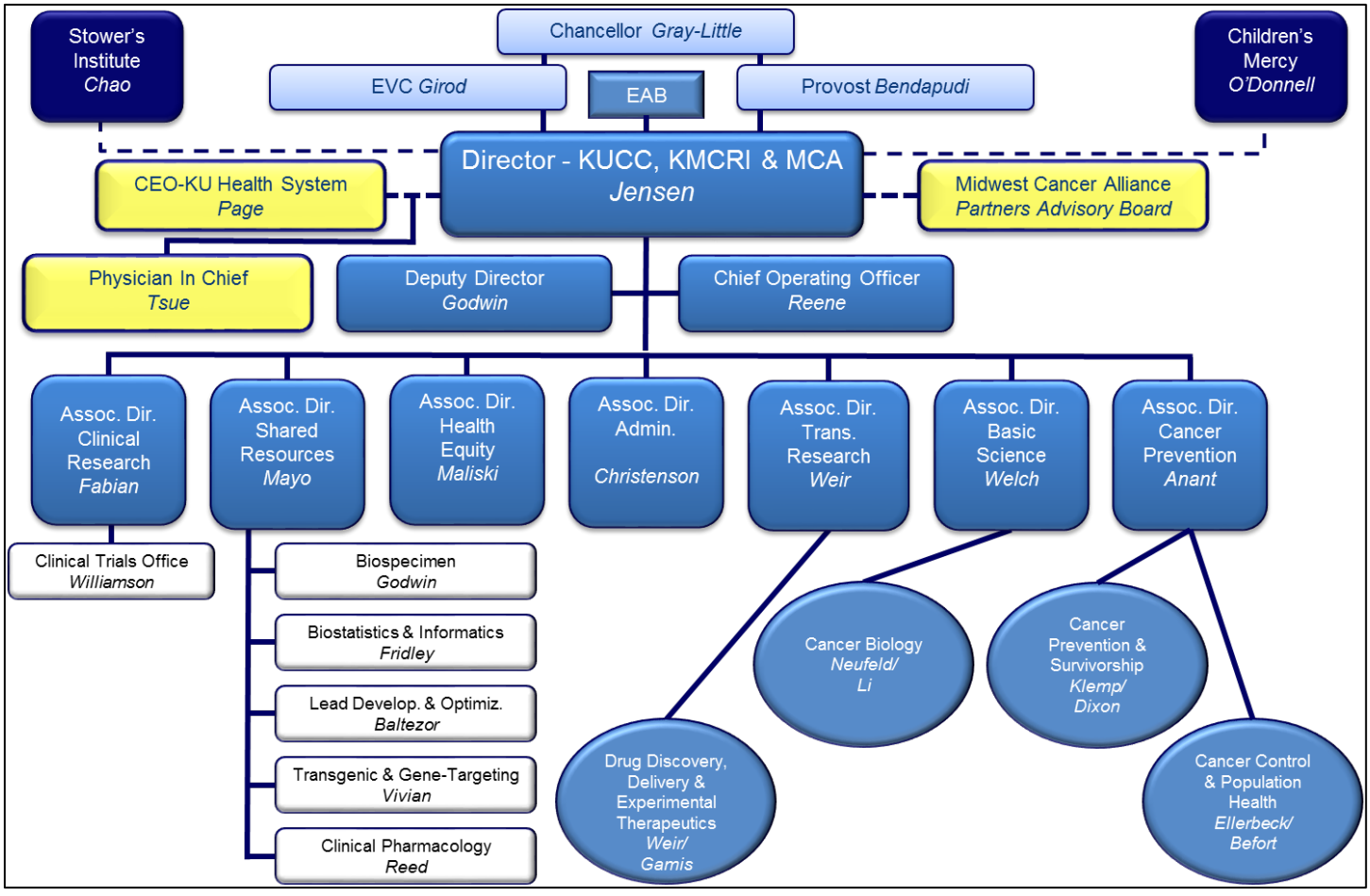
KUCC receives funding from many different sources (see Other Attachments in the Admin Core). **Table 1** provides information on annual funding from the institution and individual consortium partners.

Table 1. Institutional Funds

Institution	Annual Funding
The University of Kansas	**$1,274,280**
The University of Kansas Health System	**$3,591,927**
Stowers Institute for Medical Research	**$ 239,844**
Children's Mercy	**$1,500,000**
State of Kansas	**$5,000,000**
Johnson County Tax (JCERT)	**$3,388,123**

KUCC is led by Roy A. **Jensen**, MD. **Jensen** directly reports to both the Executive Vice Chancellor at the KU Medical Center campus (Doug Girod, MD) and the Provost at the KU-Lawrence campus (Neeli Bendapudi, PhD). Additionally, **Jensen** has a dotted line reporting relationship to the Stowers President and Chief Executive Officer, David Chao, PhD, the Children's Mercy President and Chief Executive Officer, Randall O'Donnell, PhD, and the KU Health System Chief Executive Officer, Bob Page. The reporting structure and organization of KUCC is presented in **Figure 11**.

Figure 11. The University of Kansas Cancer Center Organizational Chart



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The University of Kansas Cancer Center
Reporting Date: 12/31/2015
Data Table 1A – Senior Leaders

Name of Senior Leader	Title of Leader	Degree(s)	New Leader?
Jensen, Roy A.	Principal Investigator, Director	MD	N
Godwin, Andrew K.	Deputy Director	PhD	Y
Anant, Shrikant	Associate Director for Cancer Prevention & Control	PhD	N
Christenson, Teresa J.	Associate Director for Administration	BS	N
Fabian, Carol J.	Associate Director for Clinical Research	MD	Y
Maliski, Sally L.	Associate Director for Health Equities	PhD, RN, FAAN	Y
Mayo, Matthew S.	Associate Director for Shared Resources	PhD, MBA, FASA	N
Reene, Jeffrey C.	Chief Operating Officer	MBA	N
Weir, Scott J.	Associate Director for Translational Research	PharmD, PhD	N
Welch, Danny R.	Associate Director for Basic Science	PhD	N

The University of Kansas Cancer Center
Reporting Date: 12/31/2015
Data Table 1B – Research Programs

Program Code	Program Name	Program Leaders	Degree(s)	New Leader?	New Program?	Members
CB	Cancer Biology	Neufeld, Kristi L. Li, Linheng	PhD PhD	Yes No	No	61
CCPH	Cancer Control & Population Health	Ellerbeck, Edward F. Befort, Christie A.	MD, MPH PhD	No Yes	No	35
CPS	Cancer Prevention & Survivorship	Klemp, Jennifer R. Dixon, Dan A.	PhD, MPH PhD	Yes Yes	No	31
D3ET	Drug Discovery, Delivery & Experimental Therapeutics	Weir, Scott J. Gamis, Alan S.	PharmD, PhD MD	No Yes	No	60

P30CA168524

The University of Kansas Cancer Center
Reporting Date: 12/31/2015
Data Table 1C – Cancer Center Membership

Type of Member	Total Number
Programmatically Aligned Members (Individuals)	187
Non-Programmatically Aligned Members (Individuals)	0
Grand Total – Total Number of Cancer Members (Individuals)	**187**

The University of Kansas Cancer Center
Reporting Date: 12/31/2014
Data Table 1D – Shared Resources

Name of Shared Resource	Resource Director(s)	Degree(s)	New Leader?	New Resource?	Developing Resource?	Category**
Biospecimen	Godwin, Andrew K.	PhD	No	No	No	4.06
Biostatistics & Informatics	Fridley, Brooke L.	PhD	No	No	No	6.01, 7.01
Lead Development & Optimization	Baltezor, Michael J.	PhD	No	No	No	1.37 (Drug Discovery, Drug Development, and Drug Optimization services)
Transgenic & Gene-Targeting	Vivian, Jay L.	PhD	No	No	No	1.03
Clinical Pharmacology	Reed, Gregory A.	PhD	No	Yes	No	4.05
Health Communications Research	Geana, Mugur V.	MD, PhD	No	No	Yes	3.06 (Research, design, planning, implementation and evaluation of strategic health communication campaigns)
Cell Authentication and Pathogen Screening	Kumaraswamy, Easwari	PhD	Yes	Yes	Yes	1.37
Nutrition	Debra Sullivan Hamilton-Reeves, Jill	PhD, RD PhD, RD, CSO	Yes Yes	Yes	Yes	3.05

University of Kansas Cancer Center
Reporting Date: 12/31/2015
Data Table 2A - Active Funded Projects

PEER-REVIEWED RESEARCH PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Abrahamson DR	NIGMS	5P20GM104936-09	9/27/2007	6/30/2017	MOLECULAR REGULATION OF CELL DEVELOPMENT AND DIFFERENTIATION	$437,447	$660,546				
Abrahamson DR Krieg AJ	NIGMS	5P20GM104936-09	7/1/2015	6/30/2016	MOLECULAR REGULATION OF CELL DEVELOPMENT AND DIFFERENTIATION (FUNCTIONAL ANALYSIS OF HISTONE DEMETHYLASE ACTIVITY IN HYPOXIC CANCER CELLS)			CB	100%	$150,000	$226,500
Abrahamson DR Slawson CE	NIGMS	5P20GM104936-09	7/1/2015	6/30/2016	MOLECULAR REGULATION OF CELL DEVELOPMENT AND DIFFERENTIATION (TARGETING AND REGULATION OF O-GLCNAC TRANSFERASE AT M PHASE)			CB	100%	$150,000	$226,500
Anant S Umar S	NCI	5R01CA190291-02	8/1/2014	7/31/2019	BITTER MELON COMPONENT AND COLON CANCER PREVENTION	$360,735	$544,710	CPS	100%	$360,735	$544,710
Anant S Weir SJ	NCI	5R01CA182872-02	1/1/2014	12/31/2018	NOVEL DUAL NOTCH/PXR TARGETING FOR COLON CANCER THERAPY	$416,214	$628,483	CPS	100%	$208,107	$314,242
Anant S Weir SJ					NOVEL DUAL NOTCH/PXR TARGETING FOR COLON CANCER THERAPY			D3ET	100%	$208,107	$314,242
Apte UM	NIDDK	5R01DK098414-03	4/1/2013	3/31/2018	MECHANISMS OF LIVER REGENERATION AFTER ACETAMINOPHEN-INDUCED ACUTE LIVER FAILURE	$217,500	$328,425	CB	100%	$217,500	$328,425
Azuma Y Clarke DJ (Univ Minnesota)	NIGMS	5R01GM112793-02	1/12/2015	12/31/2018	REGULATION OF KINETOCHORE FUNCTION BY TOPOISOMERASE II	$226,800	$265,300	CB	100%	$113,400	$132,650
Banerjee S	VA	1BX001989A	11/20/2012	12/31/2016	THE ROLE OF CCN5 IN PROGRESSION OF BREAST CANCER	$227,848	$227,848	CPS	100%	$227,848	$227,848
Banerjee SK	VA	2I01BX001002-05	10/30/2015	11/30/2019	ROLE OF CYR61/CCN1 IN PANCREATIC CANCER PROGRESSION AND THERAPY	$238,772	$238,772	CPS	100%	$238,772	$238,772
Befort C	NCI	5R01CA155014-05	8/1/2011	5/31/2016	GROUP PHONE-BASED WEIGHT CONTROL AMONG RURAL BREAST CANCER SURVIVORS	$347,308	$510,955	CPS	100%	$347,308	$510,955
Befort C	PCORI	OB-1402-09413	1/1/2015	12/31/2019	MIDWESTERN COLLABORATIVE FOR TREATING OBESITY IN RURAL PRIMARY CARE	$1,542,640	$2,003,429	CCPH	100%	$1,542,640	$2,003,429
Behbod F	NCI	5R21CA185460-02	5/1/2014	4/30/2016	(PQC3) ESSENTIAL ROLE OF BCL9 IN PROMOTION OF HUMAN DCIS TO INVASIVE DUCTAL CARCI	$108,750	$164,213	CPS	100%	$108,750	$164,213
Behbod F	NCI	5R21CA187890-02	9/1/2014	8/31/2016	ELUCIDATING CELLULAR HETEROGENEITY AMONG CANCER STEM CELLS BY RAMAN SPECTROSCOPY	$112,314	$145,059	CPS	100%	$112,314	$145,059
Behbod F	AACR		8/1/2014	7/31/2016	ESSENTIAL ROLE OF BCL9 IN DCIS PROGRESSION TO INVASIVE BREAST CANCER	$82,273	$90,500	CPS	100%	$82,273	$90,500
Blagg BSJ	NCI	5U01CA109265-09	7/1/2004	6/30/2019	HSP90 INHIBITORS	$151,915	$218,972	D3ET	100%	$151,915	$218,972
Blagg BSJ	NINDS	5R01NS075311-04	4/1/2012	3/30/2016	CHAPERONE THERAPEUTICS FOR THE TREATMENT OF DPN	$218,750	$317,274	D3ET	100%	$218,750	$317,274
Blagg BSJ	NCI	2R01CA120458-10A1	5/19/2006	6/30/2019	DEVELOPMENT AND EVALUATION OF PURINE AND COUMARIN BASED HSP90 INHIBITORS	$277,849	$372,418	D3ET	100%	$277,849	$372,418

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Blagg BSJ	NCI	5U01CA120458-09	5/19/2006	6/30/2019	DEVELOPMENT AND EVALUATION OF PURINE AND COUMARIN BASED HSP90 INHIBITORS	$248,460	$326,800	D3ET	100%	$248,460	$326,800
Blagg BSJ	NCI	5R01CA167079-04	4/6/2012	3/31/2017	DEVELOPMENT OF HSP90 INHIBITORS FOR THE TREATMENT OF CANCER	$263,376	$312,346	D3ET	100%	$263,376	$312,346
Caburnay CA Doolittle GC	NCI Health Communication Impact, LLC	1R44CA192442-01	9/1/2015	7/31/2017	RECRUITING UNDERSERVED POPULATIONS INTO CLINICAL TRIALS WITH CUSTOMIZABLE MEDIA	$62,593	$62,593	CCPH	100%	$62,593	$62,593
Calvet JP	NIDDK	1P30DK106912-01	9/15/2015	6/30/2020	KANSAS PKD RESEARCH AND TRANSLATION CORE CENTER	$726,145	$1,088,089				
Calvet JP	NIDDK	1P30DK106912-01	9/15/2015	6/30/2020	KANSAS PKD RESEARCH AND TRANSLATION CORE CENTER - ADMINISTRATIVE CORE			ZY	100%	$73,155	$110,464
Calvet JP	NIDDK	1P30DK106912-01	9/15/2015	6/30/2020	KANSAS PKD RESEARCH AND TRANSLATION CORE CENTER (PILOT AND FEASIBILITY CORE)			ZY	100%	$159,341	$240,605
Calvet JP Wallace DP	NIDDK	1P30DK106912-01	9/15/2015	6/30/2020	KANSAS PKD RESEARCH AND TRANSLATION CORE CENTER (BIOMEDICAL RESEARCH CORE 3: PKD BIOMARKERS CORE)			ZY	100%	$158,667	$231,197
Calvet JP Ward CJ	NIDDK	1P30DK106912-01	9/15/2015	6/30/2020	KANSAS PKD RESEARCH AND TRANSLATION CORE CENTER (BIOMEDICAL RESEARCH CORE 1: GENE TARGETING CORE)			ZY	100%	$106,380	$160,634
Carlson SE	NICHD	5R01HD047315-09	7/1/2004	1/31/2017	DHA SUPPLEMENTATION AND PREGNANCY OUTCOME	$311,002	$463,431	CPS	100%	$311,002	$463,431
Chen YC	NCI VIRGINIA POLYTECHNIC INST	5R01CA154364-05	7/1/2013	4/30/2016	SIPSMARTER: A NUTRITION LITERACY APPROACH TO REDUCING SUGAR-SWEETENED BEVERAGES	$34,566	$51,790	CCPH	100%	$34,566	$51,790
Cheng N	ACS	RSG-13-182-01-CSM	7/1/2013	6/30/2017	BARRIERS TO BREAST CANCER TREATMENT DUE TO CCL2/CCR2 CHEMOKINE SIGNALING	$150,000	$180,000	CB	100%	$150,000	$180,000
Cheng N	Susan G. Komen Foundation	CCR13261859	8/16/2013	8/15/2016	MOLECULAR SWITCHING OF DCIS TO INVASIVE CARCINOMAS BY CCR2 CHEMOKINE RECEPTORS	$120,000	$150,000	CB	100%	$120,000	$150,000
Cheng N Behbod F	NCI	5R01CA172764-03	9/1/2013	6/30/2018	PROGRESSION OF DCIS TO INVASIVE BREAST CANCER THROUGH CCR2 CHEMOKINE SIGNALING	$274,254	$414,124	CB	100%	$137,127	$207,062
Cheng N Behbod F	NCI	5R01CA172764-03	9/1/2013	6/30/2018	PROGRESSION OF DCIS TO INVASIVE BREAST CANCER THROUGH CCR2 CHEMOKINE SIGNALING			CPS	100%	$137,127	$207,062
Chennathukuzhi V	NICHD	5R01HD076450-03	8/12/2013	4/30/2018	THE ROLE OF REST IN THE PATHOGENESIS OF UTERINE FIBROIDS	$227,306	$326,867	D3ET	100%	$227,306	$326,867
Chien JR	ACS	RSG-14-067-01-TBE	7/1/2014	6/30/2018	MECHANISM OF CARBOPLATIN RESISTANCE IN OVARIAN CANCER	$163,958	$196,750	CB	100%	$163,958	$196,750
Chien JR	DOD	W81XWH-14-1-0116	5/15/2014	5/14/2016	TARGETING FOXM1 PATHWAY IN OVARIAN CANCER	$113,565	$171,483	CB	100%	$113,565	$171,483
Choi WS	NCI	5R01CA174481-03	4/1/2013	3/31/2018	WEB-BASED SMOKING CESSATION PROGRAM FOR TRIBAL COLLEGE STUDENTS	$416,590	$565,964	CCPH	100%	$416,590	$565,964
Collie-Akers VL	NCCDPHP	1U58DP005806-01	9/30/2014	9/29/2017	HEALTH FOR ALL: HEALTHY PLACES THAT PROMOTE HEALTH EQUITY AMONG LATINOS IN KANSAS CITY, KS	$569,137	$723,299	CCPH	100%	$569,137	$723,299

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Cox LS	NIDA Pinnacle Technology Inc	5R01DA035796-02	6/1/2014	3/31/2019	ADVANCING TOBACCO USE TREATMENT FOR AFRICAN AMERICAN SMOKERS	$427,801	$631,776	CCPH	100%	$427,801	$631,776
Cupertino AP Ellerbeck EE	NIMHD Agile Heatlh	1R41MD010318-01	8/1/2015	7/31/2016	LATINOS KICK BUTS: MOBILE ENGAGEMENT AND CESSATION SUPPORT FOR LATINO SMOKERS	$149,688	$149,688	CCPH	100%	$149,688	$149,688
Cupertino AP	NIH Office of Director	1R25OD020214-01	9/3/2015	8/31/2020	S.C.O.R.E: STUDENTS FOR COMMUNITY-ORIENTED RESEARCH AND EDUCATION	$213,995	$231,007	CCPH	100%	$213,995	$231,007
Daley CM	NCI	1R21CA191158-01A1	4/1/2015	3/31/2017	DEVELOPMENT OF A TOBACCO HEALTH LITERACY INSTRUMENT	$140,250	$211,778	CCPH	100%	$140,250	$211,778
Daley CM	NIMHD	5R01MD007800-02	7/10/2014	4/30/2017	SMOKELESS TOBACCO CESSATION AMONG AMERICAN INDIANS USING IN-PERSON GROUPS	$250,000	$377,500	CCPH	100%	$250,000	$377,500
Dhar A	NCI	5R01CA125262-06	9/15/2008	7/31/2016	CHEMOPREVENTION OF PANCREATIC CANCER BY EGCG	$187,120	$280,680	CPS	100%	$187,120	$280,680
Ding WX	NIAAA	5R01AA020518-05	8/1/2011	7/31/2016	MECHANISMS REGULATING AUTOPHAGY IN ALCOHOL-INDUCED LIVER INJURY	$218,250	$327,375	CB	100%	$218,250	$327,375
Ding WX Jaeschke HW	NIDDK	5R01DK102142-02	9/25/2014	5/31/2018	AUTOPHAGY AND DRUG-INDUCED LIVER INJURY	$225,000	$339,750	CB	100%	$225,000	$339,750
Donnelly JE	NHLBI	5R01HL111842-04	5/4/2012	4/30/2017	A RANDOMIZED TRIAL OF RECOMMENDATIONS FOR EXERCISE TO PREVENT WEIGHT REGAIN	$460,645	$677,148	CPS	100%	$460,645	$677,148
Donnelly JE	NICHD	1R01HD079642-01A1	3/6/2015	2/28/2020	WEIGHT MANAGEMENT FOR ADOLESCENTS WITH IDD	$363,841	$549,400	CPS	100%	$363,841	$549,400
Doolittle GC	CDC Kansas Dept of Health & Environment	U58DP003889-04	6/30/2012	6/29/2017	CANCER PREVENTION AND CONTROL PROGRAMS FOR STATE, TERRITORAL AND TRIBAL ORGANIZATIONS	$50,770	$50,770	CCPH	100%	$50,770	$50,770
Ellerbeck EF	PCORI	CER-1306-02901	4/1/2014	3/31/2017	SMOKING CESSATION VERSUS LONG-TERM NICOTINE REPLACEMENT AMONG HIGH-RISK SMOKERS	$498,964	$698,550	CCPH	100%	$498,964	$698,550
Fabian CJ	NCI Oregon Health and Science University	5UG1CA189974-02	8/1/2014	7/31/2019	SWOG NCORP RESEARCH BASE	$18,790	$28,374	CPS	100%	$18,790	$28,374
Fabian CJ	Susan Komen Foundation	SAC110051	9/22/2010	9/21/2016	DEVELOPMENT OF BIOMARKERS OF RESPONSE TO PREVENTION INTERVENTIONS WITH LIGNANS.	$51,000	$51,000	CPS	100%	$51,000	$51,000
Fabian CJ	Susan Komen Foundation	KG 101039	9/24/2010	10/1/2016	FLAXSEED LIGNAN AS A PREVENTION STRATEGY FOR PRE-MENOPAUSAL WOMEN AT HIGH RISK FOR DEVELOPMENT OF BREAST CANCER.	$863,000	$863,000	CPS	100%	$863,000	$863,000
Fawcett SB Collie-Akers VL	NIH Battelle Memorial Institute	268201000041C-13-0-	8/15/2011	8/14/2016	STUDYING COMMUNITY PROGRAMS TO REDUCE CHILDHOOD OBESITY: TASK 1 - SCIENTIFIC LEADERSHIP & PROJECT MANAGEMENT	$209,845	$306,978	CCPH	100%	$209,845	$306,978
Fawcett SB Collie-Akers VL	NIH Battelle Memorial Institute	268201000041C-13-0-	8/15/2011	8/14/2016	STUDYING COMMUNITY PROGRAMS TO REDUCE CHILDHOOD OBESITY: TASK 8 - DATA ANALYSIS AND DISSEMINATION OF RESULTS	$256,098	$373,411	CCPH	100%	$256,098	$373,411
Fields PE	NIDDK	5R01DK091277-04	4/15/2012	3/31/2017	THE ROLE OF THE HISTONE METHYLTRANSFERASE DOT1L IN ERYTHROPOIESIS	$217,500	$328,425	CB	100%	$217,500	$328,425
Forrest ML	NCI	5R01CA173292-03	3/1/2013	2/28/2018	BIOMATERIALS FOR TREATMENT OF HEAD AND NECK CANCER	$195,937	$289,331	D3ET	100%	$195,937	$289,331

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Freudenthal BD	NIEHS	4R00ES024431-02	9/30/2015	8/31/2018	DNA REPAIR STRATEGIES THAT IMPACT GENOMIC STABILITY DURING OXIDATIVE STRESS	$184,249	$249,000	CB	100%	$184,249	$249,000
Gajewski BJ	NINR	5R03NR013236-02	5/21/2014	4/30/2016	A NOVEL METHOD FOR EXPEDITING THE DEVELOPMENT OF PATIENT REPORTED OUTCOME MEASURES	$48,500	$73,235	CCPH	100%	$48,500	$73,235
Gibbs H	NICHD	5R03HD081730-02	8/1/2014	7/31/2016	ADAPTATION AND VALIDATION OF A NUTRITION LITERACY ASSESSMENT INSTRUMENT	$53,693	$80,082	CCPH	100%	$53,693	$80,082
Gibson MC	NIGMS	1R01GM111733-01A1	8/1/2015	7/31/2020	MITOTIC ROUNDING AND PLANAR SPINDLE ALIGNMENT IN PROLIFERATING EPITHELIA	$176,000	$290,400	CB	100%	$176,000	$290,400
Godwin AK	NCI	5R01CA140323-05	4/1/2010	1/31/2016	EXPLOITING BIOLOGICAL NETWORKS TO IMPROVE CLINICAL TREATMENT OF OVARIAN CANCER	$206,260	$309,390	D3ET	100%	$206,260	$309,390
Godwin AK	NCI	3R01CA140323-05S1	4/1/2010	1/31/2016	EXPLOITING BIOLOGICAL NETWORKS TO IMPROVE CLINICAL TREATMENT OF OVARIAN CANCER	$56,093	$84,070	D3ET	100%	$56,093	$84,070
Godwin AK	NCI	3R01CA140323-05S2	4/1/2010	1/31/2016	EXPLOITING BIOLOGICAL NETWORKS TO IMPROVE CLINICAL TREATMENT OF OVARIAN CANCER	$71,222	$107,546	D3ET	100%	$71,222	$107,546
Godwin AK	NCI University of Texas Health Science Center	3U01CA086402	5/15/2000	6/30/2016	EDRN - SAN ANTONIO CENTER FOR BIOMARKERS OF RISK FOR PROSTATE CANCER [SABOR]	$82,533	$124,625	D3ET	100%	$82,533	$124,625
Godwin AK	NCI Fox Chase Cancer Center	3U01CA113916	3/31/2005	6/30/2016	FOX CHASE CLINICAL EPIDEMIOLOGY AND VALIDATION CENTER	$32,805	$49,536	D3ET	100%	$32,805	$49,536
Greiner KA	NCI	5U54CA154253-05	9/17/2010	8/31/2016	KANSAS COMMUNITY CANCER HEALTH DISPARITIES NETWORK	$565,498	$814,582	CCPH	100%	$565,498	$814,582
Greiner KA	NCI	3U54CA154253-05S1	9/17/2010	8/31/2016	KANSAS COMMUNITY CANCER HEALTH DISPARITIES NETWORK	$66,225	$100,000	CCPH	100%	$66,225	$100,000
Greiner KA	NCI	3U54CA154253-05S2	9/17/2010	8/31/2016	KANSAS COMMUNITY CANCER HEALTH DISPARITIES NETWORK	$213,346	$322,152	CCPH	100%	$213,346	$322,152
Greiner KA	NCI	5R01CA158238-04	9/15/2011	7/31/2016	TAILORED TOUCHSCREEN COLORECTAL CANCER PREVENTION IN AMERICAN INDIAN COMMUNITIES	$338,264	$504,749	CCPH	100%	$338,264	$504,749
Gudima SO	NCI	5R01CA166213-04	4/1/2012	3/31/2017	SUPER-INFECTION AND VIRUS SPREAD DURING CHRONIC HEPADNAVIRAL INFECTION	$265,339	$319,945	CB	100%	$265,339	$319,945
Hagan CR	NCI	4R00CA166643-03	9/23/2012	3/31/2018	CK2-DEPENDENT PHOSPHORYLATION OF PROGESTERONE RECEPTORS MEDIATES PROLIFERATIVE SI	$164,900	$249,000	CB	100%	$164,900	$249,000
Hanzlik R	NIGMS	5P30GM110761-02	7/1/2015	6/30/2016	PROTEIN STRUCTURE AND FUNCTION	$750,000	$1,125,000				
Hanzlik R	NIGMS	5P30GM110761-02	7/1/2015	6/30/2016	PROTEIN STRUCTURE AND FUNCTION (PILOT PROJECTS PROGRAM)			D3ET	100%	$250,000	$375,000
Iwakuma T	NCI	5R01CA174735-02	5/1/2014	4/30/2019	THE ROLE OF MDM2-MTBP AXIS IN CANCER METASTASIS	$207,500	$313,325	CB	100%	$207,500	$313,325
Jaeschke HW	NIGMS	5P20GM103549-10	6/1/2006	6/30/2016	NUCLEAR RECEPTORS IN LIVER HEALTH AND DISEASE	$1,309,790	$1,977,783	CB	100%	$1,309,790	$1,977,783
Jensen RA	NCI	5P30CA168524-04	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT	$1,000,000	$1,510,000				
Jensen RA	NCI	5P30CA168524-04	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT (BIOSPECIMEN SHARED RESOURCE)			ZY	100%	$44,237	$44,237
Jensen RA	NCI	5P30CA168524-04	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT (BIOSTATISTICS AND INFORMATICS SHARED RESOURCE)			ZY	100%	$147,933	$147,933

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Jensen RA	NCI	5P30CA168524-04	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT (CANCER BIOLOGY)			ZY	100%	$25,632	$25,632
Jensen RA	NCI	5P30CA168524-04	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT (CANCER CENTER ADMINISTRATION)			ZY	100%	$76,416	$76,416
Jensen RA	NCI	5P30CA168524-04	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT (CANCER CONTROL AND POPULATION HEALTH)			ZY	100%	$43,462	$43,462
Jensen RA	NCI	5P30CA168524-04	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT (CANCER PREVENTION)			ZY	100%	$25,632	$25,632
Jensen RA	NCI	5P30CA168524-04	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT (CLINICAL TRIALS MANAGEMENT SHARED RESOURCE)			ZY	100%	$76,896	$76,896
Jensen RA	NCI	5P30CA168524-04	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT (DEVELOPMENTAL FUNDS)			ZY	100%	$198,737	$198,737
Jensen RA	NCI	5P30CA168524-04	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT (DRUG DISCOVERY; DELIVERY AND EXPERIMENTAL THERAPEUTICS)			ZY	100%	$51,263	$51,263
Jensen RA	NCI	5P30CA168524-04	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT (LEAD DEVELOPMENT AND OPTIMIZATION SHARED RESOURCE)			ZY	100%	$58,606	$58,606
Jensen RA	NCI	5P30CA168524-04	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT (PLANNING AND EVALUATION)			ZY	100%	$20,532	$20,532
Jensen RA	NCI	5P30CA168524-04	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT (PROTOCOL REVIEW AND MONITORING SYSTEM)			ZY	100%	$12,782	$12,782
Jensen RA	NCI	5P30CA168524-04	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT (SENIOR LEADERSHIP)			ZY	100%	$217,872	$727,872
Jensen RA Ellerbeck EF Cupertino AP	NCI	3P30CA168524-04S1	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT (E-DECIDETE: MOBILE CESSATION SUPPORT FOR LATINO SMOKERS IN MEXICO)	$134,239	$179,698	CCPH	100%	$134,239	$179,698
Jiao L Chen GJ	NCI BAYLOR COLLEGE OF MEDICINE	5R01CA172880-03	9/20/2013	7/31/2016	ADVANCED GLYCATION END-PRODUCTS AND RISK OF PANCREATIC CANCER	$25,086	$37,881	CCPH	100%	$25,086	$37,881
Karanicolas J	NIGMS	5R01GM099959-04	4/1/2012	3/31/2017	IDENTIFYING INHIBITORS OF PROTEIN INTERACTIONS USING POCKET OPTIMIZATION	$190,000	$277,075	D3ET	100%	$190,000	$277,075
Kimler BF	ACS	IRG-09-062-04	1/1/2013	12/31/2016	INSTITUTIONAL RESEARCH GRANT	$90,000	$90,000	CPS	100%	$90,000	$90,000
Klemp J	CDC Kansas Dept of Health & Environment	U58DP006113-01	9/30/2015	9/29/2018	INCREASING THE IMPLEMENTATION OF EVIDENCE-BASED CANCER SURVIVORSHIP INTERVENTIONS TO INCREASE QUALITY AND DURATION OF LIFE AMONG CANCER PATIENTS	$262,500	$262,500	CPS	100%	$262,500	$262,500
Kluding PM	NIDDK University of Utah	3R01DK064814	4/1/2015	3/31/2020	ACTIVITY FOR DIABETIC POLYNEUROPATHY: THE "ADAPT STUDY"	$112,626	$154,938	CPS	100%	$112,626	$154,938
Koestler DC	NCI Tufts University	5R01CA166150-04	7/1/2015	6/30/2016	MICROBIOMES IN HUMAN PANCREATIC CANCER	$22,200	$33,522	CB	100%	$22,200	$33,522
Kulsea P	NINDS	5R21NS092001-02	2/1/2015	1/31/2017	IN VIVO ANALYSIS OF TRKB SIGNALING DURING SYMPATHETIC NERVOUS SYSTEM DEVELOPMENT AND NEUROBLASTOMA PATHOGENESIS	$125,000	$206,250	CB	100%	$125,000	$206,250
Kumar TR	NCI	4R01CA166557-04	1/1/2013	12/31/2017	CHEMOPREVENTION OF PITUITARY GONADOTROPE TUMORS	$186,750	$281,992	CB	100%	$186,750	$281,992
Kumar TR	NICHD University of Colorado Denver	1R01HD081162-01A1	8/28/2015	5/31/2020	DYSREGULATION OF FSH IN OBESITY: FUNCTIONAL AND STATISTICAL ANALYSIS	$242,440	$343,237	CB	100%	$242,440	$343,237

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Lamb AL	NSF	1403293	7/15/2014	6/30/2017	ENZYMES OF ORNITHINE-HYDROXAMATE SIDEROPHORES	$409,104	$606,000	D3ET	100%	$409,104	$606,000
Lamb AL	NIAID	5K02AI093675-04	3/1/2011	2/29/2016	STRUCTURE-FUNCTION ANALYSES OF SIDEROPHORE BIOSYNTHETIC ENZYMES	$99,000	$106,920	D3ET	100%	$99,000	$106,920
Landau MJ	NCI	5R01CA185378-02	6/1/2014	5/31/2018	COGNITIVE AND EMOTIONAL PROCESSES OF METAPHORIC CANCER COMMUNICATIONS	$305,663	$327,411	CCPH	100%	$305,663	$327,411
Leeder JS	NICHD University of Washington	1R01HD081299-01A1	4/1/2015	2/29/2020	PBPK PREDICTION OF ONTOGENY MEDIATED ALTERATION IN HEPATIC DRUG ELIMINATION	$240,739	$240,739	D3ET	100%	$240,739	$240,739
Li B	NCI	5R21CA175279-02	1/1/2014	12/31/2015	PROSTATE-TARGETED CRMP4 SARNA AS ANTI-METASTATIC THERAPY	$108,750	$164,213	D3ET	100%	$108,750	$164,213
Li L	NIDDK	5U01DK085507-07	9/30/2009	8/31/2019	CELLULAR, MOLECULAR, AND FUNCTIONAL CHARACTERIZATION OF QUIESCENT/ACTIVE INTESTIN	$220,905	$364,493	CB	100%	$220,905	$364,493
Li L	NIDDK	3U01DK085507-07S1	9/30/2009	8/31/2019	CELLULAR, MOLECULAR, AND FUNCTIONAL CHARACTERIZATION OF QUIESCENT/ACTIVE INTESTIN	$35,080	$57,882	CB	100%	$35,080	$57,882
Lundquist EA	NINDS	5R01NS040945-12	1/18/2001	5/31/2016	CYTOSKELETAL SIGNALING AND AXON GUIDANCE	$206,872	$296,452	CB	100%	$206,872	$296,452
Lunte SM	NSF	1411993	9/1/2014	8/31/2017	MICROANALYTICAL TECHNIQUES TO STUDY SINGLE CELL BIOCHEMICAL PROCESSES	$503,210	$650,000	CPS	100%	$503,210	$650,000
Lunte SM	NIGMS	5P20GM103638-04	7/12/2012	6/30/2017	MOLECULAR ANALYSIS OF DISEASE PATHWAYS	$1,411,972	$2,117,958				
Lunte SM	NIGMS	5P20GM103638-04	7/1/2015	6/30/2016	MOLECULAR ANALYSIS OF DISEASE PATHWAYS (ADMINISTRATIVE CORE)			ZY	100%	$413,119	$619,680
Lunte SM	NIGMS	5P20GM103638-04	7/1/2015	6/30/2016	MOLECULAR ANALYSIS OF DISEASE PATHWAYS (MICROFABRICATION AND MICROFLUIDICS CORE D)			ZY	100%	$137,851	$206,777
Lunte SM Ackley BD	NIGMS	5P20GM103638-04	7/1/2015	6/30/2016	MOLECULAR ANALYSIS OF DISEASE PATHWAYS (IDENTIFYING MRNAS ASSOCIATED WITH A SYNAPTOGENIC CALCIUM-MEDIATED PATHWAY)			D3ET	100%	$120,308	$180,462
Lunte SM Azuma M	NIGMS	5P20GM103638-04	7/1/2015	6/30/2016	MOLECULAR ANALYSIS OF DISEASE PATHWAYS (FUNCTIONAL ANALYSIS OF EWING SARCOMA PROTEINS EWS/FLI1 AND EWS IN ZEBRAFISH)			CB	100%	$122,884	$184,326
Lunte SM Dhar P	NIGMS	5P20GM103638-04	7/1/2015	6/30/2016	MOLECULAR ANALYSIS OF DISEASE PATHWAYS (DETERMINING THE PHYSIOLOGICAL OPTIMAL SURFACE VISCOSITY)			CPS	100%	$122,236	$183,354
Lunte SM Johnson MA	NIGMS	5P20GM103638-04	7/1/2015	6/30/2016	MOLECULAR ANALYSIS OF DISEASE PATHWAYS (NEUROTRANSMITTER INTERACTIONSON SUB-SECOND TIMESCALES)			D3ET	100%	$122,138	$183,206
Lunte SM Lunquist EA	NIGMS	5P20GM103638-04	7/1/2015	6/30/2016	MOLECULAR ANALYSIS OF DISEASE PATHWAYS (GENETICS AND MODEL ORGANISMS CORE B)			ZY	100%	$177,044	$265,566
Lunte SM Peterson B	NIGMS	5P20GM103638-04	7/1/2015	6/30/2016	MOLECULAR ANALYSIS OF DISEASE PATHWAYS (SYNTHETIC MOLECULAR PROBES FOR IN VIVO IMAGING CORE C)			ZY	100%	$196,392	$294,587
Martin LE	NCI University of Missouri Kansas City	5R21CA184834-02	5/19/2014	8/31/2016	(PQA3) NEURAL PREDICTORS OF SELF-REGULATION OF SMOKING URGES AT A STRESSFUL MOMEN	$122,361	$164,213	CCPH	100%	$122,361	$164,213

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McGuirk JP	NHLBI University of Nebraska Medical Center	5U10HL069233-15	9/30/2001	6/30/2017	NEBRASKA/KANSAS BLOOD AND MARROW TRANSPLANT RESEARCH NETWORK	$125,999	$154,372	D3ET	100%	$125,999	$154,372
Moise AR	NICHD	5R01HD077260-02	4/17/2014	3/31/2019	MOLECULAR DETERMINANTS OF RETINOID METABOLISM IN EMBRYONIC TISSUES	$264,170	$306,111	CB	100%	$264,170	$306,111
Mure M	NIGMS	5R01GM113101-02	9/22/2014	7/31/2018	UNDERSTANDING THE ROLES OF PTM'S IN MODULATING MOLECULAR FUNCTIONS OF LYSYL OXIDASE-LIKE 2 IN BREAST CANCER CELLS	$195,000	$287,219	CB	100%	$195,000	$287,219
Neufeld K	NSF	1456538	4/15/2015	3/31/2018	COLLABORATIVE RESEARCH: BETA-CATENIN REGULATION DURING ASYMMETRIC STEM CELL DIVISIONS	$266,666	$400,000	CB	100%	$266,666	$400,000
Nicot CP	NCI	5R01CA106258-11	4/1/2004	5/31/2016	HTLV-I TAX INDUCES DNA BREAKS AND INHIBITS HR REPAIR THROUGH ACTIVATION OF NF-KB	$149,339	$224,009	CB	100%	$149,339	$224,009
Nollen NL	PCORI	AD-1310-08709	10/1/2014	9/30/2017	INFORMING TOBACCO-TREATMENT GUIDELINES FOR AFRICAN AMERICAN NON-DAILY SMOKERS	$497,976	$680,971	CCPH	100%	$497,976	$680,971
Nollen NL	NIDA Pinnacle Technology Inc	5R01DA031815-04	5/1/2012	4/30/2017	UNDERSTANDING DISPARITIES IN QUITTING IN AFRICAN AMERICAN AND WHITE SMOKERS	$486,405	$666,846	CCPH	100%	$486,405	$666,846
Peterson KR	NHLBI	5R01HL111264-03	8/15/2013	5/31/2017	MECHANISMS OF HBF ACTIVATION BY NON-DELETIONAL HPFH	$246,250	$371,837	CB	100%	$246,250	$371,837
Peterson KR Slawson CE	NIDDK	5R01DK100595-03	1/1/2014	12/31/2016	REGULATION OF GLOBIN GENE SWITCHING BY O-GLCNAC POST-TRANSLATIONAL MODIFICATION	$156,600	$236,466	CB	100%	$156,600	$236,466
Prisinzano TE	NIGMS	5R24GM111385-02	8/1/2014	7/31/2017	LEGACY CONTINUATION OF THE KU CMLD MISSION	$344,634	$516,951	D3ET	100%	$344,634	$516,951
Ramaswamy M	NCI	5R01CA181047-02	4/1/2014	3/31/2019	SEXUAL HEALTH EMPOWERMENT FOR CERVICAL HEALTH LITERACY AND CANCER PREVENTION	$218,527	$313,325	CCPH	100%	$218,527	$313,325
Richter KP	NIDA	5R13DA015046-14	8/1/2002	7/31/2017	AMERSA ANNUAL NATIONAL CONFERENCE	$46,500	$46,500	ZY	100%	$46,500	$46,500
Richter M	NIMH PINNACLE TECHNOLOGY, INC	9R44MH107036-02	12/1/2011	2/28/2017	A TISSUE IMPLANTABLE MICROBIOSENSOR	$122,188	$177,284	D3ET	100%	$122,188	$177,284
Richter M	NIDA Pinnacle Technology Inc	5R44DA033701-03	9/30/2013	2/29/2016	DEVELOPMENT OF A NICOTINE BIOSENSOR	$306,456	$443,956	D3ET	100%	$306,456	$443,956
Roy A	NIAID Kansas State University	1R21AI115187-01A1	7/15/2015	6/30/2016	HIGH-THROUGHPUT FLUORESCENCE SCREENING FOR INHIBITORS OF TONB-DEPENDENT IRON TRANSPORT	$50,000	$75,000	D3ET	100%	$50,000	$75,000
Savage CR Donnelly JE	NIDDK	5R01DK085605-05	4/1/2010	1/31/2016	NEUROIMAGING STUDIES OF REWARD, IMPULSIVITY, AND ADHERENCE TO AN EXERCISE PROGRAM	$488,003	$576,124	CCPH	65%	$351,906	$376,062
Savage CR Donnelly JE	NIDDK				NEUROIMAGING STUDIES OF REWARD, IMPULSIVITY, AND ADHERENCE TO AN EXERCISE PROGRAM			CPS	35%	$136,097	$200,062
Scott EE	NIGMS	2R37GM076343-10	1/1/2006	2/29/2020	STRUCTURAL BASIS OF CYTOCHROME P450 ACTIVITY	$230,000	$341,187	D3ET	100%	$230,000	$341,187
Scott EE Aube J (UNC)	NIGMS	5R01GM102505-04	7/1/2012	3/31/2016	STRUCTURE AND FUNCTION OF CYTOCHROME P450 17A1	$190,000	$277,878	D3ET	100%	$95,000	$138,939

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Siahaan TJ	NINDS	5R01NS075374-05	8/15/2011	6/30/2016	MODULATING THE BBB TO IMPROVE DRUG DELIVERY TO THE BRAIN	$222,710	$304,650	D3ET	100%	$222,710	$304,650
Smith PG	NICHD	5R01HD049615-09	4/16/2006	6/30/2017	IDENTIFYING THERAPEUTIC TARGETS FOR VULVODYNIA	$246,189	$349,752	CPS	100%	$246,189	$349,752
Soares MJ	NICHD	5P01HD079363-02	7/1/2015	6/30/2019	STEM CELLS AND EPIGENETICS OF TROPHOBLAST LINEAGE DEVELOPMENT: RESEARCH PROJECT III: HISTONE H3K9 METHYLATION AND TROPHOBLAST LINEAGE DEVELOPMENT			CB	100%	$179,178	$270,558
Soares MJ	NICHD	1R21HD082535-01	4/1/2015	3/31/2017	NATURAL KILLER CELLS AND HEMOCHORIAL PLACENTATION	$125,000	$188,750	CB	100%	$125,000	$188,750
Soares MJ	NIH Office of Director	5R21OD010478-02	5/27/2013	4/30/2016	RAT MODELS FOR SEX STEROID ACTION	$142,650	$215,402	CB	100%	$142,650	$215,402
Soares MJ	NICHD	5R01HD020676-27	7/1/1986	4/30/2017	TROPHOBLAST DIFFERENTIATION	$255,114	$385,221	CB	100%	$255,114	$385,221
Soares MJ	NICHD	5P01HD079363-02	7/24/2014	6/30/2019	STEM CELLS AND EPIGENETICS OF TROPHOBLAST LINEAGE DEVELOPMENT	$715,073	$1,079,760				
Soares MJ Paul S	NICHD	5P01HD079363-02	7/1/2015	6/30/2019	STEM CELLS AND EPIGENETICS OF TROPHOBLAST LINEAGE DEVELOPMENT (RESEARCH PROJECT I: TEAD4 ORCHESTRATION OF TROPHOBLAST DEVELOPMENT)			CB	100%	$182,534	$275,627
Soares MJ Rumi M AK	NICHD	5P01HD079363-02	7/1/2015	6/30/2019	STEM CELLS AND EPIGENETICS OF TROPHOBLAST LINEAGE DEVELOPMENT (RESEARCH PROJECT II: SATB REGULATION OF THE TROPHOBLAST STEM CELL STATE)			CB	100%	$184,448	$278,516
Soares MJ	NICHD	5P01HD079363-02	7/1/2015	6/30/2019	STEM CELLS AND EPIGENETICS OF TROPHOBLAST LINEAGE DEVELOPMENT (CORE A - ADMINISTRATIVE CORE UNIT)			ZY	100%	$48,588	$73,368
Soares MJ	NICHD	5P01HD079363-02	7/1/2015	6/30/2019	STEM CELLS AND EPIGENETICS OF TROPHOBLAST LINEAGE DEVELOPMENT (RESEARCH PROJECT III: HISTONE H3K9 METHYLATION AND TROPHOBLAST LINEAGE DEVELOPMEN)			CB	100%	$179,178	$270,558
Soares MJ Wolfe MW	NICHD	5P01HD079363-02	7/1/2015	6/30/2019	STEM CELLS AND EPIGENETICS OF TROPHOBLAST LINEAGE DEVELOPMENT (CORE B - STEM CELL AND TROPHOBLAST ANALYSIS CORE)			ZY	100%	$120,325	$181,691
Staudinger JL	NIDDK	5R01DK090558-04	7/6/2011	4/30/2016	INFLAMMATION, PXR MODIFICATION AND DRUG DISPOSITION	$217,500	$315,780	CB	100%	$217,500	$315,780
Sullivan DK Donnelly J	NIDDK	5R01DK094833-04	9/25/2012	6/30/2016	A VIRTUAL REALITY INTERVENTION (SECOND LIFE) TO IMPROVE WEIGHT MAINTENANCE	$411,268	$611,139	CPS	100%	$411,268	$611,139
Tang L	NIGMS	5R01GM090010-05	9/1/2010	8/31/2016	GENOME PACKAGING IN DNA VIRUSES	$188,100	$270,426	CB	100%	$188,100	$270,426
Thyfault J	NIDDK	7R01DK088940-05	7/25/2011	3/31/2016	AEROBIC FITNESS, MITOCHONDRIAL DYSFUNCTION, AND FATTY LIVER DISEASE	$187,500	$283,125	CB	100%	$187,500	$283,125
Tran PV	NIDDK	1R01DK103033-01A1	4/1/2015	3/31/2020	HEDGEHOG SIGNALING AS A THERAPEUTIC TARGET FOR CYSTIC KIDNEY DISEASE	$234,611	$348,755	CB	100%	$234,611	$348,755
Tran PV	NIGMS	5P20GM104936-09	7/1/2015	6/30/2016	MOLECULAR MECHANISM OF THM1-MEDICATED RENAL CYSTOGENESIS	$150,000	$226,500	CB	100%	$150,000	$226,500

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Tunge J	NSF	1465172	7/1/2015	6/30/2018	CATALYTIC SYNTHESIS VIA C-C CLEAVAGE	$308,751	$435,000	D3ET	100%	$308,751	$435,000
Umar S	NCI	5R01CA185322-02	1/5/2015	12/31/2019	EPIGENETICS AND INFECTION-INDUCED EMT OF COLONIC CRYPTS - TARGET FOR CHEMOPREVENTION	$263,084	$380,222	CPS	100%	$263,084	$380,222
Van Veldhuizen PJ	NCI Southwest Oncology Group (SWOG)	3969	8/5/2004	12/31/2020	SWOG: SOUTHWEST ONCOLOGY GROUP- UNIVERSITY OF KANSAS	$38,798	$38,798	CPS	100%	$38,798	$38,798
Van Veldhuizen PJ	NCI Southwest Oncology Group (SWOG)	10867	10/30/2013	12/31/2020	SWOG: SOUTHWEST ONCOLOGY GROUP- UNIVERSITY OF KANSAS	$409,164	$409,164	CPS	100%	$409,164	$409,164
Volkin D Forrest ML Middaugh CR *et al*	FDA	5U01FD005285-02	9/10/2014	3/31/2017	DEVELOPMENT OF AN INTEGRATED MATHEMATICAL MODEL FOR COMPARATIVE CHARACTERIZATION OF COMPLEX MOLECULE	$133,333	$200,000	D3ET	100%	$133,333	$200,000
Volkin D Karanicolas J	NIH Health Research Inc	272201400021C-2-0-1	9/30/2015	9/29/2016	B CELL EPITOPE DISCOVERY AND MECHANISMS OF ANTIBODY PROTECTION	$247,558	$371,337	D3ET	100%	$247,558	$371,337
Waitman RL	PCORI	CDRN-1306-04631 MC	4/1/2015	9/30/2016	THE GREATER PLAINS COLLABORATIVE	$2,044,128	$2,879,054	CPS	100%	$2,044,128	$2,879,054
Wallace DP	NIDDK	2R01DK081579-06A1	7/1/2008	4/30/2019	ROLE OF PERIOSTIN IN POLYCYSTIC KIDNEY DISEASE	$225,000	$339,750	CB	100%	$225,000	$339,750
Ward CJ	NIDDK	5R01DK080688-05	12/3/2013	5/31/2016	FUNCTIONAL ANALYSIS OF PKD PROTEINS IN URINARY EXOSOMES	$217,500	$328,425	CB	100%	$217,500	$328,425
Weinman SA	NIAAA	5R01AA012863-15	9/27/2000	2/28/2017	MECHANISMS OF LIVER INJURY BY HEPATITIS C AND ALCOHOL	$331,842	$501,081	CB	100%	$331,842	$501,081
Welch DR	NCI	5R01CA134981-06	9/1/2009	5/31/2016	KISS1: DEFINING MECHANISMS FOR ANTIMETASTATIC THERAPY	$186,243	$281,227	CB	100%	$186,243	$281,227
Welch DR	Susan G. Komen Foundation	SAC110037	7/28/2011	9/27/2016	REGULATION OF METASTASIS BY MITOCHONDRIAL DNA	$160,000	$200,000	CB	100%	$160,000	$200,000
Workman JL	NIGMS	5R01GM047867-23	8/1/1992	7/31/2016	MECHANISMS OF TRANSCRIPTIONAL REGULATION IN CHROMATIN	$200,000	$318,000	CB	100%	$200,000	$318,000
Workman JL Abmayr SM	NIGMS	5R01GM099945-04	5/1/2012	4/30/2016	ANALYSIS OF METAZOAN SAGA COMPLEX FUNCTION IN GENE EXPRESSION	$190,000	$307,800	CB	100%	$190,000	$307,800
Xu L	Susan G. Komen Foundation	PDF14301553	8/2/2014	8/1/2017	NOVEL ANTI-METASTAMIR THERAPY FOR METASTATIC BREAST CANCER	$180,000	$180,000	D3ET	100%	$180,000	$180,000
Xu L Aube J (UNC)	NCI	1R01CA191785-01A1	7/1/2015	5/31/2020	MOLECULAR CANCER THERAPY TARGETING HUR-ARE INTERACTION	$290,500	$432,001	D3ET	100%	$145,250	$216,001
Xu L Neufeld KL Aube J (UNC)	NCI	5R01CA178831-02	9/19/2014	8/31/2017	SMALL MOLECULES MODULATING RNA-BINDING PROTEIN MSI1	$291,662	$432,491	D3ET	100%	$97,221	$144,164
Xu L Neufeld KL Aube J (UNC)					SMALL MOLECULES MODULATING RNA-BINDING PROTEIN MSI1			CB	100%	$97,221	$144,164
Zeng Y	NCI	5R21CA186846-02	8/1/2014	7/31/2017	INTEGRATED MICROFLUIDIC EXOSOME PROFILING FOR EARLY DETECTION OF CANCER	$162,276	$212,274	D3ET	100%	$112,276	$137,274

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Zeng Y Lunte S	NCI Univ of KS Med Ctr Research Institute	5R21CA186846-02	7/1/2015	6/30/2016	INTEGRATED MICROFLUIDIC EXOSOME PROFILING FOR EARLY DETECTION OF CANCER: DEVELOPMENT OF A LIVER-ON-A-CHIP TECHNOLOGY FOR STUDY OF LIVER DISEASE			CPS	100%	$50,000	$75,000
			Peer-Reviewed Research Subtotals:			$37,853,542	$53,006,095			**$36,715,801**	**$51,342,166**

NON-PEER-REVIEWED RESEARCH PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Ablah E	Kansas Health Foundation		1/1/2015	12/31/2017	WORKWELL KANSAS: PHASE II	$1,000,000	$1,000,000	CCPH	100%	$1,000,000	$1,000,000
Abhyankar A	Therakos, Inc.		5/12/2010	12/31/2016	A STUDY OF EXTRACORPOREAL PHOTOPHEREIS WITH UVADEX IN THE SETTING OF A STANDARD MYELOABLATIVE CONDITIONING REGIMEN IN UNRELATED DONOR	$32,412	$32,412	D3ET	100%	$32,412	$32,412
Abhyankar S	GlaxoSmithKline (fka: Glaxo Wellcome)		2/1/2013	12/31/2020	A PHASE III, RANDOMISED, OBSERVER-BLIND, PLACEBO CONTROLLED, MULTICENTRE, CLINICAL TRIAL TO ASSESS THE PROPHYLACTIC EFFICACY, SAFETY, AND IMMUNOGENICITY OF GSK BIOLOGICALS HERPES ZOSTER GE/AS01B CANDIDATE VACCINE WHEN ADMINISTERED	$53,043	$70,548	D3ET	100%	$53,043	$70,548
Abhyankar S	University of Nebraska Medical Center	PROTOCOL #0901	2/14/2012	12/31/2020	A RANDOMIZED, MULTI-CENTER, PHASE III OF ALLOGENEIC STEM CELL TRANSPLANATION COMPARING REGIMEN INTENSITY IN PATIENTS WITH MYELODYSPLASTIC SYNDROME OR ACUTE MYELOID LEUKEMIA	$15,275	$20,316	D3ET	100%	$15,275	$20,316
Abhyankar S	Pfizer		2/1/2013	12/31/2020	AN OPEN LABEL, RANDOMIZED PHASE 3 STUDY OF INOTUZUMAB OZOGAMICIN COMPARED TO A DEFINED INVESTIGATOR'S CHOICE IN ADULT PATIENTS WITH RELAPSED OR REFRACTORY CD22- POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)	$18,933	$25,181	D3ET	100%	$18,933	$25,181
Aljitawi OS	Medtronic Inc		12/4/2012	12/31/2020	A PHASE IIB, MULTICENTER, OPEN-LABEL, SAFETY AND EFFICACY STUDY OF HIGH DOSE MELPHALAN HCL FOR INJECTION (PROPYLENE GLYCOL-FREE) FOR MYELOABLATIVE CONDITIONING IN MULTIPLE MYELOMA PATIENTS UNDERGOING AUTOLOGOUS TRANSPLANTATION	$42,149	$56,058	CB	100%	$42,149	$56,058
Aljitawi OS	Hope Foundation		1/1/2014	12/31/2015	PILOT STUDY EXPLORING THE USE OF HYPERBARIC OXYGEN IN AUTOLOGOUS PBSC TRANSPLANTATION	$108,883	$129,854	CB	100%	$108,883	$129,854

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Berkland C	American Heart Assoc - Midwest Affiliate		7/1/2014	6/30/2016	NON-ABSORBED MICELLE SEQUESTRANT POLYMERS FOR THE TREATMENT OF WESTERN DIET-INDUCED OBESITY	$95,224	$95,224	D3ET	100%	$95,224	$95,224
Calvet JP	Polycystic Kidney Disease Foundation		3/1/2014	2/28/2016	ROLE OF CFTR AND NKCC1 IN POLYCYSTIC KIDNEY DISEASE	$80,000	$80,000	CB	100%	$80,000	$80,000
Chen GJ	Veteran Affairs Medical Center		3/1/2014	9/30/2016	VALUE OF DELIVERY OF TARGETED THERAPY FOR VETERANS WITH ADVANCED LUNG CANCER	$61,459	$61,459	CCPH	100%	$61,459	$61,459
Clough L	Ansun BioPharma, Inc.		4/29/2014	12/31/2021	A PHASE II, RANDOMIZED, DOUBLE BLIND, PLACEBO CONTROLLED STUDY TO EXAMINE THE EFFECTS OF DAS181 IN IMMUNOCOMPROMISED SUBJECT WITH LOWER RESPIRATORY TRACT PARAINFLUENZA INFECTION ON SUPPLEMENTAL OXYGEN	$40,112	$53,349	D3ET	100%	$40,112	$53,349
Clough L	Merck, Sharp and Dohme Corp.		7/9/2014	12/31/2021	A PHASE III RANDOMIZED, PLACEBO-CONTROLLED CLINICAL TRIAL TO EVALUATE THE SAFETY AND EFFICACY OF MK-8228 FOR THE PREVENTION OF CLINICALLY SIGNIFICANT HUMAN CYTOMEGALOVIRUS INFECTION IN ADULT, CMV-SEROPOSITIVE ALLOGENIC HEMATOPOIETIC STEM CELL TRANSPLANT	$28,032	$35,632	D3ET	100%	$28,032	$35,632
Clough L	Optimer Pharmaceuticals Inc		8/20/2012	12/31/2020	DEFLECT1 A PHASE 3B, MULTI CENTER, DOUBLE BLIND, RANDOMIZED, PLACEBO CONTROLLED STUDY TO DEMONSTRATE THE SAFETY AND EFFICACY OF FIDAXOMICIN FOR PROPHYLAXIS AGAINST CLOSTRIDIUM DIFFICILE	$42,742	$56,846	D3ET	100%	$42,742	$56,846
Collie-Akers VL	KS Health Foundation		6/1/2014	5/31/2016	CREATING HEALTHY PLACES AND SPACES TO PROMOTE HEALTHY EATING AND ACTIVE LIVING AMONG LATINOS IN KANSAS CITY, KANSAS	$90,764	$99,842	CCPH	100%	$90,764	$99,842
Collie-Akers VL	Robert Wood Johnson Univ of California - Berkeley		6/1/2014	5/31/2016	IN-DEPTH EXAMINATION OF DIVERSE SCHOOLS WITH DECLINING BMIS	$53,572	$60,000	CCPH	100%	$53,572	$60,000
Fabian CJ	Breast Cancer Research Foundation		10/1/2014	9/30/2016	WILL THE OMEGA-3 FATTY ACID DHA PREVENT DEVELOPMENT OF COGNITIVE DYSFUNCTION DUE TO CHEMOTHERAPY?	$208,000	$250,000	CPS	100%	$208,000	$250,000
Fabian CJ Khan QJ Sharma P	GlaxoSmithKline (fka: Glaxo Wellcome)		1/25/2011	12/31/2020	PHASE II TRIAL OF LAPATINIB AND RAD-001 FOR HER2 POSITIVE METASTATIC BREAST CANCER	$49,955	$66,440	D3ET	100%	$49,955	$66,440
Faseru B	KANSAS DEPT OF HEALTH AND ENVIRONMENT		3/18/2013	7/31/2016	EPIDEMIOLOGY SUPPORT FOR KANSAS HEALTH ASSESSMENT AND PROMOTION ACTIVITIES	$63,447	$65,299	ZY	100%	$63,447	$65,299
Fields TA	Polycystic Kidney Disease Foundation		3/1/2014	2/28/2016	PRE-CLINICAL ASSESSMENT OF MCP-1/CCR2 INHIBITION AS TREATMENT FOR ADPKP	$80,000	$80,000	CB	100%	$80,000	$80,000
Forrest ML	NanoPharm, LLC	IND0069745	11/1/2011	12/31/2015	TRANSLATIONAL DEVELOPMENT OF INTRALYMPHATIC CHEMOTHERAPIES	$188,690	$188,690	D3ET	100%	$188,690	$188,690

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Forrest ML Schoeneich C	Inez Jay Fund	FND0074591	7/1/2015	6/30/2016	MECHANISTIC UNDERSTANDING OF OXIDATION OF THERAPEUTIC PROTEINS AFTER SUBCUTANEOUS ADMINISTRATION	$30,000	$30,000	D3ET	100%	$30,000	$30,000
Ganguly S	Sanofi-Aventis US Inc		7/17/2012	12/31/2020	A PHASE 2 STUDY OF SAR245409 IN PATIENTS WITH RELAPSED OR REFRACTORY MANTLE CELL LYMPHOMA, FOLLICULAR LYMPHOMA, OR CHRONIC LYMPHOCYTIC LEUKEMIA/SMALL LYMPHOCYTIC LYMPHOMA	$25,137	$33,432	CB	100%	$25,137	$33,432
Ganguly S	Ambit Biosciences Corporation		9/12/2014	12/31/2020	A PHASE 3 OPEN-LABEL RANDOMIZED STUDY OF QUIZARTINIB (AC220) MONOTHERAPY VERSUS SALVAGE CHEMOTHERAPY IN SUBJECTS WITH FLT3-ITD POSITIVE ACUTE MYELOID LEUKEMIA (AML) REFRACTORY TO OR RELAPSED AFTER FIRST-LINE TREATMENT WITH OR	$14,728	$19,589	CB	100%	$14,728	$19,589
Ganguly S	Janssen Research and Development, L.L.C.		2/5/2013	12/31/2020	RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE 3 STUDY OF IBRUTINIB, A BRUTON'S TYROSINE KINASE (BTK) INHIBITOR, IN COMBINATION WITH BENDAMUSTINE AND RITUXIMAB (BR) IN SUBJECTS WITH RELAPSED OR REFRACTORY CHRONIC LYMPHOCYTIC	$83,975	$111,687	CB	100%	$83,975	$111,687
Godwin AK	Inhibikase Therapeutics, Inc		12/7/2015	12/6/2016	EVALUATION OF RE-ENGINEERED PROTEIN KINASAE INHIBITORS IN A GIST ANIMAL MODEL	$25,918	$39,655	D3ET	100%	$25,918	$39,655
Godwin AK	Braden's Hope Foundation		9/1/2015	8/31/2016	THE ACHILLES' HEEL AND NOVEL TARGETED THERAPIES OF EWING SARCOMA	$100,000	$100,000	D3ET	100%	$100,000	$100,000
Hagan CR	V Foundation for Cancer Research		1/1/2015	12/31/2017	PROGESTERONE RECEPTOR PROMOTES INFLAMMATION IN BREAST CANCER	$100,000	$100,000	CB	100%	$100,000	$100,000
Holzbeierlein JM	Heat Biologics, Inc.		10/28/2014	12/30/2020	A PHASE 1/2, PLACEBO-CONTROLLED, RANDOMIZED STUDY TO EVALUATE THE SAFETY, IMMUNE RESPONSE AND CLINICAL ACTIVITY OF HS-410 IN PATIENTS WITH HIGH-RISK NON-MUSCLE INVASIVE BLADDER CANCER WHO HAVE UNDERGONE TRANSURETHRAL	$30,639	$40,750	D3ET	100%	$30,639	$40,750
Holzbeierlein JM	Argos Therapeutics, Inc.		5/13/2013	12/31/2020	AN INTERNATIONAL PHASE 3 RANDOMIZED TRIAL OF AUTOLOGOUS DENDRITIC CELL IMMUNOTHERAPY (AGS-003) PLUS STANDARD TREATMENT OF ADVANCED RENAL CELL CARCINOMA (ADAPT)	$31,258	$41,573	D3ET	100%	$31,258	$41,573
Huang CH Neupane PC	Celgene Corporation		10/31/2014	12/31/2020	A PHASE III, RANDOMIZED, OPEN-LABEL, CROSS-OVER, MULTI-CENTER, SAFETY AND EFFICACY STUDY TO EVALUATE NAB-PACLITAXEL (ABRAXANE) AS MAINTENANCE TREATMENT AFTER INDUCTION WITH NAB-PACLITAXEL PLUS CARBOPLATIN IN SUBJECTS WITH SQUAMOUS CELL	$18,086	$24,055	D3ET	100%	$9,043	$12,028

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Kambhampati S	Celgene Corporation		10/29/2012	12/31/2021	A PHASE 2, MULTI-CENTER, RANDOMIZED, OPEN-LABEL, PARALLEL-GROUP STUDY OF A LENALIDOMIDE (REVLIMID) REGIMIN FOR A SEQUENTIAL AZACITICINE (VIDAZA) PLUS LENALIDOMIDE (REVLIMID) REGIMIN VERSUS AN AZACITICINE (VIDAZA) REGIMEN FOR THERAPY OF OLDER SUBJECTS	$77,575	$103,175	D3ET	100%	$77,575	$103,175
Jaeschke HW	Hubert and Richard Hanlon Trust		1/6/2014	12/31/2016	MECHANISMS OF ALCOHOLIC HEPATITIS IN HUMANS	$50,000	$50,000	CB	100%	$50,000	$50,000
Johnson GA	NRG Oncology Foundation, Inc.		3/1/2014	12/31/2020	GOG STUDIES	$18,303	$24,343	D3ET	100%	$18,303	$24,343
Karanicolas J	Inez Jay Fund		7/1/2014	6/30/2016	IDENTIFYING STABILIZERS OF P53 USING POCKET COMPLEMENTARITY	$28,000	$28,000	D3ET	100%	$28,000	$28,000
Khan QJ	Oncothyreon, Inc.		5/27/2014	12/31/2020	PHASE 1B, OPEN-LABEL STUDY TO ASSESS THE SAFETY AND TOLERABILITY OF ONT-380 COMBINED WITH ADO-TRASTUZUMAB EMTANSINE (T-DM1)	$86,276	$114,534	D3ET	100%	$86,276	$114,534
Lai SM	KANSAS DEPT OF HEALTH AND ENVIRONMENT		8/15/2015	8/14/2016	KANSAS CANCER REGISTRY	$831,402	$831,402	CCPH	100%	$831,402	$831,402
Lin TL	AbbVie, Inc.		1/27/2015	12/31/2020	A PHASE 1/2 STUDY OF ABT-199 IN COMBINATION WITH LOW-DOSE CYTARABINE IN TREATMENT-NAIVE SUBJECTS WITH ACUTE MYELOGENOUS LEUKEMIA WHO ARE >= 65 YEARS OF AGE AND WHO ARE NOT ELIGIBLE FOR STANDARD ANTHRACYCLINE-BASED INDUCTION THERAPY	$52,061	$69,176	D3ET	100%	$52,061	$69,176
Lin TL	Pfizer Inc		11/28/2012	12/31/2020	A PHASE 1B STUDY TO EVALUATE THE SAFETY AND PRELIMINARY EFFICACY OF PF-04449913, AN ORAL HEDGEHOG INHIBITOR, IN COMBINATION WITH INTENSIVE CHEMOTHERAPY, LOW DOSE ARA-C OR DECITABINE IN PATIENTS WITH ACUTE MYELOID LEUKEMIA OR HIGHRISK	$16,266	$21,634	D3ET	100%	$16,266	$21,634
Lin TL	Celator Pharmaceuticals Inc		10/6/2014	12/31/2020	AN OPEN LABEL PHASE II PHARMACOKINETIC AND PHARMACODYNAMIC ASSESSMENT OF THE POTENTIAL FOR QTC PROLONGATION FOLLOWING FIRST INDUCTION TREATMENT WITH CPX-351 (CYTARABINE: DAUNORUBICIN) LIPOSOME INJECTION IN ACUTE LEUKEMIAS AND MDS PATIENTS	$184,265	$245,007	D3ET	100%	$184,265	$245,007
Lin TL	Celator Pharmaceuticals Inc		3/8/2013	12/31/2020	PHASE III, MULTICENTER, RANDOMIZED, TRAIL OF CPX-351 (CYTARABINE:DAUNORUBICIN) LIPOSOME INJECTION VERSUS CYTARABINE AND DAUNORUBICIN IN PATIENTS 60-75 YEARS OF AGE WITH UNTREATED HIGH RISK (SECONDARY) AML	$25,503	$33,919	D3ET	100%	$25,503	$33,919

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Mayo MS	NuFactor		1/1/2013	12/31/2016	DATA COORDINATING CENTER FOR NUFACTOR IG TREATMENT OUTCOMES ASSESSMENT AND CLINICAL GUIDLINES STUDY	$244,090	$324,640	ZY	100%	$244,090	$324,640
McGuirk JP	Astellas Pharma US, Inc.		10/31/2013	12/30/2020	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE 3 TRIAL TO EVALUATE THE PROTECTIVE EFFICACY AND SAFETY OF A THERAPEUTIC VACCINE, ASP0113, IN CYTOMEGALOVIRUS (CMV)-SEROPOSITIVE RECIPIENTS UNDERGOING ALLOGENEIC, HEMATOPOIETIC CELL TRANSPLANT (HCT)	$36,204	$48,151	D3ET	100%	$36,204	$48,151
McGuirk JP	Fresenius Biotech		2/6/2012	12/31/2020	A RANDOMIZED, PROSPECTIVE, DOUBLE BLIND, PLACEBOCONTROLLED, PHASE 3 STUDY OF US-ATG-F PROPHYLAXIS AS A SUPPLEMENT TO STANDARD OF CARE PROPHYLAXIS TO PREVENT MODERATE TO SEVERE CHRONIC GVHD IN ADULT ACUTE MYELOID LEUKEMIA, ACUTE LYMPHOID LEUKEMIA,	$43,777	$58,224	D3ET	100%	$43,777	$58,224
Neupane PC	Celgene Corporation		10/31/2014	12/31/2020	A PHASE III, RANDOMIZED, OPEN-LABEL, CROSS-OVER, MULTI-CENTER, SAFETY AND EFFICACY STUDY TO EVALUATE NAB-PACLITAXEL (ABRAXANE) AS MAINTENANCE TREATMENT AFTER INDUCTION WITH NAB-PACLITAXEL PLUS CARBOPLATIN IN SUBJECTS WITH SQUAMOUS CELL	$18,086	$24,055	D3ET	100%	$18,086	$24,055
Neupane PC	VentiRx Pharmaceuticals		2/11/2014	12/31/2020	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF CHEMOTHERAPY PLUS CETUXIMAB IN COMBINATION WITH VTX-2337 IN PATIENTS WITH RECURRENT OR METASTATIC SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK	$129,239	$171,887	D3ET	100%	$129,239	$171,887
Pacheco CM	Robert Wood Johnson Foundation		9/1/2014	8/31/2016	SMOKING RESTRICTIVE POLICIES AND ITS IMPACTS ON SMOKING AT TRIBAL	$46,146	$51,683	CCPH	100%	$46,146	$51,683
Perez R	Millennium Pharmaceuticals Inc		9/13/2013	12/31/2020	A PHASE 1 PHARMACOKINETIC STUDY OF ORAL MLN9708 IN PATIENTS WITH ADVANCED SOLID TUMORS OR HEMATOLOGIC MALIGNANCIES WITH VARYING DEGREES OF LIVER DYSFUNCTION	$19,984	$26,579	D3ET	100%	$19,984	$26,579
Perez R	ImmunoGen, Inc		2/19/2014	12/31/2020	A PHASE 1, FIRST-IN-HUMAN STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS AND PHARMACODYNAMICS OF IMGN853 IN ADULTS WITH OVARIAN CANCER AND OTHER FOLR1-POSITIVE SOLID TUMORS	$131,534	$174,940	D3ET	100%	$131,534	$174,940

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Perez R	TetraLogic Pharmaceuticals Corporation		4/10/2014	12/31/2020	A PHASE 1B, OPEN-LABEL, NON-RANDOMIZED MULTICENTER STUDY OF BIRINAPANT IN COMBINATION WITH CONATUMUMAB IN SUBJECTS WITH RELAPSED EPITHELIAL OVARIAN CANCER, PRIMARY PERITONEAL CANCER OR FALLOPIAN TUBE CANCER	$106,076	$141,081	D3ET	100%	$106,076	$141,081
Perez R	Novartis Pharmaceuticals Corp		3/19/2014	3/19/2016	A PHASE IB, MULTI-CENTER, TWO PARALLEL GROUP, OPEN-LABEL, DRUG-DRUG INTERACTION STUDY TO ASSESS THE EFFECT OF LDE225 ON THE PHARMACOKINETICS OF BUPROPION AND WARFARIN IN PATIENTS WITH ADVANCED SOLID TUMORS	$111,347	$148,092	D3ET	100%	$111,347	$148,092
Perez R	Bristol-Myers Squibb Company		6/25/2012	12/31/2020	A PHASE IB, OPEN-LABEL, MULTICENTER STUDY OF BMS-936564 IN COMBINATION WITH LENALIDOMIDE (REVLIMID) PLUS LOW-DOSE DEXAMETHASONE, OR WITH BORTEZOMIB (VELCADE) PLUS DEXAMETHASONE IN SUBJECTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA	$52,690	$70,078	D3ET	100%	$52,690	$70,078
Perez R	Dompe s.p.a.		2/15/2013	12/31/2020	A SINGLE ARM, PREOPERATIVE, PILOT STUDY TO EVALUATE THE SAFETY AND BIOLOGICAL EFFECTS OF ORALLY ADMINISTERED REPARIXIN IN EARLY BREAST CANCER PATIENTS WHO ARE CANDIDATES FOR SURGERY	$50,843	$67,621	D3ET	100%	$50,843	$67,621
Perez R	Millennium Pharmaceuticals Inc		8/13/2013	12/31/2020	PHASE 1/1B PHARMACOKINETICS STUDY OF ORAL MLN9708 PLUS DEXAMETHASONE IN RELAPSED/REFRACTORY MULTIPLE MYELOMA PATIENTS WITH NORMAL RENAL FUNCTION OR SEVERE RENAL IMPAIRMENT	$30,178	$40,137	D3ET	100%	$30,178	$40,137
Perez R	Eli Lilly & Company		6/22/2012	12/31/2020	PHASE 2 STUDY TO EVALUATE THE PHARMACOKINETICS AND DRUG-DRUG INTERACTION OF CETUXIMAB AND CARBOPLATIN IN PATIENTS WITH RECURRENT OR METASTATIC CARCINOMA OF THE HEAD AND NECK	$89,372	$118,752	D3ET	100%	$89,372	$118,752
Perez R	Dompe s.p.a.		4/24/2013	12/31/2020	PHASE IB PILOT STUDY TO EVALUATE REPARIXIN IN COMBINATION WITH CHEMOTHERAPY WITH WEEKLY PACLITAXEL IN PATIENTS WITH HER-2 NEGATIVE METASTATIC BREAST CANCER (MBC)	$49,184	$65,415	D3ET	100%	$49,184	$65,415

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Raja V	Bristol-Myers Squibb Company		4/2/2014	12/31/2020	A PHASE IIIB-IV SAFETY TRIAL OF NIVOLUMAB (BMS-936558) IN SUBJECTS WITH ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER WHO HAVE PROGRESSED DURING OR AFTER RECEIVING AT LEAST ONE PRIOR SYSTEMIC REGIMEN	$121,510	$159,883	D3ET	100%	$121,510	$159,883
Rajewski R	Ligand Pharmaceuticals, Inc.		8/1/2012	3/31/2016	EVALUATING THE USEFULNESS OF CAPTISOL AS A CONSUMER PRODUCT ADDITIVE	$221,928	$221,928	D3ET	100%	$221,928	$221,928
Schoeneich C	Genentech, Inc.		4/8/2014	3/31/2016	ANALYSIS OF LIGHT-INDUCED ANTIBODY AGGREGATES	$19,292	$30,000	D3ET	100%	$19,292	$30,000
Schoeneich C	Genentech, Inc.		4/8/2014	7/31/2016	DETECTION AND MECHANISM OF D-AMINO ACID FORMATION	$165,611	$258,000	D3ET	100%	$165,611	$258,000
Schoeneich C	Genentech, Inc.		4/8/2014	7/31/2016	OXIDATIVE DEGRADATION OF POLYSORBATE	$154,093	$240,000	D3ET	100%	$154,093	$240,000
Sharma P	Conquer Cancer Foundation of ASCO		7/1/2015	6/30/2018	EVALUATION OF BRCANESS PHENOTYPE AS PROGNOSTIC MARKER IN TRIPLE-NEGATIVE BREAST CANCER UTILIZING SPECIMENS FROM SWOG 9313	$140,187	$150,000	D3ET	100%	$140,187	$150,000
Sharma P	Novartis Pharmaceuticals Corp		2/12/2015	12/31/2020	PHASE I/II STUDY OF BYL719 AND NAB-PACLITAXEL (ABRAXANE) IN PATIENTS WITH LOCALLY RECURRENT OR METASTATIC HER-2 NEGATIVE BREAST CANCER	$28,418	$32,641	D3ET	100%	$28,418	$32,641
Sharma P	Celgene Corporation		6/29/2015	12/31/2020	ROMIDEPSIN IN LOCALLY RECURRENT OR METASTATIC TRIPLE NEGATIVE BREAST CANCER	$36,458	$47,664	D3ET	100%	$36,458	$47,664
Soares MJ	Lalor Foundation Inc		6/1/2015	5/31/2016	EPIGENETIC REGULATION OF TROPHOBLAST DEVELOPMENT	$45,000	$50,000	CB	100%	$45,000	$50,000
Staudinger JL Azuma Y	Inez Jay Fund		7/1/2015	6/30/2016	SUMOYLATION OF BAG3 IN HEPATOCYTES AND HEPATOMA CELL LINES	$20,000	$20,000	CB	100%	$20,000	$20,000
Thyfault J	Veteran Affairs Medical Center	12402	10/1/2015	9/30/2017	MITOCHONDRIAL MITOPHAGY IN THE DEVELOPMENT AND TREATMENT OF NAFLD	$85,800	$85,800	CB	100%	$85,800	$85,800
Thyfault J	Veteran Affairs Medical Center	12326	8/1/2015	7/31/2017	MITOCHONDRIAL MITOPHAGY IN THE DEVELOPMENT AND TREATMENT OF NAFLD	$39,409	$39,409	CB	100%	$39,409	$39,409
Van Veldhuizen PJ	Agensys, Inc.		9/24/2013	12/31/2020	A PHASE 1 STUDY OF THE SAFETY AND PHARMACOKINETICS OF ESCALATING DOSES OF ASG-22CE GIVEN AS MONOTHERAPY IN SUBJECTS WITH METASTATIC UROTHELIAL CANCER THAT EXPRESS NECTIN-4	$44,093	$58,644	D3ET	100%	$44,093	$58,644
Van Veldhuizen PJ	Altor Bioscience Corporation		11/19/2012	12/31/2020	A PHASE IB/II TRIAL OF ALT-801 IN COMBINATION WITH CISPLATIN AND GEMCITABINE IN MUSCLE INVASIVE OR METASTATIC UROTHELIAL CANCER	$31,473	$41,859	D3ET	100%	$31,473	$41,859
Van Veldhuizen PJ	Prometheus Laboratories, Inc.		7/31/2012	12/31/2020	PROLEUKIN OBSERVATIONAL REGISTRY TO EVALUATE THE TREATMENT PATTERNS AND CLINICAL RESPONSE IN MALIGNANCY	$30,902	$41,099	D3ET	100%	$30,902	$41,099

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Volkin D Middaugh CR	Janssen Research and Development, LLC		7/24/2015	7/23/2017	EVALUATE THE FEASIBILITY OF DEVELOPING ULTRA-HIGH CONCENTRATION FORMULATION	$128,200	$200,000	D3ET	100%	$128,200	$200,000
Volkin D Middaugh CR	Medimmune, Inc.		6/1/2009	9/15/2016	STABILITY AND DYNAMICS OF IMMUNOGLOBULINS	$891,978	$1,307,746	D3ET	100%	$891,978	$1,307,746
Wallace DP	Polycystic Kidney Disease Foundation		4/1/2012	3/31/2016	PKD RESEARCH BIOMATERIALS AND CELLULAR MODELS CORE	$50,000	$50,000	CB	100%	$50,000	$50,000
Wallace DP	Allen Foundation		2/1/2014	1/31/2017	ROLE OF PHOSPHODIESTERASES IN CYST GROWTH IN AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD)	$75,000	$90,000	CB	100%	$75,000	$90,000
Wallace DP	NovaTarg		9/21/2015	8/31/2017	SYNTHESIZE AND EVALUATE NOVEL, POTENT AND OCT2-SELECTIVE BIGUANIDES FOR LEAD OPTIMIZATION	$86,610	$130,781	CB	100%	$86,610	$130,781
Welch DR	National Foundation for Cancer Research		1/1/2014	12/31/2016	NFCR CENTER FOR METASTASIS RESEARCH	$130,435	$150,000	CB	100%	$130,435	$150,000
Williamson SK	Daiichi Sankyo Pharma Development		3/22/2013	12/31/2020	A PHASE 3, RANDOMIZED, DOUBLE-BLIND STUDY OF TIVANTINIB (ARQ 197) IN SUBJECTS WITH MET DIAGNOSTIC-HIGH INOPERABLE HEPATOCELLULAR CARCINOMA (HCC) TREATED WITH ONE PRIOR SYSTEM THERAPY	$20,557	$27,341	D3ET	100%	$20,557	$27,341
Yacoub A	Gilead Sciences, Inc.		2/9/2015	12/31/2020	A PHASE 3, RANDOMIZED STUDY TO EVALUATE THE EFFICACY OF MOMELOTINIB VERSUS BEST AVAILABLE THERAPY IN ANEMIC OR THROMBOCYTOPENIC SUBJECTS WITH PRIMARY MYELOFIBROSIS, POST-POLYCYTHEMIA VERA MYELOFIBROSIS, OR POST-ESSENTIAL	$55,296	$73,478	D3ET	100%	$55,296	$73,478
Yacoub A	Celgene Corporation		10/15/2014	12/31/2020	A PHASE 3B RANDOMIZED STUDY OF LENALIDOMIDE (CC-5013) PLUS RITUXIMAB MAINTENANCE THERAPY FOLLOWED BY LENALIDOMIDE SINGLE-AGENT MAINTENANCE VERSUS RITUXIMAB MAINTENANCE IN SUBJECTS WITH RELAPSED/REFRACTORY FOLLICULAR,	$21,185	$28,175	D3ET	100%	$21,185	$28,175
Yacoub A	MEI Pharma, Inc.		7/30/2014	12/31/2020	A PHASE II OPEN-LABEL, SINGLE-ARM, TWO-STAGE, MULTICENTER TRIAL OF PRACINOSTAT IN COMBINATION WITH AZACITIDINE IN ELDERLY (AGE MORE THAN 65 YEARS) PATIENTS WITH NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA (AML)	$27,835	$37,021	D3ET	100%	$27,835	$37,021
Yacoub A	Janssen Research and Development, L.L.C.		9/24/2014	12/31/2020	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE 3 STUDY OF THE BRUTON'S TYROSINE KINASE INHIBITOR, PCI-32765 (IBRUTINIB), IN COMBINATION WITH EITHER BENDAMUSTINE AND RITUXIMAB (BR) OR RITUXIMAB, CYCLOPHOSPHAMIDE,	$32,978	$43,795	D3ET	100%	$32,978	$43,795

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Yacoub A	Seattle Genetics, Inc.		8/16/2013	12/31/2020	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE 3 STUDY OF BRENTUXIMAB VEDOTIN AND CHP (A+CHP) VERSUS CHOP IN THE FRONTLINE TREATMENT OF PATIENTS WITH CD30-POSITIVE MATURE T-CELL LYMPHOMAS	$29,028	$36,339	D3ET	100%	$29,028	$36,339
Yacoub A	Millennium Pharmaceuticals Inc		12/12/2013	12/31/2020	A RANDOMIZED, OPEN-LABEL, PHASE 3 TRIAL OF A+AVD VERSUS ABVD AS FRONTLINE THERAPY IN PATIENTS WITH ADVANCED CLASSICAL HODGKIN LYMPHOMA	$75,529	$100,454	D3ET	100%	$75,529	$100,454
Yacoub A	Incyte Corporation		7/16/2013	12/31/2020	POLYCYTHEMIA VERA SYMPTOM STUDY EVALUATING RUXOLITINIB VERSUS HYDROXYUREA IN A RANDOMIZED, MULTICENTER, DOUBLE-BLIND, DOUBLE-DUMMY, PHASE 3 EFFICACY AND SAFETY STUDY OF PATIENT REPORTED OUTCOMES	$29,796	$39,628	D3ET	100%	$29,796	$39,628
Yacoub A	Myeloproliferative Disorders-Research Co		3/4/2015	12/31/2020	SINGLE ARM SALVAGE THERAPY WITH PEGYLATED INTERFERON ALFA-2A FOR PATIENTS WITH HIGH RISK POLYCYTHEMIA VERA OR HIGH RISK ESSENTIAL THROMBOCYTHEMIA WHO ARE EITHER HYDROXYUREA RESISTANT OR INTOLERANT OR HAVE HAD A ABDOMINAL VEIN THROMBOSIS	$16,917	$22,500	D3ET	100%	$16,917	$22,500
			Non-Peer-Reviewed Research Subtotals:			$8,196,352	$9,934,601			$8,187,309	$9,922,574
					Grand Totals	**$46,049,894**	**$62,940,696**			**$44,903,110**	**$61,264,739**

PEER-REVIEWED TRAINING PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Daley CM	Susan G. Komen Foundation	GTDR15333785	8/13/2015	8/12/2018	CONTINUING AN AMERICAN INDIAN BREAST CANCER DISPARITIES TRAINING PROGRAM	$135,000	$135,000	CCPH	100%	$135,000	$135,000
Gomez C *(Mentor: Neufeld KL)*	DOD	W81XWH-16-1-0115	8/1/2016	7/31/2017	A ROLE FOR APC IN GOBLET CELL FUNCTION AND THE UNFOLDED PROTEIN RESPONSE (UPR)	$108,000	$108,000	CB	100%	$108,000	$108,000
Hagenbuch B	NIEHS	5T32ES007079-35	7/1/1979	6/30/2017	TRAINING PROGRAM IN ENVIRONMENTAL TOXICOLOGY	$310,062	$332,910	D3ET	100%	$310,062	$332,910
Hamilton-Reeves J Barohn RJ	NCATS	5KL2TR000119-05	3/1/2014	2/28/2017	HEARTLAND INSTITUTE FOR CLINICAL AND TRANSLATIONAL RESEARCH (PREVENTING THE PROGRESSION OF CACHEXIA IN BLADDER CANCER PATIENTS)	$88,223	$88,223	CPS	100%	$88,223	$88,223

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Koestler DC Barohn RJ	NCATS	5KL2TR000119-05	3/1/2014	2/28/2017	HEARTLAND INSTITUTE FOR CLINICAL AND TRANSLATIONAL RESEARCH (INTEGRATIVE GENOMICS FOR UNDERSTANDING THE DEVELOPMENT AND PROGRESSION OF EPITHELIAL OVARIAN CANCER)	$92,742	$92,742	CB	100%	$92,742	$92,742
Lin TL	NCI	5K23CA158146-04	8/18/2012	7/31/2016	CHEMOTHERAPY RESISTANCE IN ALL: ROLE OF THE BONE MARROW MICROENVIRONMENT	$162,000	$174,960	D3ET	100%	$162,000	$174,960
Lumpkins CY	NCI	5K01CA164009-06	9/22/2011	8/31/2016	COMMUNICATING COLORECTAL CANCER PREVENTION THRU URBAN AFRICAN AMERICAN CHURCHES	$102,159	$110,332	CCPH	100%	$102,159	$110,332
Pesseto Z Mentor: (Godwin AK) Barohn RJ	NCATS	5KL2TR000119-05	3/1/2014	2/28/2017	HEARTLAND INSTITUTE FOR CLINICAL AND TRANSLATIONAL RESEARCH (A MULTI-PRONGED DRUG REPURPOSING APPROACH TO DEVELOP INDIVIDUALIZED THERAPIES FOR EWING SARCOMA)	$73,989	$73,989	D3ET	100%	$73,989	$73,989
Peterson B	ACS		8/1/2015	7/31/2016	MEDICINAL CHEMISTRY PREDOCTORAL FELLOWSHIP	$26,000	$26,000	D3ET	100%	$26,000	$26,000
Peterson B	NIGMS	5K12GM063651-14	7/1/2001	7/31/2017	UNIVERSITY OF KANSAS/HASKELL INDIAN NATIONS UNIVERSITY IRACDA PROJECT	$481,796	$518,455	D3ET	100%	$481,796	$518,455
Prisinzano TE Lamb AL	NIGMS	2T32GM008545-22	7/1/1994	6/30/2020	TRAINING GRANT IN DYNAMIC ASPECTS OF CHEMICAL BIOLOGY	$347,360	$364,909	D3ET	100%	$347,360	$364,909
Pruitt M *(Mentor: Baumann P)*	NCI	1F31CA200228-01	9/1/2015	8/31/2019	THE RANDOMIZATION OF THE TELOMERASE RNA TEMPLATE TO DEFINE THE ROLE OF TELOMERE SEQUENCE IN TELOMERE STRUCTURE, FUNCTION, AND CELLULAR SURVIVAL	$30,188	$30,188	CB	100%	$30,188	$30,188
Siahaan TJ Volkin D	NIGMS	5T32GM008359-25	9/27/1989	6/30/2019	PHARMACEUTICAL ASPECTS OF BIOTECHNOLOGY	$324,643	$342,192	D3ET	100%	$324,643	$342,192
Zhang Y	NCI	5K22CA184146-02	9/18/2014	8/31/2017	METABOLIC REPROGRAMMING IN LIVER CANCER CELLS BY A NOVEL TUMOR SUPPRESSOR	$31,650	$34,182	CB	100%	$31,650	$34,182
					Peer-Reviewed Training Totals	$2,313,812	$2,432,082			**$2,313,812**	**$2,432,082**

Children's Mercy **P30CA168524**
Reporting Date: 12/31/2015
Data Table 2A - Active Funded Projects

PEER-REVIEWED PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Myers A	PCORI	7954291	5/1/2015	2/28/2016	ENGAGING COMMUNITIES IN INFECTIOUS DISEASES RESEARCH AND INTERVENTION DEVELOPMENT	$13,500	$15,000	CCPH	100%	$13,500	$15,000
					Peer-Reviewed Research Totals:	$13,500	$15,000			**$13,500**	**$15,000**

NON-PEER-REVIEWED PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Chastain K	Braden's Hope Foundation		8/30/2015	9/1/2016	IN VITRO AND IN VIVO TESTING OF THREE NOVEL COMPOUNDS IN PEDIATRIC RHABDOMYOSARCOMA	$193,000	$193,000	D3ET	100%	$193,000	$193,000
					Non-PeerReviewed Research Subtotals:	$193,000	$193,000			**$193,000**	**$193,000**
					Grand Totals:	$206,500	$208,000			**$206,500**	**$208,000**

PEER-REVIEWED TRAINING PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Leeder JS	NICHD	2T32HD069038-06	5/1/2011	4/30/2017	CHILDREN'S MERCY HOSPITAL COLLABORATIVE FELLOWSHIP PROGRAM IN PEDIATRIC PHARMACOLOGY	$134,764	$108,186	D3ET	100%	$134,764	$108,186
					Peer-Reviewed Training Subtotals:	$134,764	$108,186			**$134,764**	**$108,186**

The University of Kansas Cancer Center
Reporting Date: 12/31/2015
Data Table 2B – Active Funded Projects

Specific Funding Source	Project Direct Costs	Project Total Costs	Total Number of Projects
NCI Peer-Reviewed Projects	9,559,178	13,489,788	62
Other NIH Peer-Reviewed Projects	18,198,165	26,346,751	84
Other Peer-Reviewed Projects	9,227,458	11,774,627	26
Subtotal of Peer-Reviewed Projects	**36,715,801**	**51,342,166**	**169**
Industry Non-Peer-Reviewed Projects	4,524,086	6,107,443	57
Other Non-Peer-Reviewed Projects	3,663,223	3,815,131	28
Subtotal of Non-Peer-Reviewed Projects	**8,187,309**	**9,922,574**	**85**
Grand Total (All Projects)	**44,903,110**	**61,264,739**	**254**

P30CA168524

Children's Mercy
Reporting Date: 12/31/2015
Data Table 2B – Active Funded Projects

Specific Funding Source	Project Direct Costs	Project Total Costs	Total Number of Projects
NCI Peer-Reviewed Projects			
Other NIH Peer-Reviewed Projects			
Other Peer-Reviewed Projects	13,500	15,000	1
Subtotal of Peer-Reviewed Projects	**13,500**	**15,000**	**1**
Industry Non-Peer-Reviewed Projects			
Other Non-Peer-Reviewed Projects	193,000	193,000	1
Subtotal of Non-Peer-Reviewed Projects	**193,000**	**193,000**	**1**
Grand Total (All Projects)	**206,500**	**208,000**	**2**

The University of Kansas Cancer Center **P30CA168524**
Reporting Period 01/01/2015 - 12/31/2015
Data Table 3 - Newly Registered Patients/Participation in Interventional Treatment Trials by Anatomic Cancer Site

KUMC Tumor Registry-Academic Site		
PrimarySite	**Newly registered patients**	**Patients newly enrolled in interventional treatment trials**
Lip, Oral Cavity and Pharynx	133	10
Esophagus	45	2
Stomach	43	0
Small Intestine	19	0
Colon	104	13
Rectum	59	2
Anus	14	0
Liver	151	17
Pancreas	123	15
Other Digestive Organ	45	1
Larynx	37	4
Lung	276	9
Other Respiratory and Intrathoracic Organs	22	0
Bones and Joints	26	0
Soft Tissue	39	4
Melanoma, skin	218	4
Kaposi's sarcoma	2	0
Mycosis Fungoides	2	2
Other Skin	15	0
Breast – Female	421	54
Breast – Male	4	0
Cervix	39	4
Corpus Uteri	144	1
Ovary	76	13
Other Female Genital	29	1
Prostate	297	19
Other Male Genital	44	0
Urinary Bladder	173	9
Kidney	248	7
Other Urinary	8	1
Eye and Orbit	6	1
Brain & Nervous System	223	4
Thyroid	107	0
Other Endocrine System	44	0
Non-Hodgkin's Lymphoma	155	37
Hodgkin's Lymphoma	23	3
Multiple Myeloma	95	17
Lymphoid Leukemia	52	5
Myeloid and Monocytic Leukemia	129	40
Leukemia, other	28	0
Other Hematopoietic	43	32
Unknown Sites	39	3
Ill-Defined Sites	18	0
TOTAL	**3818**	**334**

The University of Kansas Cancer Center **P30CA168524**
Reporting Period 01/01/2015 - 12/31/2015
Data Table 3 - Newly Registered Patients/Participation in Interventional Treatment Trials by Anatomic Cancer Site

The Childrens Mercy Hospital Tumor Registry

PrimarySite	Newly registered patients	Patients newly enrolled in interventional treatment trials
Lip, Oral Cavity and Pharynx	2	0
Esophagus	0	0
Stomach	0	0
Small Intestine	1	0
Colon	0	0
Rectum	0	0
Anus	0	0
Liver	4	0
Pancreas	0	0
Other Digestive Organ	0	0
Larynx	0	0
Lung	1	0
Other Respiratory and Intrathoracic Organs	0	0
Bones and Joints	7	0
Soft Tissue	13	3
Melanoma, skin	0	0
Kaposi's sarcoma	0	0
Mycosis Fungoides	1	0
Other Skin	0	0
Breast – Female	0	0
Breast – Male	0	0
Cervix	0	0
Corpus Uteri	0	0
Ovary	3	0
Other Female Genital	0	0
Prostate	0	0
Other Male Genital	1	0
Urinary Bladder	1	0
Kidney	6	0
Other Urinary	0	0
Eye and Orbit	1	0
Brain & Nervous System	46	6
Thyroid	4	0
Other Endocrine System	8	0
Non-Hodgkin's Lymphoma	10	1
Hodgkin's Lymphoma	3	0
Multiple Myeloma	0	0
Lymphoid Leukemia	35	27
Myeloid and Monocytic Leukemia	10	2
Leukemia, other	3	0
Other Hematopoietic	5	0
Unknown Sites	2	0
Ill-Defined Sites	1	0
TOTAL	168	39

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

NATIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
BMT CTN	Multiple	NCT02081248	BMT CTN 1205	Abhyankar, S	D3ET	10/14/2014		N/A	Hsr	Easy to Read Informed consent (ETRIC) for Hematopoietic Cell Transplantion Clinical Trials	Y		20	6	7	0	0	
BMT CTN NHLBI	Multiple	NCT02208037	BMT CTN 1203	Abhyankar, S	D3ET	11/20/2014		II	Sup	A Multi-center Phase II Trial Randomizing Novel Approaches for Graft-versus-Host Disease Prevention Compared to Contemporary Controls	Y		10	10	11	0	0	
BMT CTN	Multiple	NCT01597778	BMT CTN 1101	Aljitawi, O	D3ET	10/9/2012		III	Tre	A Multi-Center, Phase III, Randomized Trial of Reduced Intensity (RIC) Conditioning and Transplantation of Double Unrelated Umbilical Cord Blood (dUCB) versus HLA-Haploidentical Related Bone Marrow (haplo-BM) for Patients with Hematologic Malignancies	Y		20	8	17	0	0	
Alliance for Clinical Trials in Oncology	Other Endocrine System	NCT01841736	A021202	Al-Kasspooles, M	D3ET	7/28/2014		II	Tre	Prospective Randomized Phase II Trial of Pazopanib (NSC # 737754, IND 75648) Versus Placebo in Patients With Progressive Carcinoid Tumors	Y		5	0	1	1	1	Meets definition of Rare Cancer and/or Molecular Target with low frequency
COG	Lymphoma	NCT01979536	ANHL12P1	August, K	D3ET	3/19/2014		II	Tre	A Randomized Phase II study of Brentuximab Vedotin (NSC# 749710) and Crizotinib (NSC# 749005) in Patients with Newly Diagnosed Anaplastic Large Cell Lymphoma (ALCL) IND #117117	Y		5	1	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Bone	NCT02470091	AOST1321	August, K	D3ET	12/28/2015		II	Tre	Denosumab in Treating Patients With Recurrent or Refractory Osteosarcoma	Y		5	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Bone	NCT02484443	AOST1421	August, K	D3ET	12/17/2015		II	Tre	Dinutuximab in Combination With Sargramostim in Treating Patients With Recurrent Osteosarcoma	Y		5	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
GOG	Multiple	NCT00719303	GOG 0225	Chapman, J	D3ET	1/10/2013		III	Tre	Can Diet and Physical Activity Modulate Ovarian, Fallopian Tube and Primary Peritoneal Cancer Progression-Free Survival?	Y		20	3	12	0	0	
GOG	Cervix	NCT01266460	GOG 0265	Chapman, J	D3ET	8/10/2015		II	Tre	A Phase II Evaluation of ADXS11-001 (NSC 752718, BB-IND #13,712) in the Treatment of Persistent or Recurrent Squamous or Non-Squamous Cell Carcinoma of the Cervix	Y		3	0	0	0	0	
GOG	Cervix	NCT01414608	GOG 0274	Chapman, J	D3ET	8/30/2012	06/12/2015	III	Tre	A PHASE III TRIAL OF ADJUVANT CHEMOTHERAPY AS PRIMARY TREATMENT FOR LOCALLY ADVANCED CERVICAL CANCER COMPARED TO CHEMORADIATION ALONE: THE OUTBACK TRIAL	Y		5	1	5	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

NATIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
ECOG CTSU/SWOG	Multiple	NCT02115282	E2112	Doolittle, G	D3ET	6/18/2015		III	Tre	A Randomized Phase III Trial of Endocrine Therapy plus Entinostat/Placebo in Men and Postmenopausal Women with Hormone Receptor-Positive Advanced Breast Cancer	Y		10	0	0	2	2	Protocol open only at community and MCA sites.
ECOG CTSU/SWOG	Lung	NCT01107626	ECOG E5508	Doolittle, G	D3ET	10/15/2014	05/08/2015	III	Tre	Randomized Phase III Study of Maintenance Therapy with Bevacizumab, Pemetrexed, or a Combination of Bevacizumab and Pemetrexed Following Carboplatin, Paclitaxel and Bevacizumab for Advanced Non-Squamous NSCLC	Y		8	0	0	3	3	Protocol open only at MCA sites
SWOG	Melanoma, skin	NCT02196181	SWOG S1320	Doolittle, G	D3ET	8/17/2015		II	Tre	A Randomized, Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAFV600E/K Mutant Melanoma	Y		16	2	2	0	0	
BMT CTN	Multiple Myeloma	NCT02322320	BMT CTN 07LT	Ganguly, S	D3ET	4/24/2015		III	Tre	Continued, Long-Term Follow-Up and Lenalidomide Maintenance Therapy for Patients Who Have Enrolled on BMT CTN 0702	Y		14	3	3	0	0	
BMT CTN	Multiple Myeloma	NCT02440464	BMT CTN 1302	Ganguly, S	D3ET	9/1/2015		II	Tre	Multicenter Phase II, Double-blind Placebo Controlled Trial of Maintenance Ixazomib after Allogeneic Hematopoietic Stem Cell Transplantation for High Risk Multiple Myeloma	Y		24	0	0	0	0	
COG	Brain	NCT01217437	ACNS0821	Ginn, K	D3ET	4/21/2011		II	Tre	Temozolomide with Irinotecan versus Temozolomide, Irinotecan plus Bevacizumab (NSC# 704865, BB-IND# 7921) for Recurrent/Refractory Medulloblastoma/CNS PNET of Childhood, A COG Randomized Phase II Screening Trial	Y		8	1	5	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT01553149	ACNS1022	Ginn, K	D3ET	6/1/2011		II	Tre	Low-Dose or High-Dose Lenalidomide in Treating Younger Patients With Recurrent, Refractory, or Progressive Pilocytic Astrocytoma or Optic Pathway Glioma	Y		5	0	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
ECOG CTSU/SWOG	Kidney	NCT01575548	ECOG E2810	Hashmi, M	D3ET	12/10/2013		III	Tre	Randomized, Double-Blind Phase III Study of Pazopanib vs. Placebo in Patients with Metastatic Renal Cell Carcinoma Who Have No Evidence of Disease Following Metastatectomy	Y		10	0	3	0	0	
SWOG	Urinary Bladder	NCT02177695	S1314	Hashmi, M	D3ET	6/19/2015		II	Tre	A RANDOMIZED PHASE II STUDY OF CO-EXPRESSION EXTRAPOLATION (COXEN) WITH NEOADJUVANT CHEMOTHERAPY FOR LOCALIZED, MUSCLE-INVASIVE BLADDER CANCER	Y		12	2	2	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

NATIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
SWOG	Prostate	NCT01809691	SWOG S1216	Hashmi, M	D3ET	9/11/2013		III	Tre	A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 With Androgen Deprivation Therapy + Bicalutamide in Patients With Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer	Y		30	2	8	3	12	
COG	Multiple	NCT01307579	ACCL0933	Hetherington, M	D3ET	8/18/2011		III	Sup	A Randomized Open-Label Trial of Caspofungin versus Fluconazole to Prevent Invasive Fungal Infections in Children Undergoing Chemotherapy for Acute Myeloid Leukemia (AML)	Y		5	0	7	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Leukemia	NCT01503632	ACCL1033	Hetherington, M	D3ET	8/2/2012		III	Sup	A Comprehensive Approach to Improve Medication Adherence in Pediatric ALL	Y		12	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT01817075	ACCL1034	Hetherington, M	D3ET	12/28/2013		III	Sup	To determine whether chlorhexidine gluconate cleansing decreases central line associated bloodstream infection in children with cancer or those receiving an allogeneic hematopoietic cell transplantation.	Y		10	0	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT01503515	ACCL1131	Hetherington, M	D3ET	6/27/2013		III	Sup	A Phase III Open-Label Trial of Caspofungin vs. Azole Prophylaxis for Patients at High-Risk for Invasive Fungal Infections (IFI) Following Allogeneic Hematopoietic Cell Transplantation (HCT)	Y		25	4	9	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Lymphoma, Leukemia	NCT01190930	AALL0932	Hetherington, M	D3ET	9/14/2010		III	Tre	Treatment of Patients with Newly Diagnosed Standard Risk B-Precursor Acute Lymphoblastic Leukemia (B-ALL) or Localized B-Lineage Lymphoblastic Lymphoma (B-Lly)	Y		110	14	60	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Leukemia	NCT01406756	AALL1131	Hetherington, M	D3ET	12/15/2011		III	Tre	A Phase III Randomized Trial for Newly Diagnosed *High Risk B-precurso* r Acute Lymphoblastic Leukemia (ALL) Testing Clofarabine (IND# 73789, NSC# 606869) in the Very High Risk Stratum	Y		45	8	26	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Lymphoma, Leukemia	NCT02112916	AALL1231	Hetherington, M	D3ET	9/27/2014		III	Tre	A Phase III Randomized Trial Investigating Bortezomib (NSC# 681239; IND# 58443) on a Modified Augmented BFM (ABFM) Backbone in Newly Diagnosed T-Lymphoblastic Leukemia (T-ALL) and T- Lymphoblastic Lymphoma (T-LLy)	Y		10	1	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

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COG	Leukemia	NCT02101853	AALL1331	Hetherington, M	D3ET	8/18/2015		III	Tre	Risk-Stratified Randomized Phase III Testing of Blinatumomab (IND#117467, NSC#765986) in First Relapse of Childhood B-Lymphoblastic Leukemia (B-ALL)	Y		5	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT01371981	AAML1031	Hetherington, M	D3ET	8/16/2011		III	Tre	A Phase III Randomized Trial for Patients with de novo AML using Bortezomib and Sorafenib for Patients with High Allelic Ratio FLT3/ITD	Y		15	1	9	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
NCI	Brain	NCT01381718	ACCL0922	Hetherington, M	D3ET	12/19/2012		II	Tre	Randomized Phase II placebo-controlled trial that will evaluate brain tumor survivors for neurocognitive deficit.	Y		20	1	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT00085735	ACNS0331	Hetherington, M	D3ET	11/15/2004	07/08/2015	III	Tre	A Study Evaluating Limited Target Volume Boost Irradiation and Reduced Dose Craniospinal Radiotherapy and Chemotherapy in Children with Newly Diagnosed Standard Risk Medulloblastoma	Y		15	0	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT00392327	ACNS0332	Hetherington, M	D3ET	6/20/2007		III	Tre	Efficacy of Carboplatin Administered Concomitantly With Radiation and Isotretinoin as a Pro-Apoptotic Agent in Other Than Average Risk Medulloblastoma/PNET Patients	Y		10	0	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT00336024	ACNS0334	Hetherington, M	D3ET	9/17/2007		III	Tre	A Phase III Randomized Trial for the Treatment of Newly Diagnosed Supratentorial PNET and High Risk Medulloblastoma in Children < 36 Months Old with Intensive Induction Chemotherapy with Methotrexate Followed by Consolidation with Stem Cell Rescue vs. the Same Therapy Without Methotrexate	Y		5	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT01096368	ACNS0831	Hetherington, M	D3ET	5/20/2010		III	Tre	Phase III Randomized Trial of Post-Radiation Chemotherapy in Patients with Newly Diagnosed Ependymoma	Y		8	0	3	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT01602666	ACNS1123	Hetherington, M	D3ET	7/25/2012		II	Tre	Phase II Trial of Response Based Radiation Therapy for Patients with Localized Central Nervous System Germ Cell Tumors	Y		12	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT02017964	ACNS1221	Hetherington, M	D3ET	1/24/2014		II	Tre	Study is to see if subjects with M0 Desmoplastic Medulloblastoma treated with usual chemotherapy without intraventricular methotrexate maintain good survival outcome.	Y		8	2	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

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COG	Multiple	NCT01231906	AEWS1031	Hetherington, M	D3ET	1/20/2011		III	Tre	Randomized Phase 3 trial will test the efficacy of adding vincristine-topotecan cyclophosphamide to the interval compressed 5 drug backbone.	Y		25	1	8	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT02306161	AEWS1221	Hetherington, M	D3ET	12/8/2015		II	Tre	Randomized Phase II Trial Evaluation the Addition of the IGF-1R Monoclonal Antibody Receptor Ganitumab to Multiagent Chemotherapy for Patients with Newly Diagnosed Metastatic Ewing Sarcoma	Y		6	1	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Liver	NCT00980460	AHEP0731	Hetherington, M	D3ET	11/19/2009		III	Tre	A Phase III Study . The purpose of this study is to get rid of the cancer and not have it come back in a greater number of children with hepatoblastoma.	Y		8	0	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Lymphoma	NCT02166463	AHOD1331	Hetherington, M	D3ET	6/22/2015		III	Tre	A Randomized Phase III Study of Brentuximab Vedotin (SGN-35, IND #117117) for Newly Diagnosed High Risk Classical Hodgkin Lymphoma (cHL) in Children and Adolescents	Y		20	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT00567567	ANBL0032	Hetherington, M	D3ET	1/7/2002	07/31/2015	III	Tre	Phase III Randomized Study of Chimeric Antibody 14.18 (ch14.18) in High Risk Neuroblastoma Following Myeloblative Therapy and Autologous Stem Cell Transplant	Y		40	0	13	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT02176967	ANBL1232	Hetherington, M	D3ET	3/6/2015		III	Tre	Utilizing Response- and Biology-Based Risk Factors to Guide Therapy in Patients with Non-High Risk Neuroblastoma	Y		10	1	3	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Lymphoma, Leukemia	NCT01595048	ANHL1131	Hetherington, M	D3ET	5/1/2013		III	Tre	Study to find out what effects using rituximab in combination with the DA-EPOCH chemotherapy regimen will have on children with PMLBL	Y		2	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT02180867	ARST1321	Hetherington, M	D3ET	5/13/2015		II/III	Tre	Pazopanib Neoadjuvant Trial in Non-Rhabdomyosarcoma Soft Tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minues Pazopanib (NSC# 737754, IND #118613)	Y		5	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Leukemia	NCT01824693	ASCT1221	Hetherington, M	D3ET	4/13/2014		II	Tre	A randomized Phase II trial designed to identify which myeloablative hematopoietic cell transplant (HCT) preparative regimen has a lower relapse and treatment related mortality (TRM) rate in children with juvenile myelomonocytic leukemia (JMML).	Y		5	1	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

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SWOG	Kidney	NCT01120249	SWOG S0931	Holzbeierlein, J	D3ET	12/15/2011		III	Tre	EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy, a Phase III Study	Y		25	4	17	6	7	
Alliance for Clinical Trials in Oncology	Lung	NCT02193282	A081105	Huang, C	D3ET	5/6/2015		III	Tre	Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients With Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-small Cell Lung Cancer (NSCLC)	Y		24	0	0	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency
ECOG CTSU/Alliance	Lung	NCT02201992	E4512	Huang, C	D3ET	5/6/2015		III	Tre	A Phase III Double-Blind Trial for Surgically Resected Early Stage Non-small Cell Lung Cancer: Crizotinib Versus Placebo for Patients With Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein	Y		8	0	0	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency
SWOG	Lung	NCT00946712	SWOG S0819	Huang, C	D3ET	1/21/2010	05/01/2015	III	Tre	A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab With or Without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC)	Y		35	0	19	0	27	Protocol suspended to new enrollment in 2014 by sponsor and never re-opened at site.
SWOG	Lung	NCT02154490	SWOG S1400	Huang, C	D3ET	2/6/2015		II/III	Tre	A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer	Y		12	0	0	7	7	
ECOG CTSU/SWOG	Other Hematopoietic	NCT00843882	ECOG E2905	Kambhampati, S	D3ET	9/2/2010	10/31/2015	III	Tre	Randomized Phase III Trial Comparing the Frequency of Major Erythroid Response (MER) to Treatment with Lenalidomide (Revlimid®) Alone and in Combination with Epoetin Alfa (Procrit®) in Subjects with Low- or Intermediate-1 Risk MDS and Symptomatic Anemia	Y		0	0	0	0	1	Protocol was open at an NCTN component site.
NCCTG CTSU/RTOG	Brain and Nervous System	NCT01372774	NCCTG N107C / RTOG 1270	Kumar, P	D3ET	10/28/2013	12/18/2015	III	Tre	A Phase III Trial of Post-Surgical Stereotactic Radiosurgery (SRS) Compared With Whole Brain Radiotherapy (WBRT) for Resected Metastatic Brain Disease	Y		10	2	6	2	2	
NRG	Lung	NCT02186847	NRG-LU001	Kumar, P	D3ET	6/9/2015		II	Tre	Randomized Phase II Trial of Concurrent Chemoradiotherapy +/- Metformin HCL in Locally Advanced NSCLC	Y		20	0	0	3	3	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

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RTOG NSABP	Breast-Female	NCT01872975	NSABP B-51/RTOG 1304	Kumar, P	D3ET	12/16/2013		III	Tre	A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy	Y		10	1	1	3	4	
RTOG CTSU/EORTC	Brain and Nervous System	NCT00626990	RTOG 0834	Kumar, P	D3ET	7/2/2015	09/16/2015	III	Tre	Phase III Trial on Concurrent and Adjuvant Temozolomide Chemotherapy in non-1p/19q Deleted Anaplastic Glioma: The CATNON Intergroup Trial	Y		10	0	0	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency
RTOG	Prostate	NCT01368588	RTOG 0924	Kumar, P	D3ET	02/06/2012		III	Tre	Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial	Y		15	2	7	2	7	
RTOG	Head and Neck	NCT01953952	RTOG 1221	Kumar, P	D3ET	11/13/2014	02/16/2015	II	Tre	Randomized Phase II Trial of Transoral Endoscopic Head And Neck Surgery followed by Risk-Based IMRT and Weekly Cisplatin versus IMRT and Weekly Cisplatin for HPV Negative Oropharynx Cancer	Y		10	0	0	0	0	
ECOG CTSU/SWOG	Lymphoid Leukemia	NCT02003222	ECOG E1910	Lin, T	D3ET	10/6/2014		III	Tre	A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL-negative B lineage Acute Lymphoblastic Leukemia in Adults	Y		25	1	3	0	0	
SWOG	Myeloid and Monocytic Leukemia	NCT01802333	SWOG S1203	Lin, T	D3ET	10/21/2013	11/04/2015	III	Tre	A Randomized Phase III Study of Standard Cytarabine plus Daunorubicin (7+3) Therapy or Idarubicin with High Dose Cytarabine (IA) versus IA with Vorinostat (IA+V) in Younger Patients with Previously Untreated Acute Myeloid Leukemia (AML)	Y		30	10	26	0	0	
SWOG	Multiple Myeloma	NCT01668719	SWOG S1211	Lipe, B	D3ET	4/16/2013		I/II	Tre	A Randomized Phase I/II Study of Optimal Induction Therapy of Bortezomib, Dexamethasone and Lenalidomide with or without Elotuzumab (NSC-764479) for Newly Diagnosed High Risk Multiple Myeloma (HRMM)	Y		20	4	9	3	3	
RTOG	Head and Neck	NCT00956007	RTOG 0920	Lominska, C	D3ET	5/3/2010	12/22/2015	III	Tre	A Phase III Study of Postoperative Radiation Therapy (IMRT)+/- Cetuximab for Locally-Advanced Resected Head and Neck Cancer	Y		30	0	9	2	4	Biomarker-driven trial with high screen fail rate

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

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RTOG	Head and Neck	NCT01810913	RTOG 1216	Lominska, C	D3ET	9/4/2013		II/III	Tre	Randomized Phase II/III Trial of Surgery and Postoperative Radiation Delivered with Concurrent Cisplatin Versus Docetaxel Versus Docetaxel and Cetuximab for High-Risk Squamous Cell Cancer of the Head and Neck	Y		10	1	2	1	3	
COG CTSU/NRG	Soft Tissue	NCT02180867	COG ARST1321	Mammen, J	D3ET	3/27/2015		II/III	Tre	Pazopanib Neoadjuvant Trial in Non-Rhabdomyosarcoma Soft Tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib	Y		12	1	1	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency
NRG	Head and Neck	NCT02254278	NRG-HN002	Mammen, J	D3ET	6/19/2015		II	Tre	A Randomized Phase II Trial for Patients with p16 Positive, Non-Smoking Associated, Locoregionally Advanced Oropharyngeal Cancer	Y		16	1	1	1	1	
RTOG	Esophagus	NCT01196390	RTOG 1010	Mammen, J	D3ET	8/23/2012	11/10/2015	III	Tre	A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma	Y		8	0	2	0	4	
RTOG	Multiple	NCT01672892	RTOG 1203	Mitchell, M	D3ET	8/15/2014	08/27/2015	III	Tre	A Randomized Phase III Study Of Standard Vs. IMRT Pelvic Radiation For Post-Operative Treatment Of Endometrial And Cervical Cancer (TIME-C)	Y		10	3	4	0	0	
Alliance for Clinical Trials in Oncology	Prostate	NCT01949337	A031201	Sharma, P	D3ET	2/20/2015		III	Tre	Phase III Trial of Enzalutamide (NSC # 766085) Versus Enzalutamide, Abiraterone and Prednisone for Castration Resistant Metastatic Prostate Cancer	Y		20	4	4	4	4	
NRG AstraZeneca	Multiple	NCT02032823	NSABP B-55 / D081CC00006	Sharma, P	D3ET	2/16/2015		III	Tre	A Randomised, Double-blind, Parallel Group, Placebo-controlled Multi-centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients With Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy	Y		20	1	1	0	0	
SWOG	Breast-Female	NCT01272037	SWOG S1007	Sharma, P	D3ET	4/19/2011	10/15/2015	III	Tre	A Phase III, Randomized Clinical Trial Of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less	Y		60	3	12	7	21	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

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SWOG	Multiple	NCT01674140	SWOG S1207	Sharma, P	D3ET	3/18/2014		III	Tre	Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk Hormone Receptor-Positive and HER2/NEU Negative Breast Cancer. e3 Breast Cancer Study-evaluating everolimus with endocrine therapy	Y		20	0	0	6	8	
ECOG CTSU/NRG	Head and Neck	NCT01898494	E3311	Shnayder, Y	D3ET	6/15/2015		II	Tre	Phase II randomized trial of Transoral Surgical Resection followed by low-dose or standard-dose IMRT in resectable p16+ Locally advanced oropharynx cancer.	Y		5	0	0	0	0	
BMT CTN	Myeloid and Monocytic Leukemia	NCT02345850	BMT CTN 1301	Shune, L	D3ET	11/25/2015		III	Sup	A Randomized, Multi-Center, Phase III Trial of Calcineurin Inhibitor-Free Interventions for Prevention of Graft-versus-Host Disease	Y		15	0	0	0	0	
Alliance for Clinical Trials in Oncology CTSU/CALGB	Non-Hodgkins Lymphoma	NCT01511562	CALGB 51101	Shune, L	D3ET	10/1/2015		II	Tre	A Randomized Phase II Trial of Myeloablative verses non-Myeloablative Consolidation Chemotherapy for Newly Dianosed Primary CNS B-cell Lymphoma	Y		6	0	0	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency
Alliance for Clinical Trials in Oncology	Breast-Female	NCT01901094	A011202	Wagner, J	D3ET	7/2/2014		III	Tre	A Randomized Phase III Trial Evaluating the Role of Axillary Lymph Node Dissection in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy	Y		10	7	9	0	0	This is a high screen fail trial.
Alliance for Clinical Trials in Oncology	Breast-Female	NCT01439711	CALGB 40903	Wagner, J	D3ET	4/22/2015	01/11/2016	II	Tre	Phase II Study of Neoadjuvant Letrozole for postmenopausal women with estrogen receptor positive ductal carcinoma in situ (DCIS)	Y		10	0	0	0	0	
SWOG	Colon	NCT01349881	SWOG S0820	Williamson, S	CPS	3/20/2013		III	Pre	A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon Cancer, Phase III - Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)	Y		10	0	1	0	1	
CALGB CTSU/SWOG	Prostate	NCT01238172	CALGB 70807	Williamson, S	D3ET	2/14/2012	10/01/2015	N/A	Tre	The Mens Eating and Living (MEAL) Study: A Randomized Trial of Diet to Alter Disease Progression in Prostate Cancer Patients on Active Surveillance	Y		10	0	8	1	2	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

NATIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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CALGB CTSU/SWOG	Colon	NCT01150045	CALGB 80702	Williamson, S	D3ET	3/18/2011	11/20/2015	III	Tre	A Phase III Trial of 6 versus 12 Treatments of Adjuvant FOLFOX Plus Celecoxib or Placebo for Patients with Resected Stage II Colon Cancer	Y		50	3	7	7	31	
CALGB CTSU/SWOG	Prostate	NCT00430183	CALGB 90203	Williamson, S	D3ET	9/26/2007	03/04/2015	III	Tre	Randomized Phase III Study of Neo-Adjuvant Docetaxel and Androgen Deprivation Prior to Radical Prostatectomy Versus Immediate Radical Prostatectomy in Patients with High-Risk, Clinically Localized Prostate Cancer	Y		20	0	10	0	3	
ECOG CTSU/SWOG	Pancreas	NCT01824875	ECOG E2211	Williamson, S	D3ET	8/27/2014		II	Tre	A Randomized Phase II Study of Temozolomide or Temozolomide and Capecitabine in Patients with Advanced Pancreatic Neuroendocrine Tumors	Y		6	3	3	1	1	Meets definition of Rare Cancer and/or Molecular Target with low frequency
SWOG	Multiple	NCT01498289	SWOG S1201	Williamson, S	D3ET	8/7/2012	04/01/2015	II	Tre	A Randomized Phase II Pilot Study Prospectively Evaluating Treatment for Patients Based on ERCC1 (Excision Repair Cross-Complementing 1)for Advanced/Metastatic Esophageal, Gastric or Gastroesophageal Junction (GEJ) Cancer	Y		10	0	0	1	4	
SWOG	Liver	NCT02042443	SWOG S1310	Williamson, S	D3ET	12/8/2014	05/15/2015	II	Tre	Randomized Phase II Trial of Single Agent MEK Inhibitor Trametinib (GSK1120212) vs 5-Fluorouracil or Capecitabine in Refractory Advanced Biliary Cancer	Y		10	2	2	0	0	
SWOG	Colorectal	NCT02164916	SWOG S1406	Williamson, S	D3ET	1/16/2015		II	Tre	Randomized Phase II Study of Irinotecan and Cetuximab with or without Vemurafenib in BRAF Mutant Metastatic Colorectal Cancer.	Y		15	2	2	0	0	
Alliance for Clinical Trials in Oncology	Lymphoid Leukemia	NCT01886872	A041202	Yacoub, A	D3ET	7/23/2014	12/28/2015	III	Tre	A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Brutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (> 65 years of age) with Chronic Lymphocytic Leukemia (CLL)	Y		10	1	1	4	5	
ECOG CTSU/SWOG	Multiple Myeloma	NCT01169337	ECOG E3A06	Yacoub, A	D3ET	11/15/2013		II/III	Tre	Randomized Phase III Trial of Lenalidomide Versus Observation Alone in Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma	Y		20	5	9	3	3	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

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Giselle Sholler	Brain	NCT02395666	NMTRC003B	August, K	D3ET	6/18/2014		II	Pre	Preventative Trial of Difluoromethylornithine (DFMO) in High Risk Patients With Neuroblastoma That is in Remission	Y		30	2	11	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Giselle Sholler	Multiple	NCT02162732	NMTRC009	August, K	D3ET	11/21/2014			Tre	Molecular-Guided Therapy for Childhood Cancer	Y		8	2	3	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Giselle Sholler	Multiple	NCT02139397	NMTRC010B	August, K	D3ET	6/18/2014		I/II	Tre	Study of DFMO in Combination With Bortezomib for Relapsed or Refractory Neuroblastoma	Y		10	0	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Giselle Sholler	Multiple	NCT00601003	V0706	August, K	D3ET	1/5/2011		II	Tre	Study of Nifurtimox to Treat Refractory or Relapsed Neuroblastoma or Medulloblastoma	Y		8	0	4	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
NIH	Lung	NCT02050308	KUMC 13613	Choi, W	CCPH	5/12/2015		III	Pre	Web-Based Smoking Cessation Program for Tribal College Students	N		300	87	87	0	0	Protocol enrollment and activities are all web-based. All subjects are from Salish Kootenai College in Montana
NIH	Smoking Cessation	NCT02360631	STUDY00000721	Cox, L	CCPH	7/21/2015		N/A	Pre	Advancing Tobacco Use Treatment for African American Smokers	N	500	500	68	111	0	0	
NIH	Smoking Cessation		STUDY00002725	Cupertino, P	CCPH	9/9/2015		N/A	Pre	Latinos Kick Buts: Mobile Engagement and Cessation Support for Latino Smokers	N	100	100	56	56	0	0	
PCORI	Smoking Cessation	NCT02148445	STUDY00000666	Ellerbeck, E	CCPH	5/15/2014	11/30/2015	N/A	Pre	Smoking Cessation versus Long-term Nicotine Replacement among High-risk Smokers	N	400	400	245	398	0	0	
Susan G. Komen for the Cure	Breast-Female	NCT01276704	KUMC 12377	Fabian, C	CPS	11/9/2010		II	Pre	Flaxseed Lignan as a Prevention Strategy for Pre-Menopausal Women at High Risk for Development of Breast Cancer	Y	231	121	27	105	17	61	
St. Baldricks Foundation	Lymphoid Leukemia		STUDY00000227	Gibson, C	CCPH	9/30/2013	09/01/2015	N/A	Sup	Telephonic Health Coaching for Children with Acute Lymphoblastic Leukemia	Y	24	12	3	15	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
NIH NCI	Cancer Prevention		KUMC 12873	Greiner, A	CCPH	12/24/2012		N/A	Pre	Tailored Touchscreen Colorectal Cancer Prevention in American Indian Communities	N	460	460	38	202	0	0	
NCI	Cancer Prevention		KUMC 13509	Greiner, A	CCPH	2/1/2014		N/A	Pre	Latino and American Indian Health Workers Promoting Healthy Diets	N	120	120	0	60	0	0	Protocol is a small pilot study linked to our U54 Community Networks Program Center grant which is in its final year. We have been analyzing data to build a pilot intervention this year and that is why no one was recruited this last year. In 2016 we anticipate recruiting participants for the intervention.

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

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Department of Defense (DOD) Sidney Kimmel Comprehensive Cancer Center	Prostate	NCT02286921	J14146	Holzbeierlein, J	D3ET	9/24/2015		II	Tre	A Randomized Phase II Study Comparing Bipolar Androgen Therapy vs. Enzalutamide in Asymptomatic Men with Castration Resistant Metastatic Prostate Cancer: The TRANSFORMER Trial	Y		10	1	1	0	0	
NCI	Cancer Prevention		STUDY00000316	Lumpkins, C	CCPH	4/14/2014		N/A	Hsr	Communicating Colorectal Cancer Prevention Through Urban African American Churches - The Pilot Intervention	N	240	240	114	168	0	0	
University of Texas Health Science Center	Multiple Sites	NCT01911208	RECRUIT	McGuirk, J	D3ET	5/20/2015		N/A	Hsr	A Randomized Recruitment Intervention Trial (RECRUIT)	Y		15	4	6	0	0	
Patient-Centered Outcomes Research Institute (PCORI)	Other Hematopoietic	NCT02200133	13-SCP	McGuirk, J	D3ET	6/2/2015		N/A	Sup	Randomized Study of Individualized Care Plans for Hematopoietic Cell Transplant Survivors	Y		100	42	42	0	0	
NIH Pfizer	Smoking Cessation	NCT01836276	KUMC 12990	Nollen, N	CCPH	2/1/2013	12/10/2015	IV	Pre	Understanding Disparities in Quitting in African American and White Smokers	Y	448	448	19	449	0	0	
Patient-Centered Outcomes Research Institute (PCORI)	Smoking Cessation	NCT02244918	STUDY00001602	Nollen, N	CCPH	5/15/2015		IV	Pre	Informing Tobacco Treatment Guidelines for African American Non-Daily Smokers	N	384	384	86	124	0	0	
NIDDKD	Cancer Prevention	NCT02010463	KUMC 11951	Savage, C	CCPH	11/1/2011	04/28/2015	N/A	Pre	Neuroimaging Studies of Reward, Impulsivity, and Adherence to an Exercise Program	N	200	200	22	181	0	0	
Myeloproliferative Disorders-Research Consortium	Other Hematopoietic	NCT01259817	MPD-RC-111	Yacoub, A	D3ET	3/27/2015	01/01/2016	II	Tre	Single Arm Salvage Therapy with Pegylated Interferon alfa-2a for Patients with High Risk Polycythemia Vera or High Risk Essential Thrombocythemia who are either Hydroxyurea Resistant or Intolerant or have had a Abdominal Vein Thrombosis	Y		20	14	14	0	0	
Myeloproliferative Disorders-Research Consortium	Myeloid and Monocytic Leukemia	NCT01259856	MPD-RC-112	Yacoub, A	D3ET	6/4/2015		III	Tre	Randomized Trial of Pegylated Interferon Alfa-2a versus hydroxyurea Therapy in the Treatment of high Risk Polycythemia Vera and high Risk Essential Thrombocythemia	Y		12	8	8	0	0	
Myeloproliferative Disorders-Research Consortium	Myelofibrosis	NCT01790295	MPD-RC-114	Yacoub, A	D3ET	6/17/2015		II	Tre	Exploring the potential of dual kinase JAK 1/2 Inhibitor Ruxolitinib (INC424) with Reduced Intensity Allogeneic Hematopoietic Cell Transplantation in Patients wtih Myelofibrosis	Y		4	1	1	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

INSTITUTIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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The SWOG/Hope Foundation Impact Award	Multiple	NCT02087657	Auto-HBO	Aljitawi, O	D3ET	3/13/2014	01/22/2015	Device	Tre	Pilot Study Exploring the Use of Hyperbaric Oxygen in Autologous PBSC Transplantation	N	20	20	0	23	0	0	Protocol suspended to new enrollment throughout 2015 while amendment was written
KU Endowment Association Frontiers	Multiple	NCT02099266	BMT-2011-08-01	Aljitawi, O	D3ET	6/4/2013	02/23/2015	Device	Tre	A Pilot Study to Determine the Safety and Efficacy of Using Hyperbaric Oxygen Therapy to Improve Umbilical Cord Blood Stem Cell Homing and Subsequent Engraftment	N	15	15	3	15	0	0	
KU Endowment Association U-Systems	Breast-Female	NCT02488187	KUMC 12801	Amin, A	CPS	12/17/2012		Feasibility/Pilot	Dia	Comparison of Preoperative Automated Breast Ultrasound and MRI to Determine Therapeutic Management of Newly Diagnosed Breast Cancer Patients	N	200	200	65	97	0	0	
Millennium Pharmaceuticals	Lymphoma, Leukemia	NCT02535806	MERCY01	August, K	D3ET	6/11/2015		II	Tre	MERCY01 - A Pilot Study of Mitoxantrone-Based Four Drug Reinduction in Combination with Bortezomib for Relapsed or Refractory Acute Lymphoblastic Leukemia or Lymphoblastic Lymphoma in Children and Young Adults	N	10	10	1	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
American Cancer Society	Breast-Female		STUDY00000502	Cupertino, P	CCPH	1/31/2014		N/A	Pre	ACS-NFL A.M.I.G.A. (Helping Women with Information, Generosity and Support) for Breast Cancer Early Detection	N	1500	1500	661	1312	0	0	
Thomas Jefferson University	Multiple	NCT01833351	KUMC 12680	Drisko, J	D3ET	7/1/2011	09/11/2015	I	Tre	Pharmacokinetic Evaluation of Intravenous Ascorbic Acid	N	66	66	4	34	0	0	
Investigator	Prostate	NCT01777061	KUMC 13429	Dusing, R	D3ET	4/19/2013		N/A	Dia	Clinical Management Decisions Based on [11C]acetate Positron Emission Tomography Performed on Prostate Cancer Patients with Biochemical Recurrence	N	250	250	113	249	0	0	
Investigator	Breast-Female	NCT00291096	KUMC 4601	Fabian, C	CPS	7/25/1989		N/A	Pre	High Risk Breast Clinic-Breast Tissue Biomarkers Predicting Short Term Risk of Breast Cancer	N	3000	3000	82	2668	0	0	
Investigator	Breast-Female	NCT02101970	STUDY00000703	Fabian, C	CPS	3/24/2014	04/23/2015	II	Pre	Randomized Pilot Trial of Omega-3 Fatty Acids or Placebo in Peri- or Post-menopausal Women at High Risk For Breast Cancer Undergoing a Weight Loss Intervention	N	50	50	10	46	0	0	
Breast Cancer Research Foundation	Breast-Female	NCT02517502	STUDY00002415	Fabian, C	CPS	8/18/2015		Feasibility/Pilot	Sup	Docosahexaenoic Acid (DHA) To Prevent Development of Cognitive Dysfunction Due to Chemotherapy	Y	50	40	3	3	0	0	
Celgene University of Nebraska	Non-Hodgkins Lymphoma	NCT01035463	RV-LYM-PI-0328	Ganguly, S	D3ET	3/10/2015	07/14/2015	I/II	Tre	Phase I/II Study of Lenalidomide Maintenance Following BEAM (+/- Rituximab) for Chemo-Resistant or High Risk Non-Hodgkin's Lymphoma	Y		20	4	4	0	0	
Cancer Prevention and Survivorship Pilot Project	Cancer Prevention		STUDY00002779	Gibson, C	CPS	9/10/2015		Feasibility/Pilot	Sup	Televideo Exercise and Nutrition Program for Adult Survivors of Pediatric Cancer	N	24	24	9	9	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

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Baylor University Medical Center	Liver	NCT02081755	HCCBAYLOR12	Gilroy, R	D3ET	12/18/2014		IV	Tre	A 36 month multi-center, open label, randomized, comparator study to evaluate the efficacy and safety of everolimus immunosuppression treatment in liver transplantation for hepatocellular carcinoma exceeding Milan criteria.	Y		35	11	11	0	0	
NIH Pilot Grant	Prostate	NCT02252484	STUDY00001274	Hamilton-Reeves, J	CPS	10/21/2014		Feasibility/Pilot	Pre	Energy Balance for Prostate Cancer Survivorship	N	40	40	17	20	0	0	
American Cancer Society and Nestle HealthCare Nutrition	Urinary Bladder	NCT01868087	KUMC 13730	Hamilton-Reeves, J	CPS	8/15/2013	04/14/2015	Feasibility/Pilot	Sup	Impact Advanced Recovery® for Radical Cystectomy Patients	N	30	30	1	30	0	0	
GlaxoSmithKline	Breast-Female	NCT01283789	2010-IIT-Novartis-RAD-001	Khan, Q	D3ET	2/22/2011		II	Tre	Phase II Trial of Lapatinib and RAD-001 for HER2 Positive Metastatic Breast Cancer	N	45	45	0	20	0	0	Protocol was temporarily suspended to enrollment most of 2015.
University of Kansas Cancer Center	Multiple	NCT02595320	2015-X7-7-LQT	Khan, Q	D3ET	10/1/2015		II	Tre	Randomized open-label trial of dose dense, fixed dose capecitabine compared to standard dose capecitabine in metastatic breast cancer and advanced/metastatic GI cancers.	Y	183	183	9	9	6	6	
Department of Defense (DOD)	Prostate	NCT00669162	KUMC 12313	Kumar, P	D3ET	2/24/2011	07/30/2015	I/II	Tre	A Phase I/II Trial of Post-Prostatectomy Radiation Therapy, Hormonal Therapy and Concurrent Docetaxel for High Risk Pathologic T2-T3N0M0 Prostate Cancer	Y	25	25	0	21	0	6	Protocol was temporarily suspended to enrollment all of 2015.
Investigator	Cancer Prevention		STUDY00001320	LeMaster, J	CCPH	1/22/2015		Feasibility/Pilot	Pre	A Touch-to-Screen Implementations Intentions intervention to increase colonoscopy screening rates among Bhutanese refugees	N	20	20	10	10	0	0	
Investigator	Multiple Myeloma		KUMC 13350	Lipe, B	D3ET	8/16/2012	05/30/2015	Feasibility/Pilot	Bas	Correlation Between Bone Metabolism and Risk Group of MGUS and Pilot trial of vitamin D supplementation	Y	55	55	3	56	0	6	
Investigator	Smoking Cessation		STUDY00001782	Martin, L	CCPH	12/2/2014		N/A	Pre	Smoking Cessation, Cognitive Control and Reward Processing: An fMRI Pilot study	N	50	50	39	50	0	0	
AngioDynamics University of Arkansas	Breast-Female	NCT01420380	104603	McGinness, M	D3ET	4/12/2011		N/A	Tre	ABLATE Trial: Radiofrequency Ablation After Breast Lumpectomy (eRFA) Added To Extend Intraoperative Margins in the Treatment of Breast Cancer	Y		40	8	34	0	0	
FRONTIERS	Prostate	NCT02198859	KUMC 13582	Mirza, M	D3ET	4/11/2014		I	Tre	Phase 1 Study of Evaluation of Lithium and its effect on clinically localized prostate cancer	N	18	18	3	9	0	0	
Investigator	Multiple		KUMC 13833	Mische Lawson, L	D3ET	8/29/2013	06/29/2015	N/A	Sup	Effectiveness of Music and Art in Reducing Symptoms Related to Blood and Marrow Transplantation: A Pilot Study	N	60	60	18	42	0	0	

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Cedars-Sinai Medical Center	Breast-Female	NCT02360917	IIT 2014-01	Myers, J	CPS	7/29/2015		N/A	Sup	Emerging from the Haze™ – A multi-center, wait-list controlled trial to measure impact of a multi-dimensional psycho-educational program on subjective cognitive complaints after breast cancer treatment using virtual technology	Y		35	7	7	0	0	
University of Chicago	Head and Neck	NCT01111058	09-266-B	Neupane, P	D3ET	6/8/2012	04/01/2015	II	Tre	Randomized Double-Blind Phase II Trial of Everolimus versus Placebo as Adjuvant Therapy in Patients with Locally Advanced Squamous Cell Cancer of the Head and Neck (SCCHN)	Y		10	2	9	0	0	
Investigator	Cervix	NCT02128659	KUMC 13559	Ramaswamy, M	CCPH	3/26/2013		N/A	Pre	Sexual Health Empowerment for Cervical Health Literacy and Cancer Prevention	N	200	200	155	223	0	0	
Univ. of Kansas Cancer Center	Breast-Female	NCT02413320	2014-BRST-TNBC-LQT	Sharma, P	D3ET	7/9/2015		II	Tre	Randomized open label Phase II trial of neoadjuvant Carboplatin plus Docetaxel or Carboplatin plus Paclitaxel followed by Adriamycin plus Cyclophosphamide in stage I-III triple-negative breast cancer.	Y	100	100	6	6	6	6	
Novartis Pharmaceuticals	Breast-Female	NCT02379247	CBYL719XUS06T	Sharma, P	D3ET	3/3/2015		I/II	Tre	Phase I/II study of BYL719 and Nab-Paclitaxel (Abraxane) in patients with locally recurrent or metastatic HER-2 negative breast cancer	Y	54	34	9	9	0	0	
Celgene	Multiple	NCT02393794	RM-CL-PI-002783	Sharma, P	D3ET	7/17/2015		I/II	Tre	Phase I/II trial of Cisplatin + Romidepsin in locally recurrent or metastatic triple negative breast cancer or BRCA 1/BRCA 2 mutation associated locally recurrent or metastatic breast cancer	N	54	54	4	4	0	0	
Investigator	Head and Neck	NCT02338102	STUDY00000087	Shnayder, Y	D3ET	10/24/2013	06/11/2015	Feasibility/Pilot	Sup	Nasal Saline Irrigation after Radiation Therapy for Oropharyngeal Cancer: A Pilot Study	N	40	40	0	36	0	0	
Brain Tumor Trials Collaborative (BTTC)	Brain and Nervous System	NCT01434602	BTTC09-01	Taylor, S	D3ET	4/17/2014		I/II	Tre	BTTC09-01: A Phase I-II trial Everolimus and Sorafenib in Patients with Recurrent High-Grade Gliomas	Y		10	0	2	0	0	Trial was suspended to new enrollment on 3/19/2015.
Weill Cornell Medical College	Prostate	NCT00859781	0810010067 (J591+Ketoconazole)	Williamson, S	D3ET	12/14/2012	04/28/2015	II	Tre	A Randomized Phase 2 Trial of 177Lu Radiolabeled Monoclonal Antibody HuJ591 (177Lu-J591) and Ketoconazole in Patients with High-Risk Castrate Biochemically Relapsed Prostate Cancer After Local Therapy	Y		10	1	3	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

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Albert Einstein College of Medicine of Yeshiva University	Myelodysplastic Syndrome	NCT01772420	2012-407	Yacoub, A	D3ET	7/31/2015		II	Tre	Phase II Study of Lenalidomide and Eltrombopag in Patients with Symptomatic Anemia in Low or Intermediate I Myelodysplastic Syndrome (MDS)	Y		15	5	5	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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Novartis Pharmaceuticals	Non-Hodgkins Lymphoma		CCTL019B2206	Abhyankar, S	D3ET	7/29/2015		II	Oth	A multicenter study of apheresis collection of peripheral blood mononuclear cells (PBMC)in patients with CD19 expressing malignancies who could be eligible for a CTL019 clinical research trial	Y		15	9	9	0	0	
GlaxoSmithKline	Multiple	NCT01610414	115523 (Zoster-002)	Abhyankar, S	D3ET	3/11/2013	03/13/2015	III	Sup	Observer-blind study to evaluate efficacy, safety, and immunogenicity of GSK Biologicals' Herpes Zoster vaccine GSK1437173A	Y		30	0	28	0	0	
Kyowa Pharmaceutical	Non-Hodgkins Lymphoma	NCT01728805	0761-010	Abhyankar, S	D3ET	4/30/2015	11/30/2015	III	Tre	Open-Label, Multi-Center, Randomized Study of Anti-CCR4 Monoclonal Antibody KW-0761 (mogamulizumab) Versus Vorinostat in Subjects with Previously Treated Cutaneous T-Cell Lymphoma	Y		5	2	2	0	0	
Hoffman-LaRoche Abbvie	Non-Hodgkins Lymphoma	NCT02187861	BO29337	Abhyankar, S	D3ET	5/14/2015	02/19/2016	II	Tre	A Phase II, Open-Label Study Evaluating the Safety and Efficacy of GDC-0199 (ABT-199) plus Bendamustine plus Rituximab (BR) in Comparison with BR Alone or GDC-0199 plus Rituximab (R) in Patients with Relapsed and Refractory Follicular Non-Hodgkin's Lymphoma	Y		5	3	3	0	0	
Incyte Corporation	Pancreas	NCT02119663	INCB 18424-363	Al-Rajabi, R	D3ET	5/28/2015	02/15/2016	III	Tre	A Randomized, Double-Blind, Phase 3 Study of the JAK 1/2 Inhibitor, Ruxolitinib or Placebo in Combination With Capecitabine in Subjects With Advanced or Metastatic Adenocarcinoma of the Pancreas Who Have Failed or Are Intolerant to First-Line Chemotherapy (The JANUS 2 Study)	Y		10	0	0	0	0	This is a high screen fail trial.
NewLink Genetics Corporation	Pancreas	NCT01836432	NLG-0505	Al-Rajabi, R	D3ET	5/19/2014	12/17/2015	III	Tre	A Phase III Study of Chemotherapy With or Without Algenpantucel-L (HyperAcute®- Pancreas) Immunotherapy in Subjects with Borderline Resectable or Locally Advanced Unresectable Pancreatic Cancer	Y		20	11	15	0	0	
Millennium Pharmaceuticals	Lymphoma	NCT01492088	C25002	August, K	D3ET	6/1/2013		I/II	Tre	Study of Brentuximab Vedotin (SGN-35) in Pediatric Patients With Relapsed or Refractory Systemic Anaplastic Large-Cell Lymphoma or Hodgkin Lymphoma	Y		5	0	3	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Celgene, COG	Leukemia	NCT02538965	CC-5013-AML-002, AAML1522	August, K	D3ET	12/3/2015		II	Tre	A Study of Lenalidomide in Pediatric Subjects With Relapsed or Refractory Acute Myeloid Leukemia	Y		5	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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Ansun Biopharma, Inc	Other Hematopoietic	NCT01644877	DAS181-2-05	Clough, L	D3ET	5/5/2014		II	Sup	A Phase II, Randomized, Double-Blind, Placebo-controlled study to examine the effects of DAS181 in immunocompromised subjects with Lower Respiratory Tract Parainfluenza Infection on Supplemental Oxygen	Y		6	2	3	0	0	
Ansun Biopharma, Inc	Other Hematopoietic	NCT01924793	DAS181-2-06	Clough, L	D3ET	2/18/2014		II	Sup	An Open Label study to examine the effects of DAS181 administered by Dry Powder Inhaler (DPI) or Nebulized formulation in Immunocompromised subjects with Parainfluenza (PIV) infection	Y		6	0	0	0	0	Open label extension protocol - on temporary suspension
Merck and Co.	Other Hematopoietic	NCT02137772	MK-8228-001	Clough, L	D3ET	7/18/2014		III	Sup	A Phase III Randomized, Placebo-controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-8228 (Letermovir) for the Prevention of Clinically Significant Human Cytomegalovirus (CMV) Infection in Adult, CMV-Seropositive Allogeneic Hematopoietic Stem Cell Transplant Recipients	Y		10	2	4	0	0	
Optimer Pharmaceuticals	Multiple	NCT01691248	OPT-80-302	Clough, L	D3ET	10/3/2012	01/08/2015	III	Sup	DEFLECT-1: A Phase 3b Multi-Center, Double-Blind, Randomized, Placebo Controlled Study to Demonstrate the Safety and Efficacy of Fidaxomicin for Prophylaxis against CLostridium difficilE-Associated Diarrhea in Adults Undergoing Hematopoietic Stem Cell Transplantation	Y		20	0	14	0	0	
Prometheus Laboratories	Melanoma, skin	NCT01856023	12PLK02	Doolittle, G	D3ET	9/30/2014	06/29/2015	IV	Tre	Open-Label, Randomized, Multi-Center Study Comparing the Sequence of High Dose Aldesleukin (Interleukin-2) and Ipilimumab (Yervoy®) in Patients with Metastatic Melanoma	Y		15	1	1	0	0	
Novartis Pharmaceuticals	Breast-Female	NCT02278120	CLEE011E2301	Doolittle, G	D3ET	8/28/2015		III	Tre	A Phase III randomized, double-blind, placebo-controlled study of LEE001 or placebo in combination with tamoxifen and goserelin or a non-steroidal aromatase inhibitor (NSAI) and goserelin for the treatment of premenopausal women with hormone receptor positive, HER2-negative, advanced breast cancer	Y		18	0	0	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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Hoffman-LaRoche	Melanoma, skin	NCT01667419	GO27826	Doolittle, G	D3ET	9/24/2013	09/16/2015	III	Tre	A PHASE III, RANDOMIZED, DOUBLE-BLIND,PLACEBO-CONTROLLED STUDY OF VEMURAFENIB RO5185426) ADJUVANT THERAPY IN PATIENTS WITH SURGICALLY RESECTED, CUTANEOUS BRAF-MUTANT MELANOMA AT HIGH RISK FOR RECURRENCE	Y		8	1	1	0	0	
NewLink Genetics Corporation	Melanoma, skin	NCT02054520	NLG0304	Doolittle, G	D3ET	12/9/2015		II	Tre	A Phase 2b Study of Immune Checkpoint Inhibition With or Without Dorgenmeltucel-L (HyperAcute Melanoma) Immunotherapy for Stage IV Melanoma Patients	Y		12	0	0	0	0	
Bayer Healthcare Pharmaceuticals US Oncology	Colorectal	NCT02425683	USOR 13050	Flanagan, J	D3ET	8/27/2015		II	Tre	A randomized, Phase II Study of High-Risk Colorectal Cancer Patients (Stage IIIC) treated with Either Regorafenib or Standard of Care (No Treatment) after Adjuvant FOLFOX	Y		5	0	0	0	0	Open only at community sites. Enrollment low due to US Oncology Research contract negotiations.
Pfizer	Non-Hodgkins Lymphoma	NCT02213263	B3281006 / USOR 14020	Flanagan, J	D3ET	2/3/2015		III	Tre	A Phase 3, Randomized, Double-Blind Study Of PF-05280586 Versus Rituximab For The First-Line Treatment Of Patients With CD20-Positive, Low Tumor Burden, Follicular Lymphoma	Y		4	0	0	0	0	Open only at community sites. Enrollment low due to US Oncology Research contract negotiations.
Momenta Pharmaceuticals, Inc.	Pancreas	NCT01621243	MOM-M402-103 / USOR 13131	Flanagan, J	D3ET	6/18/2015		I/II	Tre	A Phase I/II , Two-Part, Multicenter Study to Evaluate the Safety and Efficacy of M402 in combination with nabpaclitaxel and gemcitabine in patients with metastatic pancreatic cancer	Y		4	0	0	1	1	Open only at community sites. Enrollment low due to US Oncology Research contract negotiations.
Ambit Biosciences Corporation	Myeloid and Monocytic Leukemia	NCT02039726	AC220-007	Ganguly, S	D3ET	12/9/2014		III	Tre	RANDOMIZED STUDY OF QUIZARTINIB (AC220) MONOTHERAPY VERSUS SALVAGE CHEMOTHERAPY IN SUBJECTS WITH FLT3-ITD POSITIVE ACUTE MYELOID LEUKEMIA (AML) REFRACTORY TO OR RELAPSED AFTER FIRST-LINE TREATMENT WITH OR WITHOUT HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT) CONSOLIDATION	Y		8	4	4	0	0	Biomarker-driven trial with high screen fail rate
Medimmune	Non-Hodgkins Lymphoma	NCT01453205	CD-ON-MEDI-551-1088	Ganguly, S	D3ET	1/6/2015	09/18/2015	II	Tre	A Phase 2 Randomized Open-label Study of MEDI-551 in Adults With Relapsed or Refractory DLBCL	Y		10	4	4	0	0	
Argos	Kidney	NCT01582672	AGS-003-007	Holzbeierlein, J	D3ET	8/15/2013	07/15/2015	III	Tre	An International Phase 3 Randomized Trial of Autologous Dendritic Cell Immunotherapy (AGS-003) Plus Standard Treatment of Advanced Renal Cell Carcinoma (ADAPT)	Y		10	1	3	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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Heat Biologics	Urinary Bladder	NCT02010203	HS410-101	Holzbeierlein, J	D3ET	12/19/2014	02/16/2016	I/II	Tre	A Phase 1/2, Placebo-Controlled, Randomized Study to Evaluate the Safety, Immune Response and Clinical Activity of HS-410 in Patients with High-Risk Non-Muscle Invasive Bladder Cancer Who Have Undergone Transurethral Resection of Bladder Tumor (TURBT) and Received Prior Treatment with Induction Bacillus Calmette–Guérin (BCG)	Y		20	3	3	0	0	
NewLink Genetics Corporation	Lung	NCT01774578	NLG0301	Huang, C	D3ET	4/10/2014		II/III	Tre	An Open-label, Randomized Phase IIB/III Active Control Study of Second-line HyperAcute®-Lung (tergenpumatucel-L) Immunotherapy versus Docetaxel in Progressive or Relapsed Non-Small Cell Lung Cancer	Y		20	4	12	0	0	
Onconova Therapeutics, Inc.	Myelodysplastic Syndrome	NCT01928537	04-24 (Onconova)	Kambhampati, S	D3ET	3/31/2014	01/09/2015	III	Tre	Phase IIIB, Open-label, Multi-Center Study of the Efficacy and Safety of Rigosertib Administered as 72-hour Continuous Intravenous Infusions in Patients with Myelodysplastic Syndrome with Excess Blasts Progressing On or After Azacitidine or Decitabine	Y		5	0	1	0	0	
Millenium Pharmaceuticals	Breast-Female	NCT02049957	C31001	Khan, Q	D3ET	5/29/2015	01/21/2016	I/II	Tre	A Phase 1b/2 Study of Safety and Efficacy of MLN0128 (Dual TORC1/2 Inhibitor) in Combination with Exemestane or Fulvestrant Therapy in Postmenopausal Women with ER+/HER2-Advanced or Metastatic Breast Cancer that has Progressed on Treatment with Everolimus in Combination with Exemestane or Fulvestrant	Y		6	1	1	0	0	
Oncothyreon, Inc	Multiple	NCT01983501	ONT-380-004	Khan, Q	D3ET	11/3/2014	07/21/2015	I	Tre	Phase 1b, Open-Label Study to Assess the Safety and Tolerability of ONT-380 Combined with Ado-Trastuzumab Emtansine (T-DMI)	Y		10	5	5	0	0	
Cerulean Pharma Inc	Kidney	NCT02187302	CRLX101-208	Komiya, T	D3ET	7/2/2015	10/19/2015	II	Tre	A Randomized, Phase 2 Study to Assess the Safety and Efficacy of CRLX101 in Combination with Bevacizumab in Patients with Metastatic Renal Cell Carcinoma (RCC) versus Standard of Care (SOC)(Investigator's Choice)	Y		12	1	1	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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Incyte Corporation	Lung	NCT02119650	INCB 18424-266	Komiya, T	D3ET	9/17/2014		II	Tre	A Randomized, Double-Blind Phase 2 Study of Ruxolitinib or Placebo in Combination With Pemetrexed/Cisplatin and Pemetrexed Maintenance for Initial Treatment of Subjects With Nonsquamous Non–Small Cell Lung Cancer That Is Stage IIIB, Stage IV, or Recurrent	Y		10	0	0	3	3	Biomarker-driven trial with high screen fail rate
Merck and Co.	Lung	NCT02142738	MK-3475-024	Komiya, T	D3ET	8/6/2015	09/22/2015	III	Tre	A Randomized Open-Label Phase III Trial of MK-3475 Versus Platinum Based Chemotherapy in 1L Subjects With PD-L1 Strong Metastatic Non-Small Cell Lung Cancer	Y		12	0	0	0	0	Biomarker-driven trial with high screen fail rate
Pfizer	Multiple	NCT02312037	B1761026	Lin, T	D3ET	3/9/2015		IV	Oth	Gemtuzumab Ozogamicin (Mylotarg (Registered)) Expanded Access Protocol For Treatment Of Patients In The United States With Relapsed/Refractory Acute Myelogenous Leukemia Who May Benefit From Treatment And Have No Access To Other Comparable/Alternative Therap	Y		5	2	2	0	0	
Astellas Pharma US	Myeloid and Monocytic Leukemia	NCT02236013	2215-CL-0103	Lin, T	D3ET	3/17/2015		I	Tre	A Phase 1 Study of ASP2215 in Combination with Induction and Consolidation Chemotherapy in Patients with Newly Diagnosed Acute Myeloid Leukemia	Y		8	0	0	0	0	Protocol was temporarily suspended to enrollment most of 2015.
Pfizer	Multiple	NCT01546038	B1371003	Lin, T	D3ET	8/27/2013	03/04/2015	II	Tre	A Phase 1b/2 Study to Evaluate the Safety and Efficacy of PF-04449913, an Oral Hedgehog Inhibitor, in Combination with Intensive Chemotherapy, Low Dose ARA-C or Decitabine in Patients with Acute Leukemia or High-Risk Myelodysplastic Syndrome	Y		10	0	4	0	0	
Novartis Pharmaceuticals	Myeloid and Monocytic Leukemia	NCT01744665	CAMN107A US37	Lin, T	D3ET	2/3/2014	01/13/2015	II	Tre	A phase II randomized, multicenter study of treatment-free remission in chronic myeloid leukemia in chronic phase (CML-CP) patients who achieve and sustain MR4.5 after switching to nilotinib	Y		10	0	1	0	1	Sponsor reported slow accrual study-wide.
Celator Pharmaceuticals Inc	Multiple	NCT02238925	CLTR0310-206	Lin, T	D3ET	10/7/2014	06/01/2015	II	Tre	An Open Label Phase II Pharmacokinetic and Pharmacodynamic Assessment of the Potential for QTC Prolongation Following First Induction Treatment with CPX-351 (CYTARABINE:DAUNORUBICIN Liposome Injection) in Acute Leukemias and MDS Patients	Y		12	12	18	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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Karyopharm Therapeutics, Inc	Myeloid and Monocytic Leukemia	NCT02088541	KCP-330-008	Lin, T	D3ET	11/18/2015		II	Tre	A randomized, open label, phase 2 wstudy of the selectibe inhibitor of nuclear export 9SINE) selinexor 9KPT-330) versus specified physician's choice in patients > 60 years old with relapsed/refractory acute myeloid leukemia (AML) who are ineligile for intensive chemortherapy and/or transplantation	Y		5	0	0	0	0	
AbbVie	Myeloid and Monocytic Leukemia	NCT02287233	M14-387	Lin, T	D3ET	3/5/2015		I	Tre	A Phase 1/2 Study of ABT-199 in Combination with Low-Dose Cytarabine in Treatment-Naïve Subjects with Acute Myelogenous Leukemia Who Are ≥ 65 Years of Age and Who Are Not Eligible for Standard Anthracycline-Based Induction Therapy	Y		12	4	4	0	0	
Janssen	Multiple Myeloma	NCT02136134	54767414MMY3004	Lipe, B	D3ET	5/11/2015	07/09/2015	III	Tre	Phase 3 STudy Comparing Daratumumab, Bortezomib and Dexamethasone (DVd) vs Bortezomib and Dexamethasone (Vd) in Subjects with Relapsed or Refractory Multiple Myeloma	Y		20	3	3	0	0	
Array BioPharma	Multiple Myeloma	NCT02092922	ARRAY-520-215	Lipe, B	D3ET	6/30/2015	06/30/2015	II	Tre	A Multicenter Phase 2 Study of Single-agent Filanesib (ARRY-520) in Patients with Advanced Multiple Myeloma	Y		15	0	0	0	0	On day of site activation, received sponsor letter closing the study to enrollment.
EMD Serono	Melanoma, skin	NCT01973608	EMR 062235-005	Lominska, C	D3ET	1/22/2015	02/11/2015	II	Tre	A Safety Study for MSB0010445 in Combination with Stereotactic Body Radiation in Advanced Melanoma Subjects Following Prior Treatment with Ipilimumab	Y		10	0	0	0	0	
Astellas Pharma US Abbott Laboratories	Multiple	NCT01877655	0113-CL-1004	McGuirk, J	D3ET	2/6/2014	05/12/2015	III	Pre	A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial to Evaluate the Protective Efficacy and Safety of a Therapeutic Vaccine, ASP0113, in Cytomegalovirus (CMV)-Seropositive Recipients Undergoing Allogeneic, Hematopoietic Cell Transplant (HCT)	Y		30	0	2	0	0	
Novartis Pharmaceuticals	Non-Hodgkins Lymphoma	NCT02445248	CCTL019C2201	McGuirk, J	D3ET	7/29/2015		II	Tre	A phase II, single arm, multicenter trial to determine the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL)	Y		15	9	9	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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Polyphor Ltd	Multiple	NCT01413568	POL-4	McGuirk, J	D3ET	10/31/2014	07/24/2015	I/II	Tre	A Phase I/II Study Evaluating the Safety and Efficacy of Intravenous POL6326 for the Mobilization and Transplantation of HLA-Matched Sibling Donor Hematopoietic Stem Cells in Patients with Advanced Hematological Malignancies	Y		10	0	0	0	0	
Novartis	Lymphoma		CCTL019B2206	Myers, G	D3ET	10/16/2014		NA	Oth	A MULTICENTER STUDY OF APHERESIS COLLECTION OF PERIPHERAL BLOOD MONONUCLEAR CELLS (PBMC) IN PATIENTS WITH CD19 EXPRESSING MALIGNANCIES WHO COULD BE ELIGBLE FOR A CTL019 CLINICAL RESEARCH TRIAL	Y		6	3	3	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Novartis	Leukemia	NCT02445222	CCTL019A2205B	Myers, G	D3ET	10/28/2014		II	Tre	A PHASE II, SINGLE ARM, MULTICENTER TRIAL TO DETERMINE THE EFFICACY AND SAFETY OF CTL019 IN PEDIATRIC PATIENTS WITH RELAPSED AND REFRACTORY B-CELL ACUTE LYMPHOBLASTIC LEUKEMIA	Y		6	1	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Novartis	Leukemia	NCT02435849	CCTL019B2202	Myers, G	D3ET	6/4/2015		II	Tre	A PHASE II, SINGLE ARM, MULTICENTER TRIAL TO DETERMINE THE EFFICACY AND SAFETY OF CTL019 IN PEDIATRIC PATIENTS WITH RELAPSED AND REFRACTORY B-CELL ACUTE LYMPHOBLASTIC LEUKEMIA	Y		6	2	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
CytRx	Soft Tissue	NCT02049905	ALDOXORUBICIN-P3-STS-01	Myron, M	D3ET	4/23/2015	11/26/2015	III	Tre	A Multicenter, Randomized, Open-Label Phase 3 Study to Investigate the Efficacy and Safety of Aldoxorubicin Compared to Investigator's Choice in Subjects with Metastatic, Locally Advanced, or Unresectable Soft Tissue Sarcomas Who Either Relapsed or Were Refractory to Prior Non-Adjuvant Chemotherapy	Y		8	0	0	3	3	Protocol open only at community sites.
Janssen	Soft Tissue	NCT00210665	ET743-SAR-3002	Myron, M	D3ET	6/29/2012	10/30/2015	III	Tre	A Multicenter, Open-Label Single-Arm Study of YONDELIS (trabectedin)for Subjects With Locally Advanced or Metastatic Soft Tissue Sarcoma Excluding Leiomyosarcoma and Liposarcoma Who Have Relapsed or Are Refractory to Standard of Care Treatment	Y		20	0	0	8	17	Protocol open only at community sites.

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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Merck and Co.	Head and Neck	NCT02358031	3475-048	Neupane, P	D3ET	12/3/2015		III	Tre	A Phase 3 Clinical Trial of Pembrolizumab (MK-3475) in First Line Treatment of Recurrent/Metastic Head and Neck Squamous Cell Carcinoma	Y		10	0	0	0	0	
Celgene	Lung	NCT02027428	ABI-007-NSCL-003	Neupane, P	D3ET	1/23/2015		III	Tre	A THREE-PART, RANDOMIZED, OPEN-LABEL, CROSSOVER, MULTI-CENTER, SAFETY AND EFFICACY STUDY TO EVALUATE NAB-PACLITAXEL (ABRAXANE®) AS MAINTENANCE TREATMENT AFTER INDUCTION WITH NAB-PACLITAXEL PLUS CARBOPLATIN IN SUBJECTS WITH SQUAMOUS CELL NON-SMALL CELL LUNG CANCER (NSCLC)	Y		6	2	2	0	0	
Medimmune	Head and Neck	NCT02262741	D4190C00011	Neupane, P	D3ET	8/4/2015	12/10/2015	I	Tre	A Phase 1 Study to Evaluate the Safety, Tolerability, and Efficacy of MEDI4736 in Combination with Tremelimumab or Tremelimumab Alone in Subjects with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck	Y		7	0	0	0	0	
VentiRx Pharmaceuticals	Head and Neck	NCT01836029	VRXP-A202	Neupane, P	D3ET	5/9/2014	08/26/2015	II	Tre	A Randomized, Double-Blind, Placebo-Controlled Study of Chemotherapy Plus Cetuximab in Combination with VTX-2337 in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck	Y		10	8	10	0	0	
Onyx Pharmaceuticals	Multiple Myeloma	NCT01568866	2011-003	Pendergrass, K	D3ET	11/2/2012	09/03/2015	III	Tre	A Randomized, Open-label, Phase 3 Study of Carfilzomib Plus Dexamethasone vs. Bortezomib Plus Dexamethasone in Patients with Relapsed Multiple Myeloma	Y		5	0	0	0	2	Protocol open only at community sites.
BioMarin	Breast-Female	NCT01945775	673-301	Pendergrass, K	D3ET	2/20/2015		III	Tre	A Phase 3, Open-Label, Randomized, Parallel, 2-Arm, Multi-Center Study of BMN 673 versus Physician's Choice in Germline BRCA Mutation Subjects with Locally Advanced and/or Metastatic Breast Cancer, Who Have Received No More than 2 Prior Chemotherapy Regimens for Metastatic Disease	Y		10	0	0	0	0	Protocol open only at community sites.
Millenium Pharmaceuticals	Non-Hodgkins Lymphoma	NCT00931918	C05013	Pendergrass, K	D3ET	6/17/2011	04/28/2015	II	Tre	An Open-Label, Randomized, Phase 2 Study to Assess the Effectiveness of RCHOP With or Without VELCADE in Previously Untreated Patients with Non-Germinal Center B-Cell-like Diffuse Large B-Cell Lymphoma	Y		4	0	0	0	1	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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Millenium Pharmaceuticals	Multiple Myeloma	NCT01850524	C16014	Pendergrass, K	D3ET	4/15/2014	01/29/2015	III	Tre	A Phase 3, Randomized, Double-Blind, Multicenter Study Comparing Oral MLN9708 Plus Lenalidomide and Dexamethasone Versus Placebo Plus Lenalidomide and Dexamethasone in Adult Patients With Newly Diagnosed Multiple Myeloma	Y		5	0	0	0	0	
Eli Lilly	Head and Neck	NCT01063075	14E-MC-JXBB	Perez, R	D3ET	8/30/2012	04/02/2015	II	Tre	Phase 2 Study to Evaluate the Pharmacokinetic and Drug-Drug Interaction of Cetuximab and Carboplatin in Patients with Advanced Solid Tumors	Y		15	9	18	0	0	
Onyx Pharmaceuticals	Multiple Myeloma	NCT01832727	2012-001	Perez, R	D3ET	2/16/2015	06/22/2015	I/II	Tre	Phase 1b/2, Multicenter, Open-label Study of Oprozomib and Dexamethasone in Patients with Relapsed and/or Refractory Multiple Myeloma	Y		10	2	2	0	0	
Agensys, Inc.	Lymphoid Leukemia	NCT02175433	AGS67E-14-1	Perez, R	D3ET	9/26/2014		I	Tre	A Phase I Study Evaluating Safety, Tolerability and Pharmacokinetics of Escalating Doses of AGS67E Given as Monotherapy in Subjects with Refractory or Relapsed Lymphoid Malignancies	Y		10	5	5	0	0	
Agensys, Inc.	Urinary Bladder	NCT02091999	ASG-22CE-13-2	Perez, R	D3ET	5/19/2014		I	Tre	A Phase 1 Study of the Safety and Pharmacokinetics of Escalating Doses of ASG-22CE Given as Monotherapy in Subjects with Metastatic Urothelial Cancer and Other Malignant Solid Tumors that Express Nectin-4	Y		12	5	6	0	0	Biomarker-driven trial with high screen fail rate
Millenium Pharmaceuticals	Multiple	NCT01830816	C16015	Perez, R	D3ET	9/12/2013	02/19/2015	I	Tre	Phase 1/1b Pharmacokinetics Study of Oral MLN9708 in Patients with Relapsed/Refractory Multiple Myeloma and Advanced Solid Tumors with Normal Renal Function or Severe Renal Impairment	Y		10	0	6	0	0	
Millenium Pharmaceuticals	Multiple Sites	NCT01912222	C16018	Perez, R	D3ET	10/18/2013	03/03/2015	I	Tre	A Phase 1 Pharmacokinetic Study of Oral MLN9708 in Patients with Advanced Solid Tumors or Hematologic Malignancies with Varying Degrees of Liver Dysfunction	Y		10	0	3	0	0	
Altor Bioscience	Urinary Bladder	NCT01326871	CA-ALT-801-01-10	Perez, R	D3ET	1/4/2013	02/25/2015	I/II	Tre	A Phase 1b/II Trial of ALT-801 in Combination with Cisplatin and Gemcitabine in Muscle Invasive or Metastatic Urothelial Cancer	Y		16	0	7	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
Novartis Pharmaceuticals	Multiple	NCT01769768	CLDE225A2112	Perez, R	D3ET	4/30/2014		I	Tre	A Phase Ib, Multi-Center, Two Parallel Group, Open-Label, Drug-Drug Interaction Study to Assess the Effect of LDE225 on the Pharmacokinetics of Bupropion and Warfarin in Patients with Advanced Solid Tumors	Y		10	8	13	0	0	
Medimmune	Multiple	NCT02118337	D6020C00001	Perez, R	D3ET	8/10/2015		I	Tre	A Phase 1, Open-label Study to Evaluate the Safety and Tolerability of MEDI0680 (AMP-514) in Combination with MEDI4736 in Subjects with Advanced Malignancies	Y		36	0	0	0	0	Trial was suspended by the sponsor on the day of activation pending review of dose escalation data. Not open to new enrollment as of 7/1/2016.
ImmunoGen, Inc	Multiple	NCT01609556	IMGN853-0401	Perez, R	D3ET	7/25/2014		I	Tre	A Phase 1, First-in-Human Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of IMGN853 in Adults with Ovarian Cancer and other FOLR1-Positive Solid Tumors	Y		15	6	7	0	0	This is a high screen fail trial.
Incyte Corporation	Multiple	NCT02327078	INCB 24360-204	Perez, R	D3ET	6/23/2015		I/II	Tre	A Phase 1/2 Study of the Safety, Tolerability, and Efficacy of INCB24360 Administered in Combination With Nivolumab in Select Advanced Cancers	Y		18	3	3	0	0	
Medimmune	Multiple	NCT00983619	MI-CP204	Perez, R	D3ET	11/18/2014	09/23/2015	I	Tre	An Open-Label, Phase 1/2 Study of MEDI-551, a Humanized Monoclonal Antibody Directed Against CD19, in Adult Subjects with Relapsed or Refractory Advanced B-cell Malignancies	Y		10	1	1	0	0	
Dompe s.p.a.	Breast-Female	NCT01861054	REP0210	Perez, R	D3ET	4/26/2013	04/01/2015	II	Tre	A Single Arm, Preoperative, Pilot Study to Evaluate the Safety and Biological Effects of Orally Administered Reparixin in Early Breast Cancer Patients who are Candidates for Surgery	Y		12	0	4	0	0	
TetraLogic Pharmaceuticals	Multiple	NCT01940172	TL32711-POC-0090-PTL	Perez, R	D3ET	8/12/2014	05/22/2015	I	Tre	A Phase 1b, Open-Label, Non-Randomized Multicenter Study of Birinapant in Combination with Conatumumab in Subjects with Relapsed Epithelial Ovarian Cancer, Primary Peritoneal Cancer or Fallopian Tube Cancer	Y		10	5	6	0	0	
Bristol-Myers Squibb	Lung	NCT02066636	USON 13-179 / BMS CA209-153	Raja, V	D3ET	10/28/2014	03/30/2015	III	Tre	A Phase IIIb/IV Safety Trial of Nivolumab (BMS-936558) in Subjects with Advanced or Metastatic Non-Small Cell Lung Cancer Who Have Progressed During or After Receiving At Least One Prior Systemic Regimen (CA209153)	Y		5	0	0	12	15	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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DFINE, Inc	Multiple	NCT02225223	DF-14-01	Sayed, D	D3ET	4/29/2015		Device	Tre	Evaluation of Targeted Radiofrequency Ablation and Vertebral Augmentation prior to or following Radiation Therapy to Treat Painful Metastatic Vertebral Body Tumor(s)	Y		20	2	2	0	0	
Celgene	Breast-Female	NCT02374099	CC-486-BRSTM-001	Sharma, P	D3ET	11/17/2015		II	Tre	A phase 2, randomized, open-label, two-arm study to assess the efficacy and safety of the epigenetic modifying effects of CC-486 (Oral Azacitidine)in combination with Fulvestrant in postmenopausal women with ER+, HER2- metastatic breast cancer who have progressed on an aromatase inhibitor	Y		10	0	0	0	0	
Northwest Biotherapeuticis, Inc.	Brain and Nervous System	NCT00045968	020221 (DCVax®-L)	Taylor, S	D3ET	4/9/2013		III	Tre	A Phase III Clinical Trial Evaluating DCVax®-L, Autologous Dendritic Cells Pulsed with Tumor Lysate Antigen for the Treatment of Glioblastoma Multiforme	Y		20	2	13	0	0	This is a high screen fail trial.
Janssen Previously Aragon	Prostate	NCT01946204	ARN-509-003	VanVeldhuizen, P	D3ET	7/2/2014	07/30/2015	III	Tre	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men with Non-Metastatic (M0) Castration-Resistant Prostate Cancer	Y		10	0	0	0	0	
ImpediMed Limited	Multiple	NCT02167659	L-DEX	Wagner, J	CPS	5/20/2015		Device	Sup	A Randomized Trial Evaluating Bioimpedance Spectroscopy Versus Tape Measurement in the Prevention of Lymphedema Following Locoregional Treatment for Breast Cancer	Y		100	42	42	0	0	
Acceleron	Liver	NCT02024087	A041-05	Williamson, S	D3ET	11/20/2014	02/15/2016	I/II	Tre	A Phase 1b, Open Label Study of Dalantercept plus Sorafenib in Patients with Advanced Hepatocellular Carcinoma	Y		10	3	3	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency
ArQule	Liver	NCT01755767	ARQ 197-A-U303	Williamson, S	D3ET	5/9/2013	01/15/2016	III	Tre	A Phase 3, Randomized, Double-Blind Study Of TIVANTINIB (ARQ 197) In Subjects With MET Diagnostic-High Inoperable Hepatocellular Carcinoma(HCC)Treated With One Prior Systemic Therapy	Y		10	1	4	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency
Bristol-Myers Squibb	Kidney	NCT02231749	CA209-214	Williamson, S	D3ET	6/17/2015	09/23/2015	III	Tre	A Phase 3, Randomized, Open-Label Study of Nivolumab Combined with Ipilimumab Versus Sunitinib Monotherapy in Subjects with Previously Untreated, Advanced or Metastatic Renal Cell Carcinoma (CheckMate 214, CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 214)	Y		10	1	1	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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The Rogosin Institute	Colorectal	NCT02046174	RI-MB-203	Williamson, S	D3ET	5/27/2015		II	Tre	A Phase IIb, Nonrandomized, Open-Label Trial with Mouse Renal Adenocarcinoma (RENCA) Cell Containing Agarose-Agarose Macrobeads Compared with Best Supportive Care in Patients with Treatment-Resistant, Metastatic Colorectal Carcinoma	Y		25	6	6	2	2	
Sotio a.s.	Prostate	NCT02111577	SP005	Williamson, S	D3ET	8/5/2015		III	Tre	A Randomized, Double Blind, Multicenter, Parallel-Group, Phase III Study to Evaluate Efficacy and Safety of DCVAC/PCa Versus Placebo in Men with Metastatic Castration Resistant Prostate Cancer Eligible for 1st Line Chemotherapy	Y		10	2	2	0	0	
Millenium Pharmaceuticals	Hodgkins Lymphoma	NCT01712490	C25003	Yacoub, A	D3ET	3/31/2014	08/07/2015	III	Tre	A Randomized, Open-label, Phase 3 Trial of A+AVD Versus ABVD as Frontline Therapy in Patients With Advanced Classical Hodgkin Lymphoma	Y		10	3	5	2	2	
Celgene	Non-Hodgkins Lymphoma	NCT02285062	CC-5013-DLC-002	Yacoub, A	D3ET	12/18/2015		III	Tre	Phase 3 randomized, double-blind, placebo controlled, multicenter study to compare the efficacy and safety of lenalidomide (CC-5013) plus R-CHOP chemotherapy (R2-CHOP) versus placebo plus R-CHOP Chemotherapy in subjects with previously untreated activated B-Cell type Diffuse Large B-Cell Lymphoma	Y		14	0	0	0	0	
Celgene	Non-Hodgkins Lymphoma	NCT01996865	CC-5013-NHL-008	Yacoub, A	D3ET	1/5/2015		III	Tre	A phase 3 randomized study of lenalidomide (CC-5013) plus rituximab maintenance therapy followed by lenalidomide single-agent maintenance versus rituximab maintenance in subjects with relapsed/refractory follicular, marginal zone or mantle cell lymphoma	Y		20	5	5	2	2	
Novartis Pharmaceuticals	Myelodysplastic Syndrome	NCT02159040	CICL670AUS47	Yacoub, A	D3ET	2/24/2015	08/07/2015	II	Tre	A 2-year, multi-center, Phase II, open-label, fixed-dose, randomized comparative trial of azacitidine, with or without deferasirox in patients with higher risk myelodysplastic syndromes	Y		10	0	0	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Interventional:

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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Gilead Sciences	Multiple	NCT02101268	GS-US-352-1214	Yacoub, A	D3ET	1/28/2015	01/12/2016	III	Tre	A Phase 3, Randomized Study to Evaluate the Efficacy of Momelotinib versus Best Available Therapy in Anemic or Thrombocytopenic Subjects with Primary Myelofibrosis, Post-polycythemia Vera Myelofibrosis, or Post-Essential Thrombocythemia Myelofibrosis who were Treated with Ruxolitinib	Y		5	4	4	0	0	
MEI Pharma	Myelodysplastic Syndrome	NCT01993641	MEI-005	Yacoub, A	D3ET	8/14/2014	01/08/2015	II	Tre	A Phase II Simon Two-Stage Study of the Addition of Pracinostat to a Hypomethylating Agent (HMA) in Patients with Myelodysplastic Syndrome (MDS) Who Have Failed to Respond or Maintain a Response to the HMA Alone	Y		7	0	1	0	0	
Janssen	Non-Hodgkins Lymphoma	NCT01974440	PCI-32765FLR3001	Yacoub, A	D3ET	11/17/2014	11/05/2015	III	Tre	A Randomized, Double-blind, Placebo-controlled Phase 3 Study of the Bruton's Tyrosine Kinase Inhibitor, PCI-32765 (Ibrutinib), in Combination with Either Bendamustine and Rituximab (BR) or Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (R-CHOP) in Subjects with Previously Treated Indolent Non-Hodgkin Lymphoma (iNHL)	Y		10	2	3	0	0	
Astex Pharmaceuticals	Myeloid and Monocytic Leukemia	NCT02348489	SGI-110-04	Yacoub, A	D3ET	8/18/2015		III	Tre	A Phase 3, Multicenter, Open-label, Randomized Study of SGI-110 versus Treatment Choice (TC) in Adults with Previously Untreated Acute myeloid Leukemia (AML) Who Are Not Considered Candidates for Intensive Remission Induction Chemotherapy	Y		8	3	3	0	0	
Seattle Genetics	Non-Hodgkins Lymphoma	NCT01777152	SGN35-014	Yacoub, A	D3ET	8/23/2013		III	Tre	A randomized, double-blind, placebo-controlled, phase 3 study of brentuximab vedotin and CHP (A+CHP) versus CHOP in the frontline treatment of patients with CD30-positive mature T-cell Lymphomas	Y		10	2	3	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Observational:

NATIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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GOG	Other Female Genital	NCT01500512	GOG 0270	Chapman, J	D3ET	3/21/2013	02/25/2015	N/A	Oth	GROningen INternational Study on Sentinel Nodes in Vulvar Cancer (GROINSS-V)II: An Observational Study	Y		6	0	1	0	0	
COG	Multiple	NCT01117168	ACCRN07	Hetherington, M	D3ET	4/8/2008		NA	Oth	Protocol for the Enrollment on the Official COG Registry, The Childhood Cancer Research Network (CCRN)	Y		N/A	80	507	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital; Site target enrollment is 200 per year.
COG	Multiple	NCT00736749	ALTE05N1	Hetherington, M	D3ET	6/17/2010		NA	Oth	Umbrella Long-Term Follow-up Protocol	Y		100	0	6	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT00772200	ALTE07C1	Hetherington, M	D3ET	4/2/2009		NA	Oth	Neuropsychological, social, emotional & behavioral outcomes in children with cancer	Y		20	1	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
NMDP	Other Hematopoietic	NCT01351545	10-CBA	McGuirk, J	D3ET	9/6/2011		N/A	Oth	A multicenter access and distribution protocol for unlicensed cryopreserved cord blood units (CBUs) for transplantation in pediatric and adult patients with hematologic malignancies and other indications	Y		N/A	8	40	0	0	
BMT CTN NIH	Other Hematopoietic	NCT02016781	BMT CTN 1102	McGuirk, J	D3ET	2/10/2014		N/A	Oth	A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Aged 50-75 with Intermediate-2 and High Risk Myelodysplastic Syndrome	Y		20	6	12	0	0	
BMT CTN	Multiple	NCT01879072	BMT CTN 1202	McGuirk, J	D3ET	8/27/2014		N/A	Oth	Prospective Multi-Cohort for the Evaluation of Biomarkers Predicting Risk of Complications and Mortality Following Allogeneic HCT	Y		80	0	10	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Observational:

INSTITUTIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
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Frontiers: HICTR	Brain and Nervous System		KUMC 12996	Choi, I	D3ET	12/21/2011		N/A	Oth	Metabolic Biomarkers of Brain Lesion Activity in Living Human Brain	N	30	30	3	19	0	0	
University of Kansas Cancer Center	Multiple		STUDY00002442	Geana, M	CCPH	09/25/2015	02/29/2016	N/A	Oth	Accrual for Cancer Clinical Trials - A Strategic Communication Campaign to Increase Knowledge and Chage Attitudes and Beliefs	Y	200	0	0	0	165	167	Recruitment occurred at sites affiliated with our primary insitution/Midwest Cancer Alliance members
Institutional	Multiple		TeleMed	Hall, N	D3ET	4/10/2015		NA	Oth	Outreach Medicine and the Role of Telemedicine in Pedatric Hematology Oncology	N	64	64	42	42	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Investigator	Colorectal		STUDY00001172	Hines, R	CCPH	8/7/2014	05/01/2015	Feasibility/Pilot	Oth	Pilot testing a patient questionnaire in colorectal cancer (CRC) patients	Y	100	100	4	4	37	43	
Investigator	Cancer Prevention		KUMC 11930	Martin, L	CCPH	9/8/2009		N/A	Oth	fMRI Studies of Decision-Making	N	96	96	0	107	0	0	Temporary suspension due to funding. Enrollment to resume in 2016
Investigator	Breast-Female		KUMC 12614	Sharma, P	CPS	3/22/2011		N/A	Oth	Prospective evaluation of GErmline mutations, Cancer outcome and Tissue biomarkers (P.R.O.G.E.C.T.): A registry for patients with triple negative breast cancer and germline mutations	Y	N/A	N/A	133	421	98	269	

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AO Spine North America	Non Cancer	NCT01825161	SPN-12-002	Arnold, P	D3ET	2/25/2014		N/A	Oth	The Epidemiology, Process and Outcomes of Spine Oncology (EPOSO)	Y		25	2	6	0	0	
Monteris Medical	Brain and Nervous System	NCT01651078	CPL00020-09	Chamoun, R	D3ET	12/17/2014	12/31/2015	N/A	Oth	LAASR: Laser Ablation After Stereotactic Radiosurgery	Y		5	2	2	0	0	
Prometheus Laboratories	Multiple	NCT01415167	10PLK13	Doolittle, G	D3ET	9/5/2012		N/A	Oth	Proleukin® Observational Registry to Evaluate the Treatment Patterns and Clinical Response in Malignancy	Y		60	12	52	0	0	
Novartis Pharmaceuticals	Non-Hodgkins Lymphoma	NCT02445222	CCTL019A2205B	McGuirk, J	D3ET	12/28/2015		N/A	Oth	Long Term Follow-Up of Patients Exposed to Lentiviral-Based CD19 directed CART Cell Therapy	Y		7	0	0	0	0	
DFINE, Inc	Ill-Defined Sites	NCT02419703	DF-15-03	Sayed, D	D3ET	10/29/2015		N/A	Oth	The STAR™ Tumor Ablation Registry	Y		50	2	2	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Ancillary/Correlative:

NATIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
COG	Lymphoma, Leukemia	NCT00897325	AALL05B1	Hetherington, M	D3ET	2/9/2007		NA	Oth	A Children's Oncology Group Protocol for Collecting and Banking Relapsed Acute Lymphoblastic Leukemia Research Specimens	Y		N/A	0	9	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Leukemia	NCT01142427	AALL08B1	Hetherington, M	D3ET	8/23/2010		N/A	Oth	Classification of Acute Lymphoblastic Leukemia	Y		115	32	126	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Leukemia	NCT00959283	AAML08B1	Hetherington, M	D3ET	8/10/2009		NA	Oth	Biology Study of Transient Myeloproliferative Disorder (TMD) in Children with Down Syndrome (DS)	Y		8	0	3	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT00898079	ABTR01B1	Hetherington, M	D3ET	3/9/2004		NA	Oth	A Children's Oncology Group Protocol for Collecting and Banking Pediatric Research Specimens Including Rare Pediatric Tumors	Y		100	6	26	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT00898755	ABTR04B1	Hetherington, M	D3ET	9/10/2007		NA	Oth	Establishing Continuous Cell Lines and Xenografts from Pediatric Cancers for Biological and Pre-Clinical Therapeutic Studies	Y		10	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT00919750	ACNS02B3	Hetherington, M	D3ET	7/21/2004		NA	Oth	A Children's Oncology Group Protocol for Collecting and Banking Pediatric Brain Tumor Research Specimens	Y		80	6	41	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Ewing Sarcoma	NCT00899990	AEWS07B1	Hetherington, M	D3ET	3/28/2008		NA	Oth	A Children's Oncology Group Protocol for Collecting and Banking Ewing Sarcoma Specimens	Y		40	1	13	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT00082745	ALTE03N1	Hetherington, M	D3ET	10/5/2004		NA	Oth	Key Adverse Events After Childhood Cancer	Y		50	1	16	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Lymphoma	NCT01793233	ALTE11C1	Hetherington, M	D3ET	8/15/2014		NA	Oth	Longitudinal Assessment of Ovarian Reserve in Adolescents with Lymphoma	Y		25	2	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT00904241	ANBL00B1	Hetherington, M	D3ET	9/1/2000		NA	Oth	Neuroblastoma Biology Studies	Y		250	7	76	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Lymphoma	NCT01000753	ANHL04B1	Hetherington, M	D3ET	10/20/2006		NA	Oth	Rare and Cutaneous Non-Hodgkin Lymphoma Registry	Y		5	0	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Sarcoma	NCT00899275	AOST06B1	Hetherington, M	D3ET	4/4/2008		NA	Oth	A Children's Oncology Group Protocol for Collecting and Banking Osteosarcoma Specimens	Y		25	1	9	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Ancillary/Correlative:

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Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
COG	Kidney	NCT00898365	AREN03B2	Hetherington, M	D3ET	6/14/2006		NA	Oth	Renal Tumors Classification, Biology and Banking Study	Y		100	1	39	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT00919269	D9902	Hetherington, M	D3ET	8/18/2000		NA	Oth	A Group Wide Protocol for Collecting and Banking Pediatric Cancer Research Specimens. A Intergroup Rhabdomyosarcoma Study Group Protocol.	Y		100	1	49	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Alliance for Clinical Trials in Oncology	Lung	NCT02194738	A151216	Huang, C	D3ET	5/6/2015		N/A	Oth	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)	Y		16	0	0	4	4	
ECOG CTSU	Breast-Female	NCT00433511	EL112LAB / E5103	Sharma, P	D3ET	9/17/2013		N/A	Oth	EL112LAB: North American Breast Cancer Groups Biospecimen Bank for Determinants of Late Relapse in Operable Breast Cancer	Y		15	1	7	0	0	
ECOG CTSU/SWOG	Breast-Female	NCT00310180	EL112LAB / PACCT-1	Sharma, P	D3ET	9/17/2013		N/A	Oth	EL112LAB: North American Breast Cancer Groups Biospecimen Bank for Determinants of Late Relapse in Operable Breast Cancer	Y		15	0	3	0	4	

EXTERNALLY PEER-REVIEWED												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH	Head and Neck		13-413	Lominska, C	D3ET	3/31/2015		N/A	Oth	UNDERSTANDING THE MECHANISM OF RADIOTHERAPY-INDUCED DENTITION BREAKDOWN	Y		50	7	7	0	0	
Myeloproliferative Disorders-Research Consortium	Myeloid and Monocytic Leukemia	NCT00665067	MPD-RC-107	Yacoub, A	D3ET	3/27/2015		N/A	Bas	Correlative Biomarker Study for MPD-RC Treatment Studies in the Philadelphia Chromosome Negative Myeloproliferative neoplasms	Y		30	25	25	0	0	

The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Report Prepared: 08/15/2016
Data Table 4 - Clinical Research Protocols

Ancillary/Correlative:

INSTITUTIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
The University of Kansas - Investigator	Unknown Sites	NCT01166776	KUMC 12129	Aljitawi, O	D3ET	6/25/2010		N/A	Bas	Decellurization of Umbilical Cord Whartons Jelly for Tissue Regenerative Applications Including Avascular Necrosis	N	65	65	9	57	0	0	
American Cancer Society	Leukemia		Ikaros	August, K	D3ET	11/21/2011		NA	Bas	Characterizing the expression pattern of the Ikaros family of transcription factors in T-ALL patients.	N	10	10	2	7	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
NCI	Breast-Female		KUMC 11513	Behbod, F	CPS	11/4/2008		N/A	Bas	The study of molecular and cellular basis for the invasive phenotype in human ductal carcinoma in situ	Y	600	600	28	388	55	161	
Midwest Cancer Alliance	Multiple		SID	Chastain, K	D3ET	3/11/2015		NA	Bas	Development of a novel drug screening system for pediatric solid tumors through a 'Sarcoma in a Dish' in vitro model	N	60	60	5	5	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Thomas Jefferson University	Multiple Sites		KUMC 12845	Drisko, J	D3ET	11/7/2011	09/11/2015	N/A	Bas	Evaluation of Intravenous Ascorbic Acid: Imaging with MRI-Spectroscopy	N	10	10	4	10	0	0	
KUCC Pilot Award	Colorectal		KUMC 13370	Greiner, A	CCPH	5/1/2013		N/A	Oth	A Translational Approach to Understanding African American Colorectal Cancer Health Disparities	N	40	40	20	39	0	0	
The Childrens Mercy Hospital	Leukemia		Guest Doxo	Guest, E	D3ET	3/5/2014		NA	Bas	Using doxorubicin as a target-therapeutic agent in pediatric acute leukemia	N	100	100	17	37	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Investigator	Multiple		Heme-2011-08-01	Kambhampati, S	D3ET	2/20/2012	02/09/2015	N/A	Bas	Down-regulation of complement regulatory protein expression as a new approach to increase efficacy of antibody therapy in low grade lymphoproliferative disorders.	N	60	60	0	71	0	0	Accrual goals were exceeded in Sept 2014. The PI was working on a protocol revision to include additional samples. Protocol never reopened to enrollment.
American Cancer Society	Lung		STUDY00000888	Pacheco, C	CCPH	11/1/2014	08/31/2015	N/A	Oth	American Indian Comprehension of Informed Consent and Trust of Medical Researchers	N	170	170	100	153	0	0	
Midwest Cancer Alliance / Alex's Lemonade Stand	Multiple		Exosomes	Samuel , G	D3ET	3/15/2013		NA	Bas	Pediatric Sarcoma Exosomes (Protocol has been approved - information sharing only)	N	N/A	25	2	20	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
Imago BioSciences Inc	Myeloid and Monocytic Leukemia		IMG-CTP-001	Lin, T	D3ET	8/17/2015		N/A	Bas	A Study of Minimal Residual Disease (MRD) after Standard-of-Care Induction in Patients with Acute Myeloid Leukemia (AML)	Y		8	3	3	0	0	

UNIVERSITY OF KANSAS CANCER CENTER
Reporting Date: 12/31/2015
Data Table 5 - Comparison of Current and Requested CCSG Budgets

CCSG Budget Category	Current Budget (direct costs)* 07/01/2016-06/30/2017	Requested Budget (direct costs)* 07/01/2017-06/30/2018
Professional Personnel		
Senior Leadership	464,228	244,331
Program Leaders	173,608	148,429
Administration	223,819	133,129
Planning & Evaluation	15,000	15,000
Shared Resources and Services		
Lead Development & Optimization Shared Resource	44,476	84,436
Biospecimen Shared Resource	50,114	99,601
Biostatistics & Informatics Shared Resource	133,147	179,090
Transgenic & Gene-Targeting Shared Resource		60,496
Clinical Pharmacology Shared Resource		75,908
Clinical Protocol and Data Management	83,833	99,879
Protocol Review and Monitoring System	36,049	37,122
Early Phase Clinical Research Support	-	37,699
Development Funds	175,726	324,880
Total Direct Costs	**1,400,000**	**1,540,000**

Overall – Other Attachments

Information on Consortium

Partner Institutions	
The University of Kansas Medical Center	3901 Rainbow Boulevard, Kansas City, Kansas, 66160
The University of Kansas	1450 Jayhawk Boulevard, Lawrence, Kansas, 66045
The University of Kansas Health System	3901 Rainbow Boulevard, Kansas City, Kansas, 66160
Stowers Institute for Medical Research	1000 E. 50th Street, Kansas City, Missouri, 64110
Children's Mercy Kansas City	2401 Gillham Road, Kansas City, Missouri, 64108

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Roy Middle Name A Last Name*: Jensen Suffix: MD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Pathology & Lab Medicine
Division: School of Medicine
Street1*: MS 3045, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-4700 Fax Number: 913-588-4701

E-Mail*: RJENSEN@kumc.edu

Credential, e.g., agency login: JENSENRA

Project Role*: PD/PI Other Project Role Category:

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Jensen_Bio_CCSG1019913951.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ○ Yes ● No

*Agency-Defined Phase III Clinical Trial? ○ Yes ○ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ● Yes ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

● Yes ○ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

☐ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator / Change of Institution Section

☐ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

☐ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	Overall_SpecificAims_Final1019799885.pdf
3. Research Strategy*	Dir_Over_Six_Ess_ResearchStrategy_final1020031040.pdf
4. Progress Report Publication List	Progress_Report_Publications_Overall1019799902.pdf
Human Subjects Section	
5. Protection of Human Subjects	Protection_of_Human_Subjects__OVERALL1019799890.pdf
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	Inclusion_of_Women_Minorities__OVERALL1019799891.pdf
8. Inclusion of Children	Inclusion_of_Children_OVERALL1019799892.pdf
Other Research Plan Section	
9. Vertebrate Animals	Vertebrate_Animals___OVERALL1019913925.pdf
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	Overall_LettersofSupport1019974045.pdf
14. Resource Sharing Plan(s)	Resource_Sharing_Plan_OVERALL1019799889.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

Overall – Specific Aims

Since designation as an NCI Cancer Center in 2012, KUCC leadership has carefully considered the needs of the catchment area and consulted membership, patients, key stakeholders and institutional leaders in developing a vision for the growth, development and transformation of KUCC into a leading cancer research and treatment organization worthy of NCI Comprehensive Cancer Center designation. Therefore, KUCC aims to:

- Leverage our collective state-of-the-art basic, clinical, translational and population research programs to understand cancer at a fundamental level and catalyze a comprehensive, multidisciplinary approach to defeating cancer locally, regionally, nationally and globally;
- Develop, promote and implement a cancer center culture whose highest priority is to foster the discovery and advancement of new and more effective therapeutic approaches for the benefit of its patients;
- Discover and develop paradigm changing therapeutic advances delivered in a compassionate, caring and cost-effective manner resulting in improved survival and quality of life for our patients;
- Proactively execute cancer prevention and control strategies to mitigate the increase in cancer incidence and mortality predicted for the twenty-first century;
- Train the next generation of leaders in cancer research, clinical care and advocacy; and
- Lead the effort to reduce the burden of cancer in our region and serve as a national model in doing so.

This vision guides KUCC forward and throughout this application many examples of our progress in implementing the vision will be demonstrated.

Part I: Director's Overview

History and Overview

The University of Kansas Cancer Center (KUCC) received National Cancer Institute (NCI) cancer center designation in July 2012, as a result of an expansive university, community and regional effort that began in earnest in July 2004. In conjunction with its consortium partner, the Stowers Institute for Medical Research, KUCC was rightfully proud of this achievement, but immediately set about planning to achieve comprehensive status at the next competitive renewal. In fact, KUCC's famous "countdown clock" was reset for September 26, 2016 on the day following the announcement by then Secretary of Health and Human Services, Kathleen Sebelius, that we had achieved designation. It should be noted, that her announcement was especially meaningful to us, since it was then Governor Sebelius of Kansas who had first put KUCC on the launching pad towards designation with a $5M annual state appropriation in 2007. This appropriation has been renewed each year since by a broad political spectrum of Kansas governors and legislators and continues to be a critical source of unrestricted funds for KUCC.

The drive for NCI designation was part of a deliberate strategy by then Dean Barbara Atkinson to initiate a renaissance at the University of Kansas Medical Center (KUMC) when she was appointed in 2002. Dean Atkinson quickly established cancer as the number one priority of KUMC, and commenced a national search for a full-time director of what was then known as the Kansas Cancer Institute. In 2004, she appointed Roy A. **Jensen**, MD, as director, a nationally recognized breast cancer researcher and pathologist from Vanderbilt-Ingram Comprehensive Cancer Center.

Since his appointment, **Jensen** has received unprecedented institutional, community and state support to build a world-class cancer center for the region. In 2006, former Chancellor Robert Hemenway declared that attaining NCI designation for KUCC was the number one priority of the entire University. This declaration helped catalyze a significant expansion of the research and clinical programs at KUCC and KUMC in general. In fact, since 2004, KUMC has more than doubled its faculty and Kansas has experienced one of the largest percentage increases in NIH funding of any state in the country, largely due to the NIH portfolio of KUMC. In 2009, for the first time in its history, KUMC passed the $100M mark for total research funding. Community support from the Kansas Masonic Foundation, now totaling more than $30M, solidified the research component of the Cancer Center, which was renamed the Kansas Masonic Cancer Research Institute (KMCRI). In 2007, the commitment to further grow the KMCRI was bolstered by then Governor Kathleen Sebelius and the Kansas Legislature who made a $5M appropriation to the KMCRI that has continued since that time. 2007 also marked the year in which **Jensen** brokered a new affiliation agreement between the University and The University of Kansas Health System that brought the cancer research (KMCRI) and cancer clinical programs together as **The University of Kansas Cancer Center (KUCC)**, with **Jensen** as the director. In August 2009, Bernadette Gray-Little was appointed Chancellor and reiterated the commitment to NCI designation, declaring it the University's number one research priority. With the achievement of designation as a cancer center in 2012, this goal has been transformed to achieving designation as an NCI Comprehensive Cancer Center.

Establishment of a Vision for The University of Kansas Cancer Center

Since designation, KUCC leadership has carefully considered the needs of the catchment area and consulted membership, patients, key stakeholders and institutional leaders in developing a vision for the growth, development and transformation of KUCC into a leading cancer research and treatment organization worthy of NCI Comprehensive Cancer Center designation. Therefore, KUCC resolves to:

- Leverage our collective state-of-the-art basic, clinical, translational and population research programs to understand cancer at a fundamental level and catalyze a comprehensive, multidisciplinary approach to defeating cancer locally, regionally, nationally and globally;
- Develop, promote and implement a cancer center culture whose highest priority is to foster the discovery and advancement of new and more effective therapeutic approaches for the benefit of its patients;
- Discover and develop paradigm changing therapeutic advances delivered in a compassionate, caring and cost-effective manner resulting in improved survival and quality of life for our patients;

- Proactively execute cancer prevention and control strategies to mitigate the increase in cancer incidence and mortality predicted for the twenty-first century;
- Train the next generation of leaders in cancer research, clinical care and advocacy; and
- Lead the effort to reduce the burden of cancer in our region and serve as a national model in doing so.

This vision guides KUCC forward and throughout this application many examples of our progress in implementing the vision will be demonstrated.

In 2004, upon **Jensen's** arrival, the KMCRI had a total of $23M in total cancer-related research funding, of which $4.9M was from the NCI. Under **Jensen**'s leadership, KUCC currently has 187 members that have garnered $61.2M in total overall cancer-related funding, of which $13.4M is from the NCI. KUCC operates as a matrix-organization facilitating horizontal and vertical integration that includes: the KUMC campuses in Kansas City, Wichita and Salina, the University of Kansas in Lawrence (KU-Lawrence) and its #8 ranked School of Pharmacy (per NIH funding), The University of Kansas Health System and (via consortium agreements) the Stowers Institute for Medical Research and Children's Mercy. The cancer research capabilities fueled by Cancer Center faculty grants, contracts and institutional resources led to the development of four research programs and five shared resources (**Table 1**).

Table 1. KUCC Research Programs and Shared Resources

KUCC Research Programs	KUCC Shared Resources
Cancer Biology (CB)	Biospecimen (BSR)
Cancer Control and Population Health (CCPH)	Biostatistics and Informatics (BISR)
Cancer Prevention and Survivorship (CPS)	Clinical Pharmacology (CPSR)
Drug Discovery, Delivery and Experimental Therapeutics (D3ET)	Lead Development and Optimization (LDOSR)
	Transgenic and Gene-Targeting (TGTSR)

KUCC has well-recognized national expertise and critically important, distinguishing assets in three areas that differentiate KUCC from other cancer centers. KUCC has used these assets (listed below) to build an exciting and dynamic cancer research center poised to make major contributions to the fight against cancer.

- Innovative Drug Discovery and Development Capabilities
- Stowers Institute for Medical Research
- Access to Neglected, Critically Underserved Populations (Rural America, Children and Native Americans)

Innovative Drug Discovery and Development Capabilities
KUCC strategically aims to build a dynamic environment for the development and advancement of promising new drug therapies to cancer patients. Critical to this pursuit was the establishment of key competencies and capabilities that translate cancer research insights into validated cancer drug targets, and the discovery and optimization of new therapeutic agents. In addition, KUCC recognizes that streamlining the advancement of new drug therapies through the early drug development process into clinical trials is critical to KUCC's success. Furthermore, discovering, delivering and advancing new drug therapies requires expertise from a broad range of scientific disciplines including cell biology, biochemistry, medicinal chemistry, physical chemistry, structural biology, drug metabolism, bioanalytical chemistry, pharmacokinetics, pharmacogenomics, pharmacogenetics, biostatistics, bioinformatics, cancer biology, clinical research and regulatory science. Therefore, **Jensen** and the KUCC leadership team had the forethought to partner with 1) the University of Kansas in Lawrence recognizing its rich history of medicinal and pharmaceutical chemistry research conducted by the faculty within the School of Pharmacy; 2) Stowers and its world class cancer biology research; and most recently 3) Children's Mercy and its pediatric clinical pharmacology program. Leveraging each institution's resources and faculty expertise, KUCC is uniquely positioned to accomplish each step along the drug discovery and development continuum.

Development of new therapies, especially in the era of targeted treatments and personalized medicine, is driven by understanding the underlying cell biology, molecular biology and biochemistry of tumor cells and their surrounding microenvironments. Therefore, the goals and objectives of the KUCC Cancer Biology (CB) research program are to understand the molecular mechanisms that define normal and neoplastic cell growth in order to identify and characterize molecules, pathways and processes that are involved in tumor growth and

progression which can serve as useful biomarkers or as new cellular targets for cancer therapy. The CB program is positioned to be a major stimulus for discoveries that feed into KUCC's drug discovery and development pipeline.

To assist KUCC investigators in translating their basic cancer discoveries and to guide the drug development continuum, KUCC developed the Lead Development and Optimization shared resource (LDOSR). The LDOSR provides faculty access to expertise in target identification and validation, screening compounds, preclinical candidate development, drug delivery and preclinical proof of concept animal studies. Lead chemical candidates are selected, evaluated and optimized for *in vivo*, nonclinical proof of concept studies. Over the course of the last year these activities have been further enhanced by formation of the Target Acceleration Group, a multidisciplinary team of experts that drive developmental therapeutic projects across KUCC.

To provide the final component needed to achieve translation from bench to bedside, KUCC gained support from Johnson County, Kansas voters during the November 2008 election to establish the Johnson County Education and Research Triangle (JCERT) tax, a 1/8th cent sales tax that generates over $5M annually. The JCERT tax has no sunset provision and revenue from this tax supported the establishment of the University of Kansas Clinical Research Center (KU CRC). The KU CRC opened in January 2012 and houses KUCC's cancer clinical research infrastructure and the Midwest Cancer Alliance. The JCERT tax enhances KUCC's ability to attract world-class researchers and to develop new and innovative approaches to prevent and treat cancer. It also ensures maintenance of the facilities for clinical research. **Jensen** developed the idea for this facility, worked with the legislature to enact enabling legislation and led the public campaign for passage of the ballot initiative. This state-of-the-art facility is described in Essential Characteristics – Physical Space.

As a result of strong intra- and inter-programmatic interactions, and the utilization of KUCC's shared resources, the KUCC portfolio of innovative drug discovery and development projects has expanded exponentially under the leadership of **Jensen** and Associate Director for Translational Research, Scott **Weir**, (listed below). These projects span the continuum of the drug discovery, delivery and development resources brought together by KUCC. By January 2017, KUCC will have advanced 15 new cancer therapies into the clinic.

KUCC Portfolio of Innovative Drug Discovery and Development Projects

- Nanotax® - Trial initiated → 2008; Study Published → 2015
- Ciclopirox Olamine - Trial initiated → 2009; Study Published → 2014
- Melphalan Captisol® - Trial initiated → 2009; Study Published → 2014
- 6-Mercaptopurine - Trial initiated → 2011; Manuscript Submitted → 2015
- Tigecycline - Trial initiated → 2011; Manuscript In Preparation → 2015
- Auranofin - Trial initiated → 2011; Enrollment Complete
- Nicotinamide - Trial initiated → 2014; NCT02558595 Initiated
- Niacinamide - Trial initiated → 2015; Enrolling
- CB-5083 - Trial initiated → 2014; Enrolling
- Ethacrynic Acid - Trial initiated → 2016; Enrolling
- Pyrimethamine - FDA review in process; Trial initiation planned Fall 2016
- Daunorubicin - Trial initiation planned Fall 2016
- Ciclopirox Prodrug - IND submission planned; Protocol design in progress
- MSCTC-00100 - Pre-IND meeting with FDA complete; IND submission planned 1Q 2017
- Metarrestin - NExT proposal; Protocol design in progress

Stowers Institute for Medical Research

In October 2009, The University of Kansas and Stowers reached an agreement to support cancer investigators and develop a joint cancer research agenda. Both institutions realized and valued the benefits to be obtained from a formal scientific collaboration and in 2015 the consortium agreement was renewed. Stowers is an independent, freestanding research institution founded by the late Jim, and Virginia Stowers. Mr. and Mrs. Stowers were motivated to found Stowers by a combination of their own experiences surviving cancer (prostate and breast, respectively) and their desire to give future generations better choices for treatment in the face of serious illness. Jim and Virginia Stowers endowed the Institute with gifts totaling over $2B. Eleven Stowers scientists are members of the KUCC Cancer Biology research program and have KUMC faculty appointments.

Cancer-related NIH funding (non-NCI) awarded to Stowers totals about $1M annually. Regarding other funding, Stowers investigator Scott **Hawley**, PhD holds an American Cancer Society Professorship and is a member of the National Academy of Sciences. Stowers' scientists have leadership roles within KUCC; for example, Linheng **Li**, PhD is co-leader of the Cancer Biology research program. Additionally, several of the Stowers scientists have taught in a KUMC graduate course on Cancer Biology (**Hawley**, **Li**, **Baumann**) and several PhD students in the Stowers graduate program have taken the KU School of Medicine graduate Cancer Biology course. Last but not least, Stowers scientists have assisted in KUCC investigator recruitment, providing the KUCC Director with essential feedback on the quality of the candidates. Stowers specifically played a major role in the recruitment of Danny **Welch** as the Associate Director for Basic Science and Education and Tom **Curran** as the new director of the Children's Research Institute at Children's Mercy.

Collaborative research efforts between KUCC members at KUMC and Stowers have resulted in a number of significant publications. One study, a joint effort between Cancer Biology program members, **Ding** (CB) at KUMC and **Li** (CB) at Stowers, described how the Dlk1-Gtl2 locus preserves LT-HSC function by inhibiting the PI3K-mTOR pathway to restrict mitochondrial metabolism (Qian, *Cell Stem Cell,* 2016). Another study, between **Workman** (CB) at Stowers and **Dutta** (D3ET) at KU-Lawrence, described how the histone acetyltransferase Enok regulates oocyte polarization by promoting expression of the actin nucleation factor spire (Huang, *Genes & Development*, 2014).

Critically Underserved Populations

In the KUCC catchment area, which includes 105 counties in Kansas and 18 counties in Western Missouri, it is estimated that over 22,000 people will be diagnosed with cancer, and more than 8,500 people will die from cancer in 2016. Cancer causes ~15 deaths per day in both Kansas and Western Missouri, and accounts for approximately 22% of all deaths. Cancer is the leading cause of death in Kansas and this has been the case since 2010. The KUCC vision consists of not only achieving research excellence and delivering advanced care in the Kansas City metro area, but also ensuring that cancer patients across the state and region have access to cutting-edge clinical trials and cancer care close to home. Many Kansas residents, whether they lived in the urban areas of Kansas City and Wichita, or the sparsely populated counties of western Kansas, often had to drive several hundred miles to access the nearest NCI designated cancer center (**Figure 1**) prior to our designation in 2012. In a state covering over 92,000 square miles with only four tertiary care hospitals (Kansas City-1, Topeka-1 and Wichita-2) it is difficult to deliver primary care to the entire population, let alone provide sophisticated cancer care. Despite these challenges, in 2015 KUCC's academic clinical program extended care to over 3,900 new cancer patients and placed 457 patients on therapeutic clinical trials, representing 9% of the index cancer cases.

Figure 1

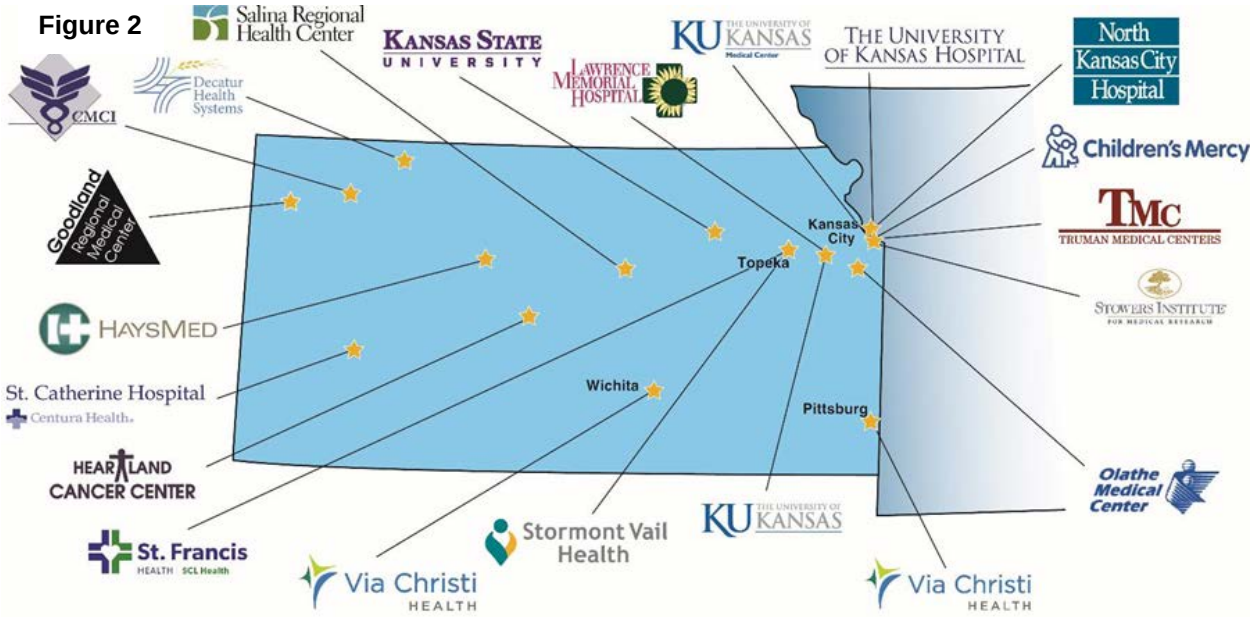
Kansas also has a surprisingly diverse population including a rapidly growing Hispanic community, African-American urban poor, significant Native American communities (four reservations), immigrant Asian populations associated with the meatpacking industry and elderly rural whites. KUCC is committed to addressing the

challenges and meeting the needs of these populations and other underserved minorities, indeed KUCC believes the strong relationship to these communities is a differentiating asset. With the addition of Children's Mercy as a consortium partner, KUCC now has direct access to over 95% of the childhood cancer cases that occur within the catchment area and a greatly increased capacity to impact cancer prevention initiatives such as the regional effort to increase HPV vaccination.

The KUCC Cancer Control and Population Health (CCPH) research program was developed explicitly to identify better ways to bring cancer control efforts into high risk and underserved communities. Specifically, the CCPH research program brings together an interdisciplinary team of researchers focused on 1) identifying new strategies to improve smoking cessation and enhancing the capability of clinical systems to deliver proven smoking cessation services, and 2) advancing the science of translating cancer control into communities and clinical practice, with a particular emphasis on addressing the translational research needs of the underserved in our catchment area. Since the creation of the CCPH research program, KUCC members have made remarkable progress in developing the infrastructure to conduct cancer control research in underserved, regional rural, American Indian, African American and Latino communities as witnessed by their impressive accrual of underserved populations to cancer control trials.

As the only academically-based clinical and basic cancer research center in the region, KUCC is the only institution capable of serving as an NCI-designated cancer center for Kansas and western Missouri and meeting the needs of diverse underserved populations. To address specific population-based needs, KUCC utilizes two established programs. The first is the Midwest Cancer Alliance (MCA), which was created in 2007 as a network of regional hospitals to ensure the latest clinical discoveries were extended to patients throughout the region. The MCA members include those institutions depicted in the map (**Figure 2**). This past year, the scope of the MCA has been significantly expanded by the incorporation of the Kansas Patients and Providers Engaged in Prevention Research (KPPEPR). This network of over 75 primary care practices across the state of Kansas has a longstanding history of supporting cancer prevention and control research initiatives and will greatly expand our ability to conduct trials and implementation research focused at the level of the primary care practitioner. The second is the Community Partnership for Health (CPH) program, a component of the Clinical and Translational Science Award that supports Frontiers: The Heartland Institute for Clinical and Translational Research at KUMC. The CPH program has considerable reach in the Kansas City region and across Kansas through many practice and research networks. CPH also has investigators experienced with working in and with diverse communities available for consultation and collaboration with KUCC members. Simultaneously developing KUCC and Frontiers has been a coordinated effort to maximize benefit, facilitate shared resources and avoid unnecessary duplication. KUCC and Frontiers leadership see mutual value in both the KUCC MCA and the Frontiers CPH program sharing these respective resources and having a common leadership: The MCA director sits on the CPH Community Council and the CPH director (**Greiner**) is an accomplished investigator in the CCPH program and is the principal investigator of a newly awarded NCI R01 (R01CA188898).

Figure 2



To fully leverage the patient perspective and KUCC's critically underserved populations **Maliski** and other KUCC members are working to develop an initiative known as PIVOT: Patient and Investigator Voices Organizing Together. PIVOT is an evolving community of patient research advocates learning and working with academic research stakeholders to enhance research to more effectively address patients' needs and desired outcomes. PIVOT aims to engage patients, caregivers and communities to inform, collaborate, support and shape cancer research to optimally reflect what is important to patients. The PIVOT initiative expands on KUCC's mission to empower patients, reach underserved communities and advance quality cancer research and care. PIVOT will ultimately provide resources to expand KUCC's focus on patient-centered research and care by offering an engagement venue and framework encouraging a culture that welcomes diverse patient perspectives and experiences.

Given the above historical overview and a strong commitment to serve Kansas and western Missouri, the specific goals of KUCC, significant administrative highlights and research accomplishments leading up to the submission of this competitive renewal are presented below.

Development of The University of Kansas Cancer Center (Highlights and Accomplishments)
Over the last four years substantial progress has been made garnering institutional commitment, recruiting key leadership positions, building nationally significant research programs, developing KUCC's clinical research program, improving and expanding facilities and fostering transdisciplinary and collaborative interactions. With input from KUCC membership and approval by the KUCC leadership and External Advisory Board, KUCC established three central goals that will ensure KUCC makes a national impact in the fight against cancer and improve the lives of cancer patients and their families:

- **Goal 1**: Become a leading academic institution for transforming discoveries from the laboratory into new anticancer drug therapies. This will be achieved through effective collaborative partnerships with academia, industry, government and disease philanthropy organizations and by advancing new therapeutics into Phase I clinical trials.

- **Goal 2**: Provide an optimal environment for basic, translational, clinical, and population-based research in oncology by developing and fostering a collaborative, collegial and dynamic culture of scientific inquiry supported by outstanding nationally-recognized cancer research programs and high quality investigator-focused, customer-friendly shared resources utilizing the latest technology.

- **Goal 3**: Be a nationally recognized leader in partnering with community oncologists and other key stakeholders to develop, promote and foster the adoption and implementation of evidence-based cancer prevention, diagnosis, treatment, control and survivorship practices throughout our service area.

Strengthening the KUCC Leadership Team
Since the arrival of **Jensen** in 2004, the KUCC leadership team has been built to leverage a group of exceptional scientists and leaders. Each of these leaders has proven to be an outstanding addition to the team and all have played key roles in developing and implementing the KUCC vision and continued recruitment of additional faculty. The KUCC leadership team includes three new additions since our initial designation (listed chronologically):

2012
Andrew **Godwin**, PhD, Deputy Director, was promoted from Associate Director for Translational Research-Correlative Science in 2012. He also holds the title of Director, Molecular Oncology, Director, Biospecimen Shared Resource and Chancellor's Distinguished Chair in Biomedical Sciences Endowed Professor. **Godwin**, an NCI-funded scientist, was recruited in 2010 from Fox Chase Cancer Center (FCCC) in Philadelphia, PA where he held several leadership positions including: 1) Co-leader of the Women's Cancer Program, 2) Director, Clinical Molecular Genetics Laboratory, 3) Director, Biosample Repository, 4) Co-principal investigator of the FCCC-University of Pennsylvania NCI-supported Ovarian Cancer SPORE (Specialized Program of Research Excellence) and 5) Associate Director of the NCI-funded Early Detection Research Network Clinical Validation Center programs at FCCC. He has a research program that focuses on translational oncology research and is a highly published (>350 manuscripts) and cited (nearly 30,000) scientist.

2016
Carol **Fabian**, MD, Associate Director for Clinical Research, was promoted from co-leader of the Cancer Prevention and Survivorship Program in 2016 following the departure of Parvesh Kumar, MD who left to become the founding director of the cancer center at the University of Nevada-Las Vegas. **Fabian** is a breast medical oncologist who enjoys an international reputation in translational research in breast oncology. She has served on multiple study sections, is past chair of the American Society of Clinical Oncology's Prevention Committee, serves on editorial boards of multiple journals and for the past six years has led the Southwest Oncology Group's Cancer Survivorship Committee. **Fabian** is highly regarded as a clinician and was instrumental in bringing the multidisciplinary outpatient cancer treatment center to the University of Kansas. **Fabian** has received many accolades and awards during her long career at KUCC including the University Distinguished Professor Award. She is widely acknowledged to be one of the most notable clinical and translational investigators in the history of the University of Kansas Medical Center.

Sally **Maliski**, RN, PhD, FAAN, Associate Director for Health Equity, was recruited from the University of California, Los Angeles to be the Dean of the School of Nursing and to oversee cancer disparities and health equity research and outreach efforts for the Cancer Center. **Maliski** has had a distinguished career focusing on cancer disparities in the Hispanic community particularly as it relates to men with prostate cancer. Since her arrival in early 2016, she has been working to develop a comprehensive program that will identify, implement and fund research that is critical to reducing cancer-related health disparities; work to ensure that health disparities are addressed at the levels of basic discovery, clinical trials and community engagement; engage with communities to ensure that the cancer-related interests and needs of underrepresented populations are identified and addressed; develop specific, targeted research interventions in collaboration with those in underserved populations to reduce cancer disparities; facilitate partnerships with community and health care organizations such as safety net clinics, hospitals and the MCA to promote early detection screening, education and cancer prevention strategies; and coordinate efforts across programs to increase recruitment of underrepresented populations into cancer research.

The Institute for Advancing Medical Innovation (IAMI)
In 2006, KUCC invested $300,000 to create the Office of Therapeutics, Drug Discovery and Development (OTDD). OTDD quickly established innovative drug discovery, development and translational research best practices and initiated multiple developmental therapeutics projects focused on cancer. Through novel partnerships with industry, academia, government and disease philanthropy partners, OTDD was successful in advancing several new cancer treatments to patients from 2006-2008. Leveraging these successes, KUCC was awarded an $8.1M grant by the Ewing Marion Kauffman Foundation in January 2009, along with an $8.0M matched investment made by the KU Endowment Association to expand the OTDD to create The Institute for Advancing Medical Innovation (IAMI). IAMI is a nationally recognized proof of concept center focused on transforming basic research into new drug therapies, diagnostics and medical devices, and then translating those medical innovations to patients. IAMI enabled KUCC to recruit additional pharmaceutical industry experts to further enhance the D3ET research program, and expand its capacity to support drug discovery, delivery and experimental therapeutics efforts across the entire Cancer Center. IAMI relies on an Industry Advisory Board to select high-potential projects based on laboratory and bedside discoveries made by KUCC members. Product development-focused investments are made to support execution of project plans by empowered, multidisciplinary, multi-organizational project teams co-led by KUCC members and an IAMI project manager. KUCC’s investment in translational research is further leveraged by the institution, as IAMI is also positioned as one of the key differentiators in the Frontiers CTSA application. To date, IAMI has invested >$8.1M in 48 drug, diagnostic and medical device projects. Nine investments have resulted in royalty-bearing license agreements and one drug product, Epaned™, has been approved. IAMI's therapeutic areas of focus are cancer and rare diseases. To date, IAMI has invested $2.8M in 15 cancer projects. IAMI is recognized nationally for its product development-focused translational research methods and processes, including its successful partnerships such as The Learning Collaborative (IAMI, NCATS, The Leukemia and Lymphoma Society) and Sarcoma Learning Collaborative (IAMI, NCATS, Children's Mercy). Furthermore, KUCC is leveraging the "learnings" from these partnerships to establish collaborations with other NCI Cancer Centers including Kentucky, New Mexico, Iowa and Washington University in St. Louis.

Recent Major Scientific Accomplishments
Major scientific accomplishments of KUCC and how each relate to KUCC's overall vision are presented below:

Leverage our collective state-of-the-art basic, clinical, translational and population research programs to understand cancer at a fundamental level and catalyze a comprehensive, multidisciplinary approach to defeating cancer locally, regionally, nationally and globally.
KUCC is proud of the fact that two D3ET members (**Middaugh** and **Volkin**) were responsible for the development of the Gardasil HPV vaccines while employed at Merck. This achievement represents one of the most important advances in cancer prevention of the last 50 years and has the potential to prevent over 30,000 cases of HPV-related cancer in the US alone. It is therefore quite ironic that in 2013, Kansas was identified as having the lowest HPV vaccination rate in the country. This stunning and embarrassing finding led to an immediate call by KUCC leadership to develop a comprehensive response to this critical issue. Initially, KUCC recruited new faculty to the CCPH program (**Myers** and **Ault**) and developed an HPV immunization action team that aims to a) enhance the understanding of the problem; b) raise community awareness of the issue; and c) foster research that could help address the problem. CCPH members **Ellerbeck** and **Cupertino** are working with the Kansas Department of Health and Environment (KDHE) and the Immunize Kansas Coalition to identify research needs specific to the KUCC catchment area. Additionally, a new data-use agreement with the KDHE allowed CCPH members to analyze and present HPV immunizations by middle school catchment area and highlight the importance of linking HPV immunization to the required 7th grade TDAP immunization. With the support of Patient-Centered Outcomes Research Institute (PCORI) and KUCC pilot funds, these data are now being used to work with and engage pediatricians, school nurses and public health professionals in both Kansas and Missouri to lay out the critical groundwork needed for HPV vaccine implementation research. KUCC will and must do better and has developed a plan to do so. The results of these efforts should be available by early next year.

Develop, promote and implement a cancer center culture whose highest priority is to foster the discovery and advancement of new and more effective therapeutic approaches for the benefit of its patients.
A multidisciplinary, multi-organizational team of basic, translational and clinical scientists co-led by **Li** (CB) and Melinda Broward (LDOSR Project Director), have advanced a laboratory discovery generated at Stowers to a clinical proof of concept trial in acute myeloid leukemia for both adult and pediatric patients. Loss of the PTEN tumor suppressor activates the PI3K-AKT pathway. If Wnt signaling is abnormally activated at the same time, β-catenin is then phosphorylated by Akt at the c-terminal serine 552. **Li** demonstrated that serine 552 phosphorylation is critical to the successful interaction between Akt and β-catenin (Perry, *Genes Dev*, 2011). This successful interaction induces proliferation of leukemia stem cells. **Roy** (D3ET) identified through high throughput screening that anthracyclines inhibit cooperation between Akt and β-catenin *in vitro.* **Li** established *in vivo* proof of principle, demonstrating that anthracyclines administered at 1/40th the cytotoxic dose, depleted leukemia initiating LSCs in a validated mouse model. **Lin** (D3ET) and **Li** established that the target, i.e., phosphorylated serine 552, was present in 6/10 AML patients, 5/10 B-ALL patients and 7/10 T-ALL patients. As a result, **Lin** and **Perez** (D3ET) have initiated a hypothesis-driven investigator-initiated clinical trial that is enrolling AML and ALL patients to evaluate low-dose daunorubicin as an inhibitor of β-catenin S552 phosphorylation.

Discover and develop paradigm changing therapeutic advances delivered in a compassionate, caring and cost-effective manner resulting in improved survival and quality of life for our patients.
Weir (D3ET) and **Anant** (CPS) discovered and developed Ciclopirox Prodrug (CPX-POM), a potential breakthrough treatment in the management of high-grade non-muscle invasive bladder cancer NMIBC (Issued US Patent 8609637). Ciclopirox (CPX) possesses anti-cancer activity against NMIBC *in vitro* and *in vivo* via novel mechanisms of action. In contrast to current standard of care treatment, the patented prodrug CPX-POM delivers the CPX to the entire urinary tract. CPX acts as an anti-cancer agent, in part, by inhibiting the Notch signaling pathway via inhibition of the γ-secretase complex. In collaboration with John Taylor (UConn Health Sciences), the team demonstrated that systemic administration of CPX-POM delivers bioactive concentrations of CPX to the urinary tract, resulting in decreased tumor size, migration to lower stage tumors, and reduction in downstream Notch signaling pathway proteins *in vivo*. The LDOSR, under the leadership of **Baltezor** (D3ET), provided drug synthesis, formulation development, preclinical safety and pharmacokinetic support. CPX-POM has been licensed to a local biotechnology firm, CicloMed LLC. KUCC is partnering with CicloMed to advance

CPX- POM to clinical proof of concept, with Eugene **Lee** (CB) evaluating this agent in patients beginning early 2017. The LDOSR and Clinical Pharmacology Shared Resource (**Reed**, D3ET) support drug development efforts sponsored by CicloMed. In response to the 2012 CCSG critique, CPX-POM represents the first KU-invented anti-cancer agent advanced from the bench to the bedside at KUCC. CPX-POM will represent one of the first new agents directed against NMIBC in decades.

Proactively execute cancer prevention and control strategies to mitigate the increase in cancer incidence and mortality predicted for the twenty-first century.
African Americans (AA) smoke fewer cigarettes per day than the general population, but experience disproportionately greater smoking attributable morbidity and mortality. CCPH members (**Faseru**, **Nollen**, **Cox**) along with collaborators across the country (J. Ahluwalia (University of Minnesota Medical School), N. Benowitz (UCSF), and R. Tyndale (University of Toronto)) are leading efforts to understand the interplay of biology, behavior and pharmacology as it relates to smoking cessation among AAs. Together, this team has received federal funding (NIH or PCORI) for seven clinical trials, enrolled more than 3,000 AA smokers and published more than 50 articles, including work supporting a report to the FDA on the hazards of menthol in tobacco products. **Cox** and **Nollen** are currently leading efforts to address the harms of 'light' and non-daily smoking among AA smokers and testing new treatment strategies (**Cox**, *J National Cancer Institute*, 2012). With important implications for the FDA and regulation of cigarette additives, they extended their prior work to show that menthol is a deterrent to successful cessation, even among light smokers. This work has helped to provide the scientific foundation for the recent FDA proposal to ban menthol and all other flavors in tobacco products currently under review.

Train the next generation of leaders in cancer research, clinical care and advocacy.
In 2015, **Welch** and **Jensen** led a national effort to help define the education criteria for CCSG institutions (**Welch**, *Cancer Res,* 2015). This initiative played a critical role in the planning and implementation of KUCC cancer educational efforts. Since NCI-designation, KUCC has greatly expanded its educational initiatives and currently provides formal and informal training in both professional skills as well as career development for faculty and staff. In addition to a weekly CME-accruing seminar series, which features internal and external speakers representing all research programs, in 2016, the University of Kansas Board of Regents approved a new graduate (MS and PhD) program in Cancer Biology, which provides foundational knowledge to graduate students and postdoctoral fellows on all campuses using state-of-the-art video conferencing. Faculty members have been active in working with students to secure F-series grants and two T32 in chemical biology and pharmaceutical aspects of biotechnology. Over the last grant period, KUCC increased it's funding of training grant awards from $1.3M to $2.4M.

Lead the effort to reduce the burden of cancer in our region and serve as a national model in doing so.
KUCC has been very effective in developing, advocating for and obtaining passage of important public policy measures that will have a significant impact on cancer incidence and mortality in our region. Examples of these efforts are listed below.

- Played a key role in convincing the state of Kansas to pass a strong Clean Indoor Air bill that prohibits smoking in public places;
- Obtained a regulatory ruling from the Office of the Kansas State Insurance Commissioner that mandates insurance coverage for routine care for patients participating in clinical trials coverage, including Phase I clinical trials;
- Developed and obtained passage of a bill establishing equivalent insurance coverage for oral chemotherapy agents;
- Established a special license plate that supports breast cancer care and research throughout the Midwest Cancer Alliance;
- Advocated for and obtained passage of the Johnson County Education and Research Tax bill, which is a 1/8 cent sales tax that goes to support the KUCC clinical trials program. Currently this effort provides over $5M in support of our clinical research efforts;
- In conjunction with a number of advocacy groups, KUCC backed an increase of the Kansas state tax on tobacco products by 50 cents per pack;
- KUCC successfully promoted raising the age requirement to purchase tobacco products to age 21 in 18 municipalities throughout greater metropolitan Kansas City. These ordinances collectively impact over

1.4M people on both sides of the state line;
- KUCC successfully supported passage of a bill mandating Radon testing for any home sold in the state of Kansas; and
- In collaboration with the American Cancer Society, KUCC developed, advocated for and obtained passage of one of the strongest Indoor Tanning bills in the country. This bill prohibits anyone under the age of 18 from using a tanning facility and does not allow for parental exceptions.

Summary and Consideration for Comprehensive Status

The University of Kansas Cancer Center has experienced significant growth, expansion and enhancement of its national impact over the last decade. With the strong support of university, state and local leadership KUCC has engaged in a concerted effort to establish an outstanding cancer research and clinical care facility worthy of recognition as an NCI-designated Comprehensive Cancer Center. With the submission of this first competitive renewal, it is KUCC's assessment, and the assessment of the KUCC External Advisory Board that KUCC meets the criteria and requests to be considered for comprehensive status.

KUCC has over $61M of cancer research funding spanning basic research, clinical investigation and cancer control/prevention and population science. KUCC has exceptional strength in stem cell biology, transcriptional and translational regulation, metastasis research, drug discovery and development, tobacco control and breast cancer prevention. In the 2016 US News & World Report assessment, The University of Kansas Cancer Center was ranked #25 for cancer programs, after having been unranked prior to 2011. KUCC also had the 4th best mortality index for cancer care in US News & World Report list despite having experienced a rapid expansion of the clinical program over the last decade. Indeed KUCC has more than tripled the number of cancer patients cared for at the institution since 2004. Coincident with this expansion KUCC has seen a 10-fold increase in accruals to therapeutic clinical trials from 2004 to 2015, and a 7-fold increase in bone marrow transplants since 2007 (now the 10th largest program in the country). In addition, for the first time, KUCC has enabled local phase I clinical trial access for patients within the catchment area.

KUCC has nearly tripled its cancer research funding from 2004-2015 and doubled its academic productivity from 2011-2015 as measured by peer-reviewed publications. KUCC has seen significant increases in intra-programmatic (86%), inter-programmatic (168%) and cross-campus member (53%) publications; and multi-PI grant funding and collaborations (63%). As a testament to the quality of its research efforts, multiple KUCC members have been recognized by their peers through election to a number of prestigious organizations. KUCC now has three National Academy of Science members (**Curran**, **Hawley**, **Krumlauf**), one National Academy of Inventors member (**Stella**), one Royal Society of London member (**Curran**), seven American Academy of Arts and Sciences members (J. **Conaway**, R. **Conaway**, **Curran**, **Hawley**, **Krumlauf**, **Li**, **Workman**); one Howard Hughes Medical Institute member (**Baumann**), one American Cancer Society Research Professor (**Hawley**) and one Pew Scholar (**Baumann**). In addition, **Thrasher** is currently the president of the American Urology Association, **Welch** was elected president of the Cancer biology Training Consortium (CABTRAC) and **Jensen** was recently selected as vice president/president-elect of the Association of American Cancer Institutes.

Over the course of their careers, KUCC scientists have been responsible for: helping define the stem cell niche for the intestine and bone marrow (**Li**); pioneering and validating the role of KRAS testing in defining the treatment for colon cancer (**Godwin**); developing the major technique to assess efficacy of chemoprevention agents in breast cancer (**Fabian**); discovering and characterizing multiple metastasis suppressor genes (**Welch**); discovering the role of mi-RNA expression in BRCA1-mediated tumor suppression (**Jensen**); establishing DCLK1 as a marker of quiescent/reserve stem cells in the intestine (**Anant**); providing some of the first evidence that menthol plays a significant role in maintaining nicotine addiction (**Faseru**, **Nollen**, **Cox**); formulating the drugs Taxol®, Velcade®, (**Stella**) and the Gardasil® vaccine (**Middaugh**, **Volkin**) and providing national leadership in re-engineering the Clinical and Translational Science Award program (**Weir**). In addition, KUCC was named the academic drug discovery and development partner for The Leukemia and Lymphoma Society.

KUCC's strategy focusing on leveraging regional scientific assets to build a nationally significant cancer research center that is a leading institution for transforming laboratory and bedside discoveries into new

therapeutic approaches is driving the success of its translational and trans-disciplinary research efforts as witnessed by the opening of 15 phase I trials driven by KUCC science since 2009; including three new chemical entities and one novel cellular therapy emerging in the last four years, two of which represent first-in-class inhibitors (the p97 inhibitor, CB-5083 and the perinucleolar compartment disassembler, Metarrestin).

The University of Kansas serves as the flagship research institution and the only academic medical center in the region. As such, it is responsible for the education of approximately half the physicians and a major proportion of allied healthcare professionals throughout the region. The majority of oncology care providers within the catchment area have received at least a portion of their training at KUCC and nearly all graduate students, residents and fellows engaged in cancer research and clinical training within the region are affiliated with KUCC. To facilitate and expand cancer research, education and training opportunities KUCC drove the creation of two new departments with an exclusive (Cancer Biology) or major (Biostatistics) focus on cancer. As a result, KUCC has nearly doubled the training grant support at our center since 2012. In addition, **Welch** and **Jensen** led an initiative to define cancer education and training standards for NCI designated centers (**Welch**, *Cancer Res*, 2016).

KUCC leadership has carefully defined its catchment area and leveraged the Midwest Cancer Alliance KPPEPR and PIVOT initiatives to address regional needs. As a result of these efforts KUCC has successfully advocated for a robust public policy agenda that has been detailed above. In addition, members of the Cancer Control and Population Health research program have developed substantial engagement efforts specifically designed and tailored for underserved and underrepresented populations including African-Americans, Native Americans, Hispanics and rural Americans.

Throughout this undertaking KUCC has had exceptional support. For example, as a result of efforts by county officials, voters approved a 1/8th cent sales tax initiative to fund the Cancer Center, making KUCC the only NCI-designated cancer center supported by a local tax. In addition, KUCC has raised over $194M of philanthropic support since 2004 for the development and expansion of the Cancer Center. Finally, KUCC enjoys unparalleled bipartisan support from state and local governments. These achievements, perhaps more than any others, are the ones for which KUCC is most proud.

Part II: Six Essential Characteristics

Physical Space

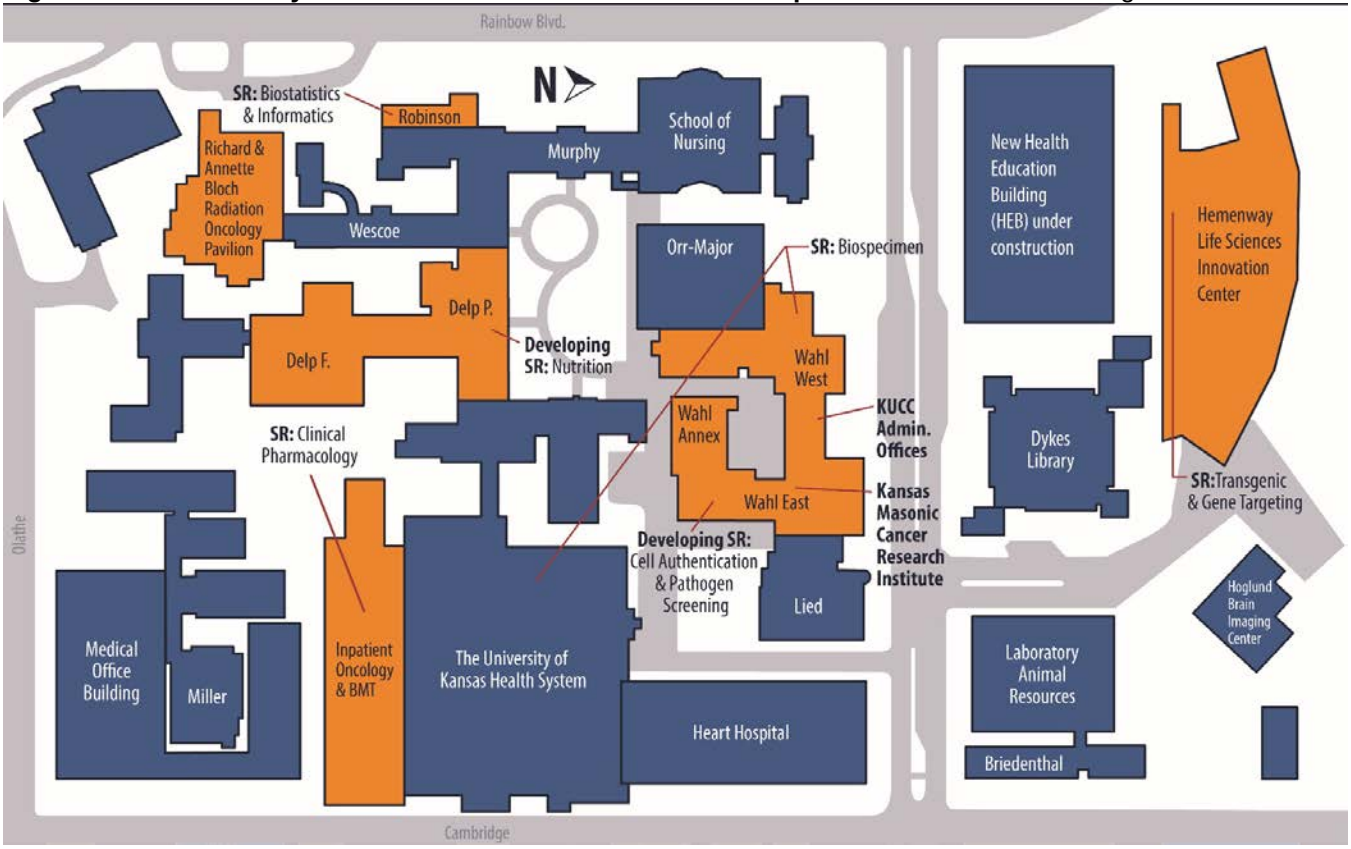
KUCC facilities are located on the KUMC Kansas City and Wichita campuses (with medical schools in Kansas City, Wichita and Salina), the University of Kansas in Lawrence (main and west campuses), the Stowers Institute for Medical Research in Kansas City, MO and Children's Mercy in Kansas City, MO. Physical space for each of the institutions is described below and additional maps can be found in the Overall Facilities and Resources section.

Research Facilities

The University of Kansas Medical Center: The Medical Center in Kansas City includes The University of Kansas Health System, the Schools of Medicine, Nursing and Health Professions, as well as the Graduate School that offers master and doctorate degrees in all three disciplines. A map showing the KUMC campus and the location of buildings that house KUCC activities is shown in **Figure 3**.

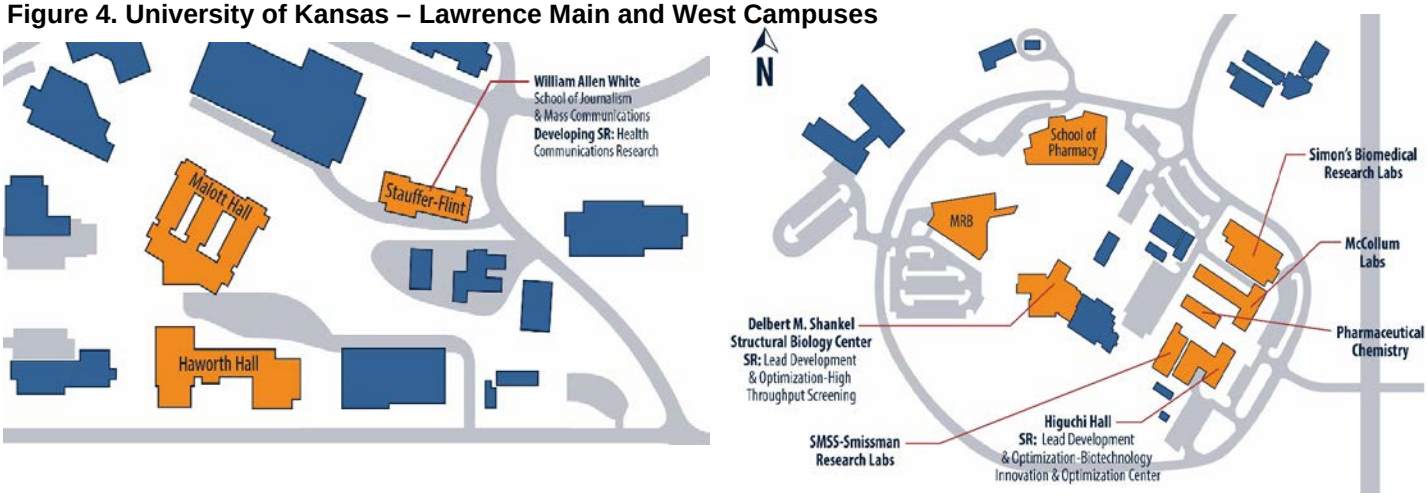
There are 126 KUCC members located at KUMC. The primary research building for the Cancer Center on the KUMC campus is the 170,000 sq. ft. Kansas Masonic Cancer Research Institute (KMCRI). This building complex contains wet lab bench space, an administrative area and selected shared resources. In 2009, **Jensen** successfully secured funds from the Kansas Bioscience Authority ($26.4M) and from the University of Kansas Medical Center ($26.4M) to completely renovate the Wahl/Hixon building complex that has become the KMCRI. The final phase of the renovation was completed in 2012. The KMCRI renovations not only provided new space for Cancer Center recruits, but allowed KUCC to better cluster investigators working in related research areas. This strategic reassignment of space resulted in increased intra-and inter-programmatic interactions as described in Cancer Focus. Additional KUCC members use more than 50,000 sq. ft. of laboratory and office space on the KUMC campus.

Figure 3. The University of Kansas Medical Center – Main Campus. Golden colored buildings house KUCC activities.



University of Kansas, Lawrence, KS: There are 38 KUCC members located at KU-Lawrence. On the main undergraduate campus, KUCC members are located in Malott, Haworth and Stauffer-Flint Halls (**Figure 4 –** map on left). However, in the Spring of 2016, KU Lawrence broke ground on the Central District project, which when fully completed will totally replace Malott and Haworth Halls and provide brand new, state-of-the-art biomedical research facilities on the Lawrence campus. This project represents a tremendous opportunity to refuel and expand the core of basic cancer researchers associated with the Lawrence campus and KUCC leadership is working closely with the newly appointed KU-Lawrence Provost, Neeli Bendapudi to translate this vision into reality.

Figure 4. University of Kansas – Lawrence Main and West Campuses



The University of Kansas-Lawrence West campus is a five-minute drive from the main campus. KUCC members conduct their research in the School of Pharmacy building, the Delbert M. Shankel Structural Biology Center, the Multipurpose Research Building, the Simons Biomedical Research Lab and the McCollum Laboratories (**Figure 4 –** map on right). The School of Pharmacy is an 110,000 sq. ft. building that serves the

Pharmacy graduate program's mission of educating researchers in drug discovery, design and development. **Jensen** played a key role in informing the legislature on the necessity for this building and was critical to securing its approval. Additionally, the High Throughput Screening and Biotechnology Innovation and Optimization Center (parts of the Lead Development and Optimization shared resource) are located on the KU Lawrence West Campus. KU-Lawrence is a 45 minute-drive from the KUMC campus in Kansas City.

University of Kansas School of Medicine, Wichita, KS: At the University of Kansas School of Medicine campus in Wichita, KUCC occupies clinical and office space primarily for clinical trials, prevention and survivorship research. The three KUCC members associated with the Wichita campus occupy approximately 1,500 sq. ft. of office and clinical space in the Kansas Health Foundation Center for Primary Care building. The School of Medicine in Wichita is a three-hour drive from Kansas City.

Stowers Institute for Medical Research (Stowers): Eleven KUCC members are housed at Stowers in Kansas City, Missouri. The Stowers campus has 880,000 sq. ft. and includes state-of-the-art research laboratories and 13 core technology centers including bioinformatics, proteomics and imaging. Counting support and administrative staff, Stowers has approximately 550 employees. Stowers is a 10-minute drive from the KUMC main campus.

Children's Mercy: Nine KUCC members are located at Children's Mercy (also in Kansas City, Missouri), but membership is expected to grow. Children's Mercy has a medical staff of more than 750 pediatric specialists, including more than 20 board-certified physicians to provide comprehensive pediatric cancer care to patients and families. There is currently over 48,000 sq. ft. of research space. The new Center for Pediatric Genomic Medicine laboratory is located in Crown Center and occupies approximately 3,500 sq. ft. This state-of-the-art facility allows Children's Mercy to perform a far greater number of diagnostic testing and genome analyses for its patients – a new service available inside a children's hospital for the very first time. In Spring of 2017, Children's Mercy will be breaking ground on a 400,000 sq. ft. building for the Children's Research Institute directed by Tom **Curran** (CB). This research institute will focus the hospital's future research efforts in pediatric genomic medicine including cancer, clinical pharmacology, health services and outcomes and health care delivery. Children's Mercy is a 10-minute drive from the KUMC main campus.

Clinical Facilities

KU Clinical Research Center: The KU Clinical Research Center (KU CRC) houses many clinical and translational activities of the Cancer Center. **Jensen** secured the donation of this $7M building from the Hall Family Foundation and as described in the Director's Overview, a county tax (JCERT) generates over $5M per year which is used in part to support renovations and maintenance of this 82,000 sq. ft. building. The KU CRC opened in January 2012 and houses KUCC's Clinical Trials Office, the early phase clinical research unit, the Clinical Pharmacology shared resource and the MCA. KU CRC offers an easily accessible ambulatory (outpatient) setting like typical physician offices and a comfortable, non-hospital, overnight patient setting. KUCC occupies two floors of the building and the CTSA program occupies the remaining floor. KUCC members have access to the CTSA-supported clinical research facilities housed in this building (e.g., the metabolic kitchen, the human physiology laboratory for exercise testing, dual energy x-ray absorptiometry scanning, and other testing and assessment capabilities. The concept of a modular flexible design allows the facility to adapt to the continuous change in the scope and volume of grants and clinical trials. The building is five minutes from the outpatient clinical facility in Westwood and 10 minutes from the main KUMC campus.

Children's Mercy Pediatric Clinical Research Unit: The Pediatric Clinical Research Unit, located in Children's Mercy Hall Tower, is a state-of the art, 5,000 sq. ft. facility dedicated to the support of clinical-translational research. This unit and its staff of experienced research nurse coordinators support the activities of the Experimental Therapeutics in Pediatric Cancer program and the hospital's pivotal role as the Pediatric Clinical Pharmacology core of the NIH-funded Pediatric Trials Network.

The University of Kansas Health System Clinical Oncology Facilities: KUCC's cancer patient care program ranks No. 25 among the nation's top 50 in U.S. News & World Report's Best Hospitals 2016-17. The clinical program of the Cancer Center is jointly administered by KUCC and the KU Health System leadership team, specifically the Physician-in-Chief, Terry **Tsue**. Inpatient cancer services use 26,334 sq. ft. of space and include

55 beds on the KUMC main campus. Radiation Oncology occupies 21,000 sq. ft. and is also located on the main KUMC campus. The Richard and Annette Bloch Cancer Care Pavilion of KU Health System, is located in Westwood, Kansas, a five-minute drive from the KUMC main campus, houses all outpatient cancer services and provides 62,500 sq. ft. including 4,230 sq. ft. for the Breast Cancer Prevention Center, 1,425 sq. ft. for the Breast Cancer Survivorship Center and 7,500 sq. ft. for the bone marrow transplant facility. KUCC clinicians occupy an additional 8,300 sq. ft. of office space located in the east wing of the Westwood facility. Research nurses and data managers for the Clinical Trials Office are also located in 1,340 sq. ft. of the cancer clinical services area of the Bloch Cancer Care Pavilion. In 2015 the KU Health System broke ground on a 12-story 550,000 sq. ft. bed tower for the hospital. This facility will house 12 new operating rooms, 132 patient beds and will be primarily devoted to surgical oncology and ENT. The expected date of completion is Fall 2017.

Administrative and Shared Resource Facilities

Administrative Facilities: Administration for KUCC is housed in 6,000 sq. ft. of the KMCRI on the main KUMC campus in Kansas City and shares this space with the Department of Cancer Biology. This office space provides administrative and fiscal oversight of cancer center functions. These functions include grant development; human resources; communications; Cancer Center Support Grant management; Cancer Center, Clinical Trial Office and shared resource financial administration; outreach and information dissemination; and information technology.

Shared Resource Facilities: KUCC shared resources occupy more than 33,000 sq. ft. of space located in a number of facilities on the KUMC campus, the KU Lawrence west campus, The University of Kansas Health System's Westwood campus and the KU Clinical Research Center. Locations are indicated in **Figures 3** and **4** and additional maps can be found in the Overall Facilities and Resources section.

KUCC supports five established shared resources and three developing shared resources (denoted with an *) with the following scientific directors and space allotment:

- Biospecimen (BSR) – Director, Andrew **Godwin**, PhD – KUMC and KU Health System campuses, 3,655 sq. ft.
- Biostatistics and Informatics (BISR) – Director, Brooke **Fridley**, PhD – KUMC campus, 9,028 sq. ft.
- Lead Development and Optimization (LDOSR) – Director, Michael **Baltezor**, PhD – KUMC and KU-Lawrence West campuses, 13,640 sq. ft.
- Transgenic and Gene-Targeting (TGTSR) – Director, Jay **Vivian**, PhD – KUMC campus, 2,714 sq. ft.
- Clinical Pharmacology (CPSR) – Director, Gregory **Reed**, PhD – KUMC and KU Health System campuses, 1,776 sq. ft.
- *Health Communications Research (HCRSR) – Director, Mugur **Geana**, MD, PhD – KU-Lawrence campus, 741 sq. ft.
- *Nutrition (NSR) – Co-Directors, Debra **Sullivan**, PhD and Jill **Hamilton-Reeves**, PhD, RD – KUMC campus, 998 sq. ft.
- *Cell Authentication and Pathogen Screening (CAPSSR) – Director, Easwari **Kumaraswamy**, PhD – KUMC campus, 651 sq. ft.

Shared Resource Access and Oversight: KUCC provides financial and administrative support for each shared resource and KUCC members have priority access and are encouraged to utilize the cutting-edge technology and specialized expertise offered. Each shared resource is fully equipped to provide KUCC investigators with access to up-to-date research technology, equipment and technical support that would otherwise be too difficult or expensive for individual investigators or programs to develop. The availability of these shared resources significantly increases the ease with which cancer-related research can be conducted. Associate Director for Shared Resources, **Mayo**, and Assistant Director for Administration, **Harlan-Williams**, meet with shared resource Directors and Assistant Directors quarterly to discuss budgets, identify appropriate utilization metrics and tracking mechanisms, prevent duplication of aims and services, and increase communication across all KUCC shared resources. **Mayo** ensures open communication, beneficial integration with institutional cores and clarity of fiscal and programmatic accountability. Beginning in 2014, an annual survey was designed by **Mayo**, **Harlan-Williams**, Shared Resource Directors and **Gajewski** (CCPH), an expert in survey development. The anonymous surveys request feedback on the satisfaction of services received from CCSG-supported/KUCC shared resources and solicit ideas for the development of expanded capabilities or new shared resources.

Organizational Capabilities

KUCC is a matrix consortium cancer center representing an alliance of institutions partnering in cancer research, drug discovery and development, cancer prevention and control and adult and pediatric oncology care. KUCC serves as the umbrella organization for the cancer partnership between the University of Kansas (including the Lawrence campus and the medical center campuses in Kansas City, Wichita and Salina), the Stowers Institute for Medical Research, Children's Mercy and The University of Kansas Health System. Deputy Director, **Godwin**, Chief Operating Officer, Reene, and all Associate Directors report to the KUCC Director, **Jensen**. **Jensen** reports directly to both the Executive Vice Chancellor at the KU Medical Center campus (Doug Girod, MD) and the Provost at the KU-Lawrence campus (Neeli Bendapudi, PhD). **Jensen** has a dotted line reporting relationship to the Stowers President and Chief Executive Officer, David Chao, PhD, the Children's Mercy President and Chief Executive Officer, Randall O'Donnell, PhD, and the KU Health System Chief Executive Officer, Bob Page (**Figure 5**).

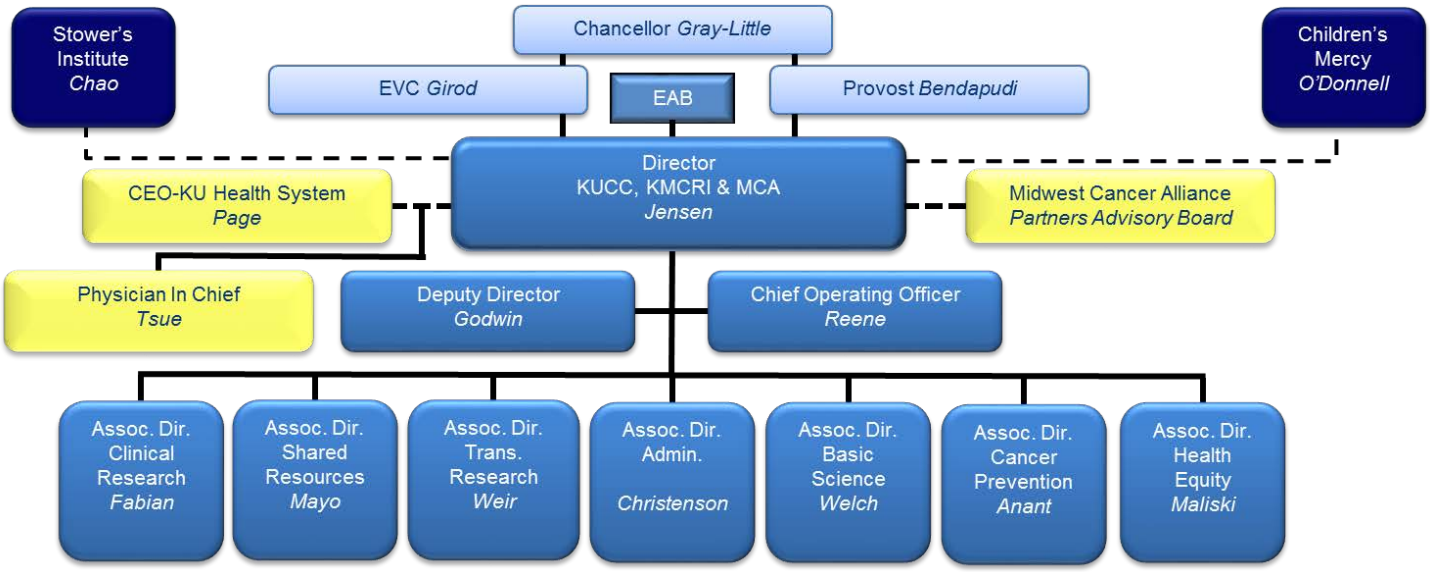
KUCC is committed and its Senior Leadership and Research Programs are organized to foster scientific interactions, respond to evaluation, apply resources to the catchment area, train the next generation of cancer leaders and collaborate with consortium partners to lead the effort to reduce the burden of cancer throughout the region.

Senior Leadership Organization

Jensen has assembled a team of seven associate directors that resolve to work together to accomplish the vision set forth in the Director's Overview (see organizational chart in **Figure 5**). A full description of the Cancer Center Senior Leadership, with brief biographies and a description of roles, duties, responsibilities and interactive relationships, can be found in the Administration and Senior Leadership section.

- Associate Director for Administration, Teresa Christenson, ASA
- Associate Director for Basic Science and Education, Danny **Welch**, PhD
- Associate Director for Cancer Prevention and Control, Shrikant **Anant**, PhD
- Associate Director for Clinical Research, Carol **Fabian**, MD
- Associate Director for Health Equity, Sally **Maliski**, PhD, RN, FAAN (no CCSG funds requested)
- Associate Director for Shared Resources, Matthew **Mayo**, PhD, MBA, FASA (no CCSG funds requested)
- Associate Director for Translational Research, Scott **Weir**, PharmD, PhD

Figure 5. KUCC Organizational Chart



Research Programs Organization

KUCC has 187 members from four different campuses (KUMC, KU-Lawrence, Stowers and Children's Mercy) that are organized into four research programs (co-leaders listed in *italics*):

- Cancer Biology (CB) – *Kristi* ***Neufeld***, PhD (KU-Lawrence) and *Linheng* ***Li***, PhD (Stowers) – 61 members
- Cancer Control and Population Health (CCPH) – *Edward* ***Ellerbeck***, MD, MPH (KUMC) and Christie **Befort**, PhD (KUMC) – 35 members
- Cancer Prevention and Survivorship (CPS) – *Dan* ***Dixon***, PhD (KUMC) and *Jennifer* ***Klemp***, PhD, MPH (KUMC) – 31 members
- Drug Discovery, Delivery and Experimental Therapeutics (D3ET) – *Scott* ***Weir*** (KUMC) and *Alan* ***Gamis***, MD (Children's Mercy) – 60 members

Member Interactiveness: The Program Leaders from each research program collaborate with an Associate Director to guide program growth and development. Associate Directors and Program Leaders are responsible for fostering multidisciplinary, multi-programmatic research activities and are charged with identifying initiatives and technologies that would benefit program members and KUCC as a whole. Additionally, Program Leaders value input from fellow program members to represent the various campuses and provide leadership for specific programmatic scientific themes. Program Leaders are part of the KUCC Membership Committee which annually reviews all applications and current members. This committee and the membership criteria is detailed in the Planning and Evaluation section. With proper membership alignment, KUCC research programs drive inter- and intra-programmatic collaborations and develop innovative research ideas that lead to multidisciplinary grants.

KUCC senior leadership and research program leaders interact in various advisory panels and committees (described in Planning and Evaluation) to develop and implement their collective vision for growth, development and transformation of KUCC into a leading cancer research and treatment organization worthy of NCI Comprehensive Cancer Center designation. The Associate Director for Administration ensures the administration group efficiently and effectively supports the KUCC vision.

Fostering Scientific Interactions

A major focus of KUCC is to promote opportunities for interactions and collaborations among Cancer Center members from different disciplines, research programs and campuses. Scientific, clinical and educational opportunities are provided through Research Program Meetings, the Pilot Project Program, the annual KUCC Research Symposium, the weekly KUCC seminar series, the Grants Development Office, the Target Acceleration Group and the Investigator-Initiated Trial Steering Committee.

Research Program Meetings: Research program meetings are designed to facilitate intra- and inter-programmatic collaboration and bring program members together to advance joint research initiatives. Additionally, research program meetings provide a platform for members to voice needs for access to shared resources or the development of new shared resources. Each KUCC research program engages their members in different ways. For example, the Cancer Control and Population Health (CCPH) research program hosts quarterly 'Science Friday' meetings. These meetings are scheduled for two hours on a Friday afternoon with different members invited to give a 20-minute presentation about their research. These meetings wrap-up with networking during a happy hour. The Drug Discovery, Delivery and Experimental Therapeutics (D3ET) research program utilizes a monthly webinar series that meets via Zoom at the noon hour on the first Friday of each month. Each month a different member gives a 45-minute presentation about their research. The Cancer Biology (CB) research program hosts an annual day-long, off-site meeting with breakfast, lunch and dinner provided. Speakers include an external keynote speaker and internal pilot award recipients with an emphasis on highlighting research from all campuses. Finally, the Cancer Prevention and Survivorship (CPS) research program holds half-day meetings in the afternoon multiple times a year. These meetings are typically centered on a particular scientific theme.

Pilot Project Program: The major purpose of the Pilot Project Program is to provide support for highly-meritorious cancer research and promote new, exciting and innovative approaches towards this disease. The projects may be risky, but must demonstrate a sound scientific rationale. Innovation is highly valued and proposals that leverage scientific strengths of the Cancer Center or represent new technological approaches are especially sought out. Applicants must demonstrate collaboration between at least two Cancer Center members, one of which must have Full membership standing, unless the request for application is made specifically for junior investigators. KUCC aims to increase interdisciplinary collaboration amongst Cancer

Center members and leverage resources to foster the discovery and advancement of new and more effective preventive or therapeutics strategies. Ultimately, the goal is to have the proposal lead to research that leads to new knowledge in basic, clinical, population or translational science that impacts the cancer burden in our catchment area.

Annual Research Symposium: KUCC utilizes the annual Research Symposium to foster a culture of cancer centeredness, collegiality and collaboration. Additionally, the event is an opportunity for the Director and Senior Leadership to update faculty and staff on plans and priorities for KUCC and elicit feedback from membership. Each fall the program includes oral presentations from external speakers invited by each of the research programs, internal speakers, including faculty, post-doctoral fellows and graduate students and poster sessions. In 2014, KUCC began to sponsor the annual Research Symposium in collaboration with the Multidisciplinary Oncology Conference organized by KU Health System clinicians. This provides additional platforms for basic, population, translational and clinical scientists, physicians, nurses, fellows, residents and students to interact and learn about the work going on at KUCC and abroad. Moreover, continuing medical education credits are now offered.

Cancer Center Seminar Series: KUCC holds a weekly seminar to highlight research from all four programs and high profile external speakers. From 2012-2015, KUCC has hosted over 150 speakers (internal and external) to present on topics relevant to KUCC members and to the sponsoring research programs. This forum is also utilized for potential recruits to present their research initiatives. This seminar series is managed by **Welch** and utilizes modern tele- and video-conferencing (Zoom, Adobe Connect) to facilitate interactive participation across all campuses (KUMC, KU-Lawrence, Stowers and Children's Mercy).

Grants Development Office: The Grants Development Office (GDO) assists Cancer Center members to successfully compete for extramural funding by circulating grant opportunities from the NCI, ACS, DoD, Susan G. Komen Foundation and other national organizations that would emphasize multidisciplinary, multi-investigator, collaborative ideas. The GDO works hand-in-hand with the University grants and contracts office, Research Institute (RI) at KUMC, KU-Lawrence, Stowers and Children's Mercy. The GDO also coordinates the pilot project program including the request for applications, review process and award notification for the Cancer Center.

Target Acceleration Group (TAG): In 2014, KUCC organized TAG to help facilitate basic and clinical scientific interactions. TAG aims to accelerate KUCC member projects around an identified cancer target, through screening, hit identification, medicinal chemistry optimization, secondary *in vitro* assay confirmation, drug delivery for both *in vitro* and *in vivo* tertiary assays, eADME pharmacokinetics and *in vivo* preclinical proof of principle. This group provides a "critical mass" of scientific expertise, centralizes access to information and resources, coordinates across shared resources, fosters intra-programmatic, inter-programmatic and inter-NCI center collaborations and is the genesis for creation of multidisciplinary, multi-organizational teams to advance projects from the bench to the bedside.

Investigator-Initiated Trial Steering Committee (IITSC): In 2015, KUCC formed the IITSC in order to: 1) address unmet needs in the clinical care of KUCC patients; 2) enable and advance hypothesis-driven IITs that could compete for external funding opportunities; 3) create a rich translational medicine culture for basic and clinical scientists, providing access to mentors and supporting faculty and staff career development; and 4) effectively and efficiently utilize KUCC shared resources to support IITs. The IITSC provides an interactive venue for basic and clinical researchers to present IIT concepts arising from laboratory and bedside discoveries, as well as a structure for defining and refining IIT concepts prior to and following discussion. Investigators receive instant feedback from clinical researchers, representatives from relevant KUCC shared resources (i.e., Biospecimen, Lead Development and Optimization, Clinical Pharmacology and Biostatistics and Informatics) and the Clinical Trials Office.

Evaluation Processes

KUCC utilizes an External Advisory Board and a number of internal mechanisms to inform, guide and review the wide-ranging activities of Cancer Center strategic initiatives and operations. Additional details are provided in the Planning and Evaluation section.

External Advisory Board (EAB): KUCC meets annually with its EAB to receive independent, objective feedback about the strength of the research programs, its administrative structure, its progress in shared resource development and its clinical trial operations. The EAB includes current and former directors of NCI-designated Cancer Centers with national experts in cancer research and administration that guide and inform KUCC's strategic vision (**Table 2**). The EAB meetings are detailed strategic reviews of KUCC structure and operations. They played a critical role in the preparation of the initial CCSG application to become an NCI-designated Cancer Center and continue to advise Cancer Center leadership as we prepare to apply for comprehensive status.

Table 2. The University of Kansas Cancer Center External Advisory Board

Name	Title	Institution
George J. Weiner, MD Chair (2008)	Director Professor, Department of Internal Medicine	Holden Comprehensive Cancer Center, University of Iowa Health Care
Laurence H. Baker, DO (2008)	Professor, Departments of Internal Medicine and Pharmacology	University of Michigan Medical School
Stephen W. Byers, PhD (2010)	Director of Shared Resources	Lombardi Cancer Center Georgetown Univ. Medical Center
Webster Cavenee, PhD (2014)	Director	Ludwig Institute for Cancer Research, University of California, San Diego
Mark S. Clanton, MD, MPH, FAAP (2007)	Medical Director	TMF Health Quality Institute
Michael W. Darling, MHA (2005)	Associate Director for Administration	Indiana University Simon Cancer Center
Ernest T. Hawk, MD, MPH (2008)	Vice President for Cancer Prevention & Population Sciences	The University of Texas MD Anderson Cancer Center
Janet A. Houghton, PhD (2015)	Professor, Molecular Medicine, Department of Cancer Biology	Lerner Research Institute, Cleveland Clinic
Candace S. Johnson, PhD (2005)	President & CEO Cancer Center Director Chair, Department of Pharmacology & Therapeutics	Roswell Park Cancer Institute
Guillermina "Gigi" Lozano, PhD (2014)	Professor and Chair, Department of Genetics	The University of Texas MD Anderson Cancer Center
Alfred I. Neugut, MD, PhD (2010)	Professor of Epidemiology Associate Director for Population Sciences Co-Director, Cancer Prevention Program	Herbert Irving Comprehensive Cancer Center, Columbia University Health Sciences
Timothy R. Rebbeck, PhD (2014)	Professor, Cancer Epidemiology	Harvard T.H. Chan School of Public Health Dana-Farber Cancer Institute
Larry J. Schaaf, PhD (2005)	Director, Clinical Treatment Unit	The Ohio State University Comprehensive Cancer Center
Robert C. Young, MD (2013)	President; Director Emeritus	RCY Medicine; Fox Chase Comprehensive Cancer Center

Internal Advisory Mechanisms: KUCC uses a number of mechanisms to provide objective evaluation of its components and advice to the Director. There are four major advisory groups: 1) Associate Directors Council, 2) Leadership Council, 3) Program Leaders Council, and 4) Shared Resource Directors. Each meeting aims to discuss and set priorities for their specific areas of responsibility and advise the Director on any major decisions. For more details about these groups and other internal advisory mechanisms, refer to the Planning and Evaluation component.

- The Associate Director's Council, which includes the Director, Deputy Director and Associate Directors, meets twice monthly for purposes of strategic planning and decisions on resource allocation.
- The Leadership Council, which includes the Director, Deputy Director, Associate Directors, Program Leaders, and the COO, meets every other month to evaluate and discuss KUCC programs and initiatives and foster scientific collaborations.
- The Program Leader's Council, which includes the Director, Associate and Assistant Directors for Administration and Program Leaders, meets every other month to discuss strategies to communicate with and engage Cancer Center members, recruitment efforts to increase each program's scientific depth and

breadth and understand specific needs for each program such as new shared resources.
- Shared Resource meetings, which include the Associate Director for Shared Resources, the Assistant Director for Administration and the directors of each shared resource, convene quarterly to help identify issues with organization, metrics, or usage and on an *ad hoc* basis when items for discussion are more pressing.

Midwest Cancer Alliance Partners Advisory Board: The MCA Partners Advisory Board is an advisory group to the Cancer Center Director and conveys regional interests and financial support to the research programs of KUCC (**Table 3**). Its members include a number of health organizations and practices throughout Kansas. This group represents an important connection to the regional medical community and enables KUCC to continuously assess their needs.

Table 3. Midwest Cancer Alliance Partners Advisory Board

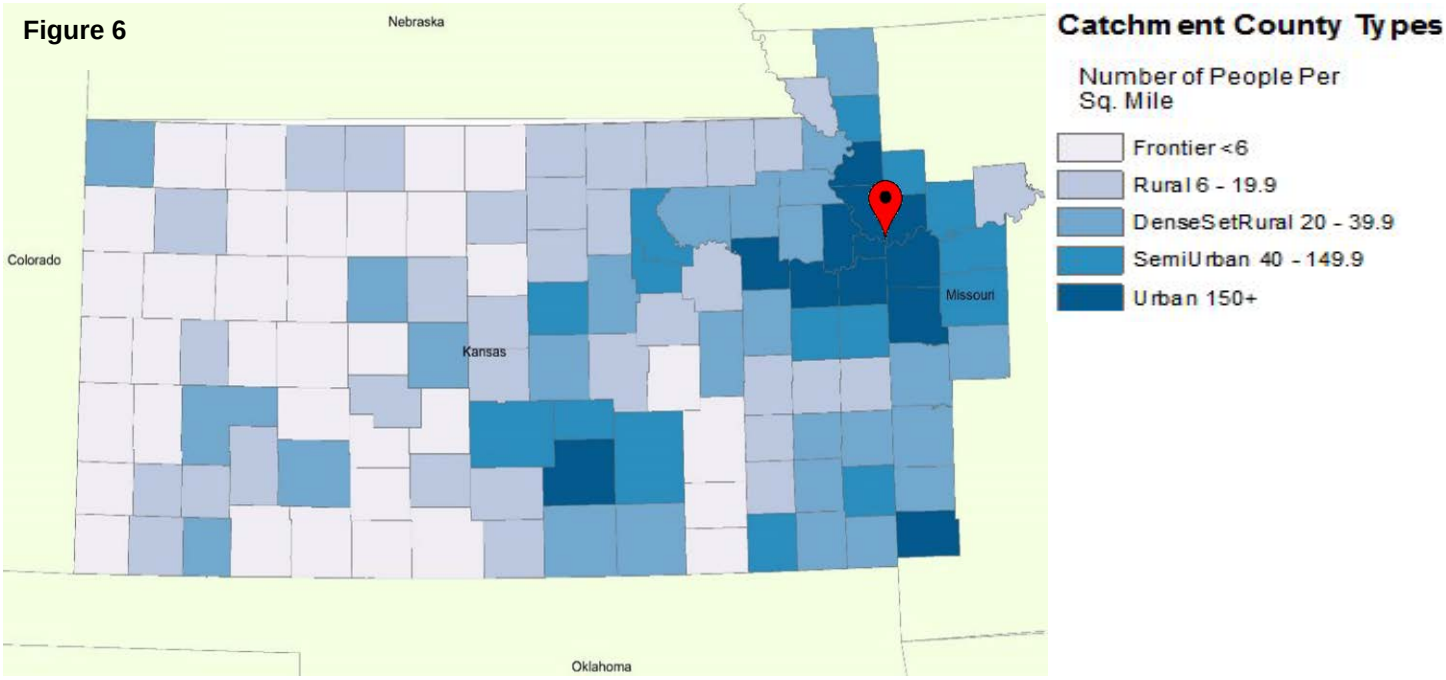
Name	Title	Institution
Robba Moran (Chair)	Member	Kansas Board of Regents
Bernadette Gray-Little	Chancellor	University of Kansas
Doug Girod, MD	Executive Vice Chancellor	University of Kansas Medical Center
Bob Page	President and CEO	University of Kansas Health System
Charlie Shields	President and CEO	Truman Medical Center
David Chao, PhD	President	Stowers Institute for Medical Research
Duane Cantrell	President and CEO	Kansas Bioscience Authority
Jeff Colyer, MD	Lieutenant Governor	State of Kansas
Jeffrey Reene	COO	KUCC
John Jeter, MD	President and CEO	Hays Medical Center
Randall O'Donnell, PhD	President and CEO	Children's Mercy
Robin Denell, PhD	Director, Terry C. Johnson Center for Basic Cancer Research	Kanas State University
Roy Jensen	Director	KUCC
Sandra Lawrence	Executive Vice President, CFO	Children's Mercy

Strategic Plan: In 2010, KUCC developed a Cancer Center Strategic Plan. Development and implementation of the Cancer Center Strategic Plan involves administration and leadership from the Cancer Center, University of Kansas, KU Health System, Children's Mercy and Stowers. All parties have ownership in advancing each strategic priority, measurable outcome, action item and timeline. The Associate Director for Administration, Christenson, coordinates the annual update of the strategic plan after the CCSG progress report is submitted to the NIH and the EAB meeting feedback has been received. The annual update is reviewed for progress with input from the Senior Leadership, Program Leaders and Shared Resource Directors. A *de novo* strategic plan is created every three years in order to reprioritize, refocus and leverage member expertise along with shared, clinical and institutional resources. For further details see the Planning and Evaluation component.

Catchment Area

As described above in the Director's Overview, KUCC has invested considerable effort into the definition of its catchment area. Following up on EAB recommendations, KUCC's catchment area now includes the state of Kansas and the counties in western Missouri in which there are at least 20 KUCC patients, ≥ 15% of the expected index cases or adjacent to Kansas. KUCC believes this area accurately reflects where its patients come from, where the MCA serves and where there is a research focus (**Figure 6**). This area includes 105 counties in Kansas plus 18 counties in Missouri representing over 4.4M people. Ninety six of those 123 counties (78%) are either rural or frontier counties, a significantly underserved population. A catchment area committee meets quarterly to discuss strategies to refine the KUCC catchment area, understand the demographics and identify unmet needs of the population. More details about this committee can be found in Planning and Evaluation.

Figure 6



Training and Education

Cancer Education Seminars and Conferences: In addition to the weekly Cancer Center seminar series, KUCC, in partnership with all consortium members, offers a number of cancer education conferences that provide members the opportunity to interact and share ideas about cancer-related topics. These cancer education opportunities include: Biostatistics Seminar Series, Introduction to Biostatistics for Clinical and Translational Researchers short course, Cancer & Developmental Biology Seminar Series, Brain Tumor Conference, Clinical & Translational Research Seminar Series, Hepatocellular Carcinoma Conference, Lung Conference, Lymphoma & Myeloma Conference, Multidisciplinary Tumor Conference, Sarcoma Conference, Veterans Administration Bone Marrow Conference, Veterans Administration Chest Conference, Breast Tumor Board, Head & Neck Tumor Board, Thyroid Tumor Board and the Veterans Administration Tumor Board. Additionally, these programs are offered to members of the Midwest Cancer Alliance through Interactive Tele-Video Conference. This allows physicians throughout the state who are not able to travel to Kansas City to take advantage of the outstanding continuing education opportunities offered through KUCC.

Department of Cancer Biology: The Department of Cancer Biology, an academic department closely affiliated with the KU Cancer Center, recently received approval from the Kansas Board of Regents to develop and implement MS and PhD graduate programs in Cancer Biology. While the program focuses on graduate education it will actually function as a centerpiece for didactic education throughout the Cancer Center since residents, medical fellows and post-doctoral fellows can take advantage of the courses. Likewise, **Welch** serves as Chair of the KUMC postdoctoral affairs office, which coordinates professional development for post-graduates throughout the campus. Although the latter activities are not solely for KUCC members, it is important to note that KUCC leadership is setting the pace for these activities throughout the campus.

Cancer Biology Training Consortium (CABTRAC): CABTRAC was established in 2005 to facilitate the exchange of ideas between individuals and institutions dedicated to the mission of training the next generation of cancer researchers. The consortium works closely with over 80 institutions within the US as well as the National Cancer Institute's Cancer Training Branch. KUCC's Associate Director for Basic Science, Danny **Welch**, is the president of this national organization. **Welch** and **Jensen** worked with CABTRAC and faculty at other NCI-designated Cancer Centers to publish the essential components of Cancer Education (**Welch**, *Cancer Res*, 2015).

Centers of Biomedical Research Excellence (COBRE): Associate Directors, **Welch** and **Anant**, recently submitted a COBRE application to create a Center for Tumor Microenvironment Research (CTMER, P20 GM121306-01). Tumor microenvironment was considered a priority area for expansion when the KUCC

strategic plan was developed. Thus, it became the focus of this transdisciplinary and multi-departmental initiative. Members (full and associate) from all four KUCC programs are involved in the CTMER. The goals of the COBRE RFA are to build research infrastructure and develop junior faculty into strong, independent researchers. Following an institution-wide competitive process, the CTMER was chosen by KUMC leadership to submit an application in 2016. **Welch** and **Anant** led a selection process from which four projects were chosen as the initial components. At least three others are in the queue once faculty 'graduate' (i.e., receive RO1 funding). In addition to the Administration & Mentoring Core, three new scientific core facilities are being developed. All are considered important for the broader KUCC research community and all represent possible developing shared resources for future CCSG applications – Cell Authentication & Pathogen Screening, Cell Isolation & Histology and Cell Metabolism. KUCC has committed support for peer-reviewed pilot projects, equipment for the core facilities and for future faculty recruitment to the CTMER.

Grant Rounds: In 2012, **Welch** and **Anant** established "Grant Rounds" to facilitate the development of grant ideas from all faculty, particularly, junior faculty and post-doctoral fellows. This group convenes every other Friday to learn about and provide feedback on a specific grant proposal under development. To date, the program has been very successful. For example, **Cheng** (CB) and **Behbod** (CPS) received funding from NIH, DOD and Komen. **Chien** (CB) has received multiple grants from DOD and ACS. **Iwakuma** (CB), initially funded by ACS, was recently awarded a five-year RO1 grant. **Hagan** (CB) was recently awarded grants from Komen and the V Foundation. These grants were all discussed and vetted at Grant Rounds sessions.

Consortium Centers

KUCC has consortium agreements with both Stowers and Children's Mercy. The memorandum of understanding with Stowers includes the provision that Stowers investigators engaged in cancer research are eligible to be KUCC members and serve in leadership roles. Stowers investigators who are KUCC members have access to KUCC shared resources and as such, KUCC members who are collaborating with Stowers investigators have access to their core technology centers and facilities. Furthermore, all cancer clinical trial protocols involving a collaboration between cancer researchers from both institutions are subject to the same governing Protocol Review and Monitoring System and the same Data Safety and Monitoring Plan.

In late 2012, Children's Mercy and KUMC announced plans to develop an integrated pediatric program across the Kansas City metropolitan area that would enhance clinical care and expand research initiatives for children with cancer throughout our region. The alliance between KUCC and Children's Mercy was formalized in 2015. Similar to the consortium agreement with Stowers, Children's Mercy researchers engaged in cancer research are eligible to be KUCC members and serve in leadership roles. Children's Mercy researchers have access to KUCC shared resources and cancer clinical trial protocols involving a collaboration between cancer researchers from both institutions are subject to the same governing Protocol Review and Monitoring System and the same Data Safety and Monitoring Institutional Plan. Children's Mercy researchers have been added to the appropriate research programs, the Protocol Review and Monitoring Committee, the Data Safety and Monitoring Board, the Leadership Council and the Associate Directors council.

KUCC administrative offices communicate with Cancer Center members located at Stowers or Children's Mercy in the same manner as members located at KUMC or KU in Lawrence, via emails, tele- and video conference. In addition, one Associate Director meeting per month is held at Stowers and one administrator from Children's Mercy and one from Stowers report to Christenson for CCSG-related activities.

Transdisciplinary Collaboration and Coordination

KUCC aims to provide the optimal environment to focus the power of precision medicine, basic science inquiry, drug discovery and development and behavioral interventions to decrease cancer incidence, morbidity and mortality. With this goal in mind, KUCC utilizes multiple approaches to promote member interactions and foster transdisciplinary collaborations including the Pilot Project Program, Program Project Development Grants, Research Program Meetings and Development Funds, Disease Working Groups, the Molecular Tumor Board, the Target Acceleration Group and the Investigator-Initiated Trial Steering Committee. These activities supported KUCC members publishing 1,741 cancer-relevant manuscripts from 2012-2015. Two hundred fifty three (15%) of those publications resulted from inter-programmatic interactions, 451 (26%) were from intra-programmatic interactions and 981 (56%) were with scientists from other institutions. Underscoring each of these transdisciplinary and/or translational opportunities is the KUCC

administration team who works with the appropriate leaders to facilitate the planning, organization, execution and communication to ensure effective implementation and optimal endpoints.

Promoting Transdisciplinary Collaborations

Pilot Project Program: Since 2005, the KUCC Pilot Project Program has offered two rounds of pilot project funding each year, one in the spring and one in the fall. All applicants must demonstrate collaboration between no less than two Cancer Center members, one of which must have Full membership standing, unless the request for application is made specifically for junior investigators. Awards are generally $35,000, but can be up to $50,000 for one year. In the previous funding period, 43 pilot projects were awarded, totaling $1,216,143. These 43 investigators collaborated with 70 other Cancer Center members and 27 (63%) were inter-programmatic collaborations. KUCC aims to increase interdisciplinary collaboration amongst Cancer Center members and leverage resources to foster the discovery and advancement of new and more effective preventive or therapeutics strategies. Ultimately, the goal is to have the funded research make an impact in the fields of basic, clinical, population or translational science and on the cancer burden in the KUCC catchment area. For more details about the Pilot Project Program, see the Developmental Funds section.

Program Project Development Grants: In response to a recommendation by the KUCC External Advisory Board to focus on multidisciplinary team science initiatives, KUCC developed a special call for proposals from multi-investigator teams to develop collaborative projects that would be competitive in applying for cancer-related research program project grants, COBREs, SPOREs or similar funding mechanisms. Collaborative applications required at least two KUCC members and funded proposals were given $50,000 for one year. The project teams were eligible to receive an additional $50,000 for a second year pending a brief progress report. The progress report included an updated budget justification and a summary of a discussion with a program director or other official of the potential funding agency. Evaluation criteria included: research theme and its relevance to the funding agency's mission, scientific merit of each project and the entire program as a whole; cancer relevance; qualifications, experience and productivity of the research team; collaboration amongst Cancer Center members; project feasibility given environment, budget, and time; and likelihood that the research team can leverage this funding to compete successfully for an NCI program project grant application or similar award in the future. Three teams were selected to receive funding for year one (2014) and year two (2015) (**Table 4**).

Table 4. Program Project Developmental Grants

Members	Programs	Title
Jeremy Chien, Andrew Godwin, Scott Weir, Brooke Fridley, Devin Koestler	D3ET, CB, CCPH	The Ovarian Cancer Learning Collaborative
Carol Fabian, Christie Befort, Susan Carlson, Dan Dixon, Bruce Kimler, Jennifer Klemp, Deb Sullivan, Henry Yeh	CPS, CCPH	Combined Weight Loss and Omega-3 Fatty Acids for Breast Cancer Prevention
Shrikant Anant, Scott Weir, Shahid Umar, Dan Dixon, Kristi Neufeld, Liang Xu	CPS, D3ET, CB	RNA Binding Proteins in Colorectal Cancers

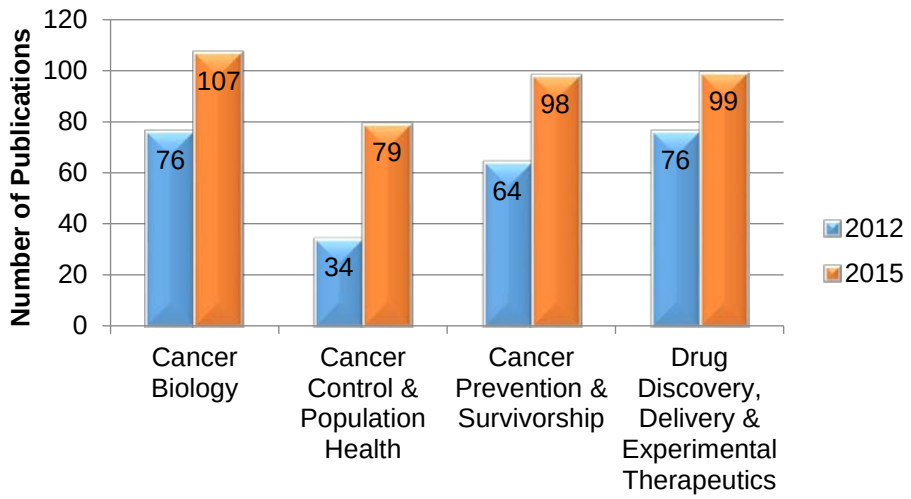
Intra- and Inter-Programmatic Activities

Research Program Meetings and Development Funds: Inter-programmatic interactions are also fostered by joint research program meetings. For example, the CPS and CCPH research programs have held joint meetings and D3ET and CB are currently planning a joint meeting to be held in 2017. Additionally, in 2013, the Cancer Center began providing each research program $50,000 to use at their discretion. These funds are directed by the program leaders and have supported grant reviews, visiting speakers, program retreats, travel awards and program-specific pilot projects.

Through the efforts of program meetings and development funds, new collaborations and interactions are becoming established and resulting in increased numbers of collaborative publications. **Figure 7** compares the number of publications from 2012 to 2015 in which there are at least two authors from two different campuses (KUMC, KU-Lawrence, Stowers or Children's Mercy) in each research program. Additionally, KUCC has experienced an increase in the number of multi-PI grant awards. In 2012, KUCC had 19 active multi-PI grants, however in 2015, there were 31 active multi-PI grants.

Moving Scientific Findings

Figure 7



Disease Working Groups (DWGs): The DWGs provide a forum for exchange of research ideas and an opportunity to identify potential collaborative opportunities between clinical and basic science research investigators. Meetings include review of the clinical trial portfolio and accrual activity, educational sessions, investigator presentations on current areas of active research, brainstorming sessions and presentations on possible translational concepts. **Fabian**, Associate Director for Clinical Research, oversees and coordinates the DWGs. As shown in **Table 5**, there are 13 Disease Working Groups: 10 disease-specific and three non-disease-specific, but focused more broadly to identify clinical research to meet the needs of the patient population in their unique settings. The three non-disease specific DWGs include: 1) Pediatric Oncology, 2) Early Phase Clinical Trials and 3) the Midwest Cancer Alliance.

Table 5. Disease Working Groups and Leadership

Disease Working Group	Name of Chair (s)	Title, Department
Brain	Sarah Taylor, MD Roukoz Chamoun, MD	Professor, Internal Medicine Asst. Professor, Neurosurgery
Breast	Priyanka Sharma, MD Melissa Mitchell, MD, PhD Jamie Wagner, DO, FACOS	Assoc. Professor, Internal Medicine Asst. Professor, Radiation Oncology Asst. Professor, Surgery
Gastrointestinal	Mazin Al-Kasspooles, MD, FACS Raed Al-Rajabi, MD	Assoc. Professor, Surgery Asst. Professor, Internal Medicine
Genitourinary	Jeffrey Holzbeierlein, MD, FACS Xinglei Shen, MD	Assoc. Professor, Urology Asst. Professor, Radiation Oncology
Gynecological	Julia Chapman, MD, FACOG	Assoc. Professor, Obstetrics/Gynecology
Head & Neck	Lisa Shnayder, MD, FACS/ Prakash Neupane, MD Chris Lominska, MD	Assoc. Professor, Otolaryngology Assoc. Professor, Internal Medicine Asst. Professor, Radiation Oncology
Leukemia/Myeloid	Sunil Abhyankar, MD Tara Lin, MD	Professor, Internal Medicine Asst. Professor, Internal Medicine
Lung	Chao Huang, MD, FACP Fen Wang, MD, PhD Nirmal Veeramachaneni, MD	Assoc. Professor, Internal Medicine Assoc. Professor, Radiation Oncology Assoc. Professor, Cardiothoracic Surgery
Lymphoma/Myeloma	Sid Ganguly, MD, FACP	Professor, Internal Medicine
Melanoma/Sarcoma	Joshua Mammen, MD, PhD, FACS Howard Rosenthal, MD	Assoc. Professor, Surgery Asst. Professor, Orthopedic Surgery
Pediatric Oncology	Doug Meyers, MD Keith August, MD	Assoc. Professor, Children's Mercy Asst. Professor, Children's Mercy
Early Phase Clinical Trials	Raymond Perez, MD	Professor, Internal Medicine
Midwest Cancer Alliance	Gary Doolittle, MD	Professor, Internal Medicine

Target Acceleration Group (TAG): In 2014, KUCC organized the Target Acceleration Group (TAG) to help facilitate basic and clinical scientific interactions. TAG is a multidisciplinary team of experts that move scientific findings through KUCC's translational pipeline. Specifically, TAG aims to accelerate KUCC member projects around an identified cancer target, through screening, hit identification, medicinal chemistry optimization, secondary *in vitro* assay confirmation, drug delivery for both *in vitro* and *in vivo* tertiary assays, eADME pharmacokinetics and *in vivo* preclinical proof of principle. Experts on TAG include the Associate Director for Translational Research and D3ET co-leader, **Weir**, and the leadership of the Lead Development and

Optimization shared resource, **Baltezor**, **Roy**, **Schoenen** and **Broward**. TAG has assisted KUCC researchers in advancing 24 projects at the chemistry/biology interface.

Investigator-Initiated Trial Steering Committee (IITSC): In late 2015, KUCC formed the IITSC. A primary objective of the IITSC is to mentor and educate junior investigators and to support the acceleration of scientific discovery of novel therapeutics through the conduct of IITs. Specifically, the IITSC provides an interactive venue for basic and clinical researchers to present IIT concepts arising from laboratory and bedside discoveries, as well as a structure for defining and refining IIT concepts prior to and following discussion. Investigators receive instant feedback during the meeting from the committee members. The IITSC works with KUCC members to generate pilot clinical data by conducting pilot IITs that enable significant, impactful and fundable cancer therapeutic clinical trials. The IITSC is co-chaired by **Williamson**, Medical Director of the Clinical Trials Office, and **Weir**, along with other physician scientists, shared resource directors and protocol development experts that represent critical, multidisciplinary expertise concerning different aspects of clinical trial development and implementation (**Table 6**). Since forming the IITSC in late 2015, 15 IIT concepts from 20 investigators have been presented and most are moving forward with full proposals.

Table 6. IIT Steering Committee

Name	Expertise
Stephen Williamson, MD	Co-Chair, Clinical Trials Office Medical Director, IIT Physician (solid tumors)
Scott Weir, PharmD, PhD	Co-Chair, AD Translational Research, D3ET co-leader (drug development)
Carol Fabian, MD	Associate Director, Clinical Research, IIT Physician (prevention and survivorship)
Sid Ganguly, MD	IIT Physician (hematological malignancies)
Priyanka Sharma, MD	Assistant Director, Clinical Research, IIT Physician (solid tumors)
Qamar Khan, MD	PRMC Chair, IIT Physician (solid tumors)
Andrew Godwin, PhD	Deputy Director, Biospecimen Shared Resource (biomarker development)
Gregory Reed, PhD	Clinical Pharmacology Shared Resource, Correlative Studies (PK/PD)
Brooke Fridley, PhD	Biostatistics and Informatics Shared Resource (data management)
Keith August, MD	Pediatric Oncology Phase I Director (Children's Mercy)
Hobs Apell	Clinical Trials Office, Senior Executive Director
Carolyn Foster	Clinical Trials Office, IIT Protocol Development
Kevin Schorno	Institute for Advancing Medical Innovation, IIT Project Management

Molecular Tumor Board: The Molecular Tumor Board (MTB) was formed in April 2015 as a result of KUCC's participation in IBM Watson to help physicians better maneuver through the complex and ever-changing molecular-medicine landscape aimed at matching patients with a given therapy, including clinical trials of targeted agents. This group meets to interpret test results and recommend treatments, assess scientific validity of new molecular tests and create institutional policy regarding resource development to expand molecular-based testing. The MTB, co-led by Deputy Director, **Godwin** and the Assistant Medical Director of the Clinical Trials Office, **Lin**, is comprised of medical (adult and pediatric) and surgical oncologists, pathologists, clinical geneticists, basic and translational science researchers and bioinformaticians.

The Institute for Advancing Medical Innovation (IAMI): IAMI leads the effort to advance new cancer therapeutic strategies from preclinical proof of principle to clinical proof of concept. Directed by **Weir**, IAMI employs a robust, proven product development-focused translational research process to advance cancer-relevant drug and diagnostic products to patients. IAMI forms multidisciplinary, multi-organizational project teams comprised of basic, translational and clinical researchers to develop new cancer therapeutic concepts. IAMI provides proof of concept funding or investments in KU research, manages cores and centers required to support medical innovations and establishes strategic partnerships with industry, academia, government and disease philanthropy organizations to directly impact patients' lives. To date, IAMI has invested >$8.1M in 48 drug, diagnostic and medical device projects. Nine investments have resulted in royalty-bearing license agreements, and one drug product, Epaned™, has been FDA approved. IAMI has invested $2.8M in 15 cancer projects.

Consortium Centers

KUCC works hard to maintain communication across all campuses and encourage cross-campus collaborations. Purposefully, **Jensen** has placed Stowers investigator, **Li**, as a co-leader of the Cancer Biology research program and designated **Gamis** (a Children's Mercy investigator), as a co-leader of the Drug

Discovery, Delivery and Experimental Therapeutics research program.

There are a number of collaborative scientific teams that exhibit the interactiveness of Cancer Center members across campuses. For example, a research project that crosses research programs is a chimeric antigen receptor (CAR) T cell project with **Yankee** (CB – KUMC), **Myers** (D3ET – Children's Mercy) and **McGuirk** (D3ET – KUMC). This team is using the CAR technology to develop a novel CAR-T cell construct that couples the CAR to the native T cell receptor. This construct is being developed to target both hematologic malignancies, as well as solid tumors. Additionally, **Fridley** (CCPH – KUMC) and **Flatt** (D3ET – Children's Mercy) collaborate to determine the feasibility of international specimen procurement to assess the role of ethnicity in pediatric acute lymphoblastic leukemia outcomes.

Multiple collaborative research projects between KUCC members at KUMC, KU-Lawrence and Stowers have been described previously, including **Ding** (CB) at KUMC and **Li** (CB) at Stowers, **Workman** (CB) at Stowers and **Dutta** (D3ET) at KU-Lawrence and **Li** (CB) at Stowers, **Lin** (D3ET) and **Perez** (D3ET) at KUMC and the LDOSR.

Cancer Focus

Compared to the first CCSG submission in 2011 (which presented calendar year 2010 data), KUCC has expanded its depth and breadth of cancer focus in many ways, including an increase in cancer-related funding, high-impact publications and patient accrual to therapeutic trials. Particularly, KUCC has grown its membership from 143 to 187, increased total cancer-related funding from $49,713,260 to $61,264,739, doubled publications per year from 218 to 435 and increased accrual to therapeutic trails from 296 to 457.

Funding

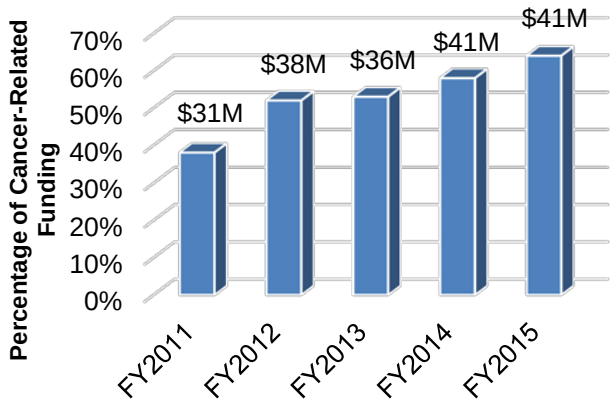
Thirty-nine KUCC members currently hold 62 NCI peer-reviewed projects totaling $13,489,788 compared to 19 members with 27 active NCI peer-reviewed grants totaling $10,423,529 in 2010. In addition, over the last grant period, KUCC increased it's funding of training grant awards from $1.3M to $2.4M. NCI funding supports research projects across all four research programs broadly related to the development of natural agents and Notch/PXR-targeting agents for cancer prevention and therapy (**Anant**, **Umar**, **Weir**, **Dhar**), weight-control strategies for cancer survivors (**Befort**), identification of risk biomarkers or other prognostic indicators for various cancers (**Behbod**, **Cheng**, **Godwin**, **Zeng**), HSP90 drug discovery efforts (**Blagg**), development of improved communication, literacy and cognitive strategies for cancer patients (**Chen**, **Landau**, **Lumpkins**, **Ramaswamy**), tobacco-related studies (**Choi**, **Daley**), development of drug delivery strategies (**Forrest**), identifying cancer disparities (**Greiner**), viral, hormonal, and microbial influence on cancer development (**Gudima**, **Hagan**, **Koestler**, **Nicot**, **Umar**), development of anti-metastatic therapies (**Welch**) and development of multiple targeted cancer therapies (**Xu**, **Neufeld**). These NCI funded cancer studies along with 107 other cancer-related, peer-reviewed grants and contracts totaling $37,852,378 drive each of KUCC's research program themes (**Table 7**).

Table 7. KUCC Research Programs and Scientific Themes

Research Program	Scientific Themes
Cancer Biology	Theme 1: Cancer Cell Biology and Stem Cell Biology Theme 2: Cell Proliferation, Differentiation and Death Theme 3: Chromatin Organization and Transcriptional Regulation Theme 4: Signaling Pathways and Development
Cancer Control and Population Health	Theme 1: Tobacco Control Theme 2: Translating Cancer Control into Clinics and Communities
Cancer Prevention and Survivorship	Theme 1: Pre-Cancerous Biology and Risk Biomarkers Theme 2: Prevention and Survivorship Translational Research
Drug Discovery, Delivery and Experimental Therapeutics	Theme 1: Discover and Deliver New Cancer Therapeutic Strategies Theme 2: Develop New Cancer Therapeutic Strategies Theme 3: Evaluate New Cancer Therapeutic Strategies in Experimental Therapeutics Trials

Furthermore, examining the total amount of extramural funding that comes to the University of Kansas Medical Center, the percentage of that amount that is from cancer-related studies has grown significantly. **Figure 8** plots the cancer funding as a percentage of the total funding received at KUMC. The dollar amounts shown at the top of each bar are the total cancer-related, peer-reviewed dollars received by KUCC members in that particular fiscal year.

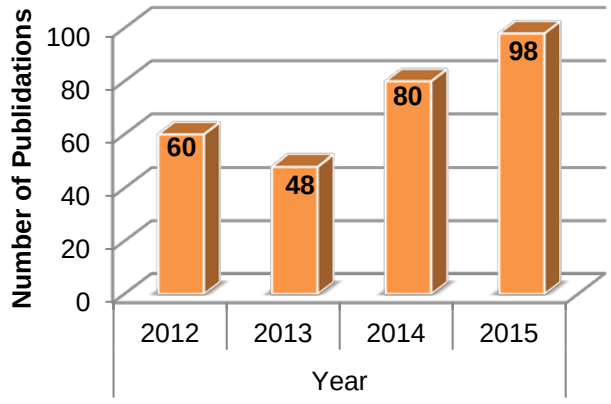
Figure 8



Publications

From 2006-2011, KUCC members published 1,311 cancer-related manuscripts (218/yr). During this most recent funding period (2012-2015), KUCC members published 1,741 publications (435/yr). While clearly the quantity of publications increased, more importantly the quality of high-impact publications has increased with a near doubling of high impact publications compared to just two years ago. **Figure 9** graphs the total number of publications for each with the number of publications with a journal impact factor ≥ 8 indicated in each bar.

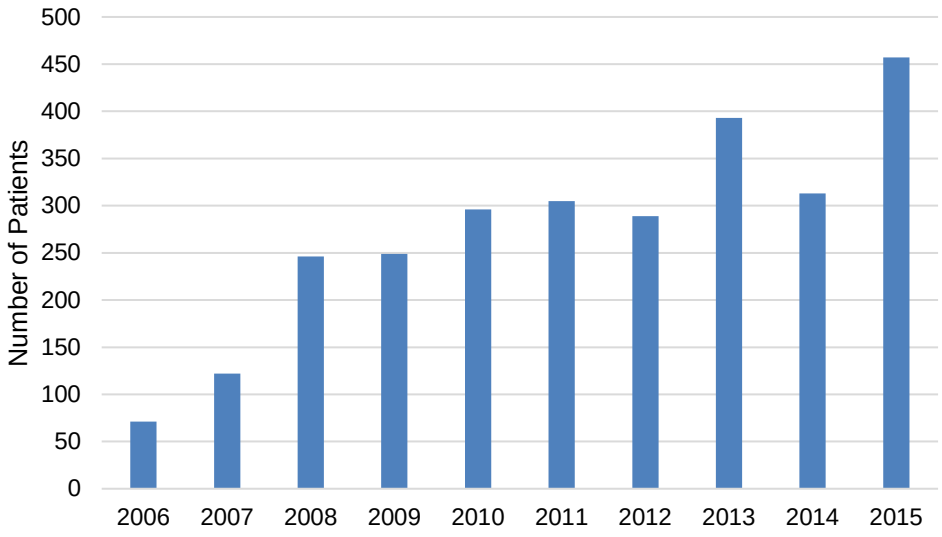
Figure 9



Accruals

When **Jensen** arrived in 2004, it was clear that there was insufficient clinical research infrastructure or culture to support a robust accrual of patients to therapeutic clinical trials. In fact in 2006, only 71 patients were accrued to therapeutic clinical trials. In contrast for 2015, 457 patients were accrued to therapeutic clinical trials (**Figure 10**). During the previous funding period, KUCC has continued to make it a priority to enroll patients on therapeutic clinical trials, with many different strategies implemented to grow the number of patients enrolled to a therapeutic clinical trial. These strategies involved improving new patient screening for enrollment, study activation timelines and the development of a guided process for investigator-initiated trial concept and protocol development. Each of these initiatives has met with success and KUCC continues to make progress as the clinical research infrastructure is expanded and developed.

Figure 10



Institutional Commitment

In June 2012, KUCC achieved NCI Cancer Center designation. Over the last four years substantial progress has been made broadening partnerships with communities throughout the KUCC catchment area, boosting recruitment of physician-scientists, augmenting clinical research and early-phase clinic trials, advancing education for the next generation of scientists and health care providers and heightening the influence of KUCC researchers in the national scientific community. The achievement of NCI comprehensive status is now the University's number one research priority.

Commitments and Resources

KUCC is recognized as a formal center within KUMC with sufficient space, positions and discretionary resources to ensure organizational stability and fulfillment of the KUCC vision. The Cancer Center is led by Director, **Jensen**, who is charged with uniting cancer research activities across four campuses — KUMC, KU-Lawrence, Stowers and Children's Mercy. From 2012-2015, KUCC continued to receive significant financial commitments from its parent institutions (The University of Kansas and its Medical Center), its clinical partner (The University of Kansas Health System), its consortium partners (Stowers and Children's Mercy), the Midwest Cancer Alliance, the Johnson County Education and Research Triangle tax, the State of Kansas and the philanthropic community. Funding is used to support recruitment, facilities, equipment, shared resources, administration and patient care services. Notable metrics of institutional support are listed below.

- From 2007 - 2015, The University of Kansas institutional support totaled $72M.
- The University of Kansas Health System provides $3.6M per year in direct support.
- Stowers renewed the Memorandum of Understanding in September 2015.
- Children's Mercy signed a Consortium Agreement in April 2015.
- The Midwest Cancer Alliance collected $1.4M from member hospitals and the MCA Partners Advisory Board contributed $8M, dollars that are used to fund collaborative cancer-focused research projects between KUCC and the partnering institution.
- The Johnson County Education and Research Triangle tax provides ≥ $5M per year in sales tax revenues supporting the KU Clinical Research Center and clinical trials research. This tax has a "no sunset" clause.
- Since 2007, the state has provided $48.8M. Specifically, the state of Kansas provides approximately $5M annually.
- KUCC has received $1,245,528 in funding from the Kansas Breast Cancer Research and Outreach License Plate Program that was signed into law in 2007.
- KUCC has also received $675,242 from the Breast Cancer Income Tax Check-off since 2008 to support pilot programs in breast cancer research.
- Since 2004, private philanthropy support totals over $194M.

Philanthropic Resources

The Cancer Center Director controls the use of all philanthropic funds for cancer and has worked closely with the KU Endowment Association to build a $331M fundraising target over a 10-year period to support the development of an NCI-designated Comprehensive Cancer Center. Thus far, the philanthropic fundraising total since **Jensen's** arrival in 2004 stands at just over $194M. This effort has been enabled by the formation of the Cancer Funding Partners, a volunteer group of civic and business leaders from Kansas City and Wichita who are committed to helping raise the necessary funds from among their peers to make NCI comprehensive designation a reality. In addition to overall fundraising, there has been a focused effort to increase the endowed funds available to KUCC. At the beginning of **Jensen's** tenure, the Cancer Center had an endowment of slightly less than $11M; currently, KUCC's endowment had grown to $36.2M, with an additional $32.5M which endows 24 cancer-focused professorships.

Clinical Resources

KUCC has access to all necessary clinical outpatient and inpatient facilities to carry out its vision and works jointly with The University of Kansas Health System to manage these facilities. Oversight of these activities are carried out by the KUCC Physician-in-Chief, Terry **Tsue**, MD, who reports directly to **Jensen** and to the KU Health System CEO, Bob Page. **Tsue** oversees the Oncology Service Line Committee that oversees cancer clinical activities.

By special arrangement with the University of Kansas Medical Center Research Institute, 50% of the indirect costs for funded clinical trials are returned to the Cancer Center. This arrangement was developed and negotiated by the KUCC Chief Operating Officer, Reene, with then KUMC Vice Chancellor for Research, Paul Terranova, PhD, in 2011. The current Vice Chancellor for Research, Richard Barohn, MD, and Associate Vice Chancellor for Research Administration, Jamie Caldwell, MBA, continue to honor this agreement. The money is used to support investigator-initiated clinical trials activity.

Directorship

KUCC is led by Director, **Jensen**, and as discussed in 'Organizational Capabilities', **Jensen** directly reports to both the Executive Vice Chancellor at the KU Medical Center campus and the Provost at the KU-Lawrence campus. Additionally, **Jensen** has a reporting relationship to the Stowers President and Chief Executive Officer, the Children's Mercy President and Chief Executive Officer, and the KU Health System Chief Executive Officer. This reporting structure integrates **Jensen** on all campuses and provides the network to accomplish strategic Cancer Center objectives. In the event that **Jensen** is not able to serve in his capacity as Director of KUCC, Deputy Director **Godwin** will be appointed Interim Director and a national search will be initiated to fill the position.

KUCC is recognized as a formal Center at KUMC and **Jensen** attends the monthly Basic Science Chair/Center and Institute Directors meeting organized by the Executive Dean of KUMC, Robert Simari, MD. This group meets to discuss institutional policy issues, budgets and academic needs. **Jensen** has served on a number of recruiting search committees at KUMC, KU-Lawrence and Children's Mercy allowing him to be involved in key decisions that impact the Cancer Center and its objectives. In the last grant period, **Jensen** served on the recruitment committees for the hiring of the Executive Vice Chancellor, Doug Girod, MD, the Dean of the School of Medicine, Robert Simari, MD, the Chair of Radiation Oncology, Allen Chen, MD and the director of the Children's Mercy Children's Research Institute, Tom **Curran**, PhD.

Across all campuses, as director of the Cancer Center, **Jensen** has the authority to:

- Allocate KUCC research space and resources;
- Develop the KUCC budget including all cancer-related philanthropic funds and fund-raising activities;
- Recruit new faculty to further KUCC's vision in cooperation with department chairs;
- Appoint and discontinue KUCC memberships - the membership committee recommends actions related to membership and processes memberships once per year, but the Director has final authority;
- Establish the organization and structure of the Senior Leadership Team;
- Establish and oversee the management of KUCC research programs;
- Establish and oversee the management of the shared resources that support KUCC member research; and
- Oversee cancer-related clinical activities conducted at the KU Health System in conjunction with the KUCC Physician-in-Chief.

Consortium Centers

KUCC has consortium agreements with both Stowers and Children's Mercy. The agreement with Stowers includes the provision that Stowers investigators engaged in cancer research are eligible to be KUCC members and serve in leadership roles. Stowers investigators who are KUCC members have access to KUCC shared resources and as such, KUCC members who are collaborating with Stowers investigators have access to Stowers core technology centers and facilities. Furthermore, all cancer clinical trial protocols involving a collaboration between cancer researchers from both institutions are subject to the same governing Protocol Review and Monitoring System and the same Data Safety and Monitoring Plan.

Similar to the consortium agreement with Stowers, Children's Mercy researchers engaged in cancer research are eligible to be KUCC members and serve in leadership roles. Children's Mercy researchers have access to KUCC shared resources and cancer clinical trial protocols involving a collaboration between cancer researchers from both institutions are subject to the same governing Protocol Review and Monitoring System and the same Data Safety and Monitoring Institutional Plan. Children's Mercy researchers have been added to the appropriate research program, the Protocol Review and Monitoring Committee, the Data Safety and Monitoring Board, the Leadership Council and the Associate Directors council.

Center Director

At the helm of KUCC is Roy A. **Jensen**, MD. **Jensen** is a nationally recognized breast cancer researcher and pathologist. **Jensen** was mentored and trained by David L. Page, MD and Harold L. Moses, MD at Vanderbilt University and has made strong contributions to the histologic and molecular characterization of pre-neoplastic and neoplastic mammary lesions. He has been a key contributor to a considerable number of seminal studies that have precisely defined, characterized and determined the clinical significance of multiple histologic abnormalities of the breast. **Jensen** was also a member of the Mouse Models Consortium group who defined the significance of common histologic lesions in the mammary glands of mouse models of breast cancer. In 1993, **Jensen** was asked by Harold Moses, MD be a part of the team formed to achieve NCI designation for the Vanderbilt-Ingram Cancer Center and for over ten years he was the director of the Human Tissue Acquisition and Pathology Shared Resource and a member of the Breast Cancer research program.

In 2004, **Jensen** was recruited from the Vanderbilt-Ingram Comprehensive Cancer Center to be the director of KUCC. **Jensen** serves as Professor of Pathology and Laboratory Medicine, Professor of Anatomy and Cell Biology, Professor of Cancer Biology, Professor of Biomedical Engineering, and Adjunct Professor of Molecular Biosciences at the University of Kansas in Lawrence and was appointed the William R. Jewell Kansas Masonic Distinguished Professor of Cancer Research in 2005. For the last 20 years, **Jensen's** research has focused on the molecular and cellular biology of breast cancer with a particular interest in BRCA1. Currently, his research focuses on understanding the tumor suppressor gene, *BRCA1*, which is involved in the repair of damaged DNA and a host of other critical cell functions. Specifically, **Jensen** aims to understand the critical role of BRCA1 expression/function/dysfunction in normal and neoplastic breast epithelium. He has been funded by the NCI, American Cancer Society, Susan G. Komen for the Cure Grant Program and Department of Defense. He has published over 110 peer-reviewed articles and 20 book chapters. In 2013, he was selected as the Honorary Medical Alumnus of The University of Kansas Medical Center.

Jensen is an active member of the Cancer Prevention and Survivorship research program and the Breast Disease Working Group and has established a number of inter- and intra- programmatic collaborations focused on the role of BRCA1 in breast epithelial stem cells (**Behbod**, **Anant**, **Harlan-Williams**), BRCA1 miRNA regulatory mechanisms (**Kumaraswamy**) and molecular mechanisms of natural products in cancer prevention (**Anant**). **Jensen** also has an active interest in mentoring scientists on all professional levels. He serves as the primary mentor to graduate students and postdoctoral fellows in his laboratory and co-mentor for young investigators (**Sharma, Cheng**) in other departments, and has recently graduated two MD/PhD students from his laboratory (Shane Stecklein and Wenjia Wang). In 2014, he received the Mentorship Award from the University of Kansas Medical Center. Moreover, **Jensen** collaborated with Associate Director for Basic Science and Education, **Welch**, and leaders from multiple other Cancer Centers to define the critical elements and best practice strategies for the development of integrated educational programs. These programs would be directed at achieving a work force of professionals that broadly appreciate the principals of academic medicine spanning the breadth of knowledge necessary to advance the goal of improving the current practice of cancer care medicine (**Welch**, *Cancer Res,* 2015).

Locally, **Jensen** is engaged in university, statewide and regional activities related to supporting KUCC. He successfully worked with the state legislature to obtain a $5M annual appropriation for KUCC, developed a breast cancer vehicle license plate fundraiser, instituted a KUCC check-off on the state income tax form, convinced the legislature to support a new School of Pharmacy building, obtained a regulatory clarification from the state insurance commissioner regarding mandating coverage for routine care for patients on clinical trials, developed the concept and led the public campaign to pass the Johnson County Education and Research Triangle Tax in support of the KU Clinical Research Center, led a statewide initiative to raise the tobacco tax, and advocates for the Tobacco 21 initiative. Additionally, **Jensen** successfully executed an initial affiliation agreement and extension with Stowers, formalized a consortium agreement with Children's Mercy and a clinical integration agreement with KU Health System. He is a member of the oversight committee for the Institute for Advancing Medical Innovation, served a six-year term on the Board of Directors of the University of Kansas Medical Center Research Institute and currently serves on the KUMC Research Oversight Committee. He participates on the internal advisory board for the Department of Biostatistics and the Center for Biomedical Research Excellence for Cancer Therapeutics at KU-Lawrence. **Jensen** has led KUCC efforts to provide funding for the expansion of physical space and has engaged in numerous other fundraising activities that have brought in over $194M from all sources for the Cancer Center since his arrival in 2004.

Nationally, **Jensen** regularly advocates on Capitol Hill for biomedical research funding. He has cultivated relationships with Kansas Senator Jerry Moran, Kansas Representative Kevin Yoder and Missouri Senator Roy Blunt to advocate for increased biomedical research funding and has helped to establish them as some of NIH's strongest advocates. **Jensen** has served on numerous grant review panels, study sections, and site visit teams for the NIH, the Department of Defense-Breast Cancer Research Program, the Medical Research Council of Canada, the California Breast Cancer Research Program and the Susan G. Komen Breast Cancer Foundation. He has been active on multiple committees of several scientific organizations including the American Association for Cancer Research, United States and Canadian Academy of Pathology, and the Susan G. Komen Breast Cancer Foundation Advisory Council. Specifically, **Jensen** serves on the Science Policy and Governmental Affairs Committees for the American Association for Cancer Research, and the Federation of American Societies for Experimental Biology, the American Association of Cancer Researcher Publications Committee, and the Science Policy Working Group of the American Society for Investigative Pathology and co-chairs the research committee for C-Change. In 2013, he successfully chaired the program committee for the Association of American Cancer Institute's annual meeting and was elected to the Board of Directors of that organization. **Jensen** also serves on Subcommittee A for the National Cancer Institute and has participated in over 20 site visits. Furthermore, he serves as Chair of the University of Oklahoma Stephenson Cancer Center External Advisory Board and as a member of the Georgia Cancer Center, Augusta University External Advisory Board. In addition, he regularly serves as a reviewer for numerous cancer-related journals, has served on the editorial board of *Human Pathology* and currently serves on the editorial board of the *Journal of Mammary Gland Biology and Neoplasia*. In summer 2016, he was elected as the Vice President/ President-Elect of the Association of American Cancer Institutes.

Jensen directly reports to both the Executive Vice Chancellor at the KU Medical Center campus (Doug Girod, MD) and the Provost at the KU-Lawrence campus (Neeli Bendapudi, PhD). Additionally, **Jensen** has a dotted line reporting relationship to the Stowers President and Chief Executive Officer, David Chao, PhD, the Children's Mercy President and Chief Executive Officer, Randall O'Donnell, PhD, and the KU Health System Chief Executive Officer, Bob Page. In the event that **Jensen** is not able to serve in his capacity as Director of KUCC, Deputy Director **Godwin** will be appointed Interim Director and a national search will be initiated to fill the position. **Jensen** devotes 50% of his time to advancing the Cancer Center's scientific and administrative objectives for the Cancer Center Support Grant. In addition to the duties outlined in the 'Institutional Commitment' section, **Jensen** also works diligently to:

- Set the long-term vision for the Cancer Center and oversee its implementation;
- Promote interdisciplinary coordination and collaboration among KUCC members;
- Serve as a liaison with community, civic and state government leaders;
- Raise philanthropic funds to support all aspects of KUCC; and
- Maintain collegial, progressive relationships with all research partners.

In doing so, **Jensen** has formalized an Internal Advisory Board with representatives from Children's Mercy, Stowers, KU-Lawrence and KUMC (**Table 8**). This group meets twice a year to provide feedback on strategic initiatives, coordinate recruitment, research and clinical priorities.

Table 8. Internal Advisory Board

Institution	Advisors
KUMC	Alan Yu, MB, BChir and Doug Girod, MD
KU – Lawrence	Steven Soper, PhD and Neeli Bendapudi, PhD
Stowers	Scott Hawley, PhD and Rob Krumlauff, PhD
Children's Mercy	Steve Leeder, PhD and Tom Curran, PhD

Progress Report Publications

See detail listing of publications within specific components.

Protection of Human Subjects – OVERALL

Select components of this CCSG application involve the potential use of human subjects (Developmental Funds, Biospecimen Shared Resource, Biostatistics and Informatics Shared Resource, Clinical Pharmacology Shared Resource, Clinical Protocol and Data Management, Protocol Review and Monitoring System and Early Phase Clinical Research Support). Please refer to the specific components listed for an appropriate description of the Protection of Human Subjects.

In general, the Human Subjects Committee (HSC) is designated as the Institutional Review Board (IRB) for the University of Kansas Medical Center, as required by 45 CFR 46 and 21 CFR 56. The HSC is responsible for reviewing, approving, modifying, rejecting and monitoring research involving human subjects.

The purpose of the HSC is to ensure, both in advance and by periodic review, that appropriate steps are taken to protect rights and welfare of humans participating as research subjects. In order to approve human subjects research the HSC must determine that the research meets all federal criteria that are listed in 45 CFR 46.111.

The criteria are summarized as follows:

- Risks to subjects are minimized. Note that all risks should be considered, including the potential for economic, legal, physical, psychological and social harm.
- Risks to subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result.
- Selection of subjects is equitable.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, except in cases in which the requirement is waived.
- Informed consent will be appropriately documented as required.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Inclusion of Women & Minorities – OVERALL

Select components of this CCSG application involve the potential use of human subjects (Developmental Funds, Biospecimen Shared Resource, Biostatistics and Informatics Shared Resource, Clinical Pharmacology Shared Resource, Clinical Protocol and Data Management, Protocol Review and Monitoring System and Early Phase Clinical Research Support). Please refer to the specific components listed for an appropriate description of the Inclusion of Women and Minorities.

Inclusion of Children – OVERALL

Select components of this CCSG application involve the potential use of human subjects (Developmental Funds, Biospecimen Shared Resource, Biostatistics and Informatics Shared Resource, Clinical Pharmacology Shared Resource, Clinical Protocol and Data Management, Protocol Review and Monitoring System and Early Phase Clinical Research Support). Please refer to the specific components listed for an appropriate description of the Inclusion of Children.

Vertebrate Animals – OVERALL

The University of Kansas Medical Center (KUMC) is fully accredited by the Association for the Assessment of Accreditation of Laboratory Animal Care, International (AAALAC), which requires the adherence to the highest standards of animal care and use by accredited institutions. In addition to the AAALAC accreditation, KUMC is registered as a research facility with the United States Department of Agriculture (USDA) in accordance with the Animal Welfare Act and all amendments. Registration requires all animal facilities are inspected by the USDA to ensure that all activities involving research animals are in compliance with all applicable laws and regulations. KUMC also holds a Category I Assurance with the Public Health Service (through the NIH's Office of Laboratory Animal Welfare). These three relationships confirm the integrity of the program structure, function and foundation.

KUMC maintains an animal program that is registered with the USDA, assured through the NIH/PHS, and accredited with AAALAC International.

USDA
Certificate # 48-R-0003; Customer # 1460
Status: Current; No outstanding citations or non-compliances.

NIH/PHS
Assurance Number: A3237-01
Status: Current through June 2018; No outstanding citations or non-compliances.

AAALAC
Accreditation Number: #000785
Accreditation effective date: 11/19/10- present

Select components of this CCSG application involve the potential use of vertebrate animals (Developmental Funds, Lead Development and Optimization Shared Resource, Biostatistics and Informatics Shared Resource and Transgenic and Gene-Targeting Shared Resource). Please refer to the specific components listed for an appropriate description of Vertebrate Animals.

References Cited – OVERALL

Qian P, He XC, Paulson A, Li Z, Tao F, Perry JM, Guo F, Zhao M, Zhi L, Venkatraman A, Haug JS, Parmely T, Li H, Dobrowsky RT, **Ding** WX, Kono T, Ferguson-Smith AC, **Li** L. The Dlk1-Gtl2 Locus Preserves LT-HSC Function by Inhibiting the PI3K-mTOR Pathway to Restrict Mitochondrial Metabolism. *Cell Stem Cell.* 2016 Feb 4;18(2):214-28. doi: 10.1016/j.stem.2015.11.001. Epub 2015 Nov 25. PubMed PMID: 26627594.

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Cox LS, **Nollen** NL, **Mayo** MS, **Choi** WS, **Faseru** B, Benowitz NL, Tyndale RF, Okuyemi KS, Ahluwalia JS. Bupropion for smoking cessation in African American light smokers: a randomized controlled trial. *J Natl Cancer Inst*. 2012 Feb 22;104(4):290-8. doi: 10.1093/jnci/djr513. Epub 2012 Jan 25. PubMed PMID: 22282543; PubMed Central PMCID: PMC3283533.

Welch DR, Antalis TM, Burnstein K, Vona-Davis L, **Jensen** RA, Nakshatri H, Riegel AT, Spitz DR, Watson DK, Weiner GJ; Cancer Biology Training Consortium. Essential Components of Cancer Education. *Cancer Res*. 2015 Dec 15;75(24):5202-5. doi: 10.1158/0008-5472.CAN-15-2077. Epub 2015 Dec 1. Review. PubMed PMID: 26627010; PubMed Central PMCID: PMC4681646.

KU THE UNIVERSITY OF KANSAS
Office of the Chancellor

Roy A. Jensen, MD
Director, The University of Kansas Cancer Center
3901 Rainbow Boulevard, 2017A Wahl Hall West
Kansas City, KS 66160

Dear Dr. Jensen:

On behalf of the University of Kansas, I want to express the institution's support for The University of Kansas Cancer Center's application for National Cancer Institute Comprehensive Cancer Center designation. Obtaining this designation remains the top research goal of our university.

The center has garnered $13.5 million in total NCI funding and $61.2 million in total overall cancer-related funding. Twelve years ago, total funding was $23 million. As a result of the increase in funding, the KU Cancer Center has been able to recruit stellar scientists to leadership positions. Since 2012, 37 strategic researchers have been recruited and hired.

Throughout this effort, KU has experienced strong public support and ongoing financial commitments from state policymakers. This includes bipartisan support from three governors, who together with the Kansas Legislature have appropriated $5 million in annual state funds every year since 2007. This unfailing support, despite shifts in Kansas' political climate, demonstrates our state's continued commitment to the success of the Cancer Center.

Another expression of deep public commitment came in 2008, when voters in Johnson County, Kansas, passed a 1/8-cent sales tax that will generate approximately $5 million a year for the KU Clinical Research Center. The Clinical Research Center has experienced increased clinical research activity over the last several years, including a 30 percent increase in patient visits for each of the last two years.

Finally, we have received considerable philanthropic support through KU's "Far Above" campaign. Since 2008, $194 million was raised for cancer research and the KU Cancer Center. For example, a Kansas City-based family foundation recently donated $7 million to the KU Cancer Center, funding new faculty and researchers at the Clinical Research Center. The gift also supports efforts by the cancer center, Children's Mercy Hospital and the Stowers Institute for Medical Research to develop pediatric cancer drugs.

The public support the KU Cancer Center has received in its pursuit of Comprehensive designation has been positive and overwhelming. The University of Kansas fully supports the KU Cancer Center's application for Comprehensive designation.

Sincerely,

Bernadette Gray-Little

Bernadette Gray-Little
Chancellor

230 Strong Hall | 1450 Jayhawk Boulevard | Lawrence, KS 66045-7535 | (785) 864-3131 | Fax (785) 864-4120 | www.ku.edu

THE UNIVERSITY OF KANSAS Medical Center

September 16, 2016

Roy A. Jensen, MD
Director
The University of Kansas Cancer Center
3901 Rainbow Boulevard, 2017A Wahl Hall West
Kansas City, KS 66160

Dear Dr. Jensen,

I am writing to pledge my full support in The University of Kansas Cancer Center's pursuit of NCI Comprehensive Cancer Center designation. By serving the region as an NCI-designated cancer center for the last five years, KU Cancer Center has been an immense resource to the people of Kansas. Based on its expertise in drug discovery, development and delivery; strong research in cancer prevention and control; and community-based approach to cancer research through the Midwest Cancer Alliance, the University of Kansas Cancer Center deserves the NCI's most elite distinction, Comprehensive Cancer Center status.

It is remarkable to consider the amount of progress that has been made in a relatively short amount of time. It was just ten years ago when former Chancellor Robert Hemenway made achieving NCI designation the utmost priority for the University of Kansas. Committing to this goal launched a significant investment of resources into expanding clinical research programs at both the Cancer Center and University of Kansas Medical Center. Since then, the medical center has doubled its faculty. Kansas has experienced one of the largest percentage increases in NIH funding of any state in the country, largely due to the NIH portfolio of the medical center. In 2009, the medical center passed the $100 million mark for total research funding – for the first time in its history. Community support from the Kansas Masonic Foundation, now totaling more than $30 million, helped set the research component of the Cancer Center. These are just a few highlights of the efforts made by the University, community and other supporters, demonstrating their commitment to the long-term success of the Cancer Center.

The University of Kansas Cancer Center has succeeded in recruiting some of the nation's top cancer researchers. Many of those recruits have noted that their decision to join the KU Cancer Center was based on the overwhelming amount of public support the center receives and its sterling reputation. I couldn't agree more. When I assumed my position as executive vice chancellor three years ago, I saw a Cancer Center, newly NCI-designated, dedicated to solidifying its status as a leader in cancer research and cancer care. Today, the KU Cancer Center is strongly positioned for the next step: NCI Comprehensive status.

Sincerely,

Douglas A. Girod, MD FACS
Executive Vice Chancellor
The University of Kansas Medical Center
Professor, Department of Otolaryngology-Head and Neck Surgery
The University of Kansas School of Medicine

Office of the Executive Vice Chancellor
3901 Rainbow Blvd. | Mail Stop 2015 | Kansas City, KS 66160 | (913) 588-1440 | FAX (913) 588-1412 | 711 TTY | kumc.edu

THE UNIVERSITY OF KANSAS
Office of the Provost

Roy A. Jensen, MD
Director, The University of Kansas Cancer Center
3901 Rainbow Boulevard, 2017A Wahl Hall West
Kansas City, KS 66160

Dear Dr. Jensen:

I write today in support of The University of Kansas Cancer Center's application for National Cancer Institute Comprehensive Cancer Center designation. Because the University of Kansas is major comprehensive research and teaching university and a center for learning, scholarship, and creative endeavor, it is important that The University of Kansas Cancer Center embodies the highest levels of these core attributes.

We promote a culture of innovation. For example, on the Lawrence campus, the School of Pharmacy is home to some of the country's best drug developers. On the Kansas City campus, we have the nationally recognized Institute for Advancing Medical Innovation, which leverages this expertise and collaborates with researchers and other partners to get new treatments to market faster. IAMI provides proof-of-concept funding or investments in KU research, manages cores and centers required to support medical innovations, and establishes strategic partnerships with industry, academia, government and disease philanthropy organizations to directly impact patients' lives. To date, IAMI has provided in excess of $1.3 million in funding for KU Cancer Center member projects.

The Central District project is an exciting renewal of our physical facilities for the biomedical sciences on the KU-Lawrence campus that will result in all new research, teaching and office space for our faculty in the Department of Molecular Biosciences. We look forward to working with the cancer center leadership for the relocation of cancer center members into this space to optimize their effectiveness and to plan for future growth in this important focus for us.

The KU Cancer Center and its Consortium members uphold KU's vision of serving as an "intellectually vibrant" center where everyone is encouraged to learn and grow. There is an established mentor program between researchers at KU Cancer Center and Children's Mercy Hospital. Multiple times a week, seminars are held that allow individuals to discuss their research findings, encouraging back-and-forth discussion. This forum is also utilized for potential recruits to present their research initiatives.

It is the spirit of innovation and the desire to "know more" that drives the KU Cancer Center. I am impressed with what I've seen and I fully support their application for NCI Comprehensive designation.

Sincerely,

Neeli Bendapudi

Neeli Bendapudi, Ph.D.
Provost and Executive Vice Chancellor

THE UNIVERSITY OF KANSAS HOSPITAL

Bob Page
President and Chief Executive Officer
Hospital Executive Office

September 14, 2016

Douglas R. Lowy, MD
Acting Director
U.S. National Cancer Institute
6116 Executive Boulevard
Bethesda, MD 20892-8322

Dear Dr. Lowy:

The University of Kansas Hospital is proud to support The University of Kansas Cancer Center's efforts to achieve Comprehensive Cancer Center designation from the National Cancer Institute. As the clinical partner of The University of Kansas Cancer Center, we deliver the highest quality cancer care to thousands of patients from the Kansas City region and beyond. Our hospital supports the University of Kansas Medical Center's leadership role in the cancer center through a $2.5 million annual commitment for research and recruitment of top physician scientists. We also partner on dozens of important initiatives every year to increase the awareness of cancer prevention and early detection in our communities.

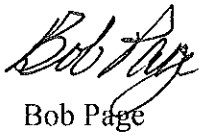
More and more patients are choosing us for their cancer care. To keep up with the demand for our services, last year we broke ground on Cambridge North Tower, which will open in late 2017 with 11 levels dedicated to patient care and include new space for our surgical oncology program. We are also expanding our Indian Creek campus in Overland Park to provide additional cancer care and other services. These additions will enable our physicians and care teams to offer the most advanced care to an even greater number of patients.

We remain equally committed to providing the highest quality care and access to clinical trials at our outpatient community locations and at partner organizations across the region. In our 18 years as an independent state authority, we have invested nearly $169 million in our clinical cancer capital programs.

Thanks to the efforts of cancer center director Roy Jensen, MD, physician-in-chief Terry Tsue, MD, and our outstanding medical and clinical staff, we are pleased our care and research continues to earn national recognition. This year we ranked 25th on *U.S. News & World Report's* Best Hospitals for cancer care.

Our collaborative efforts have helped us reduce the burden of cancer for patients and families across the region. But with cancer rates continuing to rise, we know there is much work to be done. Achieving comprehensive NCI designation would enable The University of Kansas Cancer Center to do even more by strengthening our research, education and clinical care, benefiting not only our patients today but our communities for generations to come.

Sincerely,



Bob Page
President and Chief Executive Officer

STOWERS INSTITUTE®
FOR MEDICAL RESEARCH

August 2, 2016

Roy Jensen, MD
Director
The University of Kansas Cancer Center
3901 Rainbow Boulevard
2017A Wahl Hall West, MS 1027
Kansas City, KS 66160

To Whom It May Concern:

I am writing in support of The University of Kansas Cancer Center's (KUCC) application for designation as an NCI Comprehensive Cancer Center. The University of Kansas Cancer Center has had considerable influence in the advancement of Kansas City's local basic research enterprise by establishing strong infrastructure and expertise in drug discovery and providing local researchers with access to new clinical trial capabilities.

Recognizing the need to build a strong translational research enterprise that can take basic discoveries from laboratories, translate them into drugs and therapeutic devices, and get them into the hands of enterprises that can take them to market, KUCC established a strong Drug Discovery, Development and Experimental Therapeutics Program several years ago. This program focuses on developing new drug candidates and finding new applications for or repurposing existing drugs. The launch of this program has provided local researchers with access to industrial experts like Dr. Scott Weir.

KUCC has made significant strides in the last few years in enhancing its clinical trial capabilities. Last year, KUCC and its affiliate sites had more than 180 ongoing treatment trials involving nearly 500 patients. This increase in clinical trial activity not only benefits patients, but it also heightens basic scientists' awareness of the potential clinical relevance of their research.

As NCI Consortium partners, Stowers Institute for Medical Research (Stowers) and The University of Kansas Cancer Center consistently collaborate, combining resources which allow us to aim higher in cancer research. Stowers' scientists have leadership roles within the KUCC. For example, Dr. Linheng Li, a principal investigator, serves as co-leader for the Cancer Biology program with the KUCC. Further, Stowers investigators helped found and have participated extensively with KUCC's Cancer Biology course since it was initiated more than ten years ago.

1000 E. 50th St., Kansas City, Missouri 64110
Telephone: (816) 926-4000, Fax: (816) 926-2000
www.stowers.org

Stowers' scientists have assisted in KUCC investigator recruitment, providing Dr. Jensen with thoughtful and essential candidate feedback. Research collaborations between the two entities have resulted in a number of significant publications. One study addresses a particular location in DNA, the Dlk1-Gtl2 locus, and its critical role in protecting hematopoietic stem cells by restricting metabolic activity in the cells' mitochondria. By combining forces, we can better leverage research assets, expand knowledge, and finally, advance new and more effective therapeutic approaches for patients.

In summary, The University of Kansas Cancer Center's contribution to drug discovery, as well as buildings its clinical trial capabilities, have made a solid impact on the region's cancer research landscape. Comprehensive designation will strengthen this impact even more, benefitting researchers and patients alike.

Sincerely,

David M. Chao

David M. Chao, Ph.D

Children's Mercy HOSPITALS & CLINICS Kansas City
2401 Gillham Road
Kansas City, Missouri 64108
(816) 234-3000

Randall L. O'Donnell, PhD
President and CEO

Phone: (816) 234-3650
Fax: (816) 842-6107

August 26, 2016

Roy Jensen, MD, Director
The University of Kansas Cancer Center
3901 Rainbow Boulevard
2017A Wahl Hall West, MS 1027
Kansas City, KS 66160

Dear Roy,

Children's Mercy Hospital is proud to be a member of the NCI consortium, which incorporates our clinicians into The University of Kansas Cancer Centers research programs, and we fully support the center's application for National Cancer Institute Comprehensive designation.

We were pleased last year to sign a formal consortium agreement between the KU Cancer Center and Children's Mercy Hospital. This allows our combined clinical oncology programs to provide even better care and support for a critically underserved population in cancer treatment: children. Furthermore, our joint research programs, enhanced by premier cancer biology research at the Stower's Institute, offers new vistas for exploring the mechanisms underlying childhood cancers. The new consortium enables our institutions to work jointly to further enhance clinical care for children and advance pediatric academic development. As the region's only comprehensive quaternary children's hospital, bringing our large pediatric oncology program together with the KUCC, expands clinical research initiatives for children in the KUCC catchment area and the broader Midwest region.

The KU Cancer Center's commitment to addressing multiple aspects of cancer can be illustrated by the diversity of our collaborations. One example – Children's Mercy oncologist Doug Myers is collaborating with KU immunologist Tom Yankee to use chimeric antigen receptor (CAR) technology to modify T-cells in a manner that makes them potent tumor killers. There is also ongoing partnership between investigators among the three main campuses to conduct drug screening for oncogenic pathways originally discovered at Stowers, and CMH will be actively integrated into this process. Finally, as part of an overall campaign targeted at increasing the HPV vaccination rate in Kansas, the KU Cancer Center and CMH recently co-hosted a conversation via Twitter with the goal of raising awareness about its benefits and dispelling misconceptions about the vaccine.

CMH was one of the Midwest Cancer Alliance's (the outreach arm of KUCC) first members. We are also a founding member of the Partners Advisory board. Most recently, CMH and MCA partnered to launch the KU Cancer Center Survivorship Transition Clinic. Based at The University of Kansas Hospital, the clinic is one of only half a dozen clinics in the country specifically for adult survivors of childhood cancer. The program provides these patients access to long-term care and treatment for any late effects.

Obtaining NCI Comprehensive designation is key to continuing to provide world-class cancer care to cancer patients covering the spectrum of ages, as well as increased grant funding, research support, and the overall economic impact. With this designation, patients – adults and children alike – will have access to the latest clinical trials and the most advanced cancer treatments closer to home.

Sincerely,

Randall L. O'Donnell, PhD
President and Chief Executive Officer

Children's Research Institute
Tom Curran, PhD, FRS
Executive Director & Chief Scientific Officer
2401 Gillham Road
Kansas City, MO 64108
Phone: (816) 983-6226

Re: The University of Kansas Cancer Center Application for National Cancer Institute (NCI) Comprehensive Designation

To Whom It May Concern:

It gives me great pleasure to write to you in support of The University of Kansas Cancer Center's application for National Cancer Institute (NCI) Comprehensive designation. As Executive Director and Chief Scientific Officer of the Children's Research Institute (CRI) at Children's Mercy Hospital (CMH), I believe this designation will strengthen the local research environment and fast-track new and improved cancer treatments for patients, including children.

Of the 5,000 cancer treatment centers nationally, only 1.3 percent have achieved NCI Comprehensive designation, and very few have partnered with a pediatric hospital as part of its consortium. Children's Mercy's pediatric oncology program is one of the largest in the country, serving nearly 200 patients a year. With this partnership, patients, particularly in the areas of genomics, personalized medicine and drug development, will benefit from a deeper pool of cancer specialists; researchers will have access to a broader range of subject matter experts and other resources; and, finally, more clinical trials will be available to patients of all ages.

Teamwork and the sharing of data are key in the fight against cancer. CMH and The Institute for Advancing Medical Innovation have partnered to advance multiple research collaborations more quickly. For example, the two entities have partnered with the National Center for Advancing Translational Sciences (NCATS) on the Sarcoma Learning Collaborative (SLC). The SLC is focused on discovering and developing new treatments for sarcomas affecting children,

adolescents and adults. KU's drug development and delivery experts work with clinical pharmacologists and pediatric sarcoma specialists at Children's Mercy Hospital. The KU Cancer Center also contributes researchers with a rich history of work in sarcomas.

Historically, children have been a neglected population group when it comes to cancers and other rare diseases. The University of Kansas Cancer Center and Children's Mercy Hospital have an obligation to attack childhood cancers with all that we have. Together, we can improve the health and quality of life for patients. Patients will benefit even more if The University of Kansas Cancer Center is successful in its application for designation as a comprehensive cancer center.

Sincerely,

Tom Curran, PhD, FRS

Executive Director and Chief Scientific Officer

Children's Research Institute, Children's Mercy Kansas City

Professor of Cancer Biology

School of Medicine, University of Kansas Medical Center

Capitol Building
Room 241-South
300 SW 10th Street
Topeka, KS 66612

Kansas
Office of the Governor

Phone: (785) 296-3232
Fax: (785) 368-8788
governor@ks.gov

Sam Brownback, Governor

August 23, 2016

Roy Jensen, MD
Director
The University of Kansas Cancer Center
3901 Rainbow Boulevard
2017A Wahl Hall West, MS 1027
Kansas City, KS 66160

Dear Dr. Jensen,

I am proud to support the University of Kansas Cancer Center's application for National Cancer Institute (NCI) Comprehensive Cancer Center designation. This designation will allow the cancer center to continue to expand access to the most advanced cancer care in our region and have a positive impact on cancer rates through an increased focus on prevention and early detection.

In addition to providing world-class cancer care, KU Cancer Center has been a significant influence in the public policy debate over issues that have the potential to save lives and decrease cancer in Kansas. We – myself, Kansas legislators and the KU Cancer Center – worked together to increase the tobacco tax and pass legislation prohibiting minors from using indoor tanning facilities. Both laws have the potential to protect our youth and decrease cancer rates in the years to come.

As both Governor and before that as a United States Senator, it has been my great pleasure to be a long-time advocate of the KU Cancer Center. The State of Kansas and the legislature continue to provide $5 million annually directly to the cancer center in support of its work.

The University of Kansas Cancer Center has had a tremendous impact on the lives of Kansans and has been a driving force in economic development and job creation. It is for these many reasons that I am pleased to give you my full and enthusiastic endorsement of your application for NCI Comprehensive Cancer Center designation.

Sincerely,

Sam Brownback
Governor

JERRY MORAN
KANSAS

521 DIRKSEN SENATE OFFICE BUILDING
WASHINGTON, DC 20510-1606
P: (202) 224-6521
F: (202) 228-6966

moran.senate.gov

United States Senate

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September 19, 2016

Roy A. Jensen, MD
Director
The University of Kansas Cancer Center
3901Rainbow Boulevard
2017 Wahl Hall West, MS 1027
Kansas City, KS 66160-7312

Dear Dr. Jensen:

I am writing to express my full and ongoing support of The University of Kansas Cancer Center (KUCC) in its effort to obtain National Cancer Institute Comprehensive Cancer Center designation. I strongly support your vision of eliminating cancer in our nation's heartland by strengthening KUCC's scientific research infrastructure and capabilities. I have had the pleasure of seeing first-hand the innovative research, expansion of clinical trial offerings, and excellent treatment patients receive at KUCC.

Kansas has the potential to grow as a thriving research powerhouse for medical advancement. Obtaining Comprehensive Cancer Center status would enhance KUCC's ability to discover, develop and deliver innovative therapies to patients in Kansas. KUCC is strongly positioned to be a national leader in the fight to cure cancer. Since receiving NCI designation in June 2012, KUCC has expanded its efforts to improve the health outcomes in our region through population-based cancer education, prevention and early-detection. In fact, *U.S. News & World Report* recently ranked The University of Kansas Hospital's cancer program as the 25th in the nation.

Furthermore, there are 47 Comprehensive Cancer Centers across the country, but none are located in Kansas. With this designation, KUCC patients would have greater access to the latest clinical trials, and the most advanced cancer treatments closer to their homes. Comprehensive Cancer Center designation would also provide KUCC additional resources to attract and support talented investigators and emerging researchers devoted to the fight against cancer. This designation would also mean that NCI investments will continue to have a substantial impact on job creation and economic growth in the region.

Medical research leading to the prevention and cure of diseases plays a critical role in keeping our nation healthy and reducing health care costs. KUCC is positioned to deliver results that will have a transformational impact on the fields of cancer research and medicine, and drive

HAYS OFFICE
1200 MAIN STREET
SUITE 402
HAYS, KS 67601

MANHATTAN OFFICE
923 WESTPORT PLACE
SUITE 210
MANHATTAN, KS 66502

OLATHE OFFICE
23600 COLLEGE BOULEVARD
SUITE 201
OLATHE, KS 66061

PITTSBURG OFFICE
306 N. BROADWAY STREET
SUITE 125
PITTSBURG, KS 66762

WICHITA OFFICE
3450 N. ROCK ROAD, BLDG 200
SUITE 209
WICHITA, KS 67226

economic development in Kansas now and well into the future. I am proud to lend my support to this world-class facility and will continue to partner with you in this important endeavor.

Very truly yours,

Jerry Moran

PAT ROBERTS
KANSAS

109 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510–1605
202–224–4774

http://roberts.senate.gov

United States Senate

WASHINGTON, DC 20510–1605

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HEALTH, EDUCATION, LABOR, AND PENSIONS

ETHICS

RULES

September 19, 2016

Roy A. Jensen, M.D.
Director, The University of Kansas Cancer Center
3901Rainbow Boulevard
2017 Wahl Hall West, MS 1027
Kansas City, KS 66160-7312

Dear Dr. Jensen,

I write in support of the University of Kansas Cancer Center's (KUCC) application for National Cancer Institute Comprehensive Cancer Center designation.

As a senior member of the Senate Finance Committee and the Senate Health, Education, Labor and Pensions Committee, which have jurisdiction over healthcare issues, as well as co-chair of the Senate Rural Health Caucus, I have been uniquely positioned to champion many healthcare priorities for our state. Since coming to the Senate, I have worked to further the life science research goals of the University of Kansas. As the senior Senator from Kansas representing the KUCC, I have had the pleasure of seeing first-hand the innovative research, expansion of clinical trial offerings across the state, and excellent treatment patients receive here. Seeing the fruits of KUCC's labor rewarded back in 2012, when NCI designation was received, has been a true highlight of my tenure.

Kansas is enjoying significant economic growth as a result of KUCC's commitment to medical research and technical innovation in the fight against cancer. Since receiving NCI designation, KUCC has expanded its efforts to improve the quality of health in Kansas through population-based cancer education, prevention, and early-detection. In fact, *U.S. News & World Report* recently ranked The University of Kansas Hospital's Cancer program number 25 in the nation. Comprehensive Cancer status will further that growth while broadening KUCC's ability to discover, develop, and deliver innovative therapies to patients in Kansas and across the nation.

Thank you for your leadership on this effort. I would appreciate any updates on the progress of this application as they become available and please do not hesitate to let me know how I can be of further assistance.

Sincerely,

Pat Roberts

Pat Roberts
United States Senator

KEVIN YODER
3RD DISTRICT, KANSAS

215 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-2865

DISTRICT OFFICE:
7325 WEST 79TH STREET
OVERLAND PARK, KS 66204
(913) 621-0832

http://yoder.house.gov

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STATE, FOREIGN OPERATIONS AND RELATED PROGRAMS

Congress of the United States
House of Representatives
Washington, DC 20515–1603

August 15, 2016

Roy A. Jensen, M.D., Director
The University of Kansas Cancer Center
Kansas Masonic Cancer Research Institute
William R. Jewell, M.D. Distinguished Masonic Professor
3901 Rainbow Blvd
2017 Wahl Hall West
Mail Stop 1027
Kansas City, Kansas 66160-7312

Dear Dr. Jensen,

I write to express my strong support of the University of Kansas Cancer Center's application for National Cancer Institute Comprehensive Cancer Center designation. As your U.S. Representative, I have had the opportunity to see first-hand the promising new research and excellent care that patients receive at the University of Kansas Cancer Center and strongly believe the work being done by our talented leaders at KUCC is an excellent example of the benefits that come from NCI designation.

The University of Kansas Cancer Center is strongly positioned to continue to be a national leader in research and patient care. In fact, since the University of Kansas Cancer Center first achieved National Cancer Institute (NCI) designation in June 2012, the University of Kansas Cancer Center has continued to enhance the quality of health in our regional communities through population-based cancer education, prevention and screenings. *U. S. News and World Report* recently ranked The University of Kansas Hospital's Cancer program number 25 in the nation. Designation as an NCI Comprehensive Cancer Center also continues to generate significant economic development opportunities in our region, including the creation of 2,895 jobs and $1.2 billion in total financial economic impact.

As you know, I have been working hard to encourage my colleagues to double federal funding for the National Institutes of Health over the next 10 years. I firmly believe that we should be advocating for federal investment in research now in order to bend the cost curve down the road and save lives. The exciting research taking place at the University of Kansas Cancer Center plays a critical role in this process. I look forward to hearing of your continued success as a NCI designated cancer center. If you need any further information regarding this proposal, please don't hesitate to let me know.

Sincerely,

Kevin

Kevin Yoder
Member of Congress

LYNN JENKINS, CPA
2ND DISTRICT, KANSAS

VICE CHAIR
HOUSE REPUBLICAN CONFERENCE

ASSISTANT WHIP

COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON TRADE

SUBCOMMITTEE ON OVERSIGHT

Congress of the United States
House of Representatives
Washington, DC 20515–1602

1526 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-6601

3550 SW 5TH STREET
TOPEKA, KS 66601
(785) 234-5966

1001 N. BROADWAY STREET, SUITE C
PITTSBURG, KS 66762
(620) 231-5966

HTTP://LYNNJENKINS.HOUSE.GOV

September 13, 2016

Roy A. Jensen, MD
Director
University of Kansas Cancer Center
3901 Rainbow Boulevard
Kansas City, KS 66160-7312

Dear Dr. Jensen:

I am writing to pledge my support to The University of Kansas Cancer Center as it applies to achieve National Cancer Institute (NCI) Comprehensive Cancer Center designation. Comprehensive designation will allow KU Cancer Center to build upon all that is has achieved with its NCI designation. This designation promotion would allow KU Cancer Center to offer the very best prevention and treatment available, and to conduct the most sophisticated research.

Like most people, I have witnessed what a devastating disease cancer is. It is a sickness that has the ability to strike at any time, and any age and rip families apart. Still, I hope and believe we will see a time when it is wiped out. The University of Kansas Cancer Center is working towards making that goal a reality. Kansans are fortunate to have an NCI-designated cancer center accessible to all, providing high-quality cancer care for those in need. We need more programs like it, and I introduced legislation last year supporting accreditation of cancer programs in Kansas and across the country.

Our state is unique in that it has a large rural population; the Midwest Cancer Alliance (MCA) helps ensure that members of rural communities get access to the latest cancer care without having to travel excessive distances to receive treatment. MCA's network of state and regional hospitals ensures the latest clinical discoveries are extended to patients throughout Kansas, and not only to those in urban areas.

The University of Kansas Cancer Center has expanded it basic research capabilities, recruited premier physician scientists and significantly increased its clinical trials capacity. It provides an invaluable service to Kansans because of its commitment to outstanding and high quality care. These efforts have had a significant impact on both cancer care and the regional economy.

The University of Kansas Cancer Center is in a position to be a national leader in the fight to cure cancer. I am proud to voice my full support of this world-class facility as it seeks designation as a Comprehensive Cancer Center.

Sincerely,

Lynn Jenkins

Lynn Jenkins, CPA
Member of Congress

PRINTED ON RECYCLED PAPER

State of Kansas

Susan Wagle

Senate President

Roy A. Jensen, MD
Director
The University of Kansas Cancer Center
3901 Rainbow Boulevard, 2017A Wahl Hall West
Kansas City, KS 66160

Dear Dr. Jensen:

It is with great excitement that I am writing to endorse the University of Kansas Cancer Center's application for National Cancer Institute (NCI) Comprehensive status. This designation will allow the cancer center to provide Kansans with the most advanced cancer care.

Cancer has hit close to me and my family, so I certainly understand the importance of having an NCI-designated center easily accessible to Kansas cancer patients. Our state is unique in that it has a large rural population; the Midwest Cancer Alliance (MCA) helps ensure that members of rural communities get access to the latest cancer care, all while remaining close to home. MCA was created in 2007 as a network of state and regional hospitals to ensure the latest clinical discoveries were extended to patients throughout Kansas and the surrounding region.

In addition to providing world-class cancer care, the KU Cancer Center has been a significant influencer in advocating for public policies that have the potential to save lives and decrease the incidence of cancer. Partnering with the American Cancer Society and melanoma survivors, KU Cancer Center worked with legislators to pass a state law that prohibits minors from using indoor tanning beds. The law went into effect July 1, 2016, and has the potential to decrease cases of skin cancer by 10-20 percent over the next several years.

Data shows that Kansas is dead-last in HPV vaccination rates, and KU Cancer Center has taken it upon themselves to educate our communities about the importance of this anti-cancer vaccine. Members of KU Cancer Center are now working with the Kansas Department of Health and the Environment (KDHE) and the Immunize Kansas Children coalition to address this urgent matter.

Finally, KU Cancer Center helped launch the Tobacco 21 effort. This legislation raised the age of tobacco and e-cigarette sales from age 18 to 21, impacting 11 regional communities covering almost 2 million people on both sides of the state line. In all of these instances, KU Cancer Center has advocated for a policy that can cause a real shift in the way we approach cancer prevention.

Cancer is the number one cause of death in Kansas. KU Cancer Center approaches this terrible disease holistically – from prevention to treatment to survivorship. It is because of this that I support The University of Kansas' application for NCI Comprehensive Cancer Center status.

Sincerely,

Susan Wagle
President of the Kansas Senate

SENATOR 30TH DISTRICT
SEDGWICK COUNTY
4 N. SAGEBRUSH ST.
WICHITA, KANSAS 67230

ROOM 333-E
STATE CAPITOL
TOPEKA, KANSAS 66612
785 296-2419

Office of the Mayor

Mayor Sylvester "Sly" James, Jr.

29th Floor, City Hall
414 East 12th Street
Kansas City, Missouri 64106

(816) 513-3500
Fax: (816) 513-3518

August 26, 2016

Roy Jensen, MD, Director
The University of Kansas Cancer Center
3901 Rainbow Boulevard
2017A Wahl Hall West, MS 1027
Kansas City, KS 66160
Dear Dr. Jensen,

Please accept this letter in support of The University of Kansas Cancer Center's application for National Cancer Institute (NCI) Comprehensive Cancer Center designation. Our community is fortunate to have the only NCI-designated cancer center in the region offering patients access to the most advanced cancer care and the greatest chance of survivorship close to home.

Since achieving NCI designation in 2012, The University of Kansas Cancer Center (KUCC) has greatly increased its basic medical research and clinical trials capacity, producing a significant impact on both cancer care and the area's economic development. KUCC has continued to expand its partnerships, most notably, adding Children's Mercy Hospital as a cancer center consortium partner in an effort to better aid a critically underserved population: children. The collaboration with Children's Mercy and the Stowers Institute has enabled KUCC to build an optimized environment for the development and advancement of promising new drugs therapies to cancer patients, including children, adolescents and adults.

Going above and beyond its world-class cancer care, KU Cancer continues to be a significant influencer in advocating for sound public health policies that have the potential to save the lives of individuals in our region. KU Cancer Center provided leadership in the regional Tobacco 21 effort, raising the age of tobacco and e-cigarette sales from 18 to 21 in 15 regional communities, including Kansas City, Missouri. And finally, NCI Comprehensive Cancer Center designation would help our region meet the challenges and needs of our minority and high-risk populations through expanded cancer control efforts.

Cancer's impact goes beyond the state line. The University of Kansas Cancer Center's efforts to reduce the burden of this terrible disease is important to the citizens of our city. I thank you for your time and consideration of this request.

Sincerely,

Sylvester "Sly" James, Jr.
Mayor of Kansas City, Missouri

Unified Government of
Wyandotte County/Kansas City, Kansas
Mark R. Holland, Mayor/CEO

August 12, 2016

Roy Jensen, MD
Director
The University of Kansas Cancer Center
3901 Rainbow Boulevard
2017A Wahl Hall West, MS 1027
Kansas City, KS 66160

Dear Dr. Jensen:

On behalf of the Unified Government of Wyandotte County and Kansas City, Kansas, I am pleased to offer our support for The University of Kansas Cancer Center's application for National Cancer Institute Comprehensive Cancer Center designation.

Our community is privileged to have the only NCI designated cancer center in our region offering patients and their families access to the very best cancer care close to home. KU Cancer Center has greatly increased its basic research capabilities, recruited top-tier physician scientists and substantially increased the clinical trials capacity. KU Cancer Center serves as an invaluable service to the residents of Wyandotte County because of its commitment to outstanding and high quality care. These efforts have had a significant impact on both cancer care and the regional economy.

In addition to providing world-class cancer care, KU Cancer Center has been a significant influencer in advocating for sound public health policies that have the potential to save the lives of thousands of Kansans each year. KU Cancer Center, in partnership with the American Cancer Society, worked tirelessly with legislators to pass a state law that prohibits minors from using indoor tanning facilities. The law went into effect July 1, 2016, and has the potential to decrease skin cancer rates by 10-20 percent over the next several years.

And, KU Cancer Center took a leadership role in the regional Tobacco 21 effort. This initiative raises the age of tobacco and e-cigarette sales from 18 to 21, impacting 15 regional communities, including Wyandotte County, covering 1.2 million people on both sides of the state line.

Wyandotte County, the State of Kansas and private philanthropy continue to show tremendous support for the cancer center. It is because the KU Cancer Center exemplifies the very best in medical research and patient care that the next natural step is achieving NCI Comprehensive Cancer Center designation.

Sincerely,

Mark Holland
Mayor/CEO

701 North 7th Street, Suite 926
Kansas City, Kansas 66101
Phone: (913) 573-5010
Fax: (913) 573-5020

KANSAS MASONIC FOUNDATION
50 YEARS 1966-2016

August 22, 2016

Roy Jensen, MD
Director
The University of Kansas Cancer Center
3901 Rainbow Boulevard
2017A Wahl Hall West, MS 1027
Kansas City, KS 66160

Dear Dr. Jensen:

On behalf of the Kansas Masons, I want to express my full support of The University of Kansas Cancer Center's application for National Cancer Institute (NCI) Comprehensive Cancer designation. For over 40 years, the Kansas Masons have provided financial support to help the cancer center achieve its goals of delivering the most advanced patient care and access to clinical trials close to home.

Over the years, the Kansas Masonic Foundation has worked to raise more than $25 million for the cancer center and is pleased with our recent commitment of $5 million to permanently endow the Midwest Cancer Alliance (MCA), the outreach division of the cancer center. In addition to providing long-term sustainability, this gift will allow MCA to extend cancer prevention, early-detection, and survivorship research support to primary care providers and communities across the state.

Through our successful partnership with MCA, the Kansas Mason's continue to provide free public cancer screenings at locations across the state. In 2015, we were able to conduct 22 cancer screenings reaching nearly 2,000 Kansans. We plan to reach 26 communities in 2016. Through our support and partnership with The University of Kansas Cancer Center, the Midwest Cancer Alliance has extended programs to individuals from 100 of Kansas' 105 counties in the last six years.

With NCI Comprehensive Cancer designation, the cancer center will receive critical funding needed to make a national impact on the fight against cancer and improving the lives of cancer patients and their families. Most importantly, it furthers our vision of impacting the cancers in our state and supporting cancer prevention, education and treatment for Kansans.

We are proud of our long-term partnership and want to confirm our deep commitment to the continued success of The University of Kansas Cancer Center.

Sincerely,

Robert Shively, CAE, CFRE
Executive Director

Michael J. Tavares
President

Robert A. Shively, CAE, CFRE
Executive Director

BOARD OF TRUSTEES

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H. Wayne Rector
Kansas City

Mikel J. Stoops
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Robert C. Talbott
Wichita

Donald W. Wheeler
Fort Scott

Lincoln L. Wilson, Jr.
Aurora, Co

PRESIDENTIAL APPOINTEE
Mark E. Smith
Wallace

DeBRUCE FOUNDATION

September 8, 2016

Roy A. Jensen, MD
Director
The University of Kansas Cancer Center
3901 Rainbow Boulevard, 2017A Wahl Hall West
Kansas City, KS 66160

Dear Dr. Jensen:

It gives me great pleasure to write to you in support of The University of Kansas Cancer Center's application for National Cancer Institute (NCI) Comprehensive designation. As a longtime resident of Kansas City, I am committed to the advancement of life sciences within our community. I believe The University of Kansas Cancer Center's (KUCC) contributions to cancer research has already made a significant impact on the region's research landscape, and NCI Comprehensive designation will strengthen this imprint even more.

KUCC has a strong translational research program that can take basic discoveries from laboratories and then translate them into drugs and therapeutic devices. This program, called the Institute for Advancing Medical Innovation (IAMI) focuses on developing drug candidates and finding new applications for or repurposing existing drugs, then collaborates with private sector partners for further development and commercialization.

A firm I founded, BioNovus Innovations, which commercializes novel drugs, medical devices, and other treatments from early stages of discovery and development, through regulatory approvals, marketing and distribution, recently partnered with IAMI to provide bladder cancer patients with a new treatment option – the first in about 50 years. Called Ciclopirox Prodrug, it is set to become the first KU-invented cancer drug to go from bench to bedside. This could be a game-changer in the way bladder cancer is treated, and there are more KUCC discoveries in the works. This is the first product development and commercialization collaboration between BioNovus and IAMI under a partnership agreement.

As a testament to my confidence in the work you're doing, I recently made a philanthropic commitment to help fund a joint immunotherapy professorship between KU Cancer Center and Children's Mercy. A strong message was sent to this region when these two institutions agreed to collaborate. Jointly appointed positions will help us advance cancer research and patient care from pediatrics to adults, capitalizing on the strengths of each institution.

The University of Kansas Cancer Center has had considerable influence in the advancement of Kansas City's local basic research enterprise by establishing strong infrastructure and expertise in drug discovery and providing local researchers with access to new clinical trial capabilities. NCI Comprehensive designation would further solidify The University of Kansas Cancer Center's position at the forefront of cancer care and research. KUCC and its consortium members have my full support.

Sincerely,

Paul DeBruce

411 Nichols Road, Suite 217 | Kansas City, Missouri 64112 | 816.216.1272

Resource Sharing Plan – OVERALL

The University of Kansas Cancer Center (KUCC) and its scientific community understands its responsibility to comply with the instructions for the Resource Sharing Plans provided within the SF 424 (R&R) Application General Instructions and Supplemental Grant Application Instructions. When resources are developed with NIH funds via this Cancer Center Support Grant P30 mechanism, KUCC will ensure findings are made readily available to the NIH and the scientific community in a timely manner.

Data Sharing Plan

KUCC will adhere to the Final NIH Statement on Sharing Research Data and refer to the National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research. KUCC encourages the free flow of information and ideas while recognizing the timeliness of data sharing, the rights and privacy of human subjects and issues related to proprietary data. KUCC encourages data documentation, using a data-sharing agreement and selecting an appropriate method for sharing; considering the sensitivity of the data, the size of the dataset and the volume of requests anticipated.

Additionally, KUCC encourages any user of a CCSG-supported shared resource to acknowledge the source of data upon which their manuscript is based either in the Acknowledgments section or with authorship on the paper. Furthermore, any research project that received direct cost support from the CCSG is encouraged to cite the P30 CA168524. In both cases, citing the P30 CA168524 grant number and then being compliant with the NIH Public Access Policy is required.

Sharing Model Organisms

In the event that a model organism is developed, KUCC will comply with the NIH Policy on Sharing of Model Organisms for Biomedical Research. KUCC will work with the NIH/NCI to share and disseminate the critical model organism in a timely manner.

Genome Wide Associate Studies

When applicable, KUCC will comply with the NIH Genomic Data Sharing Policy. KUCC supports the sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. All research studies funded through the CCSG involving genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data will be submitted in a timely manner.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 016060860

Legal Name*: University of Kansas Medical Center Research Institute, Inc.
Department:
Division:
Street1*: MSN 1039, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Deborah		Maloney	MSM

Position/Title: Director, Sponsored Programs Administration
Street1*: 3901 Rainbow Boulevard
Street2: Mail Stop 1039
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937
Phone Number*: 913-588-1261 Fax Number: 913-588-3225 Email: spa@kumc.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofit Organization

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Cancer Center Administration & Senior Leadership Core

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2017	06/30/2022

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Medical Center
Duns Number:	016060860
Street1*:	MSN 2029, 3901 Rainbow Blvd
Street2:	
City*:	Kansas City
County:	Wyandotte
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66160-8500
Project/Performance Site Congressional District*:	KS-003

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ❍ **Yes** ● **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ❍ No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	Administrative_Core_Project_Summary_Abstract_Final1019390374.pdf
8. Project Narrative*	
9. Bibliography & References Cited	Administrative_Core_References_Cited1019390373.pdf
10.Facilities & Other Resources	
11.Equipment	
12. Other Attachments	Admin_Core_OtherAttachments_Final1019496488.pdf

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Administrative Core – Project Summary/Abstract

The University of Kansas Cancer Center (KUCC) administration office is the principal organizational component through which the Associate Directors, Research Program Leaders and Shared Resource Directors execute their responsibilities to Cancer Center members. The administrative office provides administrative and fiscal oversight of Cancer Center functions. These functions include grant development; human resources; communications; Cancer Center Support Grant management; Cancer Center, Clinical Trial Office and shared resource financial administration; outreach and information dissemination; and information technology. The aims of the administrative office are to:

1. Provide direction, leadership and cost effective management to allow efficient use of resources for KUCC members across campuses and throughout its consortium partners;
2. Establish and maintain consistent information organization and dissemination among research programs and shared resources to ensure aims are met;
3. Enhance research and education opportunities for KUCC members, students and post-doctoral fellows by providing strategies that encourage and facilitate collaborative, cross-disciplinary investigations across campuses and consortium partners; and
4. Impact cancer in KUCC's catchment area by leveraging consortium partners, key stakeholders, community advocates and regional leaders to develop and promote research collaboration and implementation of evidence-based cancer prevention, diagnosis, treatment and survivorship practices through community partnerships directed toward urban underserved and rural communities.

The KUCC Senior Leadership team is made up of the Director, Deputy Director, Associate Directors and the Chief Operating Officer. This group meets every other week to evaluate cross-programmatic and multi-campus activities including pilot project programs, research symposia, seminars and conferences; review the progress of the research programs and shared resources; and discuss and make decisions related to the budget, resource allocation, membership, space, leadership appointments and strategic initiatives. This group aims to advance the cancer focus of KUCC by fostering collaborative initiatives, defining areas of strength, addressing areas of weakness and integrating basic scientists and clinicians for both the advancement of basic discoveries and training and educational efforts.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Teresa Middle Name Last Name*: Christenson Suffix:

Position/Title*: Associate Director for Administration
Organization Name*: University of Kansas Medical Center
Department: KU Cancer Center
Division: Medicine
Street1*: MS 1027, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-2755 Fax Number:

E-Mail*: tchristenson@kumc.edu

Credential, e.g., agency login: TCHRISTENSON

Project Role*: Other (Specify) Other Project Role Category: Core Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Christenson_bio_CCSG1018883926.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Roy Middle Name A Last Name*: Jensen Suffix: MD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Pathology & Lab Medicine
Division: School of Medicine
Street1*: MS 3045, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-4700 Fax Number: 913-588-4701

E-Mail*: RJENSEN@kumc.edu

Credential, e.g., agency login: JENSENRA

Project Role*: Other (Specify) Other Project Role Category: Director

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Andrew Middle Name Last Name*: Godwin Suffix: Ph.D.

Position/Title*: Professor/ Director of Molecular Oncology
Organization Name*: University of Kansas Medical Center
Department: Pathology & Laboratory Medicin
Division: School of Medicine
Street1*: MSN 1039, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-7073 Fax Number:

E-Mail*: agodwin@kumc.edu

Credential, e.g., agency login: AKGODWIN

Project Role*: Other (Specify) Other Project Role Category: Deputy Director

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Godwin_Bio_CCSG1018883927.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Shrikant Middle Name Last Name*: Anant Suffix: PhD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Molec and Integr Physiology
Division: School of Medicine
Street1*: MSN 3040, 3901 Rainbow Boulevard
Street2: 4019 Wahl East
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-945-6334 Fax Number: 913-945-6327

E-Mail*: sanant@kumc.edu

Credential, e.g., agency login: SANANT3

Project Role*: Other (Specify) Other Project Role Category: AD Prevention & Control

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Anant_Bio_CCSG1019712726.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Carol Middle Name J Last Name*: Fabian Suffix: MD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Medicine-Clinical Oncology
Division: School of Medicine
Street1*: MS 5015
Street2: 2330 Shawnee Mission Parkway
City*: Westwood
County: Johnson
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66205-0000

Phone Number*: 913-588-7791 Fax Number: 913-588-3679

E-Mail*: cfabian@kumc.edu

Credential, e.g., agency login: CFABIAN

Project Role*: Other (Specify) Other Project Role Category: AD Clinical Research

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Fabian_Bio_CCSG1019712727.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Sally Middle Name L Last Name*: Maliski Suffix: PhD

Position/Title*: Dean
Organization Name*: University of Kansas Medical Center Research Institute, Inc.
Department:
Division: School of Nursing
Street1*: MS 4043, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66103-2937

Phone Number*: 913-588-1665 Fax Number: 913-588-1605

E-Mail*: smaliski@kumc.edu

Credential, e.g., agency login: Maliski2

Project Role*: Other (Specify) Other Project Role Category: AD Health Communications

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Maliski_bio_CCSG1019496510.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Matthew Middle Name Stuart Last Name*: Mayo Suffix: PhD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Department of Biostatistics
Division: School of Medicine
Street1*: MS 1026, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-4735 Fax Number: 913-588-4790

E-Mail*: mmayo@kumc.edu

Credential, e.g., agency login: MATTMAYO

Project Role*: Other (Specify) Other Project Role Category: AD Shared Resources

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Mayo_bio_CCSG1019496512.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Jeff Middle Name Last Name*: Reene Suffix:

Position/Title*: Chief Operating Officer
Organization Name*: University of Kansas Medical Center
Department: University of Kansas Cancer Ce
Division: Medicine
Street1*: MS 1027, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-8500

Phone Number*: 913-588-2568 Fax Number:

E-Mail*: jreene@kumc.edu

Credential, e.g., agency login: JREENE

Project Role*: Other (Specify) Other Project Role Category: COO

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Reene_Bio_CCSG1019496513.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Scott Middle Name James Last Name*: Weir Suffix: PhD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Pharmacology
Division: School of Medicine
Street1*: MS 1018, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-4798 Fax Number: 913-588-4701

E-Mail*: sweir@kumc.edu

Credential, e.g., agency login: SJWEIR

Project Role*: Other (Specify) Other Project Role Category: AD Trans Research

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Weir_bio_CCSG1019712728.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Danny Middle Name Last Name*: Welch Suffix: PhD

Position/Title*: Chair and Professor
Organization Name*: University of Kansas Medical Center
Department: Cancer Biology
Division: School of Medicine
Street1*: MS 1027, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-945-7739 Fax Number: 913-588-4701

E-Mail*: dwelch@kumc.edu

Credential, e.g., agency login: DWELCH

Project Role*: Other (Specify) Other Project Role Category: AD Basic Science

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Welch_Bio_CCSG1019566551.pdf

Attach Current & Pending Support: File Name:

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ❍ Yes ❍ No

*Agency-Defined Phase III Clinical Trial? ❍ Yes ❍ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ❍ Yes ❍ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

❍ Yes ❍ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

❍ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

☐ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator / Change of Institution Section

☐ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

☐ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	Administrative_Core_SpecificAims_Final1019390372.pdf
3. Research Strategy*	Admin_Research_Strategy_Final1019913928.pdf
4. Progress Report Publication List	Admin_Progress_Report_Publications1019754745.pdf
Human Subjects Section	
5. Protection of Human Subjects	
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	
8. Inclusion of Children	
Other Research Plan Section	
9. Vertebrate Animals	
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	
14. Resource Sharing Plan(s)	Resource_Sharing_Plan__Generic1019913970.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Administrative Core – Specific Aims

1. Provide direction, leadership and cost effective management to allow efficient use of resources for KUCC members across campuses and throughout its consortium partners.
2. Establish, organize and maintain consistent information and dissemination across research programs, shared resources, oversight committees and consortium partners to ensure Cancer Center aims are met.
3. Enhance research and education opportunities for KUCC members, students and post-doctoral fellows by providing strategies that encourage and facilitate collaborative, cross-disciplinary investigations across campuses and consortium partners.
4. Impact cancer in KUCC's catchment area by leveraging consortium partners, key stakeholders, community advocates and regional leaders to develop and promote research collaboration and implementation of evidence-based cancer prevention, diagnosis, treatment and survivorship practices through community partnerships directed toward urban underserved and rural communities.

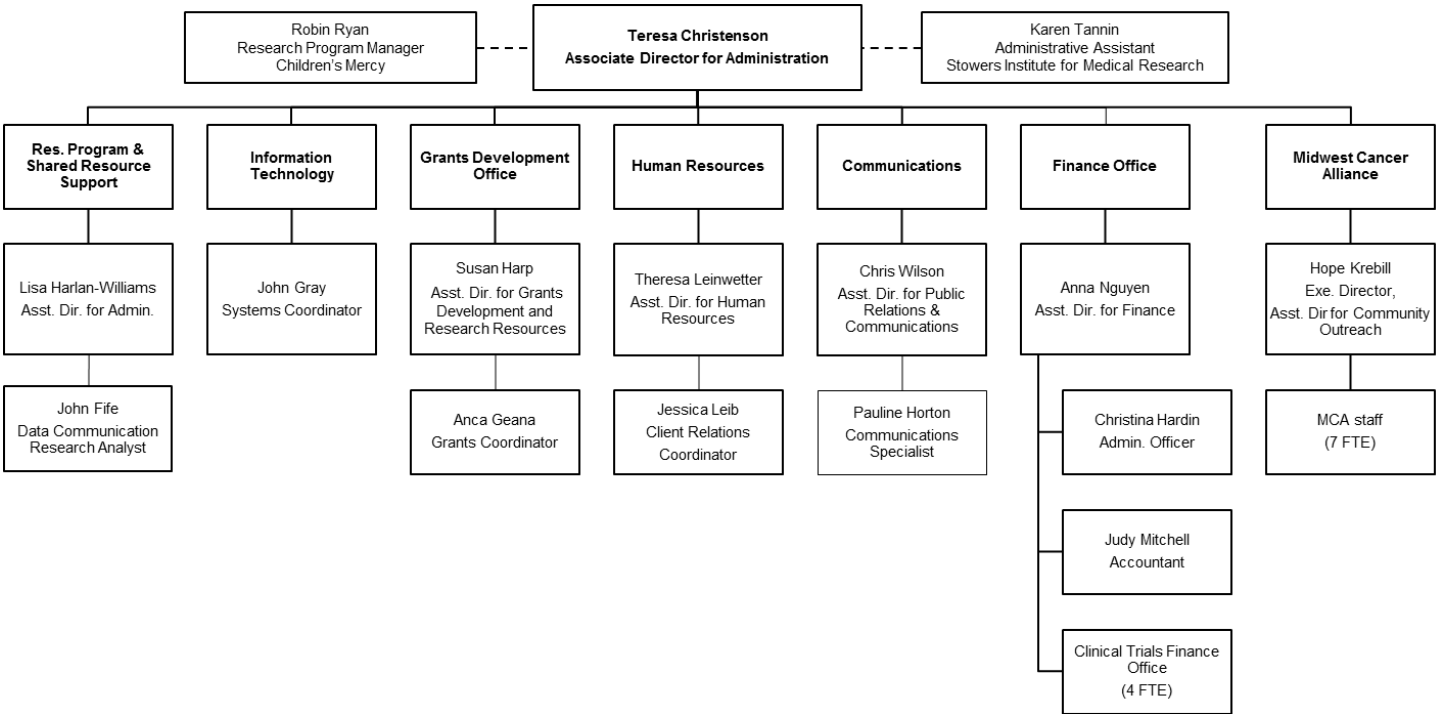
Administrative Core – Research Strategy

Part I: Cancer Center Administration

The University of Kansas Cancer Center (KUCC) administration office is the principal organizational component through which the Associate Directors, Research Program Leaders and Shared Resource Directors execute their responsibilities to Cancer Center members. The administrative office provides administrative and fiscal oversight of cancer center functions. These functions include grant development; human resources; communications; Cancer Center Support Grant (CCSG) management; Cancer Center, Clinical Trial Office and shared resource financial administration; outreach and information dissemination; and information technology.

The KUCC administrative office is led by the Associate Director for Administration, Teresa J. Christenson, who reports directly to the Cancer Center Director, Roy **Jensen**. Christenson has organized the administrative office to efficiently facilitate and implement the Director's vision and support a cancer-focused culture that fosters collaboration and productivity among Cancer Center members. **Figure 1** depicts the current administrative structure under the direction of Christenson.

Figure 1. KUCC Administrative Office Organizational Chart



Response to Prior Site Visit Review

In 2012, the administrative office received an excellent merit score. Strengths of the program were listed as the following:

- Well-defined program for pilot project grant management
- Appropriate administrative actions with the University
- Strong recruiting support

The two areas for improvement are listed below.

Areas for Improvement	Response
Administrative systems would benefit from better data integration of individual systems	The Cancer Center administration created a centralized storage of Cancer Center data in a flexible database. The database includes membership information, publications, pilot projects and shared resource usage. Data questions that once took 3 hours to complete now take 20 seconds.

Integrated Shared Resource Management System	The Cancer Center implemented the iLab Solutions shared resource management system. This web-based system provides a shared resource with tools to manage service requests and equipment reservations, track usage, billing and invoicing.

Role of Administration and Decision Making Processes

The Cancer Center Director, **Jensen**, is the ultimate decision maker for KUCC. The Associate Directors, who meet every other week, discuss matters pertaining to the four research programs and their leadership, shared resources, *ad hoc* budget requests from center members, space allocation, potential new shared resources or shared equipment requests and other center policies. They also develop the focus of pilot project requests for applications. Additionally, the KUCC program leaders meet every other month and the shared resource directors meet quarterly. These groups discuss program structure and development, shared resource services, research seminars and symposia and membership requirements. Both **Jensen** and Christenson are members of these internal advisory groups and are actively engaged in all levels of discussion and decision-making.

Research Program and Shared Resource Support
Assistant Director for Administration, Lisa **Harlan-Williams** assists the program leaders with program development (including the coordination and documentation of meetings), assists the Associate Director for Shared Resources and shared resource directors with shared resource development, and coordinates the data and information for the Cancer Center Support Grant, the External Advisory Board report and presentations. She also organizes the membership application and review process. Data Communications Research Analyst, John Fife supports **Harlan-Williams** and the research programs by maintaining membership information, publications and grant funding. Fife works with John Gray, the IT systems coordinator, to build and continually refine a database to maintain all member information (email distribution lists, publications, pilot projects, external funding and shared resources usage).

Information Technology
Gray is responsible for all Cancer Center computers, servers, printers and tele-and video-conferencing equipment. He coordinates with the University and Hospital IT staff to maintain network connections. Gray also works with the Kansas Cancer Registry and the Biospecimen Shared Resource by providing system administration and database management. Gray works with Fife to build and maintain the backend of the Cancer Center member database. Both Gray and Fife work with data directly in SQL Server, this tool primarily serves as the backend. For most frontend activities - including data entry, data importing/exporting, querying and reporting - Gray and Fife use Microsoft Access.

Grants Development Office
The administrative office recognized a need to help Cancer Center members develop and submit grants. Therefore, the administrative office facilitated the formation of the Grants Development Office (GDO). The GDO supports Cancer Center members grant activities by:

- Circulating grant opportunities from the NCI, ACS, DOD, Susan G. Komen Foundation and other national organizations that would emphasize multi-disciplinary, multi-investigator, collaborative ideas;
- Coordinating the pilot project process including the request for applications, review process and award notification for the Cancer Center. The GDO also tracks and documents relevant academic outcomes such as award of extramural funding, abstracts, presentations and publications; and
- Providing grant development support as required; including:
  - scheduling multi-investigator meetings and creating a grant development task list;
  - working with institutional grants/contracts office;
  - writing, editing and developing budgets;
  - gathering required signatures, letters of support, and other required documents; and
  - assembling all documents electronically.

The GDO is led by Susan Harp, Assistant Director for Grants Development & Research Resources. The GDO works hand-in-hand with the University grants and contracts offices, at KUMC, KU-Lawrence, Stowers and Children's Mercy on pre-award submissions. The GDO does not handle post-award functions. Since 2012, the GDO has assisted in the submission of 335 grants resulting in over $35 million awarded from a variety of funding agencies including the NIH, DOD, ACS, Komen and other private foundations.

Human Resources
Theresa Leinwetter, Assistant Director for Human Resources, manages the search and recruitment process for both faculty and staff. Faculty are appointed within university departments rather than the cancer center. Leinwetter works with the corresponding departments when hiring faculty. The KUCC hiring process includes posting all Cancer Center positions, screening and tracking applicants, coordinating visits and interviews, conducting interviews, creating offer letters, scheduling for new hire orientation and completing all new hire onboarding paperwork. She manages the Cancer Center recruitment presence on the KUCC website, Facebook, Twitter, LinkedIn, and CareerBuilder. In calendar year 2015, Leinwetter filled 34 staff positions including positions for the clinical trials office and some of the cancer center shared resources. She also works with **Jensen** and Christenson to coordinate the monthly faculty recruitment meeting.

Communications
Since KUCC includes four entities (KUMC, KU-Lawrence, Stowers and Children's Mercy) at four different locations, communications with Cancer Center members is a priority. Cancer Center communications are led by Christine Wilson, Assistant Director for Public Relations and Communications.
Internal and external communications strategies include:

- Increase awareness among civic, business and philanthropic leaders on the importance of NCI Comprehensive Cancer Center designation and benefits to our region;
- Provide opportunities to promote collaboration among internal stakeholders to support Cancer Center leadership's goal of increasing inter-programmatic research projects;
- Increase awareness of available oncology clinical trials and unique capabilities of the KU Clinical Research Center (KU CRC) to internal and external audiences to support KU CRC's goals of attracting outside funding to open new trials while adding new patients to current trials;
- Support priorities outlined by NCI to achieve CCC status by promoting Cancer Center research to external audiences – with a focus on prevention/community outreach-focused initiatives; and
- Educate target audiences and encourage collaborative Cancer Center culture by communicating newsworthy initiatives taking place at all university campuses, MCA organizations, *etc*.

Finance Office
Anna Nguyen, Assistant Director for Finance, manages the Cancer Center finance office which tracks the payroll activities and manages KUCC cash flow including tracking spends and incoming sources and provides the periodic financial management reports including projections and analysis for the KU Cancer Center's overall financial position. In addition, the finance office oversees the clinical trial office's post-award finance processes including the accounts payable and accounts receivable and provides the monthly financial management reports to the clinical trial management team. The finance office also manages the iLab Solutions system that is a web-based management service for shared resource service request management, equipment reservation and usage tracking, billing and invoicing, reporting and spend tracking tools.

Midwest Cancer Alliance
The Midwest Cancer Alliance (MCA), the outreach network of KUCC, is a membership fee-based network of hospitals and physician groups located in KUCC's catchment area with the primary purpose of leveraging unique regional resources to promote and translate the latest evidence-based clinical and community health practices for patients close to their homes. The MCA, led by Executive Director and Assistant Director for Community Outreach Hope Krebill, collaborates with local organizations to enhance their research infrastructure and to proactively execute cancer prevention and control strategies to decrease the burden of cancer in the catchment area. MCA connects KUCC researchers with communities in KUCC's catchment area by engaging MCA member physicians and research teams at a monthly tele-video disease working group which serves as a platform to present new KUCC study ideas. To increase patient engagement with research, MCA has launched PIVOT (Patient and Investigator Voices Organizing Together), an evolving community of patient research advocates learning and working with our academic research stakeholders to enhance research to more effectively address patients' needs and desired outcomes. Finally, MCA members and Kansas Patients and Providers Engaged in Prevention Research (KPPEPR) identify, enroll and/or refer participants to clinical trials. KUCC leverages in-kind research support from MCA members who provide 12 FTEs in research staffing as well as in-kind site-investigator support.

Relationship of Center to other Institutional Offices

As a matrix organization, Cancer Center members are from a variety of schools and departments at the KU Medical Centers in Kansas City, KS and Wichita, the University of Kansas in Lawrence, Stowers Institute for Medical Research and Children's Mercy in Kansas City, MO. In total, the Cancer Center has 188 full or associate members representing all of these locations.

KUCC and its members rely on multiple institutional offices, including the Research Institutes for each of the consortium members, KU Center for Technology Commercialization, animal compliance and care, human subjects committee and institutionally-owned shared resources. Legal and contracting agreements are under the authority of the Research Institute; however, budgeting and accounts payable on grants and contracts for cancer clinical trials are managed by the KUCC Clinical Trials Office. KUCC and its members also rely on the KU Health System and Children's Mercy for patient access, care and services.

Many of KUCC's leaders also have institutional roles. **Welch**, Associate Director for Cancer Biology, is the founding chair of the Cancer Biology department. **Mayo**, Associate Director for Shared Resources, is the founding chair of Biostatistics in the School of Medicine. Deputy Director, **Godwin**, is Director of Molecular Oncology for the School of Medicine, and is charged with expanding the clinical molecular pathology to support patient care and **Maliski**, Associate Director for Health Equity, is also Dean of the School of Nursing.

Cancer Center staff also interacts with many departments across the institutions. Christenson, Nguyen and Leinwetter all attend the monthly university administrative meeting. Leinwetter sits on the Medical Center HR committee and Wilson interacts with University and KU Health System communications group routinely.

Two years ago, KUCC administration purchased a web-based management software for KUCC shared resources, iLab Solutions. This software includes core facility service request management, equipment reservation and usage tracking, billing and invoicing. KUMC Hoglund Brain Imaging Center also uses this software and Nguyen manages that process as well. Another KUMC group, Frontiers, The Heartland Institute for Clinical and Translational Research will begin to use the software next year. KUCC will continue to manage the software and the relationship with iLab Solutions.

Roles of Center Administration in CCSG-related Activities

Shared Resources Oversight
KUCC provides financial support for five shared resources – Biospecimen, Biostatistics & Informatics, Transgenic & Gene-Targeting, Clinical Pharmacology and Lead Development & Optimization. Biospecimen and Clinical Pharmacology are 100% owned by the Cancer Center. The three other shared resources are owned by the institution, but receive financial support from KUCC. These shared resources provide Cancer Center investigators easy access to state-of-the-art research technology, equipment, and technical support that would otherwise be too difficult or expensive for individual investigators or programs to develop. The Associate Director for Shared Resources, **Mayo**, and Assistant Director for Administration, **Harlan-Williams**, meet with shared resource directors and assistant directors quarterly to identify appropriate utilization metrics and tracking mechanisms and prevent duplication of aims and services.

As part of a Cancer Center annual review, a shared resource survey is sent to all KUCC members. This survey is designed by **Mayo** and **Harlan-Williams** with help from Bryon **Gajewski** (CCPH), an expert in survey development. The anonymous surveys request feedback on the satisfaction of services provided by CCSG-supported/KUCC shared resources and the needs for the development of any new shared resources. Survey results are reviewed in an Associate Director's meeting and decisions on which shared resources to support and what their Cancer Center budget should be are made.

Faculty Recruitment
KUCC leadership continues to recruit new faculty with a focus on cancer research to increase the national and international status of the Cancer Center, fill critical research positions and continue enhancing the depth and breadth of scientific research within the research programs. Since 2012, 37 strategic researchers were recruited and hired. All faculty recruitments are managed through a monthly recruiting committee meeting.

Members of this committee includes **Jensen**, Leinwetter, Christenson, **Welch**, **Anant**, **Godwin**, and **Mayo**. Criteria for each position are discussed and potential candidates are developed. Each promising candidate has at least two visits to KUCC and with the appropriate institutional department and the candidate must present at least one seminar that is open to the public. Positions and final start up packages are approved by the Associate Directors of the Cancer Center, the appropriate Department Chair, and the appropriate Dean of the respective school (Medicine, Nursing, Allied Health, Pharmacy, or College of Liberal Arts and Sciences). New Cancer Center recruitments at Stowers are a collaborative effort coordinated by Robb **Krumlauf** (Scientific Director – Stowers), David Chao (CEO – Stowers), and **Jensen** (KUCC Director). New recruitments at Children's Mercy are collaborative between **Jensen**, Michael Artman (Pediatrician-in-Chief, Children's Mercy) and Tom **Curran** (Director, Research Institute, Children's Mercy) who arrived in January of 2016.

Membership
The Membership Committee annually reviews all current and new applicants and makes recommendations to the Cancer Center Director on the appropriate membership category and program assignment. The Membership Committee consists of **Jensen**, **Christenson**, **Harlan-Williams**, **Mayo** and all research program leaders. The Director has final authority in determining membership and reserves the right to reassign (or disallow) the membership category and program assignment based on current criteria. The Cancer Center may offer additional application submission and membership review opportunities during the membership year as deemed necessary.

Pilot Project and Grant Submission Process
In place since 2005, the Cancer Center Pilot Project grant program offers two rounds of funding each year and sometimes additional funding opportunity as funds permit. The goal of this program is to increase interdisciplinary collaboration in cancer research among KUCC members. Proposals must reflect novel, innovative research in cancer that has not been funded, but would be highly competitive for future extramural funding at the national level. Prior to releasing the request for proposal (RFP), the Leadership Council decides the scientific focus and budget. Cancer Center members experienced in grant review are called upon to help review the proposals; two reviewers per application provide comments and scores. Since 2012, 60 pilot projects have been awarded to Cancer Center members, for a total investment of almost $2 million.

KUCC also coordinates the receipt, review and award management process for the American Cancer Society Institutional Research Grant (ACS-IRG) awards given for the career development of junior faculty (PI: Bruce **Kimler**). The IRG funds innovative cancer research pilot projects that have the potential for future peer-reviewed funding. Since the receipt of the ACS-IRG in 2009, 13 awards have been given to Cancer Center junior faculty. These awards total $35,000 each - $30,000 from the ACS-IRG plus $5,000 from the Cancer Center. In addition, KUCC exclusively funds one complete pilot project as a matching contribution to the ACS-IRG.

Midwest Cancer Alliance Partners Advisory Board (MCA PAB)
MCA PAB Members have supported collaborative research, provided financial support to KUCC research efforts and enhanced their individual organizations' research through a total of $8,750,000 in membership fees from 2012-2016. Between 2012 through 2016 MCA PAB membership fees have supported $3,089,954 in new initiative pilot research in collaboration with KUCC.

Space Management
The Director, Deputy Director and Associate Directors review Cancer Center research space utilization annually. This review follows the University policy of allocating space based upon programmatic requirements and the extramural funding per square foot assigned to the investigator. The Cancer Center employs a "5-7-9" rule to allocate space in the KMCRI building. If an investigator has one R01 equivalent grant, then they would receive five benches, seven benches for two R01 equivalents, and nine benches for three R01 equivalent grants. Administrative space is assigned based on function.

Arranging and Documenting Meetings Organized by the Center
The general administrative office provides meeting support for the Associate Director and Leadership Council meetings. Meeting minutes are produced by Christenson. In addition, the administrative assistant manages the scheduling of center seminars and along with **Harlan-Williams**, provides program support.

Management of Philanthropic Funds
Under the direction of **Jensen**, KUCC ensures that it is spending philanthropic funds within the guidelines set forth by the donor. Each request for expenditure is reviewed by Christenson. In addition, The University of Kansas Endowment Association (KUEA) staff reviews expenditure requests from restricted philanthropic funds to ensure they are in accordance with University guidelines as well as donor wishes.

Program Support
KUCC provides financial and administrative support to the four research programs – Cancer Biology, Cancer Control & Population Health, Cancer Prevention and Survivorship and Drug Discovery, Delivery & Experimental Therapeutics. The Director (**Jensen**), Associate Director for Administration (Christenson) and the Assistant Director for Administration (**Harlan-Williams**), meet every month with all program leaders in either the Program Leaders meeting or Leadership Council to discuss the scientific direction of the programs, brainstorm intra- and inter-programmatic interactions and determine next steps as recommended by the Associate Directors meeting and External Advisory Board. Additionally, Christenson and **Harlan-Williams** meet with the program leaders individually to discuss specific program needs and plan program meetings. Program meetings specifically focused on program development with all members are expected at least twice a year, while smaller focus group meetings are expected more frequently, at least once a quarter. In addition, at least three program-focused seminars with guest speakers or program members are given each year. KUCC administration schedules the program and focus group meetings, provides agendas and relevant KUCC information to be disseminated to program members, and any other documentation necessary to facilitate the meetings.

Budgeting, Accounting, and Expenditure Monitoring
KUCC maintains account records, monitors expenses and resolves problems from all budgets. KUCC also processes payroll and handles inquiries and report requests from University Offices of Payroll and Purchasing.

Oversight of activities relevant to the CCSG grant application process
KUCC administration ensures efficient management of all aspects of the External Advisory Board site visits and the Cancer Center Support Grant (CCSG) development. Christenson and **Harlan-Williams** develop appropriate project plans with checklists and timelines. Specifically related to the CCSG, and per the CCSG guidelines, KUCC administration:

- Facilitates the development of the budget and templates for each component;
- Provides data – funding, publications, shared resource usage, pilot fund and other internal funding program recipients, clinical trials information, budget information;
- Compiles, edits, formats and develops outlines, ensures accurate completion, conversion to a pdf-format;
- Develops program presentation and shared resource template;
- Compiles supplementary documents – biosketches, letters of support, notebooks;
- Ensures proper institutional guidelines were followed with grant submission – signatures, work with RI; and
- Plans logistics of site visit.

Consortium Agreements
In October 2009, KUCC and the Stowers Institute for Medical Research (Stowers) reached an agreement to support their cancer investigators to contribute to development of a joint cancer research agenda. That agreement was renewed in 2015. Both institutions realize the mutual, beneficial effects to be obtained from a scientific collaboration that strengthens their scientific impact. Stowers was founded to seek more effective means of preventing and curing disease through basic research on genes and proteins that control fundamental processes of cellular life. Stowers is a not-for-profit corporation and a 501(c) (3) charitable organization, classified by the IRS as a Medical Research Organization.

A consortium agreement with Children's Mercy (CM) was signed in April, 2015. CM is the premier children's hospital in the region and is located 3.5 miles from the KUMC just over the border in Kansas City, Missouri. This agreement strengthens the already existing collaborations between CM and KUCC.

For both agreements, terms and conditions agreed upon are:

- Investigators at consortium sites shall be eligible for leadership roles in Cancer Center research programs;
- Investigators at consortium sites shall have access to Cancer Center shared resources;

- All cancer clinical trial protocols involving collaborations between cancer researchers from both institutions will be subject to the same governing Protocol Review & Monitoring System and Data Safety & Monitoring Board staffed and administered by the University;
- The Cancer Center Director shall have direct authority over any NCI-funded shared resources; and
- Any resolutions of differences between the parties or disputes regarding the terms of the agreement, shall be brought to the attention of the President and CEO of the Stowers Institute and/or Children's Mercy and the Chancellor of the University, who shall jointly determine a mutually acceptable resolution.

KUCC administrative offices communicate with Cancer Center members located at Stowers or Children's Mercy in the same manner as members located at KUMC or KU in Lawrence, via emails, tele- and video conference. In addition, one Associate Director meeting per month is held at Stowers. In addition, one administrator from Children's Mercy and Stowers report to Christenson for Cancer Center activities.

Future Plans

As KUCC continues to grow and evolve the administrative office must also evolve in order to support the Cancer Center's mission.

- Integration of Cancer Center data will remain a priority. As KUCC continues to change and grow, so does the database, with more developments underway. The database will soon include external funding, clinical trials and a web-based front-end that will allow more users access to view these and other approved data.

- The Cancer Center also plans to build a structure for patient engagement. The PIVOT Project will expand on KUCC's mission to empower patients and advance quality cancer research and care. PIVOT will provide resources to expand the Center's focus on patient-centered research and care by offering an engagement venue and framework encouraging a culture that welcomes diverse perspectives and experiences to the table.

Part II: Senior Leadership

The KUCC Senior Leadership team is made up of the Director, Deputy Director, Associate Directors and the Chief Operating Officer. This group meets every other week to evaluate cross-programmatic and multi-campus activities including pilot project programs, research symposia, seminars and conferences; review the progress of the research programs and shared resources; and discuss and make decisions related to the budget, resource allocation, membership, space, leadership appointments and strategic initiatives. This group aims to advance the cancer focus of KUCC by fostering collaborative initiatives, defining areas of strength, addressing areas of weakness and integrating basic scientists and clinicians for both the advancement of basic discoveries and training and educational efforts.

Roy A. Jensen, MD – Director

Qualifications and Responsibilities

On July 1, 2016, Roy A. **Jensen** began his 13th year as the Director of KUCC and his ninth year as the CEO of the Midwest Cancer Alliance. As Director, **Jensen** reports directly to the Executive Vice Chancellor for the University of Kansas Medical Center, the CEO of the University of Kansas Health System and the Provost and Executive Vice Chancellor of the University of Kansas-Lawrence. As per the consortium agreements with the Stowers Institute for Medical Research and Children's Mercy, he also **Jensen** has a dotted line reporting relationship to the CEO's of these institutions. As Director, **Jensen** is responsible for all aspects of KUCC across the consortium. In addition to his role as the founding principal investigator for the KUCC CCSG, he also maintains an active research laboratory focused on the function of the breast and ovarian cancer tumor suppressor gene, *BRCA1*.

Jensen devotes 50% of his effort to CCSG activities and his major responsibility has been to establish a vision, and build and strengthen the basic, translational, clinical, and population science research at the Cancer Center. A critical aspect of this work has been recruiting and synthesizing a strong, world-class senior leadership team to carry out Cancer Center objectives. While **Jensen** is the ultimate decision maker regarding KUCC goals, policies, and operations, he does so in conjunction with the senior leadership team by fostering

an active and open dialog across the center. The establishment of this leadership team, and its deliberations has been critical to the center's success.

Andrew K. Godwin, PhD – Deputy Director

Qualifications and Responsibilities
Godwin is an internationally recognized leader in the field of translational research and personalized cancer medicine. He is an NCI-funded investigator (continuously since his first faculty appointment) and a highly published (>350 manuscripts and scholarly review articles) and cited (>29,200; H-index of 91) scientist. **Godwin** is recognized for his molecular biology/genetic studies of gastrointestinal stromal tumors (GIST), breast and ovarian cancer, and his efforts to help bridge the gap between basic and clinical science in order to improve patient care. His research focuses on the concept of obtaining a molecular definition of a tumor to define its treatment-sensitive elements, complementing his long-standing interest in the fields of cancer genetics, molecular targeted therapeutics, predictive biomarkers, early detection, and biobanking. His recruitment to KUCC in the fall of 2010 greatly contributed towards NCI designation in 2012, and resulted in him being named the Deputy Director in 2013. **Godwin's** promotion to this key leadership position allows him to leverage his outstanding translational research experience to help advance personalized medicine at KUCC.

Prior to joining the Cancer Center, **Godwin** rose to the ranks of Senior Member at the Fox Chase Cancer Center (FCCC) in Philadelphia where he spent 26 productive years. **Godwin** was the translational science co-chair or collaborating scientist for many Gynecologic Oncology Group clinical trials evaluating molecularly targeted agents in recurrent ovarian cancer patients and now serves as a member of the Early Therapeutics and Rare Cancer and the Breast Cancer Translational Medicine committees for the Southwest Oncology Group. He is a member of multiple disease-working groups for The Cancer Genome Atlas (TCGA), and is a member of the Early Detection Research Network (EDRN), and the Consortium of Investigators of Modifiers of *BRCA1/2* (CIMBA). **Godwin** devotes 20% of his effort to CCSG activities related to building avenues of collaboration across disciplines and campuses. His past experience has made him well-qualified to lead the Cancer Center's personalized medicine initiative. **Godwin** is involved in the continuum of translational science with many basic science and clinical science collaborations.

Shrikant Anant, PhD – Associate Director for Cancer Prevention and Control

Qualifications and Responsibilities
Anant is a pioneering cell biologist with a national reputation in gastrointestinal cancer research. His research spans a wide range of activities – from understanding the molecular mechanisms of tumorigenesis and resistance of cancer cells to radiation and chemotherapeutic agents, to identifying and characterizing the role of cancer stem cells in tumorigenesis and determining the mechanisms of action for various natural products and their role in cancer prevention. In addition, his research explores the development of novel therapeutic agents from natural products. At the University of Oklahoma Cancer Institute, **Anant** was the program leader of the gastrointestinal cancers program. A professor of cell biology, medicine/ gastroenterology and nutrition, he was also director of gastroenterology research at the University of Oklahoma Health Sciences Center.

As Associate Director, **Anant** devotes 20% effort to supporting the leadership of the Cancer Control & Population Health and Cancer Prevention & Survivorship research programs by providing feedback and guidance related to activities specifically promoting intra- and inter-programmatic interactions and multi-discipline, multi-investigator cancer prevention- and cancer control-focused grant applications. He has been particularly focused on mentoring cancer center members in these programs and assisting them in developing their academic careers. In addition, he has promoted the development of multi-disciplinary teams focused on drug discovery in cancer prevention and clinics for patients at high risk for hereditary GI cancers.

Teresa J. Christenson, ASA – Associate Director for Administration

Qualifications and Responsibilities
Christenson became Associate Director for Administration in December, 2006. Prior to taking this role, she was Director of Finance for KUCC since 2005. She also worked in the School of Medicine Finance Office developing financial policies for Graduate Medical Education. Previously, Christenson was Vice President and

Actuary with ING U.S. Financial Services in West Chester, PA where she managed a variety of groups at ING including Annuity Product Development, Quality Assurance, and Customer Service Support.

Christenson's skills in project management, budget management, business requirements design, and process improvement have been critical in determining the appropriate infrastructure requirements and implementing a plan for the continued growth of KUCC's faculty, staff and shared resources. As Associate Director, Christenson devotes 80% of her effort to CCSG activities providing administrative support to effectively and efficiently meet KUCC's goals, policies, and operations. She works with the senior leadership team to identify and support critical Cancer Center research projects through the pilot project funding process and sits on the catchment area committee in order to advance initiatives relevant to KUCC's catchment area. Christenson's administrative group disseminates information across research programs, shared resources and campuses.

Carol Fabian, MD – Associate Director for Clinical Research

Qualifications and Responsibilities
Fabian has had a long career in clinical research as the PI of R01's and other peer-reviewed grants in breast cancer treatment and early phase breast cancer prevention trials, as well as, the PI of clinical and translational treatment trials in breast cancer, Hodgkin's and non-Hodgkin's lymphoma in the co-operative group setting. Most of her investigations were conducted at multiple sites and involved repeated tumor or benign tissue sampling. **Fabian** has a long history of collaboration with basic and behavioral scientists including her role as the administrative PI of a multi-PI Komen Promise Grant in which the other PIs were basic scientists conducting animal studies similar to the clinical trial. She has worked collaboratively with both KUCC leadership and members from a variety of disciplines in her previous role as co-leader of the Cancer Prevention and Survivorship research program for more than a decade and as co-leader of SWOG Survivorship Committee for the last seven years. Her primary goals for both the Cancer Center and SWOG were not only to promote the advancement of the organization, but also to develop and promote young investigators from a variety of disciplines via direct and/or referred mentoring and promoting them as PIs or co-PIs of projects generally paired with more senior investigators.

Fabian has been at KU her entire career and is ideally suited in her new role as AD of Clinical Research, in that, she is very familiar with both the investigators, administration, and the research infrastructure at the University of Kansas. She is also very familiar with the community and Midwest Cancer Alliance physicians having trained many of the clinicians as fellows. As an Associate Director, **Fabian** will devote 20% effort and her primary role will be to work with Cancer Center leadership, clinical, behavioral and translational investigators, Disease Working Group leaders, as well as community physicians, to ensure that KUCC has the necessary resources, infrastructure, and types of interventional trials in cancer treatment, survivorship and prevention in order to serve our catchment area, train and promote new investigators and either answer important questions or serve as the necessary pilots to serve as a basis for eventual larger studies.

Sally Maliski, PhD, RN, FAAN – Associate Director for Health Equity

Qualifications and Responsibilities
In response to both NCI Site Visit and EAB feedback, KUCC created the position of Associate Director for Health Equity in order to address the critical problem of cancer disparities in the KUCC catchment area. **Maliski** was recently named dean of the University of Kansas School of Nursing. Prior to her role as dean, **Maliski** served as an associate professor in the UCLA School of Nursing and an assistant researcher for the UCLA Department of Urology at the David Geffen School of Medicine. **Maliski** will make strong contributions to the Cancer Prevention and Survivorship research program with her research program on prostate cancer prevention in Latino men (R01NR014518). Her research interests focus on symptom experience and management among low-income populations currently men with prostate cancer and their partners. Her clinical focuses are oncology, hospice, and free clinic primary care.

Maliski will devote 20% effort to her Associate Director position and aims to help identify, prioritize, and address the needs of various segments of the catchment area; increase total funding for research related to health disparities issues; increase funding for minority researchers; work with KUCC leadership to implement

educational offerings on disparities research methods for Cancer Center researchers; and develop strategies to increase enrollment into clinical trials including clinical, non-clinical and survivorship trials.

Matthew S. Mayo, PhD, MBA, FASA – Associate Director for Shared Resources

Qualifications and Responsibilities
Mayo brings over two decades of experience working within, managing and creating shared resources/cores for multiple institutional center initiatives. **Mayo** created and managed the Biostatistics and Informatics Shared Resource for KUCC for over a decade and also managed the Clinical Trials Office for over five years. **Mayo** also created the Department of Biostatistics at KUMC and is its founding chair. **Mayo** has been a mentor and/or statistical advisor for eight K-awardees at the medical center. **Mayo's** research interests are primarily focused on robust regression methods, clinical trial design and experimental design.

Mayo will commit 20% effort to his Associate Director role primarily providing guidance on each shared resources' scope of services, utilization, performance, and cost effectiveness. For each shared resource, **Mayo** will also make recommendations on budget, new and/or replacement personnel, equipment and space; help establish a business plan and budget, charge-back system, metrics to track utilization and improve performance, Internal and External Advisory Boards and an annual report; conduct annual review of shared resources and directors and provide recommendations to the Director; and meet quarterly, and as needed, with each shared resource Director; bi-annually with all shared resource Directors, and bi-annually with each KUCC program to identify needs for new shared resources and refinement to existing shared resources.

Jeffrey C. Reene, MBA – Chief Operating Officer

Qualifications and Responsibilities
Reene brings more than 30 years of operations experience in the healthcare, life sciences and technology industries. He is an honors graduate of the University of Illinois where he received a B.A. in Finance and an M.B.A. As Chief Operating Officer, Reene's role includes serving as a liaison to the Executive Vice Chancellor/Executive Dean's office, focusing on external partnerships, and as an advisor to the Director. Specifically, Reene works with the Executive Vice Chancellor/Executive Dean's office at the medical center, ensuring consistency and alignment of priorities and resources for the Cancer Center; builds relationships with key external funding sources including governmental, civic and community leaders; and designed and led the build out of Midwest Cancer Alliance network of hospitals and research institutions.

Scott J. Weir, PharmD, PhD – Associate Director for Translational Research

Qualifications and Responsibilities
Weir brings more than 30 years of experience to lead KUCC's translational research enterprise. In addition to his Cancer Center responsibilities, **Weir** directs The Institute for Advancing Medical Innovation (IAMI) at KUMC. IAMI makes product development-focused investments to transform laboratory and bedside discoveries into medical innovations. Drug, diagnostic, and medical device projects are de-risked, and those that show promise, are partnered with the private sector to further develop and commercialize. **Weir's** research interests include pharmacokinetics and pharmacodynamics of anticancer agents, innovative approaches in lead optimization and early drug development, clinical pharmacology, and development of novel bladder cancer therapeutics.

Weir will commit 20% effort to his Associate Director role with the primary responsibility of enabling and facilitating intra- and inter-programmatic interactions between basic and clinical and translational researchers. Weir will help establish and advance drug discovery and development projects targeting cancer treatment and prevention and work to establish collaborations with industry, academia, government and disease philanthropy organizations. Additionally, **Weir** will work with KUCC leadership to promote new translational research funding initiatives, developing research working groups in targeted areas to promote new grant initiatives in translational research, and identifying investigator needs for shared facility or other infrastructure needs to support translational research.

Danny R. Welch, PhD – Associate Director for Basic Science

Qualifications and Responsibilities
Welch was recruited from the UAB Comprehensive Cancer Center, where he was the Leonard H Robinson (endowed) Professor of Pathology, Professor of Cell Biology and Professor of Pharmacology/Toxicology. He was a Senior Member of the UAB Comprehensive Cancer Center, Director of the Cancer Biology Graduate program and Director, Howard Hughes Med-into-Grad Graduate Program. **Welch** has been continually funded by NCI since 1993. His research focuses on the science of tumor progression, specifically the genetic regulation of cancer metastasis. His lab has developed and characterized many widely-used metastasis models, discovered six of the 30 known metastasis suppressors, and was among the first to develop Matrigel® *in vitro* invasion assays. His research has taken him into the arenas of G-protein coupled receptors, phosphoinositide signaling, tumor dormancy, chromatin structure, epigenetics, microRNA regulation and function, and mitochondrial genetics. With experience in genetics, biochemistry, molecular biology and cell biology, his research interests include breast, melanoma, ovarian, pancreatic, colorectal, glioblastoma and lymphoma. In the fall of 2010, The University of Kansas Board of Regents approved the creation of a new department for the Medical Center, the Department of Cancer Biology under his chairmanship.

Welch will commit 20% effort to his Associate Director role and primarily aims to support the leadership of the Cancer Biology research program by assisting in the planning and organizing of meetings, seminars and activities that foster inter-programmatic collaborations. Welch monitors performance of the cancer-related basic science efforts within KUCC, working closely with other Associate Directors, Department Chairs and Program Leaders to formulate scientific plans and respond to research opportunities. He also assists the Director and other KUCC leadership to identify potential new basic science recruits for KUCC that would strengthen the Cancer Biology research program and would help build collaborative research initiatives and cross-fertilization between campuses.

Establishing a Future Vision

The KUCC senior leadership team works together in many ways to realize, refine and implement a vision for the Cancer Center. **Jensen** worked with the team to carefully and thoughtfully craft the following vision:

1. Leverage our collective state-of-the-art basic, clinical, translational, and population research programs to understand cancer at a fundamental level and catalyze a comprehensive, multi-disciplinary approach to defeating cancer locally, regionally, nationally, and globally;
2. Develop, promote, and implement a cancer center culture whose highest priority is to foster the discovery and advancement of new and more effective therapeutic approaches for the benefit of its patients;
3. Discover and develop paradigm changing therapeutic advances delivered in a compassionate, caring, and cost effective manner resulting in improved survival and quality of life for our patients;
4. Proactively execute cancer prevention and control strategies to mitigate the increase in cancer incidence and mortality predicted for the twenty-first century;
5. Train the next generation of leaders in cancer research, clinical care, and advocacy; and
6. Lead the effort to reduce the burden of cancer in our region and serve as a national model in doing so.

With these goals in mind, the senior leadership team has built the center from the ground up, implemented numerous changes to enhance cancer research capacity, optimized its organizational structure, and enhanced our senior leadership team to better position KUCC for future growth as well as to ensure that the clinical, research and training missions are fully integrated across all consortium institutions.

For example, the senior leadership team, from its beginning, strongly emphasized leveraging the university's inherent strengths in drug discovery and development and has consistently organized the center around translating basic research findings into our clinics in conjunction with multiple external partners and organizations. These efforts have been detailed throughout the application and have resulted in 15 concepts being moved into clinic as Phase I trials since 2008. In 2013, **Jensen**, **Welch** and **Tsue** led the creation of a *de novo* second strategic plan. This second strategic plan evaluated the current status of KUCC and its partners and centered on an application for Comprehensive Cancer Center designation by the NCI at the time

of the cancer center support grant renewal in 2017. Priorities for the second strategic plan are detailed in the Planning and Evaluation section. The senior leadership team will convene in October, 2016 to outline and develop a third (*de novo*) strategic plan.

Fostering Basic Discovery

The KUCC senior leadership team spends a number of meetings discussing strategic recruiting efforts keeping in mind our current research portfolio and how a potential recruit could strengthen an existing program or help develop a new area. Recruiting efforts are coordinated with all campuses and the opportunities to expand the breadth and depth of our basic science discoveries and integrate them into our clinical enterprise take precedence.

In response to the need to increase therapeutic clinical trial accrual and the desire to offer more clinical trial funding opportunities, the senior leaders developed a request for proposals involving investigator-initiated early phase clinical trials. They encouraged applications for trials that included a short duration of patient follow-up with primary endpoints that could be attained within three months from enrollment, and included collaborations that crossed disciplines, research programs and campuses. Four applications were awarded $100,000 each over two years. Year one began in 2015. Additionally, **Weir**, **Fabian**, **Williamson** and **Godwin** have worked together to develop the investigator-initiated trial (IIT) steering committee. The IIT steering committee is a venue for basic and clinical researchers to present IIT concepts arising from laboratory and bedside discoveries. The IIT steering committee aims to: 1) enable and advance hypothesis-driven Investigator-Initiated Trials (IITs) that represent external funding opportunities; 2) increase patient accruals to treatment trials; 3) create a rich translational medicine culture for KUCC scientists, providing access to mentors and supporting faculty and staff career development; and 4) effectively utilize KUCC shared resources to support IITs.

Focus on KUCC's Catchment Area

The senior leadership team established a catchment area committee to specifically define and investigate the needs of our service area and focus Cancer Center resources to mitigate the impact of cancer throughout the region. This committee is led by Christenson and among others, also includes senior leaders, **Jensen** and **Mayo**. Through the efforts of this committee, a number of KUCC initiatives commenced, including a broad-based multi-institutional program to enhance uptake of the HPV vaccine, and the establishment of an Associate Director for Health Equity.

Training and Education

In 2012, Associate Directors **Welch** and **Anant** began 'Grant Rounds' to facilitate the development of grant ideas from all faculty, particularly junior faculty and post-doctoral fellows. This group convenes every other Friday to learn about and provide feedback on a specific grant proposal under development. Beyond this initiative, the senior leaders also recognized the need to foster researchers working on complementary, collaborative programs. Toward that end, **Anant** and **Welch** proposed a Center for Tumor Microenvironment Research, which was submitted for a COBRE award (1 P20 GM121306-01) to mentor young faculty, build core facilities and build collaborations within the KUCC on the topic. Tumor microenvironment was considered a priority area for expansion when the KUCC strategic plan was developed. Thus, it became the focus of this transdisciplinary, multi-departmental initiative involving all four KUCC research programs.

Furthermore, **Welch** and **Jensen** worked with the Cancer Biology Training Consortium (CABTRAC) and faculty at other NCI-designated cancer centers to publish the essential components of cancer education (**Welch**, *Cancer Res*. 2015).

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Progress Report Publications – Senior Leadership

Year 1 (Calendar Year 2012)

Garcia AA, Sill MW, Lankes HA, **Godwin** AK, Mannel RS, Armstrong DK, Carolla RL, Liepman MK, Spirtos NM, Fischer EG, Leslie KK. A phase II evaluation of lapatinib in the treatment of persistent or recurrent epithelial ovarian or primary peritoneal carcinoma: a gynecologic oncology group study. Gynecol Oncol. 2012;124(3):569-74. Epub 2011/11/01. doi: 10.1016/j.ygyno.2011.10.022. PubMed PMID: 22037316; PMCID: PMC3971755.

Stecklein SR, **Kumaraswamy** E, **Behbod** F, Wang W, Chaguturu V, **Harlan-Williams** LM, **Jensen** RA. BRCA1 and HSP90 cooperate in homologous and non-homologous DNA double-strand-break repair and G2/M checkpoint activation. Proc Natl Acad Sci U S A. 2012;109(34):13650-5. Epub 2012/08/08. doi: 10.1073/pnas.1203326109. PubMed PMID: 22869732; PMCID: PMC3427093.

Year 2 (Calendar Year 2013)

Chimonidou M, Kallergi G, Georgoulias V, **Welch** DR, Lianidou ES. Breast cancer metastasis suppressor-1 promoter methylation in primary breast tumors and corresponding circulating tumor cells. Molecular cancer research : MCR. 2013;11(10):1248-57. doi: 10.1158/1541-7786.MCR-13-0096. PubMed PMID: 23744981; PubMed Central PMCID: PMC3868947.

Kwatra D, Venugopal A, Standing D, Ponnurangam S, **Dhar** A, Mitra A, **Anant** S. Bitter melon extracts enhance the activity of chemotherapeutic agents through the modulation of multiple drug resistance. J Pharm Sci. 2013;102(12):4444-54. Epub 2013/10/17. doi: 10.1002/jps.23753. PubMed PMID: 24129966; PMCID: Pmc3939049.

Yew KH, Crow J, Hirst J, Pressetto Z, **Godwin** AK. Epimorphin-Induced MET Sensitizes Ovarian Cancer Cells to Platinum. PloS one. 2013;8(9):e72637. Epub 2013/09/17. doi: 10.1371/journal.pone.0072637. PubMed PMID: 24039787; PubMed Central PMCID: PMC3767807.

Year 3 (Calendar Year 2014)

Atay S, Banskota S, Crow J, Sethi G, Rink L, **Godwin** AK. Oncogenic KIT-containing exosomes increase gastrointestinal stromal tumor cell invasion. Proceedings of the National Academy of Sciences of the United States of America. 2014;111(2):711-6. Epub 2014/01/01. doi: 10.1073/pnas.1310501111. PubMed PMID: 24379393; PubMed Central PMCID: PMCPmc3896203.

Block MS, Charbonneau B, Vierkant RA, Fogarty Z, Bamlet WR, Pharoah PD, Rossing MA, Cramer D, Pearce CL, Schildkraut J, Menon U, Kjaer SK, Levine DA, Gronwald J, Culver HA, Whittemore AS, Karlan BY, Lambrechts D, Wentzensen N, Kupryjanczyk J, Chang-Claude J, Bandera EV, Hogdall E, Heitz F, Kaye SB, Fasching PA, Campbell I, Goodman MT, Pejovic T, Bean YT, Hays LE, Lurie G, Eccles D, Hein A, Beckmann MW, Ekici AB, Paul J, Brown R, Flanagan JM, Harter P, du Bois A, Schwaab I, Hogdall CK, Lundvall L, Olson SH, Orlow I, Paddock LE, Rudolph A, Eilber U, Dansonka-Mieszkowska A, Rzepecka IK, Ziolkowska-Seta I, Brinton LA, Yang H, Garcia-Closas M, Despierre E, Lambrechts S, Vergote I, Walsh CS, Lester J, Sieh W, McGuire V, Rothstein JH, Ziogas A, Lubinski J, Cybulski C, Menkiszak J, Jensen A, Gayther SA, Ramus SJ, Gentry-Maharaj A, Berchuck A, Wu AH, Pike MC, Van Den Berg D, Terry KL, Vitonis AF, Ramirez SM, Rider DN, Knutson KL, Sellers TA, Phelan CM, Doherty JA, Johnatty SE, deFazio A, Song H, Tyrer J, Kalli KR, **Fridley** BL, Cunningham JM, Goode EL. Variation in NF-kappaB signaling pathways and survival in invasive epithelial ovarian cancer. Cancer Epidemiol Biomarkers Prev. 2014;23(7):1421-7. Epub 2014/04/18. doi: 10.1158/1055-9965.epi-13-0962. PubMed PMID: 24740199; PMCID: Pmc4082406.

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Resource Sharing Plan

The University of Kansas Cancer Center (KUCC) and its scientific community understands its responsibility to comply with the instructions for the Resource Sharing Plans provided within the SF 424 (R&R) Application General Instructions and Supplemental Grant Application Instructions. When resources are developed with NIH funds via this Cancer Center Support Grant P30 mechanism, KUCC will ensure findings are made readily available to the NIH and the scientific community in a timely manner.

Data Sharing Plan

KUCC will adhere to the Final NIH Statement on Sharing Research Data and refer to the National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research. KUCC encourages the free flow of information and ideas while recognizing the timeliness of data sharing, the rights and privacy of human subjects and issues related to proprietary data. KUCC encourages data documentation, using a data-sharing agreement and selecting an appropriate method for sharing; considering the sensitivity of the data, the size of the dataset and the volume of requests anticipated.

Additionally, KUCC encourages any user of a CCSG-supported shared resource to acknowledge the source of data upon which their manuscript is based either in the Acknowledgments section or with authorship on the paper. Furthermore, any research project that received direct cost support from the CCSG is encouraged to cite the P30 CA168524. In both cases, citing the P30 CA168524 grant number and then being compliant with the NIH Public Access Policy is required.

Sharing Model Organisms

In the event that a model organism is developed, KUCC will comply with the NIH Policy on Sharing of Model Organisms for Biomedical Research. KUCC will work with the NIH/NCI to share and disseminate the critical model organism in a timely manner.

Genome Wide Associate Studies

When applicable, KUCC will comply with the NIH Genomic Data Sharing Policy. KUCC supports the sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. All research studies funded through the CCSG involving genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data will be submitted in a timely manner.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 016060860

Legal Name*: University of Kansas Medical Center Research Institute, Inc.
Department:
Division:
Street1*: MSN 1039, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Deborah		Maloney	MSM

Position/Title: Director, Sponsored Programs Administration
Street1*: 3901 Rainbow Boulevard
Street2: Mail Stop 1039
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937
Phone Number*: 913-588-1261 Fax Number: 913-588-3225 Email: spa@kumc.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofit Organization

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Planning and Evaluation

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2017	06/30/2022

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Medical Center
Duns Number:	016060860
Street1*:	MS 3045, 3901 Rainbow Boulevard
Street2:	
City*:	Kansas City
County:	Wyandotte
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66160-0000
Project/Performance Site Congressional District*:	KS-003

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ❍ **Yes** ● **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ❍ No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	Plan_Project_Summary_Final1019469452.pdf
8. Project Narrative*	
9. Bibliography & References Cited	
10.Facilities & Other Resources	
11.Equipment	
12. Other Attachments	Plan_Other_Attachments_Final1019754746.pdf

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Planning and Evaluation – Project Summary/Abstract

Planning and evaluation activities play a key role in the growth and continuous improvement of The University of Kansas Cancer Center (KUCC). Multiple internal committees and the External Advisory Board (EAB) guide the planning and evaluation process under the leadership of the Director, **Jensen**. The EAB serves a critical role in providing external oversight of KUCC's vision, direction, leadership, research programs and supporting infrastructure. The EAB was selected by KUCC leadership to complement the basic laboratory, prevention, cancer control and population science and clinical expertise represented within KUCC research programs, shared resources and administrative components. The EAB has made numerous major recommendations such as carefully defining the roles and responsibilities of Associate Directors and Program Leaders, recruiting strong physician scientist leaders, creating a replacement plan for senior leaders, increasing multidisciplinary science initiatives, defining the KUCC catchment area and relevant research initiatives, strengthening connections with consortium partners and leveraging KUCC's drug discovery and development capabilities.

Internally, KUCC utilizes many groups to regularly assess KUCC goals and activities. KUCC Leadership Council promotes scientific interactions between the basic, translational, and clinical elements of KUCC, plans the development of the research programs, leverages KUCC resources for maximum benefit, and oversees activities of KUCC programs. The Associate Directors meet to evaluate cross-programmatic and multi-campus activities including research symposia, seminars and conferences. The Associate Directors Council also endeavors to increase cancer focus for the center and oversee allocation of KUCC pilot grants. Each year the Associate Directors Council reviews the progress of the research programs, shared resources and administrative functions of KUCC. The Associate Directors Council makes final recommendations to the Director on practically all issues including budget, resource allocation, membership, space, leadership appointments and strategic direction. The Midwest Cancer Alliance, the outreach division of KUCC, helps promote collaboration of key hospitals and research institutions regarding research and educational activities and advises the Director on the impact of KUCC regionally.

Planning and evaluation activities are an essential component of KUCCs continued and steady improvement over the past grant period and will continue to play an essential role in the future. KUCC's EAB and key internal advisory groups have played critical roles in this process. Overall, KUCC has effectively utilized the Planning and Evaluation component of the CCSG to put in place a vigorous and robust process of vision setting, evaluation of progress, implementation of improvements and planning for the future.

Planning and Evaluation – Other Attachments

KUCC External Advisory Board

Name	Title	Institution
George J. Weiner, MD Chair (2008)	Director Professor, Department of Internal Medicine	Holden Comprehensive Cancer Center, University of Iowa Health Care
Laurence H. Baker, DO (2008)	Professor, Departments of Internal Medicine and Pharmacology	University of Michigan Medical School
Stephen W. Byers, PhD (2010)	Director of Shared Resources	Lombardi Cancer Center, Georgetown Univ. Medical Center
Webster Cavenee, PhD (2014)	Director	Ludwig Institute for Cancer Research, University of California, San Diego
Mark S. Clanton, MD, MPH, FAAP (2007)	Medical Director	TMF Health Quality Institute Former Deputy Director, NCI
Michael W. Darling, MHA (2005)	Associate Director for Administration	Indiana University Simon Cancer Center
Ernest T. Hawk, MD, MPH (2008)	Vice President for Cancer Prevention & Population Sciences	MD Anderson Cancer Center, The University of Texas
Janet A. Houghton, PhD (2015)	Professor, Molecular Medicine Department of Cancer Biology	Southern Research Institute
Candace S. Johnson, PhD (2005)	President & CEO Cancer Center Director Chair, Department of Pharmacology & Therapeutics	Roswell Park Cancer Institute
Guillermina “Gigi” Lozano, PhD (2014)	Professor and Chair, Department of Genetics	MD Anderson Cancer Center, The University of Texas
Alfred I. Neugut, MD, PhD (2010)	Professor of Epidemiology Associate Director for Population Sciences Co-Director, Cancer Prevention Program	Herbert Irving Comprehensive Cancer Center, Columbia University Health Sciences
Timothy R. Rebbeck, PhD (2014)	Professor, Cancer Epidemiology	Dana-Farber Cancer Institute, Harvard T.H. Chan School of Public Health
Larry J. Schaaf, PhD (2005)	Director, Clinical Treatment Unit	The Ohio State University Comprehensive Cancer Center
Robert C. Young, MD (2013)	President	RCY Medicine Director Emeritus, Fox Chase CCC
Former Members		
Victor Vogel, MD	Director, Breast Medical Oncology/Research	Geisinger Health System
Mary Todd, DO	Global Medical Affairs Leader, Oncology	ZYTIGA at Johnson and Johnson, Cancer Institute of New Jersey (Former Director)
Patricia Ganz, MD	Distinguished Professor, Health Policy and Management	University of California, Los Angeles
John H. Glick, MD (2006 - 2013)	Vice President, University of Pennsylvania Health System Rena Rowan Breast Center	Abramson Cancer Center, The University of Pennsylvania
Harold L. Moses, MD (2005 - 2013)	Director Emeritus	Vanderbilt-Ingram Comprehensive Cancer Center
David A. Scheinberg, MD, PhD (2008 - 2013)	Molecular Pharmacology & Chemistry Program Experimental Therapeutics Center Leukemia Service	Memorial Sloan Kettering Cancer Center

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **George J. Weiner, MD**

eRA COMMONS USER NAME (credential, e.g., agency login): gweiner

POSITION TITLE: Director, Holden Comprehensive Cancer Center; C.E. Block Chair of Cancer Research; Professor, Dept. of Internal Medicine

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Johns Hopkins University, Baltimore, MD	BA	1978	Natural Sciences
Ohio State University, Columbus, OH	MD	1981	Medicine

A. Personal Statement

I am well suited to serve as member of the The University of Kansas Cancer Center. I serve as Director of the Holden Comprehensive Cancer Center, a position I have held for the past 15 years. I have served, and currently serve in a number of national leadership roles related to cancer centers. I am the President of the Association of American Cancer Institutes, and was former chair of NCI subcommittee A (known as the cancer center parent committee). I chair the External Advisory Boards for 4 NCI designated cancer centers, and serve on 5 other cancer center EABs. I am Vice-chair of the Science Policy and Governmental Affairs Committee of the American Association for Cancer Research. I have also served as PI of the Iowa/Mayo Lymphoma SPORE P50 grant for the past 14 years. I have published extensively on results of laboratory, clinical and population based cancer research.

I am a faculty member of the Interdisciplinary Graduate Program in Immunology and train PhD students in my laboratory. In addition to the scientific contributions outlined below, I have authored or co-authored a number of recent review articles that speak to my national recognition in monoclonal antibody therapy and cancer immunotherapy in general.

a) Topalian SL, **Weiner GJ**, Pardoll DM. Cancer immunotherapy comes of age. Journal of Clinical Oncology : official journal of the American Society of Clinical Oncology. 2011;29(36):4828-36. doi: 10.1200/JCO.2011.38.0899. PMC3255990.

b) Mathur R, **Weiner GJ**. Picking the optimal target for antibody-drug conjugates. American Society of Clinical Oncology educational book / ASCO American Society of Clinical Oncology Meeting. 2013. doi: 10.1200/EdBook_AM.2013.33.e103. PMID: 23714470 (PMC# not required; not NIH funded)

c) Makkouk A, **Weiner GJ.** Cancer Immunotherapy and Breaking Immune Tolerance: New Approaches to an Old Challenge. Cancer Research. 2015;75(1):5-10. doi: 10.1158/0008-5472.CAN-14-2538. PMC4286422.

d) **Weiner GJ.** Building better monoclonal antibody-based therapeutics. Nat Rev Cancer. 2015 Jun;15(6): 361-70. doi: 10.1038/nrc3930. Review. PMC4491443.

B. Positions and Honors

Positions and Employment:

1981-1985	Resident/Chief Resident, Internal Medicine, Medical College of Ohio
1985-1989	Fellow, Hematology and Oncology, University of Michigan
1989-1994	Assistant Professor, Department of Internal Medicine, University of Iowa, Iowa City, IA
1994-2000	Associate Professor, Department of Internal Medicine, University of Iowa, Iowa City, IA
2000-Present	Professor, Department of Internal Medicine, University of Iowa, Iowa City, IA
1998-Present	Director, Holden Comprehensive Cancer Center at The University of Iowa
1998-Present	C.E. Block Chair of Cancer Research
2002-Present	Director, University of Iowa / Mayo Clinic Lymphoma SPORE

Board Certifications:

9/11/85	Board Certified in Internal Medicine
11/10/87	Board Certified in Medical Oncology
11/1/88	Board Certified in Hematology

Professional Societies Memberships and Service:

1993-Present	Faculty Member, Graduate Program in Immunology
1996-2000	ET-2 Study Section, NIH
2002-2012	American Society of Hematology Governmental Affairs Committee (Chair 2008-2012)
2004-2007	Board of Directors, Association of American Cancer Institute
2004-Present	President, Iowa Cancer Consortium
2005-Present	Leukemia and Lymphoma Society Specialized Center of Research Review Co
2005-2009	NCI Initial Review Group, Subcommittee A-Cancer Centers (Chair 2007-2009)
2007-Present	Association of American Physicians
2009-2015	NCI Lymphoma Steering Committee
2014-Present	Member American Clinical and Climatological Association
2014-Present	Vice Chair, Science Policy and Governmental Affairs Committee, American Association for Cancer Research
2012-2014	Vice President, Association of American Cancer Institute
2014-Present	President, Association of American Cancer Institutes

C. Contribution to Science

1. **My laboratory made significant contributions to understanding factors that influence the potential efficacy of use of anti-CD3-based bispecific monoclonal antibodies to retarget T cells towards malignant B cells.** These concepts included the toxicity associated with bispecific antibodies that activate T cells non-specifically (in the absence of target cells), and the value of using small antibody constructs. These concepts have held up over time, and were central to the development of BiTE antibodies including blinatumomab that was approved by the FDA in late 2014.

a) **Weiner GJ,** Hillstrom JR. Bispecific anti-idiotype/anti-CD3 antibody therapy of murine B cell lymphoma. J Immunol. 1991 Dec 1;147(11):4035-44. PMID: 1834746.
b) Link BK, **Weiner GJ**. Production and characterization of a bispecific IgG capable of inducing T-cell-mediated lysis of malignant B cells. Blood. 1993 Jun 15;81(12):3343-9. PMID: 8507872.
c) **Weiner GJ**, Kostelny SA, Hillstrom JR, Cole MS, Link BK, Wang SL, Tso JY. The role of T cell activation in anti-CD3 x antitumor bispecific antibody therapy. J Immunol. 1994 Mar 1;152(5):2385-92. PMID: 8133049.
d) Link BK, Kostelny SA, Cole MS, Fusselman WP, Tso JY, **Weiner GJ.** Anti-CD3-based bispecific antibody designed for therapy of human B-cell malignancy can induce T-cell activation by antigen-dependent and antigen-independent mechanisms. Int J Cancer. 1998 Jul 17;77(2):251-6. PMID: 9650561.

2. **My laboratory played a major role in describing the biological effects of CpG ODN (before it was known that CpG ODN functioned as TLR9 agonists).** We were the first to demonstrate the potential of CpG ODN as immune adjuvants in tumor antigen immunization. Additional potential uses of CpG ODN first described in my laboratory included evaluating their potential to enhance the efficacy of monoclonal antibody therapy by activating NK cells, and their potential to mediate activation-induced cell death of malignant B cells. Each of these preclinical observations has led to clinical evaluation.

a) Wooldridge JE, Ballas Z, Krieg AM, and **Weiner GJ**. Immunostimulatory Oligodeoxynucleotides Containing CpG Motifs Enhance Antibody Dependent Cytotoxicity *In Vitro* and Improve the Efficacy of Monoclonal Antibody Therapy *In Vivo*. Blood, 89:2994-2998. 1997.
b) **Weiner GJ**, Liu H, Woolridge JE, Dahle CE and Krieg AM. Immunostimulatory Olidodeoxynucleotides Containing the CpG Motif are Effective as Immune Adjuvants in Tumor Antigen Immunization PNAS. 94:10833-10837.1997.
c) Hartmann G, **Weiner GJ,** Krieg AM. CpG DNA: A potent signal for growth, activation, and maturation of human dendritic cells. PNAS. 96:9305-10. 1999.

d) Ballas ZK, Krieg AM, Warren T, Rasmussen W, Davis HL, Waldschmidt M, and **Weiner GJ**. Divergent Therapeutic and Immunologic Effects of Oligodeoxynucleotides with Distinct CpG Motifs. J. Immunology, 167:4878-4886, 2001.

3. **My research group, in collaboration with multiple colleagues, led a number of clinical trials exploring the potential of CpG ODN as a therapeutic agent in B cell malignancies based on the preclinical observations outlined above.** These trials involved evaluation of CpG ODN alone based on the direct effect of CpG ODN on malignant B cells, in combination with rituximab based the ability of CpG ODN to enhance NK-mediated antibody dependent cellular cytotoxicity and in combination with radioimmunotherapy based on the potential to enhance the immune response following.

a) Leonard JP, Link BK, Emmanouilides C, Gregory SA, Weisdorf D, Andrey J, Hainsworth J, Sparano JA, Tsai DE, Horning S, Krieg AM, **Weiner GJ**. Phase I trial of toll-like receptor 9 agonist PF-3512676 with and following rituximab in patients with recurrent indolent and aggressive non Hodgkin's lymphoma. Clin Cancer Res. 2007 Oct 15;13(20):6168-74. PMID: 17947483.

b) Zent CS, Smith BJ, Ballas ZK, Wooldridge JE, Link BK, Call TG, Shanafelt TD, Bowen DA, Kay NE, Witzig TE, **Weiner GJ.** Phase I Clinical Trial of CpG Oligonucleotide 7909 (PF-03512676) in Patients with Previously Treated Chronic Lymphocytic Leukemia. Leuk Lymphoma, 2012 Feb 53(2)211-217. PMC3439221.

c) Witzig TE, Wiseman GA, Maurer MJ, Habermann TM, Micallef IN, Nowakowski GS, Ansell SM, Colgan JP, Inwards DJ, Porrata LF, Link BK, Zent CS, Johnston PB, Shanafelt TD, Allmer C, Asmann YW, Gupta M, Ballas ZK, Smith BJ, **Weiner GJ**. A phase I trial of immunostimulatory CpG 7909 oligodeoxynucleotide and 90 yttrium ibritumomab tiuxetan radioimmunotherapy for relapsed B-cell non-Hodgkin lymphoma. Am J Hematol. 2013 Jul;88(7):589-93. doi: 10.1002/ajh.23460. PMC3951424.

4. **My laboratory has a long-standing interest in the exploring the complex mechanisms of action of anti-CD20, and other anti-cancer antibodies.** We described how the affinity of a monoclonal antibody for CD16 (Fcgamma receptor III) impacts on the ability of monoclonal antibodies to activate NK cells, and how modification of this interaction might lead to development of a more effective antibody. We also were the first to describe how complement can interfere with the interaction between a monoclonal antibody and CD16 which is potential explanation for why monoclonal antibodies that do not fix complement may be more effective.

a) Bowles JA, Wang SY, Link BK, Allan B, Beuerlein G, Campbell MA, Marquis D, Ondek B, Wooldridge JE, Smith BJ, Breitmeyer JB, **Weiner GJ**. Anti-CD20 monoclonal antibody with enhanced affinity for CD16 activates NK cells at lower concentrations and more effectively than rituximab. Blood. 2006 Oct 15;108(8):2648-54. PMC1895597.

b) Wang SY, Racila E, Taylor RP, **Weiner GJ**. NK-cell activation and antibody-dependent cellular cytotoxicity induced by rituximab-coated target cells is inhibited by the C3b component of complement. Blood. 2008 Feb 1;111(3):1456-63. PMC2214766.

c) Veeramani S, Wang SY, Dahle C, Blackwell S, Jacobus L, Knutson T, Button A, Link BK, **Weiner GJ**. Rituximab infusion induces NK activation in lymphoma patients with the high-affinity CD16 polymorphism. Blood. 2011 Sep 22;118(12):3347-9. doi: 10.1182/blood-2011-05-351411.PMC3179401.

d) Kern DJ, James BR, Blackwell S, Gassner C, Klein C, **Weiner GJ**. GA101 induces NK-cell activation and antibody-dependent cellular cytotoxicity more effectively than rituximab when complement is present. Leuk Lymphoma. 2013 Nov;54(11):2500-5. doi: 10.3109/10428194.2013.781169. PMC3957421.

5. **My most recent area of research focus is most relevant to the current proposal. We have been exploring how in situ manipulation of the tumor microenvironment with nanoparticles and microparticles can result in breaking of immune tolerance and enhance the efficacy of the immune response.** These studies have been done in collaboration with Dr. Aliasger Salem. Dr. Salem produces the particles and my research group has performed the immunological evaluation. Promising approaches currently under evaluation include incorporating doxorubicin and/or CpG ODN into the particles, and using them in combination with checkpoint blockade.

a) Zhang XQ, Dahle CE, Baman NK, Rich N, **Weiner GJ,** Salem AK. Potent antigen-specific immune responses stimulated by codelivery of CpG ODN and antigens in degradable microparticles. J Immunother. 2007 Jul-Aug;30(5):469-78. PMID: 17589287.

b) Makkouk A, Joshi VB, Wongrakpanich A, Lemke CD, Gross BP, Salem AK, **Weiner GJ.** Biodegradable microparticles loaded with doxorubicin and CpG ODN for in situ immunization against cancer. AAPS J. 2015 Jan;17(1):184-93. doi: 10.1208/s12248-014-9676-6. PMC4287287.

c) Makkouk A, Joshi VB, Lemke C, Wongrakpanich A, Olivier AK, Blackwell SE, Salem A, **Weiner GJ.** Three Steps to Breaking Immune Tolerance to Lymphoma: A Microparticle Approach. Cancer Immunol Res. 2015 Jan 27. pii: canimm.0173.2014. PMC4390476.

D. Research Support

Ongoing Support:

P30 CA086862 Weiner (PI) 07/14/2000 – 03/31/2018
National Cancer Institute
Cancer Center Support Grant (CCSG)
This cancer center support grant is to support the research activities of the Holden Comprehensive Cancer Center at The University of Iowa.

P30 CA086862-16S1 Weiner (PI) 07/14/2000 – 03/31/2021
National Cancer Institute
Cancer Center Support Grant (CCSG) Supplement – Community Outreach Capacity through Community Health Educator (CHE)
This project will allow the Holden Comprehensive Cancer Center and Iowa Cancer Consortium build off existing efforts and partnerships and strengths of the parent P30 to help confront disparities at the community level.

P50 CA097274-15 Weiner-Witzig (PI) 09/11/2002 – 06/30/2017
National Cancer Institute
Lymphoma SPORE
Research in this SPORE grant consists of interdisciplinary, translational lymphoma research involving the University of Iowa and the Mayo Clinic.
Role: PI; Project Leader (P2) “In Situ Immunization Using Nanoparticles”

R01 CA183702 Weigel (PI) 04/01/2015 – 03/31/2020
NIH
RET as a novel therapeutic target for breast cancer
Our recent findings identified RET as a novel therapeutic target in breast cancer. This proposal will elucidate mechanisms regulating the expression of RET, will determine the cooperative effect of EGFR and will provide important results from a randomized clinical trial that will evaluate the effectiveness of anti-RET treatment in the clinical setting.
Role: Co-Investigator

R56 AI116715 Ince (PI) 04/01/2015 – 03/31/2020
NIH
Modulation of GVHD and GVT by in Vivo Generated Regulatory T Cells
Studies will help us understand the role of intestinal immune system in regulating GVHD. We are uniquely qualified to perform these studies, based on our expertise and experience in (i) mucosal immune modulation; (ii) helminthic immune conditioning; and (iii) GVHD. These studies may lead to the identification of novel therapeutic approaches to treat devastating complication of hematopoietic stem cell transfer, GVHD, while preserving GVT.
Role: Co-Investigator

ACS-IRG-15-176-40 Weiner (PI) 07/01/1977 – 12/31/2018
American Cancer Society (ACS)
Awards fund new and junior faculty who show promise and an interest in contributing to the prevention, cure and treatment of cancer.

P30 CA086862-16 Weiner (PI) 10/01/2016 – 09/31/2017
Cancer Center Support Grant Supplement
Continuing Umbrella of Research Experience (CURE)
Grant will enable underrepresented high school and undergraduate students to work in laboratory and/or clinical research.

P30 CA086862-16 Weiner (PI) 09/01/2016 – 08/31/2017
Cancer Center Support Grant Supplement
Study Mechanisms of Cancer Sensitivity and Resistance to Therapy Utilizing Samples and Information from Human Clinical Trials
Objective is to evaluate potential of subclass mutations in p53, the guardian of the genome, as an integral biomarker for response.

P30 CA086862-16 Weiner (PI) 08/01/2016 – 07/31/2017
Cancer Center Support Grant Supplement
To support collaborative research efforts to Enhance Preclinical Drug Development and Preclinical Clinical Trials Utilizing Patient Derived Xenograph (PDX) Models
Objective is to generate patient-derived xenograft models of gynecologic cancers and melanoma, and provide proof-of-principle that these models accurately predict response.

P30 CA086862-16 Weiner (PI) 09/01/2016 – 08/31/2017
National Cancer Institute
Cancer Center Support Grant (CCSG) Supplement to Support Tissue Acquisition for Development of NCI's PDX Repository
The goal of this work is to provide human tissue to the NCI for the generation of Patient Derived Xenograft (PDX) project.

Completed Support:

P30 CA086862-15S3 Weiner (PI) 07/14/2000 – 03/31/2016
National Cancer Institute
Cancer Center Support Grant (CCSG) Supplement to Support Tissue Acquisition for Development of NCI's PDX Repository
The goal of this work is to provide human tissue to the NCI for the generation of Patient Derived Xenograft (PDX) project.

P30 CA086862-14S1 Weiner (PI) 07/14/2000 – 03/31/2016
National Cancer Institute
Cancer Center Support Grant (CCSG) Administrative Supplement – NCI Clinical Trials Reporting Program (CTRP)
Funding is to support and maintain a comprehensive database containing updated information on all NCI-funded clinical trials.

P30 CA086862-15S1 Weiner (PI) 07/14/2000 – 03/31/2016
National Cancer Institute
Cancer Center Support Grant (CCSG) Supplement – NCI Cancer Clinical Investigator Team Leadership Award (CTLA)
The CTLA Supplement is to support Dr. Mohammed Milhem's effort to strengthen his clinical research programs and enhance current clinical research.

R01 CA137198 Weiner (PI) 07/16/2009 – 06/30/2013
National Cancer Institute
Monoclonal Antibody-Induced NK Cell Activation and Complement
Objective is to evaluate the hypothesis that complement can block monoclonal antibody induced NK cell activation and antibody dependent cellular cytotoxicity and limit the efficacy of therapy, as well as evaluate strategies designed to overcome this effect, in vitro, in animal models and in clinical correlative studies.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Laurence H. Baker, DO**

eRA COMMONS USER NAME (credential, e.g., agency login): bakerl

POSITION TITLE: Collegiate Professor of Cancer Developmental Therapeutics, Department of Internal Medicine; Department of Pharmacology

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Brooklyn College of University of New York, NY	BA	1962	Biology
University of Des Moines School of Osteopathic Medicine, IA	DO	1966	Medicine
Flint Osteopathic Hospital, Flint MI	Residency	1966-1969	Resident
Wayne State University, Detroit MI	Fellowship	1970-1972	Fellow

A. Personal Statement

Throughout my career as an academic clinician, my overarching goal has been to improve upon the care of cancer patients. I have balanced efforts in patient care, teaching, and translational and clinical research with medical administration. The clinical research has focused upon discovery and development of new systemic therapies, clinical trial design, and late transitional research in sarcoma. Using an interdisciplinary model we participated in research that led to significant advances in bone sarcomas and select soft tissue sarcomas as well as for patients with anal canal cancers, head and neck cancer, and breast cancer. We established SARC as the consortium of worldwide experts in pediatric and medical oncology dedicated to clinical trials research in the treatment of sarcomas. I have served as PI of a cancer center core grant, program project grant, and cancer cooperative group set of grants. I am PI of a sarcoma SPORE grant and the SWOG Translational Medical Science Center. Currently I serve as leader of the Translational and Clinical Research Program at the University of Michigan. We established the first Sarcoma Survivorship Program emphasizing the two major adverse outcomes: recurrent cancer and acquired heart disease. The four areas of my career contributions to science include: sarcoma therapeutics, sarcoma biology, clinical trial methodology, and prevention/ survivorship.

B. Positions and Honors

Positions and Employment:

1972 – 1986 Asst Prof (1972), Assoc Prof (1976), Prof (1979), Dept of Oncology, Wayne State Univ, Detroit
1982 – 1986 Prof/Dir, Div of Med Onc, Dept of Int Med, Wayne State Univ School of Med, Detroit MI
1986 – 1992 Prof/Dir, Div of Hem and Onc, Dept of Int Med, Wayne State Univ School of Med, Detroit MI
1988 – 1994 Cancer Center Director, Wayne State Univ School of Medince, Detroit MI
1992 – 1993 Prof/Interim Chair, Dept of Int Med, Wayne State Univ School of Med, Detroit MI
1994 – 2004 Dir for Clinical Research/Deputy Dir, Univ of Mich Comprehensive Cancer Ctr, Ann Arbor MI
1994 – 2003 Prof/Assoc Chief, Div of Hem/Onc, Dept of Int Med, Univ of Mich Med School, Ann Arbor MI
2003 – 2010 Chair, Sarcoma Alliance for Research through Collaboration (SARC), Ann Arbor MI
2004 – Pres Prof of Pharmacology, Dept of Pharmacology, Univ of Mich Med School, Ann Arbor MI
2005 – 2013 Chair, SWOG, Ann Arbor, MI
2016 – Pres. Chair, Translational and Clinical Research Program, University of Michigan, Ann Arbor MI

Professional Memberships:

Member, American Society for Cancer Research
Member, American Society of Clinical Oncology

Member, American Society for Clinical Pharmacology and Therapeutics
Member, Connective Tissue Oncology Society
Member, American College of Osteopathic Internists
Member, American Association of Clinical Research
Member, American Society of Gene Therapy

Honors:

May 2006	Nobility in Science Award, Sarcoma Foundation of America
Nov 2006	UM Dean's Award for Achievement in Clinical and Health Sciences Research
May 2007	ASCO Distinguished Service Award for Scientific Leadership
March 2009	34th Annual Jeffrey A. Gottlieb Memorial Award for Outstanding Achievement in Cancer Research
Nov 2009	Connective Tissue Oncology Society (CTOS) Nina Axelrod Award
June 2010	ASCO Statesman Award
Nov 2011	American Cancer Society Distinguished Service Award
2012 – Pres	The Laurence H. Baker Collegiate Professorship in Cancer Developmental Therapeutics, University of Michigan
2014	Hematology/Oncology Fellowship Program Teacher of the Year, University of Michigan

C. Contribution to Science

1. **Sarcoma therapeutics:** A recognized authority in the innovative clinical trial design of the treatment of sarcomas, including phase I – III trials. My collaborative research efforts have been pivotal in the development of Adriamycin, Ifosfamide, oral Mesna, Imatinib and IGFR-1 kinase inhibitors.

   a) O'Bryan RM, Luce JK, Talley RW, Gottlieb JA, **Baker LH,** Bonadonna G. Phase II evaluation of adriamycin in human neoplasia. Cancer. 1973 Jul; 32(1): 1-8. PMID: 4716773
   b) Antman KA, Crowley J, Balcerzak SP, Rivkin SE, Weiss GR, Elias A, Natale RB, Cooper RM, Barlogie B, Trump DL, Doroshow JH, Aisner J, Pugh RP, Weiss RB, Cooper BA, Clamond GH, **Baker LH**. An intergroup phase III randomized study of doxorubicin and dacarbazine with or without ifosfamide and mesna in advanced tissue and bone sarcomas. J Clin Oncol. 1993 Jul; 11(7): 1276-1285. PMID: 8315425
   c) Mace JR, Keohan ML, Bernardy H, Junge K, Ciebach G, Romeis P, Thoma A, Wagner T, Mueller U, Demetri G, **Baker LH**. Crossover randomized comparison of intravenous versus intravenous/oral mesna in soft tissue sarcoma treated with high-dose ifosfamide. Clin Cancer Res. 2003 Dec; 9(16 Pt 1): 5829-5834. PMID: 14676103
   d) Pappo AS, Patel SR, Crowley J, Reinke D, Kuenkele K-P, Chawla SP, Toner GC, Maki RG, Meyers PA, Chugh R, Ganjoo KN, Schuetze SM, Juergens H, l Leahy M, Geoerger B, Benjamin RS, Helman LJ, **Baker LH**. R1507, a monoclonal antibody to the insulin-like growth factor-1 receptor (IGF-1R) is an active and promising agent in patients with recurrent or refractory Ewing's sarcoma family of tumors (ESFT): Results of a Phase II SARC Study. J Clin Oncol. 2011 Dec; 29(34): 4541-4547. PMC3236654

2. **Sarcoma biology:** I have engaged in sarcoma biology studies from within the laboratory and most particularly fostered an inter-disciplinary team approach focused on the patient, innovative clinical trials design, and the integration of laboratory and clinical research findings as they relate to new advances in the treatment of bone and soft tissue sarcomas. I served as a member of The Cancer Genome Atlas (TCGA) Committee.

   a) Dhaini HR, Thomas DG, Giordano TJ, Johnson TD, Biermann JS, Leu K, Hollenberg PF, **Baker LH**. Cytochrome P450 CYP3A4/5 expression as a biomarker of outcome in osteosarocma. *J Clin Oncol*. 2003 Jul; 21(13): 2481-2485. PMID: 12829666.
   b) Leu KM, Ostruszka LJ, Shewach D, Zalupski M, Sondak V, Biermann JS, Lee JS-J, Couwlier C, Palazzolo K, **Baker LH**. Laboratory and clinical evidence of synergistic cytotoxicity of sequential treatment with gemcitabine followed by docetaxel in the treatment of sarcomas. *J Clin Oncol*. 2004 May; 22(9):1706-1712. PMID: 15117993
   c) Andersen NJ, Nickoloff BJ, Dykema KJ, Boguslawski EA, Krivochenitser RI, Froman RE, Dawes MJ, **Baker LH,** Thomas DG, Kamstock DA, Kitchell BE, Furge KA, Duesbery NS. Pharmacologic inhibition

of MEK signaling prevents growth of canine hemangiosarcoma. Mol Cancer Ther. 2013 Sep; 12(9): 1701-14. PMC3769440.

d) Bid HK, Phelps DA, Xiao L, Guttridge DC, Lin J, London C, **Baker LH**, Mo X, Houghton PJ. The Bromodomain BET inhibitor JQ1 Supresses Tumor Angiogenis in Models of Childhood Sarcoma. Mol Cancer Ther. 2016 Feb 23. PMID: 26908627, PMCID: PMC4873398.

3. **Clinical Trial Methodology**

a) Petrou M, Quint LE, Nan B, **Baker L**. Pulmonary nodules volumetric measurement variability as a function of CT slice thickness and nodule morphology. AJR Am J Roentgenol. 2007 Feb; 188(2): 306-312. PMID: 17242235.

b) Ramsey SD, Veenstra D, Tunis SR, Garrison L, Crowley JJ, **Baker LH**. How comparative effectiveness research can help advance 'personalized medicine' in cancer treatment. Health Aff (Millwood). 2011 Dec; 30(12): 2259-2268. PMC3477796

c) Oxnard G, Morris M, Hodi S, **Baker LH**, Kris M, Venook A, Schwartz L. When progressive disease does not mean treatment failure: Reconsidering the criteria for progression. J Natl Cancer Inst. 2012 Oct; 104(20): 1534-41. PMC3708548

d) Redman MW, Goldman BH, LeBlanc M, Schott A, **Baker LH**. Modeling the relationship between progression free survival and overall survival: The phase II/III trial. Clin Cancer Res. 2013 May; 19(10): 2646-2656. PMC4131693.

4. **Prevention / Survivorship**

a) Greenberg ER, Anderson GL, Morgan DR, Torres J, Chey WD, Bravo LE, Dominguez RL, Ferreccioi C, Herrero R, Lazcano-Perez EC, Meza-Montenegro MM, Peña R, Peña EM, Salazar-Martinez E, Correa P, Martinez ME, Valdivieso M, Goodman GE, Crowley JJ, **Baker LH**. 14-day triple, 5-day concomitant and 10-day sequential therapies for Helicobacter pylori infection in seven Latin American sites: A randomized trial. Lancet. 2011 Aug; 378(9790): 507-514. PMC3313469

b) Klein EA, Thompson, Jr., Tangen CM, Crowley JJ, Lucia MS, Goodman PJ, Minasian L, Ford LG, Parnes HL, Gaziano JM, Karp DD, Lieber MM, Walther PJ, Klotz L, Parsons JK, Chin JL, Darke AK, Lippman SM, Goodman GE, Meyskens FL, Jr., **Baker LH**. Vitamin E and the risk of prostate cancer: The Selenium and Vitamin E Cancer Prevention Trial (SELECT). JAMA. 2011 Oct; 306(14):1549-1556. PMC4169010.

c) Morgan DR, Torres J, Sexton R, Herrero R, Salazar-Martinez E, Greenberg ER, Bravo LE, Dominguez RL, Ferrecio D, Lazcano-Ponce EC, Mexze-Montenegro MM, Pena E, Pena R, Correa P, Martinez ME, Chey WD, Valdivieso M, Anderson GL, Goodman GE, Crowley JJ, **Baker LH**. Risk of recurrence of Helicobacter pylori infection 1 year after initial eradication therapy in 7 Latin American communities. JAMA. 2013 Feb; 309(6): 578-586. PMC3697935.

d) Bobowski N, **Baker LH**, The University of Michigan Sarcoma Survivorship Clinic: Preventing, Diagnosing, and Treating Chronic Illness for Improved Survival and Long-Term Health. J Adolesc Young Adult Oncol. 2016 Apr 26 (Epub ahead of print). PMID: 27116634, PMC in progress.

Complete List of Published Work in My Bibliography:
http://www.ncbi.nlm.nih.gov/pubmed/?term=laurence+h.+baker

D. Research Support

Ongoing Support:

15-PAF03152 Baker (PI) 01/1/2015-12/31/2016
The Hope Foundation
Sarcoma Survivorship
Project Goals: Address the specific gaps in our knowledge such as the incidence of and risk factors for late and long-term effects of sarcoma and its treatment and appropriate follow up care and surveillance for survivors.

No Number Baker (PI) 06/12/2014 - 02/28/2019
American College of Radiology (Prime) / Cold Springs Harbor Labs (Direct)
Integrated Translational Cancer Science Center
Project Goals: The translational partnership between SWOG, Cold Spring Harbor Laboratory (CSHL), and The Jackson Laboratory (JAX) provides a powerful combination of clinical and basic research expertise for application to cancer medicine. This alliance will bridge the gap between the laboratory and patient care by elucidating the key clinical problems and challenges in oncology that can be addressed in the laboratory, discovering new diagnostic and therapeutic approaches that can be integrated into clinical trials, and providing a conduit for clinical trial results to be re-interpreted in the laboratory. This relationship will lead to a clearer understanding of the mechanisms underlying cancer and advance translational research aimed at developing effective targeted therapies.

U10 CA180944 03/01/2014 – 02/28/2019
NIH/NCI
SWOG Network Group Operations Center of the NCTN
Project Goals: Baker maintains a significant role in the translational medicine efforts of SWOG, serving as co-PI in the SWOG Integrated Translational Science Center. Dr. Baker is also to continuing with the Latin America Initiative, which most recently has resulted in the application of three more Latin American sites to join SWOG. Other duties of the chair emeritus will be as assigned. Dr. Baker will attend biannual SWOG Meetings and other meetings as appropriate.
Role: Co-Investigator

U54 CA168512 Baker (PI) 09/26/2012 – 08/31/2017
NIH/NCI
SARC Sarcoma Spore
Project 2: Identification of therapeutic windows for NF-1 related malignant peripheral nerve sheath tumor.
Role: Co-Leader *Core A, Administration.*

Recently Completed Support:

Developmental Grant Baker (PI) 04/1/2015 - 03/31/2016
NCI, Sarcoma Alliance for Research Through Collaboration (SARC)
Can Premature Death Be Predicted In Young Survivors of Osteosarcoma by Using Morphomics?
Project Goals: To develop a predictive biomarker of osteosarcoma survivors who are at risk to develop cardiac disease including cardiomyopathy, coronary artery disease, and premature aging.

No Number 06/01/2013 - 11/30/2015
PCORI (Prime) / Fred Hutchinson Cancer Research Center
A Trial of a Structured Method for Prioritizing Cancer Research
Project Goals: Baker assists in the development of the intervention within SWOG, including helping with the process to integrate additional stakeholders into disease committees, and in training and executing the use of VOI within the Executive Committee at SWOG. Baker will also assist in identifying studies for the retrospective analysis of VOI.
Role: Co-Investigator

St. Baldrick's Foundation 12/01/2013 – 11/30/2014
Translational Program of Pediatric Sarcoma Survivors to Medical Care
Project Goals: Established a subspecialty led team approach that will improve patient outcomes and better care planning and coordination for adults transitioning from a pediatric survival clinic to adult care compared to the shared card model or patients continuing in pediatric survival clinics ad infinitum.
Role: Investigator

U10 CA032102 Baker (PI) 01/01/2010 – 9/30/2013
NIH/NCI
SWOG Treatment Grant

Project Goals: Lead the Latin American Initiative in Cancer Treatment in countries of Mexico, Peru, Colombia, and Brazil. This program focuses on prevention and treatment of cancer secondary to infection.

NCI/NIH 10/01/2009 - 09/30/2013
Comparative Effectiveness Research in Genomics and Personalized Medicine
Project Goals: Established CANCERGEN: A sustainable, multidisciplinary, integrated, collaborative consortium with expertise in decision modeling, database linkage, ethics, policy, and clinical trials design, which leverages and builds upon the existing strengths of the SWOG clinical trials network to facilitate the rapid design and implementation of prospective CER studies of GPM technologies. CANCERGEN and SWOG designed and implemented a “proof-of-principle” comparative effectiveness evaluation (cost-utility analysis) in conjunction with a currently planned randomized clinical trial of gene expression profiling to guide adjuvant chemotherapy decisions among women with early-stage breast cancer and positive lymph nodes.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Stephen W. Byers, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): SBYERS

POSITION TITLE: Professor and Director

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Liverpool University, UK	BSc (hon)	06/1975	Chemistry/Biochemistry
University of Queensland, Australia	PhD	09/1981	Endocrinology
Georgetown University, Washington, DC	Postdoc	06/1984	Cell Biology

A. Personal Statement

Stephen Byers was educated in the UK and Australia. He was a Ford Foundation Scholar and came to the US in 1982 as a Rockefeller Foundation Fellow. He has authored more than 150 papers and patents in the areas of, cell adhesion, chemoprevention and the development of anti-cancer drugs. In 2003 with Dr. Aydin Tozeren, he published “New Biology for Engineers and Computer Scientists”. This book was amongst the first to recognize that Systems Biology/Medicine would require the efforts of individuals with strong quantitative skills who need to be educated in the fundamentals of “New Biology”. His laboratory has three major interests. The first relates to the role of the cadherin/catenin system in carcinogenesis, the second to studies of the anti cancer actions of vitamins A and D and cancer drug development and the third to interactions among NFκb, TGFβ, wnt and vitamin D pathways. In the early-mid 1980s as a junior faculty member, with Martin Dym he developed methods for the isolation of organotypic organoids, discovered the role of Matrigel in promoting differentiation and developed the first examples of commercial dual environment culture chambers. He went on the demonstrate the role of E-cadherin and β-catenin in promoting epithelial-mesenchymal transitions in breast cancer and discovered the role of cadherin-11 in this process. In the mid-late 1990s his group demonstrated that phosphorylation of key residues in β-catenin promoted its degradation and ubiquitination and resulted in oncogenic transformation. Together with Dr. Shah his laboratory was the first to show the interaction of the vitamin A and D pathways in the regulation of β-catenin signaling and showed that partial vitamin D antagonists could act as specific anti-cancer agents in cells that express activated β-catenin. He has more recently refocused to use his training in chemistry to work on the development of anticancer drugs, the computational repositioning of existing FDA-approved drugs for alternative targets with Dr. Dakshanamurthy, and metabolomic profiling of serum and urine as a means of predicting cancer patient outcome. Dr. Byers has mentored many pre and post-doctoral fellows as well as a number of junior faculty who have gone on to independence and significant research careers. Dr. Byers is a Professor and an Associate Director at the Lombardi Comprehensive Cancer Center, Georgetown University with appointments in the Departments of Oncology and Biochemistry, Molecular and Cellular Biology. Currently he is Director of the Lombardi Shared Resources, Director of the Translational Technologies Component of the Georgetown-Howard Universities Clinical and Translational Science Award (CTSA), a member of the Tumor Biology and Biochemistry Molecular and Cellular Biology Programs, is on the boards of Sarfez Pharmaceuticals, Adheron Therapuetics and ScienceExchange and co-founder of a company, Diviner Technologies, focused on drug discovery and repurposing.

Selected Publications (150+, one book, six published and four submitted patents; 54 cites/item; h-index 51; 8015 total citations)

a) Hadley, M.A., **Byers, S.W**. Suarez-Quian, C.A., Kleinman, H.K. and Dym, M. (1985). Extracellular matrix regulates Sertoli cell differentiation, testicular cord formation, and germ cell development *in vitro.* J. Cell Biol. 101: 1511-1522.

b) Orford, K., Crockett, C., Weissman, A. and **Byers, S.W**. 1997. Serine phosphorylation-regulated ubiquitination and proteosomal degradation of β-catenin. J. Biol. Chem. 272: 24735-38

c) Easwaran,V, Pishvaian, M., Salimuddin, and **Byers, S**. (1999) Cross regulation of β-catenin-LEF/TCF and retinoid signaling pathways. Current Biology 9: 1415-1418

d) Shah S, Naimul Islam M, Sivanesan, D, Rivzi I, Herrell, R, Aranda, A, Moras D, Welsh J and **Byers S**. The Molecular Basis of Vitamin D Receptor and β-Catenin Cross Regulation (2006). Mol. Cell 21: 799-809

B. Positions and Honors

Positions and Employment:

1976-1980 Ford Foundation Research Scholar, University of Queensland, Brisbane, Queensland, Australia
1977-1979 Lecturer in Biochemistry, Queensland Institute of Technology, Brisbane, Queensland, Australia
1980-1981 Teaching Fellow in Life Science, Griffith University, Queensland, Australia
1981-1984 Rockefeller Foundation Fellow, Department of Anatomy and Cell Biology, Georgetown University, Washington, DC
1984-1991 Assistant Professor Department of Anatomy and Cell Biology, Georgetown University, Washington, DC
1991-1997 Associate Professor - Department of Cell Biology, Georgetown University, Washington, DC
1993-1994 Sabbatical leave, Laboratory of Chemoprevention, NCI/NIH
1997-present Professor, Department of Biochemistry, Molecular and Cellular Biology, Washington, DC
1999-present Professor, Department of Oncology, Lombardi Comprehensive Cancer Center, Washington, DC
1999-2012 Director MD PhD Program, Georgetown University, Washington, DC
2005-present Director Shared Resources, Lombardi Comprehensive Cancer Center, Washington, DC
2005-present Associate Director, Lombardi Comprehensive Cancer Center, Washington, DC

Other Experience and Professional Memberships:

1986-present Served on over 30 NIH, DOD, NSF, Komen and other Foundation Study sections
1999–2001 Leader of Komen Foundation Tumor Biology Study Section
1999–2003 Member of the Komen Foundation National Grants Program Task Member
2007- NCI T32/NCI SS
2008–2011 Member of CDP SS
2009-present Serve on several Cancer Center External Advisory Boards

Honors:

1976–1981 Ford Foundation Scholarship
1981–1983 Rockefeller Foundation Fellowship
1990 Spinks Research Award, National Kidney Foundation
2002 Komen Foundation Award

C. Contributions to Science

1. **Isolation of organotypic organoids, role of Matrigel and development of dual environment culture chambers**:
   In the early-mid 1980s first as a Rockefeller fellow, then as a junior faculty member, with Martin Dym, Dr. Byers developed methods for the isolation of organotypic organoids, discovered the role of Matrigel in promoting differentiation and developed the first examples of dual environment culture chambers-subsequently commercialized by Millipore.

   a) **Byers, S.W.**, Djakiew, D., and Dym, M. (1985) Structural characteristics of epididymal epithelial cells *in vitro*. J. Reprod. Fertil. 75:401-411.

   b) Hadley, M.A., **Byers, S.W.** Suarez-Quian, C.A., Kleinman, H.K. and Dym, M. (1985). Extracellular matrix regulates Sertoli cell differentiation, testicular cord formation, and germ cell development *in vitro.* J. Cell Biol. 101: 1511-1522.

c) **Byers, S.W**., Hadley, M.A., Djakiew, D. and Dym, M. (1986). Growth and characterization of polarized monolayers of epididymal epithelial cells and Sertoli cells in dual environment culture chambers. J. Androl. 7:59-68.

d) **Byers SW,** Citi S, Anderson JM, Hoxter B. Polarized functions and permeability properties of rat epididymal epithelial cells in vitro. J Reprod Fertil 1992; 95:385-396

2. **Role of cadherins and catenins in cancer cell epithelial to mesenchymal transition:**

In the 1990s Dr. Byers and his colleagues demonstrated the role of E-cadherin and β-catenin in regulation of epithelial-mesenchymal transitions in breast cancer and discovered the role of cadherin-11 in this process.

a) Sommers C, Heckford SE, Skerker JM, Worland P, Thompson EW, **Byers SW**, Gelman EP. Loss of epithelial markers and acquisition of vimentin expression in adriamycin-resistant MCF-7 cells. Cancer Res 1992; 52:5190-5197

b) Seslar, S., T. Nakamura, and **S. W. Byers**. 1993. Regulation of fibroblast hepatocyte growth factor/scatter factor expression by human breast carcinoma cells and peptide growth factors. *Cancer Res.* 53:1233-1238.

c) Sommers, C.L., E. P. Gelmann, R. Kemler, P. Cowin, and **S. W. Byers.** 1994. Alterations in plakoglobin expression and beta-catenin phosphorylation in human breast cancer cell lines. *Cancer Res.* 54:3544-3552.

d) Pishvaian, M., Feltes, C., Thompson, P. and **Byers, S.** (1999) Expression of the mesenchymal cell-adhesion molecule cadherin-11 associated with invasive breast cancer. Cancer Research, 59; 947-952

3. **Role of β-catenin phosphorylation in its degradation and transforming activities:**

In the mid-late 1990s Dr. Byers and his colleagues demonstrated that phosphorylation of key residues in β-catenin promoted its degradation and ubiquitination and resulted in oncogenic transformation.

a) Orford, K., Crockett, C., Weissman, A. and **Byers, S.W**. 1997. Serine phosphorylation-regulated ubiquitination and proteosomal degradation of β-catenin. J. Biol. Chem. 272: 24735-38

b) Orford, K., Orford, C. and **Byers, S**. (1999) β-catenin regulates contact inhibition, anchorage-independent growth, anoikis and radiation-induced cell cycle arrest. J.Cell Biol. 146: 855-867

c) Easwaran,V. Song, V., Polakis, P. and **Byers, S**. (1999) The ubiquitin-proteosome pathway and serine kinase activity regulate APC modulation of β-catenin/LEF signaling. J. Biol Chem 274: 16641-16645.

4. **β-catenin interaction with nuclear receptors:**

Dr. Byers and his colleagues were the first to show the interaction of the vitamin A and D pathways in the regulation of β-catenin signaling and showed that partial vitamin D antagonists could act as specific anti-cancer agents in cells that express activated β-catenin.

a) Easwaran,V, Pishvaian, M., Salimuddin, and **Byers, S.** (1999) Cross regulation of β-catenin-LEF/TCF and retinoid signaling pathways. Current Biology 9: 1415-1418

b) Truica, CI, **Byers, S.** and Gelmann, EP. (2000) β-catenin enhances androgen receptor signaling. Cancer Res. 60: 4761-4769

c) Shah, S, Hecht, A, Pestell R. and **Byers. SW**. Trans-repression of β-catenin activity by nuclear receptors. (2003) J Biol Chem. 278:48137-45

d) Shah S, Naimul Islam M, Sivanesan, D, Rivzi I, Herrell, R, Aranda, A, Moras D, Welsh J and **Byers S.** The Molecular Basis of Vitamin D Receptor and β-Catenin Cross Regulation (2006). Mol. Cell 21: 799-809

5. **Drug Discovery and Repurposing, Systems Medicine:**

Dr. Byers has more recently refocused to use his training in chemistry to work on the development of anticancer drugs, the computational repositioning of existing FDA-approved drugs for alternative targets with Dr. Dakshanamurthy, and metabolomic profiling of serum and urine as a means of predicting cancer patient outcome. In 2003 with Dr. Aydin Tozeren, he published “New Biology for Engineers and Computer Scientists”. This book was amongst the first to recognize that Systems Biology/Medicine would require the

efforts of individuals with strong quantitative skills who need to be educated in the fundamentals of "New Biology".

a) Dakshanamurthy S, Issa NT, Seshasayee A, Assefnia S, Peters OT, Shah R, Madhavan S, Brown ML and **Byers SW**. Predicting new indications for old drugs using a novel proteo-chemoinformatic approach. J Med Chem (2012) 55:6832-48. PMC3419493

b) Madhavan S, Gusev Y, Natarajan T, Song L, Ms. Bhuvaneshwar K, Gauba R, Pandey A, Haddad B, Goerlitz D, Cheema C, Juhl H, Kallakury B, Marshall J, **Byers S**, Weiner L. Genome-wide multi-omics profiling of colorectal cancer identifies immune determinants strongly associated with relapse. Frontiers in Genetics. 2013 Nov 20;4:236. PMC3834519

c) Issa NT, **Byers SW** and Dakshanamurthy S. Big Data: The Next Frontier for Innovation in Therapeutics and Healthcare. Expert Rev Clin Pharmacol. (2014) 3:293-8. PMC4448933

d) Assefnia S, Dakshanamurthy S, Guidry Auvil JM, Hampel C, Anastasiadis PZ, Kallakury B, Uren A, Foley DW, Brown ML, Brenner M, Haigh D and **Byers SW**. Cadherin-11 in poor prognosis malignancies and rheumatoid arthritis: common target, common therapies (2014) Oncotarget 5: 1458-74. (Featured on cover). PMC4039224

Link to complete list of publications:

http://www.ncbi.nlm.nih.gov/sites/myncbi/stephen.byers.1/bibliography/41160915/public/?sort=date&direction=descending

D. Research Support

Ongoing Support:

PC140268 Albanese/Byers/Dakshanamurthy (PIs) 09/01/2015 - 08/31/2017
DOD
High fidelity drug repurposing, molecular profiling and cell reprogramming
The goal of this proposal is to develop effective treatments for men with high-risk and/or metastatic prostate cancer. We are combining tumor genetics and biomarker development with CRCs and drug repurposing to identify "new" therapeutic drugs to broaden the scope of FDA-approved drugs through a more personalized approach to cancer treatment; and to lay the groundwork to apply patient-specific chemotherapy to either delay or prevent the need for ADT and the possible progression to CRPC as well as to effectively treat existing CRPC.
Role: Co-PI

CA1408852 Dakshanamurthy/Byers (PIs) 09/01/2015 - 08/31/2017
DOD
Novel High-Fidelity Screening of Environmental Chemicals and Carcinogens, and Mechanisms in Colorectal Cancer
Aim 1 will identify molecular targets for ECs using our novel profiling method (TMFS). Colorectal cancer (CRC) cell networks will be created based on predicate EC-protein interaction (ECPI) map.
Aim 2 will perform well-established biochemical and biophysical binding studies to characterize the interaction of ECs with the VDR and β–catenin pathway components.
Role: Co-PI

P30 CA51008 Weiner (PI) 04/30/2010 - 04/30/2019
NIH-NCI
Cancer Center Support Grant
Stephen Byers, Director Shared Resources and co-director Proteomics and Metabolomics
Administrative position which oversees the operation of the 14 LCCC Shared Resources
Role: Associate Director of Shared Resources

R01 CA170653 Byers (PI) 09/01/2012 - 06/30/2017
NIH (no-cost extension)

Cadherin11 in cancer & rheumatoid arthritis: common target, common therapies (5).
The specific aims of this project are: 1) To reposition approved drugs as cadherin-11 inhibitors. Preliminary *in silico* repositioning identified the anti-inflammatory drug, celecoxib as a cadherin-11 inhibitor; 2) Determine the role of CCL2 and other cadherin-11 regulated genes in mediating its effects on tumorigenesis, invasion and metastasis; and 3) Determine the role of tyrosine kinase activation in mediating cadherin-11 signaling.

Completed Support:

W81XWH-12-0424 Synergistic Byers (PI) 09/01/2012 - 08/31/2016
DOD
Tumor suppressor RARRES1/TIG1 in Prostate Cancer-biomarker to Therapeutic Target.
The aims of this proposal are: (1) Study the role of RARRES1/TIG1 in human and mouse prostate cancer (PC) development; (2) Investigate the role of RARRES1/TIG1 on experimental PC; and Investigate the genetic and epigenetic regulation of RARRES1/TIG1

UL1 RR031075 Verbalis/Mellman (PI) 07/01/2010 - 06/30/2015
NIH Clinical and Translational Science Award (CTSA)
Translational Technologies Resource Component
Administrative position which oversees the operation of all GUMC and HU Shared Resources
Role: Codirector (with John Massari, Howard University)

R01 CA129813 Byers (PI) 03/01/2008 - 01/31/2014
NIH-NCI
β-catenin-specific regulation of the vitamin D pathway in colon cancer
The major goals of this project are to investigate the molecular basis of β-catenin-specific regulation of the vitamin D pathway in colon cancer.

Extension of Synergistic award Byers/Brown (PIs) 09/01/2010 - 08/31/2012
DOD
Cadherin-11 as a therapeutic target in basal-like breast cancers
Role: Dual PI

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Webster K. Cavenee, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): WCAVENEE

POSITION TITLE: Director & Distinguished Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Kansas State University, Manhattan, KS	B.Sc.	06/1973	Microbiology
University of Kansas, Kansas City, KS	Ph.D.	09/1977	Microbiology
Jackson Laboratory, Bar Harbor, ME	Post-Doc	1977-1979	Biochemistry
MIT, Cambridge, MA	Post-Doc	1979-1981	Genetics
Howard Hughes Med. Inst., Salt Lake City, UT	Post-Doc	1981-1983	Molecular Biology

A. Personal Statement

I received my graduate and postdoctoral training in cell biology, biochemistry and human genetics. I started my independent research lab in 1983 focused on the role of tumor suppressor gene mutations in predisposition to human cancers of children and adults. This has progressed over the years to the interplay between oncogenic and suppressive mutations in the genesis and progression of human tumors, particularly those of the central nervous system, and their influence on therapeutic response. This work involves cellular genetics, engineered mouse models, protein biochemistry and tumor biology. My most recognized accomplishments are my contributions to the genetic basis of cancer predisposition, tumor progression, oncogenic cellular signaling and the use of genetic approaches for cancer diagnosis and prognosis. Each of these has been recognized with numerous international awards and each is directly relevant to the KUCC CCSG. I have served on many NIH review and advisory panels including the Boards of Scientific Counselors of the National Cancer Institute and the National Institute of Environmental Health Sciences and advisory boards for several NIH Cancer Center Support, SPORE and PO1 grants, as well those of several private foundations and international institutions. I have been President of the American Association for Cancer Research. I held the position of Branch Director in the Ludwig Institute for Cancer Research for more than 30 years at McGill University and the University of California San Diego. In 2015, I became Director, Strategic Alliances-CNS of Ludwig Cancer research with global responsibilities. I am an elected member of the National Academy of Science and the National Academy of Medicine.

B. Positions and Honors

Positions and Employment:

1973-1977 Graduate Student in Microbiology, University of Kansas (Advisor: G. Melnykovych)
1977-1979 Anna Fuller Fund Postdoctoral Fellow, Jackson Laboratory (Advisor: A. Kandutsch)
1979-1981 NIH Postdoctoral Fellow, Massachusetts Institute of Technology (Advisor: R. M. Baker)
1981-1983 Associate of the Howard Hughes Medical Institute at the University of Utah (Advisor: R. L. White)
1983-1985 Assistant/Associate Professor of Microbiology and Molecular Genetics, University of Cincinnati
1985-1991 Associate/Full Professor of Biology, Medicine, Neurology and Human Genetics, McGill University and Director Montreal Branch, Ludwig Institute for Cancer Research
1991-2015 Director Ludwig Institute for Cancer Research, San Diego Branch
2015-pres Director, Strategic Alliances-CNS, Ludwig Cancer Research
1991-pres Full/Distinguished Professor, University of California San Diego, CA

Honors and Awards (Selected from 101):

1978-1979 Anna Fuller Fund Postdoctoral Fellowship
1979-1982 National Research Service Award, NCI, NIH
1983 Basil O'Connor Award, March of Dimes Birth Defects Foundation

1988 Rhoads Award, American Association for Cancer Research
1990 Charles S. Mott Award, General Motors Cancer Research Foundation
1994 Farber Award, American Association of Neurological Surgeons
2002 D.Sc. (Honoris Causis), University of Cincinnati
2002 Anthony Dipple Senior Carcinogenesis Award, European Assoc. for Cancer Res, Spain
2002 Raymond Bourgine Award, Paris, France
2007 Albert Szent-Gyorgyi Award, National Foundation for Cancer Research, NY
2007 Princess Takamatsu-AACR Award, American Assoc. Cancer Research
2008 Distinguished Achievement Medal in Human Genetics, Ohio State University
2010 Honorary Professor, Tianjin University, China; 2014, Margaret Foti Award, American Assoc. Cancer Research.

Professional Societies and Associations:

1995 American Society of Clinical Investigation, honorary member
1997 American Academy of Microbiology, fellow
1997 National Academy of Sciences
2003 National Foundation for Cancer Research, fellow
2007 National Academy of Medicine
2008 American Association Advancement of Science, fellow
2012 Leopoldina German Academy of Sciences
2013 American Assoc. Cancer Research Academy

Major Committee Assignments (selected):

1985 NCI Advisory Group on Tissue Procurement
1988-1992 Founding Council, Human Genome Organization
1989-1993 Scientific Advisory Board, Damon Runyon Cancer Research Fund
1994-1996 Scientific Advisory Board, National Neurofibromatosis Foundation
1994-2001 Scientific Advisory Board, Norris Cancer Center, University of Southern California
1994-1997 Board of Directors, American association for Cancer Research
1995-2001 Board of Directors, Damon Runyon Cancer Research Fund
1995-present Advisory Council, American Brain Tumor association
1995-2001 Scientific Advisory Board, University of Minnesota Cancer Center
1996-2001 Scientific Advisory Board, University of Michigan Cancer Center
1996-1999 Board of Scientific Counselors, National Institute of Environmental Health sciences
1996-present Scientific Advisory Board, Kimmel Foundation for Cancer Research
1997-1998 President, American Association for Cancer Research
1998-present Chair, Scientific Advisory Board, James McDonnell Foundation Brain Tumor Program
2002-2006 Scientific Advisory Board, MIT Center for Environmental Health Sciences
2002-present Scientific Advisory Board, Duke University Cancer Center
2002-present Chair, Scientific Advisory Board, Brain Tumor Research Center, University of California San Francisco
2004-2008 Chair, Scientific Advisory Board, The Goldhirsh Foundation
2007-present Chair, Scientific Advisory Board, Deutsches Krebsforschungzentrum
2013-present Chair, External Advisory Committee, National Cancer Center, Singapore.

C. Contributions to Science

1. **Cancer predisposition.** While familial occurrence of some forms of many human cancers appeared to be heritable, not all cells of an affected tissue were transformed. The studies cited below were the first to demonstrate that this was due to the heritable mutation being predisposing with the transforming event being somatic and that identifying these lesions could provide accurate premorbid predictions of cancer development. This was one of the most influential discoveries in cancer research and the coined term “loss of heterozygosity” has been cited more than 30,000 times.
   a) **Cavenee WK**, Dryja TP, Phillips RA, Benedict WF, Godbout R, Gallie BL, Murphree AL, Strong LC and White RL. Expression of Recessive Alleles by Chromosomal Mechanisms in Retinoblastoma. Nature 305: 779-784, 1983. PMID: 6633649

b) **Cavenee WK**, Hansen MF, Nordenskjold M, Kock E, Maumenee I, Squire JA, Phillips RA and Gallie BL. Genetic Origin of Mutations Predisposing to Retinoblastoma. Science 228: 501-503, 1985. PMID: 3983638
c) Koufos A, Hansen MF, Copeland NG, Jenkins NA, Lampkin BC and **Cavenee WK.** Loss of Heterozygosity in Three Embryonal Tumours Suggests a Common Pathogenetic Mechanism. Nature 316: 330-334, 1985. PMID: 2991766
d) Hansen MF, Koufos A, Gallie BL, Phillips RA, Fodstad Ø, Brøgger A, Gedde-Dahl T and **Cavenee WK**. Osteosarcoma and Retinoblastoma: A Shared Chromosomal Mechanism Revealing Recessive Predisposition. Proceedings of the National Academy of Sciences USA 82: 6216-6220, 1985. PMID: 2994066
e) **Cavenee WK**, Murphree AL, Shull MM, Benedict WF, Sparkes RS, Kock E and Nordenskjold M. Prediction of Familial Predisposition to Retinoblastoma. New England Journal of Medicine 314: 1201-1207, 1986. PMID: 3702916

2. **Brain tumor genetics.** We have used various genetic mapping strategies to identify several of the underlying lesions in human brain tumors, their temporal occurrence and their effects on pathophysiology. Many of these were confirmed through the efforts of the TCGA and several are now being used as targets for therapeutic design.
   a) James CD, Carlbom E, Dumanski JP, Hansen M, Nordenskjold M, Collins VP and **Cavenee WK.** Clonal Genomic Alterations in Glioma Malignancy Stages. Cancer Research 48: 5546-5551, 1988. PMID: 2901288
   b) Sidransky D, Mikkelsen T, Schwechheimer K, Rosenblum ML, **Cavenee W** and Vogelstein B. Clonal Expansion of p53 Mutant Cells Is Associated with Brain Tumour Progression. Nature 355: 846-847, 1992. PMID: 1311419
   c) Nishikawa R, Furnari FB, Lin H, Arap W, Berger MS, **Cavenee WK** and Huang H-J S. Loss of $P16^{INK4}$ Expression Is Frequent in High Grade Gliomas. Cancer Research 55: 1941-1945, 1995. PMID: 7728764
   d) Bögler O, Huang H-JS and **Cavenee WK**. Loss of Wild-Type p53 bestows a Growth Advantage on Primary Cortical Astrocytes and Facilitates Their in Vitro Transformation. Cancer Research 55: 2746-2751, 1995. PMID: 7796398

3. **EGF Receptor and its targeting.** The EGF receptor remains the single most altered molecule in GBM. This has led us to perform a series of studies of its pathogenic role and, as well, to develop strategies for targeting it.
   a) Nishikawa R, Ji X-D, Harmon RC, Lazar CS, Gill GN, **Cavenee WK** and Huang H-J S. A Mutant Epidermal Growth Factor Receptor Common in Human Glioma Confers Enhanced Tumorigenicity. Proceedings of the National Academy of Sciences USA 91: 7727-7731, 1994. PMID: 8052651
   b) Huang H-JS, Nagane M, Klingbeil CK, Lin H, Nishikawa R, Ji X-D, Huang C-M, Gill GN, Wiley HS and **Cavenee WK**. The Enhanced Tumorigenic Activity of a Mutant Epidermal Growth Factor Receptor Common in Human Cancers Is Mediated by Threshold Levels of Constitutive Tyrosine Phosphorylation and Unattenuated Signalling. The Journal of Biological Chemistry 272: 2927-2935, 1997. PMID: 9006938
   c) Mishima K, Johns TG, Luwor RB, Scott AM, Stockert E, Jungbluth AA, Ji X-D, Suvarna P, Voland JR, Old LJ, Huang H-JS and **Cavenee WK**. Growth Suppression of Intracranial Xenografted Glioblastomas Overexpressing Mutant Epidermal Growth Factor Receptors by Systemic Administration of Monoclonal Antibody (mAb) 806, a Novel Monoclonal Antibody Directed to the Receptor. Cancer Research 61: 5349-5354, 2001. PMID: 11454673
   d) Mellinghoff I, Wang Y, Vivanco I, Haas-Kogan DA, Zhu S, Dia EQ, Lu KV, Yoshimoto K, Huang JHY, Chute DJ, Riggs BL, Horvath S, Liau LM, **Cavenee WK**, Rao PN, Beroukhim R, Peck TC, Lee JC, Sellers WR, Stokoe D, Prados M, Cloughesy TF, Sawyers CL and Mischel PS. Molecular Determinants of the Response of Glioblastomas to EGFR Kinase Inhibitors. New England Journal of Medicine 353: 2012-2024, 2005. PMID: 16282176

4. **Drug resistance.** Having discovered targets and therapeutic approaches to those, it has become clear that human tumors can have upfront resistance or acquire resistance by a variety of mechanisms.
   a) Fenton TR, Dang J, Kuga D, Wanami A, Ponte de Albuquerque C, Bachoo RM, James CD, DePinho

RA, Mischel PS, Zhou H, **Cavenee WK**, and Furnari FB. Resistance of Glioblastoma to EGFR Inhibitors Driven by Src-mediated Phosphorylation of PTEN on Tyrosine 240. Proceedings of the National Academy of Sciences USA 109: 14164-14169, 2012. PMC3435194

b) Iwanami A, Ascuncio A, Amzajerdi N, Dang J, Yang H, Zhu S, Kohyama J, Kitabayashi I, **Cavenee WK**, Cloughesy TF, Nakamura M, Okano H, Mischel PS. PML Mediates Resistance to mTOR-targeted Therapies of Glioblastoma. Proceedings of the National Academy of Science USA 110: 4339-4334, 2013. PMC3600508

c) Nathanson DA, Gini B, Mottahedeh J, Visnyei K, Koga T, Gomez G, Eskin A, Hwang K, Wang J, Masui K, Paucar A, Yang H, Ohashi M, Zhu S, Wykosky J, Reed R, Nelson SF, Cloughesy TF, James CD, Rao PN, Kornblum HI, Heath JR, **Cavenee WK**, Furnari FB, Mischel PS.Targeted Therapy Resistance Mediated by Dynamic Regulation of Extrachromosomal Mutant EGFR DNA. Science 343:72-76, 2014. PMC4049335

d) Wykosky J, Hu J, Gomez G, Taylor T, Villa GR, Pizzo D, Vandenberg SR, Thorne AH, Chen C, Mischel PM, Gonias S, **Cavenee WK**, Furnari FB. A Urokinase Receptor-Bim Signaling Axis Emerges During EGFR Inhibitor Resistance in Mutant EGFR Glioblastoma. Cancer Research 75:394-404, 2015. PMC4297573

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1FwGRp5eqw15q/bibliograpahy/48417797/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

No Number (PI: Cavene) 09/01/1986 - present
Ludwig Institute for Cancer Research
Laboratory Support
The Ludwig Institute provides support for PI salary, core facilities, secretarial support, 2 technicians, 3 postdocs, 1 student, and some equipment and supply monies. Support is not targeted for specific projects.

No Number (Cavenee) 10/01/2013 – 12/31/2016
National Foundation for Cancer Research
NFCR Fellow Award
Support is not targeted for specific projects.

R01 NS080939 (Furnari) 09/01/2012 – 05/31/2017
NINDS/NIH
Genotypic Interactions in Brain Cancer Heterogeneity
The overall goal of this project is to dissect the mechanisms whereby GBM receptor heterogeneity drives tumor aggressiveness and therapeutic resistance.
Role: Co-Investigator

No Number (Cavenee) 01/01/2014 - 12/31/2018
The National Brain Tumor Society
Defeat GBM Program - Project 1 (Cavenee)
This is a multi-institutional program aimed at doubling survival of GBM patients.

Completed Support:
P01 CA95616 (DePinho) 03/01/2003 – 02/28/2013
NCI/NIH
Genetics and Biology of Malignant Glioma
Project 2: EGFR and PTEN in Mouse and Human Glioma
This is an inter-institutional program project between the Ludwig Institute and MD Anderson. Its purpose is to investigate the genetic defects underlying the initiation, progression, and maintenance of gliomas.
Role: PI Project 2

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Mark Stuart Clanton, M.D., M.P.H., F.A.A.P.**

eRA COMMONS USER NAME (credential, e.g., agency login): MCLANTON

POSITION TITLE: Chief Medical Officer, Accenture Operations, Texas Medicaid Project

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Howard University, Washington, DC	BS	05/1978	Microbiology
Tulane University Medical School, New Orleans, LA	MD	05/1982	Medicine
Baylor College of Medicine, Houston, TX	Residency	06/1985	Pediatrics
Harvard University School of Public Health, Boston, MA	MPH	05/1990	Public Health, Health Policy and Management

A. Personal Statement

I have over 30 years of experience in health care, health care finance, and public health. My experience includes my current work as a consultant on a FDA/NCI funded grant (R21CA180934, PI: Kymberle Sterling) that examines risk perceptions related to flavored cigars. I served on the external advisory board (EAB) of a transdiscipinary energetic research center at Washington University School of Public Health and on two NCI-supported cancer center EABs including the University of Kansas Cancer Center and the Siteman Cancer Center in St. Louis, Missouri. I am the former chair the EAB at University of Hawaii Cancer Center, which received its five-year renewal from NCI in 2012. I provide advice and feedback in the public health areas of tobacco control, healthcare disparities, cancer prevention and control and general advice on the overall performance of the cancer centers against NCI Cancer Center Support Grant expectations.

I was one of nine appointees to and a voting member of the U.S. FDA's first Tobacco Products Scientific Advisory Committee. I served as a co-author on the Tobacco Products Scientific Advisory Committee report, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations* (2011), the first Congressionally mandated report under the Family Smoking Prevention and Tobacco Control Act (FSPTCA). I also contributed to the second Congressionally mandate report of FSPTCA, *The Nature and Impact of the Use of Dissolvable Tobacco Products on the Public Health: A Report from the Tobacco Products Scientific Advisory Committee*, March 1, 2012.

From 2004-2006, I served as the principal Deputy Director of the National Cancer Institute under NCI Director Andrew von Eschenbach. My duties included providing senior executive oversight of the NCI Cancer Center Core Grant Program. The Director and staff of the Office of Cancer Centers reported to me during this time and I engaged in executive problem-solving and senior level sign-off for this program on behalf of the Director of the NCI. I also had executive level responsibility for the 13 directors of NCI offices, centers, and divisions who reported directly to me (representing 500 employees and a portfolio of ~$1.2B) and executive coordination of NCI's $5B Bypass budget (2004-2005).

B. Positions and Honors:

Positions and Employment:

1998-1999 Vice President for Managed Care and Pharmacy Programs, Blue Cross Blue Shield of Texas
1999-2002 Chief Medical Officer and Vice President for Medical Affairs, Blue Cross Blue Shield of Texas
2004-2006 Deputy Director and Deputy for Cancer Care Delivery Systems, National Cancer Institute, National Institute of Health

2004-2006	Executive member, National Cancer Advisory Board
2004-2006	Executive member, NCI Board of Scientific Advisors
2004-2006	Chairman, Health and Human Services Quality Cancer Committee
2006-2013	Chief Medical Officer, High Plains Division, American Cancer Society (Texas, Oklahoma, Nebraska, Kansas, Missouri, Hawaii)
2014	Deputy Commissioner for Chronic Disease and Chief Medical Office, Baltimore City Health Department, Baltimore, Maryland
2014-2015	Medical Director, TMF Health Quality Institute, A Medicare QIO-QIN
2015-	Chief Medical Officer, Accenture Operations, Texas Medicaid Project

Other Experience and Professional Memberships:

2006	United States Representative to the International Agency for Cancer Research, World Health Organization, Governing Council
2007-present	Member, Washington University School of Medicine in St. Louis, Siteman Comprehensive Cancer Center, External Advisory Board
2009-2013	Chairman, University of Hawaii Cancer Research Center, External Advisory Committee
2010-present	Member, Washington University in St. Louis, National Council, Institute for Public Health
2010-2014	Voting Member, Tobacco Products Scientific Advisory Committee, United State Food and Drug Administration, Department of Health and Human Service
2011-present	Member, University of Kansas Cancer Center, External Advisory Board Health
2011-present	Member, External Advisory Board, Transdisciplinary Research in Energetics and Cancer Center (NIH/NCI U54), Washington University in St. Louis, Siteman Cancer Center, Graham Colditz Principal Investigator
2013-present	Member, Scientific Advisory Board, Georgia State University, Principal Investigator, Kymberle Sterling

Honors:

2005	St. George Medal, National Cancer Control Award, American Cancer Society
2005	National Institute of Health Director's Award of Merit Outstanding contributions to the NIH 'Effective' rating under the NIH FY 2006 PART (Lead NCI's Nanomedicine contributions)
2005	Secretary's Distinguished Service Award, United States Department of Health and Human Service, Secretary Mike Leavitt, Health Care Quality Team, Implementation of the Medicare Modernization Act
2006	National Cancer Institute Director's Certificate of Appreciation, Leader of the NCI Hurricane Katrina Response Team
2006	National Institute of Health, Director's Award of Merit, NCI Hurricane Katrina and Rita Response Teams, Team Leader
2006	Secretary's Distinguished Service Award, United States Department of Health and Human Services, Secretary Mike Leavitt, NIH Katrina and Rita Response Teams
2012	Award of Merit, Outstanding Contributions to Worldwide Cancer Prevention and Control and Leadership in reducing disparities in Cancer Care.

C. Contributions to Science

My publications are mostly in the area of effects of smoking and smoking prevention.

1. **Clanton M.** The National Cancer Institute's Special Populations Networks for cancer awareness, research, and training. Cancer,15;107(8 Suppl):1931-2. 2006
2. Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, Tobacco Products Scientific Advisory Committee, member menthol report writing subcommittee, Food and Drug Administration, Department of Health and Human Services, March 18, 2011. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM247689.pdf

3. Pellbles Fagan, Eric T Moolchan, Pallav Pokhrel, Thaddeus Herzog, Kevin D Cassel, Ian Pagano, Adreian A Frank, Joseph Keawe'aimoku Kaholokula, Angela Sy, Linda A Alexander, Dennis R Trinidad, Kari-Lyn Sakuma, C /Anderson Johnson, Alyssa Antonio, Dorothy Jorgensen, Tania Lynch, Crissy Kawamoto, **Mark S Clanton.** Biomarkers of tobacco smoke exposure in racial/ethnic groups at high risk for lung cancer. Am J Public Health 2015 Jun 16:105(6):1237-45. PMC4431074.
4. Fagan P, Pokhrel P, Herzog TA, Pagano IS, Franke AA, **Clanton MS**, Alexander LA, Trinidad DR, Sakuma KL, Johnson CA, Moolchan ET. Nicotine Metabolism in Young Adult Daily Menthol and Nonmenthol Smokers. Nicotine Tob. Res. 2016 Apr;18(4):437-46. PMC4857147

Link to complete list of publications:
http://www.ncbi.nlm.nih.gov/pubmed/?term=clanton+m

D. Research Support

Ongoing Support: None

Completed Support: None

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Michael W. Darling, MHA**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Associate Director for Administration

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Indiana University, Indianapolis, Indiana	A.S.	05/1977	Respiratory Therapy
Indiana University, Indianapolis, Indiana	B.S.	05/1980	Allied Health Administration
Indiana University, Indianapolis, Indiana	MHA	05/1985	Health Administration

A. Personal Statement

I have led the IUSCC Administration since its establishment in 1992. Prior to this, I served as Division Administrator of Hematology/ Oncology (1987-1992). I have served on the Executive Committee of the Cancer Center Administrators Forum and held various leadership roles in the Association of Cancer Executives, including president. In addition, I serve on multiple external advisory boards of other NCI designated cancer centers.

B. Professional Experience

Positions and Employment:

1974-1977 Respiratory Therapy, ICU Technician
Winona Hospital, Indianapolis, Indiana
1977-1978 Respiratory Therapy, Supervisor
Indiana University Hospital, Indianapolis, Indiana
1978-1984 Director of Clinical Education
Indiana Vocational Technical College, Indianapolis, Indiana
1985-1988 Operations Analyst/Finance
Metro Health (Staff Model HMO), Indianapolis, Indiana
1988-1992 Division Administrator, Hematology/Oncology
Department of Medicine, Indiana University
Indiana University, Indianapolis, Indiana
1992-Present Associate Director for Administration
Indiana University Simon Cancer Center, Indianapolis, Indiana

Other Professional Activities:

1995 NCI Consultant, CCSG Grant Review, University of Iowa Cancer Center
1999 NCI Consultant, CCSG Grant Review, University of Iowa Cancer Center
2001 NCI Consultant, CCSG Grant Review, Case Western Reserve Cancer Center
2002 NCI Consultant, CCSG Grant Review, UC San Francisco Cancer Center
2003 NCI Consultant, CCSG Grant Review, Huntsman Cancer Institute, University of Utah
2005 NCI Consultant, CCSG Grant Review, University of Iowa Cancer Center
2005 NCI Consultant, CCSG Grant Review, USC Norris Cancer Center
2006 NCI Consultant, CCSG Grant Review, UC San Diego Cancer Center
2002-2004 Member, External Scientific Advisory Committee,
The Ohio State University Comprehensive Cancer Center

2003-2010	Member, External Scientific Advisory Committee, University of Maryland Cancer Center
2005	Administrative Consultant, Mayo Clinic Comprehensive Cancer Center
2005-Present	Member, External Scientific Advisory Committee, University of Kansas Cancer Center
2009-2013	Member, External Scientific Advisory Committee University of Kentucky Cancer Center
2012-2013	Consultant, University of Minnesota Masonic Cancer Center
2012-Present	Member, External Scientific Advisory Committee, Norris Cotton Cancer Center, Dartmouth-Hitchcock Medical Center
2014-Present	Member, External Scientific Advisory Committee, Univ. of Minnesota Masonic Cancer Center
2015-Present	Member, External Scientific Advisory Committee, University of Alabama at Birmingham Comprehensive Cancer Center

Professional Affiliations:

1992-Present	Cancer Center Administrators Forum; Executive Committee 2006-2008
1995-Present	Association of Cancer Executives; Board Member 1996-1998 and 2000-2002, National Meeting Chair 2000, President 2001; Communications and Marketing Committee 2004-2006

C. Contributions to Science: None (not applicable)

D. Research Support

Ongoing Support:

P30 CA082709 Loehrer (PI) 09/01/2014 - 8/31/2019
NIH/NCI
Cancer Center Support Grant
The major goal of this project is to establish an NCI designated Cancer Center by facilitating cancer research, education, patient care, and cancer control and prevention to accomplish its mission of reducing the incidence, morbidity, and mortality of cancer.
Role: Associate Director for Administration

Completed Support:
N/A

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Ernest T. Hawk, MD, MPH**

eRA COMMONS USER NAME (credential, e.g., agency login): EHAWK1

POSITION TITLE: Vice President and Division Head, Division of Cancer Prevention and Population Sciences / Boone Pickens Distinguished Chair for Early Prevention of Cancer

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Wayne State University, Detroit, MI	BS	06/1981	Biological Sciences
Wayne State University School of Medicine, Detroit, MI	MD	06/1985	Medicine
Emory University Affiliated Hospitals, Atlanta, GA	Residency	06/1988	Internal Medicine
University of California, San Francisco, San Francisco, CA	Fellowship	06/1993	Medical Oncology
National Cancer Institute, Bethesda, MD	Research Fellowship	06/1996	Cancer Prevention
Johns Hopkins University School Of Hygiene & Public Health, Baltimore, MD	MPH	05/1994	Epidemiology/Biostatistics

A. Personal Statement

I am the current vice president and head of the Division of Cancer Prevention and Population Sciences at MD Anderson Cancer Center (MDACC), I hold the Boone Pickens Distinguished Chair for Early Prevention of Cancer, and serve as a professor in the department of Clinical Cancer Prevention. I also serve as the CCSG Associate Director for Cancer Prevention and Population Sciences and co-lead the CCSG Gastrointestinal Cancer Program. My background includes research, education, training, and practice in medicine, epidemiology, cancer prevention, clinical trials, and drug development at several different institutions. Before coming to MD Anderson, I worked at the National Cancer Institute (NCI) for 12 years in chemopreventive drug identification, preclinical testing, and clinical development, participating in phase I-III trials of several agents including calcium, aspirin, celecoxib, DFMO, and combinations. From 2005-2007, I oversaw the NCI's cancer centers, SPORE, training, and disparities programs; and also served as a co-leader of the NCI's Translational Research Working Group. At MD Anderson, I have gained experience in T1-T4 research through oversight and collaborations with the division's five academic departments (i.e, epidemiology, behavioral science, clinical cancer prevention, disparities, and health services research), the last of which, I founded; through my leadership of the Duncan Family Institute for Cancer Prevention and Risk Assessment; and my co-leadership of the institution's recently established cancer prevention and control platform which advances health promotion and cancer control through evidence-based public policy, public and professional education, and community-based service implementation and dissemination. Beyond MD Anderson, I serve as a deputy editor for AACR's *Cancer Prevention Research*, co-chair of the AACR's Prevention Committee, and as an invited external advisor regarding cancer prevention and control, and population sciences to seven NCI-designated cancer centers, including the Fred & Pamela Buffett Cancer Center at the University of Nebraska.

B. Positions and Honors

Positions and Employment:

1997-1999 Medical Officer, Chemoprevention Branch, National Cancer Institute, Bethesda, MD
1999-2004 Chief & Medical Officer, Gastrointestinal and Other Cancers Research Group, Division of Cancer Prevention, National Cancer Institute, Bethesda, MD

2004-2007	Director, Office of Centers, Training and Resources, Office of the Director, National Cancer Institute, Bethesda, MD
2007-present	Vice President, Division of OVP, Cancer Prevention and Population Sciences, UT MD Anderson Cancer Center, Houston, TX
2007-present	Professor, Department of Clinical Cancer Prevention, Division of OVP, Cancer Prevention and Population Sciences, UT MD Anderson Cancer Center, Houston, TX
2007-present	Division Head, Division of OVP, Cancer Prevention and Population Sciences, UT MD Anderson Cancer Center, Houston, TX
2008-present	Executive Director, Duncan Family Institute for Cancer Prevention & Risk Assessment, UT MD Anderson Cancer Center, Houston, TX
2009-present	Boone Pickens Distinguished Chair for Early Prevention of Cancer, UT MD Anderson Cancer Center, Houston, TX
2012-present	Co-director, Cancer Prevention & Control Platform, UT MD Anderson Cancer Center, Houston, TX

Honors:

2002	Research Award, Distinguished Achievement in Cancer Prevention, National Cancer Institute
2007	The Nancy Terner Behrman Lecture in Honor of Betty Flehinger, PhD, Weill Cornell Medical School, NYC
2011	Outstanding Leading Mentor in Cancer Prevention, Division of Cancer Prevention and Population Sciences, UT MD Anderson Cancer Center
2014	Cancer Prevention Fellowship Distinguished Alumni Award, National Cancer Institute
2015	ASCO-American Cancer Society Award and Lecture in Cancer Prevention and Control – given for significant contributions to cancer prevention and control research or practice

C. Contribution to Science

The primary focus of my career has been on chemopreventive drug identification, preclinical testing, and clinical development. Specifically, I am interested in the potential of non-steroidal anti-inflammatory drugs (NSAIDs) to prevent cancer because of their well-documented and broad efficacy in prevention, yet very real safety concerns. Additionally, I have worked to advance participation of diverse groups in clinical cancer prevention trials. Recently, as I have become more active in cancer control efforts, my interests have expanded to include the design, implementation, dissemination and evaluation of evidence-based interventions that can significantly reduce the burden of cancer at the population level.

1. **Identification, testing, and development of cancer chemopreventive agents -** While at the NCI, my work involved pre-clinical and translational research investigations to develop novel chemopreventive agents as well as biomarkers of risk or response. As part of this work, I was actively involved in the initial design, implementation, monitoring, and analysis of a number of phase II and III trials testing the safety and efficacy of celecoxib for the prevention of colorectal cancer in individuals at increased risk. These trials demonstrated that celecoxib was, in fact, effective in the prevention of colorectal adenomas, but that it was associated with serious cardiovascular events among individuals at increased risk of cardiovascular disease, precluding its use in the general population.

    a) Steinbach G, Lynch PM, Phillips RK, Wallace MH, **Hawk E**, Gordon GB, Wakabayashi N, Saunders B, Shen Y, Fujimura T, Su LK, Levin B, Godio L, Patterson S, Rodriguez-Bigas MA, Jester SL, King KL, Schumacher M, Abbruzzese J, DuBois RN, Hittelman WN, Zimmerman S, et al.(2000). The effect of celecoxib, a cyclooxygenase-2 inhibitor, in familial adenomatous polyposis. *New England Journal of Medicine*, 29;342(26):1946-52.
    b) Solomon SD, Wittes J, Finn PV and **Hawk, E.T.** (2008). Cardiovascular risk of celecoxib in 6 randomized placebo-controlled trials: The cross-trials safety analysis. *Circulation*, 117:2104-2113. PMC2965408
    c) Bertagnolli MM, Eagle CJ, Zauber AG, Redston M, Breazna A, Kim K, Tang J, Rosenstein RB, Umar A, Bagheri D, Collins NT, Burn J, Chung DC, Dewar T, Foley TR, Hoffman N, Macrae F, Pruit RE, Saltzman JR, Salzberg B Sylwestrowicz T, **Hawk ET** for the APC Study Investigators (2009). Five-year efficacy and safety analysis of the adenoma prevention with celecoxib trial. *Cancer Prevention Research,* 2:310-321. PMC2976587.

d) Maresso KC, Tsai KY, Brown PH, Szabo E, Lippman S, **Hawk ET.** (2015) Molecular cancer prevention: Current status and future directions. *CA Cancer J Clin*, 2015 Aug 18:3322. PMC4820069.

2. **Promotion of translational research and translation of scientific evidence into clinical and public health practice** - Along with the research described above, I led the NCI's Translational Research Working Group (TRWG), formed in 2005. Over two years, the TRWG reviewed the NCI's intramural and extramural translational research portfolio and made recommendations regarding how the NCI could optimize its investment in further translational research. At MDACC, I've been involved in establishing goals, metrics, and infrastructures for translation of prevention science into cancer control actions. The Cancer Control Platform was developed over the last few years to advance evidence-based cancer control actions in public policy, public/professional education, and delivery of community-based services to reduce the cancer burden broadly, but most especially in the underserved. The platform has developed and implemented several projects to advance evidence-based, community-oriented cancer control actions to promote HPV vaccination, tobacco prevention and cessation, the adoption/maintenance of healthy lifestyles (including healthy diets, physical activity, and UV protection), cancer screening and survivorship in Houston, across Texas, and with partnering cancer institutions nationally and globally. These have resulted in new collaborative relationships and more than $13M in financial support from individual philanthropists, major corporations, state/federal agencies, and private foundations. Most recently, we've gained support from a peer-reviewed funding agency within our state (e.g., CPRIT prevention award).

a) http://www.cancer.gov/about-nci/organization/ccct/about/trwg-report.pdf
b) **Hawk ET**, Greenwood A, Gritz ER, McTiernan A, Sellers T, Hursting SD, Leischow S, Grad O; Translational Research Working Group. The Translational Research Working Group developmental pathway for lifestyle alterations. Clin Cancer Res. 2008 Sep 15;14(18):5707-13. (PMC# not requested; not NIH funded)
c) Srivastava S, Gray JW, Reid BJ, Grad O, Greenwood A, **Hawk ET;** Translational Research Working Group. Translational Research Working Group developmental pathway for biospecimen-based assessment modalities. Clin Cancer Res. 2008 Sep 15;14(18):5672-7. PMC2737183.
d) **Hawk ET**, Matrisian LM, Nelson WG, Dorfman GS, Stevens L, Kwok J, Viner J, Hautala J, Grad O; Translational Research Working Group. The Translational Research Working Group developmental pathways: introduction and overview. Clin Cancer Res. 2008 Sep 15;14(18):5664-71 (not NIH funded)

3. **Promotion, development, and implementation of prevention and control science** - At MD Anderson, I lead the Division of Cancer Prevention and Population Sciences, which includes 75+ faculty members and 600 employees. During my seven years here, I have promoted the work of our four existing departments (i.e, epidemiology, behavioral science, clinical cancer prevention, and health disparities) and developed the fifth department, health services research. Through my oversight of these departments, I have had the opportunity to expand my research interests and work in both the genetic epidemiology and clinical prevention of various cancers, primarily colorectal cancer. I have initiated, coordinated and/or participated in the design and analysis of a number of genetic association studies and both pre-clinical and clinical research seeking to identify risk factors, potential chemopreventive targets, and novel chemopreventive agents or regimens. This work has uncovered novel genetic loci that may potentially serve as risk biomarkers, and in the case of Wen, et al. (below), has resulted in a powerful risk prediction model for liver cancer in the general population.

a) Dai J, Gu J, Huang M, Eng C, Kopetz ES, Ellis LM, **Hawk E**, Wu X. (2012) GWAS-identified colorectal cancer susceptibility loci associated with clinical outcomes. *Carcinogenesis*, 33(7):1327-31. PMCID: PMC4072910.
b) Wu X, Ajani JA, Gu J, Chang DW, Tan W, Hildebrandt MA, Huang M, Wang KK, **Hawk E**. (2013) MicroRNA expression signatures during malignant progression from Barrett's esophagus to esophageal adenocarcinoma. *Cancer Prev Res (Phila)*, 6(3):196-205. PMC3608471.
c) Xu E, Gu J, **Hawk ET**, Wang KK, Lai M, Huang M, Ajani J, Wu X. (2013) Genome-wide methylation analysis shows similar patterns in Barrett's esophagus and esophageal adenocarcinoma. *Carcinogenesis*, 34(12):2750-6. PMC3845893.
d) Hassan MM, Abdel-Wahab R, Kaseb A, Shalaby A, Phan AT, El-Serag HB, **Hawk E,** Morris J, Singh Raghav KP, Lee JS, Vauthey JN, Bortus G, Torres HA, Amos CI, Wolff RA, Li D. (2015) Obesity early

in adulthood increases risk but does not affect outcomes of hepatocellular carcinoma. G*astroenterology*, 149(1):119-29. PMC4778392.

4. **Disparities in cancer, cancer care, and cancer outcomes -** My positions at NCI and MDACC have also allowed me to examine barriers to the recruitment of underserved communities (especially, racial and ethnic minorities) in preventive and therapeutic cancer trials. These individuals have been historically underrepresented in such trials, which hinders scientific and medical advances in the prevention and treatment of cancer among these populations. In addition, each NCI-designated cancer center must ensure a proportional mix of racial and ethnic minorities in their therapeutic trials that is representative of the center's catchment area. I am a co-PI on an NIH U24 grant focused on enhancing minority participation in clinical trials (EMPaCT) and this team recently published its preliminary findings along with potential steps to improve rates of participation for this historically underrepresented group in therapeutic trials.

   a) **Hawk ET**, Habermann EB, Ford JG, Wenzel JA, Brahmer JR, Chen MS Jr, Jones LA, Hurd TC, Rogers LM, Nguyen LH, Ahluwalia JS, Fouad M, Vickers SM. (2014) Five National Cancer Institute-designated cancer centers' data collection on racial/ethnic minority participation in therapeutic trials: a current view and opportunities for improvement. *Cancer*, 1;120 Suppl 7:1113-21. PMC4322861.
   b) Volk RJ, **Hawk E**, Bevers TB. (2014) Should CMS cover lung cancer screening for the fully informed patient? *JAMA*, 312(12):1193-4. PMC4367127.

Complete List of Published Works in My Bibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1v5F3Wm8b7FQa/bibliograpahy/47180690/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

P30CA016672 DePinho (PI) 09/04/1998 – 06/30/2018
NIH/NCI
Cancer Center Support Grant
The major goal of this grant is to promote cancer research, prevention, & education by supporting the research infrastructure necessary to stimulate innovation, encourage multi-disciplinary collaboration & support novel ideas through the cancer center's interdisciplinary research programs.
Role: Member, CCSG Executive Committee/Associate Director Population Sciences; co-Leader GI Program

U24MD006970 Cook (PI) 09/19/2011 – 05/31/2017
NIH/NIMHD
Enhancing Minority Participants in Clinical Trials (EMPaCT): Phase II
The major goal of this project is to increase recruitment & retention of racial/ethnic minorities into therapeutic clinical trials.
Role: Co-Principal Investigator

N01CN35159-10-0-1 Brown (PI) 09/01/2012 – 08/31/2018
NIH/NCI
Cancer Prevention Agent Development Program
The goal of this program is to conduct early phase cancer prevention trials testing novel cancer prevention agents, especially molecularly-targeted agents, to ultimately bring the most effective drugs to Phase III testing.
Role: Co-investigator

Cancer Prevention Pharmaceuticals Lynch (PI) 10/01/2013 – 09/30/2016
NIH/NCI
A Double-Blind, Randomized, Phase III Trial of the Safety and Efficacy of CPP-1X/Sulindac Compared with CPP-1X, Sulindac as Single Agents in Patients with FAP and Attenuated FAP
The goal of this study is to determine whether combination of CPP-1X + sulindac is superior to either treatment alone in delaying time to the first occurrence of any FAP-related event in patients with this disease.
Role: Other Significant Contributor

PP150012 Schmeler (PI) 12/01/2014 – 11/30/2017
CPRIT
Improving Cervical Cancer Screening and Prevention in the Lower Rio Grande Valley through Public Outreach, Patient Navigation, and Telementoring
Goals of this project are to implement two innovative, evidence-based, complementary interventions in the Lower Rio Grande Valley to increase public participation in cervical cancer screening, and increase professional capacity for accurate diagnosis and treatment of precancerous lesions to meet the demands arising from increased public participation.
Role: Co-Program Director

R01CA186566 Hassan (PI) 09/01/2014 – 08/31/2019
NIH/NCI
Genome-Wide Association Study in Hepatocellular Carcinoma (GWAS Study)
The goal of this project is to provide a detailed understanding of the genetic risk factors for development of hepatocellular carcinoma (HCC) and prognosis in the U.S. which will facilitate efforts to implement screening measures according to individual susceptibilities to HCC.
Role: Co-Investigator

P30CA016672 DePinho (PI) 09/01/2016 - 08/31/2017
NIH
Administrative Supplements for NCI-designated Cancer Centers to Support Population Health Assessment in Cancer Center Catchment Areas
The primary goal of this proposal is to substantially increase our knowledge and understanding of cancer and associated demographics, risk factors, care delivery, and outcomes impacting communities across the State of Texas.
Role: Co-Investigator

Completed Support:
N/A

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Janet A. Houghton, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): JHOUGHTON

POSITION TITLE: Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Bradford, Yorkshire, England	B.Ph. (Hons)	06/1973	Exp. Pharmacology
Membership, Pharmaceutical Society of Great Britain	M.P.S.	07/1974	Pharmacy
University of London, Sutton, Surrey, England	Ph.D.	07/1977	Animal models/biology cancer therapeutics

A. Personal Statement

I am a senior investigator with an extensive and successful track record in developing research programs in areas of high impact in cancer, in particular in colon cancer. I demonstrate broad background in cancer therapeutics, molecular pharmacology, mechanisms of drug action, new target identification, cell signaling, cell biology, animal models, and novel developmental therapeutic approaches, spanning basic, preclinical and translational research to the clinic. I have a major research interest in Hedgehog (HH) signaling in cancer, specifically in the aberrant and constitutive activation of GLI at the distal end of the pathway. Hedgehog (HH) signaling plays an important role in genomic instability, oncogenesis and maintenance of the malignant phenotype in several types of human cancers. Canonical HH signaling via the HH-GLI axis is aberrantly and persistently activated during oncogenesis and progression of primary colon cancers and in metastatic disease. Oncogenic signaling pathways, including KRAS/BRAF in colon cancer, circumvent the HH-GLI axis to converge on and further dysregulate GLI activation in tumor cells. Thus GLI, comprising GLI1 and GLI2, which are the transcriptional regulators of the HH signaling response, serves as a nodal channel through which upstream oncogenic signals converge. Targeting constitutive GLI activation induces extensive cell death in colon cancer cells, yet GLI remains an unexplored target in cancer therapeutics.

B. Positions and Honors

Positions and Employment:

1977-1980 Fellow, Dept. of Pharmacology, St. Jude Children's Research Hospital (SJCRH), Memphis, TN
1980-1982 Research Associate, Department of Pharmacology, SJCRH, Memphis, TN
1982-1985 Assistant Member, Department of Pharmacology, SJCRH, Memphis, TN
1985-1990 Associate Member, Department of Pharmacology, SJCRH, Memphis, Tennessee
1990-1999 Member, Department of Pharmacology, SJCRH, Memphis, TN
1999-2006 Member, Department of Hematology-Oncology, SJCRH, Memphis, TN
2006-2010 Senior Leader, Associate Director for the Lerner Research Institute, Case Comprehensive Cancer Center, Cleveland, OH
2006-2011 Chair, Department of Cancer Biology, Lerner Research Institute (LRI), Cleveland Clinic Foundation (CCF), Cleveland, OH
2006-2015 Full Staff; Professor; Department of Cancer Biology, Lerner Research Institute (LRI), Cleveland Clinic Foundation (CCF), Cleveland, OH
2006-2015 Full Staff (secondary appointment), Taussig Cancer Institute, CCF, Cleveland, OH
2009-2015 Professor, Department of Molecular Medicine, Cleveland Clinic Lerner College of Medicine at Case Western Reserve University, Cleveland, OH

2015- Senior Research Fellow, Endowed Chair in Cancer Biology, Division of Drug Discovery, Department of Oncology, Southern Research Institute, Birmingham, AL 35205

Other Professional Experience:

1984-1989 Member, Experimental Therapeutics II Study Section, National Cancer Institute
1997-1998 Sabbatical Visiting Professor, La Jolla Institute for Allergy and Immunology, San Diego, CA
1995-2003 Member, Experimental Therapeutics II Study Section, NCI
1994-2003 Editorial Board, Clinical Cancer Research
1996-2002 Editorial Board, Cancer Research
2002-2006 Member, NCI Subcommittee A (Cancer Centers)
2003-2005 Chair, Developmental Therapeutics Study Section, NCI
2008-2011 Member, External Advisory Board, PO1, Medical University of South Carolina, Charleston, SC
1999- Editorial Board, Pathology-Oncology Research
2001- Chair, External Advisory Board, PO1, University of Pennsylvania
2002- Senior Editor, Cancer Research
2005- Editorial Advisory Board, Current Signal Transduction Therapy
2006- Editorial Board, Cancer Biology and Therapy
2006- Member (Ad Hoc), NCI Subcommittee A (Cancer Centers)
2007- Member, External Advisory Board, Purdue University Cancer Center, Purdue, IN
2009- Science Foundation Ireland – Reviewer, SIRG Programme
2009- Austrian Science Fund – Reviewer of Proposals
2012- The French Ministry of Health and the National Cancer Institute of France (INCa) - Reviewer of Proposals
2013- Member (Ad Hoc), NCI Tumor Cell Biology (TCB) Study Section
2013- Member (Ad Hoc), Oncology 2 - Translational Clinical IRG (OTC), NCI Cancer Drug Development and Therapeutics (CDDT) SBIR/STTR Study Section (ZRG1 OTC-T 10B)
2013-2015 Member, AACR Clinical Research and Experimental Therapeutics Awards Committee
2014- Advisor, Oncompass™ (http://kpsdx.com/company/); Cooperative molecular oncology decision support services for personalized targeted treatment of cancer patients; Budapest, Hungary
2015- Member, External Advisory Board, Kansas University Cancer Center
2015- Member (Ad Hoc), NCI Basic Mechanisms of Cancer Therapeutics (BMCT) Study Section
2015-2016 Member, AACR Clinical and Translational Cancer Res. Grants Scientific Review Committee

Honors and Aawrds:

1994-1999 MERIT Award, National Cancer Institute
2006-2011 Betsy B DeWindt Endowed Chair for Cancer Research, Department of Cancer Biology, LRI, CCF, Cleveland, OH
2009-2011 Honorary Professorship, Wuxi No. 4 People's Hospital, Wuxi, People's Republic of China

Professional Memberships:

1974- Royal Pharmaceutical Society of Great Britain
1978- American Association for Cancer Research
2007- American Association for the Advancement of Science

C. Contributions to Science

1**. Mechanism of action and modulation of 5-Fluorouracil (FUra) in colon cancer**

My early postgraduate studies focused on elucidating the metabolic pathway(s) of FUra metabolism relevant to human colorectal cancers, for which I had established a panel of human colorectal carcinoma xenografts in immune-deprived mice. Colorectal cancers demonstrated lower levels of the target enzyme thymidylate synthase (TS) compared to other tumor types, responded to FUra due to TS inhibition, dTTP depletion, and induction of DNA damage. In contrast FUra induced toxicity to normal gastrointestinal tissues via incorporation of FUra into RNA. Studies focused on the reduced folate cofactor, 5,10-methylenetetrahydrofolate required in binding TS and the active metabolite of FUra, FdUMP, where the stability of the ternary complex was highly dependent on the concentration of folate cofactor. Colorectal carcinomas were deficient in optimal concentrations of 5,10-methylenetetrahydrofolate required to maximally form and stabilize the ternary complex. These findings resulted in extensive studies using the stable reduced folate leucovorin (LV) as a supplement to elevate intracellular reduced folate pools. Xenograft studies demonstrated that concentrations of LV > 200

mg/m2 were optimal in elevating these pools. These studies were instrumental in elucidating the mechanism of FUra Action, and in contributing to the design of randomized clinical trials demonstrating significantly increased response rates when FUra and LV were combined, in comparison to FUra alone, in the treatment of metastatic colorectal cancer. FUra/LV combinations became the basis for treatment of this refractory disease, and have been employed in all future studies of therapy modulation.

a) **Houghton JA**, Houghton PJ, Wooten RS. Mechanism of induction of gastrointestinal toxicity in the mouse by 5-fluorouracil, 5-fluorouridine and 5-fluoro-2'-deoxyuridine. Cancer Res 39:2406-2413, 1979.

b) **Houghton JA**, Schmidt C, Houghton PJ. The effect of derivatives of folic acid on the fluorodeoxyuridylate-thymidylate synthetase covalent complex in human colon xenografts. Eur J Cancer Clin Oncol 18:347-354, 1982.

c) **Houghton JA**, Houghton PJ. Elucidation of pathways of 5-fluorouracil metabolism in xenografts of human colorectal adenocarcinomas. Eur J Cancer Clin Oncol 19:807-815, 1983.

d) **Houghton JA**, Williams LG, Cheshire PJ, Wainer IW, Jadaud P, Houghton PJ. Influence of dose of [6RS]leucovorin on reduced folate pools and 5-fluorouracil-mediated thymidylate synthase inhibition in human colon adenocarcinoma xenografts. Cancer Res 50:3940-3946, 1990.

2. **The Fas death receptor regulates apoptosis in human colon carcinoma cells**

Before conducting a 1-yr sabbatical in the laboratories of Dr. Douglas Green in La Jolla (1997-1998), I was the first to demonstrate that the Fas death receptor, belonging to the TNF receptor superfamily, regulated apoptosis in human cancer cells, and regulated FUra-induced cytotoxicity in human colon carcinoma cells. Further, FasL was transcriptionally upregulated by NF-KB and AP-1. In a panel of ten human colon cancer cell lines, levels of the Fas antigen varied by > 1,000-fold; high Fas expression correlated with sensitivity to the cytolytic anti-Fas Ab, CH-11. We developed a rationale and hypothesis for elevating Fas expression using the cytokine IFN-γ. This sensitized colon cancer cells to FUra/LV-induced cell death, dependent on DNA damage, independent of the P53 tumor suppressor gene (mutated in 80% of colon cancers). IFN-γ increased the cytotoxic response of FUra/LV in xenograft models, and studies led to the successful completion of a Phase I clinical trial of FUra, LV and IFN-γ in patients with advanced colorectal cancer for proof of concept.

a) **Houghton JA**, Harwood FG, Tillman DM. Thymineless death in colon carcinoma cells is mediated via Fas signaling. Proc. Natl. Acad. Sci. USA 94:8144-8149, 1997.

b) **Houghton JA**, Harwood FG, Gibson AA, Tillman DM. The Fas signaling pathway is functional in colon carcinoma cells and induces apoptosis. Clin Cancer Res 3:2205-2209, 1997.

c) Tillman DM, Petak I, **Houghton JA**. A Fas-dependent component in 5-fluorouracil/ leucovorin-induced cytotoxicity in colon carcinoma cells. Clin Cancer Res 5:425-430, 1999.

d) Harwood FG, Kasibhatla S, Petak I, Vernes R, Green DR, **Houghton JA**. Regulation of FasL by NF-κB and AP-1 in Fas-dependent thymineless death of colon carcinoma cells. J Biol Chem, 275:10023-10029, 2000.

3**. Discoveries in the early biology of pediatric solid tumors**

I was instrumental in developing models of human pediatric solid tumors, in particular rhabdomyosarcoma (RMS) and osteosarcoma (OS), by establishing xenograft models in mice, and contributed to the Solid Tumor Program project grant at St. Jude Children's Research Hospital for 20 years. My programs were important in identifying new treatment approaches for these tumor types and for elucidating the mechanisms of action for key cytotoxic agents. Studies in OS focused on understanding the utility and modulation of methotrexate. In pediatric RMS, studies focused on the utility and mechanism of action of vincristine, vinca alkaloids, and alternate agents, including melphalan, which led to a Phase I trial. Studies initiated in human colon carcinoma models in death receptor signaling further led to the application of this approach in RMS models. Fas was not expressed in RMS, but receptors for the cytolytic ligand TRAIL, were expressed and were targetable. These studies led to several publications and increased knowledge of the fundamental biology of RMS.

a) Meyer WH, Loftin SK, **Houghton JA**, Houghton PJ. Accumulation, intracellular metabolism, and antitumor activity of high- and low- dose methotrexate in human osteosarcoma xenografts. Cancer Commun 2:219-229, 1990.

b) Bowman LC, **Houghton JA**, Houghton PJ. Influence of guanine nucleotides on vincristine binding in tumor cytosols and purified tubulin - evidence for an inhibitor of vincristine binding. J Cell Physiol 144:376-382, 1990.

c) Petak I, Douglas L, Tillman DM, Vernes R, **Houghton JA**. Rhabdomyosarcoma cell lines are resistant to Fas- and highly sensitive to TRAIL-induced apoptosis. Clin Cancer Res 6:4119-4127, 2000.

d) Izeradjene K, Douglas L, Delaney A, **Houghton JA**. Influence of Casein Kinase II (CK2) in TRAIL-induced apoptosis in human rhabdomyosarcoma cells. Clin Cancer Res 10:6650-6660, 2004.

4. **GLI as a critical determinant of colon cancer cell survival**

The GLI genes, GLI1 and GLI2, encode transcription factors that regulate target genes at the distal end of the canonical Hedgehog (HH) pathway (SHH->PTCH->SMO->GLI), tightly regulated in embryonic development, tissue patterning and differentiation. Both GLI1 and GLI2 are oncogenes, aberrantly and constitutively activated in many types of human cancers, progressing during oncogenesis and metastasis. Targeting HH-GLI signaling using inhibitors of SMO has met with limited success, due to circumvention of the canonical HH signaling pathway. We demonstrated that oncogene-driven signaling pathways, in particular KRAS/BRAF in colon cancer, circumvent the HH-GLI axis, converge on the GLI genes, and induce further constitutive GLI activation. Human colon carcinoma cell line models with these activated axes are minimally sensitive to inhibitors upstream of GLI. In contrast, extensive cell death occurs following inhibition of GLI (both GLI1 and GLI2) by treatment with the small molecule inhibitor GANT61, specific to targeting GLI-dependent transcription. GLI is expressed at low levels in adult tissues, and GANT61 demonstrates minimal cytotoxic activity in normal human colonic epithelial cells. Thus, GANT61 is active when GLI (GLI1, GLI2) is constitutively activated and serves as a common node of activation through which oncogenic signals converge. We have demonstrated rapid inhibition of GLI1 and GLI2 binding to target gene promoters (1 hr), reduced reporter activity specific to GLI-luciferase, and rapid inhibition of gene transcription in human colon carcinoma cell lines. Overexpression of GLI1 and/or GLI2 protects cells from GANT61-mediated cell death. Transient transfection of a GLI3R repressor inhibits both GLI1 and GLI2 transcription, inducing cellular effects that parallel those mediated by GANT61. These studies have identified GLI as a critical determinant of colon cancer cell survival.

a) Shi T, Mazumdar T, DeVecchio J, Duan Z-H, Agyeman A, Aziz M, **Houghton JA**. cDNA microarray gene expression profiling of Hedgehog signaling pathway inhibition in human colon cancer cells. PLoS ONE 5: 1-23, 2010 (pii: e13054;). PMC2948497

b) Mazumdar T, DeVecchio J, Shi T, Jones J, Agyeman A, **Houghton JA**. Hedgehog (HH) signaling drives cellular survival in human colon carcinoma cells. Cancer Res 71: 1092-1102, 2011. PMC3032813

c) Mazumdar T, DeVecchio J, Agyeman A, Shi T, **Houghton JA**. Blocking Hedgehog survival signaling at the level of the GLI genes induces DNA damage and extensive cell death in human colon carcinoma cells. Cancer Res 71:5904-5914, 2011. PMC3165104

d) Agyeman A, Mazumdar T, **Houghton JA**. Regulation of DNA damage following termination of Hedgehog (HH) survival signaling at the level of the GLI genes in human colon cancer. Oncotarget 8:854-868, 2012. PMC3478462

5. **GLI as a therapeutic target for drug discovery in cancer**

GLI1 and GLI2 are zinc finger proteins, one of the most common DNA-binding motifs in eukaryotic transcription factors. The crystal structure of the five zinc finger GLI1-DNA complex is known (PDB ID 2GLI). Using the crystal structure of the five zinc finger GLI1-DNA complex, we determined the specific GANT61-GLI binding characteristics by computational docking, and experimentally by mutagenesis and surface plasmon resonance (SPR). GANT61 is hydrolyzed in solution at all pHs to GANT61-diamine, which binds specifically to the 5-zinc finger GLI protein between zinc fingers 2 and 3 with significant interactions between its two aliphatic bridge nitrogens, E119 (1 H bond) and E167 (2 H bonds). Further, GANT61-diamine does not bind to DNA or to other zinc finger transcription factors (KLF4, TFIIβ). The important E119 and E167 GANT61 interacting sites are conserved in both GLI1 and GLI2, and mutating these sites in GLI1-WT significantly inhibits GANT61-GLI binding. GANT61 inhibits the binding of GLI to DNA and rapidly inhibits transcription at critical GLI-dependent target genes. Stalling of RNA Pol II occurs at sites of promoter proximal pausing following inhibition of GLI binding, with redistribution of pause (DSIF, NELF) and pause-release (PTEFb) factors. Inhibition of GLI-dependent transcription and interference with R-loop formation (RNA:DNA hybrids) led to the induction of DNA

damage, recognized at the initiation of S-phase with inhibition of DNA replication, inhibition of S-phase progression, and subsequent apoptosis. Our data have established the specificity and selectivity of GANT61 for targeting constitutive GLI activation in solid cancers, and the critical role of GLI in cancer cell survival. GLI1 and/or GLI2 are constitutively activated in many types of human cancers including epithelial cancers of the GI tract, brain tumors, melanoma, pediatric solid tumors, liver, lung, breast, pancreatic and prostate cancers. KRAS is mutated in 30% of all human cancers, and in 50% of colon carcinomas. Studies directed toward the development of inhibitors targeted at GLI-dependent transcription in solid tumors as a new cancer chemotherapeutic strategy are anticipated to have high impact.

a) Mazumdar T, DeVecchio J, Agyeman A, Shi T, **Houghton JA**. The GLI genes as the molecular switch in disrupting Hedgehog signaling in colon cancer. Oncotarget 2:638-645, 2011. PMC3248207

b) Agyeman A, Jha B, Mazumdar T, **Houghton JA**. Mode and specificity of binding of the small molecule GANT61 to GLI determines inhibition of GLI-DNA binding. Oncotarget 5:4492-4503,2014. (http://www.impactjournals.com/oncotarget/index.php?journal=oncotarget&page=issue&op=view&path[]=69 (front cover feature article June 30, 2014). PMC4147340

c) Patent: **Houghton JA,** Jha BK. Drug discovery for small molecules that target GLI-dependent transcription. Provisional Patent of the United States is filed on 12 March 2015 under Serial No. 62/131,911.

d) Patent: **Houghton JA**, Jha BK. Targeting GLI-Dependent Transcription by GANT61 in Human Colon Carcinoma Cells (CC); A New Therapeutic Approach. Provisional Patent of the United States is filed on 7 April 2014 under Serial No. 61/976,085.

A complete list of publications, which includes 145 original articles and 10 book chapters, may be found at: http://www.ncbi.nlm.nih.gov/myncbi/browse/collection/40609827/?sort=date&direction=descending

D. Research Support

Ongoing Support:

R01 CA 183921 Houghton (PI) 03/11/2015 - 03/10/2020
NIH-NCI
Targeting GLI-dependent transcription by GANT61 in colon cancer
Goals: To understand the mechanisms by which GANT61 inhibits GLI-dependent transcription that induces DNA damage leading to extensive cell death.

Completed Support:

P30 CA043703 Gerson (PI) 08/01/1997 - 03/31/2012
NIH-NCI
Comprehensive Cancer Center Support Grant
Goals: To promote interdisciplinary basic preclinical and translational research within the Case Comprehensive Cancer Center.
Role: Program member

R01 CA087952 Houghton (PI) 07/01/2000 - 01/31/2013
NIH-NCI
TRAIL Therapy for Rhabdomyosarcoma
Goals: To elucidate critical determinants of cell death/apoptosis induced by signaling via death receptors, and novel signaling pathways in well characterized models of human pediatric rhabdomyosarcoma.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Candance S. Johnson, DO**

eRA COMMONS USER NAME (credential, e.g., agency login): johnsoncs

POSITION TITLE: President and CEO

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
The Ohio State University, Columbus, OH	B.S.	05/1972	Biology
The Ohio State University, Columbus, OH	M.S.	05/1974	Medicine
The Ohio State University, Columbus, OH	Ph.D.	05/1977	Resident
Michigan Cancer Foundation, Detroit, MI	Post-doc Fellow	1979	Fellow

A. Personal Statement

I am the President and CEO, and the Cancer Center Director of Roswell Park Cancer Institute. Until early 2015, I was also Chair of Pharmacology & Therapeutics. My research interests include translational research to facilitate the efficient application of promising lab findings in clinical studies; preclinical design & development of more effective therapeutic approaches to cancer using highly characterized tumor models; mechanisms of vitamin D mediated anti-proliferative effects either alone or in combination with other cytotoxic agents. I received my PhD in Immunology at Ohio State University in 1977. After three years of post-doctoral training at Michigan Cancer Foundation in Detroit, I joined AMC Cancer Research Center in Denver as a Staff Scientist. During the next eight years I was appointed Laboratory Chief of Experimental Hematology, Assistant Prof of Medicine at the University of Colorado and Full Member of the Comprehensive Cancer Center in Denver. In 1989, I was recruited to University of Pittsburgh & University of Pittsburgh Cancer Institute (UPCI) where I was Professor in the Departments of Pharmacology and Medicine, Deputy Director of Basic Science at UPCI and Co-Program Leader of Molecular Therapeutics/Drug Discovery Program in the cancer center. I have maintained continuous independent peer-reviewed funding since 1979 when awarded an NIH post-doctoral fellowship from NCI. Currently, my research team has been testing the overall hypothesis that in tumors epigenetic silencing of gene expression in endothelial cells from different microenvironments impact signaling pathways & ultimately therapeutic application by utilizing a unique model system where differences exist in the epigenetic silencing of calcitriol-induced CYP24 gene expression in endothelial cells from tumor & normal microenvironments.

B. Positions and Honors

Positions and Employment:

1979-1981 Senior Research Associate, Michigan Cancer Foundation, Detroit, MI
1981-1985 Scientist, AMC Cancer Research Center, Denver, CO
1985-1988 Senior Scientist, AMC Cancer Research Center
1988-1989 Adjunct Asst Prof, Dept Medicine, Univ of Colorado School of Medicine, Denver, CO
1988-1989 Chief, Laboratory of Experimental Hematology, AMC Cancer Research Center
1989-1993 Associate Prof, Department Pathology, University of Pittsburgh School of Medicine, Pittsburgh, PA
1989-1994 Associate Prof, Department Otolaryngology, University of Pittsburgh School of Medicine (tenure conferred 1992)
1993-1994 Associate Prof, Department of Pharmacology, University of Pittsburgh School of Medicine
1995-1997 Professor, Departments Otolaryngology and Pharmacology, University of Pittsburgh School of Medicine

1997-2002	Professor, Departments of Pharmacology and Medicine, University of Pittsburgh School of Medicine
1998-2002	Deputy Director for Basic Research, University of Pittsburgh Cancer Institute, NCI designated Cancer Center
2002-2008	Senior Vice President/Associate Director, Translational Research, Roswell Park Cancer Institute, Buffalo, NY
2002-	Prof of Oncology, Department Pharmacology and Therapeutics, Roswell Park Cancer Institute
2002-	Prof, Department Pharmaceutical Sciences, University at Buffalo, NY
2005-	Wallace Chair in Translational Research
2007-2015	Chair, Department Pharmacology and Therapeutics, Roswell Park Cancer Institute, Buffalo, NY
2008-2014	Deputy Director, Roswell Park Cancer Institute, Buffalo, NY
2014-	Cancer Center Director, Roswell Park Cancer Institute, Buffalo, NY
2014-	President and CEO, Roswell Park Cancer Institute, Buffalo, NY

Other Experience and Professional Memberships

1994-	Member, NIH Reviewers Reserve
2000-2004	Member, NCI Initial Review Group, Subcommittee A-Cancer Centers (Parent Committee) NIH
2002-2014	Chair, Alliance Scientific Review Committee, Roswell Park Cancer Institute
2002-	Chair, CCSG Steering Committee, Roswell Park Cancer Institute
2003-2006	Chair, Scientific Advisory Committee, Ralph Wilson Medical Research Foundation
2004-2010	Member, DOD Prostate Cancer Consortium Scientific Oversight Committee, North Carolina
2004-	Chair, External Advisory Board, West Virginia Cancer Center, Morgantown, WV
2004-2008	Member, Scientific Advisory Council, University of Pittsburgh Cancer Institute, Pittsburgh, PA
2005-	Member, External Scientific Advisory Board, University of Kansas Cancer Center
2009-2012	Chair, External Advisory Board of the Cancer Institute of New Jersey
2010-	Member, Scientific Advisory Committee, Center for Immunotherapy, Roswell Park Cancer Inst.
2011-	Member, Internal Advisory Board, Roswell Park Cancer Institute Ovarian Cancer SPORE
2012-	Member, External Advisory Board of the Vermont Cancer Center
2013-2015	Member, American Association for Cancer Research Clinical and Translational Cancer Research Grants Scientific Review Committee.
2013-	Program Director, Program of Molecular Pharmacology, Roswell Park Division of Graduate School, University at Buffalo, Buffalo, NY
2013-	Member, Board of Directors, Health Research, Inc. (HRI)
2014-	Member, External Advisory Board for the Stony Brook Cancer Center, Stony Brook, NY
2014-	Member, Board of Directors, Catholic Health Systems
2014-	Member, STEM Advisory Board, Sacred Heart Academy, Buffalo, NY
2014-	Member, Board of Directors, Buffalo Translational Consortium (BTC)
2014-	Member, Board of Directors, Roswell Park Cancer Institute
2014-	Member, Board of Directors, Buffalo Niagara Medical Campus
2014-	Member, National Comprehensive Cancer Network (NCCN)

Honors:

2005	Wallace Chair in Translational Research
2010	Elected Fellow of the American Association for Advancement of Science
2010	University of Pittsburgh Innovator Award
2013	Medaille College Department of Communication, Excellence in Leadership Award
2013	Dr. Thomas B. Tomasi Hope Award

C. Contribution to Science

I have focused my studies on the pre-clinical development and design of more effective therapeutic approaches to cancer using mouse tumor model systems. Preclinical and clinical studies are predominantly in GU malignancies, both prostate and bladder. I have a wide variety of highly characterized and readily available murine syngeneic and human xenograft tumor models to evaluate therapeutic efficacy as well as to examine potential mechanisms of action. In addition, my research is translational as I provide the basic science interface to a number of clinical studies based on these studies.

1. I have been investigating the mechanisms of vitamin D-mediated anti-proliferative effects either alone or in combination with conventional cytotoxic agents. $1,25D_3$ shows broad spectrum anti-tumor activity *in vitro* and *in vivo*. It synergistically inhibits tumor growth with chemotherapeutic agents such as cisplatin and paclitaxel in various model systems.
   a) Hershberger PA, Modzelewski RA, Shurin ZR, Rueger RM, Trump DL, **Johnson CS.** 1,25-Dihydroxycholecalciferol (1,25-D3) inhibits the growth of squamous cell carcinoma and down-modulates p21(Waf1/Cip1) in vitro and in vivo. Cancer Res 1999; 59(11):2644-2649. PMID: 10363987.
   b) Hershberger PA, Yu W-D, Modzelewski RA, Rueger RM, **Johnson CS**, Trump DL. Calcitriol enhances paclitaxel antitumor activity in vitro and in vivo and accelerates paclitaxel-induced apoptosis. Clin Cancer Res 2001; 7(4):1043-1051. PMID: 11309356.
   c) Ma Y, Yu W-D, Hershberger PA, Flynn G, Kong R-X, Trump DL, **Johnson CS**. $1,25D_3$ potentiates the anti-tumor activity of cisplatin through increased p73 and enhanced apoptosis in squamous cell carcinoma model system. Mol Cancer Ther 2008; 7:3047-3055. PMC2587026.
   d) Luo W, Karpf AR, Deeb KK, Muindi JR, Morrison CD, **Johnson CS**, Trump DL. Epigenetic regulation of vitamin D 24-hydroxylase/CYP24A1 gene expression in human prostate cancer. Cancer Res 2010; 70(14):5953-5962. PMC2928678.

2. In addition to characterize the anti-tumor activity of vitamin D, I have elucidated the mechanisms of vitamin D anti-proliferative effects include the induction of cell cycle arrest and apoptosis in multiple model systems through the regulation of various pathways.
   a) Hershberger PA, Modzelewski RA, Shurin ZR, Rueger RM, Trump DL, **Johnson CS.** 1,25-Dihydroxycholecalciferol (1,25-D3) inhibits the growth of squamous cell carcinoma and down-modulates p21(Waf1/Cip1) in vitro and in vivo. Cancer Res 1999; 59(11):2644-2649. PMID: 10363987.
   b) McGuire TF, Trump DL, **Johnson CS**. Vitamin D_3 induced apoptosis of murine squamous cell carcinoma cells selective inductions of caspase-dependent MEK cleavage and up-regulation of MEKK-1*. J Biol Chem 2001; 276(28):26365-26373. PMID: 11331275.
   c) Hershberger PA, McGuire TF, Yu W-D, Zuhowski EG, Egorin MJ, Trump DL, **Johnson CS**. Cisplatin potentiates 1,2-dihydroxyvitamin D3-induced apoptosis. Mol Cancer Ther 2002; 1(10):821-829. PMID: 12492115.
   d) Ma Y, Yu W-D, Kong RX, Trump DL, **Johnson CS**. Role of Nongenomic Activation of Phosphatidylinositol 3-Kinase/Akt and Mitogen-Activated Protein Kinase/Extracellular Signal-Regulated Kinase Kinase/Extracellular Signal-Regulated Kinase 1/2 Pathway in 1,25D3-Mediated Apoptosis in Squamous Cell Carcinoma Cells. Cancer Res 2006; 66(16):8131-8138. PMID: 16912191.

3. Another area of my interest is the effect of glucocorticoids on vitamin D-mediated anti-tumor and anti-hypercalcemic effects through the vitamin D receptor (VDR). Our results show that dexamethasone potentiates the growth inhibitory effect of 1,25D3 through the induction of VDR transcription.
   a) Yu W-D, McElwain MC, Modzelewski RA, Russell DM, Smith DC, Trump DL, **Johnson CS**. Enhancement of 1,25-Dihydroxyvitamin D_3-mediated anti-tumor activity with dexamethasone. J Natl Cancer Inst 1998; 90(2):134-141. PMID: 9450573.
   b) Bernardi R, Trump DL, Yu W-D, McGuire TF, Hershberger PA, **Johnson CS**. Combination of 1,a,25-dihydroxyvitamin D3 with dexamethasone enhances cell cycle arrest and apoptosis: Role of nuclear receptor cross-talk and Erk/Akt signaling. Clin Cancer Res 2001; 7(12):4164-4173. PMID: 11751517.
   c) Trump DL, Potter DM, Muindi J, Brufsky A, **Johnson CS**. Phase II Trial of High Dose, Intermittent Calcitriol (1,25 dihydroxyvitamin D3) + Dexamethasone in Androgen Independent Prostate Cancer. Cancer 2006; 106(10):2136-2142. PMID: 16598750.
   d) Hidalgo AA, Deeb KK, Pike JW, **Johnson CS**, Trump, DL. Dexamethasone enhances 1α,25-dihydroxyvitamin D3 effects by increasing vitamin D receptor transcription. J Biol Chem 2011; 286(42): 36228-36237. PMC3196110.

4. Beyond the impact of vitamin D in cancer cells, additional contribution to the field is the isolation and characterization of tumor-derived endothelial cells with the potential to target for therapeutic intervention; and elucidating the mechanisms involved in the differential response of tumor-derived endothelial cells to vitamin D and steroids with therapeutic implications.

a) Modzelewski RA, Davies P, Watkins SC, Auerbach R, Chang MJ, **Johnson CS**. Isolation and identification of fresh tumor-derived endothelial cells from a murine RIF-1 fibrosarcoma. Cancer Res 1994; 54:336-339. PMID: 8275463.
b) Bernardi, RJ Modzelewski RA, Trump DL, **Johnson CS**. Anti-proliferative effects of 1α,25-dihydroxvitamin D_3 and vitamin D analogs on normal and tumor-derived murine endothelial cells. Endocrinology 2002; 143(7):2508-2514. PMID: 12072382.
c) Chung I, Wong MK, Flynn G, Yu W-D, **Johnson CS**, Trump DL. Differential anti-proliferative effects of calcitriol on tumor-derived and matrigel-derived endothelial cells. Cancer Res 2006; 66(17):8565-8573. PMID: 16951169.
d) Chung I, Yu W-D, Karpf AR, Flynn G, Bernardi RJ, Modzelewski RA, **Johnson CS**, Trump DL. Anti-proliferative effects of calcitriol on endothelial cells derived from two different microenvironments. J Steroid Biochem Mol Bio 2007; 103:768-770. PMID: 17368191.

5. Most recently, through the collaboration with other investigators, our studies have also focused on the identification of unique genomic targets in bladder cancer that predict response to certain chemotherapeutic drugs as well to design more effective therapeutic approaches to muscle invasive disease in bladder cancer.
   a) Ma Y, Yu W-D, Trump DL, **Johnson CS**. 1,25D_3 enhances antitumor activity of gemcitabine and cisplatin in human bladder cancer models. Cancer 2010; 116(13):3294-3303. PMC2891990
   b) Shen H, Morrison CD, Zhang J, Underwood W 3rd, Yang N, Frangou C, Eng K, Head K, Bollag RJ, Kavuri SK, Rojiani AM, Li Y, Yan L, Hill A, Woloszynska-Read A, Wang J, Liu S, Trump DL, **Johnson CS**. 6p22.3 amplification as a biomarker and potential therapeutic target of advanced stage bladder cancer. Oncotarget. 2013 Nov;4(11):2124-34. PMC3875774
   c) Morrison CD, Liu P, Woloszynska-Read A, Zhang J, Luo W, Qin M, Bshara W, Conroy JM, Sabatini L, Vedell P, Xiong D, Liu S, Wang J, Shen H, Li Y, Omilian AR, Hill A, Head K, Guru K, Kunnev D, Leach R, Eng K, Darlak C, Hoeflich C, Veeranki S, Glenn S, You M, Pruitt S, **Johnson CS**, Trump DL. Whole-genome sequencing identifies genomic heterogeneity at a nucleotide and chromosomal level in bladder cancer. PNAS 2014; 111(6):E672-681. PMC3926024
   d) Ma Y, Hu Q, Luo W, Pratt RN, Glenn ST, Liu S, Trump DL, **Johnson CS**.1α,25(OH)2D3 differentially regulates miRNA expression in human bladder cancer cells. J Steroid Biochem Mol Biol. 2015; 148: 166-171. PMC4361310.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/candace.johnson.1/bibliograpahy/40458126/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

P30 CA016056 Johnson (PI) 06/26/2014 – 04/30/2019
NIH/NCI
Cancer Center Support Grant
Roswell Park Cancer Institute's Cancer Center Support Grant (CCSG) includes 6 programs & 14 Cores. Support is provided for leadership, developmental funds, planning & evaluation, & administration. Two supplements focused on Experimental Therapeutics Clinical Trials Network (ETCTN) leadership and accrual are also active.
Role: Principal Investigator (*Effective 11/01/14)*

P30 CA016056 Johnson (PI) 06/16/2014 – 04/30/2019
NIH/NCI
Cancer Center Support Grant/CURE Supplement
The goals of the Continuing Umbrella of Research Experience (CURE) program at Roswell Park Cancer Institute are to: 1.Educate students about cancer biology, cancer medicine and cancer health disparities, 2.

Equip students with research, critical thinking and science communication skills, and 3. Encourage entry and retention into undergraduate and graduate biomedical training programs and cancer careers
Role: Principal Investigator (Project Lead: Adam Kisailus)

P30 CA016056 Johnson (PI) 06/16/2014 – 04/30/2019
NIH/NCI
Cancer Center Support Grant/Supplement "Enhancing Cancer Center Capacity to Meet the Needs of Diverse Communities in WNY"
The goal is to amplify our community outreach capacity within our CCSG under direction of our experienced CHE (Widman) to optimize delivery and dissemination of effective, culturally tailored, evidence-based cancer education, screening and treatment services and access to clinical research to diverse medically underserved communities in Buffalo and WNY.
Role: Principal Investigator (Project Lead: Deborah Erwin)

Completed Support:

P30 CA016056 Johnson (PI) 06/16/2014 – 08/31/2016
NIH/NCI
Cancer Center Support Grant/PDX Administrative Supplement
The funds support the provision of samples for PDX development at the NCI Frederick National Laboratory.
Role: Principal Investigator (Project Lead: Carl Morrison)

P01 CA151135 Ambrosone (PI) 08/01/2011 – 07/31/2016
NIH/NCI
Epidemiology of Breast Cancer Subtypes in African American Women: A Consortium
The overall goal of this Program Project is to pool data, samples & expertise from 4 of the largest studies of breast cancer in African-American women to identify genetic & non-genetic risk factors for early onset; basil-like breast cancers.
Role: Co-Investigator Project 4

T32 CA009072 Johnson (PI) 07/01/1978 – 01/31/2016
NIH/NCI
Drug Development & Cancer Treatment
The Molecular Pharmacology & Cancer Therapeutics (MPCT) Program provides students exposure to general/molecular pharmacology & multidisciplinary training, educational/career development training & lab research time contributing towards publication in peer reviewed journals. The MPCT program provides students with a high quality training experience as evidenced by its long track record of scientists that go on to be important contributors in cancer research.

R01 CA067267 Johnson (PI) 05/01/2095 – 04/30/2015
NIH/NCI
Anti-tumor mechanisms & therapeutic effects of vitamin D
The overall goal of this study is to examine the mechanisms of vitamin D anti-tumor activity either alone or in combination with platinum agents & to determine whether these effects can be exploited therapeutically in bladder cancer.

R01 CA095045 Johnson/Trump (PI) 09/01/2008 – 07/31/2013
NIH/NCI
Vitamin D in prostate cancer: tumor vasculature effects
The major goal of this study is to examine the effect of calcitriol both pre-clinically & clinically on tumor vasculature.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Guillermina (Gigi) Lozano, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): glozano

POSITION TITLE: Professor and Chair

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Pan American University, Edinburg, TX	B.S., Magna Cum Laude	07/1979	Biology/Mathematics
Rutgers University and the University of Medicine and Dentistry of New Jersey, Piscataway, NJ	Ph.D.	05/1986	Biochemistry
Princeton University, Princeton, NJ	Post-doc fellow	08/1987	Molecular Biology

A. Personal Statement

My laboratory has made major contributions to our understanding of the functions of the p53 tumor suppressor pathway in vivo. We identified Mdm2 and Mdm4 as critical regulators of p53 *in vivo* (Nature 378:203-206, 1995; Nat Genet 29:92-95, 2001). Other accomplishments include the generation of mice that showed that the ability of p53 to arrest the cell cycle and maintain chromosomal stability is as important as apoptosis in preventing tumorigenesis (Nat Genet 36:63 68, 2004), and mice with a common p53 missense mutation that indicated a gain-of-function phenotype (Cell 119:861-872, 2004). Other studies include the importance of Mdm2 in dampening ROS levels in hematopoietic stem cells (Cell Stem Cell 7:606-617, 2010), direct evidence that a single nucleotide polymorphism in Mdm2 predisposes mice to cancer (Cancer Cell 18:220-230, 2010) and that Wnt driven mutant p53 mouse breast tumors respond better than wild-type p53 tumors to chemotherapy (Cancer Cell 21:793-806, 2012). I have trained many undergraduate and allied health students (20), graduate students (28 plus 5 currently in the lab) and post-doctoral fellows (26 plus 3 currently in the lab). Many of my trainees run independent research programs in research institutes throughout the world. I believe in sharing the reagents my laboratory has generated so that science can move forward quickly and I have thus provided reagents to anyone who requests them; mice were shipped to more than 90 laboratories and mouse embryo fibroblasts to over 100 laboratories all over the world in the past 10 years. My program has been funded continuously by the NIH since 1988, shortly after I started my independent research program.

B. Positions and Honors

Positions and Employment:

1987-1988 Instructor, Department of Molecular Genetics, The University of Texas M. D. Anderson Hospital and Tumor Institute, Houston, TX
1987-present Member, The University of Texas Graduate School of Biomedical Sciences, Houston, TX
1988-1994 Assistant Professor, Department of Molecular Genetics, The University of Texas M. D. Anderson Cancer Center, Houston, TX
1994-1998 Associate Professor, Department of Molecular Genetics, The University of Texas M. D. Anderson Cancer Center, Houston, TX
1998-2006 Professor, Department of Molecular Genetics, The University of Texas M. D. Anderson Cancer Center, Houston, TX
2006-2008 Professor and Chair, Department of Cancer Genetics, The University of Texas M. D. Anderson Cancer Center, Houston, TX
2007-2008 Ad Interim Chair, Department of Molecular Genetics, The University of Texas M. D. Anderson Cancer Center, Houston, TX

2008-present Professor and Chair, Department of Genetics, The University of Texas MD Anderson Cancer Center, Houston, TX

Other Experience and Professional Memberships:

1998-2002 Mammalian Genetics Study Section, National Institutes of Health
2002-2007 Board of Scientific Counselors-Subcommittee B, National Institutes of Health
2005-2010 Scientific Advisory Committee, The Damon Runyon Cancer Research Foundation, Member
2007-2011 Board of Scientific Counselors, The Jackson Laboratory
2014-2017 Member (elected), Board of Directors, American Association of Cancer Research
2014-2017 Member, National Institutes of Health Council of Councils

Honors:

1990-1991 Outstanding Faculty Award, The University of Texas Graduate School for Biomedical Sciences
1992 Distinguished Alumnus Award, The University of Texas Pan American
1995 Dean's Teaching Excellence Award, The University of Texas Graduate School for Biomedical Sciences
2000-2004 Anise J. Sorrell Professorship, The University of Texas M. D. Anderson Cancer Center
2004-present Mattie Allen Fair Research Chair, The University of Texas M. D. Anderson Cancer Center
2011 Fellow, American Association for the Advancement of Science
2011 Minorities in Cancer Research Jane Cooke Wright Lectureship, American Association for Cancer Research
2012 UMDNJ-Graduate School of Biomedical Sciences Distinguished Alumnus Award, UMDNJ-Graduate School of Biomedical Sciences
2013 Women in Cancer Research Charlotte Friend Memorial Lectureship, American Association for Cancer Research
2014 Member, National Academy of Medicine (formerly the Institute of Medicine)
2015 Paul E. Darlington Mentoring Award, The Graduate School of Biomedical Sciences

C. Contributions to Science

My laboratory has made major contributions to our understanding of the functions of the p53 tumor suppressor, and to the characterization of critical regulators of the p53 pathway using animal models.

1. I established my independent research laboratory knowing that I wanted to work on the mouse as a tumor model. Since establishing the first transgenic facility at MD Anderson Cancer Center took time, I examined the p53 sequence for possible functions and thought that it might function as a transcription factor. We therefore established assays using fusions to the GAL4 DNA binding domain and showed that the p53 tumor suppressor had a potent transcriptional activation domain. In addition, we showed that several mutant p53 proteins were transcriptionally inactive.

   a) Raycroft L, Wu HY, **Lozano G**. (1990) Transcriptional activation by wild-type but not transforming mutants of the p53 anti-oncogene. Science 249(4972):1049-1051.
   b) Raycroft L, Schmidt JR, Yoas K, Hao MM, **Lozano G**. (1991) Analysis of p53 mutants for transcriptional activity. Mol Cell Biol 11(12):6067-6074.
   c) Hao M, Finlay CA, **Lozano G**. (1993) A functionally inactive p53 Li-Fraumeni syndrome mutant. Oncogene 8(2):299-306.

2. The first mouse we generated was one with loss of *Mdm2*. Mdm2 had just been identified as an inhibitor of p53 transcriptional activity that was amplified in sarcomas. *Mdm2*-null mice are embryo lethal and we tested whether the lethality was due to unleashed p53 activity. To our surprise *Mdm2*/*p53* double null mice are viable. Loss of *p53* completely rescued the *Mdm2*-null lethal phenotype. We have since shown that *Mdm4* loss also leads to p53-dependent lethal phenotypes. Moreover, Mdm2 and Mdm4 form heterodimers and this interaction is also crucial for inhibition of p53 function. Lastly, we showed that the feedback loop (p53 transcriptionally upregulates Mdm2) was not important for normal development, but was critical to return p53 levels to baseline after its activation in response to stress. Thus, through a series of knockouts and conditional alleles, we established the *in vivo* significance of inhibiting p53 function.

a) Montes de Oca Luna R, Wagner DS, **Lozano G**. (1995) Rescue of early embryonic lethality in mdm2-deficient mice by deletion of p53. Nature 378(6553):203-206.
b) Parant J, Chavez-Reyes A, Little NA, Yan W, Reinke V, Jochemsen AG, **Lozano G.** (2001) Rescue of embryonic lethality in Mdm4-null mice by loss of Trp53 suggests a nonoverlapping pathway with MDM2 to regulate p53. Nat Genet 29:92-95.
c) Pant V, Xiong S, Iwakuma T, Quintas-Cardama A, **Lozano G**. (2011) Heterodimerization of Mdm2 and Mdm4 is critical for regulating p53 activity during embryogenesis but dispensable for p53 and Mdm2 stability. Proc Natl Acad Sci USA 108(29):1995-2000. PMC3141986
d) Pant V, Xiong S, Jackson JG, Post SM, Abbas HA, Quintas-Cardama A, Hamir AN, **Lozano G**. (2013) The p53-Mdm2 feedback loop protects against DNA damage by inhibiting p53 activity but is dispensable for p53 stability, development and longevity. Genes Dev 27:1857-1867. PMC3778240.

3. Data in the literature also suggested that different p53 mutants varied in their activities, the most intriguing of which was a rare p53 missense mutation first identified in humans that distinguishes the cell cycle arrest from apoptotic pathways. A knockin mouse model of this mutation showed that the ability of p53 to arrest the cell cycle and maintain chromosomal stability is as important as apoptosis in preventing tumorigenesis. Moreover, this mutant exhibits a senescence phenotype which was also tumor suppressive in a lymphoma model. Lastly, this mutant could partially rescue the *Mdm2*-null phenotype and these studies showed the importance of Mdm2 in dampening p53 levels induced by ROS in hematopoietic stem cells.

a) Liu G, Parant JM, Lang G, Chau P, Chavez-Reyes A, El-Naggar AK, Multani A, Chang S, **Lozano G.** (2004) Chromosome stability, in the absence of apoptosis, is critical for suppression of tumorigenesis in Trp53 mutant mice. Nat Genet 36(1):63-68.
b) Barboza JA, Liu G, Ju Z, El-Naggar AK, **Lozano G.** (2006) p21 delays tumor onset by preservation of chromosomal stability. Proc Natl Acad Sci U S A 103(52):19842-19847.
c) Post SM, Quintas-Cardama A, Terzian T, Smith C, Eischen CM, **Lozano G.** (2010) p53-dependent senescence delays Eμ-myc induced B-cell lymphomagenesis. Oncogene 29(9):1260-1269. PMC2903442
d) Abbas HA, Maccio DR, Coskun S, Jackson JG, Hazen AL, Sills TM, You MJ, Hirschi KK, **Lozano G.** (2010) Mdm2 is required for survival of hematopoietic stem cells/progenitors via dampening of ROS-induced p53 activity. Cell Stem Cell 7(5):606-617. PMC3026610.

4. We also examined the *in vivo* significance of GOF activity of p53 mutant proteins by generating knockin mice with a common p53 missense mutation. These mice clearly exhibited a gain-of-function phenotype in the genesis of metastatic tumors and in tumor cells via inhibition of p53 family members, p63 and p73. We also discovered that mutant p53 is inherently unstable, is stabilized by the same signals as wild type p53, and that tumor specific alterations stabilize mutant p53.

a) Lang GA, Iwakuma T, Suh YA, Liu G, Rao VA, Parant JM, Valentin-Vega YA, Terzian T, Caldwell LC, Strong LC, El-Naggar AK, **Lozano G.** (2004) Gain-of-function of a p53 hot spot mutation in a mouse model of Li-Fraumeni syndrome. Cell 119(6):861-872. PMC15607981
b) Terzian T, Suh YA, Iwakuma T, Post SM, Neumann M, Lang GA, Van Pelt CS, **Lozano G**. (2008) The inherent instability of mutant p53 is alleviated by Mdm2 or p16INK4a loss. Genes Dev 22(10):1337-1344. PMC2377188
c) Suh YA, Post SM, Elizondo-Fraire AC, Maccio DR, Jackson JG, El-Naggar AK, Van Pelt C, Terzian T, **Lozano G**. (2011) Multiple stress signals activate mutant p53 in vivo. Cancer Res 71(23):7168-7175. PMC3320147
d) Xiong S, Tu H, Kollareddy M, Pant V, Li Q, Zhang Y, Jackson JG, Suh YA, Elizondo-Fraire AC, Yang P, Chau G, Tashakori M, Wasylishen AR, Ju Z, Solomon H, Rotter V, Liu B, El-Naggar AK, Donehower LA, Martinez LA, **Lozano G.** (2014) Pla2g16 phospholipase mediates gain-of-function activities of mutant p53. Proc Natl Acad Sci USA 111(30):11145-11150. PMC4121829

5. We have also explored the clinical implications of restoring p53 activity in different contexts using a hypomorphic *p53* allele that restores *p53* gene function upon Cre-mediated recombination. Restoration of p53 has different effects in different contexts. Restoring p53 in tumors that lack *p53* causes tumor regression. Restoring p53 in a mutant p53 background or in tumors with amplified Mdm2 promotes

suppresses tumor growth but does not cause tumor regression. These data highlight the importance of context in p53 response.

a) Wang Y, Suh YA, Fuller MY, Jackson JG, Xiong S, Terzian T, Quintas-Cardama A, Bankson JA, El-Naggar AK, **Lozano G**. (2011) Restoring expression of wild-type p53 suppresses tumor growth but does not cause tumor regression in mice with a p53 missense mutation. J Clin Invest 121(3):893-904. PMC3049366
b) Li Q, Zhang Y, El-Naggar AK, Xiong S, Yang P, Jackson JG, Chau G, **Lozano G**. (2014) Therapeutic efficacy of p53 restoration in Mdm2-overexpressing tumors. Molecular Cancer Research 12:901-911. PMC4058386
c) Jackson JG, Pant V, Li Q, Chang LL, Quintas-Cardama A, Garza D, Tavana O, Yang P, Manshouri T, Li Y, El-Naggar AK, **Lozano G**. (2012) p53 mediated senescence impairs the apoptotic response to chemotherapy and clinical outcome in breast cancer. Cancer Cell 21:793-806. PMC3376352
d) Zhang Y, Xiong S, Li Q, Hu S, Tashakori M, Van Pelt C, You MJ, Pageon L, **Lozano G**. (2014) Tissue-specific and age-dependent effects of global Mdm2 loss. Journal of Pathology 233:380-391. PMC4151977.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/myncbi/browse/collection/41146342/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

R01 CA82577 Lozano (PI) 09/01/1999 - 12/31/2019
NIH/NCI
Role of p53 Missense Mutations of Tumorigenesis in Vivo
The goal of this project is to characterize a novel somatic model of p53 mutation to study the importance of a normal stroma and the immune system in breast cancer initiation, and progression.

R01 CA47296 Lozano (PI) 07/01/1988 - 11/30/2016
NIH/NCI
A Pathway of Tumor Suppression
The goal of this project is to focus on the regulation of wild-type p53 by its inhibitors Mdm2 and Mdm4.

P30 CA016672 DePinho (PI) 07/01/2013 - 06/30/2018
NIH/NCI
Cancer Center Support Grant, Cancer Genetics and Epigenetics
The goal of this project is to provide support for broad cancer center based programmatic activities in Genetics and Epigenetics.
Role: Co-Director

P30 CA016672 DePinho (PI) 07/01/2013 - 06/30/2018
NIH/NCI
Cancer Center Support Grant, Genetically Engineered Mouse Facility (GEMF)
The goal of this project is to provide support for the facility that generates genetically modified mice for the institution.
Role: Director

P30 CA016672 DePinho (PI) 07/01/2013 - 06/30/2018
NIH/NCI
Cancer Center Support Grant, Sequencing and Microarray Facility (SMF)
The goal of this project is to provide support for the sequencing and microarray core facility for the institution.
Role: Co-Director

RP130054 Krahe (PI) 06/01/2013 - 11/30/2016
CPRIT IIRA
Genes and Pathways Cooperating with p53 in LFS Tumorigenesis
The goal of this project is to understand the interactions between *p53* as a predisposing gene and subsequent cooperating somatic alterations, both genetic and epigenetic, and how they contribute to the cancer spectrum in LFS, especially sarcomas.
Role: Collaborator

Neuroendocrine Tumor Research Foundation Lozano (PI) 02/01/2016 - 01/31/2018
NETRF
The Mechanistic Underpinnings of Pancreatic Neuroendocrine Tumors
The major goal of this project is to generate and characterize mouse models which will lead to a better understanding of the role of *Daxx* in normal tissue homeostasis and how *Daxx* loss contributes to pancreatic neuroendocrine tumorigenesis.

Completed Support:

T32 CA009299 Lozano (PI) 09/30/1978 - 06/30/2016
NIH/NCI
Training Program in Molecular Genetics of Cancer
The goal of this training grant is to provide salary support for pre-doctoral and post-doctoral fellows for the 24 faculty in the program.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Alfred I. Neugut, MD, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): ain1@columbia.edu

POSITION TITLE: Myron M. Studner Professor of Cancer Research, Professor of Medicine and Epidemiology

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Columbia College, New York, NY	B.A.	1972	Chemistry
Columbia University College of Physicians & Surgeons	M.D.	1977	Medicine
Columbia University GSAS	Ph.D.	1977	Pathobiology
Columbia School of Public Health, New York, NY	M.P.H.	1983	Epidemiology
Bronx Municipal Hospital Center, NY	Residency	1980	Internal Medicine
Memorial Sloan Kettering Cancer Center, New York	Fellowship	1981	Medical Oncology
Columbia-Presbyterian Medical Center, New York, NY		1983	

A. Personal Statement

I am trained as a practicing medical oncologist, cancer epidemiologist, and health outcomes researcher, with an extensive background in academic research in cancer-related population sciences. I have held leadership and administrative positions as head of the Prevention, Control, and Disparities Program at the Herbert Irving Comprehensive Cancer Center at Columbia, and have served for a number of years as Associate Director for Population Sciences. I have also served as a consultant to several NCI-funded cancer centers to advise regarding their population science programs, and have been on numerous site visits for NCI. I also served for 4 years as interim Head of Hematology/Oncology at Columbia. I have mentored numerous predoctoral and postdoctoral trainees who have gone on to success in academia, as well as 16 junior faculty with K or equivalent mentored awards. My own research has focused on the epidemiology and health outcomes research of GI cancers and breast cancer, and I have published over 450 peer-reviewed manuscripts. We have addressed quality of care, especially receipt of appropriate therapy, treatment adherence, long term adverse effects, with a focus on patient, clinical, physician and hospital predictors of poor and good quality. I have been PI of a large case-control study of adenomatous polyps, co-PI of the Long Island Breast Cancer Study Project, PI of a DOD breast cancer center of excellence award, and PI of the Breast Cancer Quality of Care Study (BQUAL), all of which have been highly productive. For the past 10 years I have also been involved in global health with extensive efforts in South Africa and other sub-Sharan countries. We currently have a large multi-center study of HIV and breast cancer underway in South Africa (the SABCHO study), another study looking at end-of-life and terminal care practices in Soweto, and a third study looking at HIV and prostate cancer. I have studied breast cancer and colon cancer etiology and natural history and especially with regard to behavioral and emotional characteristics. I am past president and secretary-treasurer of ASPO and have served on their Executive Committee for more than a decade. I also founded the New Investigators Workshop for ASPO. I am on the Program Committee for the upcoming meeting.

B. Positions and Honors

Positions and Employment:

1983-1985 Assistant Professor of Medicine, Columbia University, NY
1985-1991 Assistant Professor of Medicine and Public Health (Epidemiology), Columbia Univ., NY
1989-1991 Deputy Director for Cancer Epidemiology and Prevention, Comprehensive Cancer Center, Columbia, New York, NY

1989-1998 Co-Director, Oncology Outpatient Unit, Presbyterian Hospital, NY
1991-1998 Associate Professor of Clinical Medicine and Public Health (Epidemiology), Columbia University
1991- Head, Program on Cancer Prevention and Control, Herbert Irving Comprehensive Cancer Center, Columbia University
1993-2008 Associate Attending Physician, Harlem Hospital Center, NY
1998-1999 Associate Professor of Medicine and Public Health (Epidemiology), Columbia University
1999-2001 Professor of Medicine and Public Health (Epidemiology), Columbia University
2001- Professor of Medicine and Epidemiology, Columbia University
2003-2007 Interim Head, Division of Medical Oncology-Hematology, Columbia University Medical Center
2004- Associate Director for Population Sciences, Herbert Irving Comprehensive Cancer Center, NY
2005- Myron M. Studner Professor of Cancer Research in Medicine
2014- Director of Faculty Development, Dept. of Epidemiology, Mailman School of Public Health, NY

Honors and Awards:

1972-1977 Medical Scientist Training Program, Columbia P & S
1981-1990 Mellon Fellow in Epidemiology and Medicine, Columbia School of Public Health and Department of Medicine, Presbyterian Hospital
1984-1986 Junior Faculty Fellow of the American Cancer Society, Columbia University,
1994-1999 Secretary-Treasurer, American Society of Preventive Oncology
1999-2001 President, American Society of Preventive Oncology
2011- Member, External Advisory Committee, University of Kansas Cancer Center
2008- Member, External Scientific Advisory Committee, Lombardi Comprehensive Cancer Center,
2015- NCORP Minority/Underserved site representative to the NCI Cancer Care Delivery Research Steering Committee.
2009- Guest lecturer, Cancer Epidemiology. French School of Public Health (Ecole Hautes d'Etudes Sante Publique), Paris France.
2014- Consultant, Population Sciences Programs, University of Maryland Greenbaum Cancer Center
2016 Recipient of the Joseph A. Fraumeni Jr. Distinguished Achievement Award of the American Society of Preventive Oncology

C. Contributions to Science

1. My initial contributions to science were in the study of the epidemiology and risk factors for adenomatous polyps. I conducted the first case-control study of adenomas and published a series of papers on dietary, tobacco and alcohol, genetic, and other risk factors for adenomas. These studies also looked at the recurrence rates of adenomas.
   a) **Neugut AI**, Johnsen C, Fink D. Serum cholesterol levels in adenomatous polyps and cancer of the colon: A case-control study. JAMA 255:365-367, 1986.
   b) **Neugut AI**, Lee WC, Garbowski GC, Waye JD, Forde KA, Treat MR, Fenoglio-Preiser C. Obesity and colorectal adenomatous polyps. JNCI 83:359-361, 1991.
   c) **Neugut AI,** Garbowski GC, Lee WC, Murray T, Nieves JW, Forde KA, Treat MR, Waye JD, Fenoglio-Preiser C. Dietary risk factors for the incidence and recurrence of colorectal adenomatous polyps: a case-control study. Ann Int Med 118:91-95, 1993.
   d) Ahsan H, **Neugut AI**, Garbowski GC, Jacobson JS, Forde KA, Treat MR, Waye JD. Family history of colorectal adenomatous polyps and increased risk for colorectal cancer. Ann Int Med 128;900-905, 1998.

2. The study of adenomas led to a focus on the use of endoscopy, especially colonoscopy, for diagnosis and screening in the colon. I published the first paper to suggest the use of colonoscopy to screen average risk asymptomatic individuals, and over the years have followed that papers with various other important papers on its use and the use of FOBT for screening.
   a) **Neugut AI**, Forde KA. Screening colonoscopy - Has the time come? Am J Gastroenterol 83:295-297, 1988.

b) Lautenbach E, Forde KA, **Neugut AI**. Colonoscopic surveillance following curative resection of colorectal cancer. Ann Surg 220:206-211, 1994.
c) Gatto NM, Frucht H, Sundararajan V, Jacobson JS, Grann VR, **Neugut AI.** Risk of perforation following colonoscopy and sigmoidoscopy: a population-based study. J Natl Cancer Inst, 95:230-236, 2003.
d) **Neugut AI,** Lebwohl B. Colonoscopy versus sigmoidoscopy screening: getting it right. JAMA 304:461-462, 2010. Doi: 10.1001/jama.2010.1001. PMID: 20664047 (PMC# not required; not NIH funded)

3. In the late 1980's, I became interested in multiple primary cancers and published probably 40 or more papers on the incidence of second primary cancers in various circumstances. A particular interest was the effect of radiotherapy on the occurrence of second malignancies. Several papers showed that breast cancer RT increased the risk of lung cancer, especially in prior smokers, as well as of esophageal carcinoma, and that prostate cancer radiotherapy increased the risk of subsequent bladder cancer.
   a) **Neugut AI,** Robinson E, Nieves J, Murray T, Tsai W-Y. Poor survival of treatment-related acute non-lymphocytic leukemia. JAMA 264:1006-1008, 1990.
   b) **Neugut AI**, Ahsan H, Robinson E, Ennis RD. Bladder carcinoma and other second malignancies after radiotherapy for prostate cancer. Cancer 79:1600-1604, 1997.
   c) Ahsan H, **Neugut AI.** Radiation therapy for breast cancer and increased risk of esophageal carcinoma. Ann Int Med 128:114-117, 1998.
   d) Kaufman EL, Jacobson JS, Hershman DK, Desai M, **Neugut AI**. Effect of breast cancer radiotherapy and cigarette smoking on risk of second primary lung cancer. J Clin Oncol 26:392-398, 2008. PMID: 18202415.

4. A more recent area of interest has been health outcomes research with a focus on quality of care. Who is not receiving proven chemotherapy or radiotherapy, why not, and are there delays or other problems with its administration? This area of research has focused on such barriers as disparities due to age, race/ethnicity, socioeconomic status including co-payments and net worth, and comorbidities. How these problems have led to worse outcomes has also been explored, including survival and long term toxicities.
   a) Sundararajan V, Mitra N, Grann VR, Jacobson JS, Heitjan DF, **Neugut AI**. Survival associated with 5-fluorouracil-based adjuvant chemotherapy among elderly patients with node-positive colon cancer. Ann Int Med 136:349-357, 2002.
   b) **Neugut AI**, Clarke Hillyer G, Kushi LH, Lamerato L, Leoce, N, Nathanson SD, Ambrosone CB, Bovbjerg D, Mandelblatt JS, Magai C, Tsai WY, Jacobson JS, Hershman DL. Non-initiation of adjuvant chemotherapy in women with localized breast cancer: the Breast Cancer Quality of Care Study (BQUAL). J Clin Oncol 30:3800-3809, 2012. PMC3478575
   c) Winner M, Mooney SJ, Hershman DL, Feingold DL, Allendorf JD, Wright JD, **Neugut AI**. Incidence and predictors of bowel obstruction in stage IV colon cancer patients: a population-based cohort study. JAMA Surgery 148:715-722, 2013. PMC4507521

5. Following on the prior topic, a more focused area of interest has been treatment adherence. We have studied the occurrence and predictors of early discontinuation of adjuvant breast and colon cancer adjuvant therapy and its effect on survival outcomes. We also have in progress a large randomized trial to determine whether text messaging may improve adherence for breast cancer patients receiving aromatase inhibitor adjuvant therapy.
   a) **Neugut AI**, Matasar M, Wang X, McBride R, Jacobson JS, Grann VR, Hershman DL. Early discontinuation of adjuvant chemotherapy for colon cancer and its impact on survival. J Clin Oncol 24:2368-2375, 2006.
   b) Hershman DL, Kushi LH, Kershenbaum A, Shaw T, Tsai WY, Gormen SK, Miles S, **Neugut AI**. Early discontinuation and non-adherence to adjuvant hormonal therapy in a cohort of 8769 early stage breast cancer patients. J Clin Oncol 28:4120-4128, 2010. PMC2953970.
   c) **Neugut AI,** Subar M, Wilde ET, Stratton SM, Brouse CH, Hillyer GC, Grann VR, Hershman DL. Association between prescription copayment amount and compliance with adjuvant hormonal therapy in women with early stage breast cancer. J Clin Oncol 29:2534-2542, 2011. PMC3138633.

d) Hershman DL, Shao T, Kushi LH, Buono D, Tsai WY, Fehrenbacher L, Kwan M, Gomez SL, **Neugut AI.** Early discontinuation and non-adherence to adjuvant hormonal therapy and mortality in women with breast cancer. Breast Cancer Res Treat 126:529-537, 2011. PMC3462663.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/alfred.neugut.1/bibliography/43843328/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

BC043120 Neugut (PI) 05/20/2005 - 06/20/2017
DOD
Racial Disparities in the initiation and intensity of adjuvant therapy for breast cancer
Racial Disparities in the initiation and intensity of adjuvant therapy for breast cancer in women (900 black, 900 white) with breast cancer. We will focus on the following: referral to oncologist, acceptance of referral, missed appointments or treatment cycles, etc. We will also identify racial differences in the distribution of these barriers.

R25 CA94061 Neugut (PI) 09/12/2012 - 08/31/2017
NCI
Training Program in Cancer Related-Populations Sciences
To develop specialized curricula and academic programs that encompass the behavioral sciences and social epidemiology.

P30 CA13696 Emerson (PI) 07/01/2003 - 06/30/2019
NCI
Cancer Center Support Grant
To support cancer research within the different Comprehensive Cancer Center's Core facilities (Head, Cancer Prevention and Control; Associate Director for Population Sciences).

P30 CA13696 Emerson (PI) 07/01/2015 - 06/30/2017
NCI (Supplement PI Neugut)
Administrative Supplement to Promote Cancer Prevention and Control Research in Low and Middle Income Countries
Palliative care and end-of-life issues among cancer patients in Soweto, South Africa
Within 5 years, low- and middle-income countries are expected to account for ~70% of the projected 20 million new cancer cases/year worldwide. Most cancers will be diagnosed at late stages, in settings where treatment facilities are minimal. In these settings, understanding palliative and end-of-life care needs may be the key to developing low-cost interventions to improve quality of life for cancer patients.

R01 CA169121 Wright (PI) 01/01/2013 - 12/31/2017
NCI
The Influence of Hospital Variability on the Management of Cancer-Associated Complications
This grant will explore how hospital factors (size, procedure volume, etc.) influence complications of cancer care and how it affects the attempts to rescue from these complications.

R01 CA166084 Hershman (PI) 02/15/2013 - 01/31/2017
NCI
Using SWOG-Medicare Database to Evaluate Long-Term Toxicities of Cancer Survivors
This proposal will evaluate long-term outcomes in patients treated on trials within SWOG on whom detailed information on chemotherapy use is available.

UM1 CA189960 Kelly, Neugut, Lassman (PIs) 08/01/2014 - 07/31/2019
NCI
Columbia University Minority/Underserved Site NCI Community Oncology Research Program
This is a community based program to serve the research needs of the community through the Herbert Irving Comprehensive Cancer Center. It will provide for minority recruitment to clinical trials, association with cooperative trial groups, and population based research efforts within the catchment area of the Cancer Center.

Brain Tumor Foundation Neugut (PI) 09/01/2014 - 08/31/2017
Brain Tumor Early Detection Study
This study in conjunction will conduct 3000 brain MRIs on asymptomatic adults nationwide to determine the prevalence of pathologic findings, in particular those of benign and malignant brain tumors. This will contribute to our understanding of whether radiologic procedures may have a role in future efforts at brain tumor early detection.

R01 CA192627 Joffe, Neugut, Ruff, Jacobson(PIs) 07/15/2015 - 06/30/2020
NCI
HIV's Effects on Breast Cancer Treatment and Outcomes in South Africa
This is a collaborative project between investigators at Columbia and the University of Witwatersrand in Johannesburg to expand a cohort study of breast cancer patients to 6 collaborating hospitals throughout South Africa to collect 4000 breast cancer patients of whom one-fifth will be HIV-positive and to investigate its impact on breast cancer treatment, outcomes and natural history.

ACS Ladas (PI) 01/01/2015 - 12/31/2019
American Cancer Society – Mentored Research Scholar
Dietary intake and obesity in children with acute lymphoblastic leukemia
This project is exploring fluctuations in macronutrients over the course of therapy in children with acute lymphoblastic leukemia.
Role: Mentor

NYS Dept of Health Neugut (PI) 01/01/2016 - 12/31/2017
Prostate Cancer Hypothesis Development Grant
Impact of HIV on the burden of prostate cancer in South Africa
This grant is investigating the impact of HIV on the natural history of prostate cancer in Soweto.

Completed Support:

Improving Cancer Care Neugut (PI) 07/01/2011 - 06/30/2016
Conquer Cancer Foundation, ASCO-Komen
Text Messaging to Reduce Early Discontinuation of Adjuvant Hormonal Therapy in Breast Cancer: A Randomized Trial
To test the efficacy of a text message reminder to reduce early discontinuation of aromatase inhibitor adjuvant therapy in a randomized trial among postmenopausal women with breast cancer.

American Cancer Society Neugut (PI) 07/01/2012 - 06/30/2016
The Relationship between Insurance and Cancer-related Prescription Drug Use
To study the effects of co-payments and deductibles on the choices patients make among cancer-related drugs using a database from a pharmacy manager.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Timothy R. Rebbeck, PhD, AM**

eRA COMMONS USER NAME (credential, e.g., agency login): Rebbeck

POSITION TITLE: Professor of Epidemiology, Harvard TH Chan School of Public Health, Dana Farber Cancer Institute

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Northwestern University, Evanston, IL	B.A.	06/1984	Biology
The Johns Hopkins University, Baltimore, MD	M.Sc.	06/1986	Epidemiology
The University of Michigan, Ann Arbor, MI	Ph.D.	01/1991	Human Genetics
University of Michigan, Ann Arbor, MI	A.M.	01/1991	Statistics

A. Personal Statement

I am a Professor of Cancer Epidemiology, at the Harvard TH Chan School of Public Health and Dana Farber Cancer Institute. My research focuses on the genetic and molecular epidemiology of cancer. I have directed multiple molecular epidemiologic studies and international consortia to identify and characterize genes that are candidates for involvement in cancer etiology, and to describe the relationship of allelic variation with biochemical or physiological traits, cancer occurrences, and cancer outcomes. My research also focuses on the roles of these factors on prostate cancer disparities and prostate cancer in Africa. My research uses a multidisciplinary approach that combines methods from epidemiology, statistics, molecular biology, and classical genetics.

B. Positions and Honors

Positions and Employment:

1994-1999 Assistant Professor of Epidemiology University of Pennsylvania, Philadelphia
1999-2004 Associate Professor of Epidemiology University of Pennsylvania, Philadelphia
2004-2015 Professor of Epidemiology, University of Pennsylvania, Philadelphia
2006-2015 Director, Center for Genetics and Complex Traits, University of Pennsylvania, Philadelphia
2007-2015 Associate Director for Population Science, Abramson Cancer Center, Philadelphia
2015-present Professor of Cancer Epidemiology, Harvard TH Chan School of Public Health, Boston, MA

Honors:

1993-1996 Preventive Oncology Academic Award
1998 CapCure Prostate Cancer Research Award
2008 Potamkin Award for Breast Cancer Research
2011-2016 Fulbright Specialist Award

C. Contributions to Science

Dr. Rebbeck has developed studies to address the causes and prevention of prostate cancer and cancer disparities:

- "Study of Clinical Outcomes, Risk and Ethnicity" (SCORE) is an ongoing, large-scale epidemiological study to evaluate risk factors for prostate cancer, with a focus on genetic markers of etiology and outcomes in African, African American, and European American men. This research began in 1994 as part of Dr. Rebbeck's Cancer Prevention Academic Award from the NCI, and has since grown to

include studies of prostate cancer outcomes as well as etiology.

- "Men of African Descent and Carcinoma of the Prostate" (MADCaP) involves 28 centers and over 15,000 men of African descent in North America, the Caribbean, Europe, and Africa to address the global epidemic of prostate cancer in the African diaspora. As a part of this work, Dr. Rebbeck received the 2011 Landon Award for International Research for the development of this consortium and its research, and was named a Fulbright Specialist to develop cancer research centers of excellence in Africa in the period 2011-2016. Additional information about MADCaP can be found at: http://madcap-africa.wix.com/madcap.

1. **Genetic Susceptibility**

Dr. Rebbeck has used the SCORE and MADCaP studies to evaluate the role of inherited genetic susceptibility in prostate cancer. His work has examined the role of genes involved in inherited susceptibility to prostate cancer, including those that regulate the metabolism of environmental carcinogens and steroid hormones in prostate cancer etiology. These genes include the *HPC2* gene found on Chromosome 17, and hormone metabolism genes including cytochromes P450 (e.g. *CYP3A4*), androgen metabolism genes (e.g., 5-alpha reductase type II). The relationship of each of the candidate genes and of multiple candidate genes and the occurrence or age of onset of prostate cancer examined. Endogenous and/or exogenous exposures and the interaction of multiple candidate genes, environments, and exposures have been examined. His contributions in this area include the discovery of one of the first genetic loci associated with aggressive prostate cancer (Rebbeck et al., *JNCI*, 1998, Jaffe et al. *Cancer Research*, 2000). He has since identified other loci associated with prostate cancer, including validation of these loci in African descent populations (Chang et al. *Cancer Epi Biom Prev* 2011). He has also contributed SCORE and MADCaP data and expertise to numerous prostate cancer GWAS studies. In recognition of this research, Dr. Rebbeck was awarded the Prostate Cancer Research Award by Association for the Cure of Cancer of the Prostate (CaPCURE).

a) **Rebbeck TR,** Jaffe JM, Walker AH, Wein AJ, Malkowicz SB. Modification of clinical presentation of prostate tumors by a novel genetic variant in CYP3A4. *J Natl Cancer Inst.* 1998;90(16):1225-1229.
b) Jaffe JM, Malkowicz SB, Walker AH, **Rebbeck TR,**et al. Association of SRD5A2 genotype and pathological characteristics of prostate tumors. *Cancer Research.* 2000;60(6):1626-1630.
c) Chang BL, Spangler E, Gallagher S, **Rebbeck TR,**et al. Validation of genome-wide prostate cancer associations in men of African descent. *Cancer Epidemiol Biomarkers Prev.* 2011;20(1):23-32. PMC3110616

2. **Multilevel Studies**

Prostate cancer etiology and outcomes are a consequence of both biological and non-biological events. Using the SCORE database, Dr. Rebbeck has developed studies that integrate genetic, biological, individual, and neighborhood-level data to better understand the complex, multifactorial effects that influence prostate cancer. Ongoing research includes the contextual effects of neighborhood-level effects (i.e., a surrogate for lifestyle, demographics, and exposure) on the relationship of genetic susceptibility and prostate cancer outcomes (Rebbeck et al. *Cancer Epi Biom Prev* 2010). Using the MADCaP consortium, Dr. Rebbeck has developed national collaborative studies of the effect of genes and environments on prostate cancer outcomes. In part, this work will elucidate the biological and non-biological reasons for the disparity in prostate cancer etiology and outcomes. Dr. Rebbeck's work currently focuses on the role of environmental stressors on telomere function, and the role of stress and telomere metrics on prostate cancer risk and outcomes. This work involves a national consortium of centers that have collected common data on neighborhood, individual, and biological measures of stress and stress response.

a) **Rebbeck TR**, Weber AL, Walker AH, et al. Context-dependent effects of genome-wide association study genotypes and macroenvironment on time to biochemical (prostate specific antigen) failure after prostatectomy. *Cancer Epidemiol Biomarkers Prev.* 2010;19(9):2115-2123. PMC2972664

3. **Biomarkers of Outcome**

Developing research by Dr. Rebbeck uses ongoing prospective follow-up in the SCORE study case-cohort and the MADCaP study to evaluate factors that predict aggressive disease and unfavorable outcomes using genotypes, tumor biomarkers, and clinical information. In particular, this work involves evaluation of African descent men, who have the most unfavorable clinical outcomes of any group after a prostate cancer diagnosis.

Dr. Rebbeck has developed collaborations with Dr. Kosj Yamoah (Thomas Jefferson University), Dr. Edward Schaeffer (Johns Hopkins University), and GenomeDx to develop molecular signatures of prostate cancer aggressiveness and outcome. This work asks whether molecular signatures provide additional predictive value beyond clinical parameters for prostate cancer outcomes in African descent men.

a) Yamoah K, Johnson M, Choeurng V, Yousefi K, Haddad Z, Den R, Lal P, Feldman M, Dicker A, Klein EA, Davicioni E, **Rebbeck TR***, Schaeffer EM* (2015) A novel biomarker signature which may predict aggressive disease in African-American men with prostate cancer, *Journal of Clinical Oncology*, In Press. (*Equal author contributions)

Complete list of Published Work in MyBibliography: http://www.ncbi.nlm.nih.gov/sites/myncbi/1dq2n9pC-oxA6/bibliography/47758039/public/?sort=date&direction=ascending

D. Research Support

Ongoing Support:

P60 MD006900 Rebbeck,T (PI) 08/27/2012 - 02/28/2017
NIH
Center of Excellence
This Center of Excellence (COE) is being submitted to address significant gaps in our knowledge about disparities prostate cancer (PCa) outcomes, and to develop interventions that can be applied to reduce these disparities between African (AA) and European (EA) Americans in Philadelphia. The mission of the proposed center is to (1) undertake research that will identify biological, behavioral, social, environmental, geospatial, physical environmental, and health care factors that influence PCa outcomes, and (2) integrate, evaluate, and disseminate this information to at-risk populations in Philadelphia communities.

P30 AI045008 Hoxie,J (PI) 07/01/2014 – 06/30/2019
NIH
Center For AIDS Research
CFAR provides administrative and shared research support to synergistically enhance and coordinate high quality AIDS research projects.
Role: Co-Investigator

U01 CA184743 Rebbeck,T (PI) 04/01/2015 – 03/31/2020
NIH
Genetics of Prostate Cancer in Africa
Specific Aim 1: Detect Novel African alleles in prostate cancer susceptibility regions identified by genome-wide association studies Hypothesis 1.1. Novel African variants exist at prostate cancer susceptibility loci that have not been previously described in European or Asian populations.

Completed Support:

R01 CA158243 Mao,J (PI) 07/01/2011 – 04/30/2016
NIH
Estrogen Deprivation and Aromatase Inhibitor Associated Arthralgia
This application entitled, "Estrogen deprivation and Aromatase Inhibitor associated Arthralgia," seeks to apply pharmacogenetic epidemiology, appropriate biomarkers, and validated patient-reported outcomes to define the role of estrogen deprivation in arthralgia (joint pain) occurrence, severity, and functional interference among postmenopausal women receiving aromatase inhibitors (AIs) as adjuvant therapy for early stage breast cancer.
Role: Co-investigator

U54 CA155850 Schmitz,K (PI) 06/24/2011 – 05/31/2016
NIH
Penn TREC Survivor Center

The primary goal of the Penn TREC Survivor Center is to leverage the considerable strengths of Penn scientists and clinicians to accelerate capacity to address obesity related challenges in cancer survivors, as well as disseminating those findings to improve outcomes for survivors.
Role: Co-Investigator

R01 CA083855 Rebbeck (PI) 09/01/2005 - 06/30/2013
NIH/NCI
Prophylactic Surgery in Carriers of BRCA1 and BRCA2 Mutations
In order to address the clinical and biological correlates of breast cancer risk and prevention in BRCA1/2 mutation carriers, we propose a cohort study using a sample of BRCA1/2 and BRCA2 mutation carriers to evaluate the role of BPO and other hormonal exposures in reducing breast cancer risk. This grant is under a one year extension.

R01 CA083855 Rebbeck (PI) 09/01/2005 – 06/30/2010
NIH
Prophylactic Surgery in Carriers of BRCA1 and BRCA2 Mutations
In order to address the clinical and biological correlates of breast cancer risk and prevention in *BRCA1/2* mutation carriers, we propose a cohort study using a sample of *BRCA1/2* and *BRCA2* mutation carriers to evaluate the role of BPO and other hormonal exposures in reducing breast cancer risk.

R01-CA102776 Rebbeck (PI) 07/01/2004 – 04/30/2010
NIH
Modifiers of Cancer Risk in BRCA 1 & 2 Mutation Carriers
The goal of this proposal is to identify genotypes involved in DNA damage recognition and repair pathways that influence BRCA 1/2 associated breast cancer risk.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Larry J. Schaaf, PhD**

eRA COMMONS USER NAME (credential, e.g., agency login): LJSCHAAF034

POSITION TITLE: Director of Strategic Alliances, Drug Development Institute and Director of the Clinical Treatment Unit (CTU) and Clinical Trials Processing Laboratory (CTPL) Shared Resource, The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Iowa, Iowa City, IA	B.S.	05/1976	Pharmacy
University of Iowa, Iowa City, IA	M.S.	05/1978	Clinical Pharmacy
Iowa City V.A. Hospital, IA	Residency	05/1978	Clinical Pharmacy
University of Arizona, Tucson, AZ	Ph.D.	12/1985	Pharmaceutical Sciences (Pharmacokinetics and Drug Metabolism)

A. Personal Statement

For the past 30 years, I have been actively involved in the translational and clinical application of drug development in cancer. I have extensive experience in conducting clinical pharmacology assessments as part of Phase I, II, and III clinical oncology trials both within the pharmaceutical industry and academic environments. I was the primary clinical pharmacologist responsible for designing and analyzing phase I and II protocols and regulatory filings for irinotecan. I have also directed clinical pharmacology teams in Italy and the U.S. that were responsible for working with clinical colleagues at a number of academic medical centers to develop and define the clinical application of a number of widely used anti-cancer drugs including exemestane, epirubicin, and sunitinib. In 2003, I assumed the role as Director of the CTU/CTPL Shared resource. My strongest qualification for serving in this role is my ability to utilize my experience to bring together basic researchers, clinical investigators, and clinical/research support staff to move novel compounds from the laboratory to the clinic. This experience also permits me to assist investigators in developing protocols whereby pharmacokinetic, pharmacodynamic and/or pharmacogenomic principles may be used to rationalize or improve drug therapy.
I devote effort to insure that CTU/CTPL Shared Resource continues to enhance the quality of clinical translational research conducted at the OSUCCC by providing improved efficiency, enhanced compliance, and cost-effective centralized support of early phase correlative studies. In 2014, I joined the Drug Development Institute to identify early stage projects with a high probability of success, advance them through the pharmaceutical development process, with the goal of partnering with industry to bring new promising cancer treatments to patients.

B. Positions and Honors

Positions and Employment:

1976-1978 Clinical Pharmacy Residency, Veterans Administration Hospital, Iowa City, IA
1978-1980 Assistant Professor of Clinical Pharmacy, College of Pharmacy, University of Oklahoma
1980-1981 Graduate Teaching Assistant in Pharmaceutics, University of Arizona
1981-1983 Graduate Associate in Teaching & Research, University of Arizona
1983-1985 Graduate Demonstrator and Part-Time Lecturer, University of Otago, Dunedin, New Zealand
1986-1991 Assistant Professor, College of Pharmacy, University of Nebraska Medical Center
1991-1996 Research Scientist II, Clinical Pharmacokinetics Unit, Upjohn, Pharmacia and Upjohn Companies
1996-1999 Senior Research Scientist III, Clinical Pharmacokinetics Unit, Pharmacia & Upjohn Company
1999-2000 Senior Scientist IV, Clinical Pharmacology, Pharmacia & Upjohn Company, Kalamazoo, MI

2000-2003 Director, Oncology, Clinical Pharmacology, Pharmacia Corporation, Kalamazoo, MI
2003-2003 Director, Oncology, Clinical Pharmacology, Pfizer Corporation, Kalamazoo, MI
2003- Director, Clinical Treatment Unit and Clinical Trials Processing Laboratory Shared Resource, The Ohio State University Comprehensive Cancer Center and Richard Solove Research Institute
2014- Director of Strategic Alliances, Drug Development Institute, The Ohio State University Comprehensive Cancer Center and Richard Solove Research Institute, Columbus, OH

Other Experience and Professional Memberships:

2003-2003 American Pharmaceutical Association
1986-1991 American Association of College of Pharmacy
1986-1991 American Association of Pharmaceutical Scientists
1991-2000 American Association of Cancer Research
1998-2000 American Society of Clinical Pharmacology and Therapeutics
1999- American Society of Clinical Oncology
2005- Cancer and Leukemia Group B (CALGB)
2005-2006 External Advisory Board, West Virginia University - Clinical Trials Research Unit (CTRU)
2006-2008 Scientific Advisory Board, AzoRx, Inc., Kalamazoo, Michigan, 2006 – 2008
2005- External Advisory Board, Kansas University Cancer Center, Kansas City

Honors and Awards:

1979 Professor of the Year, University of Oklahoma, College of Pharmacy
1982-1983 American Foundation for Pharmaceutical Education, H.A.B. Dunning Memorial Fellowship
1988-1990 Graduate Faculty Member, University of Nebraska Graduate College
1990-1991 Graduate Faculty Fellow, University of Nebraska Graduate College
1990 Outstanding Teaching Award, University of Nebraska Medical Center

C. Contributions to Science

1. **Clinical Development of Irinotecan Hydrochloride:**
As a research scientist and Director of Clinical Pharmacology – Oncology at The Upjohn Company and Pharmacia, I was the lead clinical pharmacologist for the development and FDA approval of irinotecan hydrochloride. In this role, I was responsible for developing a strategic vision and implementation plan to maximize Clinical Pharmacology contribution to product development for this novel topoisomerase inhibitor. Studies were performed to determine the metabolic fate following infusion of radiolabeled drug and to assess the impact of hepatic dysfunction on the pharmacokinetics and safety profile of irinotecan. A number of protocols were performed to assess potential drug-drug interactions between irinotecan and concomitantly administered chemotherapies.

a) Slatter JG, Su P, Sams JP, **Schaaf LJ**, Wienkers LC. Bioactivation of the anticancer agent CPT-11 to SN-38 by human hepatic microsomal carboxylesterases and the in vitro assessment of potential drug interactions. Drug Metabolism & Disposition. 1997;25(10):1157-64, 1997
b) Pitot HC, Goldberg RM, Reid JM, Sloan J, Atherton Skaff P, Erlichman C, Rubin J, Burch PA, Adjei AA, Alberts SA, **Schaaf LJ**, Elfring G, Miller LL. Phase I Dose-Finding and Pharmacokinetic Trial of Irinotecan Hydrochloride (CPT-11) Using a Once-Every-Three-Week Dosing Schedule for Patients with Advanced Solid Tumor Malignancy. Clinical Cancer Research 2000;6:2236-2244.
c) Slatter JG, **Schaaf LJ**, Sams JP, Feenstra KL, Johnson MA, Bombardt PA, Cathcart KS, Verburg MT, Pearson LK, Compton LD, Miller LL, Baker DS, Pesheck CV, Lord III RS. Pharmacokinetics, metabolism, and excretion of irinotecan (CPT-11) following iv infusion of [^{14}C]CPT-11 in cancer patients. Drug Metabolism and Disposition 2000; 28(4):423-433.
d) **Schaaf LJ**, Hammond LA, Tipping SJ, Goldberg RM, Goel R, Kuhn JG, Miller LL, Compton LD, Cisar LA, Elfring GL, Gruia G, McGovren JP, Pirotta N, Yin D, Sharma A, Duncan BA, Rothenberg ML. Phase I and Pharmacokinetic Study of Intravenous Irinotecan in Refractory Solid Tumor Patients with Hepatic Dysfunction. Clinical Cancer Research 2006; 12(12):2782-91.

2. **Phase I Assessments in Patients with Solid Tumor Malignancies:**
As Director of the Clinical Treatment Unit and Clinical Trials Processing Laboratory Shared Resource, I have assisted in the design and analysis of studies to assess the pharmacokinetics and pharmacodynamics of new agents either given alone or in combination with standard therapies to treat patients with solid tumor or hematological malignancies.

a) Ramaswamy B, Saab T, **Schaaf L**, Lesinsky G, Lucas D, Zahenk Z., Young D., Stark A., Byrd JC, Culler K, Wright J, Grever MR, Shapiro CL. A Dose-Finding and Pharmacodynamic Study of Bortezomib in Combination with Weekly Paclitaxel in Patients with Advanced Solid Tumors. Cancer Chemotherapy and Pharmacology 2010; 66(1), 151-8. PMC3540804.
b) Lam ET, Goel S, **Schaaf LJ**, Cropp GF, Hannah AL, Zhou Y, McCracken B, Haley BI, Johnson RG, Mani S, Villalona-Calero MA. Phase I Dose Escalation Study of KOS-1584, a Novel Epothilone, in Patients with Advanced Solid Tumors. Cancer Chemotherapy and Pharmacology 2011;69(2), 523-531. PMC3865603.
c) Villalona-Calero M, Phelps M, Stinchcombe T, Blachly J, Zhao W, **Schaaf L**, Starrett S, Wei L, Poi M, Wang D, Papp A, Aimiuwu J, Gao Y, Li J, Gregory Otterson, Hicks W, and Socinski M. Erlotinib in African Americans with Advanced Non-Small Cell Lung Cancer: A Prospective Randomized Study with Genetic and Pharmacokinetic Analysis. Clinical Pharmacology and Therapeutics 2014; 96(2), 182-191. PMC4180036.

3. **Phase I Assessments in Patients with Hematological Malignancies**:
As Director of the Clinical Treatment Unit and Clinical Trials Processing Laboratory Shared Resource, I have assisted in the design and analysis of studies to assess the pharmacokinetics and pharmacodynamics of new agents either given alone or in combination with standard therapies to treat patients with solid tumor or hematological malignancies.

a) Blum W, Klisovic RB, Yang X, Becker H, Yang X, Rozewski DM, Phelps MA, Garzon R, Walker A, Chandler JC, Whitman SP, Curfman J, Liu S, **Schaaf LJ**, Mickle J, Kefauver C, Devine SM, Grever MR, Marcucci G, Byrd JC. Dose escalation of lenalidomide in relapsed or refractory acute leukemias. J Clin Oncol 2010; 28(33), 4919-4925. PMC3020696.
b) Blum W, Phelps MA, Klisovic RB, Rozewski DM, Ni W, Albanese KA, Dalton JT, Rovin B, Kefauver C, Devine SM, Lucas DM, Johnson A, **Schaaf LJ**, Byrd JC, Marcucci G, Grever MR. Phase I Clinical and Pharmacokinetic Study of a Novel Schedule of Flavopiridol in Relapsed or Refractory Acute Leukemias. Haematologica 2010; 95(7), 1098-1105. PMC2895033.
c) Hofmeister CC, Yang X, Pichiorri F, Chen P, Rozewski DM, Johnson AJ, Lee S, Liu Z, Garr CL, Hade EM, Ji J, **Schaaf LJ**, Benson DM, Chan KK, Chen C-S, Farag SS, Grever MR, Byrd JC, Phelps MA. Phase I Trial of Lenalidomide and CCI-779 in Patients with Relapsed Multiple Myeloma: Evidence for Lenalidomide-CCI-779 Interaction via P-Glycoprotein. J Clin Oncol 2011; 29, 3427-3434. PMC3164245.
d) Walker AR, Klisovic R, Garzon R, **Schaaf LJ**, Humphries K, Devine S, Byrd JC, Grever MR, Marcucci G, Blum W. Phase I study of azacitidine and bortezomib in adults with relapsed or refractory acute myeloid leukemia. Leukemia & Lymphoma 2014; 55(6), 1304-1308. PMC3925754.

Research Support

Ongoing Support:
P30 CA16058 Caligiuri (PI) 12/01/2015 - 11/30/2020
NIH/NCI
The Ohio State University Comprehensive Cancer Center Support Grant
To support the programs, services, research, and administration of the OSU Comprehensive Cancer Center.
Role: Director of the OSUCCC Clinical Treatment Unit and Clinical Trials Processing Laboratory Shared Resource (CTU/CTPL SR)

Completed Support:
N/A

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Robert C. Young, MD**

eRA COMMONS USER NAME (credential, e.g., agency login): rcyoung

POSITION TITLE: President

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Ohio State University, Columbus, OH	B.Sc.	06/1960	Zoology
Cornell University Medical College, Ithaca, NY	M.D.	06/1965	Medicine
New York Hospital, New York, NY	Internship/ Residency	07/1967	Internal Medicine
Medicine Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD	Clinical Associate	07/1969	Internal Medicine/ Oncology
Yale-New Haven Medical Center, CT	Senior Resident	07/1970	Senior Residency

A. Personal Statement

RCY Medicine provides a variety of consulting services focused on the organization and proper function of Comprehensive Cancer Centers as well as services related to issues of health care quality and health policy. Dr. Robert C. Young personally provides these services based upon extensive experience in leadership roles in Cancer Centers, major national and international medical societies and various leadership positions at the National Cancer Institute, National Institutes of Health. Dr. Young also has substantial experience serving on Boards of Directors for both non-profit and for-profit organizations related to cancer care, biotechnology and pharmaceutical services.

B. Positions and Honors

Positions and Employment:

1970-1988 Senior Investigator and Attending Physician, Medicine Branch, National Cancer Institute
1974-1988 Chief, Medicine Branch, National Cancer Institute, Bethesda, MD
1988 Associate Director, Centers and Community Oncology Program, National Cancer Institute
1988-2007 President, Fox Chase Cancer Center, Philadelphia, PA
2007-2009 Chancellor, Fox Chase Cancer Center, Philadelphia, PA
2009-pres. President, RCY Medicine, Philadelphia, PA

Professional Appointments:

1972-pres. Fellow, American College of Physicians
1986-1991 American Society of Clinical Oncology, Board of Directors
1987-1993 Member, Subspecialty Board on Medical Oncology, American Board of Internal Medicine
1989-1990 President, American Society of Clinical Oncology
1996-2009 National Cancer Institute, Board of Scientific Advisors
1997-2001 Chairman, Board of Directors, National Comprehensive Cancer Network
1997-1999; 2002-2004 National Cancer Policy Board, IOM
2000-2001 President, International Gynecologic Cancer Society
2002-2003 President, American Cancer Society, Director-at-Large, National Board of Directors
2002-2011 Board of Directors, West Pharmaceutical Services, Inc. (NYSE) Lionville, PA,
2004-2009 Chairman, Board of Scientific Advisors, NCI

2005-2012 Board of Directors, Human Genome Sciences, Inc., Rockville, MD
2007-2009 Chancellor, Fox Chase Cancer Center
2009-pres. President, RCY Medicine
2009-pres. Board of Directors, AVEO Pharmaceuticals, Inc. Cambridge, MA

Certifications:

04/1970 Diplomate, American Board of Internal Medicine
10/1972 Diplomate, Subspecialty of Hematology, American Board of Internal Medicine
10/1973 Diplomate, Subspecialty of Oncology, American Board of Internal Medicine

Advisory and Editorial Boards:

1980-1984 Experimental Therapeutics Study Section, Division Research Grants, NCI
1986-1992 Editor-In-Chief, Physician Data Query (PDQ)
1986-1992 General Motors Cancer Research Foundation
1987-2001 Associate Editor, Journal of Clinical Oncology
1988-1993 Editor-in-Chief, Year Book of Oncology
1990-2015 Chairman, Editorial Board, Oncology Times
1993-1995 Chairman, Health Services Research Training Grant Review Committee, AHCPR
1995 Chairman, Kettering Selection Committee, General Motors Cancer Research Foundation
1998-date Chairman Scientific Advisory Board, Ohio State University Cancer Center
2006-2009 Chairman, Scientific Advisory Board, Huntsman Cancer Center, University of Utah
2008-2010 Chairman, External Advisory Board, Dana Farber Cancer Institute
2011-date Scientific Advisory Board, University of Kansas Cancer Center
2014-date Scientific Advisory Board, University of Oklahoma

Honors:

1977 American Society for Clinical Investigation
1979-1988 U.S. Public Health Service Awards for Research in Ovarian Cancer, 1979; Lymphoma, 1984; Testicular Cancer, 1989, PDQ, 1988
1994 Herbert J. Block Memorial Lectureship for Distinguished Achievement in Cancer, Ohio State University
2002 Bristol-Myers Squibb Award for Distinguished Achievement in Cancer Research (jointly with RF. Ozols, M.D., Ph.D.)
2004 ASCO Distinguished leadership Award for Scientific Leadership, 2004
2013 AACR Margaret Foti Award - Leadership and Extraordinary Achievements in Cancer Research

C. Contributions to Science

1. Curability of Advanced Hodgkin's Disease and Diffuse Lymphomas with Combination Chemotherapy

a) Canellos, G.P., **Young, R.C.,**Berard, C.W. and DeVita, V.T. Combination Chemotherapy and survival in advanced Hodgkin's Disease. Arch, Intern. Med 131:388-390, 1973
b) Schein, P.S., Chabner,B.A., Canellos, G.P., **Young, R.C.**,Berard, C.,and DeVita,V.T. Potential for prolonged disease-free survival following combination chemotherapy for non-Hodgkins lymphomas. Blood 43:181-189,1974
c) DeVita, V.T., Jr., Canellos, G.P., Chabner, B.A., Schein, P.S., Hubbard, S.P., **Young, R.C.** Advanced diffuse histiocytic lymphoma, a potentially curable disease. *Lancet* 1:248-250, 1975.
d) Hubbard, S.M., Chabner, B.A., DeVita, V.T., Jr., Simon, R.M., Berard, C.W., Jones, R.B., Garvin, A.J., Canellos, G.P., Osborne, C.K., **Young, R.C.** Histologic progression in non-Hodgkin's lymphoma. *Blood* 59:258-264, 1982.

2. Established the early standards of staging, grading and early clinical trial design in Ovarian Cancer

a) Bagley, C.M., **Young, R.C.**,Canellos, G.P. and DeVita, V.T. The Treatment of Ovarian Cancer: Possibilities for Progress .N. Eng. J. Med, 287:856-862,1972
b) **Young, R.C**., Chabner, B.A., Hubbard, S.P., Fisher, R.I., Bender, R.A., Anderson, T., Simon, R.M., DeVita, V.T., Jr. A prospective clinical trial of melphalan (L-PAM) vs. combination chemotherapy (Hexa-CAF). *N. Engl. J. Med.* 299:1261-1266, 1978.

c) **Young, R.C.,** Decker,D.G. Wharton,J.T., Piver, M.S.,Sindelar,W.F., Edwards,B.K.,Smith,J.P. Staging Laparotomy in Early Ovarian Cancer. JAMA 250:3072-3076,1983
d) **Young, R.C.**, Decker, D.G., Wharton, J.T., Piver, M.S., Sindelar, W.F., Edwards, B.K., Smith, J.P. Staging laparotomy in early ovarian cancer. *JAMA* 250:3072-3076, 1983.

3. Established the standard of care for early and advanced Ovarian Cancer

a) Rogan, A.M., Hamilton, T.C., **Young, R.C.**, Klecker, R.W., Ozols, R.F. Reversal of adriamycin resistance by verapamil in human ovarian cancer. *Science* 224:994-996, 1984.
b) **Young, R.C.**, Walton, L.A., Ellenberg, S.S., Homesley, H.D., Wilbanks, G.D., Decker, D.G., Miller, A., Park, R., Major, F., Jr. Adjuvant therapy in stage I and stage II epithelial ovarian cancer: results of two prospective randomized trials. *N. Engl. J. Med.* 322:1021-1027, 1990.
c) **Young, R.C.**, Brady, M.F., Nieberg, R.K., Long, H.J., Mayer, A.R., Lentz, S.S. , Hurteau, J., Alberts, D.S. Adjuvant treatment for early ovarian cancer: a randomized phase Ill trial of intraperitoneal 32P or intravenous cyclophosphamide-cisplatin: a gynecologic oncology group (GOG) study. *J. Clin. Oncol.* 21: 4350-4355, 2003.
d) Ozols, R.F., Bookman, M.A., **Young, R.C.** Intraperitoneal chemotherapy for ovarian cancer. N. Engl. J. Med. 354:1641-1643, 2006.

4. Advancement of several prominent Gynecologic Oncology Group Studies

a) Bell, J., Brady, M.F., **Young, R.C.,** Lage, J., Walker, J.L., Look, K.Y., Rose, G.S., Spirtos, N.M. Randomized phase Ill trial of three versus six cycles of adjuvant carboplatin and paclitaxel in early stage epithelial ovarian carcinoma: A Gynecologic Oncology Group study. Gyn. Oncol. 102:432-439, 2006.
b) Chan, J.K., Tian, C., Monk, B.J., Herzog, T., Kapp, D.S., Bell, J., **Young, R.C**. Prognostic Factors for Stage I and II Epithelial Ovarian Cancer: a Gynecologic Oncology Group Study. Cancer 112: 2202-10, 2008.
c) Darcy, K.M., Brady, W.E., McBroom, J.W., Bell, J.G., **Young, R.C.**, McGuire, W.P., Linnoila, R.I., Hendricks, D., Bonome, T., Farley, J.H. Associations between P53 overexpression and multiple measures of clinical outcome in high-risk, early stage or suboptimally-resected, advanced stage epithelial ovarian cancers: A Gynecologic Oncology Group Study. Gyn. Oncol. 111:487-495, 2008. PMC2615492

D. Research Support

Ongoing Support:
N/A

Completed Support:

P30 CA006927 Young (PI) 09/10/2005 - 06/30/2010
NIH
Comprehensive Cancer Center Program at Fox Chase
Support for professional personnel, including senior and program leadership, administration, planning and evaluation, developmental funds, 11 Research Programs, and 32 Shared Facilities.

IRG-92-027-09 Young (PI) 01/01/2007 - 08/31/2007
ACS Institutional Research Grant

HHMI #51004105 Young (PI) 09/01/2003 - 08/31/2007
Howard Hughes Partnership in Research Education

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Roy Middle Name A Last Name*: Jensen Suffix: MD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Pathology & Lab Medicine
Division: School of Medicine
Street1*: MS 3045, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-4700 Fax Number: 913-588-4701

E-Mail*: RJENSEN@kumc.edu

Credential, e.g., agency login: JENSENRA

Project Role*: Other (Specify) Other Project Role Category: Core Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ❍ Yes ❍ No

*Agency-Defined Phase III Clinical Trial? ❍ Yes ❍ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ❍ Yes ❍ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

❍ Yes ❍ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

❍ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ❍ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ❍ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ❍ Yes ❍ No

6. Change of Investigator / Change of Institution Section

❑ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	Plan_Specific_Aims_Final1019469451.pdf
3. Research Strategy*	Plan_Research_Strategy_Final1019913935.pdf
4. Progress Report Publication List	Progress_Report_Publications_Blank1019754748.pdf
Human Subjects Section	
5. Protection of Human Subjects	
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	
8. Inclusion of Children	
Other Research Plan Section	
9. Vertebrate Animals	
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	
14. Resource Sharing Plan(s)	Resource_Sharing_Plan__Generic1019913971.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Planning and Evaluation – Specific Aims

Aim 1 – Leverage the basic laboratory, clinical, drug discovery, prevention and survivorship and cancer control and population health expertise represented on the KUCC External Advisory Board (EAB) to improve the effectiveness of KUCC. The KUCC EAB visits annually to provide objective evaluation and constructive criticism to the Director, Senior Leaders, Program Leaders, Shared Resource Directors and the Center as a whole. KUCC draws on the EAB comments to guide strategic initiatives, grow the depth and breadth of cancer-related science and advance the impact of the Cancer Center member's research initiatives.

Aim 2 – Leverage the collective expertise and range of perspectives from key internal advisory groups. KUCC has a number of internal administrative units, councils and committees that offer a wide range of expertise to guide, develop and grow the Cancer Center. As a matrix cancer center, these constituents represent critical elements in enabling our success.

Aim 3 – Maintain a vision with goals and objectives focused to achieve the highest level of collective impact on cancer in our catchment area and nationally. KUCC created a strategic plan which is updated annually and undergoes major revisions every three years. This allows KUCC to reprioritize, refocus and leverage membership, research programs, shared resources, clinical expertise and institutional resources.

Planning and Evaluation – Research Strategy

Overview

As a matrix cancer center, planning and evaluation activities are vital to the optimal coordination, integration and effectiveness of The University of Kansas Cancer Center (KUCC). This coordination involves all of the University of Kansas campuses (Kansas City, Lawrence, Wichita and Salina), the University of Kansas Health System, the Stowers Institute for Medical Research (Stowers) and Children's Mercy (CM). Furthermore, KUCC assimilates activities of the Midwest Cancer Alliance (MCA), state and local government agencies, civic leaders, nationally-recognized cancer center experts and most importantly KUCC patients in development and growth of the Cancer Center. This section will describe the spectrum of advisory panels and committees that have informed and counseled **Jensen** and the Senior Leadership in developing their collective vision for a cancer center in our region worthy of NCI comprehensive cancer center designation.

Over the previous funding period, CCSG planning and evaluation funds were used to support the annual Research Symposium (year one only, KUCC funds were used in years 2-5) and the annual External Advisory Board (EAB) meeting (years 1-5). KUCC utilizes the annual Research Symposium to foster a culture of cancer centeredness, collegiality and collaboration. Additionally, the event is an opportunity for the Director and Senior Leadership to update faculty and staff on plans and priorities for KUCC and to receive input from membership. Each fall the program includes oral presentations from external speakers invited by each of the research programs, internal speakers (including faculty, post-doctoral fellows and graduate students), and poster sessions (**Table 1** summarizes the programs for each year). The event is held at The University of Kansas - Edwards campus in Overland Park, Kansas; a centralized location to host members from The University of Kansas Medical Center, The University of Kansas - Lawrence, Stowers and Children's Mercy. In 2014, KUCC began to sponsor the annual Research Symposium in collaboration with the Multidisciplinary Oncology Conference organized by KU Health System clinicians. The joint conference provides additional platforms for basic, population, translational and clinical scientists, physicians, nurses, fellows, residents and students to interact and learn about the work going on at KUCC and abroad. Moreover, continuing medical education credits are now offered and travel awards are provided. Since 2012, 35 travel awards (ranging from $1,000 - $3,000) have been given to student, post-doc and junior faculty poster presenters totaling $23,600. The next KUCC Research Symposium is scheduled for November 18-19, 2016.

Table 1. KUCC Research Symposium Programs

Date	External Speakers	Internal Speakers	Post-Doctoral or Graduate Speakers	Number of Attendees	Number of Posters
11/08/12	Leonard M. Neckers, PhD, Chief, Tumor Cell Biology from the National Cancer Institute	Brian Blagg, PhD (D3ET) Kristi Neufeld, PhD (CB) Jeff Holzbeierlein, MD (D3ET)	Wen Liu, PhD Agnes Walsh, PhD	139	81
11/07/13	Jack Pledger, PhD, Deputy Center Director and Associate Center Director for Basic Science, Gibbs Cancer Center Peggy Farnham, PhD, Associate Dean for Graduate Affairs, University of Southern California	Adam Krieg, PhD (CB) Nikki Cheng, PhD (CPS)	Anand Venugopal, MD/PhD student Badal Roy, PhD	165	64
11/14/14 & 11/15/14	Frederick Appelbaum, MD, Fred Hutchinson Cancer Research Center David Avigan, MD, Beth Israel Deaconess Medical Center Bruce Blazar, MD, University of Minnesota Catherine Bollard, MBChB, MD, FRACP, George Washington University		Alejandro Parrales, PhD Amber Smith, graduate student	200+	85

	Stanley Riddell, MD, Fred Hutchinson Cancer Research Center				
11/13/15 & 11/14/15	Victoria Seewaldt, MD, City of Hope Cancer Center Ralf Krahe, PhD, University of Texas MD Anderson Cancer Center Laura Damschroder, MS, MPH, Ann Arbor VA Center for Clinical Management Research John Taylor III, MD, MS, the University of Connecticut Health Center Mark Evers, MD, FACS, Director of the Markey Cancer Center at the University of Kentucky	Dan Dixon, PhD (CPS) Tomoo Iwakuma, PhD (CB) Christie Befort, PhD (CCPH) Frank Schoenen, PhD (D3ET)	Jennifer Crow, graduate student Parthasarathy Rangarajan, PhD	185	77

The annual EAB meeting is held each spring. Over the previous grant-funding period, the EAB met on May 8-9, 2013; May 21-22, 2014; April 15-16, 2015 and May 9-10, 2016. In 2012, the EAB came early on January 23-24 for a mock site visit, in preparation for the NCI site visit on February 22, 2012. KUCC provides the annual CCSG progress report for review by the EAB and presentations are given with annual updates on scientific and clinical progress. In the next CCSG funding period, KUCC requests funds to continue the support of the annual EAB meeting.

KUCC External Advisory Board (EAB)

KUCC Director, Roy A. **Jensen**, MD, has assembled a strong EAB that provides critical advice in building an outstanding cancer research center. Initially formed in late 2004 and chaired (2004-2008) by Frank Meyskens, MD of the University of California-Irvine Chao Family Cancer Center, the EAB has served and continues to serve a critical role in the planning and evaluation of KUCC's vision, direction, leadership, research programs, shared resources, and supporting infrastructure. The EAB is currently chaired by George J. Weiner, MD, Director of the Holden Comprehensive Cancer Center at the University of Iowa, and composed of an additional 13 nationally recognized leaders in cancer research, prevention, control and treatment (Table in Other Attachments). The EAB includes current and former Directors of NCI-designated Cancer Centers with national experts in cancer research and administration that guide and inform KUCC's strategic vision. The members of the EAB serve for renewable four-year terms. In the recent past, other important contributors to the EAB have included Victor Vogel, MD, the University of Pittsburgh Cancer Institute; Mary Todd, DO, Cancer Institute of New Jersey; Patricia Ganz, MD, the University of California, Los Angeles; John Glick, MD, Abramson Cancer Center of the University of Pennsylvania; Harold Moses, MD, Vanderbilt-Ingram Comprehensive Cancer Center; and David Scheinberg, MD, PhD, Memorial Sloan Kettering Cancer Center. The EAB visits KUCC on an annual basis to evaluate the strength of the Cancer Center's research programs and administrative structure, progress in shared resource development and provide **Jensen** with invaluable counsel for advancing KUCC goals. The EAB meetings are focused on providing a critical and careful review of KUCC, which was a major factor in the success of the initial CCSG application to become an NCI-designated cancer center. Since designation in July 2012, the EAB has focused its efforts on preparing KUCC to become a comprehensive cancer center. The full EAB reports from these annual meetings will be available at the site visit, but the major points of each year's review and KUCC's subsequent actions are described below.

Summary of Major EAB Recommendations and KUCC Responses (2012-2016)

2012 and 2016 Recommendation: Your leadership team includes a large number of Associate Directors. While it appears to be serving the KUCC extremely well, the sheer number of Associate Directors could be viewed negatively given the size of your center and the number of programs you have.

KUCC Response: While the number of KUCC members, number of research programs and funding totals reflect a cancer center in the early phase of its natural history, KUCC is much more complex from an organizational standpoint than one might expect. Herein, KUCC is proposing a consortium cancer center consisting of three culturally distinct institutions, representing members from four different campuses with widely divergent missions and governance structures. In this setting, collaborative efforts and institutional buy-

in are considerably facilitated by a broad-based leadership team that reflects involvement and active participation in decision making from all constituent institutions and campuses. Nevertheless, in 2013, KUCC utilized the departure of Kaphil **Bhalla** to promote Andrew **Godwin** to Deputy Director and eliminate **Godwin's** position as Associate Director for Translational Research – Correlative Science. As a result, **Weir** assumed the lead role in promoting translational activities across KUCC as Associate Director for Translational Research, but does so in collaboration with multiple members of the Leadership Council. Additionally, KUCC has decided to fund the Associate Directors for Shared Resources and Health Equity from institutional and philanthropic sources.

2012 Recommendation: Overlap between the roles of the Deputy Director and the Associate Director for Clinical Research

KUCC Response: When **Godwin** was elevated to the Deputy Director, KUCC leadership took the opportunity to re-define roles of the leadership within the Cancer Center. The Associate Director for Clinical Research, Carol **Fabian**, is directly responsible for the clinical research infrastructure. The deputy director maintains a role on the Data and Safety Monitoring Board and the Protocol Review and Monitoring Committee as a non-voting ex-officio member. **Godwin** works with the chair of both groups to nominate and approve membership. This division of responsibility between **Fabian** and **Godwin** was enacted to minimize inherent conflicts of interest that would come from one individual trying to simultaneously promote clinical research activities and oversee regulatory, compliance and safety activities.

2013 and 2015 Recommendation: Recruitment of a strong division director and several additional physician scientist faculty for the division of hematology and oncology to establish a solid basis for the further development of the clinical and translational research activities of the division and KUCC at large.

KUCC Response: KUCC agrees that this is a critically important initiative that will be essential to the goal of enhancing clinical research efforts and the overall success of the Cancer Center. KUCC has addressed this issue in a number of ways. First of all, KUCC engaged a number of senior clinical oncologists and asked them how to optimally structure this position to attract a nationally-recognized clinical leader with a strong, well-funded research program. In evaluating the feedback it was apparent that a major concern was the size of the division which was nearly 60 faculty. This necessitated that the job would require a significant commitment to personnel management and administrative issues and was likely to compromise the research efforts of any one individual overseeing a combined division of hematology and oncology. As a result, after consulting with senior leadership officials within the KU Health System, KUMC and the Department of Internal Medicine we decided to split the division into Medical Oncology and Hematologic Malignancies and Cellular Therapeutics. This approach significantly decreased the administrative burden, but obviously meant there were now two division directors to identify. Fortunately, Joseph **McGuirk** (D3ET), leader of our Bone Marrow Transplant program at KUCC was ready to step in as the division head for Hematologic Malignancies and Cellular Therapeutics. **McGuirk** has built an outstanding core of clinicians and researchers focusing on hematologic malignancies over the last several years, and this new arrangement will allow further growth and expansion of this group. Since 2007, **McGuirk** has taken a program that did less than 50 bone marrow transplants per year, to one that now does nearly 350 transplants on an annual basis. He has also significantly expanded the clinical and basic research activities and KUCC is confident that the status as a separate division will further enhance this group's academic and clinical growth. To assist the division in these efforts KUCC provided **McGuirk** with a package that includes two, $2 million endowed chairs, and $4 million in spendable funds to support research activities in the division.

An active search committee is working with an externally-retained search consultant to identify highly-qualified candidates with a proven background in clinical and translational research to lead the division of Medical Oncology. To enhance the attractiveness of the Medical Oncology division director position, KUCC has raised funds for three newly endowed chairs, two at the $2 million level and one at the $1 million level, and a total of $6 million of spendable funds to enhance research activities within the medical oncology division. The search committee has been formed, an outside recruitment firm was contracted and the committee is currently interviewing division director candidates.

2013 Recommendation: Multidisciplinary science initiatives must be a major focus for the Center during this funding cycle and COBRE, U54, P01, SPORE, PCORI and other multidisciplinary grant applications should be fostered.

KUCC Response: As a result, in 2014, KUCC issued a call for program project developmental grants at $50,000 apiece for two years. Three were awarded to **Fabian**, **Chien**/**Godwin**, and **Anant** (refer to the Developmental Funds section for more details). Good progress was made on all of these initiatives and as a result, the Associate Directors Council unanimously decided to extend the funding for all projects a second year. An additional commitment was made to **Welch** and **Anant** to develop a COBRE application that was submitted in the spring of 2016.

2014 Recommendation: Strengthen clinical investigation activities across KUCC members.

KUCC Response: In response to this recommendation, KUCC has developed a number of initiatives that will put in motion a significant expansion of KUCC's clinical research activities. A major component of the response is to identify new leadership for the division of medical oncology. This aspect of the response is described above. In addition, KUCC felt that a top to bottom review of the early phase clinical trials program was warranted. KUCC had devoted a significant amount of resources to the early phase initiative, but accruals in 2013 and 2014 had plateaued and were not commensurate with the level of investment that had been made. To understand the issues surrounding this program KUCC convened an early phase summit which involved nearly 20 individuals who had a direct or indirect role in the early phase program. This group met multiple times over a six-month period and made a number of recommendations to the Associate Director's Council. As a result of this review, Stephen **Williamson** (D3ET) was appointed as the new director of the early phase clinical trials program in 2015. Since then, KUCC has seen a nearly 50% expansion of the early phase clinical trial accruals. This committee also felt KUCC needed to increase the support for investigator-initiated clinical trials (IITs) and this resulted in the development of an RFA and the commitment of $500,000 of resources to fund IITs. Additionally, **Godwin** obtained an additional $100,000 from Radiation Oncology (matching funds for two IITs for Radiation Oncology faculty).

Another issue identified was the need to refine the structure of the Institute for Advancing Medical Innovation (IAMI). This effort was led by Associate Director for Translational Research, **Weir**. This process involved senior leadership from both KUMC and KU-Lawrence campuses and the results of this self-study, along with a number of recommendations, collectively known as IAMI 2.0, were presented to the Chancellor in September 2015. KUCC believes that this restructuring of IAMI, which involved significant commitment of university resources, will establish IAMI as a robust engine for KUCC's drug discovery and commercialization efforts and lead to a major enhancement of the Cancer Center's clinical research, developmental therapeutic and commercialization efforts.

KUCC has also developed the Investigator-Initiated Trials Steering Committee (IITSC), consisting of KUCC's senior clinical research experts that work with individual clinical investigators to develop strong clinical trial protocol in an expedited and timely manner. This group is more fully described below and in the program write-up for Drug Discovery, Development and Experimental Therapeutics and Clinical Protocol and Data Management, but it has already been responsible for a significant expansion of the number of IIT's developed by KUCC investigators.

Finally, as a result of the strong relationship developed with Children's Mercy as a member of the Midwest Cancer Alliance, **Jensen** worked with senior leadership from Children's Mercy and KUMC to bring Children's Mercy on board as a full-fledged member of the KUCC consortium. Children's Mercy has a number of nationally-recognized pediatric oncologists and a robust clinical research program, as witnessed by their participation and leadership in multiple Children's Oncology Group initiatives. This consortium arrangement is more fully described in the Six Essential Characteristics section, but greatly increases KUCC's footprint in pediatric oncology clinical research. This is particularly true given the decision by Children's Mercy to greatly enhance the academic focus of their institution by creating The Children's Research Institute (CRI) in 2015. Michael Artman, MD, Chairman of Pediatrics, and Rand O'Donnell, PhD, Children's Mercy CEO, consulted with **Jensen** and engaged an External Scientific Advisory Board who recommended that Children's Mercy embark on a plan to become a national leader in pediatric research. Tom **Curran**, PhD, FRS was recruited in

February 2016, as the Chief Scientific Officer and Executive Director of the CRI. **Curran** comes to Children's Mercy from the Children's Hospital of Philadelphia where he has served as Deputy Scientific Director since 2006 and Director of Basic Scientific Research in the Center for Childhood Cancer Research since 2007. Curran has been elected as a Fellow of the American Association for the Advancement of Science, the American Academy of Microbiology, the Royal Society, London, the Academy of the American Association for Cancer Research, and as a Member of the Institute of Medicine of the National Academies, USA, and the American Academy of Arts and Sciences. Curran is charged with developing a research infrastructure to support and expand on research strengths in Clinical Pharmacology and Therapeutics, Genomic Medicine, Health Services and Outcomes Research and Innovations in Health Care Delivery. To support the growing research focus, CM will construct a new research building adjacent to the hospital, dedicated to translational research. The overarching theme of the CRI will be to integrate research with all aspects of children's health care in a pervasive pediatric precision medicine environment. Research at CM will complement and synergize with related efforts at the University of Kansas and with the Cancer Center in particular. **Jensen** and **Weir** participated in the national search to identify **Curran** and believe that this is a seminal event in the history of KUCC and will greatly enhance the strength and significance of our collaborative efforts.

2014 Recommendation: The Midwest Cancer Alliance (MCA) has the potential to enhance clinical cancer research productivity. However, establishing a robust and scientifically productive clinical trials network is challenging and resource intensive.

KUCC Response: KUCC has increased the accrual across the MCA and has undertaken a comprehensive review of factors that influence trial accrual across the network. Specifically, a Health Communication Research shared resource project was developed to address accrual at urban and rural MCA locations; and an MCA electronic trials screening log was developed/implemented to understand the cancer case mix seen at the individual sites to assist with protocol selection. KUCC expects the screening log to also help understand the barriers that patients face when participating in clinical research studies and how these might be overcome.

In addition, KUCC has focused on the MCA as a mechanism to enhance accrual to our cancer prevention and control studies. To facilitate the conduct of cancer control and prevention trials KUCC has expanded the MCA to include the Kansas Patients and Providers Engaged in Prevention Research (KPPEPR) primary care practice research network. This resulted from a critical observation made during an analysis of the uptake of HPV vaccine in the KUCC catchment area, i.e., most primary prevention and vaccination activities are the domain of primary care practitioners and without their buy-in, they don't happen. The inclusion of primary care physicians in the network will greatly enhance KUCC's access to at risk populations and provide critical infrastructure for implementation research in cancer prevention and control.

2014 Recommendation: Another major requirement to achieve comprehensive designation will be for KUCC to demonstrate impact in its defined catchment area.

KUCC Response: KUCC developed a comprehensive plan to promote HPV vaccination across the catchment area in conjunction with the CDC, and multiple other organizations. In addition, KUCC has undertaken multiple legislative initiatives over the last several years to implement strong evidence-based public policy proposals that will have a significant impact on cancer incidence and mortality going forward (see Director's Overview).

2015 Recommendation: Strengthen your efforts in the area of therapeutic clinical trials by leveraging your relationship with Children's Mercy, your drug discovery and repurposing efforts, and recruitment of clinical investigators to adult Hematology/Oncology.

KUCC Response: Despite losing former D3ET program co-leader, Kathleen Neville, MD, to Arkansas Children's Hospital, the ties with Children's Mercy remain strong. Alan **Gamis**, MD, MPH, now co-leads the D3ET program alongside **Weir**. **Gamis** is the Associate Division Director for the Section of Oncology at Children's Mercy. Children's Mercy is also conducting a search for a Phase I / Experimental Therapeutics Program Director and multiple KUCC members are participating on the search committee. In addition, the endowment foundations for Children's Mercy and KU have recently completed a $10 million capital campaign to fund four endowed chair positions to fund faculty with joint appointments at KUMC and Children's Mercy.

At the KUMC campus, Joseph **McGuirk**, DO (D3ET), Division Director, Division of Hematologic Malignancies and Cellular Therapeutics and Director, Blood and Marrow Transplant Program, is in the process of recruiting one senior investigator and four assistant professor level faculty to enhance the research efforts in hematologic malignancies. As discussed above, we also have an ongoing search for a Medical Oncology division director and two additional senior recruits are part of this package.

2015 and 2016 Recommendation: Carefully define your catchment area to include both Kansas and appropriate areas in Missouri based on your patient referral patterns and specific cancer related challenges found by a careful analysis of incidence and mortality data. As you know from your [**Jensen's**] service on NCI Committee A, site visit committees are increasingly focusing on whether the research at the Cancer Center focuses on the research burden in their catchment areas. Your application would benefit from additional thought and study on how research in your research programs focuses on the issues you have defined as major burdens for your catchment area.

KUCC Response: In response to EAB feedback KUCC convened a catchment area committee that meets quarterly to discuss strategies to define the KUCC catchment area; understand the demographics, cancer incidence, cancer mortality, and other cancer outcomes; relate current research to those areas of need; and identify areas of need for which responsive impactful research proposals can be developed. At the recommendation of the catchment area committee and following discussion at both the Associate Directors Council and Leadership Council, the KUCC catchment area now include the state of Kansas and the counties in western Missouri in which there are at least 20 KUCC patients, ≥ 15% of the expected index cases or are immediately adjacent to the state of Kansas. KUCC believes this area accurately reflects where patients originate, where the Midwest Cancer Alliance serves and where there is substantive research focus.

2015 Recommendation: It will be very important for the D3ET program to play a leadership role in every facet of the drug development effort at KUCC and for KUCC investigators to maintain a leadership or participatory role in each phase of the preclinical and clinical evaluation of KUCC developed drugs with the acknowledgment of the need to manage conflict of interest issues.

KUCC Response: In 2014, KUCC organized the Target Acceleration Group (TAG) to help facilitate basic and clinical scientific interactions. To further support this initiative, in 2015, KUCC formed the Investigator-Initiated Trial (IIT) steering committee. Briefly, TAG aims to accelerate investigator projects from early method development around an identified cancer target through development of an early phase clinical trial. It will be more fully described below. The IIT steering committee aims to: 1) enable and advance hypothesis-driven Investigator-Initiated Trials (IITs) that represent external funding opportunities; 2) increase patient accruals to treatment trials; 3) create a rich translational research culture for basic and clinical scientists, providing access to mentors and supporting faculty and staff for career development; and 4) effectively and efficiently utilize KUCC Shared Resources to support IITs. The IIT steering committee provides a venue for basic and clinical researchers to present IIT concepts arising from laboratory and bedside discoveries. The IIT steering committee also provides a structure for defining and refining IIT concepts prior to and following discussion. Investigators receive instant feedback from experienced clinical researchers and representatives from relevant KUCC Shared Resources (i.e., Biospecimen, Lead Development and Optimization (LDO), Clinical Pharmacology, and Biostatistics) along with the KUCC Clinical Trials Office. Dedicated CTO and LDO project managers work with Cancer Center members to shepherd IIT concepts through the IIT steering committee. The committee meets on the first and third Thursdays of each month and is available to meet *ad hoc* as required. The IIT steering committee is co-chaired by Steve **Williamson**, MD, (D3ET) Medical Director of the CTO, and Scott **Weir**, PharmD, PhD, (D3ET) Associate Director for Translational Research and D3ET co-leader. Since forming the IITSC in 2015, 15 IIT concepts from 20 investigators have been presented and most are moving forward with full proposals.

2016 Recommendation: Successful completion of high profile recruitments – This will be particularly important as you work to enhance translational research taking place in the Division of Medical Oncology and the Department of Radiation Oncology.

KUCC Response: After a national search, Allen M. Chen, MD, has been appointed the new Joe and Jean Brandmeyer Chair of the Department of Radiation Oncology at KUMC. Chen will join the faculty on October 1, 2016. As described above, the search for the Medical Oncology division director is ongoing.

KUCC Internal Planning and Evaluation

Jensen utilizes a number of mechanisms to inform, guide and review the wide-ranging activities and priorities of Cancer Center strategic initiatives and operations. In addition to the meetings/councils/committees that convene as described below, **Jensen** meets with Senior Leaders from all campuses on a regular basis (**Table 2**) to ensure that KUCC and institutional goals are well aligned.

Table 2. Director One-on-One Meetings

Position	Frequency
Deputy Director – Godwin	Bi-weekly
Associate Directors – Individually	Monthly and *ad hoc*
KUCC Chief Operating Officer – Reene	Bi-weekly
KUCC Physician-in-Chief – Tsue	Bi-monthly
Stowers Institute (CEO) – Chao	Twice a year
Children's Mercy Research Institute (CEO) – Curran	Twice a year
KU-Lawrence (Provost) – Bendapudi	Twice a year
KUMC Leadership (EVC) – Girod	Monthly
KUMC Leadership (Dean) – Simari	Monthly
KU-Health System CEO – Page	Bi-monthly
KU-Health System (SVP Clinical Affairs) – Stites	Monthly

KUCC Associate Directors Council (KUCC - ADC)

The KUCC-ADC meets twice a month at either KUMC or Stowers, to evaluate inter- and intra-programmatic activities such as the annual research symposium, KUCC Seminar Series, other KUCC-sponsored conferences, allocate the annual pre-and post-doctoral trainee stipends and establish the focus and subsequently allocate the KUCC pilot research grants. Each year this group reviews the progress of the research programs, shared resources and administrative functions of KUCC. The KUCC-ADC makes final recommendations to the Director on practically all issues including budget, resource allocation, membership, space, leadership appointments and strategic direction. The KUCC-ADC is comprised of the Director (**Jensen**) and his Senior Leadership team – Deputy Director (Andrew **Godwin**); Chief Operating Officer (Jeffrey **Reene**); Associate Director for Administration (Teresa **Christenson**); Associate Director for Basic Science & Education (Danny **Welch**); Associate Director for Cancer Prevention & Control (Shrikant **Anant**); Associate Director for Clinical Research (Carol **Fabian**); Associate Director for Health Equity (Sally **Maliski**); Associate Director for Shared Resources (Matthew **Mayo**); Associate Director for Translational Research (Scott **Weir**); Medical Director (Stephen **Williamson**); Physician-in-Chief (Terry **Tsue**); Pediatrician-in-Chief and Chair of the joint Department of Pediatrics at Children's Mercy and KU Health System (Michael **Artman**) and Assistant Director for Administration (Lisa **Harlan-Williams**). This group proactively seeks input from KUCC members and is the major governing body of the Cancer Center that sets strategy, oversees operations and allocates resources within KUCC. Since its inception, all major decisions made by the Cancer Center have been discussed, vetted and evaluated by this group. Ultimately, **Jensen** is responsible for all decisions, but they always reflect the collective wisdom and consensus opinion of this group.

KUCC Leadership Council (KUCC - LC)

The KUCC-LC is a critically important internal advisory group that works together to ensure consistency in the vision and goals of the Cancer Center; to develop synergistic interactions between the basic, translational, and clinical elements of the Cancer Center; to plan proactive approaches to the development of the research base and resources; to effectively leverage available resources at the university, state, and national levels; to engage in community outreach; and to oversee all of the activities of KUCC. The KUCC-LC is comprised of the entire KUCC Senior Leadership team listed above plus Program Leaders (Ed **Ellerbeck**, Christie **Befort**, Kristi **Neufeld**, Linheng **Li**, Alan **Gamis**, Dan **Dixon**, Jennifer **Klemp**), Research Staff Investigator (Jim **Calvet**), representatives from the Midwest Cancer Alliance (Gary **Doolittle** and Hope **Krebill**), KUCC Communications Director (Christine Wilson) and KU Endowment representative (Minda Mason). The KUCC-LC meets every other month alternating with the Program Leaders meeting.

KUCC Program Leader Meetings
The Program Leader meeting, which includes the Director, Associate and Assistant Directors for Administration and Program Leaders, meets every other month (alternating with the KUCC-Leadership Council) to discuss strategies to communicate with and engage KUCC members, recruitment efforts to increase each program's scientific depth and breadth and understand specific needs for each program such as new shared resources. This group is primarily responsible for maintaining and further developing the scientific depth, breadth and quality of our four research programs.

Membership Committee
The Membership Committee annually reviews all applications and makes recommendations to the Cancer Center Director on the appropriate membership category and program assignment. The Membership Committee consists of **Jensen**, **Christenson**, **Harlan-Williams**, **Mayo** and all program leaders. The Director has final authority in determining membership and reserves the right to reassign (or disallow) the membership category and program assignment based on current criteria. The KUCC membership categories and criteria for appointment to the Cancer Center are outlined in **Table 3**. The Cancer Center may offer additional application submission and membership review opportunities during the membership year as deemed necessary.

Table 3. KUCC Membership Category and Criteria

Member Category	Criteria
Full	• Located at one of the University of Kansas campuses or at an institution with which the Cancer Center has a consortium agreement, **and** • Actively involved in cancer-related basic, translational, and/or clinical research as evidenced by being an investigator on peer-reviewed cancer-related grants or contracts (defined by the NCI) within the last year, **or** an investigator of peer-reviewed investigator-initiated cancer-related clinical trial within the last year, **and** • Author or co-author of peer-reviewed cancer-related publications within the last year, **or** • Has a significant administrative or leadership role within the Cancer Center.
Associate	• Located at one of the University of Kansas campuses or at an institution with which the Cancer Center has a consortium agreement, **and** • Engaged in cancer-focused research and/or clinical practice, but does not have peer-reviewed cancer-related funding within the last year

Recruitment Committee
The recruiting committee meets bi-monthly to discuss faculty recruits across the University. The committee discusses key positions that are necessary to achieve KUCC goals and objectives and how other University recruits may collaborate with Cancer Center faculty. The committee also plans future recruiting initiatives considering areas of perceived weakness, areas that may experience turnover, or areas of strength that warrant expansion. The recruiting committee includes: Director, **Jensen**; Deputy Director, **Godwin**, AD for Basic Science & Education, **Welch**; Chief Operating Officer, Reene; Hematology Director, **McGuirk**; AD for Shared Resources, **Mayo**; AD for Cancer Prevention and Control, **Anant**; AD for Administration, **Christenson** and HR Director, Theresa Leinwetter.

Catchment Area Committee
The catchment area committee meets quarterly and includes the Director, **Jensen**, Associate Director for Administration, Christenson, Associate Director for Shared Resources, **Mayo**, Executive Director for the Midwest Cancer Alliance, Hope **Krebill**, Assistant Director for Administration, **Harlan-Williams**, Data Analyst, John Fife, and a representative program leader from each program. This group meets to discuss strategies to define the KUCC catchment area, understand our demographics, identify unmet needs in the KUCC catchment area, identify populations impacted by the KUCC research portfolio and identify areas that new initiatives could impact and positively influence.

Shared Resource Director's Meetings
KUCC provides support for five established shared resources, Biospecimen, Biostatistics & Informatics, Clinical Pharmacology, Transgenic and Gene-Targeting, and Lead Development and Optimization and three developing shared resources, Health Communications Research, Nutrition, and Cell Authentication and Pathogen Screening. The Associate Director for Shared Resources, **Mayo**, and Assistant Director for Administration, **Harlan-Williams**, meet with established and developing shared resource directors quarterly to

identify appropriate utilization metrics and tracking mechanisms, prevent duplication of aims and services and increase communication across all KUCC shared resources. Bi-annually, Christenson, **Mayo**, and **Harlan-Williams** meet jointly with all shared resource directors to help identify issues with organization, metrics, usage and/or budget. Also bi-annually, **Mayo** and **Harlan-Williams** meet with KUCC program leaders to review current shared resources processes and services, encourage usage by their program members and understand the needs of the program members. Each established shared resource also has internal and external advisory boards that meet at least yearly for oversight.

Clinical/Translational Research Leadership Committee Meetings

The Clinical/Translational Research Leadership committee meetings are led by Assistant Director for Clinical Research, Priyanka **Sharma**, MD (D3ET). The purpose of these meetings is to provide a forum of routine information exchange amongst key institutional clinical research leaders and to raise, address and follow-up on important operational challenges and proposed solutions related to the startup, conduct and completion of KUCC's and cancer-related clinical trials. This group has led the charge to optimize the efficiency of clinical trials operations, assess the functionality of the Disease Working Groups (DWGs), reappoint or change DWG leadership, coordinate efforts with institutional offices such as Radiation Safety and attain oncology representation on the Institutional Review Board. This group meets monthly and, in addition to **Sharma**, is attended by: Hobs Apell, Richard Barohn, Gary **Doolittle**, **Godwin**, Brooke **Fridley**, **Jensen**, Qamar **Khan**, Chris Mackay, Josh **Mammen**, **Mayo**, **McGuirk**, Anna Nguyen, Reene, **Tsue**, **Welch**, and **Williamson**.

Target Acceleration Group and Investigator-Initiated Trial Steering Committee

In 2014, KUCC organized the Target Acceleration Group (TAG) to help facilitate basic and clinical scientific interactions. The TAG aims to accelerate KUCC member projects around an identified cancer target, through screening, hit identification, medicinal chemistry optimization, secondary *in vitro* assay confirmation, drug delivery for both *in vitro* and *in vivo* tertiary assays, eADME pharmacokinetics, and *in vivo* preclinical proof of principle. The TAG is made up of a multidisciplinary group with extensive pharmaceutical industry experience, including **Weir** (D3ET) Associate Director for Translational Research and D3ET co-leader; Mike **Baltezor**, PhD (D3ET), Director, Lead Development and Optimization Shared Resource; Melinda Broward (KUCC Project Management); Anu **Roy**, PhD (D3ET) Director, High Throughput Screening; and Frank **Schoenen** (Specialized Chemistry Center). This group provides a "critical mass" of scientific expertise, centralized access to information and resources, coordination across shared resources, fosters intra-programmatic, inter-programmatic and inter-NCI center collaborations, and is the genesis for creation of multidisciplinary, multi-organizational teams to advance projects from the bench to the bedside. Since its formation mid-2014, the TAG has assisted 16 KUCC researchers in advancing their projects at the chemistry/biology interface. Pilot funds supporting advancement of these projects have come from several sources including KUCC, COBRE CCET, Midwest Cancer Alliance, COBRE Protein Structure and Function, and philanthropy.

In 2015, KUCC formed the Investigator-Initiated Trial (IIT) steering committee. The IIT steering committee aims to: 1) enable and advance hypothesis-driven IITs that represent external funding opportunities; 2) increase patient accruals to treatment trials; 3) create a rich translational medicine culture for basic and clinical scientists, providing access to mentors and supporting faculty and staff career development; and 4) effectively and efficiently utilize KUCC shared resources to support IITs. The IIT steering committee is a venue for basic and clinical researchers to present IIT concepts arising from laboratory and bedside discoveries. The IIT steering committee provides a structure for defining and refining IIT concepts prior to and following discussion. Investigators receive instant feedback from experienced clinical researchers and representatives from relevant KUCC shared resources (i.e., Biospecimen, Lead Development and Optimization (LDO), Clinical Pharmacology, and Biostatistics and Informatics) along with the KUCC Clinical Trials Office (CTO). Dedicated CTO and LDO project managers work with Cancer Center members to shepherd IIT concepts to the IIT steering committee. The IIT steering committee meets on the first and third Thursdays of each month and is available to meet *ad hoc* as required. The IIT steering committee is co-chaired by Steve **Williamson**, MD, (D3ET) Medical Director of the CTO, and Scott **Weir**, PharmD, PhD, (D3ET) Associate Director of Translational Research and D3ET co-leader along with other physician scientists, shared resource directors and protocol development experts that represent critical, multidisciplinary expertise concerning different aspects of clinical trial development and implementation (**Table 4**). Since forming the IITSC, 15 IIT concepts from 20 investigators have been presented and most are moving forward with full proposals.

Table 4. IIT Steering Committee

Name	Expertise
Stephen Williamson, MD	Co-Chair, Clinical Trials Office Medical Director, IIT Physician (solid tumors)
Scott Weir, PharmD, PhD	Co-Chair, AD Translational Research, D3ET co-leader (drug development)
Carol Fabian, MD	Associate Director, Clinical Research, IIT Physician (prevention and survivorship)
Sid Ganguly, MD	IIT Physician (hematological malignancies)
Priyanka Sharma, MD	Assistant Director, Clinical Research, IIT Physician (solid tumors)
Qamar Khan, MD	PRMC Chair, IIT Physician (solid tumors)
Andrew Godwin, PhD	Deputy Director, Biospecimen Shared Resource (biomarker development)
Gregory Reed, PhD	Clinical Pharmacology Shared Resource, Correlative Studies (PK/PD)
Brooke Fridley, PhD	Biostatistics and Informatics Shared Resource (data management)
Keith August, MD	Pediatric Oncology Phase I Director (Children's Mercy)
Hobs Apell	Clinical Trials Office, Senior Executive Director
Carolyn Foster	Clinical Trials Office, IIT Protocol Development
Kevin Schorno	Institute for Advancing Medical Innovation, IIT Project Management

While the TAG and IIT Steering Committee function primarily as a means to assist individual investigators and clinicians with specific research projects they also serve as an important forum to receive input from KUCC members regarding the effectiveness of the cancer center's efforts to promote translational and clinical research across all campuses and throughout the center. For example, TAG and the IIT Steering Committee have provided important feedback on our pilot project program, mentoring activities, PRMS structure and Clinical Trials Office function, As a result, these aspects of our cancer center help to insure that information flow with the center is bi-directional in nature and not just from the top down.

Internal Advisory Board

As KUCC moves forward with its partnership with Children's Mercy, **Jensen** is formalizing an Internal Advisory Board with representatives from Children's Mercy, Stowers, KU-Lawrence, and KUMC (**Table 5**). This group meets twice a year (EAB visit and KUCC Research Symposium) to provide feedback on strategic initiatives, coordinate recruitment efforts and exchange research and clinical priorities.

Table 5. KUCC Internal Advisory Board

Institution	Advisors
KUMC	Alan Yu, MB, BChir & Doug Girod, MD
KU – Lawrence	Steven Soper, PhD & Neeli Bendapudi, PhD
Stowers	Scott Hawley, PhD & Rob Krumlauff, PhD
Children's Mercy	Steve Leeder, PhD & Tom Curran, PhD

Oncology Service Line

The oncology service line committee is responsible for coordinating all aspects of the delivery of clinical care to oncology patients throughout the University of Kansas Health System. As one of its primary aims it seeks to integrate clinical, translational and basic science research into the delivery of oncology care in order to expand KUCC's precision medicine infrastructure; develop a comprehensive cancer clinical trial enrollment plan designed to consent more patients and improve collection, storage, and retrieval of data, images and tissues for use in clinical research; establish cancer-specific disease management work groups to prioritize resources; and break barriers for distant patients with the Nurse Navigation program. The committee consists of all relevant division chiefs, chairs and senior health system officials responsible for the provision of cancer care. The Oncology Service Line is chaired by the KUCC Physician In Chief, **Tsue**.

Midwest Cancer Alliance (MCA) – Partners Advisory Board

The MCA Partners Advisory Board advances the pursuit of NCI designation for the region by facilitating collaboration of key hospitals and research institutions in the areas of research and education, leveraging regional strengths such as drug discovery and development, and addressing the continuum of cancer from prevention, early detection, treatment, and survivorship. Importantly, the MCA Partners Advisory Board serves in an advisory capacity to the Director of KUCC. Each Partners Advisory Board member provides $1,000,000 annually to the MCA; $750,000 is used to fund collaborative cancer-focused research projects between KUCC and the partnering institution, while the remaining $250,000 from each partner is used to support clinical

cancer research infrastructure. This group represents an important connection to the regional medical community and enables us to continuously assess their needs.

Cancer Funding Partners

Formed in 2009, the Cancer Funding Partners (CFP) council provides regional volunteer leadership and supports major gift fundraising for KUCC. Members serve as advocates for the Cancer Center in the community, promoting achievements and aspirations, with a focus on identifying and educating those from whom KUCC may obtain private financial support to expand cancer research, education and patient care. Membership is comprised of volunteers from the Kansas City region and across the state of Kansas and Missouri who have demonstrated an interest in and commitment to KUCC. Members include leaders from all areas of professional endeavor; some are patients or relatives of patients. Prospective council members are nominated by the council and invited by **Jensen**, in partnership with council chairpersons.

Member Responsibilities:

To facilitate securing the financial resources necessary to achieve KUCC's goals by:

- making a personal leadership gift commitment;
- identifying, qualifying, and assisting in the cultivation and solicitation of prospective donors;
- becoming a knowledgeable and passionate advocate of KUCC through site visits, printed materials, attendance at council meetings and special events, and opportunities to meet with the director and faculty;
- acting as a resource and advisor in increasing support from current donors;
- offering constructive feedback and ideas to help the center fulfill its mission; and
- participating in CFP meetings.

The CFP council meets quarterly, where progress toward fundraising goals is discussed. In addition, there is a bi-weekly call with the Chair and chair-elect to talk about ongoing progress and details. The group is comprised of 17 community members, 13/4 male/female. At this point in our Campaign for Comprehensive, the meetings focus most heavily on brainstorming and trouble-shooting each individual members' outreach activity and discussion around fundraising strategies for specific individuals, corporations or foundations.

PIVOT: Patient and Investigator Voices Organizing Together

There have been a number of efforts to diversify and include patient voices into healthcare and biomedical research at KUCC. With a longstanding tradition of community engagement and local partnerships to advance population health, KUCC has begun to employ effective engagement strategies to systematically bring patients' perspectives into the research process at early phases of our member's research by developing the PIVOT (Patient and Investigator Voices Organizing Together) initiative. PIVOT is an evolving community of patient research advocates learning and working with our academic research stakeholders to enhance research to more effectively address patients' needs and desired outcomes. PIVOT aims to engage patients, caregivers and communities to inform, collaborate, support and shape cancer research to optimally reflect what is important to patients. Patients and caregivers will bring their life experiences and a collective patient perspective to discussions, decisions and activities within various stages of partnership. PIVOT is led by Hope Krebill, Executive Director of the Midwest Cancer Alliance, Cheryl Jernigan, Survivor/Co-survivor & Lead Research Advocate, Kim **Kimminau**, PhD (CCPH), Research Director and Danielle Peereboom, Project Manager. The PIVOT leadership team will engage a small group of emerging research advocates between June and November, 2016 in order to inform the structure of PIVOT. In addition to building structure, this initial group will begin to engage with KUCC researchers. By November 2016, PIVOT plans to have a PIVOT leader team of research advocates from diverse backgrounds (cancer survivors and/or caregivers) who can represent the greater collective patient perspective in developing, implementing, and sharing research results. The PIVOT initiative expands on KUCC's mission to empower patients, reach underserved communities and advance quality cancer research and care. PIVOT will ultimately provide resources to expand KUCC's focus on patient-centered research and care by offering an engagement venue and framework encouraging a culture that welcomes diverse patient perspectives and experiences.

KUCC Strategic Plan

KUCC resolves to:

1. Lead the effort to reduce the burden of cancer in our region;
2. Promote a cancer center culture whose highest priority is to foster the discovery and advancement of new and more effective therapeutic approaches for the benefit patients and thereby stimulate and catalyze the education and training of the next generation of cancer clinicians and researchers;
3. Develop and implement paradigm changing therapeutic advances delivered in a compassionate, caring, and cost effective manner resulting in improved survival and quality of life for our patients;
4. Leverage our collective state-of-the-art basic, clinical, translational and population research programs to understand cancer at a fundamental level and enable a comprehensive, multidisciplinary approach to defeating cancer locally, regionally, nationally, and globally; and
5. Proactively execute cancer prevention and control strategies to mitigate the increase in cancer incidence and mortality predicted for the twenty-first century

To accomplish the vision set forth, KUCC developed its first strategic plan in 2010. The Associate Director for Administration, Christenson, coordinates the annual update of the strategic plan after the CCSG progress report is submitted to the NIH and the EAB meeting feedback has been received. The annual update is reviewed for progress with input from the Senior Leadership, Program Leaders and Shared Resource Directors. A *de novo* strategic plan is created every three years in order to reprioritize, refocus and leverage member expertise along with shared, clinical and institutional resources.

The primary objective of the first KUCC strategic planning initiatives was attainment of NCI designation. This accomplishment was realized in July 2012. Specifically, the first strategic plan (2010) outlined seven strategic priorities for KUCC. The seven strategic areas for development included:

1. Grow annual NCI grant funding to a level that is competitive for NCI designation;
2. Recruit 25 world-class cancer scholars;
3. Construct, renovate, and equip state-of-the-art cancer research facilities;
4. Advance the Cancer Center culture, centeredness and research infrastructure;
5. Drive regional collaborations for clinical trials (Midwest Cancer Alliance);
6. Enhance the Cancer Center's regional and national reputation; and
7. Deliver a world-class patient experience.

In 2013, **Jensen**, **Welch** and **Tsue** led the creation of the *de novo* second strategic plan. This second strategic plan evaluated the current status of KUCC and its partners and centered on an application for Comprehensive Cancer Center (CCC) designation by the NCI at the time of the cancer center support grant (CCSG) renewal in 2017. Priorities for the second strategic plan were to:

1. Evolve faculty culture toward collaboration and team science, to operate in a manner where each truly believes that the science and medicine in the cancer center are as world-class as it is, and to set standards to which others aspire;
2. Increase the NCI funding base, especially with regard to collaborative research;
3. Recruit faculty whose expertise complements that of existing faculty in order to round out the research and clinical enterprises;
4. Develop a comprehensive educational portfolio;
5. Expand infrastructure for basic laboratory research, outreach and clinical care;
6. Restructure the organization and procedures to improve communication, continuously evaluate and plan and improve the ability to quickly respond to opportunities and challenges; and
7. Improve patient access to care, patient experiences, participation in clinical trials (therapeutic and interventional), and breadth of cancers where expertise within the Cancer Center is recognized.

A meeting to kickoff the development of the third (*de novo*) strategic plan will be held October 1, 2016. This plan will be available at the spring 2017 NCI site visit.

Progress Report Publications

This component has no publications resulting from Cancer Center Support Grant funds.

Resource Sharing Plan

The University of Kansas Cancer Center (KUCC) and its scientific community understands its responsibility to comply with the instructions for the Resource Sharing Plans provided within the SF 424 (R&R) Application General Instructions and Supplemental Grant Application Instructions. When resources are developed with NIH funds via this Cancer Center Support Grant P30 mechanism, KUCC will ensure findings are made readily available to the NIH and the scientific community in a timely manner.

Data Sharing Plan

KUCC will adhere to the Final NIH Statement on Sharing Research Data and refer to the National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research. KUCC encourages the free flow of information and ideas while recognizing the timeliness of data sharing, the rights and privacy of human subjects and issues related to proprietary data. KUCC encourages data documentation, using a data-sharing agreement and selecting an appropriate method for sharing; considering the sensitivity of the data, the size of the dataset and the volume of requests anticipated.

Additionally, KUCC encourages any user of a CCSG-supported shared resource to acknowledge the source of data upon which their manuscript is based either in the Acknowledgments section or with authorship on the paper. Furthermore, any research project that received direct cost support from the CCSG is encouraged to cite the P30 CA168524. In both cases, citing the P30 CA168524 grant number and then being compliant with the NIH Public Access Policy is required.

Sharing Model Organisms

In the event that a model organism is developed, KUCC will comply with the NIH Policy on Sharing of Model Organisms for Biomedical Research. KUCC will work with the NIH/NCI to share and disseminate the critical model organism in a timely manner.

Genome Wide Associate Studies

When applicable, KUCC will comply with the NIH Genomic Data Sharing Policy. KUCC supports the sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. All research studies funded through the CCSG involving genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data will be submitted in a timely manner.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 016060860

Legal Name*: University of Kansas Medical Center Research Institute, Inc.
Department:
Division:
Street1*: MSN 1039, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Deborah		Maloney	MSM

Position/Title: Director, Sponsored Programs Administration
Street1*: 3901 Rainbow Boulevard
Street2: Mail Stop 1039
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937
Phone Number*: 913-588-1261 Fax Number: 913-588-3225 Email: spa@kumc.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofit Organization

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Developmental Funds

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2017	06/30/2022

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Medical Center
Duns Number:	016060860
Street1*:	MS 3045, 3901 Rainbow Boulevard
Street2:	
City*:	Kansas City
County:	Wyandotte
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66160-0000
Project/Performance Site Congressional District*:	KS-003

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ❍ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number 00003411

2. Are Vertebrate Animals Used?* ● **Yes** ❍ **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number A3237-01

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	Develop_Core_Project_Summary_Final1019428430.pdf
8. Project Narrative*	
9. Bibliography & References Cited	References_Cited_DF1019428431.pdf
10.Facilities & Other Resources	
11.Equipment	
12. Other Attachments	Develop_OtherAttachments_Final1019428432.pdf

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Developmental Funds – Project Summary/Abstract

The University of Kansas Cancer Center requests CCSG developmental funds to support pilot research projects, develop additional shared resources to strengthen research initiatives, support new faculty recruits and promote basic, translational and clinical science research activities. Funding pilot projects, developing shared resources, recruiting new faculty and supporting staff investigators will collectively enhance the ability of KUCC to serve the catchment area and mitigate the impact of cancer in the region. KUCC believes that these activities will enable the Cancer Center to provide the optimal environment to focus the power of precision medicine, basic science inquiry, drug discovery and development, and behavioral interventions to decrease cancer incidence, morbidity, and mortality. Furthermore, these activities will promote a cancer center culture whose highest priority is to leverage the collective state-of-the-art basic, clinical, translational and population research programs to understand cancer at a fundamental level and catalyze a comprehensive, multidisciplinary approach to defeating cancer. KUCC has demonstrated a successful track record in its investment of CCSG developmental funds and other KUCC-directed funding mechanisms and will continue to grow a strong return on investment from these funds.

Pilot Projects and Outcomes				
Funding Mechanism - CCSG Developmental Funds **16 awards given for a total investment of $478,389; awardees received 11 externally-funded grants totaling $7,600,136 and published 62 peer-reviewed articles**				
Pilot Project Title #1	**Member**	**Pilot Award Investment**	**Year**	**Program**
Biomaterials for treatment of head and neck cancer	M. Laird Forrest	$11,942	2012	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Bagby TR, Cai S, Duan S, Yang Q, Thati S, **Berkland** C, **Aires** DJ, Laird **Forrest** M. Lymphatic trafficking kinetics and near-infrared imaging using star polymer architectures with controlled anionic character. Eur J Pharm Sci. 2012.	R01CA173292: Biomaterials For Treatment of Head And Neck Cancer	$1,566,625		
Cai S, Alhowyan AA, Yang Q, Forrest WC, **Shnayder** Y, **Forrest** ML. Cellular uptake and internalization of hyaluronan-based doxorubicin and cisplatin conjugates. Journal of drug targeting. 2014;22(7):648-57. Epub 2014/06/04. doi: 10.3109/1061186x.2014.921924. PubMed PMID: 24892741.	NIH/NCI HHSN261201500047C (NCI control # N43-CO-2015-0047): Targeted nanoparticle treatment for breast cancer stem cells	$660,000		
Chakraborty A, Mucci NJ, Tan ML, Steckley A, Zhang T, **Forrest** ML, Dhar P. Phospholipid composition modulates carbon nanodiamond-induced alterations in phospholipid domain formation. Langmuir : the ACS journal of surfaces and colloids. 2015;31(18):5093-104. Epub 2015/04/16. doi: 10.1021/la504923j. PubMed PMID: 25876023; PMCID: Pmc4702515.				
Chen R, Zhao Y, Huang Y, Yang Q, Zeng X, Jiang W, Liu J, **Thrasher** JB, **Forrest** ML, Li B. Nanomicellar TGX221 blocks xenograft tumor growth of prostate cancer in nude mice. The Prostate. 2015;75(6):593-602. Epub 2015/01/27. doi: 10.1002/pros.22941. PubMed PMID: 25620467; PubMed Central PMCID: PMCPmc4376584.				
Cohen SM, Rockefeller N, Mukerji R, Durham D, **Forrest** ML, Cai S, **Cohen** MS, **Shnayder** Y. Efficacy and toxicity of peritumoral delivery of nanoconjugated cisplatin in an in vivo murine model of head and neck squamous cell carcinoma. JAMA otolaryngology-- head & neck surgery. 2013;139(4):382-7. doi: 10.1001/jamaoto.2013.214. PubMed PMID: 23599074.				
Devarajan K, **Forrest** ML, **Detamore** MS, Staecker H. Adenovector-mediated gene delivery to human umbilical cord mesenchymal stromal cells induces inner ear cell phenotype. Cellular reprogramming. 2013;15(1):43-54. doi: 10.1089/cell.2011.0097. PubMed PMID: 23379581.				
Duan S, Cai S, Yang Q, **Forrest** ML. Multi-arm polymeric nanocarrier as a nitric oxide delivery platform for chemotherapy of head and neck squamous cell carcinoma. Biomaterials. 2012;33(11):3243-53.				
Louizos C, Yanez JA, **Forrest** ML, Davies NM. Understanding the hysteresis loop conundrum in pharmacokinetic/pharmacodynamic relationships. Journal of pharmacy & pharmaceutical sciences: a publication of the Canadian Society for Pharmaceutical Sciences, Societe canadienne des sciences pharmaceutiques. 2014;17(1):34-91. Epub 2014/04/17. PubMed PMID: 24735761.				
Mellott AJ, Devarajan Ks, Shinogle H, Moore D, Talata Z, Laurence J, **Forrest** ML, Noji S, Tanaka E, Staecker H, **Detamore** MS. Non-viral reprogramming of human Wharton's jelly cells reveals differences between ATOH1 homologues. Tissue engineering Part A. 2015. Epub 2015/03/12. doi: 10.1089/ten.TEA.2014.0340. PubMed PMID: 25760435.				
Mellott AJ, **Forrest** ML, **Detamore** MS. Physical non-viral gene delivery methods for tissue engineering. Annals of biomedical engineering. 2013;41(3):446-68. doi: 10.1007/s10439-012-0678-1. PubMed PMID: 23099792.				
Ndolo RA, Luan Y, Duan S, **Forrest** ML, **Krise** JP. Lysosomotropic properties of weakly basic anticancer agents promote cancer cell selectivity in vitro. PLoS One. 2012;7(11):e49366. PMCID: 3492287.				
S. Cai, T. Zhang, W.C. Forrest, Y. Qiuhong, C. Groer, E. Mohr, D.J. **Aires,** M. S.M. Axiak-Bechtel, B.K. Flesner, C.J. Henry, K.A. Selting, D. Tate, J.A. Swarz, J.N. Bryan, M.L. **Forrest.** "Phase I/II Clinical Trial of Hyaluronan-Cisplatin Nanoconjugate for the Treatment of Spontaneous Canine Cancers." Am. J. Vet. Res., Accepted 2015. NIHMS748091				
Sestak J, Mullins M, Northrup L, Thati S, **Forrest** ML, **Siahaan** TJ, **Berkland** C. Single-step grafting of aminooxy-peptides to hyaluronan: a simple approach to multifunctional therapeutics for experimental autoimmune encephalomyelitis. Journal of controlled release : official journal of the Controlled Release Society. 2013;168(3):334-40. doi: 10.1016/j.jconrel.2013.03.015. PubMed PMID: 23541930; PubMed Central PMCID: PMC3672265.				
Sharifi S, Behzadi S, Laurent S, **Forrest** ML, Stroeve P, Mahmoudi M. Toxicity of nanomaterials. Chemical Society reviews. 2012;41(6):2323-43. Epub 2011/12/16. doi: 10.1039/c1cs15188f. PubMed PMID: 22170510.				
Sim MW, Grogan PT, Subramanian C, Bradford CR, Carey TE, **Forrest** ML, Prince ME, Cohen MS. Effects of peritumoral nanoconjugated cisplatin on laryngeal cancer stem cells. The Laryngoscope. 2015. Epub 2015/12/23. doi: 10.1002/lary.25808. PubMed PMID: 26690734.				
Sim MW, Grogan PT, Subramanian C, Bradford CR, Carey TE, **Forrest** ML, Prince ME, Cohen MS. Effects of peritumoral nanoconjugated cisplatin on laryngeal cancer stem cells. The Laryngoscope. 2015. Epub 2015/12/23. doi: 10.1002/lary.25808. PubMed PMID: 26690734.				
Ti Zhang, Shuang Cai, W.C. Forrest, Eva Mohr, Qiuhong Yang, and M. Laird **Forrest.** "Development and Validation of an Inductively Coupled Plasma Mass Spectrometry Method for Quantitative Analysis of Platinum in Plasma, Urine, and Tissues." Applied Spectroscopy, Accepted 2016.				
Yang Q, Aires DJ, Cai S, Fraga GR, Zhang D, Li CZ, **Forrest** ML. In vivo efficacy of nano hyaluronan-conjugated cisplatin for treatment of murine melanoma. Journal of drugs in dermatology : JDD. 2014;13(3):283-7. PubMed PMID: 24595572.				

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Zhang T, Cai S, Groer C, Forrest WC, Yang Q, Mohr E, Douglas J, **Aires** D, Axiak-Bechtel SM, Selting KA, Swarz JA, Tate DJ, Bryan JN, **Forrest** ML. Hyaluronan-Lysine Cisplatin Drug Carrier for Treatment of Localized Cancers: Pharmacokinetics, Tolerability, and Efficacy in Rodents and Canines. Journal of pharmaceutical sciences. 2016. Epub 2016/05/09. doi: 10.1016/j.xphs.2016.03.018. PubMed PMID: 27155765.				
Zhang T, Cui H, Fang CY, Cheng K, Yang X, Chang HC, **Forrest** ML. Targeted nanodiamonds as phenotype-specific photoacoustic contrast agents for breast cancer. Nanomedicine (London, England). 2015;10(4):573-87. Epub 2015/02/28. doi: 10.2217/nnm.14.141. PubMed PMID: 25723091.				
Zhang T, Cui H, Fang CY, Jo J, Yang X, Chang HC, **Forrest** ML. In vivo photoacoustic imaging of breast cancer tumor with HER2-targeted nanodiamonds. Proceedings of SPIE--the International Society for Optical Engineering. 2013;8815. Epub 2013/09/20. doi: 10.1117/12.2027253. PubMed PMID: 25620857; PMCID: PMC4302273.				
Zhang T, Cui H, Fang CY, Su LJ, Ren S, Chang HC, Yang X, **Forrest** ML. Photoacoustic contrast imaging of biological tissues with nanodiamonds fabricated for high near-infrared absorbance. Journal of biomedical optics. 2013;18(2):26018. doi: 10.1117/1.JBO.18.2.026018. PubMed PMID: 23400417; PubMed Central PMCID: PMC3569583.				
Zhang T, Yang Q, Forrest WC, Cai S, Aires D, **Forrest** ML. A Lanthanum-Tagged Chemotherapeutic Agent HA-Pt to Track the Distribution of Hyaluronic Acid Complexes. BAOJ pharmaceutical sciences. 2015;1(1). Epub 2016/01/13. PubMed PMID: 26756040; PMCID: Pmc4706177.				
Zhao Y, Zhang T, Duan S, Davies NM, **Forrest** ML. CD44-tropic polymeric nanocarrier for breast cancer targeted rapamycin chemotherapy. Nanomedicine : nanotechnology, biology, and medicine. 2014;10(6):1221-30. Epub 2014/03/19. doi: 10.1016/j.nano.2014.02.015. PubMed PMID: 24637218; PubMed Central PMCID: PMCPmc4119834.				
Pilot Project Title #2	**Member**	**Pilot Award Investment**	**Year**	**Program**
Impact of Vitamin D deficiency on Osteosarcoma Pathobiology	Rama Garimella	$10,000	2012	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Garimella R, Eskew J, Bhamidi P, Vielhauer G, Hong Y, Anderson HC, **Tawfik** O, Rowe P. Biological characterization of preclinical Bioluminescent Osteosarcoma Orthotopic Mouse (BOOM) model: A multi-modality approach. Journal of bone oncology. 2013;2(1):11-21. Epub 2013/02/01. doi: 10.1016/j.jbo.2012.12.005. PubMed PMID: 25688332; PMCID: PMC4327846.				
Pilot Project Title #3	**Member**	**Pilot Award Investment**	**Year**	**Program**
The role of MDM2-MTBP axis in cancer metastasis	Tomoo Iwakuma	$17,247	2012	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Agarwal N, Adhikari AS, Iyer SV, Hekmatdoost K, **Welch** DR, **Iwakuma** T. MTBP suppresses cell migration and filopodia formation by inhibiting ACTN4. Oncogene. 2012.	R01CA174735: The role of MDM2-MTBP axis in Cancer Metastasis	$939,975		
Bi Q, Ranjan A, Fan R, Agarwal N, **Welch** DR, **Weinman** SA, Ding J, **Iwakuma** T. MTBP inhibits migration and metastasis of hepatocellular carcinoma. Clinical & experimental metastasis. 2015;32(4):301-11. Epub 2015/03/12. doi: 10.1007/s10585-015-9706-5. PubMed PMID: 25759210; PMCID: Pmc4510982.	ACS: Uncovering the Mechanisms of Osteosarcoma Metastasis Suppression by MTBP	$360,000		
Harihar S, Pounds KM, **Iwakuma** T, Seidah NG, Welch DR. Furin is the major proprotein convertase required for KISS1-to-Kisspeptin processing. PloS one. 2014;9(1):e84958. Epub 2014/01/24. doi: 10.1371/journal.pone.0084958. PubMed PMID: 24454770; PubMed Central PMCID: PMCPmc3890299.				
Iwakuma T, Agarwal N. MDM2 binding protein, a novel metastasis suppressor. Cancer Metastasis Rev. 2012.				
Iyer SV, **Iwakuma** T. A novel link between the HER2-Akt and MDM2-p53 pathways via CSN6. Cell Cycle. 2012;11(22):4112. Epub 2012/10/27. PubMed PMID: 23099920; PubMed Central PMCID: PMC3524203.				
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Kibe R, Zhang S, Guo D, Marrero L, Tsien F, Rodriguez P, Khan S, Zieske A, Huang J, Li W, Durum SK, **Iwakuma** T, Cui Y. IL-7Ralpha deficiency in p53(null) mice exacerbates thymocyte telomere erosion and lymphomagenesis. Cell Death Differ. 2012.				
Kurahara H, Bohl C, Natsugoe S, Nishizono Y, Harihar S, Sharma R, **Iwakuma** T, **Welch** DR. Suppression of pancreatic cancer growth and metastasis by HMP19 identified through genome-wide shRNA screen. Int J Cancer. 2016. Epub 2016/03/26. doi: 10.1002/ijc.30110. PubMed PMID: 27012470.				
Liu W, Beck BH, Vaidya KS, Nash KT, Feeley KP, Ballinger SW, Pounds KM, Denning WL, Diers AR, Landar A, Dhar A, **Iwakuma** T, **Welch** DR. Metastasis suppressor KISS1 seems to reverse the Warburg effect by enhancing mitochondrial biogenesis. Cancer research. 2014;74(3):954-63. Epub 2013/12/20. doi: 10.1158/0008-5472.can-13-1183. PubMed PMID: 24351292; PubMed Central PMCID: PMCPmc3946400.				
Parrales A, **Iwakuma** T. Targeting Oncogenic Mutant p53 for Cancer Therapy. Frontiers in oncology. 2015;5:288. Epub 2016/01/07. doi: 10.3389/fonc.2015.00288. PubMed PMID: 26732534; PMCID: Pmc4685147.				

Sasaki H, Iyer SV, Sasaki K, **Tawfik** OW, **Iwakuma** T. An improved intrafemoral injection with minimized leakage as an orthotopic mouse model of osteosarcoma. Analytical biochemistry. 2015. Epub 2015/07/05. doi: 10.1016/j.ab.2015.06.030. PubMed PMID: 26142221.				
Pilot Project Title #4	**Member**	**Pilot Award Investment**	**Year**	**Program**
Bayesian predicion for interim review of studies with slow patient accrual	Byron Gajewski	$19,200	2013	CCPH
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Garrard L, Price LR, Bott MJ, **Gajewski** BJ. A novel method for expediting the development of patient-reported outcome measures and an evaluation of its performance via simulation. BMC medical research methodology. 2015;15:77. Epub 2015/10/01. doi: 10.1186/s12874-015-0071-5. PubMed PMID: 26419748; PMCID: Pmc4589027.	R03NR013236: A Novel Method for Expediting the Development of Patient Reported Outcome Measures	$148,735		
Gajewski B, Price LR, Bott M. Response to Sijtsma and van der Ark (2015): "Conceptions of reliability revisited and practical recommendations". Nursing research. 2015;64(2):137-9. Epub 2015/03/05. doi: 10.1097/NNR.0000000000000078. PubMed PMID: 25738625; PubMed Central PMCID: PMC4386879.				
Jiang Y, Simon S, **Mayo** MS, **Gajewski** BJ. Modeling and validating Bayesian accrual models on clinical data and simulations using adaptive priors. Stat Med. 2015;34(4):613-29. Epub 2014/11/08. doi: 10.1002/sim.6359. PubMed PMID: 25376910; PubMed Central PMCID: PMCPmc4314351.				
Garrard, L, Price, L, Bott, M **Gajewski,** B (in press), "A novel method for expediting the development of patient-reported outcome measures and an evaluation across several populations," Accepted by Applied Psychological Measurement (PMCID pending).				
Pilot Project Title #5	**Member**	**Pilot Award Investment**	**Year**	**Program**
Assessment of Molecular markers in DCIS to predict the benefit of radiotherapy	Melissa Mitchell/Fariba Behbod	$35,000	2013	D3ET/CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Badkul R, McClinton C, Kumar P, **Mitchell** M. SU-E-T-525: Dose Volume Histograms (DVH) Analysis and Comparison with ICRU Point Doses in MRI Guided HDR Brachytherapy for Cervical Cancer. Medical Physics. 2014;41(6):348-. doi: doi:http://dx.doi.org/10.1118/1.4888858.				
Mitchell MP, Abboud M, Eng C, Beddar AS, Krishnan S, Delclos ME, Crane CH, Das P. Intensity-modulated radiation therapy with concurrent chemotherapy for anal cancer: outcomes and toxicity. American journal of clinical oncology. 2014;37(5):461-6. Epub 2013/03/08. doi: 10.1097/COC.0b013e31827e52a3. PubMed PMID: 23466576.				
Pilot Project Title #6	**Member**	**Pilot Award Investment**	**Year**	**Program**
Targeting Notch-1 signaling by Tandutinib in colon cancer	Dharmalingam Subramaniam	$35,000	2013	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #7	**Member**	**Pilot Award Investment**	**Year**	**Program**
Investigation of multifactor gene-environment interactions in ovarian cancer	Brooke Fridley	$35,000	2014	CCPH
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Usset JL, Raghavan R, Tyrer JP, McGuire V, ... **Fridley** BL. Assessment of multifactor gene-environment interactions and ovarian cancer risk: candidate genes, obesity, and hormone-related risk factors. Cancer epidemiology, biomarkers & prevention : a publication of the American Association for Cancer Research, cosponsored by the American Society of Preventive Oncology. 2016. Epub 2016/03/16. doi: 10.1158/1055-9965.epi-15-1039. PubMed PMID: 26976855.				
Pilot Project Title #8	**Member**	**Pilot Award Investment**	**Year**	**Program**
Discovery of Biomarkers fo Null Cell Tumors	T. Rajendra Kumar	$35,000	2014	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Kumar TR. Extragonadal FSH Receptor: Is It Real? Biology of reproduction. 2014;91(4):99. Epub 2014/08/22. doi: 10.1095/biolreprod.114.124222. PubMed PMID: 25143358.	R01CA166557: Chemoprevention of Pituitary Gonadotrope Tumors	$1,243,900		
Wang H, Larson M, Jablonka-Shariff A, Pearl CA, Miller WL, Conn PM, Boime I, **Kumar** TR. Redirecting intracellular trafficking and the secretion pattern of FSH dramatically enhances ovarian function in mice. Proceedings of the National Academy of Sciences of the United States of America. 2014;111(15):5735-40. Epub 2014/04/08. doi: 10.1073/pnas.1321404111. PubMed PMID: 24706813; PubMed Central PMCID: PMCPmc3992661				
Wang H, Graham I, Hastings R, Gunewardena S, Brinkmeier ML, Conn PM, Camper SA, **Kumar** TR. Gonadotrope-specific deletion of Dicer results in severely suppressed gonadotropins and fertility defects. The Journal of biological chemistry. 2015;290(5):2699-714. Epub 2014/12/20. doi: 10.1074/jbc.M114.621565. PubMed PMID: 25525274; PMCID: Pmc4317015.				
Wang H, Hastings R, Miller WL, **Kumar** TR. Fshb-iCre mice are efficient and specific Cre deleters for the gonadotrope lineage. Molecular and cellular endocrinology. 2016;419:124-38. Epub 2015/10/17. doi: 10.1016/j.mce.2015.10.006. PubMed PMID: 26472536; PMCID: PMC4684453.				
Pilot Project Title #9	**Member**	**Pilot Award Investment**	**Year**	**Program**
Regulation of Epidermal Growth Factor Receptor(EGFR) by BRCA1	Easwari Kumaraswamy	$35,000	2014	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Kumaraswamy E, Wendt KL, Augustine LA, Stecklein SR, Sibala EC, Li D, Gunewardena S, **Jensen** RA. BRCA1 regulation of epidermal growth factor receptor (EGFR) expression in human breast cancer cells involves microRNA-146a and is critical for its tumor suppressor function. Oncogene. 2015;34(33):4333-46. Epub 2014/11/25. doi: 10.1038/onc.2014.363. PubMed PMID: 25417703.				
Pilot Project Title #10	**Member**	**Pilot Award Investment**	**Year**	**Program**
High throughput screening of inhibitors specific for lysyl oxidase-like 2	Minae Mure	$35,000	2014	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**

Moon HJ, Finney J, Xu L, Moore D, **Welch** DR, **Mure** M. MCF-7 cells expressing nuclear associated lysyl oxidase-like 2 (LOXL2) exhibit an epithelial-to-mesenchymal transition (EMT) phenotype and are highly invasive in vitro. The Journal of biological chemistry. 2013;288(42):30000-8. doi: 10.1074/jbc.C113.502310. PubMed PMID: 24014025; PubMed Central PMCID: PMC3798469.	R01GM113101-01: Understanding the roles of PTMs in modulating molecular	$1,436,095		
Xu L, Go EP, Finney J, Moon H, Lantz M, Rebecchi K, Desaire H, **Mure** M. Post-translational modifications of recombinant human lysyl oxidase-like 2 (rhLOXL2) secreted from Drosophila S2 cells. The Journal of biological chemistry. 2013;288(8):5357-63. doi: 10.1074/jbc.C112.421768. PubMed PMID: 23319596; PubMed Central PMCID: PMC3581389.				
Pilot Project Title #11	**Member**	**Pilot Award Investment**	**Year**	**Program**
Adolescents' responses to e-cigarette marketing messages	Yvonnes Chen	$35,000	2015	CCPH
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #12	**Member**	**Pilot Award Investment**	**Year**	**Program**
Mutant p53 degradation: its mechanisms and clinical applications	Tomoo Iwakuma	$35,000	2015	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Parrales A, **Iwakuma** T. Targeting Oncogenic Mutant p53 for Cancer Therapy. Frontiers in oncology. 2015;5:288. Epub 2016/01/07. doi: 10.3389/fonc.2015.00288. PubMed PMID: 26732534; PMCID: Pmc4685147.	R01 CA174735: The role of MDM2-MTBP axis in Cancer Metastasis	$939,975		
	ACS - RSG-09-169-01-CSM: Uncovering the Mechanisms of Osteosarcoma Metastasis Suppression by MTBP	$270,000		
Pilot Project Title #13	**Member**	**Pilot Award Investment**	**Year**	**Program**
Role of IFITM1 in aromatase inhibitor resistance in breast cancer	Joan Lewis-Wambi	$35,000	2015	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Choi HJ, Lui A, Ogony J, Jan R, Sims PJ, **Lewis-Wambi** J. Targeting interferon response genes sensitizes aromatase inhibitor resistant breast cancer cells to estrogen-induced cell death. Breast cancer research : BCR. 2015;17:6. Epub 2015/01/16. doi: 10.1186/s13058-014-0506-7. PubMed PMID: 25588716; PMCID: Pmc4336497.	F30CA203160-01: (Lui) - Role: Mentor - The role of IFN inducible transmembrane protein in AI-resistant breast cancer	$29,831		
Ogony J, Choi HJ, Lui A, Cristofanilli M, **Lewis-Wambi** J. Interferon-induced transmembrane protein 1 (IFITM1) overexpression enhances the aggressive phenotype of SUM149 inflammatory breast cancer cells in a signal transducer and activator of transcription 2 (STAT2)-dependent manner. Breast cancer research : BCR. 2016;18(1):25. Epub 2016/02/22. doi: 10.1186/s13058-016-0683-7. PubMed PMID: 26897526; PMCID: PMC4761146.	American Medical Association Foundation: The impact of interferon stimulated gene expression on patient response to aromatase inhibitor therapy for ER-positive breast cancer	$5,000		
Pilot Project Title #14	**Member**	**Pilot Award Investment**	**Year**	**Program**
Investigation of HuR as novel exosomal biomarker for colorectal cancer	Dan Dixon	$35,000	2015	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #15	**Member**	**Pilot Award Investment**	**Year**	**Program**
Tablet-based application to improve perioperative outcomes in radical cystectomy	Eugene Lee	$35,000	2015	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Dum TW, Zhang D, **Lee** EK. IgG4-Related Disease in a Urachal Tumor. Case reports in urology. 2014;2014:275850-. doi: 10.1155/2014/275850. PubMed PMID: MEDLINE:25202466.				
Hamilton-Reeves JM, Bechtel MD, Hand LK, Schleper A, **Yankee** TM, **Chalise** P, **Lee** EK, Mirza M, Wyre H, Griffin J, **Holzbeierlein** JM. Effects of Immunonutrition for Cystectomy on Immune Response and Infection Rates: A Pilot Randomized Controlled Clinical Trial. Eur Urol. 2015. Epub 2015/12/15. doi: 10.1016/j.eururo.2015.11.019. PubMed PMID: 26654125.				
Liu W, Vielhauer GA, **Holzbeierlein** JM, Zhao H, Ghosh S, Brown D, **Lee** E, **Blagg** BS. KU675, a Concomitant Heat-Shock Protein Inhibitor of Hsp90 and Hsc70 that Manifests Isoform Selectivity for Hsp90alpha in Prostate Cancer Cells. Molecular pharmacology. 2015;88(1):121-30. Epub 2015/05/06. doi: 10.1124/mol.114.097303. PubMed PMID: 25939977; PMCID: Pmc4468638.				
Parker WP, Ho PL, Melquist JJ, Scott K, **Holzbeierlein** JM, Lopez-Corona E, Kamat AM, **Lee** EK. The effect of concomitant carcinoma in situ on neoadjuvant chemotherapy for urothelial cell carcinoma of the bladder: inferior pathological outcomes but no effect on survival. The Journal of urology. 2015;193(5):1494-9. Epub 2014/12/03. doi: 10.1016/j.juro.2014.11.003. PubMed PMID: 25451834.				
Pilot Project Title #16	**Member**	**Pilot Award Investment**	**Year**	**Program**
Role of HSF1 in regulating BCR and NF-kB signaling in CLL	Rehka Rao Manepalli	$35,000	2015	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Home T, Jensen RA, **Rao** R. Heat Shock Factor 1 in Protein Homeostasis and Oncogenic Signal Integration. Cancer Res. 2015;75(6):907-12. Epub 2015/03/01. doi: 10.1158/0008-5472.can-14-2905. PubMed PMID: 25724679.				
Ganguly S, Home T, Yacoub A, Kambhampati S, Shi H, Dandawate P, Padhye S, Saluja AK, McGuirk J, **Rao** R. Targeting HSF1 disrupts HSP90 chaperone function in chronic lymphocytic leukemia. Oncotarget. 2015;6(31):31767-79. Epub 2015/09/24. doi: 10.18632/oncotarget.5167. PubMed PMID: 26397138; PMCID: Pmc4741638.				
Home T, Jensen RA, **Rao** R. Heat Shock Factor 1 in Protein Homeostasis and Oncogenic Signal Integration. Cancer Res. 2015;75(6):907-12. Epub 2015/03/01. doi: 10.1158/0008-5472.can-14-2905. PubMed PMID: 25724679.				

Funding Mechanism - KUCC Pilot Project Program **27 awards given for a total investment of $737,754; awardees received 9 externally-funded grants totaling $5,753,387, published 38 peer-reviewed articles, initiated 2 clinical trials and obtained 8 patents**				
Pilot Project Title #1	**Member**	**Pilot Award Investment**	**Year**	**Program**
Metabolic imaging markers of tumor activity in living human brain	In-Young Choi	$35,000	2012	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
P. Adany, P. Lee, S. Taylor, R. Chamoun, I.-Y. **Choi,** 3D B0-adjusted and sensitivity-enhanced spectral localization by imaging (BASE-SLIM) of patients with gliomas, Proc Int Soc Magn Reson Med 22, 3734				
Pilot Project Title #2	**Member**	**Pilot Award Investment**	**Year**	**Program**
Boron Containing Retinoid as Novel Therapeutic Agent for Glioblastoma Multiforme (GBM)	Bhaskar Das	$35,000	2012	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #3	**Member**	**Pilot Award Investment**	**Year**	**Program**
Development of genomic analysis infrastructure with application to the study of ovarian cancer	Brooke Fridley	$35,000	2012	CCPH
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Chalise P, Koestler DC, Bimali M, Yu Q, **Fridley** BL. Integrative clustering methods for high-dimensional molecular data. Translational cancer research. 2014;3(3):202-16. Epub 2014/09/23. doi: 10.3978/j.issn.2218-676X.2014.06.03. PubMed PMID: 25243110; PubMed Central PMCID: PMCPmc4166480.	R21 GM086689: Bayesian Hierarchical Nonlinear Models for Pharmacogenomic Cytotoxicity Studies	$231,525		
Pilot Project Title #4	**Member**	**Pilot Award Investment**	**Year**	**Program**
Liquid Biopsy-Based Assays to Detect Early-Stage Bladder Cancer	Andrew Godwin	$35,000	2012	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #5	**Member**	**Pilot Award Investment**	**Year**	**Program**
A Translational Approach to Understanding African American Colorectal Cancer Health Disparities	K. Allen Greiner	$35,000	2012	CCPH
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Hester CM, Jala VR, Langille MG, Umar S, **Greiner** KA, Haribabu B. Fecal microbes, short chain fatty acids, and colorectal cancer across racial/ethnic groups. World journal of gastroenterology : WJG. 2015;21(9):2759-69. Epub 2015/03/12. doi: 10.3748/wjg.v21.i9.2759. PubMed PMID: 25759547; PubMed Central PMCID: PMC4351229.	R01CA188898: Adaptive Intervention to Maximize Colorectal Screening in Safety Net Populations	$634,932	KUCC Pilot Funds:A Translational Approach to Understanding African American Colorectal Health Disparities	Frontiers Exploring African American Colorectal Cancer Health Disparities
Roy BC, Subramaniam D, Ahmed I, Jala VR, Hester CM, **Greiner** KA, Haribabu B, Anant S, Umar S. Role of bacterial infection in the epigenetic regulation of Wnt antagonist WIF1 by PRC2 protein EZH2. Oncogene. 2014. Epub 2014/12/09. doi: 10.1038/onc.2014.386. PubMed PMID: 25486432.				
Roy BC, Subramaniam D, Ahmed I, Jala VR, Hester CM, **Greiner** KA, Haribabu B, Anant S, Umar S. Role of bacterial infection in the epigenetic regulation of Wnt antagonist WIF1 by PRC2 protein EZH2. Oncogene. 2015;34(34):4519-30. Epub 2014/12/09. doi: 10.1038/onc.2014.386. PubMed PMID: 25486432; PMCID: Pmc4459936.				
Pilot Project Title #6	**Member**	**Pilot Award Investment**	**Year**	**Program**
Mechanistic effects of soy intake on the pathogenesis of prostate cancer	Jill Hamilton-Reeves	$35,000	2012	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Diggett B, Holzbeierlein J, Klemp J, Glennon C, **Hamilton-Reeves** JM. Patient-centered perspectives on the access to educational opportunities specific to lifestyle modification in men at risk for primary or secondary prostate cancer. Journal of cancer education : the official journal of the American Association for Cancer Education. 2014;29(2):252-7. Epub 2013/11/12. doi: 10.1007/s13187-013-0583-9. PubMed PMID: 24214853.				
Hamilton-Reeves JM, Banerjee S, Banerjee SK, Holzbeierlein JM, Thrasher JB, Kambhampati S, Keighley J, Van Veldhuizen P. Short-term soy isoflavone intervention in patients with localized prostate cancer: a randomized, double-blind, placebo-controlled trial. PLoS One. 2013 Jul 12;8(7):e68331. doi: 10.1371/journal.pone.0068331. Print 2013. PubMed PMID: 23874588; PubMed Central PMCID: PMC3710024.				
Pilot Project Title #7	**Member**	**Pilot Award Investment**	**Year**	**Program**
Discovery of drugs stabilizing miR-542-3p:Cox-2 mRNA Interaction	Raymond Perez	$35,000	2012	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #8	**Member**	**Pilot Award Investment**	**Year**	**Program**
Modeling Pregnancy-Related Changes in Cancer Risk using Humanized Mice	Margaret Petroff	$35,000	2012	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Hunt JS, **Petroff** MG. IFPA Senior Award Lecture: Reproductive immunology in perspective--reprogramming at the maternal-fetal interface. Placenta. 2013;34 Suppl:S52-5. doi: 10.1016/j.placenta.2012.12.005. PubMed PMID: 23294570; PubMed Central PMCID: PMC3700590.				
Jasti S, Warren BD, McGinnis LK, Kinsey WH, Petroff BK, **Petroff** MG. The autoimmune regulator prevents premature reproductive senescence in female mice. Biol Reprod. 2012;86(4):110.				

Linscheid C, **Petroff** MG. Minor histocompatibility antigens and the maternal immune response to the fetus during pregnancy. Am J Reprod Immunol. 2013;69(4):304-14. doi: 10.1111/aji.12075. PubMed PMID: 23398025.				
Perchellet AL, Jasti S, **Petroff** MG. Maternal CD4+ and CD8+ T cell tolerance towards a fetal minor histocompatibility antigen in T cell receptor transgenic mice. Biology of reproduction. 2013;89(4):102. doi: 10.1095/biolreprod.113.110445. PubMed PMID: 24025737.				
Pilot Project Title #9	**Member**	**Pilot Award Investment**	**Year**	**Program**
Heat shock proteins, hypoxia, and cancer stem cells	Prabhu Ramamoorthy	$35,000	2012	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Kaushik G, Venugopal A, **Ramamoorthy** P, Standing D, Subramaniam D, Umar S, Jensen RA, Anant S, Mammen JMV. Honokiol inhibits melanoma stem cells by targeting notch signaling. Molecular carcinogenesis. 2015;54(12):1710-21. doi: 10.1002/mc.22242. PubMed PMID: MEDLINE:25491779.				
Kwatra D, Subramaniam D, **Ramamoorthy** P, Standing D, Moran E, Velayutham R, Mitra A, Umar S, Anant S. Methanolic extracts of bitter melon inhibit colon cancer stem cells by affecting energy homeostasis and autophagy. Evidence-based complementary and alternative medicine : eCAM. 2013;2013:702869. doi: 10.1155/2013/702869. PubMed PMID: 23533514; PubMed Central PMCID: PMC3606719.				
Subramaniam D, Ponnurangam S, **Ramamoorthy** P, Standing D, Battafarano RJ, Anant S, Sharma P. Curcumin induces cell death in esophageal cancer cells through modulating Notch signaling. PLoS One. 2012;7(2):e30590. PMCID: 3281833.				
Pilot Project Title #10	**Member**	**Pilot Award Investment**	**Year**	**Program**
Drug the undruggable: inhibitors of RNA binding protein Msi1	Liang Xu	$35,000	2012	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Carlson EA, Marquez RT, Du F, Wang Y, **Xu** L, Yan SS. Overexpression of 17beta-hydroxysteroid dehydrogenase type 10 increases pheochromocytoma cell growth and resistance to cell death. BMC cancer. 2015;15:166. Epub 2015/04/17. doi: 10.1186/s12885-015-1173-5. PubMed PMID: 25879199; PMCID: PMC4384325.	R01 CA191785 (co-PIs: Xu and Aubé): Molecular cancer therapy targeting HuR-ARE interaction	$864,002		Small molecule inhibitors of RNA-binding protein HuR and the use thereof. Provisional United States Patent Application No. 62191157
Gowthaman R, Miller SA, Rogers S, Khowsathit J, Lan L, Bai N, Johnson DK, Liu C, **Xu** L, Anbanandam A, Aube J, Roy A, and Karanicolas J. "DARC: mapping surface topography by ray-casting for effective virtual screening at protein interaction sites." J Med Chem 2016 (in press). PMID: 26126123	BC151845 (Xu, L and Welch, D) - DOD BCRP Breakthrough Award Level 2: Blocking breast cancer metastasis by targeting RNA-binding protein HuR	$333,000		Small molecule inhibitors of RNA-binding protein musashi and the use thereof. Provisional United States Patent Application No. 62191878
Klionsky DJ, ... **Xu** L, …et al. Guidelines for the use and interpretation of assays for monitoring autophagy (3rd edition). Autophagy 2016, 12(1):1-222. PMID: 26799652	R01CA178831: Small Molecules Modulting RNA-Binding protein MSI1	$1,297,473		
Lan L, Appelman C, Smith AR, Yu J, Larsen S, Marquez RT, Liu H, Wu X, Gao P, Roy A, Anbanandam A, Gowthaman R, Karanicolas J, De Guzman RN, Rogers S, Aube J, Ji M, Cohen RS, Neufeld KL, **Xu** L. Natural product (-)-gossypol inhibits colon cancer cell growth by targeting RNA-binding protein Musashi-1. Molecular oncology. 2015;9(7):1406-20. Epub 2015/05/03. doi: 10.1016/j.molonc.2015.03.014. PubMed PMID: 25933687; PMCID: Pmc4523432.				
Smith AR, Marquez RT, Tsao WC, Pathak S, Roy A, Ping J, Wilkerson B, Lan L, Meng W, Neufeld KL, Sun XF, **Xu** L. Tumor suppressive microRNA-137 negatively regulates Musashi-1 and colorectal cancer progression. Oncotarget. 2015;6(14):12558-73. Epub 2015/05/06. doi: 10.18632/oncotarget.3726. PubMed PMID: 25940441; PMCID: Pmc4494958.				
Smith AR, Marquez RT, Tsao WC, Pathak S, Roy A, Ping J, Wilkerson B, Lan L, Meng W, Neufeld KL, Sun XF, **Xu** L. Tumor suppressive microRNA-137 negatively regulates Musashi-1 and colorectal cancer progression. Oncotarget. 2015;6(14):12558-73. Epub 2015/05/06. doi: 10.18632/oncotarget.3726. PubMed PMID: 25940441; PMCID: Pmc4494958.				
Wu X, Lan L, Wilson DM, Marquez RT, Tsao WC, Gao P, Roy A, Turner BA, McDonald P, Tunge JA, Rogers SA, Dixon DA, Aube J, **Xu** L. Identification and validation of novel small molecule disruptors of HuR-mRNA interaction. ACS chemical biology. 2015;10(6):1476-84. Epub 2015/03/10. doi: 10.1021/cb500851u. PubMed PMID: 25750985; PMCID: Pmc4631057.				
Wu X, Tang W, Marquez RT, Li K, Highfill CA, He F, Lian J, Lin J, Fuchs JR, Ji M, Li L, **Xu** L. Overcoming chemo/radio-resistance of pancreatic cancer by inhibiting STAT3 signaling. Oncotarget. 2016;7(10):11708-23. Epub 2016/02/18. doi: 10.18632/oncotarget.7336. PubMed PMID: 26887043.				
Pilot Project Title #11	**Member**	**Pilot Award Investment**	**Year**	**Program**
Use of Hepatocyte Nuclear Factor-4a (HNF4a) target gene signature in prognosis of Hepatocellular Carcinoma	Udayan Apte	$11,000	2013	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Walesky C, **Apte** U. Role of Hepatocyte Nuclear Factor 4alpha (HNF4alpha) in Cell Proliferation and Cancer. Gene expression. 2015;16(3):101-8. Epub 2015/02/24. doi: 10.3727/105221615x14181438356292. PubMed PMID: 25700366.				
Walesky C, Edwards G, Borude P, Gunewardena S, O'Neil M, Yoo B, **Apte** U. Hepatocyte nuclear factor 4 alpha deletion promotes diethylnitrosamine-induced hepatocellular carcinoma in rodents. Hepatology. 2013;57(6):2480-90. Epub 2013/01/15. doi: 10.1002/hep.26251. PubMed PMID: 23315968; PubMed Central PMCID: PMC3669646.				
Pilot Project Title #12	**Member**	**Pilot Award Investment**	**Year**	**Program**
Targeting FoxM1 enhances sensitivity to chemotherapy in ovarian cancer	Jeremy Chien	$5,000	2013	CB

Publications	External Funding Received	External Grant Award	Clinical Trials	Patents/Copyrights
Pilot Project Title #13	**Member**	**Pilot Award Investment**	**Year**	**Program**
Development of minimally invasive genetic screening assays for gynecologic cancers	Jeremy Chien	$35,000	2013	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #14	**Member**	**Pilot Award Investment**	**Year**	**Program**
Energy Balance for Prostate Cancer Prevention and Survivorship	Jill Hamilton-Reeves	$10,000	2013	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Schleper A, **Sullivan** DK, **Thrasher** JB, **Holzbeierlein** JM, **Klemp** J, **Befort** C, Hamilton-Reeves JM. Weight Management to Reduce Prostate Cancer Risk: A Survey of Men's Needs and Interests. 2016. 2016;5(1). Epub 2015-12-07. doi: 10.5539/cco.v5n1p43.				
Pilot Project Title #15	**Member**	**Pilot Award Investment**	**Year**	**Program**
The role of adenosine A3 receptor in osteosarcoma malignancy	Tomoo Iwakuma	$35,000	2013	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Sasaki H, Iyer SV, Sasaki K, Tawfik OW, **Iwakuma** T. An improved intrafemoral injection with minimized leakage as an orthotopic mouse model of osteosarcoma. Analytical biochemistry. 2015. Epub 2015/07/05. doi: 10.1016/j.ab.2015.06.030. PubMed PMID: 26142221.				
Pilot Project Title #16	**Member**	**Pilot Award Investment**	**Year**	**Program**
Phase 1/2 study to determine the feasibility and tolerability of the combination of decitabine and ponatinib in elderly patients with Acute Myeloid Leukemia	Suman Kambhampati	$35,000	2013	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #17	**Member**	**Pilot Award Investment**	**Year**	**Program**
Development of prediction models for bladder cancer recurrence using clinical, pathological, and molecular data	Devin Koestler	$35,000	2013	CCPH
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Chalise P, **Koestler** DC, Bimali M, Yu Q, **Fridley** BL. Integrative clustering methods for high-dimensional molecular data. Translational cancer research. 2014;3(3):202-16. Epub 2014/09/23. doi: 10.3978/j.issn.2218-676X.2014.06.03. PubMed PMID: 25243110; PubMed Central PMCID: PMCPmc4166480.				
Koestler DC, Jones M, Kobor M. The era of integrative genomics: more data or better methods? Epigenomics. 2014;6(5):463-7. Epub 2014/11/29. doi: 10.2217/epi.14.44. PubMed PMID: 25431938.				
Koestler DC, Marsit CJ, Christensen BC, Kelsey KT, Houseman EA. A recursively partitioned mixture model for clustering time-course gene expression data. Translational cancer research. 2014;3(3):217-32. Epub 2014/10/28. doi: 10.3978/j.issn.2218-676X.2014.06.04. PubMed PMID: 25346887; PubMed Central PMCID: PMCPmc4208690.				
Pilot Project Title #18	**Member**	**Pilot Award Investment**	**Year**	**Program**
Structure determination of Musashi-1, a drug target for brain tumors and breast and colon cancer	Audrey Lamb	$35,000	2013	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #19	**Member**	**Pilot Award Investment**	**Year**	**Program**
Evaluation of BRCAness as prognostic marker in triple-negative breast cancer patients treated with adjuvant anthracycline-based chemotherapy on INT-0137 (S9313) trial	Priyanka Sharma	$35,000	2013	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
			Randomized open label Phase II trial of neoadjuvant Carboplatin plus Docetaxel or Carboplatin plus Paclitaxel followed by Adriamycin plus Cyclophosphamide in stage I-III triple-negative breast cancer. NCT 02413320	
Pilot Project Title #20	**Member**	**Pilot Award Investment**	**Year**	**Program**
Epigenetics and Bacterial Induced Colon Cancer	Shahid Umar	$10,000	2013	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Ahmed I, Roy B, Khan SA, Septer S, **Umar** S. Microbiome, Metabolome and Inflammatory Bowel Disease. 2016.4(2), 20; doi:10.3390/microorganisms4020020				
Pilot Project Title #21	**Member**	**Pilot Award Investment**	**Year**	**Program**
Exosomes and their Non-Coding RNA Profiles in Barrett's Esophagus	Ajay Bansal	$10,000	2014	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**

Bansal A, Fitzgerald RC. Biomarkers in Barrett's Esophagus: Role in Diagnosis, Risk Stratification, and Prediction of Response to Therapy. Gastroenterology clinics of North America. 2015;44(2):373-90. Epub 2015/05/30. doi: 10.1016/j.gtc.2015.02.008. PubMed PMID: 26021200.				Tissue Biomarkers for Indication of Progression from Barrett's Esophagus to Esophageal Adenocarcinoma
Bansal A, Gupta V, Wang K. MicroRNA Expression signatures during Malignant Progression from Barrett's Esophagus. Journal of cellular biochemistry. 2016. Epub 2016/01/26. doi: 10.1002/jcb.25497. PubMed PMID: 26808728.				Serum Biomarkers for Detectionof Barrett's Esophagus
				Barrett's Esophagus Tissue Markers
Pilot Project Title #22	**Member**	**Pilot Award Investment**	**Year**	**Program**
Essential Role of BCL9 in DCIS Progression to Invasive Breast Cancer	Fariba Behbod	$10,000	2014	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
	AACR: Essential Role of BCL9 in DCIS Progression to Invasive Breast Cancer	$360,000		
	P30 GM110761-02: Crystal Structure Determination of STAT3/BCL9	$35,000		
Pilot Project Title #23	**Member**	**Pilot Award Investment**	**Year**	**Program**
Histone Demethylase Jmjda1a: Novel Target for Pancreatic Cancer	Animesh Dhar	$35,000	2014	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Sainathan S, Paul S, Ramalingam S, Baranda J, Anant S, **Dhar** A. Histone Demethylases in Cancer. Curr Pharmacol Rep. 2015;1(4):234-44. doi: 10.1007/s40495-015-0025-y.	R01CA125262: Chemoprevention of Pancreatic Cancer by EGCG	$561,360		In Vivo Method for Treating, Inhibiting and/or Prophylaxis of Cancer, such as Pancreatic Cancer
				Synthetic Crocetinic Acid Analogues and Method for Treating and/or Prophylaxis of Cancer, such as Pancreatic Cancer
Pilot Project Title #24	**Member**	**Pilot Award Investment**	**Year**	**Program**
Nuclear-associated lysyl oxidase-like 2 upregulates EMT-activating transcription factors	Minae Mure	$10,000	2014	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
	R01GM113101: Understanding the roles of PTMs in modulating molecular	$1,436,095		
Pilot Project Title #25	**Member**	**Pilot Award Investment**	**Year**	**Program**
Gamma Mangostin as a Chemopreventive Agent in Familial Adenomatous Polyposis	Seth Septer	$35,000	2014	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #26	**Member**	**Pilot Award Investment**	**Year**	**Program**
Intratumor-heterogeneity of head and neck cancer	Sufi Thomas	$6,754	2014	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Parsel SM, Grandis JR, **Thomas** SM. Nucleic acid targeting: towards personalized therapy for head and neck cancer. Oncogene. 2015. Epub 2015/11/26. doi: 10.1038/onc.2015.424. PubMed PMID: 26592450.				
Pilot Project Title #27	**Member**	**Pilot Award Investment**	**Year**	**Program**
Targeting Wnt/ß-catenin and P13K/Akt pathways and inhibiting glioblastoma stem-like cells tumorigenicity in tissue culture and xenograft model using lower dose of doxorubicin	Fen Wang	$35,000	2014	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Gracz AD, Williamson IA, Roche KC, Johnston MJ, **Wang** F, Wang Y, Attayek PJ, Balowski J, Liu XF, Laurenza RJ, Gaynor LT, Sims CE, Galanko JA, Li L, Allbritton NL, Magness ST. A high-throughput platform for stem cell niche co-cultures and downstream gene expression analysis. Nature cell biology. 2015;17(3):340-9. Epub 2015/02/11. doi: 10.1038/ncb3104. PubMed PMID: 25664616; PubMed Central PMCID: PMCPmc4405128.				
Robins HI, Zhang P, Gilbert MR, Chakravarti A, de Groot JF, Grimm SA, **Wang** F, Lieberman FS, Krauze A, Trotti AM, Mohile N, Kee AY, Colman H, Cavaliere R, Kesari S, Chmura SJ, Mehta M. A randomized phase I/II study of ABT-888 in combination with temozolomide in recurrent temozolomide resistant glioblastoma: an NRG oncology RTOG group study. J Neurooncol. 2015. Epub 2015/10/29. doi: 10.1007/s11060-015-1966-z. PubMed PMID: 26508094.				

Funding Mechanism - American Cancer Society - Institutional Review Grant
13 awards given for a total investment of $424,536; awardees received 5 externally-funded grants totaling $1,723,660, published 13 peer-reviewed articles, initiated 5 clinical trials and obtained 1 patent and 1 copywrite

Pilot Project Title #1	**Member**	**Pilot Award Investment**	**Year**	**Program**
Adaptation and Validation of a Nutrition Literacy Assessment Instrument for Cancer Survivors	Heather Gibbs	$35,000	2013	CCPH
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Gibbs H, Kennett A, Sullivan D, Kerling E, Thodosoff J. A Pilot Study to Explore the Correlation Between Parental Nutrition Literacy, BMI, and Child Healthy Eating Index-2010. Journal of Nutrition Education and Behavior. 2014;46(4):S153.	R03HD081730: Adaption and Validation of a of a Nutrition Literacy Assessment	$163,087		Nutrition Literacy Assessment Instrument for Breast Cancer Survivors
Gibbs HD, Ellerbeck EF, Befort C, Gajewski B, Kennett AR, Yu Q, Christifano D, Sullivan DK. Measuring Nutrition Literacy in Breast Cancer Patients: Development of a Novel Instrument. Journal of cancer education : the official journal of the American Association for Cancer Education. 2015. Epub 2015/05/09. doi: 10.1007/s13187-015-0851-y. PubMed PMID: 25952941.				
Gibbs HD, Kennett AR, Kerling EH, Yu Q, Gajewski B, Ptomey LT, Sullivan DK. Assessing the Nutrition Literacy of Parents and Its Relationship With Child Diet Quality. Journal of nutrition education and behavior. 2016. Epub 2016/05/25. doi: 10.1016/j.jneb.2016.04.006. PubMed PMID: 27216751.				
Pilot Project Title #2	**Member**	**Pilot Award Investment**	**Year**	**Program**
Improving Radical Cystectiomy Outcomes Through Nutrition	Jill Hamilton-Reeves	$35,000	2013	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Hamilton-Reeves JM, Bechtel MD, Hand LK, Schleper A, Yankee TM, Chalise P, Lee EK, Mirza M, Wyre H, Griffin J, Holzbeierlein JM. Effects of Immunonutrition for Cystectomy on Immune Response and Infection Rates: A Pilot Randomized Controlled Clinical Trial. Eur Urol. 2015. Epub 2015/12/15. doi: 10.1016/j.eururo.2015.11.019. PubMed PMID: 26654125.	Nestle Impact Advanced Recovery for Radical Cystectomy Patients	$50,000	ACS Impact Advanced Recovery® for Radical Cystectomy Patients	Treatment or prevention of surgery-induced cachexia and/or expression of myeloid-derived suppressor cells and pro-inflammatory cytokines
			Weight management to reduce prostate cancer risk: A survey of needs and interests in a rural population of Masons	
			NIH Pilot Grant Energy Balance for Prostate Cancer Survivorship	
Pilot Project Title #3	**Member**	**Pilot Award Investment**	**Year**	**Program**
Functional Analysis of Histone Demethylase Target Genes in Ovarian Cancer	Adam Krieg	$35,000	2013	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Finger EC, Castellini L, Rankin EB, Vilalta M, **Krieg** AJ, Jiang D, Banh A, Zundel W, Powell MB, Giaccia AJ. Hypoxic induction of AKAP12 variant 2 shifts PKA-mediated protein phosphorylation to enhance migration and metastasis of melanoma cells. Proceedings of the National Academy of Sciences of the United States of America. 2015;112(14):4441-6. Epub 2015/03/21. doi: 10.1073/pnas.1418164112. PubMed PMID: 25792458; PubMed Central PMCID: PMCPmc4394282.	P20GM104936: Functional Analysis of Histone Demethylase Activity in Hypoxic Cancer Cells	$671,573		
Ramachandran S, Ient J, Gottgens EL, **Krieg** AJ, Hammond EM. Epigenetic Therapy for Solid Tumors: Highlighting the Impact of Tumor Hypoxia. Genes. 2015;6(4):935-56. Epub 2015/10/02. doi: 10.3390/genes6040935. PubMed PMID: 26426056.				
Pilot Project Title #4	**Member**	**Pilot Award Investment**	**Year**	**Program**
Targeting Patient Derived Pancreatic Cancer Cells with a Novel Flavonoid P276	Aravind Sugumar	$35,000	2013	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #5	**Member**	**Pilot Award Investment**	**Year**	**Program**
Rural vs. urban disparities in adherence with treatment guidelines and survival for colorectal cancer patients in Kansas	Robert Hines	$30,000	2014	CCPH
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
El-Haddad B, Dong F, Kallail KJ, **Hines** RB, Ablah E. Association of marital status and colorectal cancer screening participation in the USA. Colorectal disease : the official journal of the Association of Coloproctology of Great Britain and Ireland. 2015;17(5):O108-14. Epub 2015/02/24. doi: 10.1111/codi.12926. PubMed PMID: 25704636.			Pilot testing a patient questionnaire in colorectal cancer patients	
Hines R, Markossian T, Johnson A, Dong F, Bayakly R. Geographic residency status and census tract socioeconomic status as determinants of colorectal cancer outcomes. American journal of public health. 2014;104(3):e63-71. Epub 2014/01/18. doi: 10.2105/ajph.2013.301572. PubMed PMID: 24432920.			Genentech.: Survivorship concerns for colorectal cancer patients in the post-treatment phase of care	

Hines RB, Barrett A, Twumasi-Ankrah P, Broccoli D, Engelman KK, Baranda J, Ablah EA, Jacobson L, Redmond M, Tu W, Collins TC. Predictors of guideline treatment nonadherence and the impact on survival in patients with colorectal cancer. Journal of the National Comprehensive Cancer Network : JNCCN. 2015;13(1):51-60. Epub 2015/01/15. PubMed PMID: 25583769.				
Hunninghake J, Dong F, **Hines** RB, Ablah E, Taylor S. Prevalence and Predictors of Social Support Utilization among Cancer Patients Undergoing Treatment. Kansas Journal of Medicine 2014;7(4).				
Jacobson LT, Twumasi-Ankrah P, Redmond ML, Ablah E, **Hines** RB, Johnston J, Collins TC. Characteristics Associated with Breastfeeding Behaviors Among Urban Versus Rural Women Enrolled in the Kansas WIC Program. Maternal and child health journal. 2014. Epub 2014/07/23. doi: 10.1007/s10995-014-1580-2. PubMed PMID: 25047788.				
Johnson AM, **Hines** RB, Johnson JA, 3rd, Bayakly AR. Treatment and survival disparities in lung cancer: the effect of social environment and place of residence. Lung cancer (Amsterdam, Netherlands). 2014;83(3):401-7. Epub 2014/02/05. doi: 10.1016/j.lungcan.2014.01.008. PubMed PMID: 24491311.				
Pilot Project Title #6	**Member**	**Pilot Award Investment**	**Year**	**Program**
The augmentation of chemotherapy with a low carbohydrate diet in bladder cancer	Eugene Lee	$35,000	2014	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
	Urology Care Foundation Research Scholar Award: A carbohydrate restricted diet in patients with diabetes and non-muscle invasive bladder cancer	$80,000		
Pilot Project Title #7	**Member**	**Pilot Award Investment**	**Year**	**Program**
Validation of a thrombosis risk assessment model in patients with newly diagnosed multiple myeloma	Brea Lipe	$20,000	2014	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #8	**Member**	**Pilot Award Investment**	**Year**	**Program**
American Indian comprehension of informed consent & trust of medical researchers	Christina Pacheco	$35,000	2014	CCPH
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #9	**Member**	**Pilot Award Investment**	**Year**	**Program**
Phase I pilot study of MALT1 protease inhibition with thioridazine in relapsed / refractory activated B-cell type diffuse large B-cell lymphoma.	Ruben Reyes	$30,000	2014	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #10	**Member**	**Pilot Award Investment**	**Year**	**Program**
Eliciting urologists' decision making attributes: Recruitment and data collection feasibility study	Shellie Ellis	$34,536	2015	
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #11	**Member**	**Pilot Award Investment**	**Year**	**Program**
Chemotherapy induced cognitive impairment: Assessing the relation between demylination and spatial learning deficits	David Jarmolowicz	$30,000	2015	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Kaplan SV, Limbocker RA, Gehringer RC, Divis JL, Osterhaus GL, Newby MD, Sofis MJ, **Jarmolowicz** DP, Newman BD, Mathews TA, Johnson MA. Impaired Brain Dopamine and Serotonin Release and Uptake in Wistar Rats Following Treatment with Carboplatin. ACS chemical neuroscience. 2016. doi: 10.1021/acschemneuro.5b00029. PubMed PMID: 27145395.				
Pilot Project Title #12	**Member**	**Pilot Award Investment**	**Year**	**Program**
Investigation of brain changes associated with a behavioral intervention for smoking cessation	Laura Martin	$35,000	2015	CCPH
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
	ACS RSG-16-023-01-CPPB: Smoking Cessation and Brain Activation: How Practice Changes the Brain	$759,000		
Pilot Project Title #13	**Member**	**Pilot Award Investment**	**Year**	**Program**
Cancer associated fibroblasts modulating activity of DCLK1 positive cells	Dharmalingam Subramaniam	$35,000	2015	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**

Funding Mechanism - Program Project Development Grants **3 awards given for a total investment of $300,000; awardees published 8 peer-reviewed articles and initiated 1 clinical trial**				
Pilot Project Title #1	**Member**	**Pilot Award Investment**	**Year**	**Program**
RNA Binding Proteins in Colorectal Cancers	Shrikant Anant	$100,000	2013	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #2	**Member**	**Pilot Award Investment**	**Year**	**Program**
The Ovarian Cancer Learning Collaborative (OCLC)	Jeremy Chien	$100,000	2013	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Cooley M, Fang P, Fang F, K PN, **Chien** J. Molecular determinants of chemotherapy resistance in ovarian cancer. Pharmacogenomics. 2015;16(16):1763-7. Epub 2015/11/12. doi: 10.2217/pgs.15.130. PubMed PMID: 26554863.				
Graw S, Meier R, Minn K, Bloomer C, Godwin AK, Fridley B, Vlad A, Beyerlein P, **Chien** J. Robust gene expression and mutation analyses of RNA-sequencing of formalin-fixed diagnostic tumor samples. Scientific reports. 2015;5:12335. Epub 2015/07/24. doi: 10.1038/srep12335. PubMed PMID: 26202458; PMCID: Pmc4511951.				
Lin E, **Chien** J, Ong FS, Fan J-B. Challenges and opportunities for next-generation sequencing in companion diagnostics. Expert Review of Molecular Diagnostics. 2015;15(2):193-209. doi: doi:10.1586/14737159.2015.961916. PubMed PMID: 25249308.				
Munchel S, Hoang Y, Zhao Y, Cottrell J, Klotzle B, **Godwin** AK, **Koestler** D, Beyerlein P, Fan JB, Bibikova M, **Chien** J. Targeted or whole genome sequencing of formalin fixed tissue samples: potential applications in cancer genomics. Oncotarget. 2015. Epub 2015/08/26. PubMed PMID: 26305677.				
Zhang X, Cheng L, Minn K, Madan R, **Godwin** AK, Shridhar V, **Chien** J. Targeting of mutant p53-induced FoxM1 with thiostrepton induces cytotoxicity and enhances carboplatin sensitivity in cancer cells. Oncotarget. 2014. Epub 2014/11/27. PubMed PMID: 25426548.				
Pilot Project Title #3	**Member**	**Pilot Award Investment**	**Year**	**Program**
Combined Weight Loss and Omega-3 Fatty Acids for Breast Cancer Prevention	Carol Fabian	$100,000	2013	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Fabian CJ, **Kimler** BF, Hursting SD. Omega-3 fatty acids for breast cancer prevention and survivorship. Breast cancer research : BCR. 2015;17(1):62. Epub 2015/05/06. doi: 10.1186/s13058-015-0571-6. PubMed PMID: 25936773; PubMed Central PMCID: PMCPmc4418048.			Randomized Pilot Trial of Omega-3 Fatty Acids or Placebo in Peri- or Post-menopausal Women at High Risk For Breast Cancer Undergoing a Weight Loss Intervention	
Ford NA, Rossi EL, Barnett K, Yang P, Bowers LW, Hideka B, **Kimler** BF, **Carlson** SE, Shureiqi I, deGraffenried LA, **Fabian** CJ, Hursting SD. Omega-3-Acid Ethyl Esters Block the Protumorigenic Effects of Obesity in Mouse Models of Postmenopausal Basal-Like and Claudin Low Breast Cancer. Cancer prevention research (Philadelphia, Pa). 2015. Epub 2015/06/24. doi: 10.1158/1940-6207.capr-15-0018. PubMed PMID: 26100521.				
Hidaka BH, Li S, Harvey KE, Carlson SE, **Sullivan** DK, **Kimler** BF, Zalles CM, **Fabian** CJ. Omega-3 and omega-6 Fatty acids in blood and breast tissue of high-risk women and association with atypical cytomorphology. Cancer prevention research (Philadelphia, Pa). 2015;8(5):359-64. Epub 2015/02/26. doi: 10.1158/1940-6207.CAPR-14-0351. PubMed PMID: 25712053.				

Funding Mechanism - Donor-Specified Philanthropy **3 awards given for a total investment of $105,000; awardees have no outcomes to report at this time**				
Pilot Project Title #1	**Member**	**Pilot Award Investment**	**Year**	**Program**
Immunohistochemical and Molecular Characterization of Select Primary Brain Tumors for New Chemotherapeutic Targets	Kathy Newell	$35,000	2015	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #2	**Member**	**Pilot Award Investment**	**Year**	**Program**
Glioblastoma in a Dish (GiD) – A Novel Approach for Precision Medicine	Satish Ramalingam	$35,000	2015	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #3	**Member**	**Pilot Award Investment**	**Year**	**Program**
Targeting mutant EGRF in glioma	Sufi Thomas	$35,000	2015	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**

Funding Mechanism - Early Phase Clinical Trials **4 awards given for a total investment of $200,000; awardees initiated 3 clinical trials**				
Pilot Project Title #1	**Member**	**Pilot Award Investment**	**Year**	**Program**
Randomized open label Phase II trial of neoadjuvant Carboplatin plus Docetaxel or AC followed by Carboplatin plus Paclitaxel in stage I-III triple-negative breast cancer	Priyanka Sharma	$50,000	2015	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #2	**Member**	**Pilot Award Investment**	**Year**	**Program**
Role of Bortezomib prior to stem cell mobilzation as an in vivo purgin agent to obtain Flow negative leukapheresis product in patients with multiple myeloma undergoing autolgous stem cell transplant	Siddhartha Ganguly	$50,000	2015	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #3	**Member**	**Pilot Award Investment**	**Year**	**Program**
Randomized Trial of dose Dense, Fixed Dose Capecitabine in Metastatic Breast Cancer and Advanced GI Malignancies. The X7-7 Trial	Qamar Khan	$50,000	2015	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
			Novartis ($3 million) - Multicenter IIT (FELINE trial): Letrozole Plus Ribociclib or Placebo as Neo-adjuvant Therapy in ER-positive, HER2-negative Early Breast Cancer - ClinicalTrials.gov Identifier: NCT02712723	
			AstraZeneca IRUSANAS0092: Combined Fulvestrant and Anastrazole as Neo-Adjuvant Endocrine Therapy in Postmenopausal Women with Hormone Receptor Positive Invasive Breast Cancer	
Pilot Project Title #4	**Member**	**Pilot Award Investment**	**Year**	**Program**
Phase II Randomized Clinical Trial of 3-D Conformal RT vs IMRT in Post-Prosatatectomy Prostate Cancer Patients	Parvesh Kumar	$50,000	2015	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**

Funding Mechanism - Research Program Development Funds **7 awards given for a total investment of $144,510; awardees published 2 peer-reviewed articles**				
Pilot Project Title #1	**Member**	**Pilot Award Investment**	**Year**	**Program**
Targeting Histone Demethylases in Pca	Animesh Dhar	$12,000	2015	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Sainathan S, Paul S, Ramalingam S, Baranda J, Anant S, **Dhar** A. Histone Demethylases in Cancer. Curr Pharmacol Rep. 2015;1(4):234-44. doi: 10.1007/s40495-015-0025-y.				
Pilot Project Title #2	**Member**	**Pilot Award Investment**	**Year**	**Program**
A Televideo Exercise and Nutrition Program for Adult Survivors of Pediatric Cancer	Cheryl Gibson	$12,000	2015	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #3	**Member**	**Pilot Award Investment**	**Year**	**Program**
Hormonal regulation of IKK? during DCIS transition to IDC	Kelli Valdez	$18,000	2015	CPS
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #4	**Member**	**Pilot Award Investment**	**Year**	**Program**
Regulation of EWS-Aurora B pathway during mitosis and tumorigenesis	Chad Slawson	$35,000	2015	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Lanza C, Tan EP, Zhang Z, Machacek M, Brinker AE, Azuma M, **Slawson** C. Reduced O-GlcNAcase Expression Promotes Mitotic Errors and Spindle Defects. Cell cycle (Georgetown, Tex). 2016:0. Epub 2016/04/14. doi: 10.1080/15384101.2016.1167297. PubMed PMID: 27070276.				
Pilot Project Title #5	**Member**	**Pilot Award Investment**	**Year**	**Program**
HIF and KDM4B regulated transcription in ovarian cancer	Adam Krieg	$15,000	2015	CB
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #6	**Member**	**Pilot Award Investment**	**Year**	**Program**
TBX221 Analogs for Prostate Cancer Therapy	Benyi Li	$25,000	2015	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**
Pilot Project Title #7	**Member**	**Pilot Award Investment**	**Year**	**Program**
Molecular Characterization of Circulating Ovarian Cancer-Derived Exosomes	Andy Godwin	$27,510	2015	D3ET
Publications	**External Funding Received**	**External Grant Award**	**Clinical Trials**	**Patents/Copyrights**

Staff Investigator Grants, Publications, Clinical Trials and Biosketches

Research Staff Investigator – James Calvet, PhD

Grants

Funding Mechanism	Project Number	Title	Start Date	End Date
Polycystic Kidney Disease Foundation		Role of CFTR and NKCC1 in Polycystic Kidney Disease	3/1/2014	2/28/2016
NIDDK	1P30DK106912	KANSAS PKD RESEARCH AND TRANSLATION CORE CENTER	9/15/2015	6/30/2020

Publications (2012-2015)

Intra	Inter	Title
	Yes	Pinto CS, Raman A, Reif GA, Magenheimer BS, White C, **Calvet** JP, Wallace DP. Phosphodiesterase Isoform Regulation of Cell Proliferation and Fluid Secretion in Autosomal Dominant Polycystic Kidney Disease. Journal of the American Society of Nephrology: JASN. 2015. Epub 2015/08/21. doi: 10.1681/asn.2015010047. PubMed PMID: 26289612.
	Yes	Zhou JX, Fan LX, Li X, **Calvet** JP, Li X. TNFalpha Signaling Regulates Cystic Epithelial Cell Proliferation through Akt/mTOR and ERK/MAPK/Cdk2 Mediated Id2 Signaling. PloS one. 2015;10(6):e0131043. Epub 2015/06/26. doi: 10.1371/journal.pone.0131043. PubMed PMID: 26110849.
		Antignac C, **Calvet** JP, Germino GG, Grantham JJ, Guay-Woodford LM, Harris PC, Hildebrandt F, Peters DJ, Somlo S, Torres VE, Walz G, Zhou J, Yu AS. The Future of Polycystic Kidney Disease Research--As Seen By the 12 Kaplan Awardees. Journal of the American Society of Nephrology: JASN. 2015;26(9):2081-95. Epub 2015/05/09. doi: 10.1681/asn.2014121192. PubMed PMID: 25952256; PMCID: Pmc4552123.
		Chipps E, Protzman A, Muhi MZ, Ando S, **Calvet** JP, Islam MR. Nuclear Localization Signal and p53 Binding Site in MAP/ERK Kinase Kinase 1 (MEKK1). Journal of cellular biochemistry. 2015;116(12):2903-14. Epub 2015/05/29. doi: 10.1002/jcb.25238. PubMed PMID: 26018553; PMCID: Pmc4600025.
	Yes	Tran PV, Sharma M, Li X, **Calvet** JP. Developmental signaling: does it bridge the gap between cilia dysfunction and renal cystogenesis? Birth defects research Part C, Embryo today: reviews. 2014;102(2):159-73. Epub 2014/05/28. doi: 10.1002/bdrc.21065. PubMed PMID: 24861210.
		Wetmore JB, **Calvet** JP, Yu AS, Lynch CF, Wang CJ, Kasiske BL, Engels EA. Polycystic kidney disease and cancer after renal transplantation. Journal of the American Society of Nephrology: JASN. 2014;25(10):2335-41. Epub 2014/05/24. doi: 10.1681/asn.2013101122. PubMed PMID: 24854270; PubMed Central PMCID: PMCPmc4178444.
	Yes	Zhou X, Fan LX, Li K, Ramchandran R, **Calvet** JP, Li X. SIRT2 regulates ciliogenesis and contributes to abnormal centrosome amplification caused by loss of polycystin-1. Human molecular genetics. 2014;23(6):1644-55. Epub 2013/11/10. doi: 10.1093/hmg/ddt556. PubMed PMID: 24203696; PubMed Central PMCID: PMCPmc3929098.
		Jansson K, Magenheimer BS, Maser RL, **Calvet** JP, Blanco G. Overexpression of the polycystin-1 C-tail enhances sensitivity of M-1 cells to ouabain. The Journal of membrane biology. 2013;246(7):581-90. Epub 2013/06/21. doi: 10.1007/s00232-013-9573-4. PubMed PMID: 23784065.
	Yes	Parnell SC, Puri S, Wallace DP, **Calvet** JP. Protein phosphatase-1alpha interacts with and dephosphorylates polycystin-1. PLoS One. 2012;7(6):e36798. PMCID: 3366979.
		Fan LX, Li X, Magenheimer B, **Calvet** JP. Inhibition of histone deacetylases targets the transcription regulator Id2 to attenuate cystic epithelial cell proliferation. Kidney Int. 2012;81(1):76-85.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **James P. Calvet, Ph.D.**

eRA COMMONS USER NAME: JCALVET

POSITION TITLE: Professor of Biochemistry and Molecular Biology, and Professor of Cancer Biology

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date (MM/YYY)	FIELD OF STUDY
Franklin Pierce College, Rindge, NH	B.A.	1968	Biology
SUNY, Plattsburgh, NY	M.A.	1970	Biology
Univ. of Connecticut, Storrs, CT	Ph.D.	1975	Genetics/Cell Biology
Worcester Fdn. for Exptl. Biol., Shrewsbury, MA	Post-doc Fellow	1975-1978	Molecular/Cell Biology

A. Personal Statement

I have had a long-standing interest in kidney development and signal transduction, acute and chronic kidney disease, genetic kidney disease, genetics and genomics. My early research showed the abnormal expression of proto-oncogenes in polycystic kidneys, which paved the way for further research in my lab that has uncovered many of the cellular and molecular mechanisms of renal cyst formation. The concept that renal cysts are benign neoplastic tumors is now widely accepted. My research also uncovered a Ca2+-dependent signal transduction defect in PKD cells that involves a change in the response to cAMP from anti-mitogenic to mitogenic through the ERK pathway. Further research from my group led to the discovery that cAMP drives both increased cell proliferation and cyst-filling fluid secretion in metanephric organ culture. Our research has developed unique cell culture, organ culture, and genetic mouse models of PKD, and I have written articles on ciliopathies. The lab is currently exploring the use of anti-proliferative, anti-tumor drugs to slow cyst growth. I have served on a number of kidney-related advisory committees, including membership on the NIH Cellular and Molecular Biology of the Kidney (CMBK) Study Section. I have received the Chancellor's Distinguished Teaching Award for Excellence in Teaching, and the Chancellors Club Research Award from the University of Kansas. In 2011, I was honored with the Lillian Jean Kaplan International Prize for Advancement in the Understanding of Polycystic Kidney Disease, awarded jointly by the International Society of Nephrology and PKD Foundation. I am currently the PKD Group Leader in the Cancer Biology Program of the University of Kansas Cancer Center, and I am PI/PD of a newly awarded NIH-P30 PKD Research and Translation Core Center, which has an emphasis on developing translational research. My expertise spans the biochemistry of polycystin-1 to signal transduction, to gene regulation, to mouse models of PKD, to drug development and translational research.

B. Positions and Honors

Positions and Employment:

1975-1978 Postdoctoral Fellow in Cell Biology (with Dr. Thoru Pederson), Worcester Foundation for Experimental Biology (WFEB), Shrewsbury, MA; American Cancer Society Postdoctoral Fellow
1978-1981 Senior Research Associate (with Dr. Thoru Pederson), Department of Cell Biology/Cancer Center, Worcester Foundation for Experimental Biology, Shrewsbury, MA
1981-1994 Assistant and Associate Professor, Department of Biochemistry and Molecular Biology, School of Medicine, University of Kansas Medical Center (KUMC), Kansas City, KS
1994- Professor, Department of Biochemistry and Molecular Biology, KUMC, Kansas City, KS
2009- PKD Group Leader, Cancer Biology Program, KU Cancer Center, KUMC
2009-2011 Interim Director, Kidney Institute, KUMC (Dr. Alan Yu was recruited as Director in 2011)

2012- Deputy Director, Kidney Institute, KUMC
2013- Professor (Joint Appointment), Department of Cancer Biology, KUMC, Kansas City, KS
2013- Board of Directors, Research Institute, KUMC, Kansas City, KS

Other Experience and Professional Memberships:

1993-1999 Scientific Advisory Committee, Polycystic Kidney Research Foundation (PKD Foundation)
1995 NIH Biochemistry Study Section (ad hoc), February 22-24, 1995
1998 NIH Special Study Section ZRG4 GRM(07)L, NRSA Postdoctoral Fellowships (F32); Jan 12, 1998
1999-2005 External Scientific Advisory Board, Case Western Reserve Univ. Sch. of Med., NIH PKD Center
2003 NIH Special Emphasis Panel ZDK1 GRB-6 (J1), Kidney Development and PKD, Dec 11, 2003
2004 Chair, NIH Special Emphasis Panel ZRG1 RUS-D 03, PKD Science, July 30, 2004
2007-2011 NIH Cellular and Molecular Biology of the Kidney (CMBK) Study Section Member
2007-2013 Chair, External Scientific Advisory Committee, UAB School of Medicine, NIH P30 PKD Center
2008- External Advisory Committee, Creighton Univ. Cancer and Smoking Disease Research Program
2011 Co-organizer, FASEB Summer Research Conference: Polycystic Kidney Disease, From Bench to Bedside, Saxtons River, VT, June 26 - July 1, 2011
2014 Co-organizer, FASEB Summer Research Conference: Polycystic Kidney Disease, From Molecular Mechanism to Therapy, Barga, Lucca, Italy, August 3-8, 2014

Honors:

2004 Faculty Investigator Research Award, School of Medicine, KUMC
2007 Chancellor's Distinguished Teaching Award for Excellence in Teaching, University of Kansas
2009 Chancellors Club Research Award, University of Kansas
2011 Lillian Jean Kaplan International Prize for Advancement in the Understanding of Polycystic Kidney Disease, awarded jointly by the International Society of Nephrology and PKD Foundation

C. Contribution to Science

My research over the past >25 years in the PKD field has focused on five themes: 1) abnormal cell proliferation in PKD, proto-oncogenes, cancer & PKD; 2) the functions of the polycystin proteins, heterotrimeric G-protein signaling, and NFAT activation; 3) the role of calcium, cAMP, and ERK signaling in PKD; 4) the mechanisms of early cyst formation and enlargement in embryonic kidney organ culture; and 5) PKD gene structure and expression, and regulation of promoter activity. Below are some of the highlights:

1. Cowley et al. (1987) were the first to show that PKD is associated with elevated proto-oncogene expression and therefore that PKD may be characterized by abnormal "tumor-like" growth involving increased cell proliferation. Other papers from our lab followed from this extending the initial observation. This work has been confirmed by others and forms the basis of a large body of research showing the abnormal proliferative behavior of cystic epithelial cells in all forms of PKD. In 1987 and 1991, researchers at other universities developed the first transgenic mouse models of PKD, which were constructed by overexpressing the c-myc gene and by overexpressing the SV40 LgT gene in the kidney. The observations that oncogene overexpression can cause cystic disease were consistent with the idea that cysts are the result of abnormal cell proliferation, and the concept that renal cysts are neoplastic is now widely accepted. Recently, we carried out an epidemiological study showing that despite this neoplastic growth and high c-myc expression, PKD patients are actually protected from developing cancer in a study that examined 50 different cancers (Wetmore, et al., 2014).

a) Cowley, B.D., Jr., Smardo, F.L., Jr., Grantham, J.J. and **Calvet, J.P.** (1987) Elevated c myc proto-oncogene expression in autosomal recessive polycystic kidney disease. Proc. Natl. Acad. Sci. U.S.A. 84, 8394-8398.
b) Cowley, B.D., Jr., Chadwick, L.J., Grantham, J.J., and **Calvet, J.P.** (1991) Elevated proto-oncogene expression in polycystic kidneys of the C57BL/6J (cpk) mouse. J. Am. Soc. Nephrol. 1(8), 1048-1053.
c) Wetmore, J.B., **Calvet, J.P**., Yu, A.S., Lynch, C.F., Wang, C.J., Kasiske, B.L., and Engels, E.A. (2014) Polycystic kidney disease and cancer after renal transplantation. J. Am. Soc. Nephrol. 25, 2335-2341. PMC4178444

2. Parnell et al. (1998) were the first to show that polycystin-1 binds and activates heterotrimeric G proteins and thus is a GPCR. This was followed by Parnell et al. (2002) and Puri et al. (2004) showing that AP-1 and

NFAT are downstream of polycystin-1 G-protein signaling. We also showed that the C-tail of polycystin-1 can be phosphorylated by PKA and dephosphorylated by PP1α (Parnell et al., 2012). Others in the field later confirmed that polycystin-1 activates G-protein signaling. The observation that polycystin-1 acts like a G-protein coupled receptor is significant since most known GPCRs have only 7 membrane-spanning segments rather than the 11 membrane-spanning segments in polycystin-1.

a) Parnell, S.C., Magenheimer, B.S., Maser, R.L., Rankin, C.A., Smine, A., Okamoto, T. and **Calvet, J.P.** (1998). The polycystic kidney disease-1 protein, polycystin-1, binds and activates heterotrimeric G-proteins in vitro. Biochem. Biophys. Res. Comm. 251, 625-631.
b) Parnell, S.C., Magenheimer, B.S., Maser, R.L., Zien, C.A., Frischauf, A.-M. and **Calvet, J.P**. (2002) Polycystin-1 mediated activation of c-Jun-N-terminal kinase and AP-1 is regulated by heterotrimeric G proteins. J. Biol. Chem. 277, 19566-19572.
c) Puri, S., Magenheimer, B.S., Maser, R.L., Ryan, E., Zien, C.A., Walker, D.D., Wallace, D.P., Hempson, S.J., and **Calvet, J.P.** (2004) Polycystin-1 activates the calcineurin/NFAT (nuclear factor of activated T-cells) signaling pathway. J. Biol. Chem. 279, 55455-55464.
d) Parnell, S.C., Puri, S., Wallace, D.P., and **Calvet, J.P**. (2012) Protein phosphatase-1α interacts with and dephosphorylates polycystin-1. PLoS One 7(6):e36798. PMC3366979.

3. Sutters et al. (2001) showed that cells behaving normally to cAMP treatment in an anti-proliferative fashion could be switched to PKD-like cells by overexpressing a polycystin-1 construct that acted in a dominant-negative manner. These results showed that the phenotypic conversion of a normal cell to a cAMP-responsive proliferating, PKD-like cell could be attributed directly to a disruption of polycystin-1 function. The Puri et al. (2004) paper showed that polycystin-1 could directly regulate intracellular calcium through G-protein signaling. Because of this paper and many others in the field that had associated the polycystins with calcium signaling, the next step was to see if disruption of intracellular calcium could cause this PKD-like phenotypic switch. As such, Yamaguchi et al. (2004) then demonstrated that the “PKD phenotype” seen in primary ADPKD cystic epithelial cells could indeed be mimicked by treating normal cells with calcium channel blockers to lower intracellular calcium. As a result of these treatments, normal cells switched their phenotype, or were “transformed” from growth inhibition by cAMP to growth stimulation by cAMP. These studies led to the hypothesis that the primary cellular defect in PKD is an abnormality in calcium mobilization, which derepresses B-Raf, allowing it to be activated by cAMP to then stimulate ERK. This calcium abnormality is also thought to alter normal gene expression bringing about a change in cellular signaling that allows cells to proliferate in response to cAMP. Thus, this research has identified the mechanisms triggering the abnormal cell proliferation in PKD by showing that decreased intracellular calcium alone can transform renal epithelial cells to an abnormal cAMP-proliferative phenotype. The significance of this work to the field of PKD is that it has led to an understanding of the pathways that can be targeted for therapy to treat the disease, in particular the idea of targeting cAMP. In 2005, the Novartis Foundation held a discussion meeting in London to evaluate the role of calcium in PKD. We have gone on to show that calcium channel blocker treatment exacerbates cyst growth and kidney enlargement the Cy/+ rat model of PKD in a paper with Shizuko Nagao and Darren Wallace (Nagao et al., 2008).

a) Sutters, M., Yamaguchi, T., Maser, R.L., Magenheimer, B.S., St. John, P.L., Abrahamson, D.R., Grantham, J.J. and **Calvet, J.P**. (2001) Polycystin-1 transforms the cAMP growth-responsive phenotype of M-1 cells. Kidney Int. 60, 484-494.
b) Yamaguchi, T., Wallace, D.P., Magenheimer, B.S., Hempson, S.J., Grantham, J.J., and **Calvet, J.P**. (2004) Calcium restriction allows cAMP activation of the B-Raf/ERK pathway, switching cells to a cAMP-dependent growth-stimulated phenotype. J. Biol. Chem. 279, 40419-40430.
c) Nagao, S., Nishii, K., Yoshihara, D., Kurahashi, H., Nagaoka, K., Yamashita, T., Takahashi, H., Yamaguchi, T., **Calvet, J.P**., and Wallace, D.P. (2008) Calcium channel inhibition with verapamil accelerates polycystic kidney disease progression in the Cy/+ rat. Kidney Int. 73, 269-277. PMID: 17943077 (PMC# not required; not NIH funded).

4. The importance of cAMP to PKD, which was originally championed by Jared Grantham, comes from the discoveries that cAMP stimulates both cell proliferation and CFTR-dependent cyst-filling fluid secretion. In Magenheimer et al. (2006), the role of cAMP in the early cyst-forming process was directly tested using mouse embryonic kidneys in organ cultures stimulated with cAMP. These experiments demonstrated for the first time that developing embryonic kidney tubules are capable of fluid secretion and that this secretion is entirely dependent on CFTR. It was also shown that Pkd1 -/- kidneys have a tubular defect that results in profound

cystic dilation when cAMP is used to stimulate fluid secretion, and that this cyst-forming process is dependent not only on CFTR but also on NKCC1, thus implicating chloride ion in the cyst-filling fluid secretion. These experiments suggest that cyst growth in ADPKD could be inhibited by targeting both cell proliferation and fluid secretion. The usefulness of this metanephric organ culture system is demonstrated in a Nature Medicine paper that examined the effects of TNFα on cyst formation, which was a collaborative effort with Rong Li's lab and Xiaogang Li at the Stowers Institute (Li et al., 2008).

a) Magenheimer, B.S., St. John, P.L., Isom, K.S., Abrahamson, D.R., De Lisle, R.C., Wallace, D.P., Maser, R.L., Grantham, J.J., and **Calvet, J.P**. (2006) Early embryonic renal tubules of wild-type and PKD kidneys respond to cAMP stimulation with CFTR/NKCC1-dependent cystic dilation. J. Am. Soc. Nephrol. 17, 3424-3437.
b) Li, X., Magenheimer, B.S., Xia, S., Johnson, T., Wallace, D.P., **Calvet, J.P.**, and Li, R. (2008) A tumor necrosis factor-alpha-mediated pathway promoting autosomal dominant polycystic kidney disease. Nature Medicine 14, 863-868. PMC3359869

5. In collaboration with Dr. Rafiq Islam, our lab has also pioneered studies on PKD1 gene structure and regulation. Rodova et al. (2002) were the first to report the isolation and functional characterization of the PKD1 promoter, showing that it is a target of β-catenin/TCF signaling. Other work from our lab and through collaboration has gone on to show that the PKD1 promoter is regulated by Ets family transcription factors, p53 and Mekk1 (Islam et al., 2010), and is a target of retinoic acid, which acts through Sp1 (Islam et al., 2008). The p53 paper is particularly novel because it showed that Mekk1 has a kinase-independent, transcriptional co-repressor function, in addition to its role as a cytosolic MAP3K. These papers have set the stage for future in vivo studies that could attempt to upregulate PKD1 gene expression to overcome the effects of haploinsufficiency caused by the PKD1 heterozygous state. During the course of studying the PKD1 gene we also found that the last intron of the gene (intron 45) is remarkably conserved in evolution, indicating that it has a novel function not seen before in an intron (Rodova et al., 2003). It is now known that this intron encodes a novel microRNA.

a) Rodova, M., Islam, M.R., Maser, R.L. and **Calvet, J.P**. (2002) The polycystic kidney disease-1 promoter is a target of the β-catenin/T-cell factor pathway. J. Biol. Chem. 277, 29577-29583.
b) Rodova, M., Islam, M.R., Peterson, K.R. and **Calvet, J.P**. (2003) Remarkable sequence conservation of the last intron in the PKD1 gene. Molec. Biol. Evol. 20, 1669-1674.
c) Islam, M.R., Puri, S., Rodova, M., Magenheimer, B.S., Maser, R.L., and **Calvet, J.P**. (2008) Retinoic acid-dependent activation of the polycystic kidney disease-1 (PKD1) promoter. Am. J. Physiol. Renal Physiol. 295(6), F1845-F1854. PMC2604834
d) Islam, M.R., Jimenez, T., Pelham, C., Rodova, M., Puri, S., Magenheimer, B.S., Maser, R.L., Widmann, C., **Calvet, J.P**. (2010) MAP/ERK kinase kinase 1 (MEKK1) mediates transcriptional repression by interacting with polycystic kidney disease-1 (PKD1) promoter-bound p53 tumor suppressor protein. J. Biol. Chem. 285, 38818-38831. PMC2998141

Complete List of Published Work in MyBibliography (from >100 total publications:
http://www.ncbi.nlm.nih.gov/myncbi/browse/collection/48048066/?sort=date&direction=descending

D. Research Support

Ongoing Support:

P30 DK106912 J. Calvet (PI) 09/15/2015 – 06/30/2020
NIH/NIDDK
Kansas PKD Research and Translation Core Center
Major Goals: The overall goal of the PKD Center is to develop target identification for PKD therapy. This grant will support four biomedical research cores and five pilot & feasibility grants per year.

PKD Foundation Grant 192G14a J. Calvet (PI) 03/01/2014 – 02/28/2017
PKD Foundation (no cost extension)
The Roles of CFTR and NKCC1 in Polycystic Kidney Disease

The goals of this project are to utilize mouse genetic models, novel drug testing, and cell culture to determine the extent to which the chloride channels CFTR and NKCC1 are involved in cyst growth in PKD kidneys.

Completed Research Support

R43 DK096808 C. Rogers (PI) 12/15/2014 – 08/31/2016
NIH/NIDDK
Development of a Porcine Model of Autosomal Dominant Polycystic Kidney Disease
This is a Phase I SBIR to develop and characterize a PKD1 pig model for commercialization in partnership with Exemplar Genetics in Iowa City, Iowa.
Role: Co-Investigator

R01 DK081579 D. Wallace (PI) 08/21/2009 – 07/31/2014
NIH/NIDDK
Role of Periostin in Polycystic Kidney Disease
The goal of this project is to determine if periostin (previously named osteoblast specific factor 2) is an autocrine mitogen that accelerates cyst growth and promotes interstitial remodeling in ADPKD.
Role: Co-Investigator

No number J. Calvet (PI) 09/01/2009 – 08/31/2012
Institute for Advancing Medical Innovation
HSP90 Inhibition for PKD Therapy.
The goals were: 1) HSP90 inhibition will be shown to slow PKD cell proliferation and inhibit fluid secretion in cell culture and in cultured embryonic kidneys. 2) HSP90 inhibition will be shown to ameliorate PKD in mouse and rate models of PKD.

P50 DK057301 J. Calvet (PI, Center Director) 09/30/2005 – 08/31/2011
NIH/NIDDK
Kansas Interdisciplinary Center for PKD Research.
This PKD Center addresses questions about the molecular and cellular pathogenesis of cyst development and growth with a focus on cell proliferation. Project 2 (Calvet, P.I.) “Polycystin-1 Mediated Calcium and cAMP Signaling” examines the cAMP signaling pathway in embryonic kidneys and was to generate a knock-in mouse model in which there is a mutation in the G protein binding region of polycystin-1.

Clinical Staff Investigator – Joel McGuirk, DO

Grants

Funding Mechanism	Project Number	Title	Start Date	End Date
University of Michigan		Multi-center single arm Phase II Study of Myeloablative Allogeneic Stem Cell Transplantation for no	5/31/2012	12/31/2021
Private Sponsor		Phase II Study of Reduced-Intensity Allogeneic Stem Cell Transplant for High-Risk Chronic Lymphocytic	2/6/2012	12/31/2020
NIH / University of Nebraska Medical Center	U10HL069233[34-5234-2005-002]	Nebraska/Kansas Blood and Marrow Transplant Research Network	4/25/2011	12/31/2020
Fresenius Biotech		A randomized, prospective, double blind, placebo-controlled, phase 3 study of US-ATG-F prophylaxis as	2/6/2012	12/31/2020
Astellas Pharma US, Inc.		A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial to Evaluate the Protective Efficacy an	10/31/2013	12/30/2020

Clinical Trials

Funding Source	Primary Site	Title	Phase	Open Date	Close Date
University of Michigan	Leukemia, other	Ph II Study of Myeloablative Allogeneic Stem Cell Transplantation for non-remission AML using Clofarabine and Busulfan x 4 (CloBu4) regimen	II	8/7/2012	
University of Minnesota	Leukemia, other	KIR Genotyping for Unrelated Donor (URD) Selection Prior to Hematopoietic Cell Transplantation (HCT) for AML: Selecting a Favorable KIR Donor	N/A	7/11/2012	
Fresenius Biotech North America, Inc.	Multiple	Phase III Study of US-ATG-F Prophylaxis as a Supplement to SOC Prophylaxis to Prevent Moderate to Severe Chronic GVHD in Adult AML, ALL, and Myeloid Myeloma	III	3/1/2012	
CIBMTR	Other Hematopoietic	Study of Hematopoietic Stem Cell Donor Safety and QOL	N/A	6/2/2012	
Investigator	Multiple	Outcomes Complications and Survival of Allogeneic and Autologous Hematopoietic Stem Cell Transplant	II	1/23/2001	
Investigator	Multiple	Assessment of Intracellular Cancer-Relevant Targets and Molecular Determinants of Apoptotic Signaling in Patient-Derived Leukemia, Lymphoma, Multiple Myeloma, and Myeloproliferative Neoplasm Cells	N/A	11/10/2010	3/4/2013
Fresenius Biotech	Multiple	A Randomized, Prospective, Double-Blind, Placebo-Controlled, Phase 3 Study of US-ATG-F Prophylaxis as a Supplement to Standard of Care Prophylaxis to Prevent Moderate to Severe Chronic GVHD in Adult Acute Myeloid Leukemia, Acute Lymphoid Leukemia, and Mye	III	3/1/2012	
Masonic Cancer Center, Univ of Minnesota	Myeloid and Monocytic Leukemia	KIR Genotyping for Unrelated Donor (URD) Selection Prior to Hematopoietic Cell Transplantation	N/A	7/7/2011	2/17/2014

		(HCT) for AML: Selecting a Favorable KIR Donor			
Univ of Michigan	Leukemia, Other	Multi-center single arm Phase II Study of Myeloablative Allogeneic Stem Cell Transplantation for non-remission Acute Myeloblastic Leukemia (AML) using Clofarabine and Busulfan x 4 (CloBu4) regimen	II	8/7/2012	12/9/2013
BMT CTN CALGB	Lymphoid Leukemia	Phase II Study of Reduced-Intensity Allogeneic Stem Cell Transplant for High-Risk Chronic Lymphocytic Leukemia	II	8/6/2012	1/27/2014
CIBMTR	Other Hematopoietic	A Multicenter Study of Hematopoietic Stem Cell Donor Safety and Quality of Life	N/A	6/2/2010	5/31/2013
NMDP	Other Hematopoietic	A multicenter access and distribution protocol for unlicensed cryopreserved cord blood units (CBUs) for transplantation in pediatric and adult patients with hematologic malignancies and other indications	N/A	9/6/2011	
BMT CTN CALGB	Lymphoid Leukemia	Phase II Study of Reduced-Intensity Allogeneic Stem Cell Transplant for High-Risk Chronic Lymphocytic Leukemia	II	8/6/2012	1/27/2014
Masonic Cancer Center, Univ of Minnesota	Myeloid and Monocytic Leukemia	KIR Genotyping for Unrelated Donor (URD) Selection Prior to Hematopoietic Cell Transplantation (HCT) for AML: Selecting a Favorable KIR Donor	N/A	7/7/2011	2/17/2014
Astellas Pharma US Abbott Laboratories	Multiple	A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial to Evaluate the Protective Efficacy and Safety of a Therapeutic Vaccine, ASP0113, in Cytomegalovirus (CMV)-Seropositive Recipients Undergoing Allogeneic, Hematopoietic Cell Transplant (HCT)	III	2/6/2014	
Fresenius Biotech	Multiple	A Randomized, Prospective, Double-Blind, Placebo-Controlled, Phase 3 Study of US-ATG-F Prophylaxis as a Supplement to Standard of Care Prophylaxis to Prevent Moderate to Severe Chronic GVHD in Adult Acute Myeloid Leukemia, Acute Lymphoid Leukemia, and Mye	III	3/1/2012	10/22/2014
Polyphor Ltd	Multiple	A Phase I/II Study Evaluating the Safety and Efficacy of Intravenous POL6326 for the Mobilization and Transplantation of HLA-Matched Sibling Donor Hematopoietic Stem Cells in Patients with Advanced Hematological Malignancies	I/II	10/31/2014	
NMDP	Other Hematopoietic	A multicenter access and distribution protocol for unlicensed cryopreserved cord blood units (CBUs) for transplantation in pediatric and adult patients with	N/A	9/6/2011	

		hematologic malignancies and other indications			
BMT CTN NIH	Other Hematopoietic	A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Aged 50-75 with Intermediate-2 and High Risk Myelodysplastic Syndrome	N/A	2/10/2014	
BMT CTN	Multiple	Prospective Multi-Cohort for the Evaluation of Biomarkers Predicting Risk of Complications and Mortality Following Allogeneic HCT	N/A	8/27/2014	
Novartis Pharmaceuticals	Non-Hodgkin's Lymphoma	A phase II, single arm, multicenter trial to determine the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL)	II	7/29/2015	
Patient-Centered Outcomes Research Institute (PCORI)	Other Hematopoietic	Randomized Study of Individualized Care Plans for Hematopoietic Cell Transplant Survivors	N/A	6/2/2015	
University of Texas Health Science Center	Multiple Sites	A Randomized Recruitment Intervention Trial (RECRUIT)	N/A	5/20/2015	
Astellas Pharma US Abbott Laboratories	Multiple	A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial to Evaluate the Protective Efficacy and Safety of a Therapeutic Vaccine, ASP0113, in Cytomegalovirus (CMV)-Seropositive Recipients Undergoing Allogeneic, Hematopoietic Cell Transplant (HCT)	III	2/6/2014	5/12/2015
Polyphor Ltd	Multiple	A Phase I/II Study Evaluating the Safety and Efficacy of Intravenous POL6326 for the Mobilization and Transplantation of HLA-Matched Sibling Donor Hematopoietic Stem Cells in Patients with Advanced Hematological Malignancies	I/II	10/31/2014	7/24/2015
BMT CTN	Multiple	Prospective Multi-Cohort for the Evaluation of Biomarkers Predicting Risk of Complications and Mortality Following Allogeneic HCT	N/A	8/27/2014	
BMT CTN NIH	Other Hematopoietic	A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Aged 50-75 with Intermediate-2 and High Risk Myelodysplastic Syndrome	N/A	2/10/2014	
NMDP	Other Hematopoietic	A multicenter access and distribution protocol for unlicensed cryopreserved cord blood units (CBUs) for transplantation in pediatric and adult patients with hematologic malignancies and other indications	N/A	9/6/2011	

Novartis Pharmaceuticals	Non-Hodgkin's Lymphoma	Long Term Follow-Up of Patients Exposed to Lentiviral-Based CD19 directed CART Cell Therapy	N/A	12/28/2015	

Publications (2012-2015)

Intra	Inter	Title
Yes	Yes	Ganguly S, Home T, Yacoub A, Kambhampati S, Shi H, Dandawate P, Padhye S, Saluja AK, **McGuirk** J, Rao R. Targeting HSF1 disrupts HSP90 chaperone function in chronic lymphocytic leukemia. Oncotarget. 2015;6(31):31767-79. Epub 2015/09/24. doi: 10.18632/oncotarget.5167. PubMed PMID: 26397138; PMCID: Pmc4741638.
Yes	Yes	Ganguly S, McRae J, He JH, Divine C, Abhyankar S, Aljitawi O, McGuirk JP. Routine radiographic screening after completion of initial chemotherapy and relapse-free survival after transplant in patients with relapsed lymphoma. Leukemia & lymphoma. 2015;56(2):518-9. doi: 10.3109/10428194.2014.921916. PubMed PMID: WOS:000349662000041.
Yes	Yes	Iliff A, Divine C, Diaz F, Aljitawi O, Abhayankar S, McGuirk J, Ganguly S. Adequacy of Peripheral Blood Stem Cell Mobilization in Patients with Relapsed B Cell Non Hodgkin Lymphoma Treated with Bendamustine. Leukemia & lymphoma. 2015:1-5. Epub 2015/08/22. doi: 10.3109/10428194.2015.1080365. PubMed PMID: 26294340.
Yes	Yes	Lin TL, Williams T, He J, Aljitawi OS, Ganguly S, Abhyankar S, Fleming A, Male H, McGuirk JP. Rates of complete diagnostic testing for patients with acute myeloid leukemia. Cancer medicine. 2015;4(4):519-22. Epub 2015/01/27. doi: 10.1002/cam4.406. PubMed PMID: 25620650; PubMed Central PMCID: PMC4402066.
Yes	Yes	Aljitawi O, Ganguly S, Lin TL, Mahnken J, Palla SL, Bunch J, Supancic S, Singh AK, Shune L, Abhyankar S, Allin D, McGuirk J. First Report on an Ongoing Pilot Clinical Study Incorporating Hyperbaric Oxygen into Autologous Peripheral Blood Stem Cell Transplantation. Biology of Blood and Marrow Transplant. 2015;21(2):S128-S9. doi: 10.1016/j.bbmt.2014.11.174.
Yes	Yes	Bray WM, Bivona C, Rockey M, Henry D, Grauer D, Abhyankar S, Aljitawi O, Ganguly S, McGuirk J, Singh A, Lin TL. Outcomes for newly diagnosed patients with acute myeloid leukemia dosed on actual or adjusted body weight. Cancer chemotherapy and pharmacology. 2015;76(4):691-7. Epub 2015/08/02. doi: 10.1007/s00280-015-2829-1. PubMed PMID: 26231954; PMCID: Pmc4725583.
Yes	Yes	Brownback KR, Simpson SQ, Pitts LR, Polineni D, McGuirk JP, Ganguly S, Aljitawi OS, Lin TL, Singh A, Abhyankar S. Effect of extracorporeal photopheresis on lung function decline for severe bronchiolitis obliterans syndrome following allogeneic stem cell transplantation. Journal of clinical apheresis. 2015. Epub 2015/06/03. doi: 10.1002/jca.21404. PubMed PMID: 26031713.
Yes	Yes	Ganguly S, McRae J, He J, Divine CL, Abhyankar S, Aljitawi O, McGuirk J. Routine Radiographic Screening for Lymphoma before Autologous Stem Cell Transplantation (auto-SCT) Does Not Improve Relapse-Free Survival after Auto-SCT. Biology of Blood and Marrow Transplant. 2014;20(2):S109-S10. doi: 10.1016/j.bbmt.2013.12.156.
Yes	Yes	Luu Tran H, Mahmoudjafari Z, Rockey M, Henry D, Grauer D, Aljitawi O, Abhyankar S, Ganguly S, Lin T, McGuirk J. Tolerability and outcome of once weekly liposomal amphotericin B for the prevention of invasive fungal infections in hematopoietic stem cell transplant patients with graft-versus-host disease. Journal of oncology pharmacy practice : official publication of the International Society of Oncology Pharmacy Practitioners. 2014. Epub 2014/12/05. doi: 10.1177/1078155214560920. PubMed PMID: 25471252.
Yes		McClune BL, Ahn KW, Wang HL, Antin JH, Artz AS, Cahn JY, Deol A, Freytes CO, Hamadani M, Holmberg LA, Jagasia MH, Jakubowski AA, Kharfan-Dabaja MA, Lazarus HM, Miller AM, Olsson R, Pedersen TL, Pidala J, Pulsipher MA, Rowe JM, Saber W, van Besien KW, Waller EK, Aljurf MD, Akpek G, Bacher U, Chao NJ, Chen YB, Cooper BW, Dehn J, de Lima MJ, Hsu JW, Lewis ID, Marks DI, McGuirk J, Cairo MS, Schouten HC, Szer J, Ramanathan M, Savani BN, Seftel M, Socie G, Vij R, Warlick ED, Weisdorf DJ. Allotransplantation for patient's age >/=40 years with non-Hodgkin

		lymphoma: encouraging progression-free survival. Biology of blood and marrow transplantation: journal of the American Society for Blood and Marrow Transplantation. 2014;20(7):960-8. Epub 2014/03/20. doi: 10.1016/j.bbmt.2014.03.013. PubMed PMID: 24641829; PubMed Central PMCID: PMCPmc4057955.
Yes	Yes	Prochaska L, Vacek J, Madan R, Abhyankar S, Ganguly S, McGuirk JP, Lin TL, Aljitawi OS. Intestinal ischemia after allogeneic stem cell transplantation: a report of four cases. Transplantation proceedings. 2014;46(5):1536-9. doi: 10.1016/j.transproceed.2013.12.066. PubMed PMID: 24935326.
	Yes	Wieliczka ML, Ganguly S, Abhyankar S, Lin T, McGuirk JP, Aljitawi OS. Rituximab as a treatment for factor VIII inhibitor in a patient with chronic GVHD. Bone marrow transplantation. 2014;49(4):588. doi: 10.1038/bmt.2013.229. PubMed PMID: 24442248
Yes	Yes	Aljitawi OS, Ganguly S, Abhyankar SH, Ferree M, Marks R, Pipkin JD, McGuirk JP. Phase IIa cross-over study of propylene glycol-free melphalan (LGD-353) and alkeran in multiple myeloma autologous transplantation. Bone marrow transplantation. 2014;49(8):1042-5. doi: 10.1038/bmt.2014.120. PubMed PMID: 24911220.
Yes		Aljitawi OS, Xiao Y, Eskew JD, Parelkar NK, Swink M, Radel J, Lin TL, Kimler BF, Mahnken JD, McGuirk JP, Broxmeyer HE, Vielhauer G. Hyperbaric oxygen improves engraftment of ex-vivo expanded and gene transduced human CD34(+) cells in a murine model of umbilical cord blood transplantation. Blood cells, molecules & diseases. 2014;52(1):59-67. doi: 10.1016/j.bcmd.2013.07.013. PubMed PMID: 23953010; PubMed Central PMCID: PMC4075130.
Yes	Yes	Brownback KR, Simpson SQ, McGuirk JP, Lin TL, Abhyankar S, Ganguly S, Aljitawi OS. Pulmonary manifestations of the pre-engraftment syndrome after umbilical cord blood transplantation. Annals of hematology. 2014;93(5):847-54. doi: 10.1007/s00277-013-1981-0. PubMed PMID: 24346710; PubMed Central PMCID: PMC4109706.
Yes	Yes	Hawkinson D, Abhyankar S, Aljitawi O, Ganguly S, McGuirk JP, Horvat R. Delayed RSV diagnosis in a stem cell transplant population due to mutations that result in negative polymerase chain reaction. Diagnostic microbiology and infectious disease. 2013;75(4):426-30. doi: 10.1016/j.diagmicrobio.2012.12.014. PubMed PMID: 23415542.
Yes	Yes	Alhafez A, Aljitawi OS, Lin TL, Ganguly S, Abhyankar S, McGuirk JP. Bendamustine associated with irreversible ascending paralysis. Case reports in hematology. 2013;2013:931519. doi: 10.1155/2013/931519. PubMed PMID: 23533850; PubMed Central PMCID: PMC3600208.
	Yes	Fiskus W, Verstovsek S, Manshouri T, Smith JE, Peth K, Abhyankar S, McGuirk J, Bhalla KN. Dual PI3K/AKT/mTOR inhibitor BEZ235 synergistically enhances the activity of JAK2 inhibitor against cultured and primary human myeloproliferative neoplasm cells. Molecular cancer therapeutics. 2013;12(5):577-88. doi: 10.1158/1535-7163.MCT-12-0862. PubMed PMID: 23445613.
Yes	Yes	Ganguly S, Amin M, Divine C, Aljitawi OS, Abhyankar S, McGuirk JP. Decitabine in patients with relapsed acute myeloid leukemia (AML) after allogeneic stem cell transplantation (allo-SCT). Annals of Hematology. 2013;92(4):549-50. Epub 2012/11/01. PubMed PMID: 23111661.
Yes	Yes	Ganguly S, Divine CL, Aljitawi OS, Abhyankar S, McGuirk JP, Graves L. Prophylactic use of zoledronic acid to prevent early bone loss is safe and feasible in patients with acute myeloid leukemia undergoing allogeneic stem cell transplantation. Clin Transplant. 2012;26(3):447-53.
Yes	Yes	Ganguly S, Jain V, Divine C, Aljitawi O, Abhyankar S, McGuirk J. BU, melphalan and thiotepa as a preparative regimen for auto-transplantation in Hodgkin's disease. Bone Marrow Transplant. 2012;47(2):311-2.
Yes	Yes	Abhyankar S, DeJarnette S, Aljitawi O, Ganguly S, Merkel D, McGuirk J. A risk-based approach to optimize autologous hematopoietic stem cell (HSC) collection with the use of plerixafor. Bone marrow transplantation. 2012;47(4):483-7. Epub 2011/07/05. doi: 10.1038/bmt.2011.133. PubMed PMID: 21725372.

Yes	Yes	Aljitawi OS, Coats A, Zhang D, Ganguly S, Abhyankar S, Lin T, McGuirk JP. Umbilical cord graft- versus-leukemia effect induces remission without the price of graft-versus-host disease: the possible role of NK cells. Clinical Transplantation. 2012;26(5):663-4. Epub 2012/09/04. PubMed PMID: 22938188.
		Bao L, Cowan MJ, Dunham K, Horn B, McGuirk J, Gilman A, Lucas KG. Adoptive immunotherapy with CMV-specific cytotoxic T lymphocytes for stem cell transplant patients with refractory CMV infections. J Immunother. 2012;35(3):293-8. PMCID: 3306600.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Joseph P. McGuirk, DO**

eRA COMMONS USER NAME (credential, e.g., agency login): JMCGUIRK

POSITION TITLE: Professor of Medicine, Division Director, Hematologic Malignancies & Cellular Therapeutics, Medical Director, Blood & Marrow Transplant Program

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Missouri, Columbia, MO	B.A.	05/1986	Biology
Kansas City University of Medicine and Biosciences, Kansas City, MO	D.O.	05/1990	Medicine
Yale-New Haven Hospital, New Haven, CT	Internship	06/1991	Internal Medicine
Yale-New Haven Hospital, New Haven, CT	Residency	06/1992	Psychiatry
Yale-New Haven Hospital, New Haven, CT	Residency	06/1993	Internal Medicine
Memorial Sloan-Kettering Cancer Center, New York, NY	Fellowship	06/1996	Medical Oncology

A. Personal statement

I have worked in the field of hematologic malignancies for over 25 years and have performed over 3000 transplant procedures, and currently serve as the Schutte-Speas Professor in Hematology-Oncology and the Division Director of Hematologic Malignancies and Cellular Therapeutics at the University of Kansas Cancer Center. I actively serve on numerous editorial review boards and have authored/co-authored over 150 peer-reviewed abstracts and publications and serve on several committee assignments, including co-chair of the ASBMT Reimbursement Committee (2011-present), as well as acting as the ASBMT liaison for the ASCO Clinical Practice Committee. I have obtained considerable insight and expertise as a principal investigator (PI) on a significant number of multi-institutional and collaborative registry clinical trials, including numerous pharmaceutical-sponsored, NCI and NIH-funded investigational clinical trials, including those offered via the Center for International Blood & Marrow Transplant Research Clinical Trials Network (CIBMTR CTN). My broad background and specific training and expertise in the treatment of hematologic malignancies is exemplified by the following publications.

a) Lin TL, Williams T, He J, Aljitawi OS, Ganguly S, Abhyankar S, Fleming A, Male H, **McGuirk JP**. Rates of complete diagnostic testing for patients with acute myeloid leukemia. Cancer Med. 2015 Apr;4(4):519-22. PMC4402066
b) Ganguly S, Home T, Yacoub A, Kambhampati S, Shi H, Dandawate P, Padhye S, Saluja AK, **McGuirk J**, Rao R. Targeting HSF1 disrupts HSP90 chaperone function in chronic lymphocytic leukemia. Oncotarget. 2015 Oct 13;6(31):31767-79. PMC4741638.
c) Anasetti C, Logan BR, Lee SJ, Waller EK, Weisdorf DJ, Wingard JR, Cutler CS, Westervelt P, Woolfrey A, Couban S, Ehninger G, Johnston L, Maziarz RT, Pulsipher MA, Porter DL, Mineishi S, McCarty JM, Khan SP, Anderlini P, Bensinger WI, Leitman SF, Rowley SD, Bredeson C, Carter SL, Horowitz MM, Confer DL; Blood and Marrow Transplant Clinical Trials Network. Peripheral-blood stem cells versus bone marrow from unrelated donors. Collaborator **McGuirk** J N Engl J Med. 2012 Oct 18;367(16):1487-96. PMC3816375

d) Fiskus W, Verstovsek S, Manshouri T, Smith JE, Peth K, Abhyankar S, **McGuirk J**, Bhalla KN. Dual PI3K/AKT/mTOR inhibitor BEZ235 synergistically enhances the activity of JAK2 inhibitor against cultured and primary human myeloproliferative neoplasm cells. Mol Cancer Ther. 2013 May;12(5):577-88. PMID: 23445613 (PMC# not required; not NIH funded).

B. Positions and Honors

Positions and Employment:

1996-1997 Assistant Professor of Medicine, Staff Physician, Blood and Marrow Transplantation, Medical University of South Carolina, Charleston, SC
1997-1999 Assistant Professor of Medicine, Associate Director, Blood & Marrow Transplantation, Yale University School of Medicine, New Haven, CT
1999-2007 Associate Professor, University of Missouri, Kansas City, MO
2000-2007 Medical Director, Blood & Marrow Transplantation, Kansas City Cancer Center, St. Luke's Hospital, Kansas City, MO
2007-2010 Medical Director, BMT, St. Luke's Hospital Kansas City Cancer Ctr, Kansas City, MO
2007-2010 Associate Professor of Medicine, University of Kansas Medical Center, Kansas City, KS
2010-present Professor of Medicine, University of Kansas Medical Center, Kansas City, KS
2013-2015 Interim Director, Division of Hematology Oncology, University of Kansas Medical Center, Kansas City, KS
2015-present Division Director, Hematologic Malignancies and Cellular Therapeutics, University of Kansas Medical Center, Kansas City, KS
2015-present Schutte /Speas Professor in Hematology-Oncology, University of Kansas Medical Center, Kansas City, KS

Honors & Awards:

1986 Phi Beta Kappa, University of Missouri
1990 Valedictorian
1990 Golden Stethoscope Award
2006-present Kansas City Magazine – Super Doctors
2008 Ingram's Magazine – Top Doctors
2013 National Marrow Donor Program® (NMDP) Innovations Award

Membership in Professional Societies:

1990-present American College of Physicians
1996-present American Society of Blood and Marrow Transplant
1996-present American Society of Hematology
1999-present Southwest Oncology Group (SWOG)
2001-present Leukemia & Lymphoma Society Board Member
2007-present Member of Multidisciplinary Cancer Committee (KUMC)
2007-present Hematology/BMT Disease Working Group Committee (KUMC)
2007-present KUCC Protocol Review Monitoring Committee (KUMC)
2007-present Kansas University Cancer Center Infection Prevention Committee
2008-present KUMC Blood Utilization Committee
2009-present CIBMTR Acute Leukemia Working Committee
2009-present CIBMTR Graft Sources and Manipulation Working Committee
2009-present NMDP Radiation Injury Treatment Network Steering Committee
2009-present Chairman, University of Kansas RITN Working Committee (KUMC)
2010-present KC Round Table of Hematology and Oncology (Chairman)
2011-present American Society of Blood and Marrow Transplant
2011-present KUMC Academic Practice Committee
2011-present KUMC Oncology Service Line Committee
2011-present NMDP Reimbursement and Coding Committee
2011-present American Society of Clinical Oncology/ASBMT Liaison for the ASCO Clinical Practice Committee
2013-present NMDP SCI Physician Workforce Working Group

2014-present Midwest Stem Cell Therapy Center – Advisory Board
2014-present Chairman, Cancer Pharmacy and Therapeutics, KUMC
2014-present Blood and Lymphatic Cancer; Targets and Therapy – Editorial Board
2015-present Cellular Therapeutics Working Group (CIBMTR)
2015-present Myeloid DWG (Disease Working Group)
2015-present Lymphoid DWG (Disease Working Group)
2016-present Quality and Patient Experience Committee
2016-present American Society of Blood and Marrow Transplant Board or Directors
2016-present Genetic Testing/Molecular Diagnostics Formulary Working Group
2016-present Personalized Medicine Clinical Operations Working Group
2016-present Perinatal Stem Cell Society - member

C. Contributions to Science

Major contributions:

1. Cellular Therapeutics

a) Fiskus W, Verstovsek S, Manshouri T, Smith JE, Peth K, Abhyankar S, **McGuirk J,** Bhalla KN. Dual PI3K/AKT/mTOR inhibitor BEZ235 synergistically enhances the activity of JAK2 inhibitor against cultured and primary human myeloproliferative neoplasm cells. Mol Cancer Ther. 2013 May;12(5):577-88. PMID: 23445613 (not NIH funded)

b) Williams CB, Kambhampati S, Fiskus W, Wick J, Dutreix C, Ganguly S, Aljitawi O, Reyes R, Fleming A, Abhyankar S, Bhalla KN, **McGuirk JP**. Preclinical and phase I results of decitabine in combination with midostaurin (PKC412) for newly diagnosed elderly or relapsed/refractory adult patients with acute myeloid leukemia. Pharmacotherapy. 2013 Dec;33(12):1341-52. PMID: 23798029 (not NIH funded)

c) Ganguly S, Home T, Yacoub A, Kambhampati S, Shi H, Dandawate P, Padhye S, Saluja AK, **McGuirk J**, Rao R. Targeting HSF1 disrupts HSP90 chaperone function in chronic lymphocytic leukemia. Oncotarget. 2015 Oct 13;6(31):31767-79. PMC4741638.

d) **McGuirk JP**, Smith JR, Divine CL, Zuniga M, Weiss ML. Wharton's Jelly-Derived Mesenchymal Stromal Cells as a Promising Cellular Therapeutic Strategy for the Management of Graft-versus-Host Disease. Pharmaceuticals (Basel). 2015 Apr 16;8(2):196-220. PMC4491656

2. Leukemia-Lymphoma Research

a) Abhyankar SH, Chiang KY, **McGuirk JP**, Pati AR, Godder KT, Welsh JA, Waldron RL, McElveen JL, Henslee-Downey PJ. Late onset Epstein-Barr virus-associated lymphoproliferative disease after allogeneic bone marrow transplant presenting as breast masses. Bone Marrow Transplant. 1998 Feb;21(3):295-7. PMID: 9489654 (not NIH funded)

b) Balusu R, Fiskus W, Rao R, Chong DG, Nalluri S, Mudunuru U, Ma H, Chen L, Venkannagari S, Ha K, Abhyankar S, Williams C, **McGuirk J**, Khoury HJ, Ustun C, Bhalla KN. Targeting levels or oligomerization of nucleophosmin 1 induces differentiation and loss of survival of human AML cells with mutant NPM1. Blood. 2011 Sep 15;118(11):3096-106. PMID: 21719597 (not NIH funded)

c) Fiskus W, Verstovsek S, Manshouri T, Rao R, Balusu R, Venkannagari S, Rao NN, Ha K, Smith JE, Hembruff SL, Abhyankar S, **McGuirk J**, Bhalla KN. Heat shock protein 90 inhibitor is synergistic with JAK2 inhibitor and overcomes resistance to JAK2-TKI in human myeloproliferative neoplasm cells. Clin Cancer Res. 2011 Dec 1;17(23):7347-58. PMC3743080.

d) Lin TL, Williams T, He J, Aljitawi OS, Ganguly S, Abhyankar S, Fleming A, Male H, **McGuirk JP**. Rates of complete diagnostic testing for patients with acute myeloid leukemia. Cancer Med. 2015 Apr;4(4):519-22. 2015 Jan 26. PMC4402066

3. Stem Cell Transplantation

a) **McGuirk J**, Hao G, Hou W, Abhyankar S, Williams C, Yan W, Yuan J, Guan X, Belt R, Dejarnette S, Wieman J, Yan Y. Serum proteomic profiling and haptoglobin polymorphisms in patients with GVHD after allogeneic hematopoietic cell transplantation. J Hematol Oncol. 2009 Apr 20;2:17. PMC2678154

b) **McGuirk JP**, Weiss ML. Promising cellular therapeutics for prevention or management of graft-versus-host disease (a review). Placenta. 2011 Oct;32 Suppl 4:S304-10. PMC3760226.

c) Ganguly S, Amin M, Divine C, Aljitawi OS, Abhyankar S, **McGuirk JP**. Decitabine in patients with relapsed acute myeloid leukemia (AML) after allogeneic stem cell transplantation (allo-SCT). Ann Hematol. 2013 Apr;92(4):549-50. PMID: 23111661 (not NIH funded)
d) Ganguly S, McRae J, He J, Divine C, Abhyankar S, Aljitawi O, **McGuirk JP**. Routine radiographic screening after completion of initial chemotherapy and relapse-free survival after transplant in patients with relapsed lymphoma. Lymphoma. 2015 Feb;56(2):518-9. PMID: 24828868 (not NIH funded)

Complete list of publications (56 in total):
http://www.ncbi.nlm.nih.gov/sites/myncbi/1RwG2P8t9f5Q1/collections/48747521/public/

D. Research Support

Ongoing Research Support:

U10HL069233 [34-5234-2005-002] (McGuirk, J.) 08/01/2011 - 06/30/2017
University of Nebraska Medical Center (NIH)
Nebraska/Kansas Blood and Marrow Transplant Research Network
Major Goals: Multicenter grant to conduct Phase II and Phase III studies that provide new information to improve hematopoietic stem cell transplantation (HSCT) therapy to treat both malignant and non-malignant diseases.

In addition, Dr. McGuirk is involved in several Clinical Trials sponsored by pharmaceutical companies. Due to confidentiality agreements signed with the entities involved, certain information cannot be disclosed.

Recently Completed Research Support (clinical trials):

- A Multi-Center, Phase II Trial of Non-Myeloablative Conditioning (NST) and Transplantation of Partially HLAMismatched Bone Marrow for Patients with Hematologic Malignancies. **Closed**
- A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Prochymal™ (Ex-vivo Cultured Adult Human Mesenchymal Stem Cells) Infusion in Combination with Corticosteroids for the Treatment of newly diagnosed Acute GVHD. **Closed**
- A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety Of Prochymal™ (Ex-vivo Cultered Adule Human Mesenchymal Stem Cells) Infusion For The Treatment Of Steriod-Refractory Acute GVHD. **Closed**
- A Phase 2 Clinical Trial to Evaluate the Safety, Immunogenecity, and Clinical Benefit of a CMV Immunotherapeutic Vaccine in Donors and CMV-Seropositive Recipients Undergoing Allogeneic, Matched Hematopoietic Cell Transplant (HCT). **Closed**
- A Phase III, Double Blind, Randomized Study to Evaluate Safety and Efficacy of BAL8557 Versus Voriconazole for Primary Treatment of Invasive Fungal Disease Caused by Aspergillus Species or Other Filamentous Fungi. **Closed**

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Roy Middle Name A Last Name*: Jensen Suffix: MD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Pathology & Lab Medicine
Division: School of Medicine
Street1*: MS 3045, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-4700 Fax Number: 913-588-4701

E-Mail*: RJENSEN@kumc.edu

Credential, e.g., agency login: JENSENRA

Project Role*: Other (Specify) Other Project Role Category: Core Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ○ Yes ● No

*Agency-Defined Phase III Clinical Trial? ○ Yes ○ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ● Yes ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

● Yes ○ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

☐ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator / Change of Institution Section

☐ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

☐ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	Develop_Specific_Aims_Final1019428433.pdf
3. Research Strategy*	Develop_Core_Research_Strategy_Final1019913933.pdf
4. Progress Report Publication List	Develop_Progress_Report_Publications1019754747.pdf
Human Subjects Section	
5. Protection of Human Subjects	Protection_of_Human_Subjects___DEVELOPMENTAL_FUNDS1019799839.pdf
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	Inclusion_of_Women_Minorities___DEVELOPMENTAL_FUNDS1019799840.pdf
8. Inclusion of Children	Inclusion_of_Children___DEVELOPMENTAL_FUNDS1019799841.pdf
Other Research Plan Section	
9. Vertebrate Animals	Vertebrate_Animals___DEVELOPMENTAL_FUNDS1019799848.pdf
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	
14. Resource Sharing Plan(s)	Resource_Sharing_Plan__Generic1019913973.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Developmental Funds – Specific Aims

In the proposed funding period, The University of Kansas Cancer Center (KUCC) requests CCSG Developmental Funds to support the following strategic Specific Aims:

Aim 1 – Support pilot research projects: The major purpose of the Pilot Project Program is to provide support for highly innovative research proposals in new, exciting, and potentially breakthrough areas of cancer research. The goal is to provide an opportunity to generate critical preliminary data, test new hypotheses and evaluate the feasibility of ideas that might allow for rapid advancement in the field and make an impact on population, basic, clinical or translational science.

Aim 2 – Develop additional shared resources to strengthen research initiatives: KUCC is dedicated to supporting its member's research initiatives by providing resources/services/technical expertise that may otherwise be inaccessible. KUCC leadership surveys its members in order to understand the needs of our investigators. In response to those needs, KUCC has chosen to support the development of three new shared resources.

Aim 3 – Support new faculty recruits: To actively build and improve the research environment, KUCC is committed to recruiting additional cancer researchers to increase the national and international status of the Cancer Center, enhance the number of NCI/cancer-related grants, fill critical research positions and build the four cancer research programs. Each purposeful hire aims to further the scientific vision, mission and goals of the Cancer Center.

Aim 4 – Promote basic science and clinical science research activities: KUCC recognizes the contributions of key individuals who promote scientific and clinical activities within the center. Specifically, KUCC selected one Research and one Clinical Staff Investigator who are instrumental in the development and implementation of the Cancer Center vision.

Developmental Funds – Research Strategy

Overview

From 2012-2015, The University of Kansas Cancer Center (KUCC) used Cancer Center Support Grant (CCSG) Developmental Funds to support pilot projects, develop shared resources and supplement start-up packages for faculty recruits. Sixteen pilot projects totaling $478,389 were awarded to 15 different Cancer Center members, spanning all four research programs. Awardees published 62 peer-reviewed articles from these research projects. Furthermore, in the first three years (2012, 2013, 2014) with an investment of $268,389, members were awarded seven external peer-reviewed grants totaling $6.3M, resulting in a 23-fold return on investment (see Pilot Projects and Outcomes table in Other Attachments). Two developing shared resources received support during the previous funding period, the Transgenic & Gene-Targeting shared resource (TGTSR) and the Health Communications Research shared resource (HCRSR). In 2015, a total of 26 Cancer Center members utilized the TGTSR services and eight Cancer Center members utilized the HCRSR. The usage of the TGTSR is so robust, the Cancer Center transitioned it to an established shared resource, with funds being requested in the renewal application. The HCRSR continues to develop and build up its user base. Cancer Center faculty Joan **Lewis-Wambi** (CB), Bret **Freudenthal** (CB), Christy **Hagan** (CB) and Subhrajit **Saha** (CB) jointly received over $3.2 M in start-up funds. In addition, KUCC supported 36 other faculty recruits.

Moving forward, KUCC requests CCSG Developmental Funds to continue the support of pilot projects, developing shared resources and start-up packages for future recruits. Additionally, KUCC requests CCSG Developmental Funds to support one Research and one Clinical Staff Investigator. KUCC believes initiatives supported by CCSG developmental funds will enable the Cancer Center to provide the optimal environment to focus the power of precision medicine, basic science inquiry, drug discovery and development, and behavioral interventions to decrease cancer incidence, morbidity, and mortality. Furthermore, these initiatives will promote a cancer center culture whose highest priority is to leverage the collective state-of-the-art basic, clinical, translational and population research programs to understand cancer at a fundamental level and catalyze a comprehensive, multidisciplinary approach to defeating cancer.

Response to Previous Review

Developmental Funds received an evaluation of 'Excellent' merit in the 2012 review. The table below outlines several points of criticism along with responses.

Point	Response
The pilot award program has been in place since 2005; criteria for awards are fairly standard, although they do not highlight any specific program in need of improvement or future emphasis. A more strategic use of these funds to facilitate programmatic emphasis going forward would be useful.	Based on the scientific environment and areas of need, KUCC leadership developed very specific RFAs for pilot funding. For example, one round of funding specifically funded investigators that had submitted an NCI grant, been competitively scored, but not funded. Other specific criteria included funding early phase clinical trials and teams to develop program project applications.
Authority for decision-making is under the direction of the Deputy Director who was recruited in 2010, with a rotating membership of leaders on the committee. Final approval is given by the Director. However, a more stable involvement of the Associate Directors in the decision-making process would facilitate the more strategic deployment of these resources.	The pilot review committee consists of the Leadership Council with *ad hoc* additions of KUCC members if particular expertise is required for the review. The committee chairmanship rotates among the Deputy Director and the Associate Directors. Final approval is given by the Director.
Although the overall success rate for subsequent extramural funding is reported to be approximately 30%, the degree of success in engendering collaborations is not as apparent, and both collaborations and publications need to be additional metrics success.	KUCC began to track collaboration metrics following the site visit and they are being reported along with subsequent peer-reviewed grants and publications.
The small amount of Developmental Funds devoted to future recruitments is reasonable; however, future strategic planning should prioritize these recruitments.	The KUCC recruiting committee meets monthly to discuss each strategic hire and resources dedicated to that individual.

Pilot Project Program

The major purpose of the Pilot Project Program is to provide support for highly meritorious research in new, exciting and potential breakthrough areas related to cancer. Innovative cutting-edge research, which strengthens scientific areas relevant to the catchment area, makes available new technology or expertise, or demonstrates potential to enhance the research portfolio of the Cancer Center will be prioritized. KUCC aims to increase interdisciplinary collaboration amongst Cancer Center members and leverage resources to foster the discovery and advancement of new and more effective preventive or therapeutic strategies. Ultimately, the goal is to have the funded research make an impact in the fields of basic, clinical, population or translational science and on the cancer burden in KUCC's catchment area.

Criteria for applications

A request for applications is issued to all Cancer Center members and broadcasted to all KUCC campuses via the respective research grant and contract offices. Specifically, the University of Kansas Medical Center Research Institute in Kansas City, the Kansas University Center for Research on the Lawrence Campus, the Stowers Institute and Children's Mercy send the announcement to all research administrators, Deans, Chairs, Faculty, and Investigators. Applications must demonstrate collaboration between at least two Cancer Center members, one of which must have full membership standing, unless the request for application is made specifically for junior investigators. The pilot research proposal must be cancer-related and must not overlap with existing funding (different focus and different aims). Awards are generally $35,000, but can be up to $50,000 for one year. There is intentional flexibility of funding to provide support for a variety of studies and to provide a mechanism to support personnel and/or supplies as necessary. Salary for the PI, travel, subscriptions, memberships, or indirect costs is not allowed. Applications from under-represented minorities, women, and junior investigators are especially encouraged and KUCC works with the Office of Cultural Enrichment and Diversity to identify means to seek out meritorious applicants for awards from these groups.

Guidelines for selection of Pilot Projects

A letter of intent (LOI) is due to the applicant's program leader four weeks prior to the full application due date. The LOI must include the title of the project, intent to use any of the Cancer Center shared resources, name of Cancer Center collaborator(s), type of research (Basic Science, Clinical, Population, Translational), and a basic outline of the research plan. The LOIs help determine the number and expertise of reviewers needed. Members of Leadership Council and other non-conflicted Cancer Center members review applications (two reviewers per application), score (NIH scoring system) and make recommendation for funding awards. Evaluation criteria include:

- Interdisciplinary Collaboration: Does this application show evidence of true collaboration between two members of different departments? Or are the investigators from different disciplines but in the same department?
- Potential for Extramural Funding: Please evaluate the likelihood that this proposal will lead to submission of a potentially fundable RO1, RO3 or R21 grant from the National Cancer Institute or comparable grant from other funding agencies.
- Thematic Compatibility: Does this proposal fit with a major theme of one of KUCC's programs and address a major issue in the catchment area?
- Scientific Merit and Significance: Will accomplishment of the specific aims advance our knowledge of cancer etiology, prevention or cure? And will the result impact our catchment area?
- Approach: Are the specific aims carefully designed and organized in such a fashion to produce meaningful, achievable conclusions?
- Novelty and Originality: Is this truly something new?
- Capability of the PI and Co-PI to Accomplish the Research: Is the PI appropriately trained and experienced enough or is the mentoring strong enough that the proposal can be successfully carried out?
- Environment: Can this laboratory do the proposed studies?

The Assistant Director for Grant Development and Research Resources, Susan Harp, receives all applications, coordinates the reviews from the review committee, assembles the evaluations, and holds a meeting with the Director and a small committee for final scoring and ranking.

Expectations of the awardees
Awardees are expected to complete the work in one year. Projects that include animals or human subjects must be reviewed in accordance with the University of Kansas Medical Center guidelines. Projects involving human subjects through interventional or clinical studies must be submitted to the KUMC Institutional Review Board (IRB) and approved by the Protocol Review and Monitoring Committee (PRMC). Final IRB/PRMC approval is not required to submit an application; approval can be noted as "pending". All projects involving animals must be submitted to the Institutional Animal Care and Use Committee (IACUC). Funds will not be released to the awardee until final IRB/PRMC/IACUC approvals have been received. Additionally, if the funds are from the CCSG, awardees are required to cite the CCSG P30 and remain compliant with the NIH Public Access Policy.

A final progress report is due three months after the end of the grant period and participation in the annual KUCC Research Symposium (poster or oral presentation) is strongly encouraged. At the conclusion of, or prior to the conclusion of the pilot project, it is expected that the investigators will have submitted a competitive grant to the NCI or other cancer research funding organization for extramural funding.

KUCC monitors and evaluates the effectiveness of the Pilot Project Program as determined by the quality of publications including proper acknowledgement and citation of KUCC and the CCSG, the acquisition of external funds for research related to the scientific goals of pilot studies, collaborations established and use of KUCC shared resources. Other measures of success may include the establishment of new technology or areas of research within KUCC that are used by KUCC members, enrollment on clinical trials or patents. These outcomes are reported to the NCI Office of Cancer Centers at the time of annual noncompeting renewal.

Awardees Scientific Achievements
In the previous grant funding period (2012-2015) KUCC awarded CCSG Developmental Funds to 16 pilot projects totaling $478,389 to 15 different Cancer Center members, spanning all four research programs (see Table in Other Attachments). Below are a few selected examples of awardees scientific achievements.

Tomoo **Iwakuma**, MD, PhD (CB) - The Role of MDM2-MTBP Axis in Cancer Metastasis → R01CA174735. In 2014, Cancer Biology research program member, **Iwakuma** turned a KUCC pilot awarded in 2012 into an NCI funded R01 that aims to characterize the role of the mouse double minute (MDM2) and MDM2 binding protein (MTBP) interaction in cancer metastasis. This project will determine the mechanism by which MTBP inhibits cancer metastasis and MDM2 promotes tumor progression in a p53-independent manner through inhibition of MTBP. Given that metastasis is the major cause of cancer mortality in our catchment area, a study that provides new insights into mechanisms of metastasis will significantly contribute to the improvement of the survival and quality of life of many cancer patients. **Iwakuma** recently published results from these studies and demonstrated that expression of MTBP was significantly reduced in human hepatocellular carcinoma (HCC) tissues compared to adjacent non-tumor tissues. MTBP expression was negatively correlated with capsular/vascular invasion and lymph node metastasis. Furthermore, overexpression of MTBP resulted in the suppression of the migratory and metastatic potential of the HCC cells, while its down regulation increased migration (Bi, *Clin Exp Metastasis*. 2015). As a potential mechanism for reduced MTBP expression in tumors, **Iwakuma** found that MTBP expression was increased following the treatment with histone deacetylase inhibitors. His studies, for the first time, provide mechanistic evidence of a role for MTBP in the suppression of clinical HCC metastasis.

M. Laird **Forrest**, PhD (D3ET) - Biomaterials for Treatment of Head and Neck Cancer → R01CA173292. **Forrest**, a D3ET research program member on the KU-Lawrence campus, was awarded a pilot project in 2012. In 2013, he transitioned the pilot award into an R01 that aims to expand the synthetic development and biological evaluation of a new polymeric biomaterial for chemotherapy of the head and neck tissues. **Forrest's** innovative approach is the first nanoparticle system specifically engineered for targeted drug delivery into cancerous lymph nodes and tissues after peri-tumoral injection. The new biomaterial, star nanoconjugates, can be targeted to head and neck squamous cell carcinoma (HNSCC) tumors without expensive and less robust homing ligands, such as antibodies or aptamers. **Forrest** recently published results demonstrating tolerability and efficacy in canines (Zhang, *J Pharm Sci.* 2016). Based on these extensive results in rodents and canines, this platform is expected to significantly impact human health by reducing the need for extensive surgery and radiotherapy, treatments that cause permanent disfigurement and reduce quality-of-life, and provide a much

safer alternative to systemic chemotherapy that can be administered to even advanced-stage patients with low performance status.

Byron **Gajewski**, PhD (CCPH) - A Novel Method for Expediting the Development of Patient Reported Outcome Measures → R03NR013236. **Gajewski**, a Cancer Control and Population Health program member, was awarded a pilot grant in 2013 that he then transitioned to an R03 in 2014. His work aims to test and disseminate an innovative Ordinal Bayesian Instrument Development (OBID) method that seamlessly integrates expert and participant data, while using fewer subjects than classical approaches, to achieve a coherent and economical estimate of validity evidence for new instrument development. Health research can take several years to translate into important changes in health care due in part to the time it takes to develop and test valid and reliable instruments. Using statistical models derived from both experts and participants, **Gajewski's** study expedites psychometric instrument development, in particular for studies from small populations (e.g. research on health disparities and on rare diseases) and/or studies with limited resources. A tested and disseminated OBID method will allow investigators to decrease the development time by reducing the number of participants needed by transferring the number of responses needed from participants to expert panels. **Gajewski** demonstrated the impact of this model in a recent Statistics in Medicine publication (Jiang, *Stat Med.* 2015). Understanding that slow recruitment in clinical trials leads to increased costs and resource utilization, which includes both the clinic staff and patient volunteers, **Gajewski** proposed two hierarchical extensions to the existing Bayesian constant accrual model: the accelerated prior and the hedging prior. The new proposed priors are able to adaptively utilize the researcher's previous experience and current accrual data to produce the estimation of trial completion time. The performance of these models, including prediction precision, coverage probability, and correct decision-making ability, is evaluated using actual studies from KUCC and simulation. The results showed that a constant accrual model with strongly informative priors is very accurate when accrual is on target or slightly off, producing smaller mean squared error, high percentage of coverage, and a high number of correct decisions as to whether or not continue the trial, but it is strongly biased when off target.

Other KUCC Funding Mechanisms

KUCC also supports and supplements other pilot funding mechanisms detailed below. The application and review process is the same as described above for CCSG-supported pilot awards.

1. **Pilot Project Program** – KUCC complements the CCSG Developmental Funds awarded to members. Since, 2012, KUCC has provided 27 pilot project awards, totaling $737,754 (**Table 1**).

Table 1. KUCC Funded Pilot Project Awards

Member Last Name	Member First Name	Program	Title
Apte	Udayan	CB	Use of Hepatocyte Nuclear Factor-4α (HNF4α) Target Gene Signature in Prognosis of Hepatocellular Carcinoma
Bansal	Ajay	CPS	Exosomes and Their Non-Coding RNA Profiles in Barrett's Esophagus
Behbod	Fariba	CPS	Essential Role of BCL9 in DCIS Progression to Invasive Breast Cancer
Chien	Jeremy	CB	Targeting FOXM1 Enhances Sensitivity to Chemotherapy in Ovarian Cancer
Chien	Jeremy	CB	Development of Minimally Invasive Genetic Screening Assays for Gynecologic Cancers
Choi	In-Young	CPS	Metabolic Imaging Markers of Tumor Activity in Living Human Brain
Das	Bhaskar	D3ET	Boron Containing Retinoid as Novel Therapeutic Agent For Glioblastoma Multiforme (GBM)
Dhar	Animesh	CPS	Histone Demethylase JMJDA1a: Novel Target for Pancreatic Cancer
Fridley	Brooke	CCPH	Development of Genomic Analysis Infrastructure with Application to the Study of Ovarian Cancer
Godwin	Andrew	D3ET	Liquid Biopsy-Based Assays to Detect Early-Stage Bladder Cancer
Greiner	Allen	CCPH	A Translational Approach to Understanding African American Colorectal Cancer Health Disparities
Hamilton-Reeves	Jill	CPS	Mechanistic Effects of Soy Intake on the Pathogenesis of Prostate Cancer
Hamilton-Reeves	Jill	CPS	Energy Balance for Prostate Cancer Prevention and Survivorship
Iwakuma	Tomoo	CB	The Role of Adenosine A3 Receptor in Osteosarcoma Malignancy

Kambhampati	Suman	D3ET	Phase 1/2 Study to Determine the Feasibility and Tolerability of the Combination of Decitabine and Ponatinib in Elderly Patients with Acute Myeloid Leukemia
Koestler	Devin	CB	Development of Prediction Models for Bladder Cancer Recurrence Using Clinical, Pathological and Molecular Data
Lamb	Audrey	D3ET	Structure Determination of Musashi-1, a Drug Target for Brain Tumors and Breast and Colon Cancer
Mure	Minae	CB	Nuclear-Associated Lysyl Oxidase-Like 2 Upregulates EMT-Activating Transcription Factors
Perez	Raymond	D3ET	Discovery of Drugs Stabilizing Mir-542-3p:Cox-2 mRNA Interaction
Petroff	Margaret "Peggy"	CPS	Modeling Pregnancy-Related Changes in Cancer Risk Using Humanized Mice
Ramamoorthy	Prabhu	CPS	Heat Shock Proteins, Hypoxia and Cancer Stem Cells
Septer	Seth	CPS	Gamma Mangostin as a Chemopreventive Agent in Familial Adenomatous Polyposis
Sharma	Priyanka	D3ET	Evaluation of *BRCA*ness as Prognostic Marker in Triple-Negative Breast Cancer Patients Treated with Adjuvant Anthracycline-Based Chemotherapy on INT-0137 (S9313) Trial
Thomas	Sufi	CB	Intratumor-Heterogeneity of Head and Neck Cancer
Umar	Shahid	CP	Epigenetics and Bacterial Induced Colon Cancer
Wang	Fen	D3ET	Targeting Wnt/ß-Catenin and P13K/Akt Pathways and Inhibiting Glioblastoma Stem-Like Cells Tumorigenicity in Tissue Culture and Xenograft Model Using Lower Dose Of Doxorubicin
Xu	Liang	D3ET	Drug the Undruggable: Inhibitors of RNA Binding Protein Msi1

2. **The American Cancer Society – Institutional Research Grant (ACS-IRG)** - Bruce **Kimler**, PhD (CPS), is the PI of an ACS-IRG (IRG-09-062-04). The Cancer Center supplements an extra $5,000 to each $30,000 project provided by the ACS-IRG plus one entire project ($35,000). In total, the ACS-IRG has supported 13 Cancer Center members, totaling $424,536 (**Table 2**).

Table 2. ACS-IRG Pilot Project Awards

Member Last Name	Member First Name	Program	Title
Gibbs	Heather	CCPH	Adaptation and Validation of a Nutrition Literacy Assessment Instrument for Cancer Survivors
Hamilton-Reeves	Jill	CPS	Improving Radical Cystectomy Outcomes Through Nutrition
Krieg	Adam	CB	Functional Analysis of Histone Demethylase Target Genes in Ovarian Cancer
Sugumar	Aravind	CPS	Targeting Patient Derived Pancreatic Cancer Cells with a Novel Flavonoid P276
Hines	Robert	CCPH	Rural vs. Urban Disparities in Adherence with Treatment Guidelines and Survival for Colorectal Cancer Patients in Kansas
Lee	Eugene	CB	The Augmentation of Chemotherapy with a Low Carbohydrate Diet in Bladder Cancer
Lipe	Brea	D3ET	Validation of a Thrombosis Risk Assessment Model in Patients with Newly Diagnosed Multiple Myeloma
Pacheco	Christina	CCPH	American Indian Comprehension of Informed Consent & Trust of Medical Researchers
Reyes	Ruben	D3ET	Phase I Pilot Study of MALT1 Protease Inhibition with Thioridazine in Relapsed / Refractory Activated B-Cell Type Diffuse Large B-Cell Lymphoma
Ellis	Shellie	CCPH	Eliciting Urologists' Decision Making Attributes: Recruitment and Data Collection Feasibility Study
Jarmolowicz	David	CPS	Chemotherapy Induced Cognitive Impairment: Assessing the Relation Between Demyelination and Spatial Learning Deficits
Martin	Laura	CCPH	Investigation of Brain Changes Associated with a Behavioral Intervention for Smoking Cessation
Subramaniam	Dharmalingam	CPS	Cancer Associated Fibroblasts Modulating Activity of DCLK1 Positive Cells

3. **Program Project Development Grants** - In response to a recommendation by the KUCC External Advisory Board to focus on multidisciplinary team science initiatives, KUCC developed a special call for proposals from multi-investigator teams to develop collaborative projects that would be competitive in applying for cancer-related research program project grants, COBREs, SPOREs, or similar funding mechanisms. Collaborative applications required at least two KUCC members and funded proposals were given $50,000 for one year. The project teams were eligible to receive an additional $50,000 for a second year pending a brief progress report. The progress report included an updated budget justification and a summary of a discussion with a program director or other official of the potential funding agency. Evaluation criteria included: research theme and its relevance to the funding agency's mission, scientific merit of each project and the entire program as a whole; cancer relevance; qualifications, experience and productivity of the research team; collaboration amongst Cancer Center members; project feasibility given environment, budget, and time; and likelihood that the research team can leverage this funding to compete successfully for an NCI program project grant application or similar award in the future. Three teams were selected to receive funding for year one (2014) and year two (2015) (**Table 3**).

Table 3. Program Project Developmental Grants

Members	Programs	Title
Jeremy **Chien**, Andrew **Godwin**, Scott **Weir**, Brooke **Fridley**, Devin **Koestler**	D3ET, CB, CCPH	The Ovarian Cancer Learning Collaborative
Carol **Fabian**, Christie **Befort**, Susan **Carlson**, Dan **Dixon**, Bruce **Kimler**, Jennifer **Klemp**, Deb **Sullivan**, Henry **Yeh**	CPS, CCPH	Combined Weight Loss and Omega-3 Fatty Acids for Breast Cancer Prevention
Shrikant **Anant**, Scott **Weir**, Shahid **Umar**, Dan **Dixon**, Kristi **Neufeld**, Liang **Xu**	CPS, D3ET, CB	RNA Binding Proteins in Colorectal Cancers

4. **Donor-Specified Philanthropy** - Through philanthropic funds donated to KUCC, three research awards have been provided specifically for brain cancer research, totaling $105,000 (**Table 4**).

Table 4. Philanthropy-Funded Awards

Member Last Name	Member First Name	Program	Title
Ramalingam	Satish	CPS	Glioblastoma in A Dish (GID) – A Novel Approach for Precision Medicine
Thomas	Sufi	CB	Targeting Mutant EGRF in Glioma
Newell	Kathy	D3ET	Immunohistochemical and Molecular Characterization of Select Primary Brain Tumors for New Chemotherapeutic Targets

5. **Investigator-Initiated Clinical Trials** - To foster more investigator-initiated early phase clinical trials, the Cancer Center developed a request for proposals and awarded $100,000 each to four trials over two years (**Table 5**). Year one began in 2015.

Table 5. Early Phase Clinical Trials

Member Last Name	Member First Name	Program	Title
Sharma	Priyanka	D3ET	Randomized Open Label Phase II Trial of Neoadjuvant Carboplatin plus Docetaxel or Carboplatin plus Paclitaxel Followed by Adriamycin plus Cyclophosphamide in Stage I-III Triple-Negative Breast Cancer
Ganguly	Siddhartha	D3ET	Role of Bortezomib Prior to Stem Cell Mobilization as an *In Vivo* Purging Agent to Obtain Flow Negative Leukapheresis Product in Patients with Multiple Myeloma Undergoing Autologous Stem Cell Transplant
Khan	Qamar	D3ET	Randomized Trial of Dose Dense, Fixed Dose Capecitabine in Metastatic Breast Cancer and Advanced GI Malignancies: The X7-7 Trial
Kumar	Parvesh	D3ET	Phase II Randomized Clinical Trial of 3-D Conformal RT vs. IMRT in Post-Prostatectomy Prostate Cancer Patients

6. **Research Program Development Funds** - KUCC provides each research program up to $50,000 to use at their discretion. These funds are directed by the program leaders and have supported grant reviews, visiting speakers, program retreats, travel awards and program-specific pilot projects.

In total, from 2012-2015, Cancer Center members received $2,390,189 from either KUCC CCSG developmental funds or other pilot funding mechanisms (**Table 6**). As detailed in the Pilot Projects and Outcomes table in the Other Attachments, these research projects have generated over $15M in external funding (a > 6-fold return on investment), 123 publications, 10 clinical trials, nine patents and one copyright.

Table 6. KUCC-Directed Funds

Award Mechanism (no. of projects funded)	Sum of Amount
CCSG Development Funds – Pilot Project Program (16)	$478,389
KUCC Pilot Project Program (27)	$737,754
ASC-IRG (13)	$424,536
Program Project Development Grants (3)	$300,000
Donor-Specified Philanthropy (3)	$105,000
Early Phase Clinical Trials (4)	$200,000
Research Program Development Funds (7)	$144,510
Total	**$2,390,189**

Below are a few selected examples of awardees scientific achievements:

Heather **Gibbs**, PhD (CCPH) - Adaptation and Validation of a Nutrition Literacy Assessment Instrument → R03HD081730. **Gibbs** is an Assistant Professor in the Department of Dietetics and Nutrition. Her research is focused on nutrition literacy and how better nutrition literacy can impact dietary quantity and quality. In 2013, **Gibbs** was awarded an ACS-IRG pilot to produce a valid tool for measuring nutrition literacy among breast cancer survivors and those at high-risk for breast cancer. The pervasive consumption of a Western diet, a diet consumed largely within a plentiful food environment, suggests that improving nutrition literacy is a critical target for improving overall health. **Gibbs** has engaged nutrition experts and breast cancer survivors to adapt the Nutrition Literacy Assessment Instrument (NLAI) to the breast cancer population. **Gibbs** tested the adapted instrument in an ongoing intensive weight loss intervention study of breast cancer survivors (Christie **Befort's**, PhD, (CCPH program member - Group Phone-Based Weight Control Among Rural Breast Cancer Survivors) as well as two groups (breast cancer survivors and primary breast cancer prevention) not receiving weight loss intervention. The results indicated that the NLAI for Breast Cancer is content valid and demonstrates promising reliability and construct validity related to diet quality, through a larger sample size, and removal of non-discriminating items is needed to confirm these findings (**Gibbs**, *J Cancer Educ*. 2015). **Gibbs** was awarded an NIH R03 in 2014, to adapt the tool on a larger scale for a chronic disease population, which shares similar health issues as the breast cancer survivor population. **Gibbs** expects the NLAI will provide an objective basis for determining educational needs related to nutrition and can have broader application in public health programs that target diet quality, as an outcome measure for nutrition education efforts, and as the basis of research tools for identifying nutrition literacy in various populations.

Liang **Xu**, PhD (D3ET) - Small Molecules Modulating RNA-Binding Protein Musashi-1 (Msi1) → R01CA178831. In 2012, **Xu** was awarded KUCC pilot funds to identify inhibitors of RNA-Binding protein Msi1. The funds allowed him to work with Jeff **Aubé** (UNC), Kristi **Neufeld** (CB) and the Lead Development and Optimization shared resource to screen for small molecules that inhibited Msi1. In 2014, this team used their preliminary data to be awarded a multi-PI RO1 aimed to obtain a series of small molecule compounds as chemical probes that potently bind to Msi1 and modulate its function, and ultimately select 1-2 most drug-like lead compounds for further development as a whole new class of molecular cancer therapy that inhibit cancer with Msi1 overexpression. Their study identified (-)-gossypol as a potential small molecule inhibitor of MSI1-RNA interaction, and suggests that inhibition of MSI1's RNA binding activity may be an effective anti-cancer strategy (Lan, *Mol Oncol.* 2015).

Shahid **Umar**, PhD (CPS) - Epigenetics and Infection-Induced EMT of Colonic Crypts - Target for Chemoprevention → R01CA185322. In 2013, the Cancer Prevention and Survivorship leaders invested program development funds in **Umar** and his studies in epigenetics and bacterial-induced colon cancer. In 2015, **Umar** was awarded an NIH R01 to further develop his hypothesis that Citrobacter rodentium infection-induced epigenetic signaling via EZH2 (Enhancer of Zeste Homolog-2) in stem and/or progenitor cells of genetically susceptible mice will promote epithelial-mesenchymal transition (EMT) of colonic crypts. Additionally, **Umar** aims to determine if Tributyrin, an inhibitor of EZH2, will mitigate epigenetically-linked EMT and/or metastatic process by upregulating WIF1 (Wnt Inhibitory Factor 1). Utilizing an infection-induced model

of hyperplasia and/or carcinogenesis, **Umar** intends to examine how enteric pathogens and dietary interventions modulate the process of epigenetically regulated and stem cell-driven EMT and metastasis, which is expected to help him design novel inhibitors to prevent diseases with infectious etiology.

Minae **Mure**, PhD (CB) - Understanding the Roles of PTM's in Modulating Molecular Functions of Lysyl Oxidase-Like 2 (LOXL2) In Breast Cancer Cells → R01GM113101. **Mure** and her laboratory have discovered that nuclear (unglycosylated) LOXL2 induces epithelial-to-mesenchymal transition (EMT, the first step of metastasis) of breast cancer cells and promotes cell proliferation and invasion much more effectively than secreted (N-glycosylated) LOXL2 does *in vitro*. **Mure** was awarded a KUCC pilot project in 2013 and an R01 in 2014. Her central hypothesis is that unglycosylated LOXL2 localizes to the nucleus, and there induces EMT and invasion by stabilizing Snail1 transcription factor in an amine oxidase activity-dependent fashion. Therefore, her R01 develops strategies to inhibit the activity of LOXL2, which could potentially be developed into a targeted therapy for cancers expressing nuclear LOXL2. **Mure** teamed up with Associate Director for Basic Science, Danny **Welch**, PhD (CB), to demonstrate that expression of LOXL2 in a variety of cell types was associated with initiation of epithelial-to-mesenchymal transition, a process involved in metastasis (Moon, *J Biol Chem*. 2013).

Priyanka **Sharma**, MD (D3ET) - Randomized open label Phase II trial of neoadjuvant Carboplatin plus Docetaxel or Carboplatin plus Paclitaxel followed by Adriamycin plus Cyclophosphamide in stage I-III triple-negative breast cancer. Sporadic and germline *BRCA* mutation associated triple-negative breast cancer (TNBC) share several pathological and molecular similarities. These similarities have led to the exploration of DNA damaging agents in the general population of patients with TNBC and growing evidence suggests that platinum compounds may be active in a significantly larger number of TNBC patients beyond germline *BRCA* mutation carriers. Currently, Anthracylines (A), Cyclophosphamide(C) and taxanes (T) form the backbone of systemic chemotherapy for stage I-III TNBC. Recent studies demonstrate that addition of neoadjuvant Carboplatin (Cb) to A/C/T-based chemotherapy improves pathological complete response (pCR) in patients with stage I-III TNBC (pCR improvement form 41% to 54% with addition of Cb). However, this improvement in pCR rate comes at the cost of increase in toxicity (dose reductions/omissions needed in 40- 50% of patients) and also an increase in the financial cost of chemotherapy. Furthermore, A and C, although very active for treatment of breast cancer, have well known small, but serious long-term risks (secondary leukemia and myelodysplatic syndrome, heart failure, premature menopause). Therefore, development of effective chemotherapy regimens that are devoid of long-term side effects are desirable. Several *in vitro* studies have demonstrated synergy between platinum compounds and taxanes in TNBC cell lines. Efficacy of anthracycline-devoid neoadjuvant platinum/taxane chemotherapy combination in sporadic and *BRCA*-associated TNBC has not been well studied. **Sharma** and her team recently demonstrated in an observational cohort that the pCR achieved with CbD chemotherapy is comparable to the pCR noted with addition of Cb to AC/Paclitaxel (P) chemotherapy (AC, Cb+P) (**Sharma**, *Clin Cancer Res*, 2016). Thus, **Sharma** proposed a randomized neoadjuvant open label phase II study to further estimate and compare pCR rates of CbD and AC, Cb+P in stage I-III TNBC. She received the 2015 Conquer Cancer Foundation of ASCO Advanced Clinical Research Award in Breast Cancer as a result of these efforts. **Sharma** will utilize the already established infrastructure/data/tissue/blood collection from an ongoing multisite IRB-approved prospective TNBC registry called P.R.O.G.E.C.T (PROspective evaluation of GErmline mutations, Cancer outcome and Tissue biomarkers, NCT02302742), which is supported by the Biospecimen share resource.

Developing Shared Resources

In response to KUCC External Advisory Board input, KUCC began to develop and support additional shared resources for cancer control and basic scientists: 1) the Health Communications Research shared resource (HCRSR) and 2) the Transgenic & Gene-Targeting shared resource (TGTSR). Associate Director for Shared Resources, Matthew **Mayo**, PhD (CB), worked with Mugur **Geana**, MD, PhD (CCPH), director of the HCRSR and Jay **Vivian**, PhD (CB), director of the TGTSR, to develop a three-page summary document that outlined services, current usage and budget to justify support and development. **Mayo** then presented the information at an Associate Director's meeting, which unanimously agreed to support further development of these resources. The developing shared resource directors then presented to Leadership Council and to several research program meetings to inform Cancer Center members of their services. Developing shared resources are expected to track usage and generate an annual report, just like an established shared resource. The

scientific directors attend the quarterly meetings with **Mayo**, **Harlan-Williams** and the other scientific directors of established KUCC shared resources.

The Transgenic & Gene-Targeting shared resource (TGTSR) is an important shared resource providing centralized technical services for the production of transgenic and gene-targeted rodents and genetically altered and patient-specific pluripotent stem cells for Cancer Center members. **Vivian** and his staff assist investigators in detailed consultations in the beginning stages of experimental designs and offer an array of services including genome editing (including CRISPR/Cas), mitochondrial/nuclear transfer, and human iPS cell models. In 2015, the TGTSR supported 26 Cancer Center members, spanning all four research programs. Because of consistently strong usage, KUCC has transitioned the TGTSR to an established shared resource requesting CCSG funds.

The Health Communications Research shared resource (HCRSR) is a developing shared resource that provides strategic health communication research, media messages and media application development, as well as support for communication campaign implementation, delivery and evaluation. The HCRSR collaborates with faculty from the KU School of Journalism and Mass Communications, the professional production and development resources available at KU Lawrence, and establishes relationships with dedicated vendors for controlled outsourcing of specialized services. The HCRSR also collaborates with the Communications staff at KUCC and KUMC for specific projects, as needed. The main services include:

- Theoretical and methodological support for the inclusion of communication interventions or outreach strategies as an integral part of grant proposals;
- Development of purposeful evidence-based communication plans for the implementation of audience-specific research projects;
- Design and production of messages and media tools (print, broadcast, web, mobile), used as part of research projects; and
- Management of research-specific communication campaigns, from delivery to impact evaluation.

In 2015, the HCRSR supported eight Cancer Center members, the majority of which were members of the Cancer Control and Population Health research program. It also designed an evidence-based intervention for the Midwest Cancer Alliance focused on accrual to cancer clinical trials. The HCRSR also secured $200,000 in funding from the Hearst Foundation to develop resources to promote applied research and interventions to increase recruitment of underserved populations into cancer clinical trials. A portion of this funding is currently used by the HCRSR to test an educational intervention for oncologists to promote their engagement with patients on clinical trials recruitment.

KUCC will also support the development of a Nutrition Shared Resource (NSR). The proposed NSR developed in response to Cancer Center member feedback and research needs. The NSR will provide essential support and critical expertise for basic, clinical, and population studies evaluating the effects of nutrition on cancer therapies, cancer prevention, and cancer population studies and is available for human studies and in the future, animal studies. The NSR's vision is to enhance the use of nutrition strategies to reduce the burden of cancer in the KUCC catchment area. The NSR will advise investigators on the value added to proposed studies by the inclusion of quantitative measurements of dietary intake, standardized meals, cooking/nutrition classes, nutrition status/malnutrition screening, body composition, and nutrition literacy. Nineteen Cancer Center members are already utilizing the NSR services across all four research programs. Many of the current users are anticipated to expand their projects and increase the usage of the NSR services. The timeline for development of the NSR will be approximately two years. The NSR will be co-led by Debra **Sullivan**, PhD, RD (CPS) and Jill **Hamilton-Reeves**, PhD, RD, CSO (CPS).

Considering the NIH initiative to enhance reproducibility and transparency, KUCC will also support the creation of a developing Cell Authentication and Pathogen Screening Shared Resource (CAPSSR). The primary goal of the CAPSSR is to provide KUCC members (who are conducting *in vitro* cell culture and *in vivo* animal studies) access to specialized, reliable, cost-effective and high-quality services in cell line authentication, *Mycoplasma* detection and mouse pathogen screening that will enhance scientific interaction and greater productivity. In addition, the CAPSSR will offer services to develop Standard Operating Procedures (SOPs) to prevent recurrent/ persistent contaminations. There is a great need for scientists to authenticate their human cell lines for correct origin and check for *Mycoplasma* contamination for both scientific publications and grant

applications. The proposed core will be of immense help to KUCC members in meeting the rapidly evolving requirements of funding agencies and scientific journals regarding these issues. The key beneficiaries of the CAPSSR services initially will be Cancer Center members. In the future, the resource aims to expand its service to all institutional investigators. KUCC conducted a survey among its members to identify potential users of the CAPSSR and out of 39 respondents, 23 indicated they are interested. The use of in-house services can be more convenient, faster and cost-effective than performing it in their lab or outsourcing it to commercial entities. The CAPSSR will be led by Easwari **Kumaraswamy**, PhD (CPS).

Faculty Start-Up
KUCC is committed to recruiting additional cancer researchers to increase the national and international status of the Cancer Center, address important catchment area issues, enhance the number of NCI/cancer-related grants, fill critical research positions and build the four cancer research programs. Each purposeful hire aims to further the scientific vision, mission and goals of the Cancer Center and its research programs. The CCSG Developmental Funds requested will be used to supplement recruitment packages of future recruits primarily through purchase of key equipment items or services.

In 2012 and 2013, KUCC budgeted $45,000 for recruiting. KUCC leadership committed these developmental funds to Joan **Lewis-Wambi**, PhD (CB). **Lewis-Wambi** joined the Department of Cancer Biology at KUMC in 2012 as an Assistant Professor. Her previous support from the NCI (5K01CA120051) and the DOD (BC111364) lead to the identification of novel pathways of endocrine-resistance in breast cancer. She used that knowledge to help develop alternative treatment options for patients with endocrine resistant and metastatic disease. **Lewis-Wambi** has demonstrated that constitutive overexpression of interferon-stimulated genes (ISGs) enhances the progression of aromatase inhibitor (AI)-resistant breast cancer and that suppression of interferon induced transmembrane protein1 (IFITM1) and other ISGs sensitize AI-resistant cells to estrogen-induced cell death. ER-positive breast cancers are dependent on estrogen for survival and growth, and when these cancer cells are deprived of estrogen they tend to die. Long term, however, some breast cancer cells develop strategies to allow them to survive and grow in an estrogen-depleted environment. **Lewis-Wambi** proposes that long term estrogen deprivation of ERα positive breast cancer cells elicits a stress response in the cell resulting in increased expression and activation of IFN regulatory factor (IRF)-7, a known stress response gene. The activated IRF-7 binds the IFNα promoter, resulting in IFNα production and secretion from the cell. IFNα then triggers a JAK/STAT signaling pathway that ultimately results in the sustained/constitutive overexpression of numerous ISGs including IFITM1 and IRF-7. This process initiates further IFNα production triggering autocrine cytokine signaling, reinforcing the production and accumulation of ISGs. The ISGs are pro-survival and facilitate cell survival and proliferation under the stressful (estrogen depleted) conditions. Loss of expression of the ISGs reduces the ability of the resistant cells to survive in an estrogen-depleted environment, causing them to die (Choi, *Breast Cancer Res*. 2015).

Bret **Freudenthal**, PhD, (CB) recently joined the Department of Biochemistry & Molecular Biology at KUMC as an Assistant Professor. **Freudenthal's** major areas of research include: elucidating how DNA damage is generated, processed, and repaired; identifying DNA polymerase strategies during replication and repair; and developing approaches to manipulate the DNA damage response to treat and prevent cancer. His recently published studies reveal how AP endonuclease 1 (APE1) complexes with DNA with and without damage. DNA apurinic-apyrimidinic (AP) sites are prevalent noncoding threats to genomic stability and are processed by APE1. APE1 incises the AP-site phosphodiester backbone, generating a DNA-repair intermediate that is potentially cytotoxic. The molecular events of the incision reaction remain elusive, owing in part to limited structural information. These structures reveal that APE1 molds the T-G mismatch into a unique Watson-Crick-like geometry that distorts the active site, thus reducing incision. These snapshots provide mechanistic clarity for APE1 while affording a rational framework to manipulate biological responses to DNA damage (**Freudenthal**, *Nat Struct Mol Biol.* 2015). **Freudenthal** was recently given the Young Scientist Award by the Environmental Mutagenesis and Genomics Society and will be giving a keynote lecture at their upcoming national meeting in September 2016.

Christy **Hagan**, PhD, (CB) is also a new Assistant Professor in the Department of Biochemistry & Molecular Biology at KUMC. **Hagan's** lab studies the role of hormones in breast cancer. In particular, she is interested in how the ovarian steroid hormone, progesterone, works together with its receptor, the progesterone receptor (PR), to influence breast cancer biology. ER action in breast cancer has been well studied and as a result, ER

has proven to be an excellent target for current endocrine-based therapies. However, despite convincing clinical trial data implicating progesterone in the development of invasive breast cancer, the role of progesterone/PR in breast cancer has been largely understudied. Furthermore, many protein kinases (MAPK, ck2) known to modify and activate PR have been shown to be dysregulated in breast cancer. These same kinases are also known contributors to breast cancer development/progression. Hagan published that the PR interacts with protein kinases, which then alters its phosphorylation and transcription factor function in breast cancer models (**Hagan**, *Nucleic Acids Res*. 2013). **Hagan** was recently awarded Komen (Basic/Translation and Clinical) and DOD (BC151392) grants to expand the understanding of novel pro-inflammatory Progesterone Receptor/STAT5 gene programs in breast cancer.

Subhrajit **Saha**, PhD, (CB) recently joined KUMC in the Department of Radiation Oncology with a secondary appointment in Department of Cancer Biology as an Assistant Professor. **Saha's** (K01DK096032) research aims to develop novel therapeutic strategies to increase the efficacy of radiotherapy by radio-sensitizing the malignant tissue along with ameliorating the radiation toxicity on normal tissue. His major areas of research include: 1) the identification of macrophage derived Wnt in intestinal regeneration following radiation injury; 2) the elucidation of the role that chemokine receptor CCR2 has in the recruitment of circulating monocytes in irradiated intestine and mitigation of radiation injury; and 3) adoptive cell therapy with *ex-vivo* modulated autologous macrophages to induce Wnt secretion for intestinal injury. **Saha** and colleagues use a genetically engineered mouse model to elucidate the role of macrophage derived Wnt to mitigate radiation induced intestinal injury. He has shown how a special type of blood cell (macrophages), homes into the small bowel and stimulates the stem cells in the intestine to proliferate and repair injury (Ó Broin, *Int J Radiat Oncol Biol Phys,* 2015). These studies will help devise new strategies to treat radiation injury of the small bowel, which is one of the main reasons for death after radiation exposure.

Future Recruits

Within the next five years, KUCC will take the lead and work collaboratively with other departments in recruiting additional basic, translational and clinical researchers (**Table 7**).

Table 7. KUCC Future Recruits

Year	Position	Year	Position
2017	Radiation Oncology Chair Gyn/Onc Div Director GU Medical Oncologist Med Onc Div Director/AD Clinical Research Urologist/D3ET Program Leader Clinical Scholar (Phase I) Bioinformatics (GERA) - Clinical Database	**2020**	Bioinformatics (Population-Based Genomics) Molecular Pathologist CCPH program Physician Medical Geneticist Leukemia and Blood Disorders Oncologic Rehabilitation Physician Basic Scientist (Tumor Immunologist) Cancer Genetics/Epigenetics
2018	GI/Pancreas Clinician Hepatologist D3ET Physician Scientist (Phase I) Translational Researcher (Prostate) CCPH Clinical Scholar CPS Clinical Scholar Cancer Epidemiologist D3ET Physician Scientist (Colon)	**2021**	Translational Researcher (Prostate) Basic Scientist (Metabolism) Basic Scientist (Systems Biology) Translational Researcher (Prevention/Survivorship) Research Pathologist Cellular Therapeutics (GMP Leader) Head and Neck Surgical Oncologist
2019	Cancer Metabolism Scientist CB Basic Scientist (Tumor Microenvironment) CB Basic Scientist (Cell Cycle Regulation) CB Basic Scientist (Stem Cells) CB Translational Researcher (Breast) Physician Scientist (Lung) Translational Researcher (GU) Cancer Metabolism Scientist		

Staff Investigators
KUCC has chosen two investigators who play critical roles in catalyzing and fostering scientific and clinical research excellence across the center. James **Calvet**, PhD, (CB) and Joseph **McGuirk**, DO (D3ET) contribute significantly to the development of the Cancer Center's basic science and clinical research activities. In the previous funding period, KUCC did not request funds for Staff Investigators, however in the proposed application, KUCC is requesting support for **Calvet** as a Research Staff Investigator and for **McGuirk** as a Clinical Staff Investigator.

Research Staff Investigator - James **Calvet**, PhD is a Professor in the Department of Biochemistry and Molecular Biology at KUMC with a joint appointment in the Department of Cancer Biology, and he is a member of the Cancer Biology research program. **Calvet** has a long-standing interest in kidney development and signal transduction, acute and chronic kidney disease, genetic kidney disease, cancer genetics and genomics. His early research showed the abnormal expression of proto-oncogenes in polycystic kidneys, which paved the way for further research in his lab that has uncovered many of the cellular and molecular mechanisms of renal cyst formation. The concept that renal cysts are benign neoplastic tumors is now widely accepted. **Calvet's** lab is currently exploring the use of anti-proliferative, anti-tumor drugs to slow cyst growth. He has over 100 publications. **Calvet** has served on a number of NIH advisory committees, including regular membership on the NIH Cellular and Molecular Biology of the Kidney Study Section. **Calvet** has also received the Chancellor's Distinguished Teaching Award for Excellence in Teaching, and the Chancellors Club Research Award from the University of Kansas. In 2011, he was honored with the Lillian Jean Kaplan International Prize for Advancement in the Understanding of Polycystic Kidney Disease, awarded jointly by the International Society of Nephrology and PKD Foundation. **Calvet** has been funded by the NIH since 1980 and is the PI/PD of a newly awarded NIH-P30 PKD Research and Translation Core Center (P30DK106912), which has an emphasis on developing translational research and supports one pilot grant per year specifically on the relationship between cancer and PKD. **Calvet's** research expertise spans the biochemistry of polycystin-1 to signal transduction, to gene regulation, to mouse models of PKD, to drug development and translational research. He recently spearheaded a large epidemiological study to examine the incidence of all cancers in PKD patients and found that there is a significantly lower incidence of cancer in post-transplant PKD patients compared with non-PKD patients. As for his role with the Cancer Center, **Calvet** has been an advisor to the Cancer Biology research program since 2010. He attends KUCC leadership council meetings, program leader meetings and works closely with CB co-leaders, Kristi **Neufeld**, PhD (on the KU-Lawrence campus) and Linheng **Li**, PhD (on the Stowers campus) to represent basic science on the KUMC campus, along with Associate Director for Basic Science & Education, Danny **Welch**, PhD. **Calvet** facilitates inter-programmatic interactions with D3ET as one of his research project's aims to identify Lonidamine derivatives using the high throughput screening laboratory of the Lead Development & Optimization shared resource. **Calvet** also attends the grant rounds meetings and advises junior investigators with their grant ideas. As a research staff investigator, **Calvet** would continue to contribute in all of the ways he already does by being an active participant in the leadership team and a mentor of junior faculty pursuing cancer research.

Clinical Staff Investigator - Joseph **McGuirk**, DO is the Schutte-Speas Professor in Hematology-Oncology, the Division Director of Hematologic Malignancies and Cellular Therapeutics, and a member of the Drug Discovery, Delivery and Experimental Therapeutics research program. **McGuirk** has worked in the field of hematologic malignancies for over 25 years and has performed over 3000 transplant procedures. He actively serves on numerous editorial review boards, has authored/co-authored over 150 peer-reviewed publications, and serves on several committee assignments, including co-chair of the ASBMT Reimbursement Committee (2011-present), as well as acting as the ASBMT liaison for the ASCO Clinical Practice Committee. **McGuirk** has obtained considerable insight and expertise as a PI on a significant number of multi-institutional and collaborative registry clinical trials, including numerous pharmaceutical-sponsored, NCI and NIH-funded investigational clinical trials, including those offered via the Center for International Blood & Marrow Transplant Research Clinical Trials Network (CIBMTR CTN - U10HL069233). **McGuirk** and colleagues have interest in the therapeutic potential of Wharton's Jelly (WJ)-derived mesenchymal stromal cells (MSCs) and published a study suggesting that these MSCs may be a safe and effective cellular therapy for the management of graft-versus-host disease (**McGuirk**, *Pharmaceuticals (Basel).* 2015.). **McGuirk** is a major driver of KUCC's clinical research efforts and has been essential in promoting a culture of clinical investigation across the center.

P30CA168524

Progress Report Publications – Development Funds

Year 2 (Calendar Year 2013)

Fridley BL, Jenkins GD, Grill DE, Kennedy RB, Poland GA, Oberg AL. Soft truncation thresholding for gene set analysis of RNA-seq data: Application to a vaccine study. Scientific reports. 2013;3:2898. Epub 2013/10/10. doi: 10.1038/srep02898. PubMed PMID: 24104466; PubMed Central PMCID: PMC3793215.

Larson NB, **Fridley** BL. PurBayes: estimating tumor cellularity and subclonality in next-generation sequencing data. Bioinformatics. 2013 Aug 1;29(15):1888-9. doi: 10.1093/bioinformatics/btt293. Epub 2013 Jun 6. PubMed PMID: 23749958; PubMed Central PMCID: PMC3712213.

Moon HJ, Finney J, Xu L, Moore D, **Welch** DR, **Mure** M. MCF-7 cells expressing nuclear associated lysyl oxidase-like 2 (LOXL2) exhibit an epithelial-to-mesenchymal transition (EMT) phenotype and are highly invasive in vitro. The Journal of biological chemistry. 2013;288(42):30000-8. doi: 10.1074/jbc.C113.502310. PubMed PMID: 24014025; PubMed Central PMCID: PMC3798469.

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Year 3 (Calendar Year 2014)

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Year 4 (Calendar Year 2015)

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Protection of Human Subjects – DEVELOPMENTAL FUNDS

The Human Subjects Committee (HSC) is designated as the Institutional Review Board (IRB) for the University of Kansas Medical Center, as required by 45 CFR 46 and 21 CFR 56. The HSC is responsible for reviewing, approving, modifying, rejecting and monitoring research involving human subjects. The University of Kansas Cancer Center Support Grant is an umbrella grant to the institution and therefore not reviewed by the IRB. However, any pilot projects involving human subjects research are required to obtain appropriate IRB review and approval prior to the release of funds and implementation of the project. Any human subjects research project at the University of Kansas Medical Center is subject to regulatory requirements for legally effective informed consent and ongoing IRB oversight. Human subjects research is conducted under FWA#00003411 and complies with DHHA and FDA standards.

Inclusion of Women & Minorities – DEVELOPMENTAL FUNDS

The University of Kansas Cancer Center is committed, along with the NIH, to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study. As such, KUCC will adhere to the NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research. Specifically, in the case of any clinical trial in which women or members of minority groups will be included as subjects, KUCC will ensure that the trial is designed and carried out in a manner sufficient to provide for valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

OMB Number:0925-0001 and 0925-0002
Expiration Date: 10/31/2018

***Study Title:** Developmental Funds- Any human subject study funded by CCSG funds will be required to submit a PHS inclusion enrollment report.

***Delayed Onset Study?** ☑ Yes ❑ No

If study is not delayed onset, the following selections are required:

Enrollment Type ❑ Planned ❑ Cumulative (Actual)

Using an Existing Dataset or Resource ❑ Yes ❑ No

Enrollment Location ❑ Domestic ❑ Foreign

Clinical Trial ❑ Yes ❑ No

NIH-Defined Phase III Clinical Trial ❑ Yes ❑ No

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/Alaska Native										
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More than One Race										
Unknown or Not Reported										
Total										

Inclusion of Children – DEVELOPMENTAL FUNDS

In the same manner, The University of Kansas Cancer Center will adhere to the guidelines set forth by the NIH for the Inclusion of Children as Participants in Research Involving Human Subjects. KUCC understands the goal of this policy is to increase the participation of children in research so that adequate data will be developed to support the treatment modalities for disorders and conditions that affect adults and may also affect children.

Vertebrate Animals – DEVELOPMENTAL FUNDS

Per institutional guidelines, any pilot projects involving animal studies that are funded with designated Developmental Funds from the University of Kansas Cancer Center Cancer Center Support Grant (1-P30-CA168524-01) will be required to be reviewed and obtain approval from the Institutional Animal Care and Use Committee (IACUC) within the University of Kansas Medical Center Office of Animal Welfare.

The University of Kansas Medical Center (KUMC) is fully accredited by the Association for the Assessment of Accreditation of Laboratory Animal Care, International (AAALAC), which requires the adherence to the highest standards of animal care and use by accredited institutions. In addition to the AAALAC accreditation, KUMC is registered as a research facility with the United States Department of Agriculture (USDA) in accordance with the Animal Welfare Act and all amendments. Registration requires all animal facilities are inspected by the USDA to ensure that all activities involving research animals are in compliance with all applicable laws and regulations. KUMC also holds a Category I Assurance with the Public Health Service (through the NIH's Office of Laboratory Animal Welfare). These three relationships confirm the integrity of the program structure, function and foundation.

KUMC maintains an animal program that is registered with the USDA, assured through the NIH/PHS, and accredited with AAALAC International.

USDA
Certificate # 48-R-0003; Customer # 1460
Status: Current; No outstanding citations or non-compliances.

NIH/PHS
Assurance Number: A3237-01
Status: Current through June 2018; No outstanding citations or non-compliances.

AAALAC
Accreditation Number: #000785
Accreditation effective date: 11/19/10- present

Developmental Funds – References Cited

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Resource Sharing Plan

The University of Kansas Cancer Center (KUCC) and its scientific community understands its responsibility to comply with the instructions for the Resource Sharing Plans provided within the SF 424 (R&R) Application General Instructions and Supplemental Grant Application Instructions. When resources are developed with NIH funds via this Cancer Center Support Grant P30 mechanism, KUCC will ensure findings are made readily available to the NIH and the scientific community in a timely manner.

Data Sharing Plan

KUCC will adhere to the Final NIH Statement on Sharing Research Data and refer to the National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research. KUCC encourages the free flow of information and ideas while recognizing the timeliness of data sharing, the rights and privacy of human subjects and issues related to proprietary data. KUCC encourages data documentation, using a data-sharing agreement and selecting an appropriate method for sharing; considering the sensitivity of the data, the size of the dataset and the volume of requests anticipated.

Additionally, KUCC encourages any user of a CCSG-supported shared resource to acknowledge the source of data upon which their manuscript is based either in the Acknowledgments section or with authorship on the paper. Furthermore, any research project that received direct cost support from the CCSG is encouraged to cite the P30 CA168524. In both cases, citing the P30 CA168524 grant number and then being compliant with the NIH Public Access Policy is required.

Sharing Model Organisms

In the event that a model organism is developed, KUCC will comply with the NIH Policy on Sharing of Model Organisms for Biomedical Research. KUCC will work with the NIH/NCI to share and disseminate the critical model organism in a timely manner.

Genome Wide Associate Studies

When applicable, KUCC will comply with the NIH Genomic Data Sharing Policy. KUCC supports the sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. All research studies funded through the CCSG involving genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data will be submitted in a timely manner.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 016060860

Legal Name*: University of Kansas Medical Center Research Institute, Inc.
Department:
Division:
Street1*: MSN 1039, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Deborah		Maloney	MSM

Position/Title: Director, Sponsored Programs Administration
Street1*: 3901 Rainbow Boulevard
Street2: Mail Stop 1039
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937
Phone Number*: 913-588-1261 Fax Number: 913-588-3225 Email: spa@kumc.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofit Organization
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Biospecimen Shared Resource

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2017	06/30/2022

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Medical Center
Duns Number:	016060860
Street1*:	MSN 1039, 3901 Rainbow Boulevard
Street2:	
City*:	Kansas City
County:	Wyandotte
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66160-0000
Project/Performance Site Congressional District*:	KS-003

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ❍ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number 00003411

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	BSR_ProjectSummary_Final1019616610.pdf
8. Project Narrative*	
9. Bibliography & References Cited	BSR_ReferencesCited_Final1019799832.pdf
10.Facilities & Other Resources	BSR_Facilities_Final21019799834.pdf
11.Equipment	
12. Other Attachments	BSR_OtherAttachments_Final1019913915.pdf

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Biospecimen Shared Resource – Project Summary

The Biospecimen Shared Resource (BSR), led by Andrew K. **Godwin**, PhD (Director, BSR; Deputy Director, KUCC, and D3ET member) and by Rashna **Madan**, MBBS, FCAP, FASCP (Assistant Director, BSR) plays a vital role in the University of Kansas Cancer Center (KUCC) by its ethical collection, storage, annotation, and distribution of high quality biospecimens, such as fresh/fresh-frozen tumor tissues of varying histology and bodily fluids (blood, saliva, urine, ascites fluids) which are essential to support translational research and investigator-initiated studies. The BSR also provides expert histopathology support and combines the expertise of pathologists, translational researchers, and technical personnel to produce a comprehensive and focused approach to support the research activities at KUCC. The BSR is overseen by an internal advisory board (IAB) and the director and assistant director, **Godwin** and **Madan**, respectively. Colleen Reilly (Project Manager) provides the day-to-day staff supervision and Cassaundra Shipman (Program Development Manager) oversight of participant consenting. The BSR is staffed by four research coordinators who identify participants and administer informed consent, one clinical laboratory supervisor, two lab technicians who handle the processing and banking of biospecimens, one histotechnologist who performs advanced histology services, including histology support for therapeutic clinical trials, and one cancer registrar who performs searches for samples to match user requests and enters clinical information not available electronically into our developing Curated Cancer Clinical Outcomes Database (C^3OD). Additionally tissue biospecimen collection is facilitated by pathology assistants, residents and fellows at the KU Hospital and the Indian Creek Campus as part of the KU Health System's commitment to the Cancer Center's BSR. The BSR is fully equipped for biospecimen collection, processing, and distribution, and thus, the BSR adheres to the OSHA laboratory standards for handling cryogens, ISBER Best Practice for Repositories, and NCI Best Practices for Biospecimen Resources, and has developed Standard Operating Procedures to govern each of these processes. The collection, processing, and distribution of samples by the BSR staff has grown substantially over the past four years (2012-2015) and now includes collections of pediatric sarcomas from ICC and underserved populations from the satellite biospecimen bank at Truman Medical Center, a member of the Midwest Cancer Alliance and the Kansas City safety-net health system. Together, this essential KUCC shared resource, houses over 9,000 tissues and more than 20,000 blood samples (including either single or repeat draws from individuals diagnosed with cancer, benign disease, or no evidence of cancer) from >17,000 participants (enrolled by the end of 2015) and distributed nearly 16,000 specimen aliquots since 2012. In CY15 (the reporting year), the BSR services were used by 74 investigators, 44 who were KUCC members, an increase of nearly 2-fold during the funding period.

Biospecimen Shared Resource - Facilities and Other Resources

Laboratory

In late 2011, the BSR received a dedicated space on the ground floor of Wahl Hall West (WHW) and the Hixon Buildings on the KUMC campus, provided by **Jensen** (Director, KUCC). This renovated space that consists of

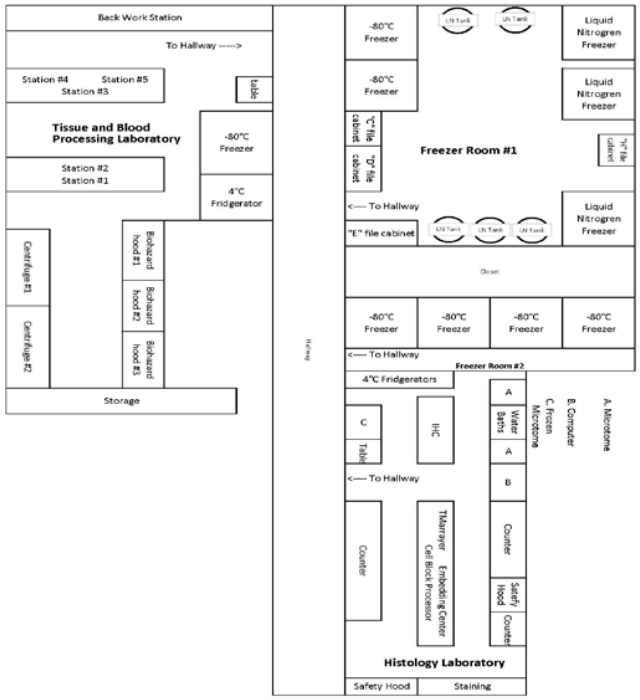


Figure 1. BSR Laboratories and Long-Term Storage

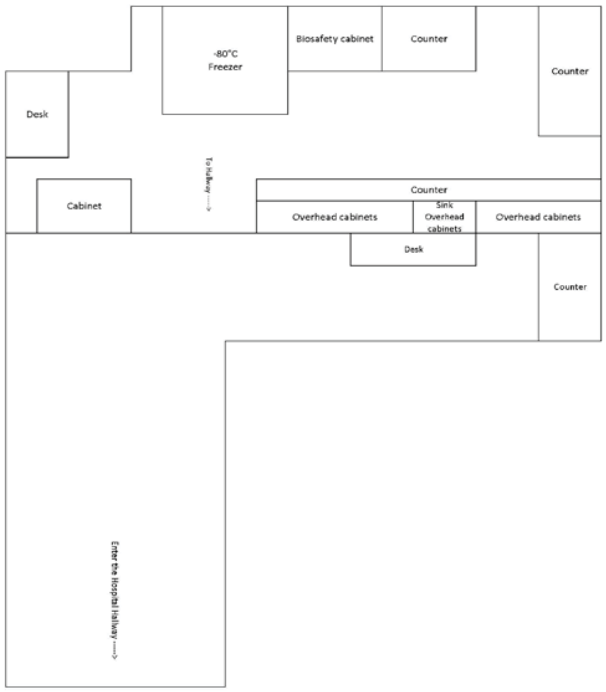


Figure 2. Overflow BSR Laboratory Space.

over 2,200 sf of laboratory and office space was designed to house the administrative, banking, and histology core activities (**Figures 1 & 2**). The laboratory space houses individual laboratories for blood/tissue processing, core histology, and long-term banking. Shared lab space (240 sf) in the KUH is provided for tissue collection. **Godwin** has an office (150 sf) within his research lab provided by KUCC on the 4th floor of WHE. **Madan** has an office (90 sf) provided by the Department of Pathology on the 1st floor of the KUH. Reilly has an office space (~500 sf) provided by the KUCC in G001 WHW, which is shared by the research coordinators, data entry staff, and the tumor registrar. Since 2012, additional space to support patient recruitment efforts on the Westwood Cancer Center campus was provided by Jeff Wright (Vice President, Cancer Services for KUH) and KUH, providing room for the Program Manager who oversees consenting and the Research Coordinators to conduct confidential patient consenting for valuable specimen collection (**Figure 3**). KUH also provided a dedicated space with a private phlebotomy station in the Breast Imaging Clinic to support the BSR's Early Detection Screening Project (**Figure 4**).

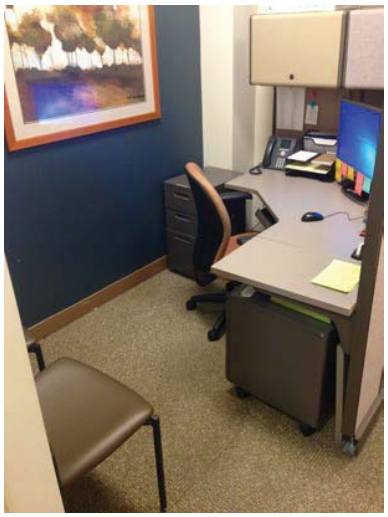


Figure 3. Westwood Cancer Center space for new patient consenting.

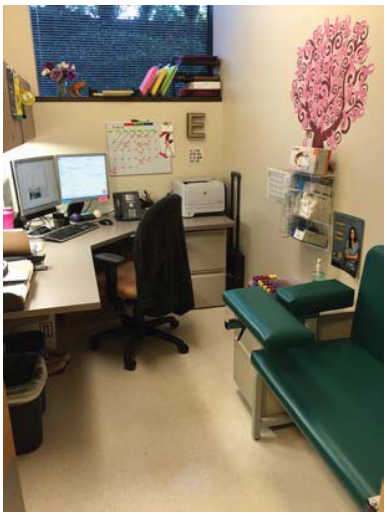


Figure 4. EDSP space for consenting and blood draws.

University of Kansas Hospital – Surgical Pathology:
Leftover tissue from surgical specimens is collected in the surgical pathology grossing rooms located at KUH and the Indian Creek campus utilizing fully equipped and ventilated grossing stations (7 at KUH and 1 at ICC; *e.g.,* **Figure 5**)


Figure 5. Pathology Grossing Station.

KUH Indian Creek Campus – Surgical Pathology:
Space has been reserved to house a 60L liquid nitrogen storage dewar. This dewar has a rack system for cryovials (1,600 capacity, **Figure 6**). It also features a sonar alarm system for low liquid levels. This dewar is used to temporarily store specimens. Once a week, pathology staff uses KUH's courier system to transfer specimens back to KUMC campus using dry ice. This dewar is on a regular refill schedule. There is also cabinet space for other miscellaneous BSR supplies (extra vials, protocol documentation, shipping supplies, etc.).

KUH Indian Creek Campus – Perioperative Services:
Nurses in this area are on the study team and enroll eligible patients for donation. For consenting, each perioperative room is an individual wall enclosed pod for insured confidentiality. Space has also been provided in the perioperative area for biorepository materials such as consents, enrolled patient notifications, and other supporting BSR materials.

KUH Indian Creek Campus – Preanesthesia Services:
Preanesthesia nurses are also on the study team. They consent and draw blood on eligible patients who decide to enroll ahead of their surgery date. In their clinic room, they have reserved space for BSR consenting materials and blood kits for blood donations. This room is individually wall enclosed for insured confidentiality when consenting.


Figure 6. 60L Liquid Nitrogen Dewar.

Equipment (KUMC campus)
The major equipment located within the main laboratory of the BSR includes: 2 -80°C Thermo Scientific Model Forma 900 series upright freezers; 6 -80°C Eppendorf New Brunswick Model U700; and 3 MVE TEC 1500 Series-190 and a Enviro Alert system Model EA 800-IP. The freezers have emergency back-up electrical support. The freezers are available for the purpose of storing tissue and blood samples. Also available is an ArcticTemp refrigerator/freezer, Model AT-33C for storage of reagents and tissue culture media, Beckman GS-6R tabletop centrifuge equipped with a GH 3.8 rotor with adapters, two Sorvall Legend XTR tabletop centrifuge equipped with 75003608 rotors with adapters, Eppendorf microcentrifuges 5424 & 5424R with built-in compressor, BioRad TC20 automated cell counter, Qiagen QIAsymphony DNA isolation Instrument model SP (**Figure 7**), Tecan Infinite 200 plate reader, three LabConco Class II type 2A Biosafety Cabinets, LabConco Water Pro PS station for type I, 18.2 megoh-cm water, 1 Drummond Pipet-aid, 4 Eppendorf pipet, 2 AlphaPette pipettes, 1 genemate pipette, 1 Mettler Toledo ME103 E scale, one Brady BSP31 label attachment system, one Brady LabXpert labeler device (portable), 4 Zebra GX430t labeler devices (PC), 5 computers, 4 locking file cabinet, and 2 phones.
The histology core component of the BSR is equipped to support routine paraffin processing/microtomy, frozen


Figure 7. Automated platform for DNA isolation

section microtomy, and histochemical and immunohistochemical staining (*e.g.,* **Figure 8**). The equipment includes, Sakura VIP2000 automated tissue processor, Sakura Tissue-Tek embedding center, Leica RM 2225 electronic microtome, Microm series cryostat, Biocare Autostainer, Pathology Devices TMArrayer, Hologic Cellient Cell Block Processor, ACIS II Image Analysis, Aperio Scanscope, and an Ariol Image Analysis and Scanning Systems with system application software v4.0 and HALO image analysis software: DM6000 Microscope with Multi-Bay XY stage, Leica SCN400 Slide Scanner.

Figure 8. Ariol Image Analysis and Scanning Systems and Cryostat from Microm.

The additional laboratory space provided by the KU Cancer Center in KUH 1540A (**Figure 2**) is equipped with a LabConco Purifier Class I Biosafety Cabinet, Model 39802xx and a Zebra TLP 2844 labeler device (PC), both purchased by the BSR. Other additional equipment is also available for use and include the following: refrigerated Thermo Scientific Sorvall RT1 centrifuge, ambient tabletop centrifuge, Horizon 642VES, Frigidaire refrigerator/freezer, Model FRT8B5EW6, Revco Ultima II -80°C upright freezer, Model ULT2186-9-A35, one computer, printer, and phone.

Specimens are inventoried by a secure password protected database on a HIPAA certified server maintained by the Department of Biostatistics. The unique identifiers for the patients and specimen locations within the freezers assigned by the laboratory technicians are verified by the data entry team via data management measures.

Computing Resources in BSR

The BSR is equipped with 11 computers which all have Internet 2 access via one gigabyte desktop connections, to access multiple open source software and installed with Microsoft Office Professional 2016 and Adobe Acrobat Professional. The BSR's sample inventory database, OpenSpecimen an informatics platform used internationally by biorepositories, is maintained by the BISR on HIPAA certified servers. As a web based platform, OpenSpecimen is available to research coordinators at satellite sites for accurate record keeping. KUCC investigators and other qualified collaborators may request samples from the BSR via the online request and billing system, iLab. iLab is available from the Request Page website and any investigator may choose to register for iLab at any time. The BSR also employs the secure web application REDCap to house self-reported patient history and function as an online request system for clinical trials histology requests essential for patient enrollment. All systems are connected to networked black-and-white laser printers. The Cancer Center has a dedicated information technology support that provides the first layer of hardware and software support as well as management of the dedicated servers. The Information Resources Department (IR), located in the attached Taylor Building, provides the networking infrastructure and advanced technology support for KUCC Investigators. IR supports the electronic mail system, Internet server systems, virtual private network access, technology training, and information security management.

Office: **Godwin's** office (145 sq. ft.) is located within his research laboratory. Two additional offices (141 sf and 122 sf) are located within his laboratory as well as additional desk areas and file storage. An executive assistant adjacent to his office provides secretarial services to members of his program. Two additional offices (100 sf and 112 sf) are located within the BSR as well as additional desk areas and file storage.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Andrew Middle Name Last Name*: Godwin Suffix: Ph.D.

Position/Title*: Professor/ Director of Molecular Oncology
Organization Name*: University of Kansas Medical Center
Department: Pathology & Laboratory Medicin
Division: School of Medicine
Street1*: MSN 1039, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-7073 Fax Number:

E-Mail*: agodwin@kumc.edu

Credential, e.g., agency login: AKGODWIN

Project Role*: Other (Specify) Other Project Role Category: Core Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Rashna Middle Name Last Name*: Madan Suffix: MD

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Pathology & Lab Medicine
Division: School of Medicine
Street1*: MS 3045, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-1994 Fax Number: 913-588-8780

E-Mail*: rmadan@kumc.edu

Credential, e.g., agency login: RMADAN

Project Role*: Other (Specify) Other Project Role Category: Co-Director

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Madan_Bio_CCSG1019601592.pdf

Attach Current & Pending Support: File Name:

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ○ Yes ● No

*Agency-Defined Phase III Clinical Trial? ○ Yes ○ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator / Change of Institution Section

❑ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	BSR_SpecificAims_Final1019616612.pdf
3. Research Strategy*	BSR_ResearchStrategy_Final1019913937.pdf
4. Progress Report Publication List	Progress_Report_Publications_Blank1019754752.pdf
Human Subjects Section	
5. Protection of Human Subjects	Protection_of_Human_Subjects___BIOSPECIMEN_SHARED_RESOURCE1019973966.p
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	Inclusion_of_Women_Minorities___BIOSPECIMEN_SHARED_RESOURCE1019973967.
8. Inclusion of Children	Inclusion_of_Children___BIOSPECIMEN_SHARED_RESOURCE1019973968.pdf
Other Research Plan Section	
9. Vertebrate Animals	
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	
14. Resource Sharing Plan(s)	Resource_Sharing_Plan__Generic1019799858.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

Biospecimen Shared Resource – Specific Aims

Specific Aim 1. Provide centralized and uniform collections, processing and storage (using standard operating procedures) of tissue and fluids (blood and blood byproducts, urine, saliva, ascites). The Biospecimen Share Resource (BSR) will continue to identify participants, obtain informed consent, collect tissue, blood, urine and/or saliva samples from selected populations, and obtain information on personal and family histories of cancer, clinical intervention, and lifestyle factors for use in research. The BSR banking resources to support translational research have increased nearly 7-fold since the CCSG was awarded and has expanded from 2 to 13 participating sites, which includes leveraging in-kind support from strategically selected Midwest Cancer Alliance (MCA) member locations. The BSR staff will continue to provide: i) outstanding diagnostic pathology support, ii) a comprehensive informed consent process for the use of tissue, blood, urine and/or saliva, from patients and participants for research; and iii) a specialized biospecimen bank devoted to the collection and distribution of specimens to support research.

Specific Aim 2. Biospecimen repository support of investigator-initiated clinical studies. The BSR will continue to facilitate bidirectional flow from the bench to the clinic, and to stimulate translational research associated with clinical trials. The BSR staff closely collaborates with the Clinical Trials Office (CTO) staff for the processing and storage of samples for investigator-initiated trials (IITs), such as blood and tissue samples for future companion diagnostic studies. The BSR also provides histology services, through our shared CLIA certified and CAP accredited histopathology laboratory, which is critical to meet edibility criteria required for patients to be able to participate in clinical trials offered at KUCC, our community sites, and collaborating institutes, including the MCA. The BSR staff recorded a >3.5-fold increase in the number of investigator initiated banking studies requiring informed consent expertise, laboratory space for processing, long-term banking, and/or histology expertise during the past 4 years. These long-term banks including specimens whose distribution is controlled by the PI of the study, such as the Triple Negative Breast Cancer (TNBC) Registry and the *Ductal Carcinoma In Situ* (DCIS) Biopsy Program. Future efforts will focus on further collaboration with CTO laboratory and MCA staff on specimen collection to support the increasing need for sample processing and long-term banking from MCA sites in the Kansas City area and rural Kansas.

Specific Aim 3. Provide tissue related services in cancer research. The BSR will continue to provide expert histology support and pathological evaluations of tissue samples. The number of cancer center members utilizing histology services rose >350% during the previous funding period. The BSR offers routine histology and immunohistochemistry services as well as the optimization of new antibodies, macroarrays for antibody assessment and custom tissue microarray (TMA) construction. The BSR provides staining analysis with the option of performing the latter using the Ariol digital imaging platform.

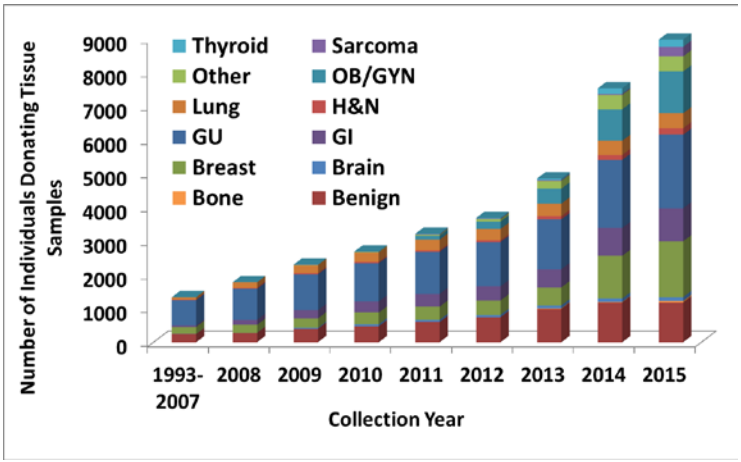
Specific Aim 4. Support the development of a curated database of clinical information. The BSR will continue to obtain supporting data from the clinical record of each participant to better annotate samples and to support patient outcome research requiring curated clinical data. The BSR database efforts are linked with the Curated Cancer Clinical Outcomes Database, C^3OD (see Biostatistics and Informatics Shared Resource section), which contains detailed clinical outcomes and phenotypes from The University of Kansas Health System's electronic medical records, clinic and hospital billing records and the KUH Cancer Registry. To support this effort, the BSR and KUH established a process in June 2015 to obtain informed consent at patient registration across the KU Health System to allow for collection of longitudinal data. This activity allows for BSR staff to access the participant's medical record, even if biospecimens are not collected, and to abstract essential data elements that will support the development of C^3OD. During the first six months of activity, over 2,500 new cancer center patients were consented by 47 Internal Review Board (IRB) trained registrars across all eight locations in the Kansas City metro area.

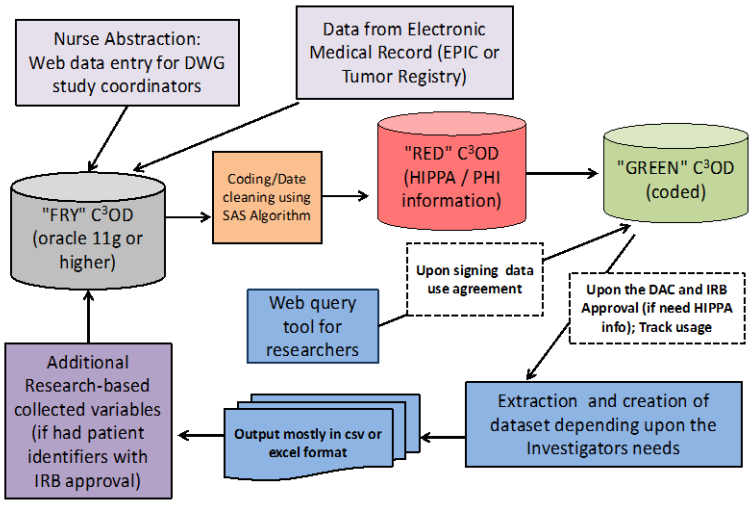
Specific Aim 5. Provide biospecimens to KU Cancer Center members (with IRB approval for individual use projects) to examine relevant properties at the molecular, cellular and tissue level. The BSR has seen substantial increase in our user base (nearly 3-fold) from 2012-2015 (4 years) and the number of NCI-funded investigators and junior faculty who are members of KUCC. The BSR will strive to maintain access to high-quality samples while maintain a subsidized rate for Cancer Center members.

Biospecimen Shared Resource – Research Strategy

Response to Previous Critique

The Biospecimen Shared Resource (BSR) received an overall merit score of "**Outstanding**". However, the BSR and KUCC leadership continues to strive to improve upon this essential shared resource.

Areas for Improvement	Response
"Samples collected from sites other than prostate, breast, kidney, and lung are very small, which may not be able to meet future needs"	Tissue availability is dependent on clinical requirements (remnant tissue left after clinical diagnosis) and the stage of diagnosis. Furthermore, since more oncologists are selecting to use neoadjuvant therapy, tissue for banking can be limited. The amount of tissue banked is, for the most part, out of the control of the BSR staff. Nevertheless, even with these challenges the BSR staff continues to expand its scope of collections and inventory to support researchers' needs. The BSR has developed additional consenting forms to collect extra biopsies to specifically bank hard-to-get tissues requested by KUCC scientists. The BSR has also expanded its collections and participating sites to enhance the resources afforded to KUCC members. During the past funding period, the BSR initiated a sarcoma program, developed a hematological cancer biobank, expanded the diversity of participants by including special populations of children, Hispanics, and underserved populations seen through our partner biobank at Truman Medical Center (TMC) in Kansas City, MO. If necessary, Hispanics are consented with a translated consent form using both a BSR coordinator and a professional translator. These expanded collections have supported new initiatives funded by MCA membership fees. Prior to the award of the CCSG grant in 2012, the BSR staff had banked tissue samples from <3,500 patients (~200 patient's tissues/year). This activity has increased 7-fold to ~1,400 patient tissue samples/year (**Figure 1**) and can grow as needed to support new scientific initiatives proposed by KUCC basic and clinical scientists.  **Figure 1. Cumulative Tissues Banked by Organ Site or Diagnosis**
"How well the [clinical data services] system will work remains to be seen, particular the quality control of clinical data entered into the system, which has potential to impact positively or negatively to the ultimate conclusions using the samples and the clinical information."	Annotation continues to be an area of focus for the BSR with the support of **Fridley** (CCPH) and the Biostatistics and Informatics Shared Resource (BISR). The BSR initially relied on clinical information through the Healthcare Enterprise Repository for Ontological Narration (HERON) at KUMC. HERON, developed by Russ **Waitman** (Director of Medical Informatics), is an i2b2- based data warehouse (http://www.i2b2.org) with a fully de-identified instance (complying with HIPAA Safe Harbor), institutional oversight, system access and data use agreements. At the BSR's request in 2012, HERON incorporated the KU Health System's (KUHS) tumor registry to help annotate the biospecimens banked to support translational research. To expand the availability and utility of the rich clinical information, in 2015 **Godwin**

	and **Fridley**, with the support of KUCC, initiated the Curated Cancer Clinical Outcomes Database (C^3OD). The development of curated research databases using standardized ontology, curation and quality control assessment, for cancer outcomes research is a focus of many cancer centers and the NIH. C^3OD combines data from the KUHS's Electronic Medical Record (EMR) system and Tumor Registry, along with manual data abstraction, for user-requested data elements not readily available within the patient's EMR (**Figure 2**, see BISR section for complete description). An important feature of C^3OD is that it will undergo constant curation and quality control to ensure the highest data quality for research dealing with health disparities, complications/adverse events following treatment, clinical outcomes and precision medicine. The BSR will continually evaluate and add variables to C^3OD for various cancer types and high-risk cancer patients. This cohort will grow, as KUCC physicians see ~ 6,200 new cancer patients yearly. When fully implemented, C^3OD will facilitate cancer-related research, with the downstream translation of findings from "bench to bedside" benefiting patient care.  **Figure 2. Overview of C^3OD (curated cancer data warehouse)**
"*The proposed strategy is to rely on the IRB of KUMC to review the merits of the applications and BSR will use their decision to prioritize the tissue distribution.*"	The Director and Assistant Director make the decisions regarding scientific merit and prioritization of biospecimen distribution. The BSR Internal Advisory Board (IAB), which meets bi-annually, provides recommendations on an *ad hoc* basis when samples are limited. The reviewer inadvertently confused the BSR IAB with the KUMC's IRB (Institutional Review Board).

Overview

Goals

Unprecedented advances in biomolecular technology have greatly increased the power and precision of analytical tools used in cancer research and accelerated the drive towards personalized medicine. Human specimens analyzed with these new technology platforms are a critical resource for basic and translational research in cancer as they provide molecular data to identify targets for therapy, biomarkers for early detection and disease monitoring, and clues regarding the taxonomies of cancer for prevention. The BSR plays a vital role in these goals by its ethical collection, storage, annotation and distribution of high-quality biospecimens, which are essential to support translational research efforts of KUCC members and the cancer community as a whole. The BSR has three major functions: 1) identify participants, administer informed consent, collect tissue and bodily fluids from selected populations, and obtain, via health history questionnaires, information on personal and family histories of cancer, clinical intervention and lifestyle factors for use in research; 2) process and house human biospecimens obtained through investigator-initiated studies; and 3) provide expert histology technical procedures and pathological evaluation of tissue samples. To achieve excellence in biobanking, the

BSR follows the principles developed by the *NCI Best Practices* to effectively develop biospecimen resources.

Qualifications

Leadership

Andrew K. **Godwin**, PhD, Shared Resource Director. **Godwin** is the Chancellor's Distinguished Chair in Biomedical Sciences endowed Professor and the Director of Molecular Oncology at The University of Kansas Medical Center (KUMC). He is a leader in the field of translational research and personalized cancer medicine and is a highly published (>350 manuscripts and scholarly review articles) and cited (>29,300; H-index of 91) scientist. **Godwin** has a long history of successful biobanking to support translational research. In 1992, he initiated a program at Fox Chase Cancer Center (FCCC) in Philadelphia, PA to collect and evaluate high-risk cancer families participating in the Family Risk Assessment Program (FRAP) for underlying genetic alterations that predispose to cancer. The FRAP, established in 1991 by Dr. Mary Daly (FCCC) became a model for subsequent high-risk screening programs and with the efforts of **Godwin** accrued specimens from >7,000 participating cancer-prone families from Pennsylvania, New Jersey and Delaware. In 1999/2000 **Godwin** was appointed founding Director of the CCSG Biosample Repository Core Facility at FCCC and nurtured and helped it grow into a fully-functioning and highly-regarded Biosample Repository supporting investigators throughout the United States [via NIH funded programs, such as The Cancer Genome Atlas (TCGA), the Specialized Programs of Research Excellence (SPORE), and the Early Detection Research Network (EDRN)]. Prior to his departure from FCCC, **Godwin** developed a repository that housed over 14,000 fresh-frozen tissue samples, over 30,000 blood samples, and >100,000 surgical pathology cases and remains a key and highly sought after resource throughout the cancer research community. On recommendations from KUCC's External Advisory Board (EAB), **Godwin** was appointed Director of the BSR in May 2011 and transformed it into an "*outstanding"* shared resource. Since his arrival in late 2010, he has worked closely in the capacity of Associate Director for Translational Research – Correlative Sciences (2010-2013) and Deputy Director (2013-present), with **Jensen** and the KUCC leadership to build and grow this valuable resource. His major responsibilities include: i) working with KUCC, KUMC and KUHS leadership to obtain the necessary resources to enhance the banking activities in order to meet the ever changing needs of translational researchers; ii) managing BSR personnel with the focus on informed consent, tissue/bodily fluid acquisition, and sample annotation; iii) establishing policies regarding standard operating procedures; and iv) presiding over the BSR's Internal Advisory Board (IAB).

Rashna **Madan**, MBBS, FCAP, FASCP, Assistant Director. **Madan** is an Associate Professor in the Department of Pathology and Laboratory Medicine at KUMC. She is an American Board of Pathology certified anatomic/clinical pathologist and cytopathologist. She received her anatomic/clinical pathology training at Montefiore Medical Center, the largest hospital system in the Bronx NY and further honed her diagnostic skills with fellowships in Cytopathology and Oncologic Pathology. The latter was at the world-renowned Memorial Sloan Kettering Cancer Center NY, NY, which has a strong culture of tissue banking and where she also gained considerable expertise in dealing with diverse cancers. She has practiced surgical and cytopathology since 2007 at KUMC where she is constantly engaged with pathology assistants and house staff and is involved at the forefront of tumor collection. Her role in the BSR is as follows: i) increase the collection of quality tumor tissue samples; ii) closely oversee the appropriate utilization and selection of tissue from the archived paraffin embedded tumor samples of the KUMC Surgical Pathology Laboratory; iii) provide quality control for all BSR tissue samples via histologic verification; iv) oversee histology services including the construction of tissue microarrays and immunohistochemistry; and v) provide histologic verification and quality control for the recently acquired Ariol digital imaging system (Leica) with capacity for immunohistochemical, fluorescence and fluorescence *in situ* hybridization analysis.

Colleen Reilly, BA, Project Manager. Reilly is a Project Manager and is responsible for overseeing the daily activities of the BSR and its staff. She has served in this role for four years and has overseen the banking of human biospecimens for a variety of needs of KUCC members, as well as, NCI-funded initiatives, *e.g.,* TCGA, CPTAC, and EDRN. She manages the private health regulations regarding the use of human samples. Reilly ensures adherence to organizational policies related to the protocol information and processes, completes annual progress reports, develops/implements procedures, coordinates tissue requests and invoices procurement charges. Reilly is responsible for training, development and supervision of staff. She facilitates communication between research investigators, CTSU study personnel, KUMC regulatory offices, clinicians, surgeons and pathologists involved in translational clinical research.

Cassaundra Shipman, BGS, MA, Program Development Manager. Shipman is responsible for overseeing all BSR consenting for biospecimens and developing new initiatives to expand patient recruitment and satisfaction. This includes managing and training research coordinator staff and others identified to consent on the protocol, as well as setting up regular meetings with various leadership teams to build and strengthen much needed symbiotic relationships. She received her Bachelor's degree in General Studies Psychology with an emphasis in Chemistry and Health Science in 2012 and her Master's degree in Organizational Leadership in 2015. Shipman is also a certified phlebotomist and nurse's aid. She contributes to many aspects of the BSR including effectively establishing the Early Detection Screening Project (EDSP), High-Risk GI and Prostate Clinic collections, and bone marrow aspirate longitudinal collections at the Westwood Cancer Center campus. She is an important representative of the BSR on the Cancer Center campus by maintaining essential and valued relationships with physicians, technicians, clinic staff and registration staff. Shipman has developed essential knowledge to navigate the various hospital/medical center information systems and databases to manage relevant clinical data.

Major Services & Facilities

Services: The BSR prospectively collects tissue and/or bodily fluids (*e.g.,* ascites, blood, saliva, urine) from cancer patients undergoing surgical biopsies or resections at the KUHS. Collections include: i) fresh and fresh-frozen tissue samples from cancer patients with both common and rare tumors ii) adjacent uninvolved tissue; iii) archival formalin-fixed paraffin-embedded (FFPE) tissue samples; iv) longitudinal blood samples collected before and during therapy; and v) longitudinal blood samples from asymptomatic women undergoing their annual mammograms. The BSR facilitates the informed consent process for prospective banking. The BSR includes various quality control measures, including H&E stains of respresentative sections of each tissue collected for review by **Madan** to ensure the presence of viable (non-necrotic) malignant tissue, and provide the estimates of tumor cellularity and percent necrosis. The BSR tracks and annotates specimens using a relational database to quickly identify appropriate specimens for investigators' requests. To maintain quality control, a research assistant audits data entry, and a log of these inspections is maintained. All data reside on a secure network server and is backed-up daily. The BSR also provides expert technical support for tissue processing, sectioning and immunohistochemistry within a CLIA certified/CAP accredited histopathology laboratory as well as image analysis and digital pathology. The BSR assists the Clinical Trials Office (CTO) and the MCA via procurement of human tissue specimens required for participating in clinical trials, *e.g.,* sterile collection of human tumor for vaccine production, FFPE tissue slides for biomarker analyses or blood samples for future correlative studies. For BSR equipment and space see "Facilities and Resources" section.

Accrual of Longitudinal Data: The BSR launched an effort in June 2015 to expand beyond a physical repository and lead an institution wide effort to collect longitudinal data from new Cancer Center patients to support clinical research and the development of C^{3}OD. With the support from Jeff Wright (Vice President, Cancer Services, KUHS), Hilary Dubinsky (Program Manager, KUHS) and Kyle Stevens (Assistant Director, IRB), 17 hospital registrars at the Westwood campus and 30 hospital registrars at the seven KUCC community oncology sites were trained on proper informed consent by Stevens. The BSR asked all KUCC patients to participate in clinical research during the registration process. During the first six months of activity (*i.e.,* last six months of the reporting year), over 2,500 new Cancer Center patients were consented by 47 IRB-trained registrars (**Figure 3** – purple box) across all eight locations in the Kansas City area (**Figure 4**). Dubinsky maintains training logs, coordinates supplies, and arranges all consent forms sent to the BSR office. Nearly 85% of the patients approached gave their consent.

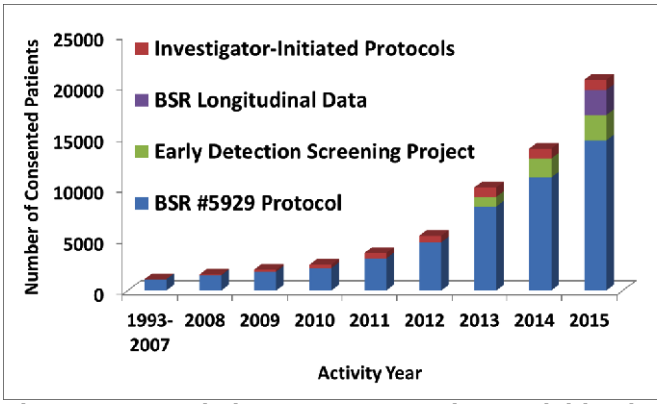


Figure 3. Cumulative BSR Consenting Activities by Protocol and Project. HSC #5929 is the umbrella protocol for BSR biospecimen collections.

Project/Performance Site(s): The BSR has developed into a matrix biobank to expand the diversity and resources available to KUCC investigators. The BSR has efforts at KUHS's main, Westwood, Indian Creek and

community oncology sites, along with Children's Mercy (CM) and Truman Medical Center (TMC) (**Figure 4**). As an MCA Partner's Advisory Board (PAB) member, TMC funded ($218,707) and designed an area specifically dedicated to serve as the oncology research laboratory with primary use as a satellite biobank for the BSR. TMC funds Patrick Todd who provides full-time research biobank support. With **Godwin's** guidance and collaboration, TMC's Pathology and Surgery Departments, and KUMC's IRB, created and executed protocols to standardize patient consent, interdepartmental notifications, tissue processing and delivery of tissue to the BSR. The TMC staff is on the study team for the BSR Biobank Protocols. TMC biobank staff directly enter TMC biobank participant clinical information into the Bio-Analytical Specimen System (BASS; **Figure 2**), KUMC's OpenSpecimen portal. The MCA's Biobank Outreach Coordinator, Hanluen Kuo, trains staff members on proper informed consent and ethical collection of tissue and blood samples and oversees interactions with the TMC's hospital registars. All samples are stored long-term at KUMC's main campus under **Godwin's** direction. For the first year of operation (12/2014 – 11/2015), TMC's biobank collected 170 blood specimens (African American = 74, Caucasian = 54, Hispanic = 8 and Other = 1) and 137 tissue specimens (African American = 87, Caucasian = 74, Hispanic = 7 and Other = 2). Satellite BSR locations, such as the biobank at TMC; enrich the diversity of specimens collected to support research.

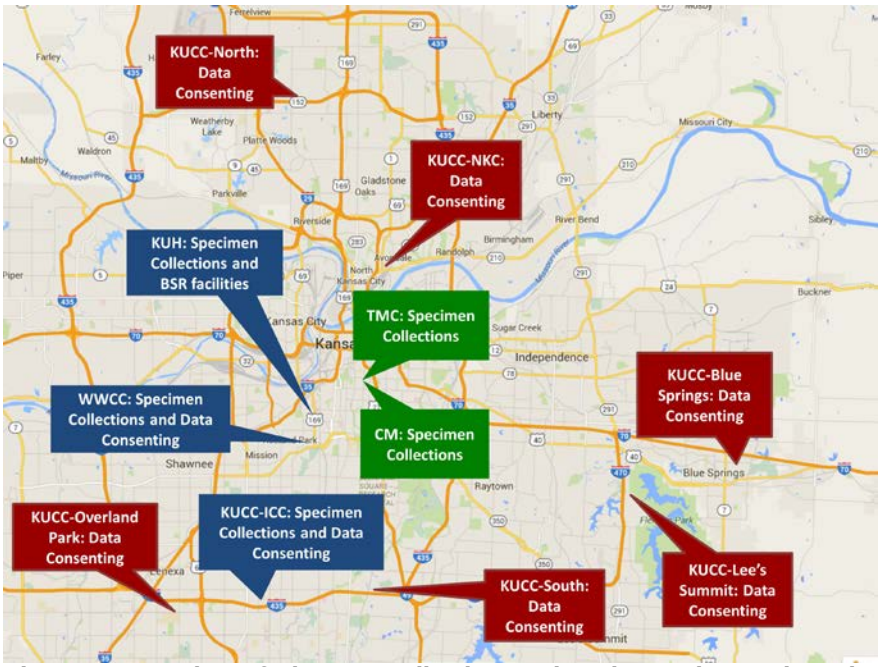


Figure 4. Location of Sites Contributing to the Biospecimen Shared Resource. CM=Children's Mercy; ICC=Indian Creek Campus; KUCC=University of Kansas Cancer Center; KUHS=University of Kansas Health System – main campus; WWCC=Westwood Cancer Center; TMC=Truman Medical Center. Red boxes indicate KUCC community oncology sites participating in clinical research database only. Green boxes represent tissue collection sites that are part of the MCA and are not part of the KU Health System. Blue boxes represent KU Health System sites that are part of KUCC.

The BSR also collaborated with CM to establish a pediatric sarcoma biobank for patients with Ewing Sarcoma, Rhabdomyosarcoma and Osteosarcoma. In 36 months of operation (3/2013-current), CM has collected 219 longitudinal blood specimen samples from pediatric patients (Ethnicity: African American = 1, Asian = 1, Caucasian = 18; Age range: 19 months - 19 years; Disease/Pathology: Ewing Sarcoma = 12, Osteosarcoma = 5, Rhabdomyosarcoma = 3). Kris Laurence, Clinical Trials Coordinator, coordinates the collection of samples at CM under Glenson Samuel's (pediatric medical oncologist, CM) supervision for processing and banking by the BSR staff to support biomarker studies. These banking efforts are supported, in part, by funds through MCA PAB membership and have helped to advance studies for underserved populations.

Effect of the Resource on Stimulating Scientific Interactions: As the BSR's capabilities continue to expand due to institutional support and KUCC's efforts to recruit additional translational scientists; the BSR not only serves as a repository and distribution facility, but also interacts with research scientists by discussing possible translational research opportunities and how the staff can support those initiatives. The following are just a few examples of initiatives directly linked to the activities of the BSR.

Scientific Accomplishments: Provided are selected examples of how the BSR staff has helped to promote investigator-initiated studies and NCI initiatives requiring biospecimens and biobanking expertise.

***Triple Negative Breast Cancer (TNBC) Registry*:** To improve the understanding of the clinical, genetic and biological aspects of triple negative breast cancer, **Sharma** (D3ET) along with support from KUCC's BSR in 2011 initiated a multisite prospective regional clinical and bio-specimen registry called P.R.O.G.E.C.T (PROspective evaluation of GErmline mutations, Cancer outcome and Tissue biomarkers, NCT02302742).

The goals of PROGECT are to prospectively assessment how treatment, demographic and germline mutations effect cancer outcomes and discover and validate tissue biomarkers of response and resistance in TNBC. This registry is focused on patients diagnosed with TNBC or patients who have a confirmed germline mutation (*e.g., BRCA1* or *BRCA2*) that predispose to breast and/or ovarian cancers. Currently the PROGECT registry is open at 13 sites including two MCA-sites in rural Kansas and one MCA-site in Missouri. This registry totals nearly 800 patient participants, with clinical, treatment and outcome information. Also being collected as part of the registry are patient samples (blood and tissue) making it a rich resource for clinical and translational research. Data generated from the registry has led to numerous publications (**Sharma**, *J Cancer Ther Res*, 2014, **Sharma**, *Clin Cancer Res*, 2016, **Sharma**, *Breast Cancer Res Treat*, 2014, **Connor**, *J Surg Oncol*, 2015) and multiple abstract presentations in *JCO* (not listed). Utilizing the data from this large registry, **Sharma** and colleagues were the first to report the prevalence of germline *BRCA* mutations in unselected TNBC and also validate NCCN guidelines for germline testing in TNBC patients (Sharma, *Breast Cancer Res Treat*, 2014). Using the treatment data from the registry **Sharma** and colleagues were also the first to report on the efficacy of anthracycline free chemotherapy in patients with TNBC (Sharma, *Clin Cancer Res*, 2016). Furthermore data and specimens collected as part of this registry have allowed **Sharma** and **Godwin** to be active contributors to large multi-institutional and international studies, which are studying genetic risk factors for triple negative breast cancer and modifiers of the hereditary susceptibility genes (Stevens, *Cancer Res*, 2012, Silvestri, *Breast Cancer Res*, 2016, Rebbeck, *JAMA*, 2015, Purrington, *Carcinogenesis*, 2014, Garcia-Closas, *Nat Genet*, 2013, Couch, *Nat Commun*, 2016, Couch, *J Clin Oncol*, 2015, Kuchenbaecker, *Nat Genet*, 2015). The registry serves as an important resource to aid in designing and accrual of local and national clinical trials for TNBC. Furthermore, when registry patients participate in therapeutic clinical trials, data sharing between the registry and clinical trial is allowing for cost and resource savings. In fact for one of the ongoing randomized clinical studys (PI: **Sharma**, NCT02393794) almost all of the data are being provided by the registry.

Clinical Trials Aided By the Registry:

1. "Phase I/II trial of Nab-Paclitaxel and BYL-719 in women with HER2 negative locally recurrent or metastatic breast cancer" (NCT02379247)
2. "Randomized open label Phase II trial of neoadjuvant Carboplatin plus Docetaxel or Carboplatin plus Paclitaxel followed by Adriamycin plus Cyclophosphamide in stage I-III triple-negative breast cancer." (NCT02413320)
3. "Phase I/II trial Romidepsin plus Cisplatin for locally recurrent metaplastic triple negative or BRCA associated breast cancer" (NCT02393794)

***Ductal Carcinoma In Situ Biopsy (DCIS) Program*:** DCIS progression has been difficult to study due to the paucity of good models. To address this deficiency **Behbod** (CPS) has developed a novel *in vivo* DCIS progression model, referred to as mouse-intraductal (MIND), in which human DCIS cells are injected intraductally and studied over time in immunocompromised mice. With the support of the BSR and through collaborations with clinicians from several hospitals in Wichita and the Kansas City area, **Behbod** has obtained a large number of patient biopsy and surgical specimens (>700) since 2009 (**Figure 5**), including 154 pathologically confirmed DCIS. They have performed intraductal injection of epithelial cells derived from a variety of premalignant breast lesions to develop some of the first human models of DCIS progression. Data generated from this collection has led to several publications (Zou, *BMC Cancer*, 2014, Yeh, *Stat Biopharm Res*, 2012, Stecklein, *Proc Natl Acad Sci U S A*, 2012, Osuala, *BMC Cancer*, 2015, Li, *Breast Cancer Res Treat*, 2012, Elsarraj, *J Mammary Gland Biol Neoplasia*, 2012, Elsarraj, *Breast Cancer Res*, 2015, Elsarraj, *J Cell Sci*, 2013, Chang, *Oncotarget*, 2016, Borrego-Diaz, *J*

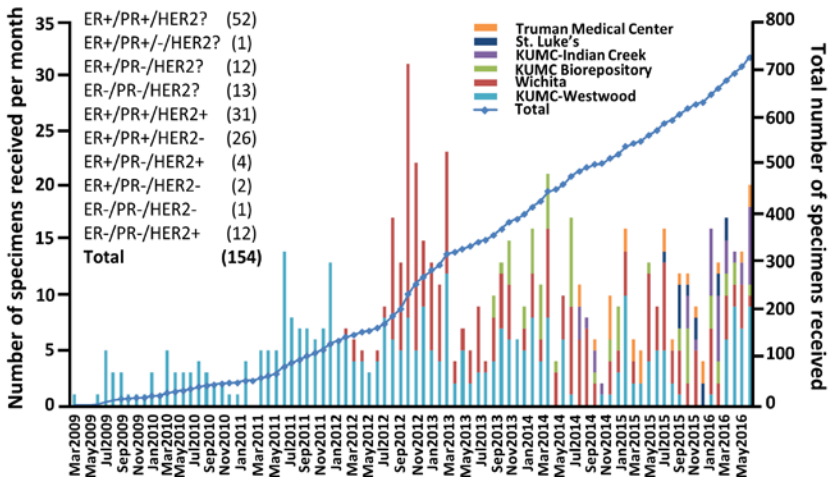


Figure 5. Patient recruitment to the DCIS study. The DCIS registry has collected more than 700 patient samples from our hospitals in Kansas City and Wichita. Each site is color-coded and each color-coded bar represents the number of samples received from each of the six tissue source sites. ?=unknown status

Neurooncol, 2012, **Behbod**, *Methods Mol Biol*, 2015, **Behbod**, *J Mammary Gland Biol Neoplasia*, 2012) and multiple grant applications.

***Applied Genomics and Cancer Therapeutic Program*:** Ovarian cancer is the most lethal gynecologic cancer in the United States due to the fact that majority of patients are diagnosed with disseminated disease and experience relapse following initial response to platinum-based chemotherapy. To address these challenges, **Chien** (CB) has developed an integrated cancer genomic program, in which whole genome, whole exome, transcriptome, and shallow whole genome sequencing were used to characterize somatic alterations in cancer genomes (**Chien**, *Nucleic acids research*, 2015, Graw, *Scientific reports*, 2015, Munchel, *Oncotarget*, 2015). One of the drug targets uncovered from the integrated genomic studies is the FoxM1 transcription factor pathway that is activated in 84% of high-grade serous ovarian cancer. His research program has shown that both loss-of-function and gain-of-function *TP53* mutations contribute to overexpression of FoxM1 in ovarian cancer and that FoxM1-TP53 axis can be targeted by FoxM1 inhibitor Thiostrepton (Zhang, *Oncotarget*, 2014). These studies utilized biospecimens collected from the BSR, and are further supported by KUCC pilot grant programs, the DOD Ovarian Cancer Research Program and the ACS Research Scholar grant.

***Support of NCI Programmatic Initiatives*:** The BSR provided support to the NCI initiatives, *e.g.,* The Cancer Genome Atlas (TCGA) program and the Clinical Proteomic Tumor Analysis Consortium (CPTAC). **Godwin** served as the PI for both awards (subcontract numbers TCGA 13XS194, CPTAC 14X215) and he, **Madan** (pathology working group), **Fridley** and **Koestler** (CCPH) were all part of the cervical disease-working group. **Godwin** is a member of the cervical, kidney, sarcoma disease working groups, as well as, ten PanCanAtlas working groups, and he and others are co-authors on a number of TCGA manuscripts (Chen, *Cell Rep*, 2016, Cancer Genome Atlas Research, *Cell*, 2015, Cancer Genome Atlas Research, *N Engl J Med*, 2016). The BSR also serves as the Benign Breast Disease/Ductal Carcinoma In Situ centralized pathology core for the Early Detection Research Network (EDRN) (U01 CA086402, **Godwin**, D3ET).

Management Structure

The BSR is directed by Andrew K. **Godwin** (Deputy Director, D3ET) and Rashna **Madan** (Assistant Director, D3ET). **Godwin** and **Madan** interact multiple times a week. **Godwin** and **Madan** meet separately with the BSR leadership (**Figure 6**) individually on a monthly basis to ensure that the BSR is running efficiently and to address any new initiatives or potential barriers. **Madan** coordinates tissue collections and oversees the day-to-day activities of the pathology assistants and house staff. She also works closely with the BSR staff to review tissues banked for research. **Madan** counsels researchers to optimize feasible tissue collections. She is actively involved with the advanced histology services provided. Both **Godwin** and **Madan** interview all candidates once vetted by the BSR staff and jointly determine whom to hire. Reilly and Shipman oversee the day-to-day activities of their respective staff members and meet regularly. Reilly and Shipman interact with their staff multiple times a week and coordinate quarterly and monthly formal meetings for BSR staff. Monthly meetings address current operations, process changes and improvements, and staff questions and concerns. Quarterly meetings address major changes, progress, project planning and goals. Reilly and Shipman formally meet with their staff on a one-on-one basis one to two times per month. They conduct formal bi-annual reviews for all BSR staff.

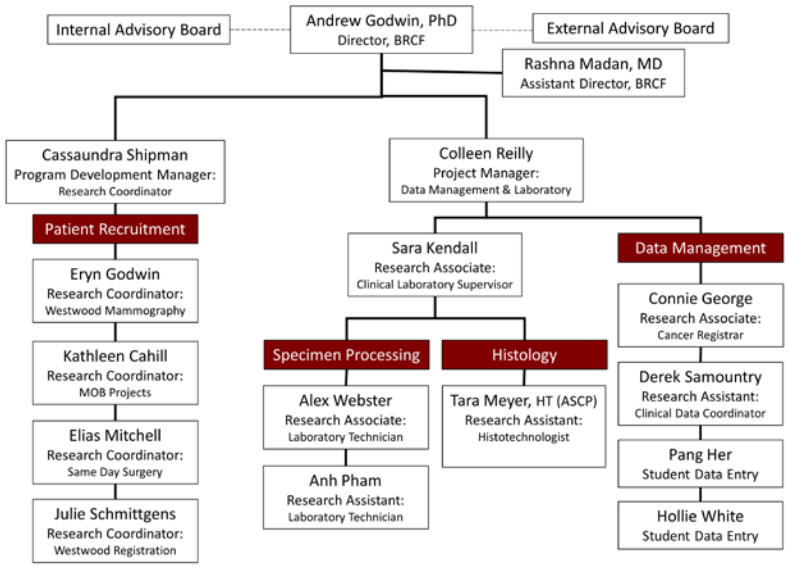


Figure 6. BSR Organizational Chart

Internal Advisory Board (IAB): The BSR was established to provide enhanced translational research opportunities to KUCC members, but is also available to KUMC (non-KUCC) faculty. The IAB membership

(**Table 1**) for the BSR meets semi-annully to discuss any issues relating to procurement and distribution of human tissue. As BSR leaders, **Godwin** and **Madan** report progress and performance of the BSR to **Jensen** (KUCC Director), **Mayo** (Associate Director for Shared Resources), Teresa **Christenson** (Associate Director for Administrative) and the IAB.

External Advisory Board (EAB): The BSR is reviewed annually and advised by members of the KUCC External Advisory Board. Dr. Stephen Byers (Professor, Oncology and Director for Shared Resources, Lombardi Comprehensive Cancer Center) is assigned as the primary reviewer of the BSR and meets with **Madan** and **Godwin** to review progress and assess areas of improvement. The EAB has made meaningful suggestions to help the BSR set both short-term and long-term goals, many of which have already been implemented.

Table 1. Internal Advisory Board Membership

Faculty Member	Position	Cancer Center Program
Jeff Burns, M.D., M.S.	Professor, Neurology and Director, Alzheimer's Disease Center (Neurology)	n/a
Brooke Fridley, Ph.D.	Associate Professor, Director of Biostatistics and Informatics Shared Resource for KUCC; Site-Director for K-INBRE Bioinformatics Core (Statistical Genomics and Bioinformatics)	CCPH
Allen Greiner, M.D., MPH	Professor and Associate Chair of Research, Department of Family Medicine (colon cancer screening and prevention research, community-based research, minority study recruitment)	CCPH
Cheryl Jernigen	Patient/Research Advocate; Lead Advocate, Greater Plains Collaborative; Chair, Breast Cancer Prevention Advisory Board	n/a
Andrea Jewell, M.D.	Assistant Professor, Department of Obstetrics and Gynecology (Gynecological Oncology)	D3ET
Joan Lewis-Wambi, Ph.D.	Assistant Professor, Department of Cancer Biology (Breast Cancer Biology)	CB
Tara Lin, M.D.	Associate Professor, Hematologic Malignancies and Cellular Therapeutics & Director, Acute Leukemia Program (Acute Leukemia & Myelodysplastic Syndrome)	D3ET
Joshua Mammen, M.D., FACS	Associate Professor, Surgery and Molecular & Integrative Physiology and Vice Chair, Surgery (Oncology)	D3ET
Kathy Newell, MD	Associate Professor, Pathology and Laboratory Medicine (Neuropathology)	n/a
Raymond Perez, M.D.	Professor, Internal Medicine and Medical Director, Clinical Research Center and chair of the early phase Disease Working Group (Hematology and Oncology)	D3ET
Prabhu Ramamoorthy, Ph.D.	Research Assistant Professor, Molecular & Integrative Physiology (Cancer Biology and Cancer Prevention).	CP
Meenakshi Singh, M.D	Professor & Chair, Department of Pathology and Laboratory Medicine (expertise in biomarkers of breast and gynecologic cancer, chemoprevention and mammary carcinogenesis models, tissue arrays, digital pathology)	CP

CB = Cancer Biology, CCPH = Cancer Control & Population Health, CPS = Cancer Prevention and Survivorship, D3ET = Drug Discovery, Delivery, & Experimental Therapeutics.

Operations & Policies

Policies, Procedures and Access: The BSR collects, processes, banks and distributes human biospecimens, primarily blood byproducts and tissue samples. Clearly some biosamples (e.g., normal/tumor tissue, whole blood, plasma, serum, lymphocytes) will be finite in quantity; however, new technologies lend to smaller amounts of biospecimens. Interested investigators must first complete an application through the BSR's online request system (iLab Solutions) available on the KUMC website so the BSR staff can assess the order and sample availability. Applications include a summary of the proposed research study. The Director and Assistant Director review applications for scientific merit, potential impact and sample availability. The requestor must provide a human subject committee (HSC) number to verify that the IRB has assessed and approved the request regarding human subjects usage. Non-KUMC investigators are also eligible for BSR resources; they are not required to obtain KUMC HSC approval but must provide proof of approval by their own IRB. There is a member access and priority system (see below) in place to ensure that KUCC members receive first priority. Biospecimens are only distributed to outside investigators when supply exceeds KUCC member demands. Each internal investigator who receives biospecimens must agree to the BSR's "Acknowledgement of Agreement" policy, while external investigators must sign an institutional Materials Transfer Agreement (MTA). When an investigator signs either of these agreements, he/she agrees to acknowledge the contributions of the BSR in all publications resulting from the use of these biospecimens. The BSR staff assembles the material and delivers in person or ships to the requesting investigator. Based on usage during the previous funding period, the BSR anticipates very few situations where resources are inadequate for the requirements of multiple investigators with projects of high scientific merit. Pre-surgical serum/plasma and primary tumor samples have formerly been the most often depleted resource. In such cases, the priority guidelines below are followed:

Member Access & Priority System (% usage by category in reporting year):
Priority 1 - Cancer Center member with NCI grant support or Cancer Center pilot funds (13.5%);
Priority 2 - Cancer Center member with cancer and/or cancer-related grants funded by NIH (non-NCI) and other peer-reviewed cancer grants as defined by NCI (19%);

Priority 3 - Non-peer review funded or unfunded KUCC investigators (*e.g.,* primarily junior investigators) (27%);
Priority 4 - NCI/NIH funded investigators outside of KUCC (27%);
Priority 5 - Other funded investigators outside of KUCC (13.5%); and
Priority 6 - Unfunded investigators outside of KUCC.

Quality Control: The BSR laboratories follow a comprehensive quality assurance and quality control program that governs every facet of the clinical laboratory operation. These procedures are detailed in the BSR Standard Operating Procedures (SOP) Manual. The BSR provides sufficient training, supervision and follow-ups to ensure the established SOPs are followed. The BSR derives paraffin blocks from each frozen sample to ensure that every sample corresponds to the desired type and quantify the relative proportions of different cell types (tumor, stroma, necrotic tissue, etc.). This separate tissue block has the same identifier that designates the frozen sample. **Madan** verifies that each sample contains either the desired neoplastic tissue or matched non-neoplastic tissue. The samples are also labeled using unique barcodes and dried blood spot (Guthrie) cards are created for each sample to provide an additional source to support analysis of a variety of biomarkers and as a means to validate identify. The BSR uses the Coriell Identity Mapping Kit on representive blood spot cards to validate identities as part of the quality assurance plan. This spot check is done randomly (~1 in 200 samples) through the Clinical Molecular Oncology Laboratory (Director, **Godwin**). Genomic DNA samples isolated from buffy coats are quantitated using picogreen and when requested by the user, the integrity of selected nucleic acid samples are assessed using a Bioanalyzer or a 1% agarose gel (10-20 kb on gel) prior to distribution. We always recommend that users, as a quality check perform a regular PCR amplification on the genomic DNA samples with a pair of primers of users' own choice (to ensure that samples are free of PCR inhibitors). The BSR rarely provide RNA specimens due to their instablity. The BSR's quality assurance plan for data management involves traditional second pass entry, one person enters the data and a second person reviews all data entered for that participant before deeming the participant and associate specimen records complete. Auditing is tracked via a data operations database which documents each users activity with the records. Errors are reported and updated accordingly.

Confidentiality: The BSR takes extensive precautions to protect participants' privacy. IRB and HIPAA regulations concerning confidentiality and information availability are strictly enforced. A series of active security procedures are used to preserve privacy. The BSR provides the patient a brochure prior to surgery that describes in lay-terminology the potential risks and benefits of the BSR banking efforts. The brochure explains that, as part of the study, blood and tissue specimens will be banked for future investigational purposes and that the patient acknowledges such use and forfeits any future rights to information or products derived from these specimens. The consent document contains a statement that consent is freely given with an option to decline, that the patient understands the potential risks and benefits of entering the study, and that the patient is free to withdraw from the study at any time. After having a chance to read, ponder, and ask questions about the program, patients who agree to participate are given the opportunity to consent to the respective level/s of participation selected, *i.e.,* tissue, blood, etc. The signed consent form is transferred to the BSR where the type of consent and date are entered into the BSR's database. The original consents are stored in locked filing cabinets. A copy of the consent document is given to the patient to retain which includes contact telephone numbers for further questions or for use if the patient wishes to withdraw consent. Should a patient withdraw from the study, his/her identifying information is removed from the database and files so that the information and specimens previously submitted will be anonymous. Any remaining biospecimen is destroyed.

Charge Back System: The BSR charges a processing fee to offset supplies and technical time. The current fee schedule has been reviewed and approved by the BSR's IAB and **Jensen**, **Mayo** and **Christenson**. The BSR has three reimbursement levels i.e., for KUCC investigators or those with NIH funding, for non-KUCC investigators without NIH funding, and for non-KUCC investigators from commercial companies. Investigators will be supplied with the accompanying relevant de-identified clinical and demographic information collected for each annotated sample. Database searches are available upon request by the BSR staff. The BSR also handles samples for specialized cohorts where a fee is determined based on the specific handling protocols required.

Planning and Oversight: Madan and **Godwin** have direct oversight for all BSR staff members and supported projects. Specifically these include all the repository's efforts on the KUMC's main campus and specimen collection efforts at the Westwood campus. **Godwin** also works with the Midwest Cancer Alliance (MCA) leadership (Gary **Doolittle**, Medical Director and Hope Krebill, Executive Director) to develop biobanking opportunities at sites outside of our main campuses. The MCA coordinates efforts at two satellite sites, KUHS's Indian Creek Campus (initiated in July 2013) and Truman Medical Center (intiated in December 2014) (**Figure 7**).

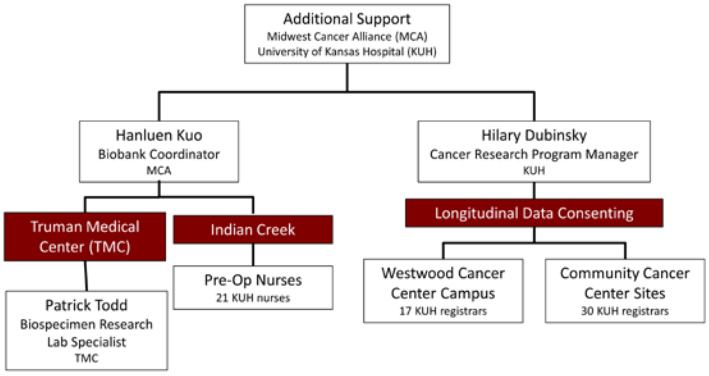


Figure 7. Leadership and Oversight of Partner Biobanks and Multi-institutional Consent for Longitudinal Database

Cancer Center Oversight: Several KUCC shared resources, including the BSR are solely supported by the CCSG and KUCC. The Associate Director for Shared Resources (**Mayo**) meets with the Shared Resource Directors regularly, conducts an annual user survey and reports these results and a summary of each SR following review by KUCC's leadership. Those solely supported by KUCC report directly to the AD for Shared Resources. Each shared resource has an Internal Advisory Board and receives external review from members of the KUCC EAB. The BSR is provided annual external review by Dr. Stephen Byers (Professor, Oncology and Director for Shared Resources, Lombardi Comprehensive Cancer Center), a member of the KUCC EAB.

Godwin also meets monthly with **Christenson** and Anna Nguyen (Finance Project Director) to review the BSR's expenses and chargebacks. Theresa Leinwetter (Director, Human Resources, KUCC) also provides oversight and guidance regarding the training and management of BSR personnel.

Usage:

While the collection, processing and distribution of samples continue to grow, so does the user base. In CY15 (the reporting year), the BSR services were used by 44 KUCC members including 24 who were NCI funded and 74 overall users (**Table 2**). The former is an increase of 1.7-fold in user base and 30% in peer review funded Cancer Center member users since the initial award of the CCSG in 2012 and corresponds to over 15,000 aliquots of samples (serum/plasma, fresh/fresh-frozen tissues, bodily fluids and FFPE samples/sections) distributed during the past four years to support research (**Figure 8**). The BSR also provided letters of support for >60 grant applications. The BSR anticipates the demand to grow further as new investigators with translational research objectives join KUCC. The BSR staff also supported a number of investigator-initiated banking studies requiring informed consent expertise, laboratory space for processing, long-term banking and/or histology expertise. The BSR saw an overall increase of >3.5-fold during the funding period, primarily driven by the need for archival patient samples to gain eligibility onto therapeutic clinical trials (**Figure 9**). Further, the number of investigator-initiated clinical studies supported by the BSR, in which the specimen usage is controlled by the PI, have remained stable.

Table 2. BSR Users During the CCSG Funding Period

Users Supported	2012	2013	2014	2015	Total Users 2012-2015	Number of Unique Users
No. of Cancer Center Users	26	38	46	44	154	71
No. of Non-Cancer Center Users	18	23	18	30	89	31
Total Users Supported by Year	44	61	64	74	243	102

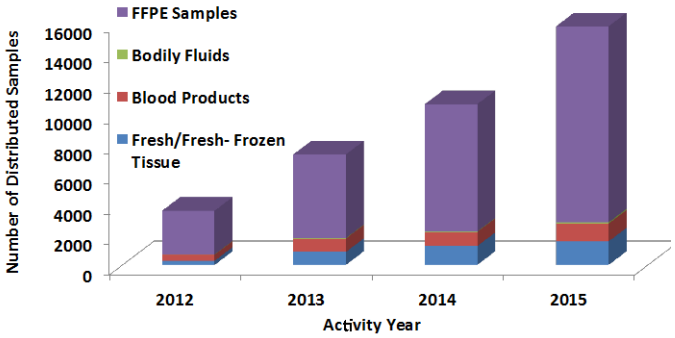


Figure 8. Type and Number of the Total Specimens Distributed to KUCC Investigators

Cost-Effectiveness: The BSR is designed to centralize the collection and banking of large numbers of human samples and large quantities of research and clinical data. Our goal is to provide well-characterized samples as efficiently as possible. Given the level of sophistication of the materials and services required for the range of studies at KUMC, this shared resource is not only cost effective but an absolute necessity. The BSR eliminates redundant infrastructure and expense required for each researcher to develop their own biosample repository and database, and to acquire the necessary pathological expertise to characterize the large volume of tissues required. The BSR enables multiple laboratories to use the same patient samples for their studies, thereby further reducing the relative cost of the studies. There are several commercial endeavors that offer human biosamples; however, the cost to obtain these samples far exceeds those levied by the BSR (*e.g.,* **Table 3**). Furthermore, MCA members have provided in-kind staff-support and banking resources, which help to maintain lower BSR costs.

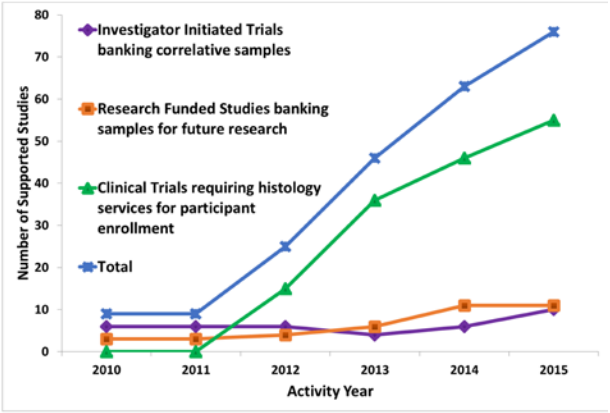


Figure 9. Number of Research and Clinical Trials Supported by Banking or Histology Services through the BSR.

Value Added: The BSR provides KUCC investigators with access to human biospecimens and accompanying information collected from individuals with or without cancer. The BSR enables investigators to use their resources in the analysis and interpretation of the experimental data rather than expending effort assembling samples. The BSR enables rapid testing of new hypotheses with numerous samples already available for study. The ability to centralize not only sample processing but also the consenting process for participants through the BSR has greatly aided our IRB's ability to oversee how patients are approached and consented at KUCC and KUHS.

Table 3. KUCC BRS Chargebacks Compared to Average Rates at Other Cancer Centers and Commercial Vendors

	KUCC			Other Centers			Commercial
	KUCC/NIH Funded	External non-NIH Funded	For-Profit/Industry	INT*	EXT*	All*	Range**
Blood Component							
Whole Blood	$45	$90	$225	$60	$75	$60	$100 to $400
Serum/Plasma (1 ml vial)	$35	$70	$175	$50	$75	$65	$95 to $300
Lymphocytes (~1.5x 10^6)	$35	$70	$175	$125	$238	$100	$100 to $300
Data Mining	$.35/field	$.70/field	$1.75/field	N/A	N/A	N/A	N/A
Tissue							
Fresh/Fresh-Frozen Tissue	$50/45	$100/90	$250/225	$35	$45	$80	$425 to $920
Unstained Slides	$3 first slide/$1.5	$6 first slide/$3	$15 first slide/$5.25	$4	$6	$6	$20 to $75
H&E Slides	$2	$4	$10	$3	$4	$8	$25 to $85
Prospective Histology Block Preparation	$53	$106	N/A	N/A	N/A	N/A	$400 to $920
TMA Custom	$600	$1,200	$3,000	$197	$268	N/A	$4,000 to $13,000
TMA Sections	$45	$90	$225	$100	$190	$107	$145 to $550
Immunohistochemistry	$25	$50	$125	$22	$31	$32	n/a
Pathology Review	$60/hr	$120/hr	$300/hr	N/A	N/A	N/A	$150

*Data obtained from public websites of Fox Chase Cancer Center, Jefferson KCC, UAB, U of Chicago, UVA, UPENN, UC Davis, MUSC tissue bank, UMass and UMGCC. Abbreviations: INT–internal, EXT–external, N/A–not available
**Data obtained from Asterand, BioreclamationIVT, Gundesen Biobank, ProteoGenex, Tissue4Research,

Furthermore, centralizing the recruiting/consenting process at KUCC has dramatically reduced how often patients are asked to participate in research studies. This has greatly improved the relationship with our patients who would frequently state, "I already gave blood for that study" when approached to participate. This cannot be overvalued in terms of patient satisfaction. The BSR also supports KUCC investigators who recruit specialized cohorts, a cost effective means to process and bank samples, eliminating redundant efforts.

Future Plans: The direction of the BSR is ultimately shaped by users and proposed users of the resource. It is difficult to predict what type of sample and/or information will be most valuable to investigators in the future; however, the BSR leadership remains open to suggestions by KUCC members. In response to investigator needs in ovarian cancer, the BSR added tampon and cytobrush collections in 2014 and are supporting a collaborative early screening study between **Chien** (CB) and investigators at the Harvard Medical School and the Broad Institute, Boston, MA. The BSR has expanded beyond solid tumor collections and developed a hematological biobank collecting blood, bone marrow and leukapheresis samples from cancer patients and

healthy donors. When the Sarcoma Center opened at the Indian Creek Campus in 2013, the BSR began working with the clinical staff and onsite pathology to collect pediatric and adult sarcoma blood and tissue specimens to support musculoskeletal oncology research. The BSR is currently evaluating adding a full-time member of the BSR staff to oversee the growing activities at the Indian Creek Campus, including nearly all of the breast cancer surgeries performed within the KU Health System. For the coming year, the BSR will support several new initiatives, including the collection of endometrial biopsies from women with abnormal bleeding and the inclusion of pregnant women with the intent of collecting cord blood samples. Importantly, the Human Subject Committee (HSC) at KUMC is highly supportive of the BSR's activities and guides investigators requiring biospecimens to work with our staff under our universal protocol (HSC #5929) to avoid redundancy.

The BSR has successfully developed protocols to efficiently recruit patients willing to participate in research. This center-wide approach has helped standardize the recruitment process and eliminate competing and redundant studies. The BSR launched a long-term successful program that collects longitudinal blood samples primarily from healthy postmenopausal women undergoing their annual screening mammograms. This observational study, referred to as the Early Detection Screening Project (EDSP), tracks changes in the participants medical history. More than 2,700 women have participated in this longitudinal bank since 2013. Over 850 women have contributed at least two samples, leading to over 3,700 corresponding blood samples. Relevant to screening studies, 64 of the participants have been subsequently diagnosed with cancer (*e.g.,* breast, colon, lung, melanoma) following their initial blood donation, providing a rich source of pre-diagnostic blood samples. Overall, the pre-diagnostic samples range from 3 to 998 days prior to cancer diagnosis.

The BSR is also working to implement mandatory online training for the purposes of awareness and increased quality of biospecimen banking. In collaboration with the Teaching and Learning Technologies department, the BSR created learning modules for all departments affiliated with BSR collections. There is a main course that all will take which highlights the BSR's purpose, activities, and importance to KU's bottom line and NCI designation. More specifically, each affiliated department will also have a course that is tailored specifically to them which allows for targeted education on the process in their area and how to improve quality of collections while increasing rate of compliance. For example, in the OR area we are emphasizing the need for tissue to be placed in sterile saline which will eliminate the loss of potential biospecimen banking to formalin. In a continued effort to raise awareness of the BSR and its successful recruitment of patients we will be working with KU's Strategic Communications Department to enhance marketing material institution wide.

The BSR will continue to improve our ability to link clinical information with a patient's sample and believe that combining clinical information (treatment, outcome, etc.) will greatly enhance the value and clinical utility of our samples. Mentioned above in Specific Aim 4, the BSR is working with **Fridley** (CCPH) and the BISR staff, to develop a de-identified database constructed from curated algorithms and quality medical abstraction accessible from an online dynamic user interface. The BSR supports this effort by collaborating with KUHS registrars to consent new KUCC patients across eight different locations for longitudinal data collection. Since all these patients are enrolled at KU Health Systems facilities, which utilize the same EMR system, EPIC, BSR staff members will be able to access their medical records and as a result of the efforts by the BISR, will be able to import data directly into C^3OD. Regarding sources outside of the Health System, *i.e.,* Truman Medical Center, the BSR staff are provided surgical pathology reports via the MCA's Biobank Coordinator. Additional programming efforts are underway to transfer pathology reports and additional medical history, laboratory, and treatment history into the BSR's database. This includes key entry into the repository's database and possibly electronic data transfer to predefined fields in the future. **Godwin**, as leader of the Personalized Medicine initiative at KUMC, is also working with KUHS leadership to explore implementing computing solutions (*e.g.,* Syapse) to integrate clinical and molecular data. Finally, **Godwin** has been grooming his predecessor. Based on the recommendation of the EAB, **Godwin** who was promoted to KUCC Deputy Director in 2013 will begin transitioning the role of the BSR director to **Madan**. He will work with **Madan** to identify a faculty partner to serve as her Assistant Director.

Progress Report Publications

This component has no publications resulting from Cancer Center Support Grant funds.

Protection of Human Subjects – BIOSPECIMEN SHARED RESOURCE

The purpose of the Institutional Review Board (IRB) is to protect human subjects involved in research. For these studies, The University of Kansas Cancer Center's Biospecimen Shared Resource (BSR) has developed an umbrella protocol (Human Subject Committee #5929) to consent, collect, bank and distribute de-identified specimens to approved researchers. All staff that are part of #5929 are required to complete the training outlined by the KUMC Human Subjects Committee (HSC). The BSR also supports investigator-initiated banking activities under separate IRB approved protocols. Protocols involving human subjects are initially reviewed by the IRB and, if approved, are reviewed on a continuing basis. A progress report and updated consent form are submitted to and reviewed by the Board at least annually and more frequently, if needed. The human subjects protection program at the University of Kansas Medical Center holds full accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Participation is voluntary and involves a rigorous and thorough review of an institute's internal program for protecting patients who enroll in clinical research.

In this application human subjects will be recruited into The University of Kansas Cancer Center's BSR to support translational research. Only de-identified specimens and matching disease-free controls and accompanying clinical information, obtained from the KUCC's BSR will be used. The BSR is HIPAA compliant and any annotated sample will be provided in a manner that protects the patient's identity. The BSR staff and the KUMC HSC are fully aware of the unique aspects of research involving human materials, the need to ensure the rights and welfare of human subjects, their privacy, and the ethical implications of information that pertains to cancer risk. The potential risks and benefits of participating in the BSR are fully explained and discussed to each potential participant through a process of informed consent, and they are given multiple opportunities to ask questions and to withdraw from participation in the BSR. Due to the sensitive nature of family and personal medical information, the BSR takes extensive precautions to protect the privacy of participants. Each patient sample is assigned a unique study code, which is the only source of identification visible on the biospecimens and any accompanying paperwork (*e.g.,* demographic data, family history data, medical history data, epidemiologic risk factors, clinical history data, pathology reports, etc.).

Risks to the Subjects

Human Subject Involvement
The BSR plays a vital role to KUCC and the cancer community as a whole by its ethical collection, storage, annotation, and distribution of high quality biological specimens and associated patient data to allow researchers to study the connection between molecular information and patients' clinical responses. Collection and use of human biological specimens is considered human subjects research when a biospecimen is collected through an interaction with the subject for an identified research project. For this activity, the BSR staff identifies participants, administer informed consent, collect tissue and bodily fluids from selected populations, and obtain, via health history questionnaires, information on personal and family histories of cancer, clinical intervention, and lifestyle factors for use in research.

Adequacy of Protection against Risks

Recruitment and Informed Consent
All participants in the BSR undergo an informed consent process including review of the informed consent document, the potential risks and benefits, and issues of cost and confidentiality. Participants are given the opportunity to discuss the study with their treating physician and family members, ask questions and if needed, arrange for a follow-up appointment to discuss the study further. If a participant signs the informed consent document, a copy of the document will be provided to the participant for his/her personal records. Patients are verbally informed at the time of the consent and presented in writing within the consent form that they can withdraw from the study at any time.

Protection Against Risk
The procedures for obtaining the samples and clinical data are part of the IRB approved protocol (HSC#5929). The tissues provided to support translational research results from excess tumor and adjacent normal tissues from medically indicated surgical specimens and therefore no additional health risk is associated with

participating. Blood is also collected for most participants. Drawing blood may cause pain, bruising, and very rarely infection. The greatest risk to the participant is the possibility of release of information from your health records. The BSR makes every effort to protect the participant's records so that their information will be kept private. The chance that a person who should not know it will learn this type of information is extremely small.

When samples are used for genetic research, some limited information about individuals, such as age or gender, is kept with the sample. Information that would directly identify the participant, such as name or address, will not be stored with the sample. The results of the research, including gene sequences, may be stored in databases accessible on the Internet so that they can support research in the United States and around the world. If some medical information associated with a given samples is included, nothing directly identifying the participant will be shared.

Potential Benefits of the Proposed Research to the Subjects and Others
The purpose of this BSR is to collect, store, and dispense human samples with supporting clinical information and to make them available to research investigators at the University of Kansas Medical Center and at other approved research institutions. Results from studies using a participant's sample will be done solely for the purpose of research, and not for the purpose of influencing their care or to directly improve their health. Therefore, the participant will not receive the results of research done with their samples.

Importance of the Knowledge to be Gained
Researchers hope to better understand the causes and potential cures for disease and human biospecimens are important, if not essential, to support these discoveries.

Collaborating Sites
Samples obtained from outside KUMC will follow the same guidelines as specified above in that all specimens and accompanying information will be de-identified to the investigators at KUMC.

Inclusion of Women & Minorities – BIOSPECIMEN SHARED RESOURCE

In accordance with federal and institutional regulations, any proposed clinical trial would be required to be designed and carried out in a manner sufficient to provide for valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

Cancer affects both men and women. According to the National Cancer Institute, in 2016, an estimated 1,685,210 new cases of cancer will be diagnosed in the United States and 595,690 people will die from the disease. Although some cancers are more prevalent (*e.g.,* breast) or exclusive (*e.g.,* ovarian and uterine corpus) in females, all patients with a diagnosis of cancer irrespective of gender or race will be included in the Biospecimen Shared Resource (BSR).

Families of all racial and ethnic groups who meet eligibility criteria will be included in the study. The BSR collects samples from both the University of Kansas Hospital, which is located in Kansas City, KS, the Indian Creek site, which is located in Overland Park, KS, Children's Mercy in Kansas City, MO and the surrounding metropolitan area, and Truman Hospital, Kansas City, MO, a member of the KU Cancer Center's Midwest Cancer Alliance (MCA). Regarding the latter, **Godwin** and MCA staff helped establish a biobank at Truman Hospital, whose staff treats a high proportion of the underserved patients in our region. Therefore, it is estimated that minority representation of the BSR study population will be ~10% African American and ~5% Hispanic, figures which are consistent with the minority composition of the Kansas City metropolitan and surrounding areas.

PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

OMB Number:0925-0001 and 0925-0002
Expiration Date: 10/31/2018

***Study Title:** Biospecimen Shared Resource - planned

***Delayed Onset Study?** ❑ Yes ☑ No

If study is not delayed onset, the following selections are required:

Enrollment Type ☑ Planned ❑ Cumulative (Actual)

Using an Existing Dataset or Resource ☑ Yes ❑ No

Enrollment Location ☑ Domestic ❑ Foreign

Clinical Trial ❑ Yes ☑ No

NIH-Defined Phase III Clinical Trial ❑ Yes ☑ No

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/Alaska Native	24	14		1	0					**39**
Asian	116	26		0	1					**143**
Native Hawaiian or Other Pacific Islander	7	1		0	0					**8**
Black or African American	1060	301		3	4					**1368**
White	10153	4470		138	31					**14792**
More than One Race	0	0		0	0					**0**
Unknown or Not Reported										
Total	**11360**	**4812**		**142**	**36**					**16350**

PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

OMB Number:0925-0001 and 0925-0002
Expiration Date: 10/31/2018

***Study Title:** Biospecimen Shared Resource - cumulative

***Delayed Onset Study?** ❑ Yes ☑ No

If study is not delayed onset, the following selections are required:

Enrollment Type ❑ Planned ☑ Cumulative (Actual)

Using an Existing Dataset or Resource ☑ Yes ❑ No

Enrollment Location ☑ Domestic ❑ Foreign

Clinical Trial ❑ Yes ☑ No

NIH-Defined Phase III Clinical Trial ❑ Yes ☑ No

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/Alaska Native	24	13	0	0	0	0	3	2	0	**42**
Asian	111	34	0	1	1	0	0	1	0	**148**
Native Hawaiian or Other Pacific Islander	6	1	0	0	0	0	0	0	0	**7**
Black or African American	976	290	0	4	3	0	108	120	1	**1502**
White	8509	3854	8	116	31	0	2363	2192	8	**17081**
More than One Race	0	0	0	0	0	0	0	0	0	**0**
Unknown or Not Reported	231	153	1	150	89	0	108	99	0	**831**
Total	**9857**	**4345**	**9**	**271**	**124**	**0**	**2582**	**2414**	**9**	**19611**

Report 2 of 2

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Inclusion of Children – BIOSPECIMEN SHARED RESOURCE

In accordance with federal and institutional regulations, any proposed clinical trial would be required to be developed to support the treatment modalities for disorders and conditions that affect adults and may also affect children.

Cancer is a disease of all ages. In 2014, an estimated 15,780 children and adolescents ages 0 to 19 were diagnosed with cancer and 1,960 died of the disease. Although, most pediatric cancers are treated at specialty hospitals in the area, including Children's Mercy, the Biospecimen Shared Resource is approved to obtain and distribute biospecimens from children and adolescents.

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Resource Sharing Plan

The University of Kansas Cancer Center (KUCC) and its scientific community understands its responsibility to comply with the instructions for the Resource Sharing Plans provided within the SF 424 (R&R) Application General Instructions and Supplemental Grant Application Instructions. When resources are developed with NIH funds via this Cancer Center Support Grant P30 mechanism, KUCC will ensure findings are made readily available to the NIH and the scientific community in a timely manner.

Data Sharing Plan

KUCC will adhere to the Final NIH Statement on Sharing Research Data and refer to the National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research. KUCC encourages the free flow of information and ideas while recognizing the timeliness of data sharing, the rights and privacy of human subjects and issues related to proprietary data. KUCC encourages data documentation, using a data-sharing agreement and selecting an appropriate method for sharing; considering the sensitivity of the data, the size of the dataset and the volume of requests anticipated.

Additionally, KUCC encourages any user of a CCSG-supported shared resource to acknowledge the source of data upon which their manuscript is based either in the Acknowledgments section or with authorship on the paper. Furthermore, any research project that received direct cost support from the CCSG is encouraged to cite the P30 CA168524. In both cases, citing the P30 CA168524 grant number and then being compliant with the NIH Public Access Policy is required.

Sharing Model Organisms

In the event that a model organism is developed, KUCC will comply with the NIH Policy on Sharing of Model Organisms for Biomedical Research. KUCC will work with the NIH/NCI to share and disseminate the critical model organism in a timely manner.

Genome Wide Associate Studies

When applicable, KUCC will comply with the NIH Genomic Data Sharing Policy. KUCC supports the sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. All research studies funded through the CCSG involving genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data will be submitted in a timely manner.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 016060860

Legal Name*: University of Kansas Medical Center Research Institute, Inc.
Department:
Division:
Street1*: MSN 1039, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Deborah		Maloney	MSM

Position/Title: Director, Sponsored Programs Administration
Street1*: 3901 Rainbow Boulevard
Street2: Mail Stop 1039
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937
Phone Number*: 913-588-1261 Fax Number: 913-588-3225 Email: spa@kumc.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofit Organization
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Biostatistics & Informatics Shared Resource

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2017	06/30/2022

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Medical Center
Duns Number:	016060860
Street1*:	3901 Rainbow Blvd
Street2:	MS 1026
City*:	Kansas City
County:	Wyandotte
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66103-0000
Project/Performance Site Congressional District*:	KS-003

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ❍ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number 00003411

2. Are Vertebrate Animals Used?* ● **Yes** ❍ **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number A3237-01

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	BISR_Project_Summary_Final1019601610.pdf
8. Project Narrative*	
9. Bibliography & References Cited	BISR_ReferencesCited_Final1019469469.pdf
10.Facilities & Other Resources	BISR_Facilities_Final1019857885.pdf
11.Equipment	
12. Other Attachments	BISR_Other_Attachments_Final1019913917.pdf

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Biostatistics & Informatics Shared Resource – Project Summary

The Biostatistics and Informatics Shared Resource (BISR) plays an essential role in the research activities of the University of Kansas Cancer Center (KUCC) by supporting the data science needs of KUCC investigators. The BISR is led by Brooke L. **Fridley**, an accomplished biostatistician with a long-standing commitment to cross-disciplinary collaborations, and includes eight additional faculty members with specialized cancer biostatistics research expertise. The BISR assists KUCC investigators by providing expertise in study design, statistical oversight and analyses, clinical research informatics and data management, electronic data collection, bioinformatics, statistical genomics and investigator initiated clinical trials.

The BISR consists of faculty and staff, whose diverse expertise and skill sets span the areas of biostatistics, bioinformatics and informatics. The considerable overlap between these three areas allow researchers to work with a single shared resource for all their data collection, analytics and statistical analysis needs. The synergy between the areas that encompass “data science” enables the BISR to support a wide-range of quality services, and in a timely and cost-effective manner. To support the research activities of KUCC members, the specific aims of this resource are to: 1) provide study design and statistical support and expertise; 2) provide bioinformatics and statistical genetics support and expertise; 3) provide informatics support for data collection and management; 4) develop and support on-going research enabling technologies, platforms and tools; and 5) educate students, fellows and faculty members of KUCC on data science and reproducible research ideas and methods used in cancer research. During the last cycle of the CCSG grant, BISR services were used by 101 KUCC members for 240 grant submissions (with subsequent awarded grants providing 34% of total support for BISR faculty and staff) and 545 projects involving data science expertise. As an essential shared resource for KUCC, the BSR leverages substantial institutional support and requests only 11% support from the CCSG.

Biostatistics and Informatics Shared Resource – Facilities and Other Resources

The Biostatistics and Informatics Shared Resource (BISR), directed by **Brooke Fridley**, is a shared institutional resource, within the Department of Biostatistics, for statistical and informatics collaboration and related methodological research for The University of Kansas Cancer Center (information at http://www.kumc.edu/school-of-medicine/department-of-biostatistics/shared-resources-and-cores-/biostatistics-and-informatics-shared-resource-university-of-kansas-cancer-center.html and http://www.kucancercenter.org/cancer-research-and-education/shared-resources/biostatistics-informatics).

The facility has available a variety of standard statistical packages such as SAS (version 9), R, Minitab, StatXact, S-PLUS, and STATA; sample size and power computation applications such as nQuery and Pass 2000, as well as custom written applications to meet specific needs and applications for Center projects. The facility also maintains and routinely updates copies of a variety of molecular databases and numerous scientific software licenses for general use, and custom software development is available when existing software does not meet investigator needs. This department of biostatistics occupies 3,028 square feet of contiguous office space at the University of Kansas Medical Center located on the 5th floor of the Robinson building.

The Department of Biostatistics at KUMC has invested over $250,000 toward hardware since 2009 to enhance the informatics and bio statistical computing abilities. All computers in the Department of Biostatistics are connected to a 1 Gigabit per second local area network that provides more than 2500 Gigabytes of network file storage. Networked file servers provide constant hardware backups of stored data through mirrored storage systems and daily tape backups are also performed. Weekly tape backups are stored off site for additional protection of research data. The network is managed by KUMC's Information Resources who provides installation, training, and maintenance on all information systems. The Department of Biostatistics local area network is connected to a switched, 1 Gigabit Ethernet backbone that provides high speed Internet access through the KUMC Internet-2 communication network. Currently KUMC's Internet2 access is via the Kansas Research and Education Network (KanREN). KanREN supports Internet2 connectivity for all of its members via a 10Gbps link to the Great Plains Network (GPN) and KUMC is connected to KanREN via a 1 Gigabit per second connection. This high-speed network provides each workstation with access to the World Wide Web, electronic mail, electronic file transfer, databases. There are also two informatics software engineers housed in the same office suite as the PI (Dr. Fridley), along with Director of Research Information Technology. As in the past, these personnel are available to the PI to answer unanticipated programming/Technical questions.

Computing Resources

Hardware: Shared high speed workstation with dual Xeon 3.40 GHz processor, 8 GB of SDRAM, over 500GB of high speed storage, digital tape backup, and a DVD read/write drive. 34 HP Intel Core I5 CPU @ 3.40 GHz processor, 16 GB of SDRAM, over 800GB of high speed storage; 4 HP Intel Core I7 CPU @ 3.60 GHz processor with 32 GB of SDRAM along with 1 TB hard drive.

Networking/Internet and Servers: HP PowerEdge 4600 file server with a 3.6GHz Xeon CPU, 8GB of DDR SDRAM, six 18GB SCSI Hard Drives in a RAID 5 configuration, 200GB digital tape backup system. Internet Explorer 11; Microsoft Outlook email; Internet 2 access through KUMC's LAN. The Department also has 14 windows 2008 R2 virtual servers - with dual Xeon processors, 8 GB SDRAM and over 240 GB of storage area ; 5 windows 2012 R2 virtual servers - with dual Xeon processors, 16 GB SDRAM and over 320 GB of storage area; 1 SUSE Linux server Quad core processor, 8 GB SDRAM. A HP PowerVault tape backup is also located in the server room along with a cooling system to maintain optimal conditions for optimal server performance. Tape backups are performed daily on modified data and full tape backups are performed weekly and stored off-site for 9 weeks.

Statistical, Mathematical and Database Software: SAS, Minitab, S-PLUS, SPSS, STATA, SOLAS, WinNonlin, Nquery, Mathcad, SigmaPlot, Excel, Access, MySQL, Oracle, PLSQL, MS Visual Studio, SQL server, Postgresql, R, RStudio, Shinyr, MATLAB.

Advanced Computing Facility (ACF) at University of Kansas
The Advanced Computing Facility (ACF) houses High Performance Computer (HPC) hardware dedicated to

life science research (1200 core cluster). This new hardware enables a 20-fold boost in computing power thanks to a $4.6 million grant from the National Institutes of Health. This University of Kansas facility is located at the Information and Telecommunication Technology Center (ITTC) in Nichols Hall in Lawrence, Kansas. The KU Community Cluster Program is a way for the research community to come together to build high performance computing capabilities in an efficient and cost-effective way. Each cluster “share owner” has priority use of their contribution to the cluster, and unused capacity is available for all share owners to use. Data center and system administration costs are included in the purchase price of nodes. The Community Cluster Program is administered through the Advanced Computing Facility (ACF).

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Brooke Middle Name L. Last Name*: Fridley Suffix: Ph.D.

Position/Title*: Associate Professor, Director of BISR
Organization Name*: University of Kansas Medical Center
Department: Biostatistics
Division: School of Medicine
Street1*: 3901 Rainbow Blvd
Street2: MS 1026
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66103-0000

Phone Number*: 913-588-4703 Fax Number: 913-588-0252

E-Mail*: bfridley@kumc.edu

Credential, e.g., agency login: FRIDLEY1

Project Role*: Other (Specify) Other Project Role Category: Core Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Fridley_bio_CCSG1018611615.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Francisco Middle Name J. Last Name*: Diaz Suffix: PhD

Position/Title*: Associate Professor
Organization Name*: University of Kansas Medical Center
Department: Biostatistics
Division: School of Medicine
Street1*: MSN 1026, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66103-0000

Phone Number*: 913-620-1541 Fax Number: 913-588-0252

E-Mail*: fdiaz@kumc.edu

Credential, e.g., agency login: FJDIAZ

Project Role*: Other (Specify) Other Project Role Category: Biostatistician

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Diaz_Bio_CCSG1019857884.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Byron Middle Name J Last Name*: Gajewski Suffix: PhD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Department of Biostatistics
Division: School of Medicine
Street1*: MS 1026, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-1603 Fax Number: 913-588-0252

E-Mail*: Bgajewski@kumc.edu

Credential, e.g., agency login: BGAJEWSKI

Project Role*: Other (Specify) Other Project Role Category: Biostatistician

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Gajewski_Bio_CCSG1019857883.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Jonathan Middle Name David Last Name*: Mahnken Suffix: PhD

Position/Title*: Associate Professor
Organization Name*: University of Kansas Medical Center
Department: Biostatistics
Division: School of Medicine
Street1*: MS 1026, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-2696 Fax Number: 913-588-0252

E-Mail*: jmahnken@kumc.edu

Credential, e.g., agency login: JMAHNKEN

Project Role*: Other (Specify) Other Project Role Category: Biostatistician

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Mahnken_Bio_CCSG1019857881.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Prabhakar Middle Name Last Name*: Chalise Suffix: PhD

Position/Title*: Research Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Department of Biostatistics
Division: School of Medicine
Street1*: MS 1026, 3901 Rainbow Blvd.
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66103-0000

Phone Number*: 913-588-4703 Fax Number: 913-588-0252

E-Mail*: pchalise@kumc.edu

Credential, e.g., agency login: PCHALISE

Project Role*: Other (Specify) Other Project Role Category: Biostatistician

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Chalise_bio_CCSG1018883930.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Devin Middle Name Last Name*: Koestler Suffix: Ph.D.

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Biostatistics
Division: School of Medicine
Street1*: 3901 Rainbow Blvd, MSN 1026
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66103-0000

Phone Number*: 913-588-4788 Fax Number: 913-588-0252

E-Mail*: dkoestler@kumc.edu

Credential, e.g., agency login: DKOESTLER

Project Role*: Other (Specify) Other Project Role Category: Biostatistician

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Koestler_bio_CCSG1019496490.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Jo Middle Name Adrianne Last Name*: Wick Suffix: PhD

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Department of Biostatistics
Division: School of Medicine
Street1*: MS 1026, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-4790 Fax Number: 913-588-0252

E-Mail*: jwick@kumc.edu

Credential, e.g., agency login: JAWICK

Project Role*: Other (Specify) Other Project Role Category: Biostatistician

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Wick_Bio_CCSG1019857882.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Jianghua Middle Name Last Name*: He Suffix: Ph.D.

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Biostatistics
Division: School of Medicine
Street1*: MS 1026, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-2985 Fax Number: 913-588-0252

E-Mail*: jhe@kumc.edu

Credential, e.g., agency login: hejiang

Project Role*: Other (Specify) Other Project Role Category: Biostatistician

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: HE_J_BIOSKETCH1019496492.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Milind Middle Name Last Name*: Phadnis Suffix: PhD

Position/Title*: Research Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Biostatistics
Division: Medicine
Street1*: MS 1026, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66103-0000

Phone Number*: 913-945-7986 Fax Number: 913-588-0252

E-Mail*: mphadnis@kumc.edu

Credential, e.g., agency login: mphadnis

Project Role*: Other (Specify) Other Project Role Category: Biostatistician

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Phadnis_Bio_CCSG1019496509.pdf

Attach Current & Pending Support: File Name:

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ○ Yes ● No

*Agency-Defined Phase III Clinical Trial? ○ Yes ○ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ● Yes ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

● Yes ○ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ❍ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ❍ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ❍ Yes ❍ No

6. Change of Investigator / Change of Institution Section

❑ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	BISR_Specific_Aims_Final1019601612.pdf
3. Research Strategy*	BISR_Research_Strategy_Final1019913936.pdf
4. Progress Report Publication List	Progress_Report_Publications_Blank1019754751.pdf
Human Subjects Section	
5. Protection of Human Subjects	Protection_of_Human_Subjects___BISR1019799865.pdf
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	Inclusion_of_Women_Minorities___BISR1019799866.pdf
8. Inclusion of Children	Inclusion_of_Children___BISR1019799867.pdf
Other Research Plan Section	
9. Vertebrate Animals	Vertebrate_Animals___BISR1019799863.pdf
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	
14. Resource Sharing Plan(s)	Resource_Sharing_Plan___BISR1019799864.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Biostatistics & Informatics Shared Resource – Specific Aims

The goal of the Biostatistics and Informatics Shared Resource (BISR) is to provide a comprehensive, multidisciplinary and collaborative approach to support the data science needs of KUCC investigators, with a focus on reproducible research. The BISR provides expertise in study design, statistical oversight and analyses, clinical research informatics and data management, electronic data collection, bioinformatics, statistical genomics and investigator initiated clinical trials. The BISR, directed by Brooke **Fridley**, consists of faculty and staff with a diverse skill set and expertise for the provision of data science support in the areas of biostatistics, bioinformatics and informatics. The considerable overlap between these three areas allow researchers to work with one shared resource for all their data collection, analytics and statistical analysis needs. The synergy between the areas that encompass data science enables the BISR to support a wide-range of quality services to researchers in a timely and cost-effective manner. To support the mission and goals of the BISR and KUCC, we proposed the following specific aims.

Aim 1: Provide Statistical Expertise in Study Design & Analysis for Cancer Center Projects

BISR faculty collaborate with KUCC investigators to design their basic, translational and clinical research projects, which encompasses a broad spectrum of pre-clinical, animal and human research studies. In addition, they oversee data cleaning and statistical analyses using statistical software ensuring appropriateness of statistical methodology, accuracy of computations and correct interpretation of results.

Aim 2: Provide Bioinformatics and Statistical Genetics Expertise in Study Design & Analysis for Cancer Genomic Projects

The bioinformatics faculty and staff serving in the BISR provide support to cancer researchers with study design, data management, bioinformatics pre-processing, statistical analysis, and visualization of large-scale molecular datasets produced by high-throughput technologies. The BISR has partnered with the KUMC Kansas-INBRE Bioinformatics Core to provide researchers with access to Ingenuity Pathway Analysis (IPA) software to enable systems biology type of analyses to be completed, along with high performance computing (HPC) and storage of bioinformatics projects BISR supports.

Aim 3: Provide Informatics Support for Data Collection & Management for Cancer Center Projects

The informatics faculty and staff serving on the BISR provide expertise in database creation & maintenance, data management, EMR data analyses, regulatory data reporting, support and training for the Comprehensive Research Information System (CRIS) and integration of third party software.

Aim 4: Develop and Support On-Going Research Enabling Technologies, Platforms, Databases and Tools to Facilitate the Timely and Accurate Completion of Cancer Center Projects

- The development of BASS (Bio-Analytical Specimen System) - BASS is the database created and maintained by BISR for the tracking of samples collected and stored in the Biospecimen Repository Core Facility (BSR), directed by **Godwin**.
- The development of the Curated Cancer Clinical Outcomes Database (C^3OD) – C^3OD pulls electronic data from the EMR and combines it with manually abstracted data. The end result will be a research repository to facilitate clinical and translational cancer research activities.
- The development and use of standardized electronic case report forms (eCRFs) - This has been done by the development of the eCRF Content Toolkit that provides standardized data field content selection options to researchers starting new studies.

Aim 5: Educate Students, Fellows and Faculty Members of KUCC on Study Design, Data Collection and Computational Analysis Aspects of Cancer Research for Reproducible Research

Faculty and staff within the BISR provide educational workshops and seminars for KUCC members that cover a broad range of statistical and bioinformatics topics. The BISR supports a number of graduate research assistants (GRAs) to help support cancer-related research projects. Involvement in these smaller research projects allow biostatistics graduate students to be exposed to cancer-related ideas, research and training in areas that are not traditionally covered in their course work.

Biostatistics and Informatics Shared Resource – Research Strategy

Response to Previous Critique

The BISR has taken steps to solidify areas found to be a weakness in the last review of the CCSG. Below are the issues identified and the BISR response.

Table 1: Cumulative Computing Resources Used

Year	2013	2014	2015
Jobs Submitted	52,339	78,898	87,082
Cores Used	52,684	82,329	99,262
Storage (non-HIPAA data)	63TB & 5% used	65.53TB & 19% used	65.53TB & 25% used

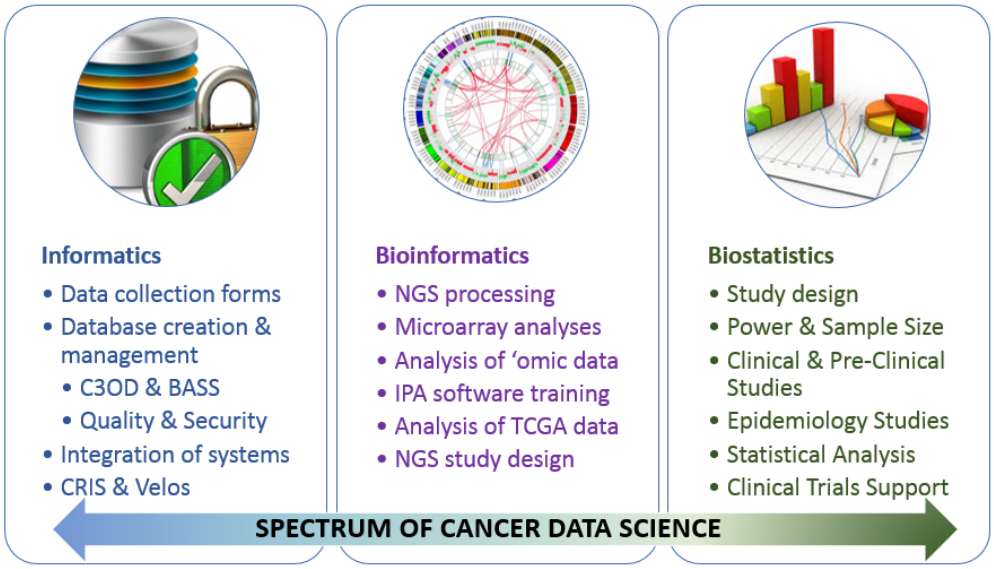
Areas for Improvement	Response
Modest data storage and computational resources	In an intra-institutional collaboration between the BISR and The University of Kansas Medical Center (KUMC) K-INBRE bioinformatics core, we have increased the computational resources tremendously over the last four years. We have purchased 13 Intel cluster nodes (two large memory and 11 standard memory) at the Advance Computing Facility (ACF) at KU-Lawrence along with over 60TBs of storage. **Table 1** shows the usage of the ACF. In addition to use of the ACF for computing, we have a contract with Globus Genomics (Galaxy-cloud based computing) and have started our production instance for the bioinformatics processing of NGS data. We have used Globus Genomics to process approximately 260 FASTQ files from RNA-seq studies. We have also successfully used Globus Genomics instance in teaching graduate level statistical genomics courses at KUMC.
Expertise in Next-Generation Sequencing (NGS)	In September 2012, **Fridley** was recruited as the Director of the BISR. In addition to this role, **Fridley** has brought her expertise in the area of statistical genomics and bioinformatics and has been leading the initiative to expand the bioinformatics and statistical genomics capabilities and resources. Devin **Koestler** was recruited in September 2013 to KUMC to further expand the BISR's expertise in bioinformatics, epigenomics, signature development, clustering and microbiome analyses. BISR faculty members (**Fridley, Koestler, Chalise**) participated in the TCGA Cervical Analysis Working Group by providing the analysis of the DNA methylation data and integrative clustering analysis. We have collaborated with the Markey Cancer Center Biostatistics and Bioinformatics Shared Resource (Weiss, Director) and have exchanged NGS pipelines.
Weakness of the clinical trial designs and analysis plans in reviewed protocols	In 2013, the Department of Biostatistics entered into a collaboration with Berry Consultants LLC, in which Dr. Scott Berry joined the faculty as an adjunct professor. This has allowed our graduate students and faculty to use their proprietary software, **FACTS or Fixed and Adaptive Clinical Trial Simulator, for the development of Bayesian adaptive clinical trials,** pioneered by Dr. Don Berry. We have begun implementing adaptive designs in many clinical trials including the following led by **Gajewski.** • Adaptive Intervention to Maximize Colorectal Screening in Safety Net Populations (PI: **Greiner**) (R01 CA188898). This study will determine which *adaptive intervention sequence pathway* is most effective in producing the highest colorectal cancer screening rates among uninsured and underinsured safety-net clinic patients 50-75 years of age. • 1cm v 2cm Margins for Intermediate Thickness Melanomas (PI: **Mammen**). This is a two-armed randomized clinical trial that will be used in a planned DOD submission. Primary endpoint is 104 weeks incidence of recurrence. A Bayesian adaptive design will be used to allow the trial the opportunity to stop early for success or futility.
Unmet needs in the CB and D3ET Programs	With the addition of bioinformatics and statistical genomics expertise (**Fridley, Koestler, Chalise**), the BISR has been able to better serve the CB and D3ET program members, which often involves the generation of high-throughput molecular data. From the initial submission of the CCSG grant in 2011 to 2015, the BISR has seen a 2.1 and 1.5 fold increase in usage for the CB and D3ET programs.

Overview

The goal of the BISR is to **provide comprehensive, multidisciplinary expertise to support the data science needs of KUCC investigators**, with a focus on reproducible research (**Figure 1**). The BISR consists of faculty and staff with a diverse skill set and expertise in providing data science support in the areas of biostatistics, bioinformatics and informatics. The considerable overlap between these three areas allows researchers to utilize one shared resource for all their data collection, analytics and statistical analysis needs. In addition to providing analytic support for cancer-related projects, the BISR is also **developing research enabling tools, technologies and resources for conducting reproducible research**, such as, providing access to software and platforms (e.g., Velos, IPA), creation and maintenance of data repositories (e.g., BASS, C^3OD), and development of new algorithms/processes (e.g., standardized eCRFs, bioinformatics pipelines).

Qualifications

Figure 1. Overview of Support Provided by the BISR



Director: Brooke L. Fridley, PhD. In September of 2012, **Fridley** was recruited from the Mayo Clinic to be Director of BISR and is responsible for oversight for all BISR activities. **Fridley** meets with faculty and staff involved in clinical trials bi-weekly; bi-weekly with the informatics support staff; and quarterly with BISR faculty to discuss operations. **Fridley** is an Associate Professor within the Department of Biostatistics and was just awarded tenure from KUMC. In addition to her role within KUCC, **Fridley** is Site Director for the K-INBRE Bioinformatics Core (P20 GM103418, DE Wright). **Fridley's** primary methodological research interests include: statistical genomics, bioinformatics and Bayesian methods and has been awarded three R21 NIH grants. **Fridley** has been a mentor and/or statistical advisor for four K-awardees and has mentored seven post-doctoral students in the area of statistical genomics/bioinformatics. In addition to her statistical research, she has had extensive experience collaborating on multiple, large-scale NIH funded cancer genomic and pharmacogenomic studies. She has been co-investigator on numerous NIH funded research projects, is a standing member of the Cancer Prevention & Research Institute of Texas (CPRIT) cancer prevention research study section, and has over 180 peer-reviewed publications. **Fridley** is an active member of many cancer, statistical and genetics organizations, including the American Association of Cancer Researchers and the International Genetic Epidemiology Society (IGES), for which she is Chair of the 2012 scientific program committee. **Fridley** is also on various editorial boards, including *Journal of the National Cancer Institute.* Lastly, **Fridley** has been instrumental in developing a standardized process for IITs (to keep cost down and decrease the time to get study started) to meet the needs of researchers in D3ET and to enhance the bioinformatics capabilities to meet the needs of genomics-based cancer research conducted by CB & CPS members.

Table 2: BISR Faculty

Name	Title	Expertise
Chalise, PhD	Research Asst. Professor	Statistical Genomics, Integrative Clustering Analysis
Diaz, PhD	Associate Professor	Clinical trials, mixed models, analysis of cell based assays
Fridley, PhD	Associate Professor	Statistical Genomics, Bayesian Methods
Gajewski, PhD	Professor	Bayesian Adaptive Designs; Psychometrics
He, PhD	Associate Professor	Survival Analysis, Meta-Analysis, Longitudinal data analysis
Koestler, PhD	Assistant Professor	Statistical Genomics, Model-based Clustering Analysis
Mahnken, PhD	Associate Professor	Censored data, health claims data analysis
Phadnis, PhD	Assistant Professor	Survival Analysis, Health Claims data, Phase I/II clinical trials
Wick, PhD	Assistant Professor	Clinical trials, Bayesian methods, risk-benefit analysis

BISR Faculty: The faculty listed in **Table 2** bring expertise in experimental and clinical trial design, such as Bayesian modeling, longitudinal data analysis, mixed linear and non-linear models, latent variable methods, psychometrics, time-series, pharmacokinetics and pharmacogenomics, survival analysis, registry and large database analysis, data mining, missing data methodology, epidemiological/observational data analysis, and -omics data analysis. They all currently support the development of KUCC research. Support for BISR faculty to collaborate with investigators on the development of research grants and projects is critical for the continued research success at KUCC. **Diaz** and **He** are currently members of the KUCC Protocol Review and Monitoring Committee (PRMC). Additionally, the BISR faculty members have not only supported KUCC research projects, but have also been active in statistical methodology research, thus staying up to date with the current state-of-

the-art methods. In completing these research projects, many faculty members also involve PhD students in biostatistics in study design and statistical analysis to strengthen students collaborative research experiences (see section on "**Scientific Accomplishments"** for additional details).

Other Faculty (Table 3): Habiger, though not supported by KUCC or the CCSG, is available to support researchers, if needed, in the areas of likelihood-based methods and imaging studies. Habiger also sits on the KUCC Data Safety Monitoring Committee to ensure the statistical review is by someone independent of the study. Bioinformatics specialists Knapp and Gunewardena (adjunct appointment in the Department of Biostatistics) are also available to assist members in the bioinformatics processing of NGS data.

Table 3: Other Faculty

Name	Title
Habiger, PhD	Associate Prof, Dept. Biostatistics
Knapp, PhD	Bioinformatics Specialist, Dept. Molecular & Integrative Physiology
Gunewardena, PhD	Research Asst. Prof, Dept. Molecular & Integrative Physiology

BISR Staff: The BISR support staff are presented in **Table 4**. No CCSG support is requested for the staff, with the exception of Dinesh Mudaranthakam, Director of Research Information Technology within the Department of Biostatistics. Additional information on the Director of Research Information Technology is provided below, as Mudaranthakam fills a critical role within the BISR.

Director, Research Information Technology: Dinesh Mudaranthakam, MS. Mudaranthakam has previously worked for Cerner (pharmacy team); his duties included: developing pharmacy solutions for patient drug dosage, physician electronic drug prescriptions and database development. He gained immense knowledge regarding patient health records and the different data structures related to patient demographics, patient diagnosis, labs and patient's treatments. Mudaranthakam joined KUMC in Oct 2012 and has since been involved with database development for KUCC research, including creation of eCRFs and Oracle databases. He also has focused on research data security issues by working with the KUMC Information Resources staff. In particular, he oversees the integration of data transfers between the EMR and Comprehensive Research Information System (CRIS), powered by Velos eResearch, along with supervising the clinical informatics specialists.

Table 4: BISR Staff

Staff	Role	KUCC Support*
Research Fellows	Hold a PhD in biostatistics or a related field working under the direction of BISR faculty on cancer projects	1.5 FTE
Senior Research Analysts	Hold a master's degree or higher in biostatistics or a related field. Support data management, analyses and presentation of results.	2.0 FTE
Clinical Information Specialists	Support the Comprehensive Research Information System (CRIS), design data collection forms (eCRFs) & databases and provide CRIS training.	0.5 FTE
Bioinformatics Specialists	Supports the development/maintenance of bioinformatics pipelines, tools and applications, along with statistical analysis of the 'omic data.	0.5 FTE
Computer Application Admin	Provides technical support for the Comprehensive Research Information System (CRIS), databases BASS & C^3OD and other systems utilized	1.2 FTE
Project Management	Facilitates project meetings, develops project budget, invoices for services completed and maintains the grant & project tracking system.	1.0 FTE
*no CCSG support requested		

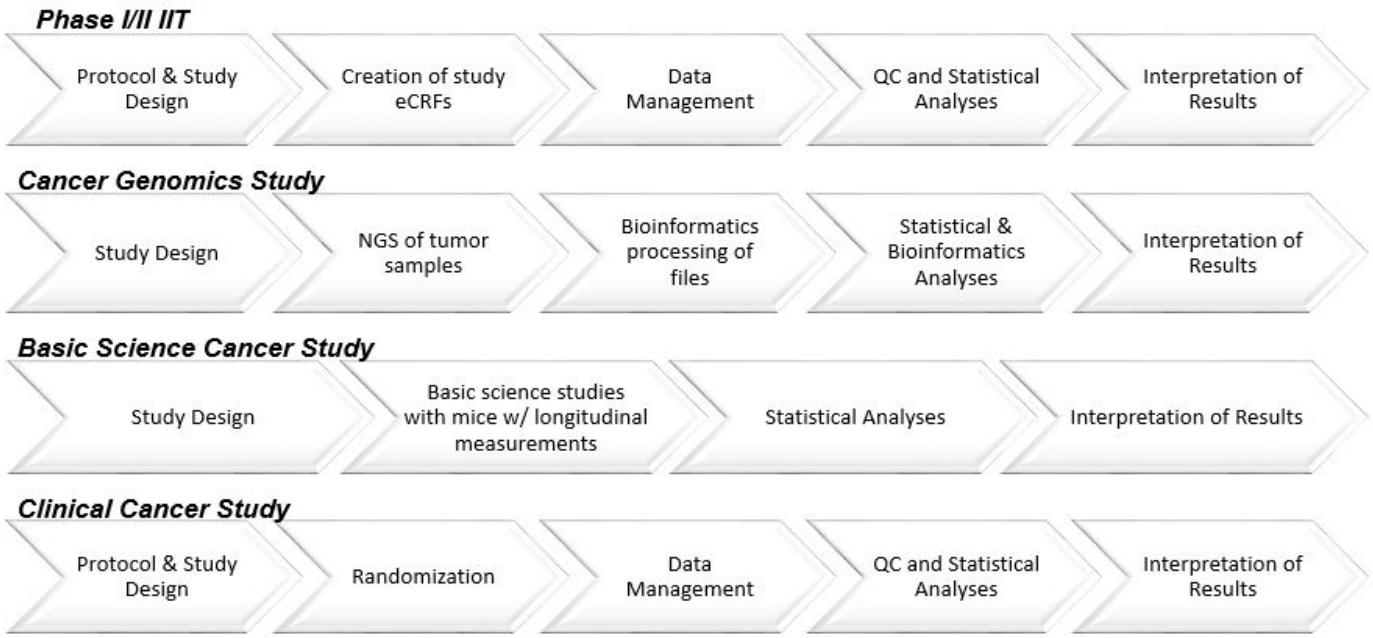
Major Services & Facilities

Services: Below is a list of major services that the BISR provides to KUCC members. Example workflows of BISR involvement in (1) IITs by D3ET members, (2) cancer genomics studies by CPS/CB/D3ET members, (3) basic science studies by CB/CPS members, and (4) clinical cancer studies by D3ET/CCPH/CPS members are presented in **Figure 2**.

Study Design: In consultation with KUCC investigators, BISR personnel will aid in the design of experiments to ensure research questions are testable with existing statistical methodology and have adequate statistical power/sample size. BISR personnel will also ensure valid conclusions can be drawn, with attention to ethical,

feasibility and cost constraints inherent in clinical research. Detailed statistical analysis plans will be established by BISR personnel, in consultation with the primary KUCC investigator(s) for each project.

Figure 2: Examples of the BISR support for a variety of cancer study types



Electronic Data Collection and Data Management: KUCC research projects can utilize the Comprehensive Research Information System (CRIS), powered by Velos eResearch. Currently, all therapeutic cancer clinical trials are supported with this system. It is a secure, 21 CFR Part 11 Compliant, robust, and scalable system that enables standardized and efficient protocol development and data entry. This web-based system allows for direct data entry from participating trial sites. CRIS supports: participant recruitment, study monitoring, trial design, protocol management, data safety monitoring, case report form construction and dissemination, integration of tissue and clinical information, clinical trial execution and query management and integration with third party clinical systems. CRIS is HL-7 compliant and can be configured to integrate with internal as well as third-party lab systems, electronic medical record systems, etc., through one integrally-designed system. CRIS supports multi-center, cooperative group, and investigator-initiated research through advanced technology and security features, all contained in one comprehensive environment. Through utilization of this comprehensive system great improvements in the research productivity, efficiency, collaboration, and integrity of data can be achieved. KUCC took the lead in initially purchasing and using Velos, and then it expanded to the Clinical Research Center (CRC). With the advent of the CTSA initiative, KUMC purchased an institutional enterprise wide license administered by the Department of Biostatistics. In addition to use of CRIS for data collected using eCRFs, BISR provides support for data management and collection using a variety of other tools, such as REDCap and OpenClinica.

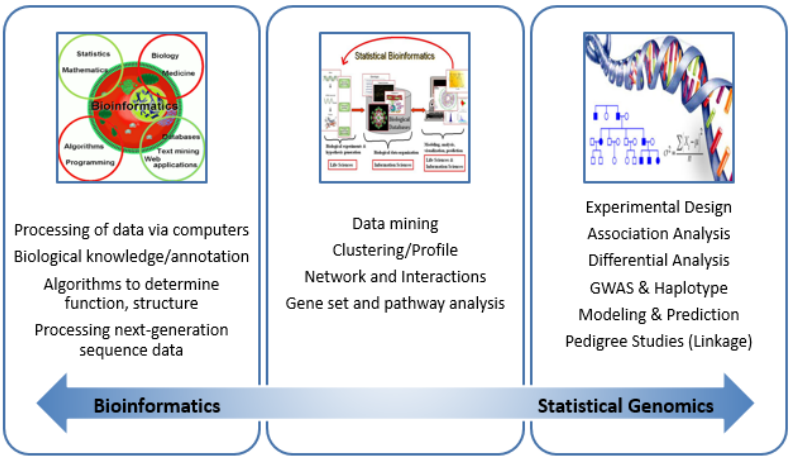
Clinical Trials: The BISR supports data management, study design and statistical analysis of phase I, phase II and phase I/II clinical trials conducted by KUCC members. To support trial design, the BISR developed an electronic Case Report From (eCRF) Content Toolkit that is flexible and not system dependent. The fields were developed using Clinical Data Acquisition Standards Harmonization (CDASH) standards published by the Clinical Data Interchange Standards Consortium (CDISC) when available and interdisciplinary collaboration with KUCC when CDASH standards were not available. Researchers use the tool to design study eCRFs by selecting the fields they want to include, indicating whether they are mandatory or optional and dictating the order of presentation. If the study requires a modified field to achieve study objectives, a new field or variable will be added to the repository of variables in the Content Toolkit. KUCC therapeutic trials use these standard eCRFs that have been implemented within the CRIS system (see section below on Electronic Data Collection and Data Management). On April 1, 2016 the BISR held the 1st eCRF/IIT Bootcamp for faculty, staff and students with the primary goal to provide hands-on experience in data management for cancer IITs using the

standardized process and eCRF toolkit recently developed in collaboration with the CTO. Four BISR faculty members, seven staff members and 13 students attended the eCRF bootcamp.

Statistical Oversight and Analyses: BISR personnel will oversee statistical analyses for research projects to ensure: appropriate statistical methodology is used; computations are accurate; and interpretations of study findings are correct. For example, violations of assumptions for the various test statistics may require that alternative statistical methodology be used after data are collected. In such an event, data transformation, randomization, permutation, or re-sampling tests; nonparametric approaches; and/or descriptive methods will alternatively be considered. Special attention will be paid to the magnitude of effect sizes as opposed to focusing solely on the statistical significance in all analyses. The primary statistical software used will be SAS or R; however, a number of other specialized statistical software packages are readily available on site, if needed.

Bioinformatics and Statistical Genomics Analyses*:* The BISR faculty and staff provide support to KUCC for the bioinformatics processing and statistical analysis of large-scale molecular datasets produced by high-throughput technologies, such as microarray or next-generation sequencing, including managing, visualizing, analyzing, and interpreting high-dimensional 'omic data produced from human or model organisms, as illustrated in **Figure 3**. The BISR has partnered with the KUMC Kansas-INBRE Bioinformatics Core, directed by **Fridley**, to provide researchers with access to Ingenuity Pathway Analysis (IPA) software and high performance computing (HPC) at KU-Lawrence. This partnership provides a large community cluster, a 20-fold increase in processing power, capability of supporting over 24,000 processing cores and 60-80 TB of storage for research projects to support the missions of both KUCC and the Kansas-INBRE. Lastly, in a collaboration with KUCC and IBM, the BISR was a beta test site for IBM's Watson Genomics, with sequencing completed at Children's Mercy.

Figure 3: Bioinformatics – Statistical Genomics Continuum

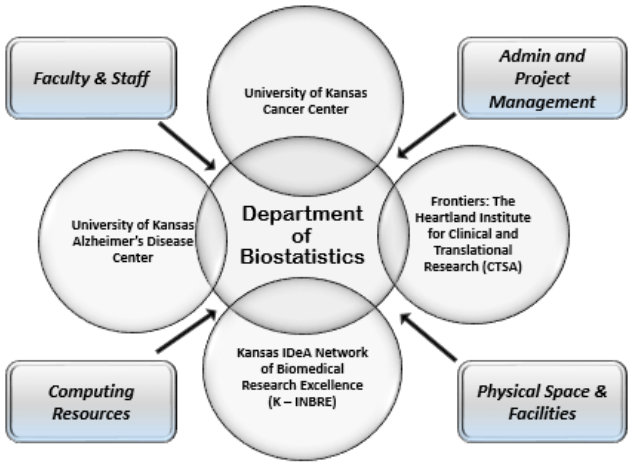


Facilities: The BISR is housed within the Department of Biostatistics, School of Medicine at KUMC. The mission of the department is to provide biostatistics and informatics expertise to support and enhance the research, service and educational needs of KUMC and its affiliates. There is over 6,000 square feet of office space within the Department of Biostatistics on the 5th and ground floors of the Robinson building at KUMC, which includes two conference rooms, various offices, student space, equipment and services such as computers, copiers, faxing, overnight mailing and portable display cases. There are 14 PhD Biostatistics faculty, two Research Instructors, one adjunct faculty, and four senior analysts and three programmers. The department's faculty members are active researchers collaborating and consulting in research projects and initiatives throughout the Medical Center, in addition to pursuit of their own research agendas and participation in curricular instruction. Expertise in the department includes linear, nonlinear, and longitudinal modeling, clinical trials and experimental design, survival analysis, categorical data analysis, robust statistics, psychometric methods, generalized linear models, missing data analysis, power analysis, Bayesian methodology and statistical genomics. The department has MS and PhD education programs in biostatistics that were created to help meet the ever-increasing demand for biostatisticians needed to take leadership roles in careers as researchers and educators in academia, government and industry. The department currently has ~30 graduate students.

Leveraging other NIH shared resources / cores: Within the Department of Biostatistics, multiple NIH shared resources and cores are housed, with departmental resources leveraged to support these multiple entities in a cost-effective and synergistic manner (**Figure 4**). **Mahnken** is director of the data management and statistics

core for Alzheimer's Disease Center, **Mayo** is director of the biostatistics core for CTSA, and **Fridley** is director of bioinformatics core for K-INBRE.

Figure 4: Shared Resources within Department of Biostatistics



Departmental Computing Resources: The Department of Biostatistics has invested over $250,000 toward hardware since 2009 to enhance the computing abilities. All computers in the Department of Biostatistics are connected to a 1 Gigabit per second local area network that provides more than 2500 Gigabytes of network file storage. Networked file servers provide constant hardware backups of stored data through mirrored storage systems and daily tape backups are also performed. Weekly tape backups are stored off site for additional protection of research data. The network is managed by KUMC's Information Resources who provides installation, training, and maintenance on all information systems. The Department of Biostatistics local network is connected to a switched, 1 Gigabit Ethernet backbone that provides high speed Internet access through the KUMC Internet-2 communication network.

- *Hardware:* Shared high speed workstation with dual Xeon 3.40 GHz processor, 8 GB of SDRAM, over 500GB of high speed storage, digital tape backup, and a DVD read/write drive. 34 HP Intel Core I5 CPU @ 3.40 GHz processor, 16 GB of SDRAM, over 800GB of high speed storage; 4 HP Intel Core I7 CPU @ 3.60 GHz processor with 32 GB of SDRAM along with 1 TB hard drive.
- *Networking/Internet and Server's:* HP PowerEdge 4600 file server with a 3.6GHz Xeon CPU, 8GB of DDR SDRAM, six 18GB SCSI Hard Drives in a RAID 5 configuration, 200GB digital tape backup system. Internet Explorer 11; Microsoft Outlook email; Internet 2 access through KUMC's LAN. The Department also has 14 windows 2008 R2 virtual servers - with dual Xeon processors, 8 GB SDRAM and over 240 GB of storage area ; 5 windows 2012 R2 virtual servers - with dual Xeon processors, 16 GB SDRAM and over 320 GB of storage area; 1 SUSE Linux server Quad core processor, 8 GB SDRAM. A HP PowerVault tape backup is also located in the server room along with a cooling system to maintain optimal conditions for optimal server performance. Tape backups are performed daily on modified data and full tape backups are performed weekly and stored off-site for 9 weeks.
- *Statistical, Mathematical and Database Software*: SAS, Minitab, S-PLUS, SPSS, STATA, SOLAS, WinNonlin, Nquery, Mathcad, SigmaPlot, Excel, Access, MySQL, Oracle, PLSQL, MS Visual Studio, SQL server, Postgresql, R, RStudio, Shinyr, MATLAB.

Security: The network is protected by a firewall and all computers are password protected. All network data are backed up nightly and stored in a secure off-site location. All individuals are required to undergo annual computer security traning in addition to human subjects and HIPPA training. Yet another level of security is conveyed by the fact that the building in which the key personnel are located has limited electronic passkey access during non-business hours i.e. between 6 pm - 6 am and 24 hrs during weekends and national holidays. In addition, access to the data centers is severely restricted requiring an electronic passkey or a physical key. Individually identifiable or deducible data will not be transmitted by unsecured telecommunications, which include the Internet, email, and electronic File Transfer Protocol. Further, the data will not be physically moved or transmitted in any way from its location without written approval from appropriate personnel. Finally, all output containing individual identifiable information is treated as confidential data. This information is never transferred electronically via email. Shredders are used on any printed material containing individual identifiers.

Advanced Computing Facility (ACF): The ACF houses the High Performance Computer (HPC) hardware dedicated to life science research (1200 cores). This new hardware enables a 20-fold boost in computing power thanks to a $4.6 million grant from the National Institutes of Health. This University of Kansas facility is located at the Information and Telecommunication Technology Center (ITTC) in Nichols Hall in Lawrence,

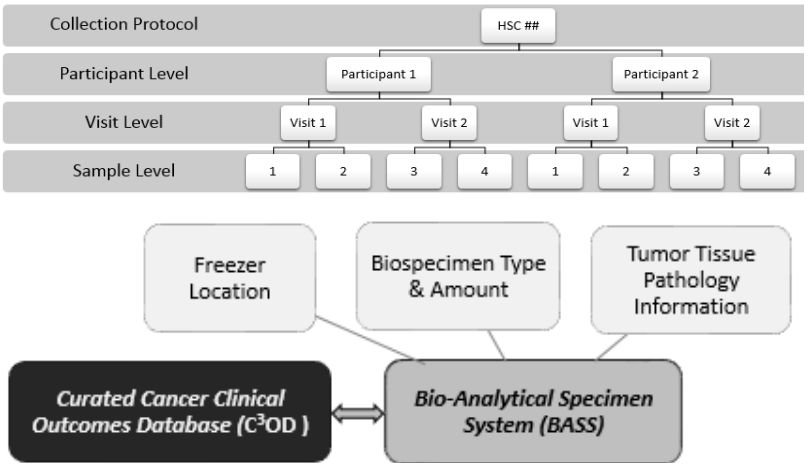
Kansas. The KU Community Cluster Program is a way for the research community to come together to build high performance computing capabilities in an efficient and cost-effective way. Each cluster "share owner" has priority use of their contribution to the cluster and unused capacity is available for all share owners to use. Data center and system administration costs are included in the purchase price of nodes. The KU Community Cluster Program is administered through the ACF. **Fridley** is a founding member of the ACF and sits on the advisory board; 13 Intel cluster nodes (two large memory and 11 standard memory) and over 60TBs of storage has been purchased for use by the KUCC BISR and the K-INBRE Bioinformatics Cores.

Ingenuity Pathway Analysis & Globus Genomics: In December, 2013, the BISR purchased an unlimited one-concurrent user license for Ingenuity Pathway Analysis (IPA), in conjunction with the K-INBRE Bioinformatics Core at KUMC. This purchase allowed KUCC members to have access to IPA for pathway analyses. As of April 1, 2016, there are 103 registered users. To enable students and staff in the BISR to complete processing of NGS data in a reproducible and documented fashion, the BISR finalized a contract with Globus Genomics and has used their user supported Galaxy cloud computing instance.

Research Enabling Resources

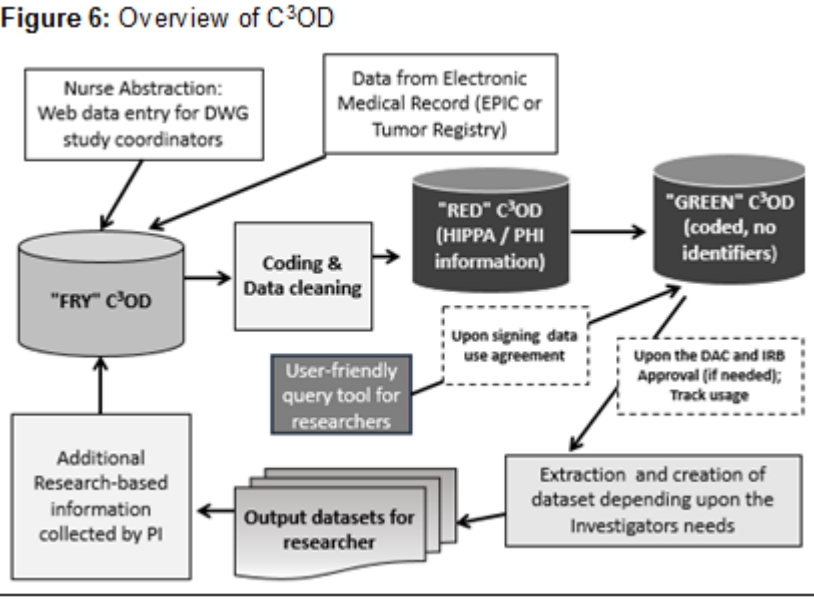
BASS (Bio-Analytical Specimen System): BASS is the database created and maintained by the BISR to track biospecimens for the Biospecimen Shared Resource (BSR) (**Figure 5**). The software architecture is based off of *caTissue*, which is now inherited by Krishagni Solutions and is named *OpenSpecimen* (http://www.openspecimen.org). *OpenSpecimen* is a complete package that helps to manage different protocols, information on biospecimens (sample type), patient consent, etc. along with a storage location. The BISR (Mudaranthakam) has integrated LDAP into *OpenSpecimen*, which covers all the security features for logging into the application using their unique employee username. Lab administrators can generate reports and audit logs to answer any scientific or administrative queries.

Figure 5: Structure of BASS



Curated Cancer Clinical Outcomes Database (C^3OD): Since 2004, around 30,000 analytic cancer cases and 20,000 non-analytic cancer cases have been seen at the University of Kansas Health System (KUHS); that is, ~50,000 cancer patients with information in the KUHS electronic medical record (EMR) system. Many of these patients (> 14,000 patients) provided biospecimens for research purposes that are being stored in the BSR. The BISR has been working with the BSR to develop and implement a Bio-Analytical Specimen System for the tracking, management and annotation of specimens. However, a limitation currently is the lack of detailed clinical and outcome information, including treatment information and time to recurrence/progression. There is also a need for the collection and organization of information on this large cohort of cancer patients to enable cutting-edge translational cancer research to be conducted at KUCC. Therefore, in the fall of 2015 the BISR began the development of a Curated Cancer Clinical Outcomes

Figure 6: Overview of C^3OD



Database (C^3OD). In the creation of C^3OD, the BISR will be using a *hybrid approach*, combining data from both the Health System's EMR system and Tumor Registry, along with manual abstraction of data from the EMR for all cancer patients seen at KUCC and KUHS, as illustrated in **Figure 6.** A unique feature of C^3OD is that it will undergo constant curation and quality control to ensure the highest data quality for translational research. A major focus will be to ensure that C^3OD is capable of dealing with health disparities and complications/adverse events and will follow treatment, outcomes and selected precision medicine metrics.

Precision Medicine & IBM's Watson Genomics: In a collaboration between IBM and KUCC, the BISR and BSR were beta testers for the early version of the "Watson Genomic Analytics Solution" in which the BISR tested and provided feedback to IBM on the tool. In completing the testing, 20 paired tumor / normal samples from the BSR were sent to Children's Mercy for whole-genome sequencing (WGS); following sequencing Children's Mercy ran their WGS pipeline for calling somatic mutations and sent the .vcf file to the BISR. The BISR then uploaded these results into the web-based tool that provided a summary report of actionable findings and corresponding treatment options for the individual patient. These reports where presented to the KUMC Molecular Tumor Board, with subsequent feedback provided to IBM.

Scientific Accomplishments

Therapeutic Clinical Trial Support: Results from a phase I study, led by **Williamson** (D3ET), of intraperitoneal (IP) nanoparticulate paclitaxel (Nanotax®) in patients with peritoneal malignancies was recently published (**Williamson**, *Cancer Chemother Pharmacol*, 2015). Twenty-one patients were enrolled onto the study to receive Nanotax® in a modified dose-escalation framework with accelerated titration. Results from this study found that IP administration did not lead to increases in toxicity, over what is seen in IV based administration. Additionally, they found that IP administration provided higher and prolonged peritoneal paclitaxel levels. This is a prototypical example of phase I studies conducted at KUCC where multiple shared resources were utilized, including the BISR (**Wick** (D3ET)), the Lead Development & Optimization shared resource (**Baltezor** (D3ET) and the Clinical Pharmacology shared resource (**Reed** (D3ET)). **Wick** participated in the study and protocol development and oversaw all data collection and statistical analyses.

Student Involvement in Research: Two students worked for a semester in the **Chien** (CB) research lab, as part of the completion of their MS in bioinformatics from Department of Bioinformatics and Biosystems Technology, Technical University of Applied Sciences Wildau, Germany. These students have since entered the PhD in biostatistics program at KUMC under the mentorships of **Fridley** and **Koestler**. While in the **Chien** lab, they published a paper entitled "Robust gene expression and mutation analyses of RNA-sequencing of formalin-fixed diagnostic tumor samples" (Graw, *Sci Rep*, 2015). This is a prime example of the importance of providing next-generation cancer researchers with research experiences early in their careers and exposing to multidisciplinary teams consisting of cancer biologists, data scientists, pathologist and clinicians.

Bioinformatics and Statistical Genomics Support: Attempts aimed at distinguishing causal methylation marks from those that are merely a consequence of disease are critical for elucidating the biological mechanisms underlying epithelial ovarian cancer (EOC). Previous analyses of genetic regulators of methylation and expression levels have revealed three-way causal relationships, where the prevailing model is one in which genetic variation influences methylation that in turn influences expression levels. In this inter-cancer center collaboration between the Mayo Clinic (Goode) and KUCC (**Fridley** (CCPH)), the BISR leveraged these findings in an attempt to filter out epigenetic marks resulting from disease, focusing attention instead, on the identification of epigenetic marks that are potential mediators of genetic risk for EOC. The BISR identified 17 CpG/SNP pairs, comprising 13 unique CpGs and 17 SNPs, which represent potential methylation-mediated relationships between genotype and EOC risk (**Koestler**, *BMC Med Genomics*, 2014). **Koestler** (CB) led the statistical analysis of the data and was first author on a manuscript describing the study findings.

Statistical Support for a Clinical Cancer Study: The report published by **Hamilton-Reeves** (CPS) and KUCC colleagues involved a small randomized controlled clinical trial (NCT01868087) focused on assessing the effects of a specialized immunonutrition drink (SIM) on immune response and infection rates for the patients who underwent radical cystectomy (RC) (**Hamilton-Reeves**, *Eur Urol*, 2016). After RC, patients are at increased risk for infections. The biomarkers such as Myeloid-derived suppressor cells (MDSCs) may expand after surgery depleting plasma arginine concentrations which in turn contributes to lower resistance to infection. This study found that participants receiving SIM had a 39% reduction in infection rate ($p = 0.027$).

Chalise (CPS) played a key role in all phases of the research, such as recruitment of the subjects using permuted block randomization design, analyzing the data using complex statistical model (generalized linear mixed model), interpreting the results and preparation of the manuscript.

Statistical Support for a Patient Reported Outcomes Study: The paper was accepted for publication in the *Journal of Cancer Education* (2016) (Garrard, *BMC Med Res Methodol*, 2015). **Gibbs** (CCPH) and KUCC colleagues involved a small cohort of breast cancer survivors to develop and test a new instrument for measuring nutrition literacy (**Gibbs**, *J Cancer Educ*, 2015). Nutrition is a critical factor for optimizing weight and improving quality of life in breast cancer survivors. The modified instrument (Nutrition Literacy Assessment Instrument for Breast Cancer, NLit-BCa) was pilot-tested with 17 high-risk women and 55 breast cancer survivors. The NLit-BCa was found to be content valid and demonstrated promising reliability and construct validity related to diet quality, and therefore has the potential for comprehensively measuring nutrition literacy in breast cancer populations. **Gajewski** (CCPH) played a key role in all phases of the research, advising on content analysis and analyzing the data using a novel statistical model (Ordinal Bayesian Instrument Development developed in collaboration with a PhD student).

Scientific Highlights Related to Technical Research within BISR: In addition to supporting KUCC members, the BISR faculty are also leaders in the areas of statistical genetics, Bayesian modeling, trial design, survival analyses, categorical data analysis and analysis of pharmacological responses. Below are a few examples of how faculty in the BISR are developing state-of-the-art methods to be used in cancer research. Note, no CCSG BISR allocated funds were used in the completion of these research projects.

- As part of a KUCC pilot project award, **Fridley** worked with a research fellow (Usset) on a new method for detecting multifactorial interactions and applied this method to data collected on thousands of ovarian cases and controls with genome-wide genetic and hormone-related risk factors information (Usset, *Cancer Epidemiol Biomarkers Prev*, 2016).
- **Koestler** and Usset developed a new method for optimizing the accuracy of cell mixture deconvolution; a statistical method for estimating the cellular composition of whole-blood based on DNA methylation. They found their method outperformed current methods (**Koestler**, *BMC Bioinformatics*, 2016).
- **Wick** and **Gajewski** developed an approach to identify the best two-arm completely randomized clinical trial design, taking into consideration both the statistical perspective and the community's perception (**Wick**, *J Biopharm Stat*, 2016).
- **Chalise** and **Fridley** developed an R package named *interSIM* for simulating multiple types of 'omic data that represents both the intra- and inter- correlation structure between features and data types. This method can be used by researchers to assess performance of bioinformatics methods (**Chalise**, *Computer Methods and Programs in Biomedicine*, 2016).
- **Diaz** has worked with KUCC's Lead Development & Optimization (LDO) shared resource and has developed methods for ranking and statistically testing the effects of chemical compounds on *in vitro* pharmacological responses from high-throughput screening assay (**Diaz**, *Comb Chem High Throughput Screen*, 2013; **Diaz**, *J Biopharm Stat*, 2015).
- **He** developed an approach to examine and model the association of body weight (measured with body mass index) and mortality as a dynamic association that may lead to different or even contradictory findings with traditional approaches (**He**, *Communications in Statistics - Simulation and Computation*, 2012; **He**, *Ann Epidemiol*, 2011). **He** and a PhD student used an innovative approach to examine the association of obesity and cancer mortality (Bimali, *Advances in Epidemiology*, 2015).
- **Gajewski** and a PhD student (Jiang) completed research to assess impact of adaptive priors on Bayesian accrual models (Jiang, *Stat Med*, 2015).

Other BISR Scientific Activities
Regular attendance by Fridley and informatics staff at CI4CC meeting: CI4CC (Cancer Informatics for Cancer Centers) is a nonprofit 501c3 organization intended to provide a focused national forum for engagement of senior Cancer Informatics leaders.

Participation in TCGA: BISR faculty (**Chalise, Koestler, Fridley**) were members of the cervical cancer analysis working group and contributed substantially to the paper currently under review at *Nature.* **Koestler** completed DNA methylation data analyses and **Chalise** completed the integrative clustering analyses.

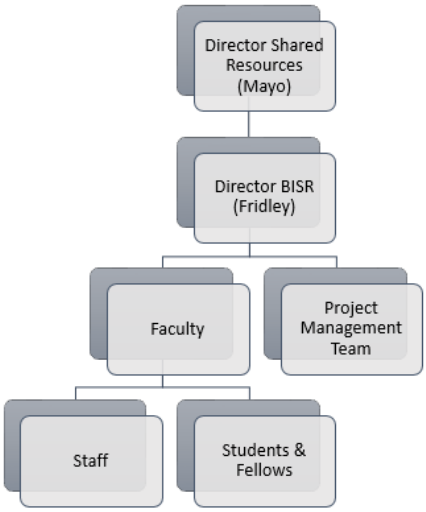
Participation in the Prostate Cancer DREAM Challenge: This challenge, organized by the Prostate Cancer Foundation, Sage Bionetworks and many cancer centers, focused on the development of improved prediction models for survival and toxicity of docetaxel treatment in patients with metastatic castrate resistant prostate cancer. The Jayhawk team involved two PhD students, two BISR staff, a research fellow, a CCPH member (**Ellis**) and three BISR faculty (**Fridley, Koestler, Chalise**). Team Jayhawk submitted an ensemble model as our prediction model and were co-winners of 2 of the 3 challenge questions.

Midwest Cancer Alliance (MCA): Through this network, the BISR has supported numerous studies, including: (1) "Determining the Feasibility of International Specimen Procurement to Assess the Role of Ethnicity in Pediatric ALL Outcomes" (Flatt at Children's Mercy (CM), **Fridley**) and (2) "MARVSmALo: Phase I Study of Vaccine Enriched, Autologous, Activated T-Cells Redirected to the Tumor Marker GD2 in Patients with Relapsed/Refractory Melanoma" (**Doolittle** at KUCC, Myers CM, Fulbright, CM, **Wick**).

Management Structure

The organizational structure for the BISR is presented in **Figure 7**. The BISR is directed by **Fridley,** who was recruited from the Mayo Clinic in 2012 to be Director of the BISR. She is also the Site Director for the Kansas-INBRE Bioinformatics Core.

Figure 7: Organizational structure



Meetings: Fridley meets with the BISR faculty and staff working on therapeutic clinical trials bi-weekly and the entire BISR faculty quarterly. Additionally, **Fridley** meets with the Research Informatics Director (**Mudaranthakam**) weekly, the C^3OD and BASS team members weekly and the CTO leadership (**Williamson, Apell**) monthly. **Fridley** is a member of the KUMC Molecular Tumor Board (led by **Godwin**), member of the IIT Steering Committee (lead by **Weir** and **Williamson**), and meets quarterly with the KUCC Associate Director for Shared Resources (**Mayo**) and the other shared resource directors (**Godwin, Reed, Baltezor, Vivian**).

Internal Advisory Board (IAB): The IAB (**Table 5**) provides feedback on usage, metrics and future directions as well as aiding in facilitating use of the BISR across the various programs within KUCC. The IAB has bi-annual meetings to discuss utilization, services provided and areas for growth/improvement.

Table 5: Internal Advisory Board Members

Member	Title	Prog.
Chien	Asst. Prof., Cancer Biology	CB
Greiner	Prof and Assoc. Chair for Research, Family Medicine	CCPH
Hamilton-Reeves	Assoc. Prof., Dietetics & Nutrition	CPS
Sharma	Assoc. Prof., Medical Oncology	D3ET

External Advisory Board (EAB): The BISR utilizes the Department of Biostatistics' EAB, where EAB members (**Table 6**) provide feedback on the vision, mission, future directions and operations of the department, as well as, the BISR. The most recent EAB meeting was held on July 18, 2016. The EAB was impressed with the amount and quality of service provided and expressed strong support for the continued development of this mutually beneficial relationship between KUCC and the Department. The BISR also receives feedback from the members of the KUCC EAB as detailed in the Planning and Evaluation section.

Table 6: External Advisor Board Members

Member	Title	Institution
Hardin	Provost	Samford University
Pollock	Chair, Dept. of Public Health Sciences	UC Davis
Wallace	Senior Research Statistician	RTI International
Weiss	Director, Shared Resources & Biostatistics, Markey Cancer Center	University of Kentucky

Operations & Policies

Member Access: Access to the BISR is obtained by the completion of a brief Project Registration Form. These forms are completed online by clicking the "Register Now" link on the Department of Biostatistics homepage (http://biostatistics.kumc.edu). Completing this form automatically updates the project tracking database and sends an email to the Project Manager of the Department of Biostatistics. Information collected on this form includes an indicator for whether the project is cancer-related, center affiliations, and other information as well as a free-text field for investigators to indicate deadlines or other relevant information. This information is obtained to route and prioritize the support provided to projects. Within two business days, the Project Manager (**Tremblay**) will contact the investigator to identify team members needed at the initial project meeting. BISR faculty and staff are then assigned to projects based on the overlap between the project needs and the BISR member's expertise, the overlap of the research field with the prior collaborations/experience of the BISR member, and the availability of the BISR member to work within the project-specific time constraints. The primary goal of this meeting is to clarify the statistical, bioinformatics and data management needs, identify relevant deadlines, and discuss budgetary matters when funding for BISR support is appropriate in following with the CCSG guidelines. Notably, these initial project meetings are always provided in kind, so a lack of financial support is never a barrier to receiving—at the very least—advice and consultation pertaining to their specific project. Further, study development time and effort are provided in kind as well for KUCC projects that will require BISR support, consistent with the CCSG guidelines. BISR support serves to improve the quality of research projects proposed, and facilitates the growth of unfunded KUCC members.

Priority System: The BISR provides statistical, bioinformatics and data management support to all KUCC investigators. The priority system is detailed below.

1. KUCC members with NCI grants or applying for NCI grants and KUCC pilots
2. KUCC members with cancer or cancer-related grants funded by other NIH institutes or other peer-reviewed grants as defined by the NCI or applying for such grants
3. KUCC-sponsored non peer-reviewed projects
4. Other grants or contracts that are not peer-reviewed
5. Unfunded projects

These priorities place the highest emphasis on peer-reviewed, funded research projects as a means of assuring that BISR support is provided to support high-quality research, consistent with the Cancer Center Support Grant guidelines. Note: Support for non-cancer or non-KUCC member's research is provided by the Department of Biostatistics, as such, only cancer, cancer-related and/or member usage is tracked by the BISR. The BISR tracks usage for all research projects and can generate usage reports.

Usage: From 2012 – 2015, the BISR has supported 98 KUCC members, with representation from all four research programs (**Table 7**). With the addition of bioinformatics expertise, the BISR has been able to better serve members in D3ET and CB. In 2010, BISR supported only 10 and 17 KUCC members from CB and D3ET, respectively. In 2015, the BISR supported 66 grant applications (submissions, resubmissions) for KUCC members. In addition, the BISR supported 240 grant submissions and over 500 projects since 2012 (**Table 8**). The BISR demonstrated growth in the number of users supported from each research program over the previous funding period (**Figure 8**). The BISR will continue to improve the efficiency in the support provided to members across all programs, specifically related to the development of inter- and intra-programmatic grants and research projects, but future growth patterns are expected to exceed current growth patterns dues to advancements in bioinformatics infrastructure and the creation of C^3OD.

Table 7: BISR 2015 Usage by Program

Year	Status	CB	CCPH	CPS	D3ET	Total Users
2015	Funded	7	14	7	6	**57**
	Unfunded	8	6	3	6	
2014	Funded	7	15	16	4	**61**
	Unfunded	6	2	3	8	
2013	Funded	10	13	13	6	**72**
	Unfunded	6	8	7	9	
2012	Funded	6	13	17	9	**69**
	Unfunded	3	9	5	7	
Total Users		**21**	**27**	**26**	**24**	**98**

Table 8: Cumulative numbers of projects supported

	2012	2013	2014	2015
# of Grants Submissions	45	119	174	240
# of Projects Supported	178	290	399	545

Figure 8: Usage by KUCC Members

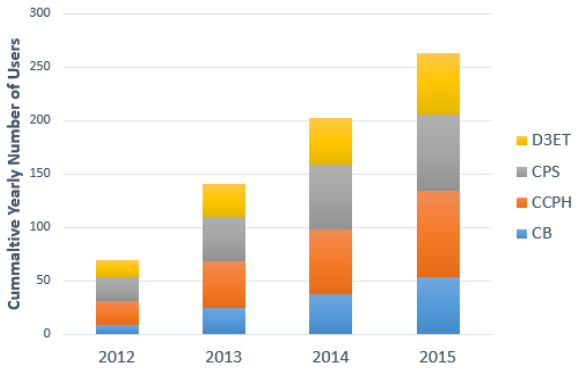
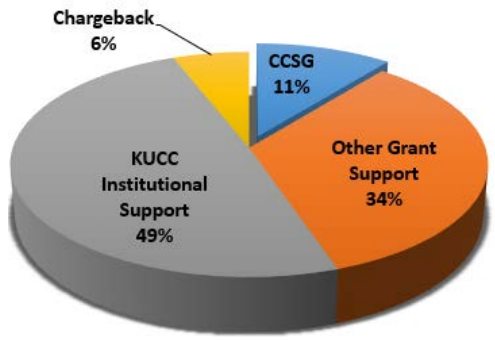


Figure 9: BISR's Support



Cost-Effectiveness

Very few projects need a full-time data scientist. By utilizing the BISR, KUCC members can have access to the support needed to design the studies and write the statistical sections for grants; then if funded, partially support the necessary faculty/staff to complete the research. KUCC support is essential for the stability of the resource, whereas, CCSG support will ensure priority access and faculty time to collaborate with KUCC investigators on grant applications, study development and pilot awards. To keep costs down staff level biostatisticians and informaticists conduct a large percentage of the work under the supervision of faculty. **Figure 9** shows the breakdown of proposed year 1 funding for the BISR; the CCSG funding accounts for ~11% of the BISR funding, with an annual direct support return on investment of approximately ½ million dollars in external funding to support BISR faculty and staff (34% of BISR support).

Value Added to KUCC

CCSG funds will be utilized for the development of cancer-related research grants and projects; prioritization is based upon the previously described system. Through the BISR tracking system we can determine whether or not a project is from a KUCC or CTSA member, avoiding any duplication with our institutional CTSA grant. Costs related to funded grants and contracts are covered as effort on those grants and contracts. Through the CCSG support, BISR faculty collaborated with KUCC members in the submission of numerous grants; resulting in $87,504,596 in awards (entire project period) in 2015.

Future Plans

Over the next five years, the BISR will continue to improve and enhance our support of KUCC research. The BISR will be focusing on the following areas to meet the growing needs of the programs:

- **Cancer Informatics:** The BISR is currently conducting a search for an informatics faculty member for BISR to oversee, advise and participate on cancer informatics projects, including the on-going development of BASS and C^{3}OD. Additionally, the BISR hopes to leverage the EMR for data-informed decision making, *in vivo* validation and natural language processing (NLP) for codifying EMR and pathology reports.
- **Precision Medicine and Pharmacogenomics:** The BISR is working closely with KUMC and KUCC leadership in the development of the infrastructure and processes for precision medicine in patient care and research. This includes, but is not limited to, the incorporation of biomarkers into adaptive designs (D3ET, CPS) and bioinformatics pipelines for NGS (D3ET, CPS, CB, CCPH).
- **Expand Expertise:** The BISR plans to develop expertise to better serve all four research programs in computational approaches to drug repurposing/repositioning and pharmacology (D3ET), tools and methods for imaging studies (CPS, CB), and prediction modeling and development of software applications for implementation research (CCPH).

Progress Report Publications

This component has no publications resulting from Cancer Center Support Grant funds.

Protection of Human Subjects – BIOSTATISTICS AND INFORMATICS SHARED RESOURCE

In accordance with federal and institutional regulations, all investigators are required to submit and obtain appropriate IRB review and approval for any proposed human subjects research study. Therefore, the projects from which the data are generated, have IRB approval.

However, there are three aspects in the Biostatistics and Informatics Shared Resource (BISR) related to human subjects and protections: (1) the storing of HIPPA protected data in C^3OD, (2) the prospective consenting of patients for research and (3) collection and storage of biospecimens. A description for these activities is provided below.

(1) Storing personal health information data and HIPPA protected information in C^3OD:

BISR will be collecting information on all cancer patients seen at the University of Kansas Hospital and storing this information within C^3OD, including HIPPA protected information. The IRB protocol for creation of C^3OD and the storing of information is currently under review by the University of Kansas Medical Center's Human Subjects Committee (HSC #3333, submitted October 2015). Additionally, a data use agreement is being put in place which will allow the transfer of data between the University of Kansas Hospital and the University of Kansas Medical Center / University of Kansas Cancer Center. The C^3OD team (faculty and staff of KUCC and the University of Kansas Medical Center) will work on the creation and maintenance of the data repository; however, they will not be conducting cancer research as part of this activity. Instead, they are serving in a technical role as an "honest broker" to provide data to the approved researcher. A tiered level of access will be used in the implementation of C^3OD with the following data use agreements.

1. Counts only (no request for individual patient data): Number of subjects meeting inclusion/exclusion criteria. Results defining a population below 10 are described as <10. This would require the researcher to only have signed C^3OD system access agreement.
2. Summary statistics only (no request for individual patient data): Summary of a few variables on a set of subjects meeting inclusion/exclusion criteria. Results defining a population below 10 are described as <10. This would require the researcher to have signed C^3OD system access agreement and data use agreement (DUA).
3. De-Identified Data: Requests for de-identified patient data is not deemed to be human subjects research. However, all data requests will be reviewed by the DAC. The DAC will be reviewing requests bi-weekly. This would require the researcher to have signed C^3OD system access agreement, signed data use agreement (DUA) and research protocol approval by the DAC. This process is similar to how NIH provides data in a de-identified manner (i.e., dbGaP http://www.ncbi.nlm.nih.gov/gap).
4. Identified Data: Identified data requests require approval by the IRB before submission of the data request to the DAC. The DAC will be reviewing requests bi-weekly. This would require the researcher to have a signed C^3OD system access agreement, data use agreement (DUA), research protocol approval by the DAC and HSC approval.

(2) As part of this project to build the cancer cohort for research, patients are being consented at time of visit to hospital onto HSC approved protocol #5929 (PI: Godwin).

All patients that are seen at KUH are giving HIPPA information on first visit and agree to have their medical records used for retrospective medical studies (opt-out consent). Researchers will not be allowed at this time to contact any patients to participate in their study, unless they have consented for a longitudinal research protocol (opt-in consent, HSC #5929). Godwin is currently prospectively consenting patients (cancer and non-cancer patients) as they are seen at KUH locations (currently 9 sites) and we will be tracking this consent information in C^3OD. However, obtaining consent from all cancer patients seen at KUH that are in the EMR would be difficult, if not impossible. We and others in the research community feel that removing the need to obtain consent for retrospective studies will not have an adverse effect on the patients. Patients that have declined to participate in research based on the new consenting will not be included in C^3OD. Only a limited dataset, with no PHI/HIPPA identifiable information, will be provided to the end user (following approval from the DAC and signing of the data use agreement), ensuring that patient privacy is protected. Identifiable

information will only be provided to an investigator after approval from the IRB and DAC. Only patients that have provided consent for HSC #5929 will be able to be contacted for research purposes.

(3) Collection and storage of biospecimens

The Biospecimen Shared Resource (BSR) identifies participants, obtains informed consent (HSC #5929), collects tissue, blood, and/or urine samples from selected populations, and obtains information on personal and family histories of cancer, clinical intervention, and lifestyle factors for use in research. The information on sample location and personal health data is stored in BASS (Bio-Analytical Specimen System), a database created and maintained by staff within the Biostatistics and Informatics Shared Resource (BISR) and BSR to track biospecimens. BASS sits on a HIPPA certified server and the software architecture is based off of caTissue, which is now inherited by Krishagni Solutions and is named as Open Specimen. Open Specimen is a complete package that helps to manage different protocols, bio specimen samples could be easily assigned to these protocols along with a storage location; the package also helps to annotate biospecimens along with patient demographics and consent information. The BISR has integrated LDAP into Open Specimen, which covers all the security features for logging into the application using their unique employee username. Lab administrators can generate reports and audit logs in order to answer any scientific or administrative queries. The application runs on Jboss web server with oracle as the backend.

Plans for Recruitment and Consent Procedures: Patients will be prospectively consented to HSC #5929 for participation in research. Additional, patients who are willing to provide biospecimens will be consented under the oversight of the BRCF. Currently, **Godwin** is prospectively consenting patients (cancer and non-cancer patients) as they are seen at KUH locations (currently 9 sites).

Issues of Risk and Protection from Risk

Physical Risk: There are no additional risks to subjects from the proposed studies, as we will rely only on previously collected data. Therefore, there will be no additional physical or health risks associated with this research.

Psychological, social, legal, or other risk: With all human subjects research comes with some risks, including loss of privacy and data confidentiality. We have strict policies and plans in place to safeguard privacy and confidentiality of data. All the servers will be maintained behind the Firewall. We will be using 3 Virtual Machine in the construction and maintenance of C^3OD (i.e., Fry- C^3OD, RED- C^3OD, GREEN- C^3OD). Except the database management team members in BISR, no other individual will have access to these systems. All the three servers will have an instance of Oracle installed and would have similar star schema database structure with the patient demographics being the key. All servers will be backed up nightly with a policy of incremental back-up every day and archiving for three years on the SAND. Before populating the data into these servers, the Information Security Team at KUMC would go through the Oracle Database Certification Process along with regular HIPAA-security certification. Every log-in to the system and query of the database will be tracked and logged and saved nightly to our central log registry to maintain the history of the information being accessed.

Informed Consent

In collaboration with KUMC's IRB staff, front desk registrars at nine locations were trained on the informed consent process and routinely evaluated for effectiveness. New patients are enrolled in the study during the registration process. Patients agree to longitudinal data collection from their medical record into an institutional database to support research projects requiring de-identified data sets. Participants are made aware at the time of consent that there is no expiration for their authorization once the form is signed. Original consent forms are locked in secure cabinets within key card access areas of the BRCF offices. Approved regulatory bodies may review signed originals upon request.

Potential Benefit

This resource will allow research questions related to cancer care, outcomes and complications, in addition to biomarker and precision medicine studies, to be conducted with the ultimate goal of improving cancer patient care and treatments. The risk to the individuals in the database is minimal but will lead to great advances in cancer care. Researchers will need to have a proposed research question that is approved by the DAC in order to get individual record level data (not including PHI or HIPPA information). Those research projects which require additional data collection from the EMR (and thus would need to have medical record number or if they need other identifiable information) will need to have an IRB approved protocol in addition to approval from the DAC to get this information. Researchers will only be able to retrieve summary statistical (counts, means, etc.) for various variables, etc. All datasets with individual record data will be created by the C^3OD team to ensure data integrity and to track data usage.

Inclusion of Women & Minorities – BIOSTATISTICS AND INFORMATICS SHARED RESOURCE

In accordance with federal and institutional regulations, any proposed clinical trial would be required to be designed and carried out in a manner sufficient to provide for valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

OMB Number:0925-0001 and 0925-0002
Expiration Date: 10/31/2018

***Study Title:** Biostatistics & Informatics Shared Resource-Any human subject study funded by CCSG funds will be required to submit a PHS inclusion enrollment report.

***Delayed Onset Study?** ☑ Yes ❑ No

If study is not delayed onset, the following selections are required:

Enrollment Type ❑ Planned ❑ Cumulative (Actual)

Using an Existing Dataset or Resource ❑ Yes ❑ No

Enrollment Location ❑ Domestic ❑ Foreign

Clinical Trial ❑ Yes ❑ No

NIH-Defined Phase III Clinical Trial ❑ Yes ❑ No

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/Alaska Native										
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More than One Race										
Unknown or Not Reported										
Total										

Report 1 of 1

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Inclusion of Children – BIOSTATISTICS AND INFORMATICS SHARED RESOURCE

In accordance with federal and institutional regulations, any proposed clinical trial would be required to be developed to support the treatment modalities for disorders and conditions that affect adults and may also affect children.

Vertebrate Animals – BIOSTATISTICS AND INFORMATICS SHARED RESOURCE

Per institutional guidelines, any pilot projects funded with designated Developmental Funds from the University of Kansas Cancer Center Cancer Center Support Grant (1-P30-CA168524-01) will be required to obtain an approved animal care and use protocol from the University of Kansas Medical Center Office of Animal Welfare.

Biostatistics and Informatics Shared Resource – References Cited

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Bimali M, **He** J. Association between Obesity and Cancer: An Analysis Using the Competing Risk Regression Approach. Advances in Epidemiology. 2015;2015:7. doi: 10.1155/2015/132961.

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Resource Sharing Plan – BIOSTATISTICS AND INFORMATICS SHARED RESOURCE

Data and information collected and housed within C^{3}OD will be shared within a timely fashion and within NIH guidelines. The goal of this research project is to facilitate data sharing within our collaborative groups and the broader community while addressing legal, regulatory, and IRB policy obligations. We recognize the value of the proposed data sets, particularly in down-stream meta-analysis. We must also respect the privacy of the patients. In additional to sharing of data, we will make available to the research community all tools and processes used in the development and management of C^{3}OD, including data dictionaries and data entry screens/modules.

Internal Data Sharing plan: Access to C^{3}OD for querying using the GUI will be obtained by submitting a data access request form to the C^{3}OD team. The C^{3}OD team will then grant them access in which they will login and authentication with KUMC Central Authentication Service. Members of KUCC will need to have academic appointments and KUMC ID to log-on to the system. After access is granted, the user will be assigned a username and password. After initial cohort identification, when a principal investigator (faculty member) wishes to have a de-identified dataset created they will then submit a data use proposal (variables, inclusion/exclusion criteria, team members, etc.) to the data access committee (DAC) for approval. Access for other research staff will be granted only if the faculty mentor is the PI on the DAC with the research staff listed as team member. The supervising faculty member (PI) assumes all responsibility for the collective actions of the group.

External Data Sharing plan: External collaborators from non-for profit and/or academic institutions will need to have an on-going collaboration with a faculty member at KUMC. External collaborators will not be able to log-on to the C^{3}OD system. If data is to be sent to this external collaborator (i.e., consortium) an IRB approved protocol must be in place and the data must be coded as to not have any patient identifiers.

Sharing of research resources*:* We are aware of and agree to abide by the NIH Grants Policy on Sharing of Unique Research Resources, including the sharing of Biomedical Research Resources, as outlined in the NIH Data Sharing Policy and Implementation Guidance (version updated on October 21, 2014 of http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm). Should any intellectual property arise which requires a patent, we would ensure that the technology remains widely available to the research community in accordance with the NIH Principles and Guidelines document. Requests from for-profit corporations to use the team's resources for commercial development will be negotiated by the University's technology transfer office. All licensing shall be subject to distribution pursuant to all institution's policies and procedures on royalty income. The technology transfer offices will report any invention disclosure submitted to them to NIH. Awardees will retain custody of and primary rights to their data and intellectual property developed under the award subject to current government policies regarding rights of access as consistent with current HHS, PHS and NIH policies. Pursuant to NIH policies, data will be released immediately following the exercise of intellectual property rights (if applicable) and the receipt of notification of acceptance for publication (if applicable). NIH recommended time period will be adhered to whenever practicable.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 016060860

Legal Name*: University of Kansas Medical Center Research Institute, Inc.
Department:
Division:
Street1*: MSN 1039, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Deborah		Maloney	MSM

Position/Title: Director, Sponsored Programs Administration
Street1*: 3901 Rainbow Boulevard
Street2: Mail Stop 1039
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937
Phone Number*: 913-588-1261 Fax Number: 913-588-3225 Email: spa@kumc.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofit Organization
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Clinical Pharmacology Shared Resource

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2017	06/30/2022

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Medical Center
Duns Number:	016060860
Street1*:	MS 1018, 3901 Rainbow Boulevard
Street2:	
City*:	Kansas City
County:	Wyandotte
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66160-0000
Project/Performance Site Congressional District*:	KS-003

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ❍ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number 00003411

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	CPSR_Project_Summary_final1019601616.pdf
8. Project Narrative*	
9. Bibliography & References Cited	CPSR_ReferencesCited_Final1019601617.pdf
10.Facilities & Other Resources	CPSR_Facilities_and_Other_Resources1019601614.pdf
11.Equipment	
12. Other Attachments	CPSR_Other_Attachments_final1019913916.pdf

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Clinical Pharmacology Shared Resource – Project Summary

Established as a University of Kansas Cancer Center (KUCC) developing shared resource in 2012 and selected as an established shared resource in 2015, the Clinical Pharmacology Shared Resource (CPSR) is led by Gregory **Reed**, PhD. This shared resource has three functional components.

1. Correlative Laboratories - directed by LaToya Berry. The Correlative Laboratories provide GXP-compliant acquisition, processing and storage or shipping of clinical research samples. Following either a sponsor's protocol or CPSR protocols, the staff efficiently and precisely prepares samples from blood (whole blood, serum, plasma or specific blood cell fractions), urine and saliva or processes tissue samples, and then stores or transfers those samples for analysis. The Correlative Laboratories are located near patient treatment areas at the KU Clinical Research Center (KU CRC), Westwood (The University of Kansas Health System's outpatient clinical facility) and at The University of Kansas Health System's main campus. The Correlative Laboratories also provide scientific and technical support to the community oncology sites and Midwest Cancer Alliance (MCA) sites to assist them in sample acquisition, processing and shipping.

2. Bioanalytical Laboratory - led by **Reed.** Located at the KU CRC, this GLP-compliant facility prepares biological fluids, cells or tissue samples, and analyzes them for concentrations of drugs, drug metabolites and other small molecule biomarkers. Analyses are performed on two UPLC-tandem quadrupole mass spectrometers, with a combined sample throughput of over 30,000 samples per year.

3. Pharmacokinetics/Pharmacodynamics (PK/PD) Unit – also directed by **Reed**. **Reed** performs calculations and modeling using the Phoenix/WinNonlin® software to define and interpret the kinetics of drugs and their actions.

In addition to these study-specific activities, the staff of the CPSR also play a major role in educating future physicians and researchers, as well as nurses and study coordinators currently involved in cancer clinical trials, on the theory and practice of clinical pharmacology and on how those applications of clinical pharmacology result in more powerful and informative results from clinical trials.

Clinical Pharmacology Shared Resource – Facilities and Other Resources

The following laboratories and facilities are located at the three main KU Cancer Center sites: the KU Clinical Research Center (KU CRC), Westwood (The University of Kansas Health System's outpatient clinical facility) and at The University of Kansas Health System's main campus.

Correlative Laboratories

KU Hospital: Located in Room 1540A KU Hospital, this laboratory provides 280 sq. ft. of workspace. The hospital lab is equipped with one refrigerated and two ambient temperature benchtop centrifuges and a 2' Class I Biosafety cabinet for sample processing. Monitored storage is available in a refrigerator/freezer and in a -20° and a -80°C freezer.

Westwood: The Correlative Lab located in Room 1107-002 and provides 576 sq. ft. of lab and storage space and is equipped with one refrigerated and two ambient temperature benchtop centrifuges and a 4' Class II Biosafety cabinet for sample processing. Monitored storage is available in a refrigerator/freezer and in a -20° and a -80°C freezer.

KU Clinical Research Center: This laboratory is located in 2101 CRC and consists of 560 sq. ft. of laboratory space with an additional 360 sq. ft. for storage of study kits and other supplies. Major equipment in the laboratory includes three refrigerated benchtop centrifuges and a 6' Class II Biosafety cabinet for processing of patient samples. The lab also contains a monitored refrigerator and monitored freezers at -20°, -40°, and -80°C.

Bioanalytical Laboratory

The Bioanalytical Laboratory at the KU Clinical Research Center is located within 30 yards of the CRC Correlative Laboratory and both the patient treatment and procedure rooms at the CRC. Room 2301 is a 525 sq. ft. laboratory equipped with a chemical fume hood, a 4' Class II Biosafety cabinet, a refrigerated benchtop centrifuge, an ambient temperature microcentrifuge, a centrifugal vacuum sample concentrator, top-loading, analytical, and microbalances, and monitored storage at 4°, -20°, and -70° C. The analytical lab is in 2305 CRC, with a direct connecting doorway from 2301. The 490 sq. ft. analytical lab is equipped with a chemical fume hood, a Millipore Class I water purification system, an absorbance/fluorescence/microplate reader, and two Waters Xevo TQ-S UPLC-MS/MS systems.

Offices

Reed's office is in 2316 CRC, and is within 20 yards of the Bioanalytical Laboratory and 40 yards of the Correlative Laboratory. Berry's modular office is directly outside of Reed's office. Desk space with networked computers and telecommunications are provided in all three Correlative Laboratories and in both rooms of the Bioanalytical Laboratory.

Computer

All CPSR labs and offices have outlets on benches and in office areas and all buildings also have our secure Wi-Fi network. The laboratories and offices are equipped with a total of nine desktop and two laptop computers, and these are loaded with standard word/data processing programs (Office, Adobe). Reed's desktop also has Phoenix WinNonlin software for PK/PD calculations and modeling and ChemBioDraw software for chemical drawing.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Gregory Middle Name A Last Name*: Reed Suffix: PhD

Position/Title*: Associate Professor
Organization Name*: University of Kansas Medical Center
Department: Pharmacology, Tox & Ther
Division: School of Medicine
Street1*: MS 1018, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-7513 Fax Number: 913-588-7501

E-Mail*: GREED@kumc.edu

Credential, e.g., agency login: GREED52

Project Role*: Other (Specify) Other Project Role Category: Core Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Reed_CCSG_Bio1019857864.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ○ Yes ● No

*Agency-Defined Phase III Clinical Trial? ○ Yes ○ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ❍ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ❍ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ❍ Yes ❍ No

6. Change of Investigator / Change of Institution Section

❑ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	CPSR_Specific_Aims_final1019601619.pdf
3. Research Strategy*	CPSR_ResearchStrategy_Final1019601618.pdf
4. Progress Report Publication List	Progress_Report_Publications_Blank1019754750.pdf
Human Subjects Section	
5. Protection of Human Subjects	Protection_of_Human_Subjects___CPSR1019799859.pdf
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	Inclusion_of_Women_Minorities___CPSR1019799860.pdf
8. Inclusion of Children	Inclusion_of_Children___CPSR1019799861.pdf
Other Research Plan Section	
9. Vertebrate Animals	
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	
14. Resource Sharing Plan(s)	Resource_Sharing_Plan__Generic1019799862.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

Clinical Pharmacology Shared Resource – Specific Aims

The Clinical Pharmacology Shared Resource (CPSR) provides essential scientific expertise and support for clinical and population studies in cancer therapeutics, cancer prevention and cancer population studies. CPSR services begin at the earliest stages of project development, with assistance in drug and dose selection and for defining dosing regimens. The CPSR then advises investigators on the potential value added to proposed studies by the inclusion of quantitative measurements of drugs or biomarkers and the determination of pharmacokinetic endpoints. This support continues through the process of protocol development and the submission of funding applications. Once projects are initiated, the personnel and facilities of the CPSR perform the acquisition, processing and analysis of patient samples as required for each study. Resulting drug and biomarker data are then analyzed and interpreted by CPSR staff, including the performance of pharmacokinetic calculations and the staff then provides support for the presentation and publication of those results. These services currently are provided to support cancer therapeutics trials, including studies of drug repurposing and novel drug combinations and also to the measurement of a full range of tobacco biomarkers for population studies of smoking cessation and of relative risks from various forms of tobacco and nicotine.

This range of services, from project inception through final presentations and reports, are represented by these specific aims:

Aim 1. To provide clinical pharmacology expertise to investigators and support them as they develop, submit and implement clinical trials in cancer therapeutics and prevention and cancer population health.

Aim 2. To develop, codify, and perform proper acquisition, processing and either short-term storage or shipping of research samples from clinical trials in cancer therapeutics and prevention and cancer population health.

Aim 3. To develop, validate and perform quantitative analysis of drugs and their metabolites and of endogenous and endogenous small molecule biomarkers, in patient samples from clinical trials in cancer therapeutics and prevention and cancer population health.

Aim 4. To perform pharmacokinetic calculations and analysis and to interpret and present those findings for clinical trials in cancer therapeutics and prevention and cancer population health.

Aim 5. To educate all Cancer Center investigators and team members in the theory and application of clinical pharmacology to research in the identification, development, and testing of new chemical entities, or for new applications of existing chemical entities, in clinical trials in cancer therapeutics and prevention and cancer population health.

The services provided by the CPSR are provided on-site at the KU Clinical Research Center (KU CRC), Westwood and at The University of Kansas Hospital, and also are available via outreach to all community oncology and Midwest Cancer Alliance (MCA) sites. Bioanalytical and pharmacokinetic services also are provided for investigators at other cancer centers in the U.S. and Canada. All activities are GXP-compliant.

In summary, the CPSR provides critical scientific and technical support for the development and performance of effective and informative clinical trials, and for the complete and accurate dissemination of the results of those trials. This support is essential for early phase clinical trials, including first-in-human studies, but also adds significant value to trials focused on new applications and new combinations of current therapeutics. This range of support and the GXP-compliant delivery of this support, provided by an integrated component of the Cancer Center, allows for the rapid and cost-effective inclusion of these key endpoints into clinical trials. This scientific and technical guidance and support from the CPSR ensure that our clinical trials are complete and maximally informative, and thus drive the development and advancement of new and more effective therapeutic and preventative approaches.

Clinical Pharmacology Shared Resource – Research Strategy

Background and Purpose

Established as a University of Kansas Cancer Center (KUCC) developing shared resource in 2012 and selected as an established shared resource in 2015, the Clinical Pharmacology Shared Resource (CPSR) is led by Gregory **Reed**, PhD. This shared resource has three functional components.

1. Correlative Laboratories - directed by LaToya Berry. The Correlative Laboratories provide GXP-compliant acquisition, processing and storage or shipping of clinical research samples. Following either a sponsor's protocol or CPSR protocols, the staff efficiently and precisely prepares samples from blood (whole blood, serum, plasma or specific blood cell fractions), urine and saliva or processes tissue samples, and then stores or transfers those samples for analysis. The Correlative Laboratories are located near patient treatment areas at the KU Clinical Research Center (KU CRC), Westwood (The University of Kansas Health System's outpatient clinical facility) and at The University of Kansas Health System's main campus. The Correlative Laboratories also provide scientific and technical support to the community oncology sites and Midwest Cancer Alliance (MCA) sites to assist them in sample acquisition, processing and shipping.

2. Bioanalytical Laboratory - led by **Reed.** Located at the KU CRC, this GLP-compliant facility prepares biological fluids, cells or tissue samples, and analyzes them for concentrations of drugs, drug metabolites and other small molecule biomarkers. Analyses are performed on two UPLC-tandem quadrupole mass spectrometers, with a combined sample throughput of over 30,000 samples per year.

3. Pharmacokinetics/Pharmacodynamics (PK/PD) Unit – also directed by **Reed**. **Reed** performs calculations and modeling using the Phoenix/WinNonlin® software to define and interpret the kinetics of drugs and their actions.

In addition to these study-specific activities, the staff of the CPSR also play a major role in educating future physicians and researchers, as well as nurses and study coordinators currently involved in cancer clinical trials, on the theory and practice of clinical pharmacology and on how those applications of clinical pharmacology result in more powerful and informative results from clinical trials.

Guidance from the CPSR is an integral component of the development of investigator-initiated trials (IITs) in the Cancer Center. CPSR input begins at the earliest stages of project development. Initial drafts of projects submitted either to the Clinical Trials Office (CTO) or the Investigator-Initiated Trials Steering Committee (IITSC) are sent to **Reed**. He reviews these early proposals for clinical studies and then suggests where and how the services of the CPSR may be applied to add value to the study. The staff of the CPSR then will provide assistance with experimental design and with the preparation and submission of grant or contract proposals and supporting protocols and documents. For active studies, the CPSR provides complete in-house services that contribute to all stages of study performance, including sample acquisition, processing, shipping or storage, method development, validation and application for bioanalysis of small molecules. Finally, through the PK/PD Unit, the staff can aid in the interpretation of data and in the reporting and publication of study results.

The services of the Clinical Pharmacology Shared Resource will:

- Add value to clinical trials;
- Accelerate and facilitate the processes of study development, activation, performance and reporting;
- Provide readily-available consultation and assistance;
- Provide rapid turnaround time for method development and sample analysis; and
- Integrate interpretation and presentation of study results as an integral part of services.

Importance of the Shared Resource

The vision statement of the Cancer Center includes a resolution to "Promote a cancer center culture whose highest priority is to foster the discovery and advancement of new and more effective therapeutic approaches for the benefit of its patients and thereby stimulate and catalyze the education and training of the next

generation of cancer clinicians, researchers, and health care professionals." The scientific and technical services of the Clinical Pharmacology Shared Resource are integral and essential components for the realization of this vision.

The Correlative Laboratories component of the CPSR coordinates the acquisition, preparation and distribution of all study-specific supplies, and then performs and documents acquisition, processing and storage or shipping of patient research samples in strict adherence with study or internal protocols. The operations performed in these laboratories are GCP- and GLP-compliant. The highly-trained, experienced staff ensures that all research samples are acquired and processed on time and according to protocol, thus maximizing the completeness and validity of these procedures. The performance and documentation of these essential clinical trial activities relies on the well-prepared and highly focused research staff of the Correlative Laboratories.

The Bioanalytical Laboratory of the CPSR provides a GLP-compliant UPLC-MS/MS-based analytical facility for the development, validation and application of methods for identification and quantification of drugs, drug metabolites and other biomarkers of exposure or efficacy for clinical trial samples. Although this service could be outsourced to contract laboratories, the advantages of maintaining this facility in-house are profound. These include the retention of scientific and quality control of the analyses, more focused and timely delivery of service to KUCC investigators than from outside laboratories and the performance of these services at lower cost than either contract or outside academic laboratories. By maintaining this in-house resource the CPSR is able to provide cost-effective preliminary work to KUCC investigators to determine feasibility and generate preliminary data for new projects.

The functions of the PK/PD Unit of the CPSR provide the broadest support for the clinical research enterprise of the Cancer Center. This unit provides consultations and tutorials to investigators in order to facilitate the formulation of research questions in cancer therapeutics or prevention, and assistance in the development and preparation of solid funding applications and study protocols. The staff continues to monitor and assess data during clinical trials, advising the investigator in a timely manner. When studies are completed, the PK/PD staff performs required calculations and statistical tests and then assist in the interpretation, reporting and publication of the findings. It is also the mission of the PK/PD Unit to educate current and future members of the cancer research team on the importance and value of understanding and including clinical pharmacology in their work.

The combined efforts of the three components of the CPSR clearly are required in order to "foster the discovery and advancement of new and more effective therapeutic approaches", and the tutorials and other presentations offered by the PK/PD Unit support the Cancer Center mission to foster "the education and training of the next generation of cancer clinicians, researchers, and health care professionals."

Relation to other Shared Resources and Core Facilities

The roles and services provided by the three components of the CPSR are distinct from and complementary to those of other KUCC and institutional shared resources. In the case of the Correlative Laboratories, their mission and services are similar to those provided by the KUCC Biospecimen Shared Resource (BSR), but for very different purposes. The Correlative Laboratories acquire, process and transfer study-specific research samples for immediate or short-term use. Sample numbers, types and specific uses are defined by each study. In contrast, the BSR acquires, processes and stores patient samples to establish a research bank of tissue and fluid samples to be stored long-term for future research. These samples are not acquired as part of any specific study, but rather to establish a source of materials for use in appropriate research projects. In addition to the different purposes for sample acquisition by the two shared resources, the policies and procedures are very different. The Correlative Laboratories have internal standard operating procedures and guidance documents, however most acquisition and processing is performed following study-specific protocols. The BSR instead uses only general, internal protocols. Sample tracking is also quite different – the BSR must maintain samples and records long-term and must be able to link specific samples to additional disease and patient information when required. The Correlative Laboratories tracks samples by patient number, time and dates of acquisition, processing and shipping or transfer. All links to additional patient information are made outside of the Correlative Laboratories. These clear differences in mission, timelines and procedures between the

Correlative Laboratories of the CPSR and the BSR support maintaining these two facilities as separate yet complementary entities within the Cancer Center.

The Bioanalytical Laboratory of the CPSR has some similar equipment to what is provided by the KUCC Lead Development and Optimization Shared Resource (LDOSR), and by the institutional Core Analytical Laboratory in the Department of Pharmacology, Toxicology and Therapeutics and the institutional Proteomics Laboratory in the Department of Biochemistry. Despite some similarities in instrumentation, the functions and services provided by these facilities differ markedly. The closest functional correspondence between facilities may be seen between the Bioanalytical Laboratory and the LDOSR. Both laboratories employ LC-MS/MS methods for quantification of drugs and their metabolites and other small molecules for research studies. Two major differences between these facilities must be emphasized – first, the LDOSR focuses on method development and validation and analysis of samples from pre-clinical studies, whereas the Bioanalytical Laboratory performs the same services primarily for clinical research samples. The second major differentiator is that the LDOSR is a non-GLP-compliant facility, whereas the Bioanalytical Laboratory performs analytical work as a GLP-compliant facility. As a result, these two facilities form a complementary and cooperative team for small-molecule bioanalysis. As an example, the analytical method for KUCC studies with ciclopirox was developed and validated at the LDOSR for support of formulation and stability studies and for analysis of pre-clinical plasma samples from rodents and dogs. The LDOSR forwarded their method to the Bioanalytical Laboratory where it was optimized for samples from human plasma, fully validated and then used to support the phase I trial of this repurposed drug. Another example of this cooperation is for the support of any KUCC IND application. The LDOSR has been analyzing drug concentrations from pre-clinical samples, but final studies require GLP-compliant bioanalysis. The Bioanalytical Laboratory will transfer and validate the assay method developed at the LDOSR and apply that to GLP-compliant analysis of pre-clinical research samples.

Two other LC-MS/MS facilities are present at KUMC. One is in the COBRE-supported Analytical Laboratory. This is an open, multi-user core laboratory primarily for investigators associated with the Liver Center and with the Department of Pharmacology, Toxicology and Therapeutics. It functions as both a research core and as a teaching facility for graduate students and post-doctoral fellows. It is more of an instrument resource and a teaching site, with actual analytical services as a minor activity. The other facility is the mass spectrometry-based Proteomics Laboratory in the Department of Biochemistry. The instrument selection and set-up, the techniques employed and the expertise of the staff are entirely focused on large molecule, peptide and protein analysis. It is clear that there is no overlap between the functions and services of either of these institutional shared resources and the Bioanalytical Laboratory of the KUCC CPSR, and that the presence of this GLP-compliant Bioanalytical Laboratory adds a significant strength to the analytical capabilities provided for the entire University community.

Goals

The goals of the CPSR are:

- To provide scientific and technical support in clinical pharmacology and related fields to all members of the Cancer Center;
- To enhance productivity and quality in clinical research by educating all members of the research team on the goals of clinical pharmacology and the roles and interactions between team members to achieve these goals; and
- To provide this support to Cancer Center members in a timely, reliable, and cost-effective manner.

These goals and the support provided to achieve them is focused primarily on Cancer Center members and their teams, but also may be extended to non-members within our collaborating institutions and outside clients.

Qualifications

Leadership
Director: Gregory **Reed**, PhD, is the Director of the CPSR. He is responsible for the operation and performance of all three components and serves as the main contact and spokesperson for the shared

resource. Direct supervision and management of the Correlative Laboratories and their staff is delegated to LaToya Berry. **Reed** is responsible for all operations of the Bioanalytical Laboratory and for all functions of the PK/PD Unit. **Reed** brings exceptional qualifications to this position. In regard to sample processing and bioanalysis, he has developed, validated and used LC-based quantitative assays for over 35 years, and has worked exclusively with LC-MS/MS assays for the past 12 years. Under his guidance, his laboratory and the GLP-compliant Bioanalytical Laboratory have developed and validated LC-MS/MS assays for over 35 drugs and their metabolites from human and rodent plasma and urine, for single drugs in human cerebrospinal fluid and human ascites fluid, and for 10 drugs in cell lysates and tissue homogenates. These quantitative assays have generated key data for several NIH-funded studies, and also for 12 non-NIH-funded clinical studies. **Reed** is a Professor in the Department of Pharmacology, Toxicology and Therapeutics in the University of Kansas Medical School of Medicine. As a professor, **Reed** provides nearly all content and instruction for medical students in Chemotherapy and in PK/PD. His role as a faculty member may readily be seen as an extension of his mission as Executive Director of the CPSR for the Cancer Center.

Correlative Laboratories Director: LaToya Berry is the Director of the Correlative Laboratories. Berry is responsible for the scheduling of personnel and management of all resources and operations for the Correlative Laboratories. She also represents the interests of the Correlative Laboratories in Executive Resource Committee (ERC) meetings and at site initiation visits and kick-off meetings for new trials. Berry worked for five years at a for-profit clinical research facility before coming to KUCC, with her last two years serving as a laboratory manager. She joined the Cancer Center in January 2012 as a Senior Lab Coordinator in the Correlative Laboratories, and in March 2015 she was promoted to her current position as Director of Correlative Laboratories. Berry is an accomplished manager, training and supervising her staff and ensuring that sample acquisition, processing and dispersal is performed according to protocols and in a timely manner. She also represents the Correlative Laboratories at both internal meetings and meetings with sponsors or study monitors. In addition, Berry plays an active role in providing in-service training for nursing staff and CTO staff with regard to research design and procedures.

Major Services & Facilities

The CPSR is structured around three inter-related components: the Correlative Laboratories, the Bioanalytical Laboratory, and the PK/PD Unit. The Correlative Laboratories are located at Westwood (The University of Kansas Health System's outpatient clinical facility) and at The University of Kansas Health System's main campus to support clinical trials involving patients receiving either in-patient or out-patient treatments. The facilities at the KU CRC, however, provide the most complete and efficient clinical pharmacology support for clinical trials. On the second floor of the KU CRC the CPSR has a Correlative Laboratory, the GLP-compliant Bioanalytical Laboratory and the offices and facilities of the PK/PD Unit all within yards of each other and of the patient treatment and examination areas. This close proximity of all functional components of the CPSR provides the most efficient realization of services.

The complete listing of the CPSR facilities, resources, personnel and the services provided are as follows:

Correlative Laboratories: Three laboratories are staffed and operated by the CPSR of the KUCC. Four full-time Correlative Laboratories personnel and a half-time student assistant report directly to Berry. These facilities and their staff members provide GXP-compliant acquisition, processing and storage or shipping of clinical research samples. The three Correlative Laboratories are located near patient treatment areas at the KU CRC, Westwood and at The University of Kansas Health System's main campus. In addition to these three sites, the Correlative Laboratories staff also provides supplies and technical assistance to the Cancer Center community oncology sites and to the affiliated MCA hospital and clinic sites.

The Clinical Laboratory at the KU CRC is located in 2101 KU CRC and consists of 560 sq. ft. of laboratory space with an additional 360 sq. ft. for storage of study kits and other supplies. Major equipment in the laboratory includes three refrigerated benchtop centrifuges and a 6' Class II Biosafety cabinet for processing of patient samples. The lab also contains a monitored refrigerator and monitored freezers at -20°, -40°, and -80°C. The Clinical Laboratory at The University of Kansas Hospital is located in 1540A and provides 280 sq. ft. of workspace. This lab is equipped with one refrigerated and two ambient temperature benchtop centrifuges, and a 2' Class I Biosafety cabinet for sample processing. Monitored storage is available in a

refrigerator/freezer and in a -20° and a -80°C freezer. The Correlative Laboratory located in Room 1107-002 at the Westwood campus provides 576 sq. ft. of lab and storage space, and is equipped with one refrigerated and two ambient temperature benchtop centrifuges, and a 4' Class II Biosafety cabinet for sample processing. Monitored storage is available in a refrigerator/freezer and in a -20° and a -80°C freezer.

These laboratories provide trained staff and equipment for the acquisition, processing, storage and shipment of biological samples generated from clinical studies including blood, urine, ascites fluid and tissue samples. All work is GCP/GLP-compliant. The Correlative Laboratories provide critical support for over 130 cancer clinical trials. The University of Kansas Hospital and the KU CRC Correlative Laboratories each have one full-time laboratory coordinator assigned to maintain and operate the laboratory, whereas two full-time coordinators are assigned to the Correlative Laboratory located at the Westwood campus. Although these laboratory coordinators have primary assignments as noted, all coordinators and a student assistant also provide coverage at any of the three Cancer Center sites and the coordinators also provide support to the community oncology and MCA sites as demanded by daily workflows.

Bioanalytical Laboratory: The Bioanalytical Laboratory at the KU CRC is a GLP-compliant, state-of-the-art facility with expanded LC-MS/MS capabilities for the support of clinical and translational studies. This laboratory is located within 30 yards of the KU CRC Correlative Laboratory and both the patient treatment and procedure rooms at the KU CRC. Currently there are no additional staff members in either the Bioanalytical Laboratory or in the PK/PD Unit, but the increasing workload will support the addition of one full-time staff member in late 2016.

Sample processing and preparation of standards, solvents, and reagents is performed in 2301 KU CRC, a 525 sq. ft. laboratory equipped with a chemical fume hood, a 4' Class II Biosafety cabinet, a refrigerated benchtop centrifuge, an ambient temperature microcentrifuge, a centrifugal vacuum sample concentrator, top-loading, analytical, and microbalances, and monitored storage at 4°, -20°, and -70° C. The analytical lab is in 2305 KU CRC, with a direct connecting doorway from 2301. The 490 sq. ft. analytical lab is equipped with a chemical fume hood, a Millipore Class I water purification system, an absorbance/fluorescence microplate reader and two Waters Xevo TQ-S UPLC-MS/MS systems. The Bioanalytical Laboratory provides analytical support for cancer therapeutic clinical trials, cancer prevention clinical trials and also for a limited number of non-cancer clinical trials. It also can provide analytical support for pre-clinical studies when GLP compliance is required.

The Bioanalytical Laboratory develops, optimizes, validates and applies LC-MS/MS methods to the identification and quantitation of drugs, drug metabolites and other small molecules from clinical samples to generate data for assessment of pharmacokinetics, for compliance or exposure determinations, and for examination of biomarkers of effect. Since its inception the Bioanalytical Laboratory has supported six cancer therapeutics trials and four cancer prevention trials at KUCC, one multi-center cancer therapeutics trial with KUCC as a clinical site and two cancer therapeutics trials for collaborators at other institutions. Currently the Bioanalytical Laboratory also is supporting three cancer prevention trials (smoking cessation) and is developing and validating assays for four additional cancer therapeutics trials.

Pharmacokinetics/Pharmacodynamics (PK/PD) Unit: The mission of the PK/PD Unit is to advise investigators on the incorporation of PK/PD to add value to clinical studies and to guide the experimental design to maximize this value. This includes the optimization of dosing and sampling protocols. Data generated by the Bioanalytical Laboratory or by third parties are used for pharmacokinetic calculations using Phoenix/WinNonlin® software. The PK/PD Unit services also include support for the interpretation of PK and PK/PD results and for the presentation of those results in reports and publications. Since its inception in 2012, the PK/PD Unit has supported nine funded cancer therapeutics trials in the Cancer Center and three funded cancer therapeutics trials at other institutions. The staff also has reviewed draft protocols or provided guidance for the development of 28 cancer clinical trial proposals.

The PK/PD Unit also presents a broad educational program for students and Cancer Center team members. **Reed** controls the content and delivers nearly all PK/PD instruction for medical students at KUMC. In addition, he and his staff introduce pharmacokinetics and pharmacokinetic sampling and as part of New Employee Orientation for the CTO of the Cancer Center. **Reed** has presented PK/PD refreshers to most of the Disease Working Groups in the Cancer Center and has given tutorials to the oncology nursing staff at The University of

Kansas Hospital, the Bone Marrow Transplant Clinic at the Westwood campus and to all study coordinators and project directors in the CTO. He also gave a PK/PD presentation to the post-doctoral fellows in the Department of Cancer Biology and discussed pathways for basic scientists to transition from pre-clinical into translational and clinical research. The overarching goals of these educational activities are to enhance the understanding and appreciation of clinical pharmacology for team members at all levels within the clinical and research enterprises of the Cancer Center, and to make all team members aware of the services and expertise available within the CPSR to guide and assist them in their work.

Quality Control

All procedures in the CPSR components are performed in accordance with internal or study-specific protocols or internal guidance documents, and meet criteria for GXP. All Bioanalytical Laboratory procedures, including batch composition, analytical methods and batch acceptance criteria are performed in accordance with the FDA guidance document on Bioanalytical Method Validation.

Scientific Accomplishments

New Drug Formulation: NanoTax®

This new formulation of paclitaxel was developed at KUCC and tested in a first-in-human clinical trial led by **Williamson** (D3ET). Patients with metastatic ovarian or colorectal cancer received intraperitoneal administration of nanoparticulate paclitaxel (NanoTax®). An LC-MS/MS assay for paclitaxel in plasma and in peritoneal fluid was developed and validated, and serial blood and peritoneal fluid samples were obtained to characterize the local and systemic pharmacokinetics of paclitaxel. It was subsequently determined that this formulation and administration route resulted in very high and sustained exposure in the peritoneal cavity (left panel) with minimal systemic exposure (right panel) (**Williamson**, *Cancer Chemother Pharmacol.*, 2015).

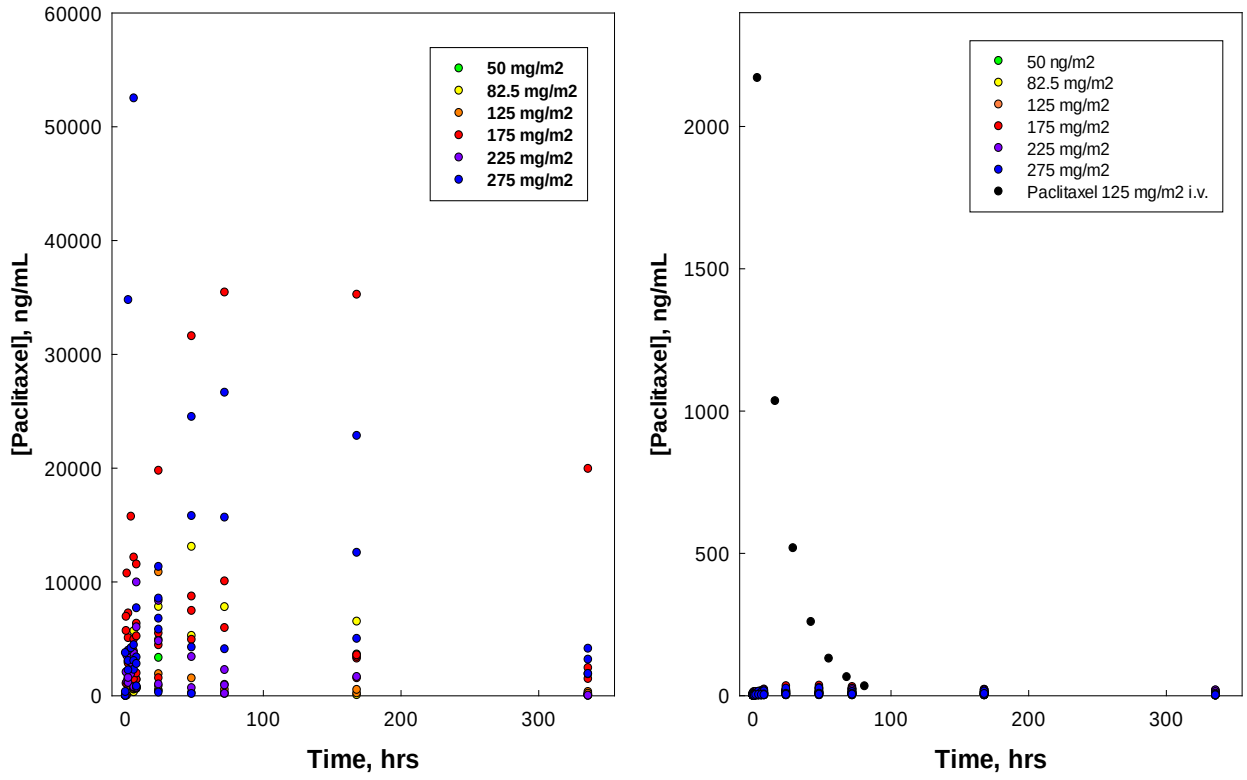


Figure 1. Paclitaxel concentrations in Peritoneal Fluid and Plasma following intraperitoneal NanoTax®
Paclitaxel concentrations were measured in peritoneal fluid (left panel) and plasma (right panel) at times from 0.5 hrs to 14 days after intraperitoneal administration of NanoTax® at doses from 50 – 275 mg/m^2. The right panel also includes data resulting from a 125 mg/m^2 intravenous dose of Cremophor-solubilized paclitaxel for comparison.

Drug Repurposing: Ciclopirox Olamine

This project was initiated by Aaron **Schimmer**, PhD, MD, FRCRC at Princess Margaret Hospital in Toronto, but designed and performed though a collaboration with Schimmer and the Leukemia and Lymphoma Society established by the Associate Director for Translational Research, Scott **Weir**, PharmD, PhD (D3ET). Ciclopirox olamine, an approved topical anti-fungal drug, was found in an *in vitro* screen to have anti-leukemic activity. The drug was reformulated for oral administration and a phase I study was performed in patients with advanced hematologic malignancies. Working closely with the LDOSR, an LC-MS/MS method for the quantification of ciclopirox in rodent plasma was adapted and validated for analysis in human plasma. Serial plasma samples from patients were obtained and analyzed, and the resulting data used to characterize the pharmacokinetics of ciclopirox and its inactive metabolite ciclopirox glucuronide (Table 1). Oral ciclopirox olamine was well-tolerated at daily doses of up to 80 mg/m^2, however about 90% of the drug was converted to an inactive metabolite (Minden, *Amer J Hematol*, 2013). Based on these findings, KUCC has developed and will begin a first-in-human clinical trial this year of a novel ciclopirox pro-drug that should overcome this first-pass effect.

Table 1. Ciclopirox Olamine Pharmacokinetic Parameters by Dose

	Ciclopirox		**Ciclopirox glucuronide**	
Dose	**Cmax, ng/mL**	**AUC (0-6 hrs), hr*ng/mL**	**Cmax, ng/mL**	**AUC (0-6 hrs), hr*ng/mL**
20 mg/m^2	47.6 (47.2, 47.9) n=2	197 n=1	813 (509, 1116) n=2	2097 (1876, 2317) n=2
40 mg/m^2	124 ± 98 (43, 233) n=3	582 (442, 721) n=2	987 ± 240 (711, 1155) n=3	3598 ± 1071 (2942, 4833) n=3
80 mg/m^2	242 ± 125 (97, 418) n=7	637 ± 197 (416, 902) n=6	4908 ± 3494 (2122, 11801) n=7	13374 ± 7617 (4127, 27424) n=7

Where sufficient data are available, results are presented as mean ± SD, minimum and maximum values, and number of patients providing data for the parameter.

Bioanalysis of Tobacco Biomarkers

The Bioanalytical Laboratory has validated UPLC-MS/MS assays for cotinine and 3-hydroxycotinine, for total nicotine equivalents (TNE), and for the carcinogenic tobacco-specific nitrosamine 4-(N-methyl-N-nitrosamino)-1-(3-pyridyl)butan-1-ol (NNAL). Additional assays will be validated for anabasine and anatabine and for 1-hydroxypyrene. These assays have been set up to support multiple smoking cessation studies led by **Ellerbeck** (CCPH), **Nollen** (CCPH), and **Richter** (CCPH). Cotinine and 3-hydroxycotinine have been measured in saliva and urine samples from study subjects, and all other assays have been validated for urine samples. The application of multiple tobacco biomarkers will allow the differentiation between smokers (positive for all analytes), users of smokeless tobacco (negative for 1-hydroxypyrene) and users of nicotine replacement therapies or nicotine e-cigarettes (negative for anatabine, anabasine, and 1-hydroxypyrene). In addition, the potential exposure to and carcinogenic risk from NNAL will be assessed for all subjects. These analyses have previously been performed as a service at a remote bioanalytical laboratory, requiring shipping of samples. The Bioanalytical Laboratory provides the same analyses and quality of service, but with distinct improvements in logistics, sample turnaround time and cost-effectiveness (see **Table 3 in Cost-Effectiveness section**). The addition of these services will support and enhance the research of these and other CCPH members, and also may provide this work as a service to researchers outside of the KU Cancer Center.

Drug-Drug Interactions: Irinotecan and Buparlisib

Irinotecan was used in combination with the PI3 kinase inhibitor buparlisib in a first-in-human study for patients with metastatic colorectal cancer. This multi-investigator trial was led by **Williamson, Godwin,** and **Baranda** (D3ET). Serial plasma samples were obtained and analyzed by UPLC-MS/MS for the determination of irinotecan, the active metabolite SN-38 and the inactive metabolite SN-38 glucuronide. Patients received their first dose of irinotecan and resulting plasma concentrations were used to define the pharmacokinetics of parent and metabolites (left panels). Daily buparlisib was then started, and after three weeks of therapy irinotecan was again administered and plasma samples obtained (right panels). Those results were used to define the steady-state pharmacokinetics of buparlisib and to investigate possible pharmacokinetic interactions between buparlisib and irinotecan. The results of this study defined the MTD for irinotecan and buparlisib in combination, and demonstrated that no significant pharmacokinetic interactions occurred between the two drugs (manuscript submitted).

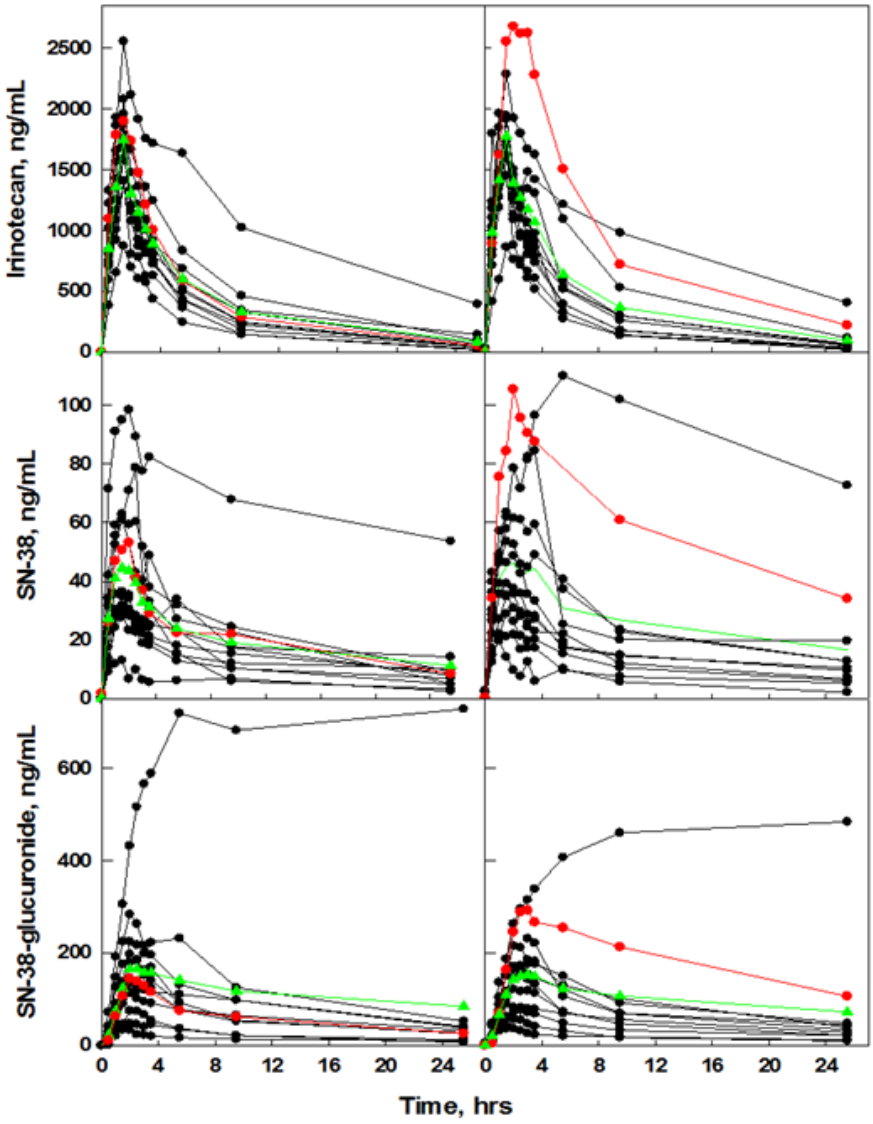


Figure 2. Individual plasma concentration profiles for Irinotecan, SN-38, and SN-38 glucuronide
Left panels present data for irinotecan alone and right panels are from irinotecan infusion in patients after three weeks of daily buparlisib. Individual plasma concentration versus time plots are in black, profiles for one patient who developed cholestatic jaundice prior to the second irinotecan infusion are in red, and the mean concentration profiles for all patients are in green.

Management Structure

Director: Gregory **Reed**, PhD, is the Director of the CPSR. He is responsible for the operation and performance of all three components, and serves as the main contact and spokesperson for the shared resource. Direct supervision and management of the Correlative Laboratories and their staff is delegated to LaToya Berry. **Reed** is responsible for all operations of the Bioanalytical Laboratory and for all functions of the PK/PD Unit. **Reed** is a Professor in the Department of Pharmacology, Toxicology and Therapeutics in the University of Kansas Medical School of Medicine. As professor, **Reed** provides nearly all content and

instruction for medical students in Chemotherapy and in PK/PD. His role as a faculty member may readily be seen as an extension of his mission as head of the CPSR for the Cancer Center.

Correlative Laboratory Director: LaToya Berry is the Director of the Correlative Laboratories. Berry is responsible for the scheduling of personnel and management of all resources and operations for the Correlative Laboratories. Four full-time Correlative Laboratories personnel and a half-time student assistant report directly to Berry. She also represents the interests of the Correlative Laboratories in ERC meetings and at site initiation visits and kick-off meetings for new trials.

Oversight of the CPSR: Reed reports to **Williamson**, the Medical Director of the CTO and the Cancer Center Associate Director for Shared Resources, **Mayo**. In addition, an Internal Advisory Board has been chosen for additional oversight and guidance for this new shared resource (**Table 2**).

Table 2. CPSR Internal Advisory Board

Name	Program	Title
Steven Leeder, PharmD, PhD	D3ET	Pediatric Clinical Pharmacology (Children's Mercy)
Bruce Kimler, PhD	CPS	Professor of Radiation Oncology
Kim Kimminau, PhD	CCPH	Associate Professor of Family Medicine

These three individuals will provide guidance to **Reed** with regard to technical aspects of running the resource, but also with regard to management, coordination with other constituencies in the Cancer Center, and marketing of the services and support offered by this shared resource. Just established, the plan for the IAB is to meet quarterly to review the performance and progress towards goals for the CPSR, and to assess the criteria and resulting fairness of allocation of services and the satisfaction of investigators and sponsors with these services.

Additional guidance is provided through interactions with Scott **Weir**, PharmD, PhD. In his roles as Associate Director for Translational Research and as Program Co-Director for D3ET, and with his experience in new drug development in pharma, **Weir** is well prepared to advise **Reed** to improve the services provided by the CPSR. His contributions both to the development of individual projects and to the broader mission and activities of the CPSR have been extremely valuable.

Operations & Policies

Policies and their implementation for the CPSR are established by **Reed** with input from Berry, and are reviewed by the IAB and by the other Shared Resource directors. Prioritization and scheduling for the Bioanalytical Laboratory is primarily based on a hierarchy of samples, with those from funded, peer-reviewed studies receiving highest priority, followed by non-peer-reviewed funded studies and then samples from unfunded projects. Adjustments can be made based on deadlines for grant submissions, required reports or meeting abstract submissions. In all cases, studies performed by Cancer Center members are the top priority, with cancer-related non-member studies given lower priority. The staff and facilities of the Correlative Laboratories are strictly utilized for clinical trials headed by Cancer Center members. At the current time, the services of the Bioanalytical Laboratory and the PK/PD Unit are not fully utilized by KUCC members, and so these services are provided to non-cancer clinical investigators as well. Currently, non-cancer studies comprise about 10% of the total workload for the Bioanalytical Laboratory and the PK/PD Unit.

Financial policies, including charge schedules, were developed with the assistance from the CTO financial team. The budget and the charge schedules for the CPSR are reviewed annually with the Associate Director for Shared Resources, **Mayo**. The CPSR target is to have the Correlative Laboratories working at about 90% of capacity, allowing 10% staff time for training and lab maintenance, and for the Bioanalytical Laboratory and the PK/PD Unit to be working at about 70% of capacity on direct, study-related activities. This will allow 30% of the staff and instrument time for these components of the CPSR to be used for method development and validation to expand our capabilities and for generation of pilot data to support funding applications for new projects. The financial model supporting the CPSR charge schedule is designed so that when these 90% and 70% utilization rates are reached, the CPSR will be financially self-sufficient based solely on charges for service.

Usage

In calendar year 2015, the CPSR supported 21 KUCC members from all four research programs. The majority of the CPSR users (52%) are from the Drug Discovery, Delivery and Experimental Therapeutics (D3ET) program while 19% are from the Cancer Biology (CB) program, 14% from the Cancer Prevention and Survivorship (CPS) program and 14% from the Cancer Control and Population Health (CCPH) program. **Table 3** describes the breakdown of funded and unfunded users for each program. The majority of CPSR users are funded.

Table 3. 2015 Clinical Pharmacology Shared Resource Users

	CB	CCPH	CPS	D3ET	Total	
Funded	2	3	3	6	14	**67%**
Unfunded	2	0	0	5	7	**33%**
Total	**4**	**3**	**3**	**11**	**21**	
Percentage	**19%**	**14%**	**14%**	**52%**		

Cost-Effectiveness of the CPSR services

Services provided by shared resources must be cost-effective, and the financial model for the charge schedules for the CPSR results in charges that are reasonable and appropriate. Charges for sample procurement, processing and storage or shipping by the Correlative Laboratories are based on the actual costs for supplies and reagents, projected costs for equipment maintenance, calibration, upkeep and personnel costs. Bioanalytical Laboratory costs include tiered charges for both method validation and for sample analysis. All cost estimates are based in part on annual costs for the fixed expenses for operation of the laboratory, including personnel, equipment costs, and service contracts. Proposed method validation and analytical costs are based on supply costs (standards, reagents, sample processing supplies) and the estimated processing and analysis time for samples for each specific assay. Based on these detailed estimates, the actual charges are extended as a tiered charge schedule, with Method Validation provided for either $4500 or $9000 per assay, and individual sample analysis charges for $49, $63 or $84 per sample, based on complexity and material costs for the assay. This tiered charge schedule was requested by the University Accounting Office and was negotiated by **Reed** with the assistance of Cancer Center financial officers. All charge estimates assume a 70% use rate for the two UPLC-MS/MS instruments, allowing 30% of total instrument time for method development and validation, annual service and calibration and possible downtime.

Two examples demonstrate the cost-effectiveness of the Bioanalytical Laboratory. The first is an illustration of relative costs for common tobacco biomarker analyses. The Bioanalytical Laboratory has become the primary analytical site for tobacco biomarkers in urine samples from subjects in several of the Cancer Center's smoking cessation studies. **Table 4** compares our charge schedule to posted charge schedule from the Tobacco Biomarker Laboratory at the University of California at San Francisco Cancer Center (UCSF), the previous provider for these analyses. The CPSR can perform the same assays, with the same validation and quality controls, but clearly provide the same service for a lower charge.

Table 4. UPLC-MS/MS Charges (per sample) for Tobacco Biomarkers

Analysis	Internal	External Academic
Cotinine/3-HC	$84/**$49**	$112/**$74**
Total nicotine equivalents	$130/**$63**	$173/**$95**
NNAL	$130/**$63**	$173/**$95**

Charges for the UCSF tobacco biomarkers service in normal font, KUCC charges in bold font.

A second example comes from a current pharma-sponsored clinical trial being performed at KUCC. The therapy includes an investigational kinase inhibitor. The CPSR proposal included the validation of an UPLC-MS/MS method for quantitation of the drug and the application of that method in-house to analyze the patient samples. The sponsor instead opted to use a contract bioanalytical laboratory. The CPSR proposed a budget

of $77 per sample, including the costs of method validation. The contract laboratory chosen is performing the same analysis for $84 per sample.

One additional feature of our in-house facility that relates to cost-effectiveness is response time for service. The CPSR turnaround time for review and suggestions on new study protocols is currently about five business days. Method validations, in accordance with FDA Guidance on Bioanalytical Method Validation, are usually complete within two weeks, and batches of up to 300 samples usually are analyzed and results reported within two weeks. This prioritization of Cancer Center samples is an important feature of this in-house facility. By way of comparison, the CPSR has waited for up to six months for bioanalytical data on pharma-sponsored studies that required shipping of patient samples to a central laboratory. Such delays are a huge impediment to decision-making and interpretations during a trial, to the timely completion and reporting of trial results and to the ultimate introduction of new therapies into the clinic.

Future Plans

The Correlative Laboratories are the most fully utilized component of the CPSR. This group provides essential services to all Cancer Center trials that require acquisition and processing of research samples from patients. The current workload for the Correlative Laboratories has them working at above 90% of capacity. Although this is the target figure for the financial model for the Correlative Laboratories, the number of clinical trials and the demands on the Correlative Laboratories staff are increasing, particularly in regard to supporting study activities at the community oncology sites and MCA sites. In response, the CPSR expects to add one additional full-time Laboratory Coordinator to handle this increased workload.

The CPSR has actively promoted the services of the Bioanalytical Laboratory and the PK/PD Unit within the Cancer Center, and has strengthened its connections with key groups within the Cancer Center. Bioanalysis and PK/PD services are particularly valuable for Early Phase studies. The recently instituted change in project development within the CTO now ensures that initial drafts of all IITs are sent to **Reed** for review, and specifically to determine if the services of the CPSR can add value to the project. This assistance with project development and design continues with the inclusion of **Reed** as a member of the IIT Steering Committee. The ability to directly discuss with the investigator the potential for CPSR contributions to strengthen a developing study has already led to new IITs being approved and prepared for activation. An additional pipeline for Bioanalytical and PK/PD services has been opened by formalizing ties from the CPSR to the LDOSR and to the Target Acceleration Group (TAG). These groups support and even drive the pre-clinical development of new therapeutics. By formalizing the interactions of the CPSR with these groups, the CPSR can provide assistance as needed with development and application of analytical techniques, and existing techniques and insights from the pre-clinical studies are efficiently shared with the CPSR to facilitate the translation of new therapies from pre-clinical to clinical trials. Four new IIT projects have come to the CPSR through the IIT Steering Committee and the LDOSR/TAG pipelines, with one beginning enrollment in July 2016 and the remaining three on track to begin by early 2017. All are early phase, with Bioanalytical and PK/PD services of the CPSR addressing their primary objectives. In addition to this increased utilization of the CPSR for early phase clinical trials, additional studies from **Nollen** (CCPH) and **Richter** (CCPH) will require Bioanalytical Lab support for measurement of tobacco biomarkers. This increase in sample volume for the Bioanalytical Laboratory will require the addition of a full-time Research Associate for sample processing and LC-MS/MS analysis. The CPSR will be listing an open position, for either a Bachelors or Masters level analytical chemist, and plan to have the position filled early in 2017.

Progress Report Publications

This component has no publications resulting from Cancer Center Support Grant funds.

Protection of Human Subjects – CLINICAL PHARMACOLOGY SHARED RESOURCE

In accordance with federal and institutional regulations, all investigators are required to submit and obtain appropriate IRB review and approval for any proposed human subjects research study. The Clinical Pharmacology Shared Resource does not conduct its own research. Rather, the projects from which any samples are generated, would have IRB approval.

Inclusion of Women & Minorities – CLINICAL PHARMACOLOGY SHARED RESOURCE

In accordance with federal and institutional regulations, any proposed clinical trial would be required to be designed and carried out in a manner sufficient to provide for valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

OMB Number:0925-0001 and 0925-0002
Expiration Date: 10/31/2018

***Study Title:** Clinical Pharmacology Shared Resource- Any human subject study funded by CCSG funds will be required to submit a PHS inclusion enrollment report.

***Delayed Onset Study?** ☑ Yes ❑ No

If study is not delayed onset, the following selections are required:

Enrollment Type ❑ Planned ❑ Cumulative (Actual)

Using an Existing Dataset or Resource ❑ Yes ❑ No

Enrollment Location ❑ Domestic ❑ Foreign

Clinical Trial ❑ Yes ❑ No

NIH-Defined Phase III Clinical Trial ❑ Yes ❑ No

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/Alaska Native										
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More than One Race										
Unknown or Not Reported										
Total										

Inclusion of Children – CLINICAL PHARMACOLOGY SHARED RESOURCE

In accordance with federal and institutional regulations, any proposed clinical trial would be required to be developed to support the treatment modalities for disorders and conditions that affect adults and may also affect children.

Clinical Pharmacology Shared Resource – References Cited

Williamson SK, Johnson GA, Maulhardt HA, Moore KM, McMeekin DS, Schulz TK, **Reed** GA, Roby KF, **Mackay** CB, Smith HJ, **Weir** SJ, **Wick** JA, Markman M, diZerega GS, **Baltezor** MJ, Espinosa J, Decedue CJ. A phase I study of intraperitoneal nanoparticulate paclitaxel (Nanotax(R)) in patients with peritoneal malignancies. Cancer chemotherapy and pharmacology. 2015;75(5):1075-87. Epub 2015/04/23. doi: 10.1007/s00280-015-2737-4. PubMed PMID: 25898813; PubMed Central PMCID: PMCPmc4506131.

Minden MD, Hogge DE, **Weir** SJ, Kasper J, Webster DA, Patton L, Jitkova Y, Hurren R, Gronda M, Goard CA, Rajewski LG, Haslam JL, Heppert KE, **Schorno** K, Chang H, Brandwein JM, Gupta V, Schuh AC, Trudel S, Yee KW, **Reed** GA, **Schimmer** AD. Oral ciclopirox olamine displays biological activity in a phase I study in patients with advanced hematologic malignancies. American journal of hematology. 2014;89(4):363-8. Epub 2013/11/26. doi: 10.1002/ajh.23640. PubMed PMID: 24273151.

Baranda JC, **Reed** GA, **Williamson** SK, Mackay CB, Scott JN, Pessetto ZY, **Perez** RP, Balmaceda JB, **Godwin** AK. First human trial of the combination of irinotecan and buparlisib in previously treated patients with metastatic colorectal cancer. *Submitted for publication*.

Resource Sharing Plan

The University of Kansas Cancer Center (KUCC) and its scientific community understands its responsibility to comply with the instructions for the Resource Sharing Plans provided within the SF 424 (R&R) Application General Instructions and Supplemental Grant Application Instructions. When resources are developed with NIH funds via this Cancer Center Support Grant P30 mechanism, KUCC will ensure findings are made readily available to the NIH and the scientific community in a timely manner.

Data Sharing Plan

KUCC will adhere to the Final NIH Statement on Sharing Research Data and refer to the National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research. KUCC encourages the free flow of information and ideas while recognizing the timeliness of data sharing, the rights and privacy of human subjects and issues related to proprietary data. KUCC encourages data documentation, using a data-sharing agreement and selecting an appropriate method for sharing; considering the sensitivity of the data, the size of the dataset and the volume of requests anticipated.

Additionally, KUCC encourages any user of a CCSG-supported shared resource to acknowledge the source of data upon which their manuscript is based either in the Acknowledgments section or with authorship on the paper. Furthermore, any research project that received direct cost support from the CCSG is encouraged to cite the P30 CA168524. In both cases, citing the P30 CA168524 grant number and then being compliant with the NIH Public Access Policy is required.

Sharing Model Organisms

In the event that a model organism is developed, KUCC will comply with the NIH Policy on Sharing of Model Organisms for Biomedical Research. KUCC will work with the NIH/NCI to share and disseminate the critical model organism in a timely manner.

Genome Wide Associate Studies

When applicable, KUCC will comply with the NIH Genomic Data Sharing Policy. KUCC supports the sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. All research studies funded through the CCSG involving genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data will be submitted in a timely manner.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 076248616

Legal Name*: University of Kansas Center for Research, Inc.
Department:
Division:
Street1*: 2385 Irving Hill Road
Street2: Youngberg Hall
City*: Lawrence
County: Douglas
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66045-7568

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Alicia		Reed	MAS

Position/Title: Interim Assistant Vice Chancellor
Street1*: Youngberg Hall
Street2: 2385 Irving Hill Road
City*: Lawrence
County:
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66045-7568
Phone Number*: 785-864-3441 Fax Number: 785-864-5025 Email: kures@ku.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofit Organization

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Lead Development & Optimization Shared Resource

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2017	06/30/2022

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Center for Research, Inc.
Duns Number:	076248616
Street1*:	2385 Irving Hill Road
Street2:	Youngberg Hall
City*:	Lawrence
County:	Douglas
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66045-7568
Project/Performance Site Congressional District*:	KS-002

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ❍ **Yes** ● **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ❍ No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ● **Yes** ❍ **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number A3339-01

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	LDOSR_Project_Summary_final1019616605.pdf
8. Project Narrative*	
9. Bibliography & References Cited	LDOSR_ReferencesCited_final1019616606.pdf
10.Facilities & Other Resources	LDOSR_Facilities_Final1019616603.pdf
11.Equipment	
12. Other Attachments	LDOSR_OtherAttachments_final1019616604.pdf

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Lead Development and Optimization Shared Resource – Project Summary

The Lead Development and Optimization Shared Resource (LDOSR) is a University of Kansas Cancer Center (KUCC) shared resource composed of three functions: 1) High Throughput Screening (HTS); 2) Medicinal Chemistry (MC); and 3) the Biotechnology, Innovation and Optimization Center (BIOC). Collectively, these three functions allow the LDOSR to accelerate projects from early method development around cancer pathways or targets, through high throughput screening, compound hit prioritization, secondary *in vitro* confirmatory assays, medicinal chemistry optimization, *in vitro* pharmacology testing, *in vivo* pharmacokinetics and drug delivery formulations for *in vivo* preclinical proof-of-concept testing.

The LDOSR has modified its composition and activities over the past four years in order to provide the best possible support to KUCC members. The Preclinical Proof of Concept (PPOC) service was eliminated from the LDOSR at the end of 2012 because many KUCC members had similar functionality within their own laboratories. Furthermore, it was realized that the LDOSR would be enhanced by a dedicated medicinal chemistry expert. Therefore, Frank **Schoenen** joined the LDOSR to provide medicinal chemistry optimization services.

In 2014, the LDOSR formed a project management service known as the Target Acceleration Group (TAG). TAG aims to accelerate projects from early method development around cancer pathways or targets and more seamlessly move projects between HTS, Medicinal Chemistry and the BIOC. TAG helps KUCC members navigate the drug discovery, delivery and development process more efficiently.

Lead Development and Optimization Shared Resource – Facilities and Other Resources

The following laboratories located on the KU Lawrence campus are available as fee-for-service or collaborative effort to support the LDOSR probe and drug development efforts.

CMLDC Synthesis Core Lab: These labs, Directed by Thomas Prisinzano, Chair of the Department of Medicinal Chemistry, include approximately 2300 square feet, comprising two-thirds fixed lab space and one-third flexible lab space with overhead utility service which accommodates 14 eight-foot fume hoods. In addition to providing facilities for traditional organic synthesis, this facility provides the capabilities required to synthesize compound sets in the 6 to 192 compound range using high-throughput methods.

CMLDC Analysis and Purification Lab: This laboratory, managed by Mr. Benjamin Neuenswander, occupies approximately 600 square feet. This is a flexible lab space with overhead utility service and a single 4-ft fume hood. Reverse phase high performance liquid chromatography using ultraviolet/visible absorption spectroscopy and mass spectrometry detection systems are available for analytical-scale pre-purification and post-purification analysis, and preparative-scale purification, in a high-throughput fashion.

CMLDC Compound Management Lab: This space, managed by Benjamin Neuenswander, occupies approximately 600 square feet. This is a flexible lab space with overhead utility service and a single 4-foot fume hood. This laboratory permits the weighing, liquid-handling, evaporation, lyophilization, compound sample organization, and storage of compound libraries required to prepare compounds for delivery to biological collaborators.

Computer: All CMLDC labs and offices have outlets on benches and in office areas (approximately 1 per 4 linear feet) and the building also has Wi-Fi capabilities. Most researchers own personal computers, and 16 computers are available in the office areas and labs, as well, and these are loaded with standard word/data processing programs (Office, Adobe) and chemistry drawing/visualization programs (ChemOffice).

The KU NMR Laboratory: directed by Justin Douglas, has state-of-the-art NMR facilities that have recently undergone major upgrades. A Bruker Avance 800 MHz instrument was installed in 2004 in the Structural Biology Center, with a cold probe (cryoprobe). Two Bruker DRX-400's (with broadband probes) are also in the SBC and available for routine hands-on analyses.

The Mass Spectrometry Laboratory (MSL): located in Malott Hall on the KU main campus (within a few minutes driving-distance of the CMLDC) is also available for use as necessary. The MSL contains six mass spectrometers: a Micromass Ultima LC-MS with a triple quadrupole analyzer, a Micromass Q-Tof2 quadrupole time of flight tandem instrument, a VG Autospec-Q tandem sector hybrid instrument, a VG ZAB high resolution double-focusing instrument, and two Nermag quadrupole instruments. The Director, Dr. Todd D. Williams, assists researchers with the design and execution of mass spectrometry experiments.

The KU X-ray Crystallography Laboratory: directed by Victor Day, PhD, is located within the SBC. This lab uses diffraction methods to determine high-precision three-dimensional crystal structures of small molecules and to identify polycrystalline materials. Single crystals are studied with molybdenum radiation using a Bruker SMART APEX diffractometer equipped with a charge-coupled device (CCD) area detector and an Oxford Cryostream low temperature device. Final structural results can usually be obtained within 24 hours of the start of data collection.

Molecular Graphics and Modeling Lab: Directed by Justin Douglas**.** Molecular modeling involves computer simulations of the structure and properties of chemical and biomolecular systems. Interactive graphics and visualization tools help users to construct and submit such simulations, and to analyze complex, often multidimensional, results. The following software is available:

- SYBYL suite of software, including the main analytical tools, subsidiary programs including VolSurf, FlexE, FlexX, FlexX-Pharm, CScore, UNITY, CombiLibMaker, DiverseSolutions, OptDesign, Selector, QSAR/CoMFA and Biopolymer
- Numerous 3D virtual chemical libraries including ChemNavigator (26+ million compounds), PubChem small molecule collection (12+ million compounds), ChemDiv, ChemBridge, Maybridge, NCI, and others

- Modeling software including AutoDock, Dock, AMBER, and CHARMm, MODELLER, and Gaussian 03
- Chemical informatics software includes the entire JChem suite (JChem Cartridge, Marvin, Instant JChem, Calculator Plug-ins, Screen, JKlustor, Reactor, Fragmenter, and Standardizer)
- Toxicology and metabolic profiling software such as DEREK and METEOR;
- In-house developed software suites, including BRCD and KU-COMB.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Michael Middle Name J Last Name*: Baltezor Suffix: PhD

Position/Title*: Director
Organization Name*: University of Kansas Center for Research, Inc.
Department: Biotech Innovation & Optim Ctr
Division:
Street1*: McCollum Laboratory
Street2: 2095 Constant Avenue
City*: Lawrence
County: Douglas
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66045-7568

Phone Number*: 785-864-1040 Fax Number:

E-Mail*: mbaltezor@ku.edu

Credential, e.g., agency login: MBALTEZOR

Project Role*: Other (Specify) Other Project Role Category: Core Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Baltezor_Bio_CCSG1018883928.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Anuradha Middle Name Last Name*: Roy Suffix:

Position/Title*: Research Lab Director
Organization Name*: University of Kansas
Department: High Throughput Screening
Division: Shankel Struct Biology Ctr
Street1*: 2034 Becker Drive
Street2:
City*: Lawrence
County: Douglas
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66047-3761

Phone Number*: 785-864-1709 Fax Number:

E-Mail*: anuroy@ku.edu

Credential, e.g., agency login: ANUROY

Project Role*: Other (Specify) Other Project Role Category: HTC Manager

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Roy_A_Bio_CCSG1019601590.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Frank Middle Name J. Last Name*: Schoenen Suffix: PhD

Position/Title*: Associate Research Professor
Organization Name*: University of Kansas
Department: Higuchi Biosciences Center
Division:
Street1*: Shankel Structural Biology Center
Street2: 2034 Becker Drive
City*: Lawrence
County: Douglas
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66047-3761

Phone Number*: 785-864-1719 Fax Number:

E-Mail*: schoenen@ku.edu

Credential, e.g., agency login: FSCHOENEN

Project Role*: Other (Specify) Other Project Role Category: Mgr Med Chem

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Schoenen_Bio_CCSG1019601591.pdf

Attach Current & Pending Support: File Name:

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ❍ Yes ❍ No

*Agency-Defined Phase III Clinical Trial? ❍ Yes ❍ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ● Yes ❍ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

● Yes ❍ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

❍ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator / Change of Institution Section

❑ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	LDOSR_SpecificAims_final1019616608.pdf
3. Research Strategy*	LDOSR_Research_Strategy_final1019754785.pdf
4. Progress Report Publication List	Progress_Report_Publications_Blank1019754749.pdf
Human Subjects Section	
5. Protection of Human Subjects	
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	
8. Inclusion of Children	
Other Research Plan Section	
9. Vertebrate Animals	Vertebrate_Animals___LDOSR1019973969.pdf
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	
14. Resource Sharing Plan(s)	Resource_Sharing_Plan__Generic1019799857.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Lead Development and Optimization Shared Resource – Specific Aims

Specific Aim 1. Provide expertise in high throughput screening, medicinal chemistry and drug delivery in an integrated manner or on a standalone basis to KUCC researchers based on their specific project activities. Utilize the Target Acceleration Group (TAG) to work with KUCC investigators and LDOSR scientists to accelerate projects from early method development around cancer pathways or targets and more seamlessly move projects between HTS, Medicinal Chemistry and the BIOC. Facilitate access to the KUCC Clinical Pharmacology Shared Resource when needed. Provide assistance to KUCC members to design and implement research studies that focus on generating the most critical and scientifically important data to reach *in vivo* proof of concept as quickly and cost-effectively as possible. Provide project management expertise to track the progress of projects versus the expected project timeline.

Specific Aim 2. Provide integrated consulting at no cost to KUCC investigators for the purpose of designing more complete and achievable research plans in grant submissions.

Specific Aim 3. HTS will provide method development around biochemical, biophysical or phenotypic screens; assay optimization for HTS adoption and assay validation; large compound library high throughput screening; hit identification, confirmation and prioritization.

Specific Aim 4. HTS will continue to integrate LESTR (Laboratory for Early Translation Research) activities and pursue sources of funding to support new projects from KUCC investigators.

Specific Aim 5. Medicinal Chemistry will expand access to synthesis laboratory capability by both expanding the use of existing facilities and access to synthetic chemists at KU Lawrence and by establishing medicinal chemistry laboratory capability within KUCC at KUMC.

Specific Aim 6. BIOC will continue to offer drug delivery services, including, bioanalytical method development, *in vitro* pharmacology testing, *in vivo* pharmacokinetic and tissue distribution testing, dosage form development, compound solubility and stability enhancement, drug-substance and dosage-form analysis.

Lead Development and Optimization Shared Resource – Research Strategy

Response to Previous Critique

The Lead Development and Optimization Shared Resource (LDOSR) received an overall merit score of "Outstanding to Excellent" with very few criticisms identified. Further comment is provided for the two initial concerns that were included in the NCI review report.

Areas for Improvement	Response
Reviewer: *"An initial concern was that approximately 65% of the usage (as reported in the application for 2010), was by two Cancer Center investigators (50% by* ***Weir*** *and 15% by* ***Blagg****); although, there were 33 Cancer Center (users). At the site visit,* ***Baltezor*** *presented usage for 2011, which showed that the usage by* ***Weir*** *decreased to 19% and* ***Blagg's*** *usage decreased to 5.5% of total facility usage in 2011.* ***Baltezor*** *explained that* ***Weir*** *has multiple funded projects with different collaborators, but all of the projects were credited to* ***Weir*** *because he was the investigator in the collaborative team directly interacting with the shared resource. In addition,* ***Baltezor*** *explained that most projects are quite expensive and therefore usage is strongly affected by the investigators ability to secure funding; also, usage by specific investigators can fluctuate greatly in different years, a point supported by the differences in usage between 2010 and 2011. Considering all of these issues together, overall the breath of utilization is considered reasonable."*	**Response:** The LDOSR has carefully monitored the usage each year since 2010. The top two users for 2012 were Ray **Perez** (16.5%) and Kathy **Roby** (8.3%); for 2013 were Ray **Perez** (14.4%) and Scott **Weir** (13.2%); for 2014 were Scott **Weir** (19.1%) and Andrew **Godwin** (7.9%) and for 2015 were Scott **Weir** (22.0%) and Shrikant **Anant** (11.3%). Also, the number of KUCC users has increased substantially from 33 in 2010 to 26 in 2011 to 36 in 2012 to 41 in 2013 to 54 in 2014 to 38 in 2015. Usage is heavily influenced by the size of the projects and the availability of funding.
Reviewer: *"Another initial concern was that efforts within this resource may not be well coordinated across campuses. However, at the site visit,* ***Baltezor*** *indicated that the leaders of the individual components of this shared resource meet frequently; there is a management team that guides projects through the process and assists with grant preparation; and the two leaders with shared resource laboratories at KU Lawrence also have offices at KUCC and spend significant time each week on both campuses. This clarification helped to alleviate the initial concern".*	**Response:** The leaders of the LDOSR laboratories continue to meet frequently with investigators on both the KU Lawrence and KUMC campuses. With an average of 67% of our capacity used by KUCC investigators and the majority of the KUCC members based at KUMC, the LDOSR leaders are in frequent meetings, telephone conversations and email communication with investigators on both campuses. The formation of the Target Acceleration Group (TAG) in late 2014 has increased the number of meetings involving all the disciplines within LDOSR.

Overview

The LDOSR is a University of Kansas Cancer Center (KUCC) shared resource composed of three functions: 1) High Throughput Screening (HTS); 2) Medicinal Chemistry (MC); and 3) the Biotechnology, Innovation and Optimization Center (BIOC). Collectively, these three functions allow the LDOSR to accelerate projects from early method development around cancer pathways or targets, through high throughput screening, compound hit prioritization, secondary *in vitro* confirmatory assays, medicinal chemistry optimization, *in vitro* pharmacology testing, *in vivo* pharmacokinetics and drug delivery formulations for *in vivo* preclinical proof-of-concept testing.

In 2014, the LDOSR and KUCC leadership organized the Target Acceleration Group (TAG) to help facilitate basic and clinical scientific interactions. The TAG aims to accelerate KUCC member projects around an identified cancer target, through all three functions of the LDOSR: HTS, MC and BIOC. The TAG is made up of a multidisciplinary group with extensive pharmaceutical industry experience, including **Weir** (D3ET) Associate Director for Translational Research and D3ET co-leader; Mike **Baltezor**, PhD (D3ET), Director, LDOSR; Melinda Broward (TAG Project Management); Anu **Roy**, PhD (D3ET) Manager, High Throughput Screening; and Frank **Schoenen** (D3ET) Manager, Medicinal Chemistry. This group provides a "critical mass" of scientific expertise, centralized access to information and resources, coordination across shared resources, fosters intra-programmatic, inter-programmatic and inter-NCI center collaborations, and is the genesis for creation of multidisciplinary, multi-organizational teams to advance projects from the bench to the bedside.

Goals

Many of the KUCC biologists and physicians that are conducting cancer research have limited expertise in, or don't have direct access to the instrumentation required for, high throughput screening, medicinal chemistry and drug formulation. Therefore, the LDOSR's primary goal is to provide expertise and the physical facilities / instrumentation in an integrated manner to assist KUCC members to move their research forward and generate information needed for grant applications and to achieve critical project milestones.

Qualifications

Leadership

Michael J. **Baltezor**, PhD, is Director of the LDOSR and provides coordination of the efforts across the three functions within the LDOSR. **Baltezor** is also the manager of the BIOC. He is a member of the D3ET research program. **Baltezor** has over 35 years of experience in new product development in the pharmaceutical, medical products and pharmaceutical contract services businesses. During this time, **Baltezor** has worked on a broad spectrum of drugs and dosage forms including tablets, capsules, oral liquids, injectable solutions and topical products. **Baltezor** contributes to the submission of research grants internal to the BIOC, as well as, grants which support KUCC members and nonmembers and is responsible for ensuring LDOSR and BIOC activities are completely integrated with KUCC.

Anuradha **Roy**, PhD, is the manager of the HTS laboratory and is responsible for the HTS activities. She is a member of the D3ET research program. **Roy** has approximately 23 years of HTS assay and drug development experience in both academic and biotech industrial laboratories. She manages the day-to-day activities of the HTS laboratory including the development of new technologies, execution of the high throughput screens, personnel management and assessment of new technologies for in-house use. She has the responsibility to ensure quality control, and that the screens are executed to the predetermined and agreed-upon standards. **Roy** assists investigators and provides expertise in HTS assay development and lead optimization.

Frank **Schoenen**, PhD, is the manager of the Medicinal Chemistry (MC) function which was added to the LDOSR in 2015. He is a member of the D3ET research program. Trained as a synthetic organic chemist, **Schoenen** has 15 years' pharmaceutical industry experience as a medicinal chemist working in inflammation and cancer therapeutics and high-throughput chemistry at the early stages of drug discovery. In 2005, **Schoenen** joined the University of Kansas Chemical Methodologies and Library Development Center (KU CMLD) as the Associate Director for the Administrative Core and the Director for the Synthesis Core, where he was responsible for imagining, creating, and operating high-functioning compound-library construction, analysis & purification and directing the synthesis and distribution of thousands of compounds to academic, government and private-sector biological collaborators throughout the world. In 2008 he became Associate Director, Project Manager and Chemistry Team Leader for the KU Specialized Chemistry Center (KU SCC), a center funded by the National Institutes of Health (NIH) Molecular Libraries Probe Production Centers Network (MLPCN) to support synthesis and medicinal chemistry aspects of hit-to-probe optimization. In these roles, **Schoenen** provided scientific leadership and management for a diverse portfolio of over 40 MLPCN projects leading to 23 probe compounds.

Staff

High Throughput Screening		
Researcher / Title	**Degree / Yrs. Exp.**	**Scientific expertise**
Peter McDonald Research Associate Senior	PhD 6 years	High content screening, siRNA screening, cell-based assays, data analysis
Coral Boyd Research Assistant	MS 2 years	Ion channel drug discovery, label-free drug discovery, automation specialist, data analysis
Melinda Broward Project Director	MS 31 years	Project management HTS collaborations and finances. Expertise in HTS ADME screening, Toxicology, *In Vivo* & *In Vitro* ADME, Pharmacology Efficacy Models, Analytical and Bioanalytical Method Development
Research Associate	MS or BS	Open Position – Recruiting

Medicinal Chemistry		
Open Position	PhD	Recruiting

Biotechnology, Innovation and Optimization Center		
Researcher / Title	**Degree / Yrs. Exp.**	**Scientific expertise**
John Haslam Research Professor	PhD 45 years	Novel drug delivery, drug solubilization, formulation development, pharmaceutical chemistry and preformulation
Lian Rajewski Research Professor	PhD 19 years	Formulation development, preformulation, pharmaceutical chemistry, novel drug delivery and drug solubilization
Karl Schorno Research Associate	PhD 45 years	Development, validation and implementation of bio-analytical methods with LC/MS/MS
Kathy Heppert Sr. Research Asst.	MS 21 years	Analytical chemistry for small and large molecules, development, validation and implementation of chromatographic methods
Jessica Wolzen Sr. Research Asst.	BS 15 years	Analytical chemistry for small and large molecules, development, validation and implementation of chromatographic methods.
William McGuiness Research Assistant	MS 22 years	Expertise in animal handling, dosing and biological sample collection and preparation
Lanaea Heine Senior Coordinator	BS 25 years	Management of laboratory and financial operations
Research Associate	PhD	Open Position

The staff at the BIOC (eight people) is a mixture of formulators, analytical and bio-analytical chemists, and preclinical/pharmacokinetic specialists with many years of pharma industry, CRO and academic research experience. Approximately half of the staff have PhD degrees and the remaining half have either MS or BS/BA degrees. The mix of expertise, experience and equipment provide for a unique capability and the ability to handle projects quickly and efficiently.

Major Services and Facilities
A map of the LDOSR facilities can be found in the Overall Facilities and Resources section.

The **High Throughput Screening Laboratory** (HTS) provides researchers with high throughput technologies and compound libraries to assist in identifying biological probes and to provide hits and leads for drug discovery. High throughput screening of large chemical libraries of compounds is a proven way to identify novel chemical entities that target a biological system of interest. In order to have this technology available to biomedical researchers in Kansas and beyond, the HTS laboratory was established in 2002 at the University of Kansas, Lawrence with support from a NIH COBRE grant, the State of Kansas and KU. There are no other HTS facilities within a 250 mile radius of KUCC member laboratories. KU-HTS is a state-of-the-art facility dedicated to providing exceptional services in advancing drug discovery research initiatives, as well as assistance in preparing grant applications. HTS personnel have extensive experience in executing biochemical, cell-based, siRNA as well as high-content screening campaigns against a plethora of target classes. KU-HTS is a fee-for-service facility dedicated to providing exceptional quality services at the lowest cost. HTS staff partners with the investigators collaboratively to expedite their drug discovery efforts.

The 4500 sq. ft. HTS Laboratory is housed in the Structural Biology Center on the KU Lawrence West Campus. The main laboratory has six different liquid handlers, eight bulk reagent dispensers and eight microplate readers to facilitate screening of compounds in a high-throughput mode. Several common signal detection technologies are also available, including UV-visible light absorbance, fluorescence, time-resolved fluorescence, FRET, TR-FRET, BRET, fluorescence polarization, AlphaScreen, Label-Free, radiometric and luminescence. The laboratory is fully equipped for conducting, cell-based, biochemical and siRNA assays and screens. There are two separate cell culture laboratories within the HTS main laboratory that house five BSL2 cell culture hoods and six Thermo Forma Series II CO_2 Incubators. Two separate rooms, with a total of 500 sq. ft. of space house the ImagXpress Micro and BD Pathway, the two high-content imaging systems. The personnel have access to Medline, Current Contents, CAB, PubMed, PubChem and Biosis. The laboratories have access to SciFinder and other on-line capabilities for database searches. Compound libraries are stored in a state-of-the-art Nexus Labstore compound management system for compound storage and retrieval. The HTS office space (740 sq. ft.) houses the office of the Manager, and also has office space available for 10 researchers and a conference room. HTS staff has individual desks, bookcases, filing cabinets and internet connections in rooms separated from the laboratories. HTS currently has three people on staff plus an open position. Melinda Broward provides TAG project management and administrative support for the group.

The HTS-ready assays can be used to screen the KU-HTS compound collection of approximately 296,672 compounds. The compound library was obtained from various sources (**Table 1**). Chemoinformatics analysis has shown the presence of 61,980 scaffolds across the entire collection. KU HTS charges for compound usage and approximately 50-80% of these charges are placed in a designated compound library account to periodically purchase compounds to update and expand the library. These KU-HTS libraries have been used extensively in screening various targets and have resulted in valuable hits. The NCI 60 panel is available to KUCC members to identify and characterize novel compounds (natural products or synthetic) for growth inhibition anticancer activity across the entire panel. Human tumor cell lines that are represented include breast, brain, colon, kidney, leukemia, lung and prostate. The individual cell lines are also available to expand and for HTS to perform a primary cell line screen against the selected compound libraries as well as secondary screening assays or counter screens.

Table 1

Library	Description
Repurposing Collection	Collection of 5,292 FDA approved compounds derived from the Prestwick, Enzo, TimTec, Selleck and BioFocus NIH clinical collection. All of the FDA-approved compounds have well-characterized bioactivity, safety and bioavailability and hits from this set of compounds ensure accelerated drug development and optimization processes.
Various Diversity Sets	(A) 5,197 unique compounds, not commercially available, from the KU CMLD Center (Chemical Methodology and Library Development Center) synthesized within the KU CMLD Center Synthesis Core as well as ~200 legacy compounds synthesized by the KU Medicinal Chemistry Department staff; (B) ChemBridge Library (43,736 compounds); (C) ChemDiv Library (56,232 compounds); (D) Life Chemicals Inc. Diversity Subset (15,040 compounds); and (E) Orthogonally Compressed Library (OCL) collection of 104,000 compounds from The Lankenau Institute for Medical Research Chemical Genomics Center. Importantly, chemoinformatics analysis has demonstrated that at least 45,000 of the 104,000 compounds from the LIMR are unique to the collection and are not represented in ChemBridge and ChemDiv diversity sets.
Bioactives Compound	A collection of 1,902 structurally diverse and cell permeable bioactive compounds and peptides which include inhibitors, natural products and chemotherapeutic agents.
GreenPharma Natural product	A collection of 480 purified, chemically diverse and drug-like compounds, a subset of a much larger set of 150,000 natural compound structures. Compounds like amino acids, peptides, nucleic acids, long fatty chains and metals were discarded and different phytochemical families were selected carefully in order to have as many family representatives as possible.
ChemDiv Central Nervous System	A set of 26,136 compounds that can cross the blood-brain barrier.
Anti-Infectives (TimTec)	A set that includes 960 low molecular weight, drug-like molecules with scaffolds found in antiseptic agents with anti-bacterial (Gram+ve and Gram-ve), anti-fungoid, anti-microbial activities.
ChemDiv Beyond the Flatland	A collection of 33,864 compounds with sp^3-hybridized carbon scaffolds
Life Natural Product	A collection of 8,128 compounds with amenable scaffold synthesis.
NCI 60	Human tumor cell line panel

The **Medicinal Chemistry** function is led by Frank **Schoenen**. Medicinal chemistry activities were a critical missing component between HTS and BIOC to facilitate hit-to-probe and probe-to-lead optimization activities. **Schoenen** brings expertise to consultations and collaborations with KUCC members including compound screening collection building, chemical tools for biological target identification, compound identity and purity quality control, identification of Pan Assay Interference and PubChem Promiscuity compounds, compound physicochemical property assessment, compound and biological data deposition to PubChem, compound scale-up for *in vivo* studies, identification of commercial sources for compound sample purchase, identification of contract research organizations for compound scale-up, hit confirmation and prioritization, hit-to-probe optimization, probe-to-lead optimization, lead-to-preclinical-candidate optimization and preclinical-candidate to clinical-candidate optimization.

In June 2008, the KU CMLD moved into new laboratories in the Structural Biology Center (SBC) on the KU Lawrence West Campus. **Schoenen** operates within the KU CMLD, directed by Thomas **Prisinzano** (D3ET), which has all of the laboratory space required to support the medicinal chemistry activities of the LDOSR. In addition to the facilities available to the **Schoenen** team for synthesis and medicinal chemistry, the KU CMLD contains a number of core laboratories which perform specialized functions, and all of these facilities are available for medicinal chemistry activities, if needed. **Schoenen's** office is located adjacent to the KU CMLD labs in the SBC building.

The **Biotechnology Innovation and Optimization Center** (BIOC) is approximately 5,000 sq. ft. composed of seven laboratory areas and associated supporting office space on two floors of McCollum Laboratories and in the Higuchi Laboratories animal facility on the KU Lawrence West Campus. The BIOC has provided drug delivery, solubilization and stabilization services to researchers since its inception in 1989 as the Center for Drug Delivery Research. Additional services include analytical chemistry and bio-analytical method development, physical /chemical characterization of drug candidates, preparation of dose formulations, animal pharmacokinetic studies and early-stage pharmacology testing. The BIOC conducts development projects for solid oral, liquid oral, topical and injectable (liquid and lyophilized) dosage forms, including development of pediatric dosage forms.

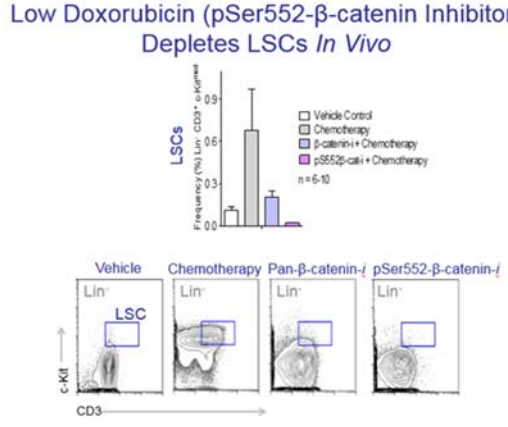
More specifically, the BIOC conducts solubility and stability screening of compounds in pH=7.4 PBS, 0.1 N HCl and a representative analytical mobile phase (50:50 acetonitrile:water) using a UV analysis. If needed, HPLC can be used for the analysis of the stability screening samples. The saturated solutions used for solubility testing are diluted to avoid precipitation problems and these diluted solutions are evaluated for the 48 hour stability evaluations. Additional pharmacology screening testing including hepatic microsomal stability, plasma stability and plasma protein binding are all conducted using validated LCMSMS bio-analytical testing. These same LCMSMS bio-analytical methods are applied for the analysis of blood and tissue samples obtained from pharmacokinetic studies. The BIOC routinely conducts both PK screening studies and more comprehensive PK studies with mice and rats. Analysis of tissue extracts including brain tissue for blood-brain-barrier penetration studies is also available. Plasma data is evaluated using WinNonLin software for the determination of routine pharmacokinetic parameters.

The major instrumentation and equipment includes fully equipped analytical laboratories containing four Shimadzu HPLC systems with UV, fluorescence, diode array and/or evaporative light scattering detectors. Additional analytical/bio-analytical equipment includes one each of: Shimadzu GC, Perkin Elmer differential scanning calorimeter, Perkin Elmer TGA7 thermogravimetric analyzer, Varian UV/Vis spectrophotometer and two Applied Biosystems Sciex 3200 LC-MS/MS systems. In the formulation laboratories, the BIOC has one each of: Glatt Air Technologies UniGlatt fluid bed coater/drier, Retsch mill, Turbula shaker/mixer, Stokes instrumented tablet press, NicaSystem AB extruder, Luwa Model QJ-320 maurumerizer, Vitris Genesis tray lyophilizer and several isolation glove boxes for hazardous chemicals.

Scientific Accomplishments

Low Dose Daunorubicin for Leukemia Patients

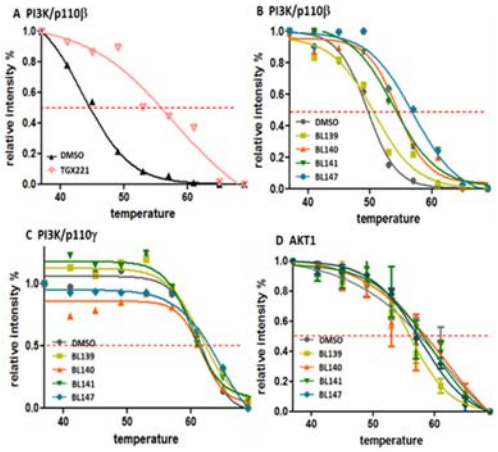
Linheng **Li** (CB) and John Perry at the Stowers Institute for Medical Research (Stowers) collaborated with TAG to develop inhibitors for PI3K-AKT and Wnt-β-catenin pathways in cancer stem cells resulting in multiple collaborations. The initial collaboration started with a two year state-funded Kansas Bioscience Authority grant in which **Roy** (LDOSR) developed a cell-based HTS assay and screened over 1,200 compounds in the FDA Repurposed library. **Li** and Perry performed additional mechanism, *in vivo*, and *in vitro* studies on the top hit compounds doxorubicin and daunorubcin. Stowers investigators, KUCC clinicians, Tara **Lin** (D3ET) and Ray **Perez** (D3ET), and bioanalytical analyst Greg **Reed** (Clinical Pharmacology Shared Resource) have been working with TAG to advance low-dose daunorubicin toward clinical trials for KUCC patients with advanced leukemia (TLL, BLL, and AML). There is currently no standard-of-care treatment option for relapsed acute leukemia patients. In late



2015, archived patient samples obtained by **Lin** were blinded and sent to Perry to determine if β-catenin was measureable in these samples and could be analyzed as a biomarker in the proposed clinical trial. An investigator-initiated trial (IIT) received approval in March 2016. Now medicinal chemist **Schoenen**, protein crystallographer Scott Lovell, and BIOC director Michael **Baltezor** have been brought onboard resulting in a grant submission in late 2015 titled, "Redesign Doxorubicin to Target β-catenin and Reduce its Binding to Topoisomerase II ". Further collaborations include nanoparticle formulation with Xiuling Lu, University of Connecticut, and based on the outcomes of the adult IIT, the potential for this therapy to treat pediatric patients will be investigated by Children's Mercy pediatric oncologists Alan **Gamis** (D3ET), Keith **August** and Erin **Guest** (D3ET).

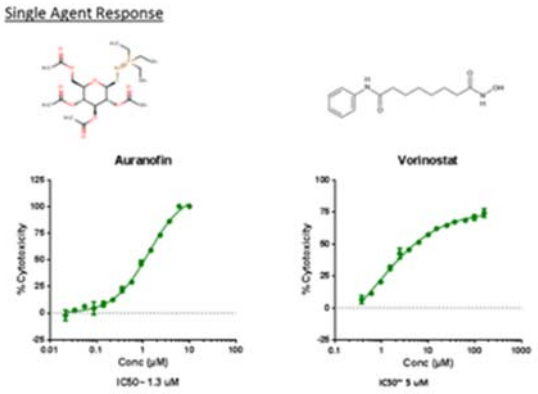
Novel PI3K/p110beta-specific chemical inhibitors for prostate cancer treatment

Benyi **Li** (D3ET) worked with TAG to develop a project plan for his D3ET pilot grant awarded in August, 2015. **Li's** pilot project goals were to characterize five TGX221 analogs which are PI3K/p110β specific inhibitors being developed for the potential treatment of prostate cancer. Due to the limited water solubility of TGX221, **Baltezor** in the BIOC has been working with **Li** to evaluate the test compounds in potentially better formulations. **Schoenen** has consulted with **Li** to evaluate his test compounds in the cellular thermal shift assay (CETSA) for their potential binding to his target proteins in cells. **Li** completed CETSA experiments and found that 3 of 4 analogs bound to the target protein. **Li** completed *in vitro* efficacy testing of his test compounds and they were ranked in order of potency to assist in structural activity relationship analysis. **Li's** work with the LDOSR resulted in RO1 and DOD grant submissions in late 2015 and early 2016 aimed to synthesize several of his TGX221 analogs, as well as, design, synthesize and optimize additional TGX221 analogs for improved physicochemical, *in vitro* and *in vivo* efficacy and improved pharmacokinetic properties.



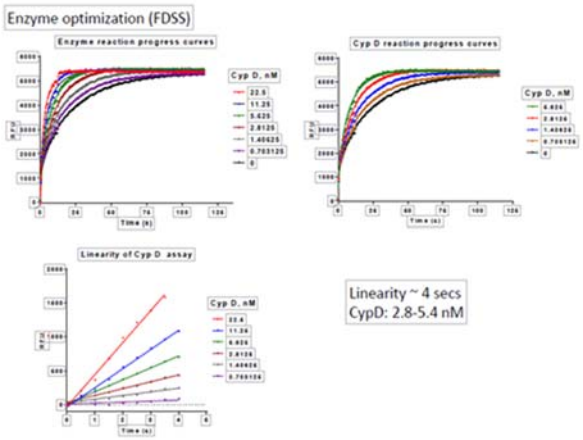
Identification of compounds that inhibit human and canine osteosarcoma

This Midwest Cancer Alliance (MCA) funded project is a multi-institutional collaboration between the LDOSR and investigators at KUMC, KU, Children's Mercy (CM) and Flint Animal Cancer Center Colorado State University (FACC). A panel of cell lines from human and canine osteosarcoma as well as control cells was selected by the team. The cell panel was screened through a validated high throughput assay at the HTS laboratory against: (1) a 2,516 FDA approved drug collection for repurposing; and (2) a 15,040 diversity collection from Life Chemicals for identifying novel scaffolds. The top FDA approved drug hits were then tested in synergy matrices in combination with selected standard-of-care agents recommended by the pediatric and animal clinicians. The significantly synergistic combinations were tested in secondary *in vitro* and mouse *in vivo* studies at KU. Data from this collaboration was presented in an abstract at the American Association for Cancer Research annual meeting in April, 2015 (Comparative Oncology Drug Discovery for Osteosarcoma in dogs and Humans, Authors: Joy Fulbright (CM), Kathleen Neville (CM), Melinda Broward (TAG), Tyce Bruns (TAG), Anu **Roy** (LDOSR), Tomoo **Iwakuma** (CB), Peter McDonald (LDOSR), Megan Ottomeyer (KCUMB) and Douglas H. Thamm, (FACC)). Studies are still underway and in early 2016 two of the drug combinations were selected for testing in clinical dog trials at Colorado State University. In addition to the FDA drugs, data generated from a larger Life Chemical Library screen is being used in a grant submission to develop probe compounds with improved efficacy.



Assay development and identification of small molecule inhibitors of Cyclophilin D, Shi-Du Yan, PhD

The LDOSR used funds from the KUCC Hall Family Foundation were to help develop and optimize a Hamamatsu FDSS 7000 based real-time kinetic assay for targeting Cyclophilin D (Cyp D) for Shi-Du Yan, PhD. The LDOSR HTS laboratory developed this assay to support a potential therapeutic strategy for implications in cancer, Alzheimer's and other neurological diseases. The assay was used to screen 2,136 compounds in the FDA Repurposed Library and 5,100 compounds in the KU CMLD Center Library. Approximately 80 hit compounds were confirmed in concentration-response studies and top hits were found to be active in different downstream assays (Valasani, *ACS Medicinal Chemistry Letters*, 2016).



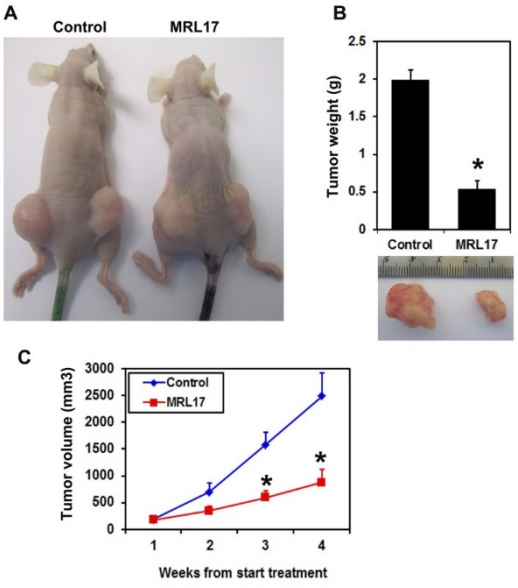
Novel Dual Notch/PXR Targeting for Colon Cancer Therapy

Anant (CPS) and **Weir** (D3ET) collaborated and identified four compounds derived from *aegle marmelos* as having activity at the DLCK1 receptor to prevent colon cancer. These four compounds, MRL-THB, MRL-DBQ, MRL 16 and MRL 17, had similar activities in the suppression of Notch1 signaling and inhibition of PXR. The BIOC was requested to evaluate the four compounds for solubility, stability, HERG, Ames mutagenicity, liver metabolism, protein binding, plasma stability and *in vivo* pharmacokinetics in mice dosed using IV, IP and oral routes. Based on the Ames testing, MRL-THB was identified as cytotoxic and was dropped. All of the compounds were very poorly soluble in water. Several formulation enhancing excipients were evaluated including HPβ cyclodextrin, Captisol, Solutol, polysorbate 80, Vitamin E TPGS and polyethylene glycol 300 and 400. The variation of pH had little effect on the solubility. Of the formulations evaluated, a combination of polyethylene glycol 400 (78%) and water (22%) worked the best. The dose tolerance to the three compounds was similar with 3mg/Kg IV, 4 to 7mg/Kg IP and 10mg/Kg orally being the highest dose possible in the mice before drug-related side effects were generated. MRL-DBQ had very short half-lives of 11 minutes by IV and 30 minutes by IP injection. No drug was detectable by the oral route. MRL 16 and MRL 17 both had half-lives around 4.7 hours for IV, IP and oral routes of delivery. The absolute oral bioavailabilities by the oral route were 92 to 96%. However, when the chemical stability of MRL 16 was evaluated in the dosing formulation at 25^{0}C for one month, approximately 23% of the drug was lost. By comparison, MRL 17 showed only a 2% loss under the same conditions. Based on the cytotoxicity of MRL-THB, the rapid metabolism of MRL-DBQ and the very poor solution stability of MRL 16, MRL 17 was the clear choice for further investigations. This work was funded by NCI Grant #1R01CA182872, Novel Dual Notch/PXR Targeting for Colon Cancer Therapy.

MRL 17 Pharmacokinetic Parameters

Parameter	Units	MRL 17		
Route of Administration		IV	IP	Oral
Dose	mg/kg	3	4	9
n		3	3	3
Terminal Slope	1/min	0.0044	0.0024	0.0025
Half-Life	min	157.9	284.8	280.9
Cmax	ng/mL	11200.0	16133.3	7073.3
AUC_{0-t}	min*ng/mL	674497.7	853808.3	1942968.3
$AUC_{0-\infty}$	min*ng/mL	680465.7	865232.4	2010791.6

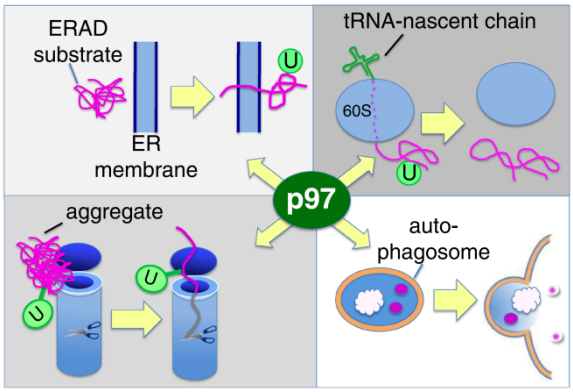
Absolute Oral Bioavailability MRL17:
(%)
96.02



Inhibitors of the AAA ATPase p97

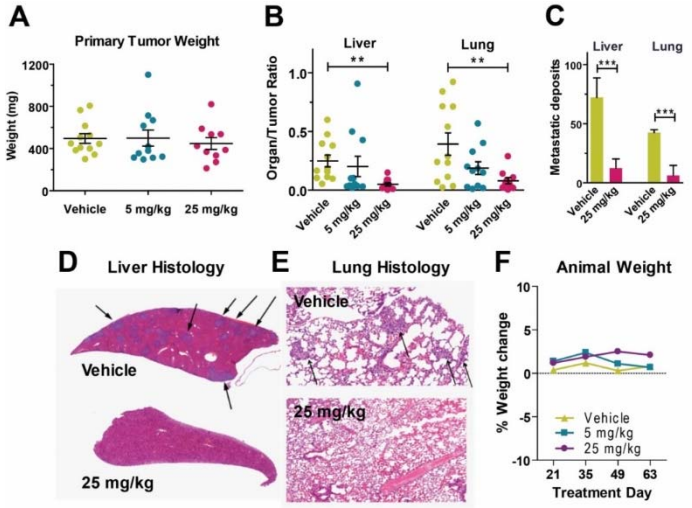
The AAA ATPase p97 participates in key steps in ubiquitin-dependent protein quality control, autophagy, and numerous fundamental cell functions. p97 is overexpressed in some cancers, and how p97 and its numerous interacting proteins (cofactors) participate in tumor development is largely unknown. **Schoenen** (D3ET), in collaboration with Professors Ray Deshaies (California Institute of Technology) and Tsui-Fen Chou (UCLA

Jonsson Comprehensive Cancer Center), was the lead medicinal chemist on the interdisciplinary team funded through the NIH MLPCN that validated the p97 inhibitor high-throughput screening hit DBeQ and that optimized DBeQ to provide lead compounds ML240 and ML241. DBeQ was the first selective p97 inhibitor. Studies using ML240 argue for the possibility of tuning small molecules to specific p97 physiological functions to treat a specified pathological state as well as generating specificity in the context of malignancies. Studies using ML241 argue for the possibility to develop domain- (i.e., p97 ATPase domain), complex- (i.e., p97 cofactor complex), and disease-specific (i.e., IBMPFD/ALS-specific) p97 inhibitors. Cleave Biosciences licensed intellectual property surrounding DBeQ, ML240, and ML241. Their derivative of these probes, CB-5083, a close structural analogue, is currently in two Phase I clinical trials, one in relapsed and refractory multiple myeloma and the other in solid tumors refractory to the standard-of-care. This project resulted in two NIH MLPCN probe compounds, ML240 and ML241, one peer-reviewed NIH MLPCN probe report, five peer-reviewed publications, and one issued patent application. **Schoenen** (D3ET) is co-investigator with principal investigator Tsui-Fen Chou on a pending NIH R21 grant application on targeting p97 ATPase via specific p97-cofactor complexes as an anticancer therapy. This inter-center collaboration has led to intra-center collaborations with **Manepalli** (D3ET) around inhibiting p97 for the treatment of diffuse large B-cell lymphoma, and **Chien** (CB) around inhibiting p97 to exploit synthetic lethality in drug-resistant ovarian cancers. Several publications have been generated from this work: Gui L, *ChemMedChem*, 2016; Fang CJ, *ChemMedChem*, 2015; Chou TF, *Mol Biol*, 2014; Chou TF, *ChemMedChem*, 2013; and Chou TF, *Proceedings of the National Academy of Sciences of the USA*, 2011.



p97 is a key player in protein homeostatis. Upper left: p97 extracts unfolded or misassembled proteins from the ER. Upper right: p97 recognizes ribosomes that have stalled during translation and releases the nascent chain from the ribosome. Lower left: protein and protein-RNA aggregates require p97 for metabolism. Lower right: p97 is required for autophagosome maturation.

Compounds that Reduce the Prevalence of the Perinucleolar Compartment Metastasis is the leading cause of cancer mortality. However the development of effective anti-cancer drugs able to specifically block metastasis has been hampered by the complexity and poor understanding of the cellular mechanisms that regulate this process. To identify small molecules that selectively target metastatic development, the perinucleolar compartment (PNC), a subnuclear structure whose formation positively correlates with the metastatic potential of cancer cells, disease progression, and inversely correlates with clinical outcome, was used as a phenotypic marker to screen the NIH MLPCN Small Molecule Repository compound collection under the auspices of the NIH MLPCN in collaboration with Sui Huang (Robert H. Lurie Comprehensive Cancer Center of Northwestern University), the National Center for Advancing Translational Sciences (NCATS), and the KU MLPCN SCC. Compound hit-to-lead optimization managed by **Schoenen** (D3ET) at the KU SCC in collaboration with Juan Marugan at the NCATS led to the MLPCN probe compound ML246, otherwise known as metarrestin, a first-in-class small-molecule that disassembles PNCs in cancer cells at submicromolar concentrations and inhibits cell migration and invasion *in vitro* without overt cytotoxicity. *In vivo,* metarrestin effectively inhibits metastatic growth in murine xenograft models of metastatic disease using human pancreatic (Udo Rudloff (NCI)), prostate (Gary Sahagian (Tufts University)), and breast (Andrew Mazar (Robert H. Lurie Comprehensive Cancer Center of Northwestern



Metarrestin treatment significantly reduces metastasis of PANC1 cells to lung and liver. After six weeks of treatment, primary tumor growth is unaffected by metarrestin (A) but a significant difference in IVIS signal is observed between mice treated once-daily with 25 mg/kg of metarrestin and vehicle ($p<.01$) in the liver and lung (B). Pathology (C) and histological examinations (D, E) show that livers and lungs from metarrestin-treated animals have much less metastatic burden than those treated by vehicle. Treatment was well-tolerated, and there are no significant (F) weight fluctuations between treatment groups across the duration of the experiment. * = P-value < 0.05. ** = P-value < 0.01. *** = P-value < 0.001.

University) cancer cells. At doses where it disassembles PNCs, metarrestin selectively disrupts nucleolar structure and inhibits Pol I transcription without affecting Pol II transcription or protein translation and without eliciting DNA damage-repair and apoptotic responses. Affinity purification using a biotin-conjugated analog of metarrestin identified eEF1A as a binding partner. Manipulation of eEF1A levels by overexpression partly recapitulates the PNC phenotype observed with metarrestin treatment *in vitro*. Metarrestin is a well-tolerated molecule with a desirable pharmacokinetic profile and a novel mode of action, representing a new therapeutic approach to the treatment of metastatic cancer. This project resulted in one NIH MLPCN probe compound, ML246, one peer-reviewed NIH MLPCN probe report, and one pending patent application. **Schoenen** is a consultant with principal investigator Sui Huang on a pending NIH R01 grant application on mechanism of action studies on metarrestin, a novel blocker of metastasis *in vivo*, toward new classes of nontoxic chemotherapies. **Schoenen** is key personnel with principal investigator Juan Marugan on a pending NCI Experimental Therapeutics grant application on metarrestin, a new approach to metastasis. This has led to intra-institutional collaborations with **Welch** (CB) on melanoma and metastasis, with **Iwakuma** (CB) around metarrestin as an agent that reduces PNC prevalence in the context of Ewing's sarcoma and metastasis. This resulted in a letter of intent being solicited by the Alan B. Slifka Foundation to submit a grant application. Intra-institutional collaborations were also initiated with Doug Thamm (University of Colorado Comprehensive Cancer Center, Rodney Page (FACC) and **Weir** (D3ET) around metarrestin as a new class of nontoxic chemotherapy for osteosarcoma. PNC project team member Udo Rudloff (NCI) is principal investigator on a pending NIH BrIDGs grant application to develop metarrestin as a new standard in the adjuvant treatment of pancreatic cancer, whereby the plan is to aim for IND filing during Q1 of 2017 and to initiate clinical study during Q2 of 2017. **Baltezor** (D3ET) and **Weir** (D3ET) are consulting for Rudloff with respect to formulation of metarrestin for preclinical tox/PK and IND studies and IND filing. (Frankowski, *National Center for Biotechnology Information*, 2010).

Small molecule disruptors of Msi RNA-HuR protein interactions

Liang **Xu** (D3ET) discovered that the AU-rich RNA-binding protein Hu antigen R (HuR) is overexpressed in a wide variety of cancers, and promotes tumorigenesis by interacting with a subset of oncogenic mRNAs implicated in tumor cell proliferation, survival, angiogenesis, invasion, and metastasis. HuR up-regulates the oncogenic Musashi-1/-2 (Msi1/2) via binding to AREs, promoting mRNA stability and translation. These HuR target genes are also involved in cancer stem cell signaling and drug resistance. A fluorescence polarization assay was optimized in HTS to study interaction of HuR protein and fluorescein labeled Msi ARE. The assay was used to screen compound libraries in two steps: (1) LESTR KUCC funded a validation screen of 7,275 compounds from the KU FDA Repurposed Collection of approved drugs and the KU CMLD Center (Jeff Aubé's NIH P50GM069663)) collection of diversity scaffolds; (2) A Life Chemicals Diversity compound screen of 15,040 compounds was funded by Barbara **Timmerman's** (D3ET) NIH-funded COBRE (NIH P30GM103495)). The Life Chemical Diversity Collection represents a larger collection of 300,000 compounds. Through high throughput screening, the hits were identified that inhibited HuR at nM to low µM Ki values. All hits were validated in **Xu's** laboratory by ALPHA screen, Surface Plasmon Resonance and Nuclear Magnetic Resonance assays. The data supported a successful NIH award (R01CA191785) and publication (Wu, *ACS Chem Biol*, 2015).

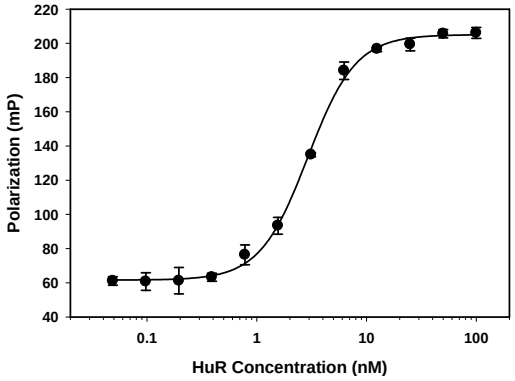
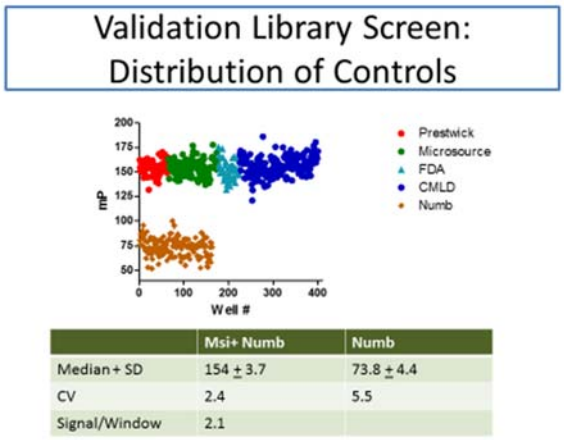


Figure 1. Binding of Msi1 to HuR Protein. The samples were treated essentially as described in the assay SOP. Fluorescein labeled Msi1 (1 nM) was mixed with increasing concentrations of HuR and polarization was measured after 1 hr on an Envision plate reader. After background subtraction, binding data were fit by least squares analysis using the four parameter Hill equation. Data points are the mean +/- S.D., n = 4

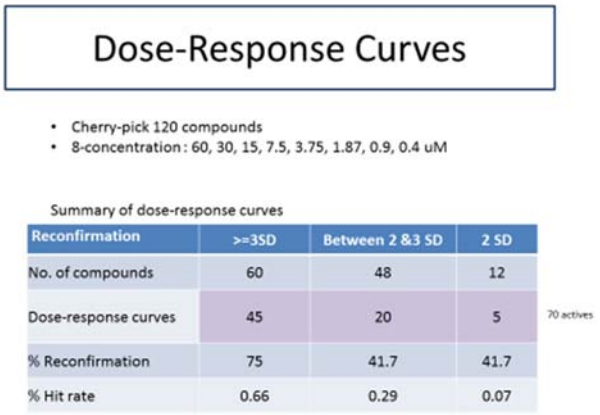
Targeting Musashi 1 (Msi1) for colorectal cancer therapeutics

Musashi-1 (Msi1), a stem cell marker overexpressed in many types of cancers, is an RNA-binding protein (RBP) that binds to and inhibits translation of target mRNAs. Kristi **Neufeld** (CB) identified this inhibition results in activation of Wnt and Notch signaling and consequently, cell cycle progression, survival and resistance to programmed cell death. Experimental manipulation to reduce Msi1 levels in breast and colon cancer cell lines led to tumor regression in mouse xenograft models. Because Msi1 stimulates both Notch and Wnt signaling and is overexpressed in a wide variety of cancers, a fluorescence polarization assay was optimized in the HTS

laboratory to study interaction of Msi protein and fluorescein-labeled Numb RNA peptide (Lan, *Molecular Oncology*, 2015). Through funding from Barbara **Timmermann's** NIH P30GM103495 grant, the assay was used to screen 7,676 compounds from the KU FDA Repurposed collection, Prestwick, Microsource, and KU CMLD Center (Jeff Aubé's NIH P50GM069663) libraries, followed by screening of additional 43,000 compounds from the ChemBridge Diversity Library set. Through high throughput screening, a number of hits at nanomolar Ki were obtained which were validated by Surface Plasmon Resonance and Nuclear Magnetic Resonance. The HTS data was used in an NIH R01 grant application which was awarded in 2014; 5R01CA178831-02 (Small Molecules Modulating RNA-Binding Protein Msi1) and a provisional patent was filed in 2014.



	Msi+ Numb	Numb
Median+SD	154 ± 3.7	73.8 ± 4.4
CV	2.4	5.5
Signal/Window	2.1	

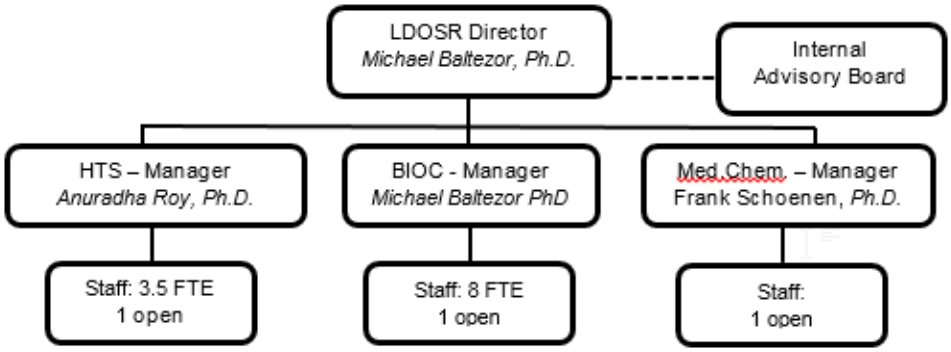


Reconfirmation	>=3SD	Between 2 &3 SD	2 SD
No. of compounds	60	48	12
Dose-response curves	45	20	5
% Reconfirmation	75	41.7	41.7
% Hit rate	0.66	0.29	0.07

70 actives

Management Structure of LDOSR

Baltezor serves as the Director of the LDOSR, working closely with the managers and staff to integrate the three functions of the LDOSR. The LDOSR receives support from a variety of sources, including The University of Kansas and KUCC. **Baltezor** meets quarterly with the KUCC Associate Director for Shared Resources (**Mayo**) and the other shared resource directors (**Godwin, Reed, Fridley, Vivian**). **Baltezor** provides annual fiscal and scientific reports to each of these groups. Additionally, the LDOSR is reviewed annually and advised by members of the KUCC External Advisory Board. Stephen Byers (Professor, Oncology and Director for Shared Resources, Lombardi Comprehensive Cancer Center) is assigned as the primary reviewer.



Operations & Policies

Policies

The following are the KU Cancer Center access priorities for LDOSR services.
Priority 1 – Cancer Center members with NCI grant support or Cancer Center pilot funds
Priority 2 – Cancer Center members with cancer and/or cancer-related grants funded by NIH (non-NCI) and other peer-reviewed grants as defined by NCI
Priority 3 – Non peer-reviewed funded or unfunded KUCC investigators (e.g., junior investigators)
Priority 4 – NCI/NIH funded investigators outside of KUCC
Priority 5 – Other funded investigators outside of KUCC
Priority 6 – Unfunded investigators outside of KUCC

Charge Back System
Prior to working on projects in LDOSR, a proposal is prepared and discussed with the investigator to ensure that scope of work, recommended activities, cost and timing are understood. There are no charges for these consultations to KUCC members.

HTS - Much of the funding for HTS is provided by investigators that use the services either as fee for service or as percent effort on grants. HTS has added 1536 well-format for a cost savings of reagents and compounds to investigators.

- Method development and screening hourly rate is $81/hr scientist staff for KUCC members and $127/hr for external academic investigators. Technical staff hourly rate for routine screening is $64/hr for KUCC members and $100.50/hr for external academic investigators.
- HTS director is added on percent effort basis on grants or charged at fee for service on non-grant funded projects. Budgets are prepared based on time required for the individual investigator's project requirements along with travel, specialized equipment and supply costs.
- Compound library charges are on a per plate basis of the selected library @ $17 to $245/plate. Specialized library rates are higher. Libraries are selected based on project interest and budgets (FDA repurposed, diverse validation sets, natural products, compounds with predicted blood-brain barrier permeability and other large diverse libraries, etc.).
- Cell-based assays require mycoplasma testing, cell banking, growth curve analysis and DMSO tolerance labor and supply charges.
- Data analysis and report writing are at standard scientist labor charges.

BIOC - Work conducted is typically covered as fee for service or as percent effort on grants.

- For projects performed as fee for service basis, senior staff labor rates are $90/hr for KU and KUCC affiliated faculty, and $142/hr for external academic researchers. Technical staff labor rates are $60/hr for KU/KUCC affiliated faculty and $95/hr for external academic researchers. Supplies are charged on an at cost basis for KU/KUCC affiliated faculty.
- For projects supported by grants and contracts, budgets are prepared based on individual pay rates and percent time, along with travel, equipment and supply requirements at cost.

MC - Much of the funding for medicinal chemistry is provided by the investigators that use the services as percent effort on grants.

- Prior to submitting a collaborative grant application, the proposed work and associated budget are discussed with the principal investigator.
- For projects supported through grants, a senior investigator and post-doctoral synthesis/medicinal chemist personnel are added on a percent effort basis in alignment with the individual principal investigator's project requirements along with associated pro-rated equipment, supplies, travel and other cost requirements.

Usage
The table below provides the detailed usage of the LDOSR services by KUCC members for 2012 through 2015. In calendar year 2015, the LDOSR supported 12 Cancer Biology members, one Cancer Control and Population Health member, six Cancer Prevention and Survivorship members and 23 Drug Discovery, Delivery and Experimental Therapeutics members. The second table indicates the number of projects supported by the LDOSR. A large portion of LDOSR users are repeat users from previous years. This speaks to the quality of the work and the data provided by the LDOSR.

Users Supported	2012	2013	2014	2015	Total Users 2012-2015	Number of Unique Users
No. of Cancer Center Users	36	41	54	42	173	134
No. of Non-Cancer Center Users	36	27	23	38	124	82
Total Users Supported by Year	**72**	**68**	**77**	**80**	**297**	**216**

Projects Supported	2012	2013	2014	2015	Total Projects 2012-2015	Number of Unique Users
No. of Peer-Reviewed Cancer Center Projects	37	39	55	49	180	86
No. of Non-peer-Reviewed Cancer Center Projects	13	28	34	13	88	48
No. of Peer-Reviewed non-Cancer Center Projects	13	9	14	17	53	28
No. of Non-peer-Reviewed non-Cancer Center Projects	26	19	12	25	82	54
Total Projects Supported by Year	**89**	**95**	**115**	**104**	**403**	**216**

Cost Effectiveness

The LDOSR has leveraged center, institutional and programmatic support to maintain fees at a low level which are competitive with internal pricing at other academic institutions. Although commercial vendors may provide similar services as the LDOSR, these costs tend to be prohibitive to academic researchers. A presence on campus greatly reduces costs associated with otherwise obtaining samples and reagents from other sources, including expensive shipping and administrative costs associated with shipping of samples. The internal costs for each of the LDOSR services are typically 50% or less of external commercial vendor costs. In addition to the laboratory services the LDOSR provides, the LDOSR staff provides free consulting to researchers to develop project plans, prepare grant proposals and assist with access to additional shared resources and core laboratories at both KU and KUMC. This consulting is often performed in an integrated manner through TAG or on an individual basis for specific projects.

Future Plans

HTS operations will continue to help support cancer probe and drug discovery efforts by KUCC investigators by providing HTS capabilities and by facilitating assay development and screening. As a shared resource of KUCC, our focus has been to improve the infrastructure: staff expertise, state-of-the-art equipment, adding improved chemical library diversity as well as specialized libraries of interest. HTS will continue to expand our clientele, both internal as well as external, to maintain our financial self-sustainability. The human genome project is providing a plethora of therapeutic targets which require us to continuously develop new methodologies and provide robust technology to pursue these targets. HTS will continue to enhance its knowledge and instrument-base in the area of label-free technology in de-orphanizing refractory cancer targets. This would be especially useful as an alternate readout for use in the hit-to-lead optimization process. Label-free technology allows work with primary cell lines and is an alternative to using engineered cell lines. HTS will continue to expand its expertise in high content assay platforms to facilitate image-based screening efforts, expand chemical library scaffold collections and attend conferences to learn about cutting-edge technologies and methodologies. HTS will continue to work closely with KUCC members and TAG to generate quality data to support highly competitive grant applications for extramural funding.

The BIOC will continue to provide formulation and drug delivery expertise to support the advancement of investigator projects. BIOC has recently expanded its testing to include octanol/water partition, PAMPA permeability and flux and CACO2 testing. BIOC has also expanded its capability to conduct metabolite testing with LCMSMS. In the future, BIC plans to improve their ability to work with nanoparticles and micelle formulations. BIOC has already worked closely with pediatric physicians at Children's Mercy and plans to expand those relationships directed at developing pediatric-specific formulations.

Medicinal Chemistry activities at KUMC are being supported through KUCC investment in laboratory space and equipment in the **Anant** (CPS) laboratory. **Anant** and post-doctoral researcher Prasad Ravindra Dandawate are working with **Schoenen** to design the synthesis and medicinal chemistry laboratory space. In addition to this synthesis and medicinal chemistry space on the KUMC campus, **Schoenen** currently has access to the facilities and resources in the NIH-funded Chemical Methodologies and Library Development Center, directed by Thomas **Prisinzano**, located on the KU Lawrence West Campus. **Schoenen** will continue to actively pursue extramural funding to support his and the TAG's inter- and intra-institutional collaborative research.

Progress Report Publications

This component has no publications resulting from Cancer Center Support Grant funds.

Vertebrate Animals – LEAD DEVELOPMENT AND OPTIMIZATION SHARED RESOURCE

VERTEBRATE ANIMALS

(a) *Proposed Use of the Animals, and Species, Strains, Ages, Sex, and Numbers to Be Used:* PK studies are one component of testing in the elucidation of structure activity relationships and optimization of compound biological performance. We plan to conduct pilot PK studies, which are sometimes referred to as Rapid Assessment of Compound Exposure (RACE) studies. This involves a PK study in mice with 3 mice (typically BALB/c mice) per time point, ten or less time points and a single route of administration (oral or injection). Depending on the specific compound and study, tissue samples may be collected for analysis in addition to the blood samples. The samples are assayed using an appropriately validated LC/MS/MS assay.

Prior to any study being conducted, a compound specific animal use statement / protocol will be prepared and submitted to the IACUC for "just in time" review and approval. Each mouse would provide a single blood sample due to the volume of blood needed for the separation of plasma and the volume needed for analysis. Each of the mice can also provide tissue samples if justified and approved in the animal use statement. All of the mice will be obtained from a vendor approved by the KU veterinarian. All studies will be conducted in the dedicated animal facilities at KU.

(b) *Justifications for the Use of Animals and for the Appropriateness of the Species and Numbers Proposed:* The pharmacokinetic studies described above provide scientifically necessary information about the concentration of investigational compounds in blood and tissues of the mice. This allows for the optimization of the design and delivery of lead compounds as well as an understanding of the rates of absorption, distribution and elimination. No *in vitro* tests have been identified that can be substituted to provide the information gathered in these studies.

(c) *Adequacy of Veterinary Care*: The animal facilities at the KU are AAALAC approved with an attending veterinarian on staff and available. The Animal Welfare Assurance Number is A3339-01. All animals are housed in secure, dedicated facilities that are maintained and serviced by a full time Animal Care Unit staff. The ACU staff monitors the condition of the animals on a routine basis. Prior to study initiation, the mice intended for used in our PK study are transferred from the general animal housing area to an animal testing laboratory which is located within the same secure area. Dedicated employees are responsible for dosing the animals and collecting samples at the collection points. These employees routinely monitor the welfare of the mice during the course of the study and any problems are brought to the attention of the veterinary staff. If any mouse should exhibit signs of acute and chronic pain or suffering, the animal will be euthanized.

(d) *Procedures for Limiting Discomfort, Distress, Pain and Injury to that which Is Unavoidable in the Conduct of Scientifically Sound Research Including the Use of Analgesic, Anesthetic, and Tranquilizing Drugs and/or Comfortable Restraining Devices:* The cardiac puncture method of blood collection is conducted after the mice have been anesthetized using inhaled isoflurane. This method is fast and reliable and is in compliance with the ACU SOP's.

(e) Methods of Euthanasia and Reason for Selection if Not Consistent with the AVMA Guidelines on Euthanasia: The use of inhaled isoflurane for deep anesthesia followed by a method to produce rapid death is consistent with the recommendations of the AVMA Guidelines on Euthanasia. The cardiac puncture process for blood collection provides for the rapid death. In addition to the heart puncture for blood collection, a thoracotomy is performed on the mice for assurance of death.

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Resource Sharing Plan

The University of Kansas Cancer Center (KUCC) and its scientific community understands its responsibility to comply with the instructions for the Resource Sharing Plans provided within the SF 424 (R&R) Application General Instructions and Supplemental Grant Application Instructions. When resources are developed with NIH funds via this Cancer Center Support Grant P30 mechanism, KUCC will ensure findings are made readily available to the NIH and the scientific community in a timely manner.

Data Sharing Plan

KUCC will adhere to the Final NIH Statement on Sharing Research Data and refer to the National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research. KUCC encourages the free flow of information and ideas while recognizing the timeliness of data sharing, the rights and privacy of human subjects and issues related to proprietary data. KUCC encourages data documentation, using a data-sharing agreement and selecting an appropriate method for sharing; considering the sensitivity of the data, the size of the dataset and the volume of requests anticipated.

Additionally, KUCC encourages any user of a CCSG-supported shared resource to acknowledge the source of data upon which their manuscript is based either in the Acknowledgments section or with authorship on the paper. Furthermore, any research project that received direct cost support from the CCSG is encouraged to cite the P30 CA168524. In both cases, citing the P30 CA168524 grant number and then being compliant with the NIH Public Access Policy is required.

Sharing Model Organisms

In the event that a model organism is developed, KUCC will comply with the NIH Policy on Sharing of Model Organisms for Biomedical Research. KUCC will work with the NIH/NCI to share and disseminate the critical model organism in a timely manner.

Genome Wide Associate Studies

When applicable, KUCC will comply with the NIH Genomic Data Sharing Policy. KUCC supports the sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. All research studies funded through the CCSG involving genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data will be submitted in a timely manner.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 016060860

Legal Name*: University of Kansas Medical Center Research Institute, Inc.
Department:
Division:
Street1*: MSN 1039, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Deborah		Maloney	MSM

Position/Title: Director, Sponsored Programs Administration
Street1*: 3901 Rainbow Boulevard
Street2: Mail Stop 1039
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937
Phone Number*: 913-588-1261 Fax Number: 913-588-3225 Email: spa@kumc.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofit Organization
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Transgenic & Gene-Targeting Shared Resource

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2017	06/30/2022

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Medical Center
Duns Number:	016060860
Street1*:	MS 3045, 3901 Rainbow Boulevard
Street2:	
City*:	Kansas City
County:	Wyandotte
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66160-0000
Project/Performance Site Congressional District*:	KS-003

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ❍ **Yes** ● **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ❍ No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ● **Yes** ❍ **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number A3237-01

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	TGTSR_ProjectSummary_Final1019496480.pdf
8. Project Narrative*	
9. Bibliography & References Cited	TGTSR_ReferencesCited_Final1019469488.pdf
10.Facilities & Other Resources	TGTSR_Facilities_Final1019754781.pdf
11.Equipment	
12. Other Attachments	TGTSR_OtherAttachments_Final1019913914.pdf

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Transgenic and Gene-Targeting Shared Resource – Project Summary

Genetically altered mouse models are important tools for the researchers at the University of Kansas Cancer Center (KUCC). The production and analysis of such models ultimately leads to a better understanding of the nature, progression and functional genomics of tumor formation. They also serve as *in vivo* models for diagnostics and treatment. The Transgenic and Gene-Targeting shared resource (TGTSR), led Jay L. **Vivian** PhD, supports members of KUCC by providing centralized and comprehensive technical services for the production of novel transgenic and gene-targeted rodents and genetically altered pluripotent stem cells. The TGTSR uses cutting edge methods, state-of-the-art instrumentation, and novel reagents for the generation of these models. The TGTSR, housed at the KUMC campus, has four full time technical staff along with **Vivian**. The Cancer Center support of the TGTSR allows for the development of specific initiatives in the Facility relevant to cancer research. For example, certain transgenic methods and mutations are particularly relevant to cancer studies, including tissue specific transgene expression, subtle mutations that recapitulate clinically identified variants and somatic mutations and strain-specific nuclear transfer. Emerging technologies, including *in vivo* genome editing methods (e.g. CRISPR/Cas9 and TALE nucleases) are providing a more rapid means of generating these types of novel mouse models of tumor progression. The integration of these continually evolving methods into the 'toolbox' of the TGTSR greatly accelerates the development of animal models of cancer, while also reducing costs to KUCC researchers on all campuses.

Transgenic and Gene-Targeting Shared Resource – Facilities and Other Resources

Scientific Environment

The research resources at the University of Kansas Medical Center provide an outstanding environment to support the Transgenic and Gene Targeting Shared Resource (TGTSR) for the University of Kansas Cancer Center (KUCC). We have assembled a multidisciplinary and collaborative team of staff to successfully support projects for KUCC investigators. The laboratories of the TGTSR have all of the necessary equipment to support the generation of mouse and stem cell models in a timely fashion. Support for KUCC researchers' efforts will leverage the skilled core facilities at the University of Kansas Medical Center for various technical needs for their studies, including the generation of mutant mice via microinjection and the generation and differentiation of mouse embryonic stem cells and patient-specific human induced pluripotent stem cells.

Laboratory

The Transgenic Facility main laboratory space consists of two rooms (G020 Hemenway, 558 sq. ft and G022 Hemenway, 85 sq. ft.) on the ground floor in Hemenway Research Building of the University of Kansas Medical Center. All equipment for dissections, survival surgeries, embryo manipulations, and microinjection (see equipment) are within this space. G021 Hemenway (96 sq. ft) is shared with the Pluripotent Stem Cell Core and is dedicated for molecular biology work.

The stem cell main laboratory space consists of two rooms G022 and G024 Hemenway (299 sq. ft. and 78 sq. ft., respectively). These rooms consist of three separated alcoves for rodent stem cell culture, human pluripotent stem cell culture, and virus manipulation, with each alcove having dedicated biosafety cabinets, incubators, and microscopes . The common room consists of shared space for centrifuges and laminar flow hood for sterile clone picking.

Clinical

N/A

Animal

(G041 Hemenway, 150 sq. ft., approx. 300 cages). The animal space, which is down the hallway from the Facility lab space, consists of a single room dedicated solely for the Transgenic Facility mice, with a dedicated flow hood for mouse husbandry. This room is within a Specific Pathogen-Free facility with filtered forced air ventilated cages and full autoclaving of mouse caging, and animals are handled under a ventilated flow hood. Full time Veterinary and animal care staff oversee provision and care of animals. Animal surgeries are performed in a dedicated room within the Transgenic Facility space in G020A Hemenway).

Computer

The TGTSR staff share office and computer resources in G025 Hemenway. Computer resources and software applications include Microsoft Office for word processing and presentation, MetaMorph Premier offline with angiogenesis module, Adobe Photoshop and Illustrator for graphics, Geneious for DNA analysis, and Filemaker database management. The computers are connected either via T1 line or wireless network to the University network for Internet, data transfer, and data storage. Shared software is installed on the workstation for DNA analysis and image acquisition and manipulation. Firecam software for acquisition of microscopy images from Leica digital camera. Software applications include Microsoft Office for word processing and presentation, MetaMorph Premier offline with angiogenesis module, Adobe Photoshop and Illustrator for graphics, Geneious for DNA analysis, and Filemaker database management.

Office

Vivian. 150 sq. ft office (Hemenway 3051) down the hall from the Vivian laboratory space.

TGTSR. The core staff share office space; 210 sq. ft. office (Hemenway G025) down the hall from the Facility labs.

Other

Core Facilities:
Transgenic Facility. The KUMC Transgenic Facility is an institutional support facility providing a centralized service for the production of transgenic and gene-targeted mice for investigators of KUMC, KU-Lawrence, and the surrounding Kansas City research community. As a fee-for-service, the Facility provides a full range of transgenic services, including proculear injection of nucleic acids (including RNA and plasmid-derived, BAC, and YAC DNA injections) and blastocyst injection of ES cells. The Facility has the necessary equipment and space for a range of state-of-the-art embryo manipulation (see Equipment below). Most work is done in the mouse, but the Facility also has the capacity to support rat embryo manipulation and pronuclear injection. The facility is equipped to offer a range of embryo services, including cryopreservation of sperm, embryos and oocytes and assisted reproductive techniques such as rederivation, in vitro fertilization, and intracytoplasmic sperm injection. The facility also offers molecular biology services of genotyping of mice and screening of ES cell clones, as well as DNA construct preparation, including BAC DNA for microinjection. The Transgenic Facility has generated hundreds of transgenic and knockout mice for studies of cancer, cardiac vascular diseases, neurological diseases, kidney diseases, cystic fibrosis, bone morphogenesis and environmental and reproductive sciences.

Pluripotent Stem Cell manipulation. The TGTSR provides support work for mouse and rat embryonic stem cells and human induced pluripotent stem cells. The Facility has several cell lines from a variety of sources to support the research needs of investigators at KUMC, including highly germline competent mouse ES cells (129- and C57Bl/6-derived) and established human iPS cells. The Facility has performed dozens of successful targeting experiments in mouse ES cells, and works closely with the KUMC Transgenic Facility to support the generation of mutant mouse models using gene targeting. The Facility also performs services for the generation of human iPS cells, and has the necessary reagents to establish and characterize human iPS cells. Genetic manipulation of human pluripotent stem cells is also offered by the Facility, using Zinc Finger Nuclease, TALEN and Cas9-mediated mutagenesis.

Transgenic Facility equipment in KLSIC G020 and G021 support a full range of transgenic services.

Embryo Manipulation: Two Nikon TE2000 inverted microscope with Nomarski-DIC, HMC and fluorescence optics, as well as new micrometers and temperature-adjustable warming/cooling stages are used for microinjection. These microscopes are equipped with motorized Narishige manipulators, a Cell Tram Air micrometer, a Femtojet and a SAS air syringe to accomplish pronuclear and blastocyst injections, and an XY Clone laser objective for zona drilling. A de Fonbrune microforge, a Kopf vertical pipette puller and a Sutter P-97 horizontal puller are utilized for making holding and injection needles.

Pluripotent stem cell culture stations: Two Biosafety cabinets dedicated to stem cell culture.; four Sanyo MCO-18M tri-gas incubators; BioRad GenePulser II electroporator for the transfection of DNA into cells.
Other equipment includes two stereo and tissue culture microscopes with video and high resolution camera capabilities; a controlled-rate freezer for embryo cryopreservation; an MVE Eterne nitrogen cryo tank auto-fill liquid nitrogen storage tank (370 liter, 15,600 vial capacity) and a vapor shipper; an embryo roller culture incubator.

Molecular Biology lab: two PCR thermocyclers including a Biorad/MJ Research Dyad thermocycler capable of 192 PCR samples simultaneously, gel electrophoresis units, a pulsed field gel electrophoresis unit, and an orbital shaker for growing bacteria. Transgenomic WAVE HPLC heteroduplex-based mutation detection system capable of analyzing 300 samples per day. Access to ABI7900 real-time PCR machine.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Jay Middle Name L Last Name*: Vivian Suffix: PhD

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Pathology & Lab Medicine
Division: School of Medicine
Street1*: MS 3045, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-0341 Fax Number: 913-588-0385

E-Mail*: jvivian@kumc.edu

Credential, e.g., agency login: JVIVIAN

Project Role*: Other (Specify) Other Project Role Category: Core Lead

Degree Type: PhD Degree Year: 1999

Attach Biographical Sketch*: File Name: Vivian_biosketch_CCSG_8_161019566553.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Melissa Middle Name Anne Last Name*: Larson Suffix:

Position/Title*: Research Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Molecular & Integ Physiology
Division: School of Medicine
Street1*: MS 3043 Kansas University Medical Center
Street2: 3901 Rainbow Boulevard
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-1005 Fax Number: 913-588-7440

E-Mail*: mlarson@kumc.edu

Credential, e.g., agency login: MLARSON2

Project Role*: Other (Specify) Other Project Role Category: Manager

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Larson_bio_CCSG1019754782.pdf

Attach Current & Pending Support: File Name:

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ❍ Yes ❍ No

*Agency-Defined Phase III Clinical Trial? ❍ Yes ❍ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ● Yes ❍ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

● Yes ❍ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

❍ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator / Change of Institution Section

❑ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	TGTSR_SpecificAims_Final1019496479.pdf
3. Research Strategy*	TGTSR_ResearchStrategy_Final1019913938.pdf
4. Progress Report Publication List	Progress_Report_Publications_Blank1019754760.pdf
Human Subjects Section	
5. Protection of Human Subjects	
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	
8. Inclusion of Children	
Other Research Plan Section	
9. Vertebrate Animals	Vertebrate_Animals___TGTSr1019799851.pdf
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	
14. Resource Sharing Plan(s)	Resource_Sharing_Plan___TGTSR1019799852.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

Transgenic and Gene-Targeting Shared Resource – Specific Aims

The complex etiology of tumorigenesis and physiological responses to cancer and cancer therapeutics require the use of animal models. Novel animal models can be designed and generated based on experimental data, including genomics data from patient samples, and are an important bridge between clinical and basic research for functional genomics, and to validate and optimize novel therapeutics identified by KUCC research efforts. The techniques employed to generate novel gene-modified animal and stem models require specialized equipment and technical expertise. By centralizing operations and reagents into the Transgenic and Gene Targeting Shared Resource (TGTSR), the generation of these models are available to KUCC investigators on all campuses at a greatly reduced time and cost. The TGTSR operations also allow us to quickly integrate enabling and accelerating methodologies (eg genome editing *in vivo*) and disseminate these capabilities to all KUCC researchers. The support by the KUCC allows the TGTSR to maintain low costs to investigators, and provides avenues for cancer-relevant initiatives. To these ends, the TGTSR has the following specific aims:

Aim 1: Provide Technical Expertise in Experimental Design for Cancer Center Projects
Vivian and the staff of the TGTSR work with Cancer Center investigators in the early stages of experimental design strategies. Through this process, the Director will work with the investigators of new projects to assess specific challenges and needs. Early optimization is particularly important given the time-consuming process of generating animal and pluripotent stem cell models.

Aim 2: Provide Technical support for in vivo genetic alteration of mice
Microinjection of embryos remains a central tool for the generation of novel mouse models. Technical services performed by the TGTSR include pronuclear injection of nucleic acids. The Facility has successfully incorporated emerging genome editing methods in the mouse and rat via *in vivo* injection, including CRISPR/Cas9 genome editing reagents. The Facility also successfully uses new transgenesis technologies, including site specific integrases (PhiC31 integrase). Novel methods of nuclear exchange between mouse strains have also been developed for understanding the role of mitochondria in tumor progression.

Aim 3: Provide Technical Support for genetic manipulation of pluripotent stem cell models
Gene targeting in mouse embryonic stem cells remains a powerful method for making complex genetic alterations which are too difficult to generate via genome editing in vivo. The TGTSR have the necessary reagents and expertise for genetic modification and validation of mouse ES cells, along with blastocyst injection to generate chimeric mice. The core also has the capability to produce induced pluripotent stem cells from both rodent and human primary cell lines, and can generate primary lines from human biopsies. New methods using genome editing tools for rapid generation of genetically modified mouse and human pluripotent stem cells will be added to the TGTSR services.

Aim 4: Provide Support for strain development and maintenance
The TGTSR provides support for researchers after the successful generation of the desired animal model. The staff of the TGTSR can provide technical guidance and services including genotyping and animal husbandry. Services include genotyping of animals, both standard gel-based genotyping and real-time SNP detection of subtle mutations. Once experiments are completed, investigators can take advantage of sperm and embryo cryopreservation services provided by the TGTSR.

Aim 5: Educate Cancer Center Researchers and trainees on new and emerging technologies for genetically altered animal models and manipulation of pluripotent stem cells
The TGTSR strives to integrate new methods for generating genetically modified animal models, and closely monitors new technologies of this rapidly evolving field. The TGTSR provides educational opportunities for Cancer Center members, staff, and trainees. These training include presentations in departmental seminars, lectures in student coursework, and workshops on new technologies. These presentations range from basic overviews of mouse genetics and stem cell biology to the latest techniques and new TGTSR services.

Transgenic and Gene-Targeting Shared Resource – Research Strategy

Overview

Goals

Core description. The Transgenic and Gene-Targeting Shared Resource (TGTSR) at The University of Kansas Cancer Center (KUCC) provides comprehensive technical services for the production of transgenic and gene-targeted mice and genetically altered pluripotent stem cells for all KUCC researchers. Embryo manipulation services include microinjection methods by pronuclear injection of nucleic acids and blastocyst injection of embryonic stem cells. The TGTSR's stem cell services include generation and genetic modification of pluripotent stem cells (mouse and human). The TGTSR also provides additional support services to support mouse genetics and stem cell research, including genotyping, cryopreservation and rederivation. The TGTSR also actively assists in nonstandard and novel projects utilizing mouse embryo or pluripotent stem cell models.

Justification. The use of genetically modified animal models has played a fundamental role in understanding the molecular underpinnings of tumorigenesis and for the generation of animal models for *in vivo* therapeutic studies. Although new methods are available for genetic modification of a range of mammalian models, the mouse remains the most readily manipulable mammalian genetic model. The techniques employed to generate novel gene-modified mouse and stem models require specialized equipment and technical expertise. By centralizing operations and reagents into the TGTSR, the generation of these models are available to all investigators at a greatly reduced time and cost. A campus-located shared resource offers a variety of advantages and allows for services not feasible in an off-campus location, including rapid delivery of animals and live cells. The TGTSR operations quickly integrate new methodologies (e.g. genome editing *in vivo*) and disseminate these capabilities to interested researchers.

History of the Shared Resource. The Transgenic and Gene-Targeting Institutional Facility at The University of Kansas Medical Center (KUMC) has provided technical support for generating transgenic and mutant mice for 20 years. The facility was originally developed in 1996 as a core in a Program Project in Reproductive Sciences (P30 HD33994, Paul Terranova, PI, with SK Dey as founding core director). The Facility has since grown to become an institutionally-supported Core Facility at KUMC, supporting a broad range of research activities. Over the years, the Facility has integrated state-of-the-art methods for mouse mutagenesis, integrating various technologies as the field evolves, including mouse embryonic stem cell technologies, and more recently, genome editing tools and human induced pluripotent stem cell models. The TGTSR receives multiple sources of support, including institutional funds from the School of Medicine, as well as several research program projects. The long-standing institutional and programmatic support for the TGTSR reflects the needs and interests in animal models for researchers at KUMC.

Given the growing needs of KUCC members, a formal affiliation of the Facility with KUCC was instituted in 2013, with the Facility recruited as a developing shared resource in the Cancer Center as the Transgenic and Gene-Targeting Shared Resource (TGTSR). The TGTSR was not part of the initial CCSG application, and since 2013 has been receiving funds from the KUCC institutional sources. The TGTSR was transitioned to an established shared resource in 2015. The support of the TGTSR by this CCSG application will allow the shared resource to expand specific initiatives and develop technologies specifically tailored to cancer biology research, and to maintain low costs to all KUCC researchers on all campuses.

Qualifications

Leadership

Director: Jay L. **Vivian**, PhD has served as the Director of the TGTSR since December 2009. **Vivian** is a highly experienced mouse developmental geneticist and brings 22 years of experience in the genetic manipulation of pluripotent stem cells and the development and analysis of mutant mouse models. **Vivian** additionally has an active research lab, and his research interests and expertise include the development of novel mutagenesis techniques, signaling pathways that mediate stem cell self-renewal and differentiation, and the analysis of mouse models of rare and difficult-to-diagnose human diseases. **Vivian's** duties as Director

involve interfacing with faculty and staff, aiding the development of strategies for the generation of transgenic and mutant models. **Vivian** also works closely with Melissa Larson in quality assurance and in the development of new and more efficient methods, and works closely with Julia Draper in pluripotent stem cell culture methods. He supervises Jennifer Pace in the design of molecular biology reagents and recombinant DNA constructs. His duties also include interfacing with the KUCC shared resource leadership and the Internal Advisory Committee to define new transgenic-related research support services.

Manager: Melissa Larson, PhD. As Manager, Larson is responsible for oversight and day-to-day management of the TGTSR, including staff oversight. Her duties also include ordering, lab maintenance and compliance. Larson's technical duties include embryo microinjection and cryopreservation, and she performs embryo transfer and mouse and cell work as needed. Larson has over 20 years of experience in the field of transgenics, studying transgenic mouse, pig and cow embryos for her Master's and PhD degrees and managing transgenic facilities at two other institutions. She has been Manager of the TGTSR since 2007.

Staff

Illya Bronshteyn, MS. Research Associate. Bronshteyn manages the mouse colonies of the TGTSR. His responsibilities include colony management, superovulating and mating donor mice, harvesting embryos for microinjection and transferring embryos into recipient females. Bronshteyn takes tail biopsies of newly-generated pups and interfaces with investigators for transfer of transgenic animals. He also performs embryo microinjection as needed and bills investigators for services. Bronshteyn has been a staff member of the TGTSR for 15 years.

Julia Draper, MS. Research Associate. Draper is responsible for all human and mouse pluripotent stem cell culture and manipulation. Draper was hired in Oct 2014 to support the newly established human pluripotent stem cell core activities. She has three years of industry experience in cell culture after obtaining her Master's in Biology at the University of Missouri-Kansas City.

Jennifer Pace, BS. Research Associate. Pace supports the genotyping services and stock development services of the TGTSR. She is responsible for all molecular biology (recombinant DNA methods, DNA preparation, PCR). She has 10 years of experience in mouse models, including eight years at the Stowers Institute.

Major Services & Facilities

The TGTSR provides comprehensive technical services for the production of transgenic and gene-targeted mice and genetically altered pluripotent stem cells. All services are provided on a fee-per-service basis, see **Table 1** for a breakdown of current fees of the major services. Embryo manipulation services include microinjection methods by pronuclear injection of nucleic acids and blastocyst injection of embryonic stem cells. The TGTSR's stem cell services include generation and genetic modification of pluripotent stem cells (mouse and human). The TGTSR also provides ancillary services to support mouse genetics and stem cell research, including genotyping, cryopreservation and rederivation.

Table 1. Fees for major TGTSR services

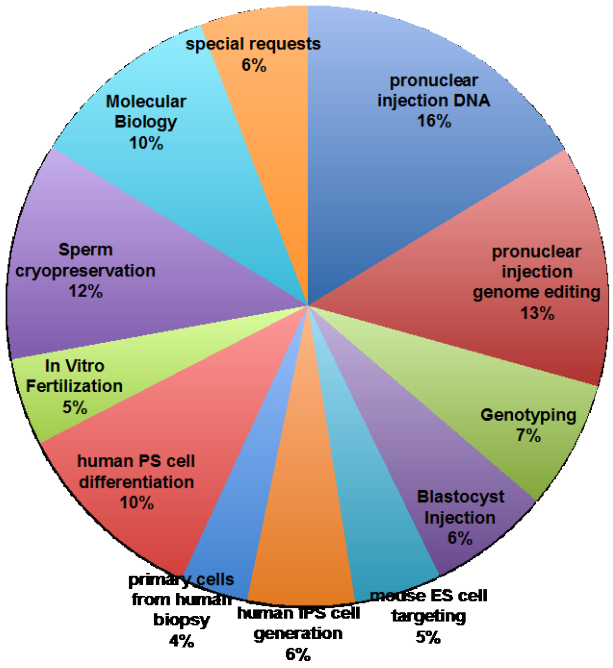
Mouse service	KUCC fee
Pronuclear Injection - DNA or CRISPR RNA	
FVB/N	$3,000
C57BL/6 or other strain	$4,000
Blastocyst Injection	$2,500
Genotyping	$8
cryopreservation	
sperm	$200
embryo	$300
In Vitro Fertilization	$1,000
Embryo Transfer Rederivation	$250

Stem cell service	KUCC fee
Mouse ES Cell Targeting	$4,500
Human iPS Cell Gene Targeting	
AAVS1	$2,000
other locus	$6,400
Karyotyping	
mouse	$300
human	$700
primary cells from skin biopsy	$500
Human iPS reprogramming	$6,000
teratoma assay	$1,700

Requests are broadly distributed amongst these services and obviously vary from year to year depending on investigator needs, see most recent (FY16) distribution of services based on revenue stream (**Figure 1**), a

good indicator of TGTSR effort. The TGTSR also actively assists in nonstandard and novel projects ('special requests') utilizing mouse or stem cell models; fees for these services are calculated based on reagent cost and staff time. Below are details on specific services provided by the TGTSR, and recent examples of successful models generated for KUCC researchers.

Figure 1. Breakdown of TGTSR service usage, by revenue, FY16



Project design: **Vivian** and Larson are available for discussions and consultation with faculty, staff, and trainees in the early stages of project development, at no cost. Projects for mouse model development are highly complex and potentially long-term experiments and every experiment is different. **Vivian** and Larson each bring over 22 years of experience in genetic modification of the mouse genome, pluripotent stem cell models, molecular biology and embryo manipulation. Such meetings are highly useful to anticipate possible issues, discuss alternative strategies, and to determine if new technologies can be integrated into an experimental design. **Vivian** and Larson can also search databases and resources for existing mouse or stem cell models, to ascertain if the desired model is already available. Such searches include animal repositories at the Jackson labs, Mutant Mouse Resource and Research Centers, and embryonic stem cell and vector resources from the International Mouse Phenotyping Consortium. **Vivian** can also assist in the design of molecular biology and recombinant DNA constructs, as needed.

Seminars and workshops. The dissemination of information about transgenesis and mutagenesis methods and core services is an important educational role of the TGTSR. The rapidly advancing field of mouse genetics continues to provide new tools and methods for generating novel animal models. **Vivian** and Larson monitor the publications regarding new methodologies in mouse genetics and pluripotent stem cell biology, and identify new techniques relevant to KUCC researchers for integration into the TGTSR's portfolio. Larson is a regular attendee of the International Society for Transgenic Technologies (ISTT) international meeting, and subscribes to the ISTT Listserve. These forums provide a means of discussing amongst other core facilities new technologies and challenges. The KUCC programs host several seminars and informal working groups for **Vivian** and Larson to present to faculty, trainees, and staff new and developing methods and services, and how these technologies can be integrated into their cancer research. Other venues include departmental and center seminars throughout KUMC and KU-Lawrence campuses. **Vivian** also gives lectures in several graduate courses to students and postdoctoral fellows on mouse genetics and pluripotent stem cell biology.

Pronuclear injection services: The introduction of nucleic acids into a fertilized egg (zygote) via pronuclear microinjection remains a primary means of manipulating the mouse genome. Larson, the manager of the TGTSR, has extensive expertise in microinjection to generate a variety of transgenic mice. The TGTSR has generated transgenic mice from multiple types of DNA constructs (plasmid, BAC and YAC). Efficiencies for these procedures vary depending on the transgene, but in a recent quality assessment survey, the TGTSR maintains high frequencies of transgene positive founder production (5-20%) from both small plasmid-derived transgenes and with large BAC and YAC constructs. High-profile manuscripts reporting mouse models developed by the TGTSR pronuclear injection services include **Peterson**, *PloS One*, 2014 and Braghini, *Experimental Biology and Medicine*, 2016.

Genome editing and CRISPR/Cas9 mutagenesis: The use of genome editing reagents for genetic manipulation has revolutionized the generation of animal and stem cell models of disease, reducing the time to make these models and greatly reducing the cost. In the past three years, the TGTSR has made a concerted

effort to successfully integrate genome editing tools into their portfolio of services for mouse and pluripotent stem cells. The different genome editing tools (Zinc Finger Nucleases, TALE nucleases, and CRIPSR/Cas9) have all been used successfully. These tools are used in either pronuclear injection to directly modify the mouse genome, or for transfection of human and mouse pluripotent stem cells for making genetic alterations *in vitro*. From these efforts, a comprehensive and successful pipeline of services has been developed for making and using genome editing tools for making mutant mice with knockouts and subtle alterations (point mutations), in several strains of mice. CRISPR/Cas9 reagents have become the primary genome editing tools currently being used by the TGTSR. Current efforts use *in vitro* transcribed RNAs (Cas9 and gRNA) via pronuclear injection. The gRNA design and validation pipeline is performed in collaboration with two cores (see below). The TGTSR has been successful in using CRISPR/Cas9 tools to make mice with small deletions (~3-50bp), large deletions (800bp-5kb) via non-homologous end joining, and point mutations by co-injection using single stranded oligonucleotides. The TGTSR has achieved high rates of mutagenesis (**Table 2**) *in vivo* for making deletions (40-80%) and targeted point mutations (14-21%).

Table 2. Summary of founder mutation frequencies from recent CRISPR/Cas9 pronuclear injections

Gene	Region of gene	Mouse strain*	Deletion frequency	Nature of deletions	Point mutation frequency
Ror1	coding	FVB/NJ	18/41 (44%)	6-~137bp	6/28 (21%)
Bhlhb9	coding	BL6	8/10 (80%)	5-18 bp	1/7 (14%)
Ttc21a	coding	F1	17/42 (40%)	6.5 kb deletion	N.D.
Ubqln2	coding	F1	4/7 (57%)	8-75 bp	ongoing
Kdr	enhancer element	F1	7/27 (26%)	~480 bp	N.D.
Lhcgr	enhancer element	F1	20/26 (77%)	~1.5-2.0kb	N.D.
*BL6: C57BL/6J; F1: C57BL/6:FVB/NJ					

Research highlight: Genome Editing. As part of an interinstitutional collaboration, **Smith** (CPS) and **Vivian** (CB) have been working closely with Sarah Soden, MD at the Center for Pediatric Genomic Medicine of Children's Mercy and the NIH Undiagnosed Disease Network in developing mouse models of rare and difficult-to-diagnose diseases. These efforts involve the use of genome editing tools to engineer mouse strains harboring subtle mutations (point mutations) recapitulating novel variants identified in whole genome or exome sequencing of patient genomes, with a focus on neurodegenerative disorders. Several mouse and induced pluripotent stem cell models have been generated from these efforts, including mice with point mutations in the *Ror1*, *Ngf*, *Bhlhb9*, and *Gemin5* loci generated via homology-directed repair *in vivo* using CRISPR/Cas9 (**Figure 2, Table 2**). These efforts have resulted in a recently funded project (NIH R21GM114647, *Role of a BHLHB9 polymorphism in the etiology of a developmental disorder*) for studying the function of BHLHB9, a putative GPCR modulator, and its role in neural differentiation and neurodegeneration. Although not cancer-related, this project highlights the utility of the genome editing approaches for quickly generating novel mutant mouse models to recapitulate clinically identified variants and testing their disease relevance, which is of high interest to the researchers at KUCC.

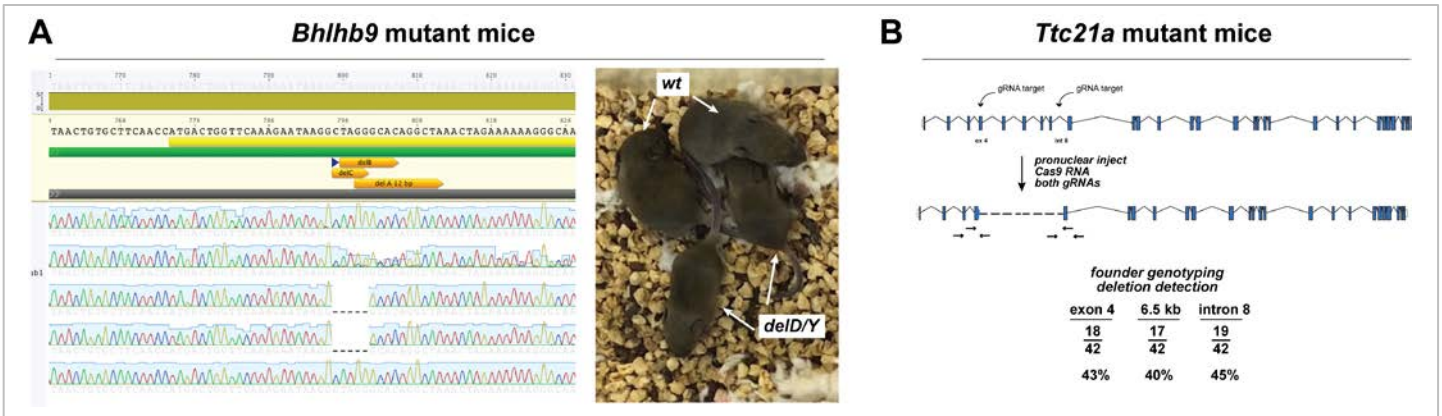


Figure 2. Mutant mouse models generated via CRISPR/Cas9 genome editing via pronuclear injection *in vivo*. **A.** *Bhlhb9* knockout mouse resulting from small 5bp deletion in *Bhlhb9* coding region. Hemizygous males carrying this mutation are small by postnatal day 7. **B.** Large deletion in *Ttc21a* from use of two gRNAs injected simultaneously. Note high frequency of founders carrying large deletion.

Gene targeting in mouse embryonic stem (ES) cells and chimeric mouse production. Genetic manipulation of mouse embryonic stem cells is a central tool for sophisticated and nearly unlimited alterations of the mouse genome. The TGTSR has extensive experience in the culture, targeting and injection of mouse ES cells. Several ES cell lines are available to investigators, including highly germline-competent E14TG2a cell line, EDJ22 cells, and JM8 cell from C57BL/6 strain used in the International Mouse Phenotyping Consortium (IMPC). The TGTSR also has successfully generated germline competent chimeric mice from ES cells from IMPC resources from both UC-Davis and EUCOMM. Drug resistant mouse embryonic fibroblasts (DR4 strain) are also available to investigators. The use of genome editing tools and pronuclear injection has allowed for the generation of certain mutant mouse models. However more complex genetic alterations still require the use of gene targeting in mouse ES cells. Thus for certain complex manipulations, including conditional alleles, large genomic alterations, and knock-in alleles, gene targeting in mouse ES cells remains a reliable tool.

High profile manuscripts reporting mouse models developed by TGTSR ES cell services include:
1. Galvin-Burgess, *Stem cells*, 2013
2. Lakatos, *BMC systems biology*, 2014
3. **Tran**, *Journal of the American Society of Nephrology,* 2014
4. **Wallace**, *Kidney international*, 2014
5. Bu, *Biology of reproduction,* 2016
6. Wilson, *Scientific reports*, 2016
7. Saha, *Molecular and cellular biology*, 2013

Human induced pluripotent stem cell services. Although currently not a major element of KUCC research, the TGTSR has invested a substantial effort in integrating human induced pluripotent stem cell models into the portfolio of stem cell services. Services include isolation and cryopreservation of primary cells from patient biopsies, reprogramming of primary cells via Sendai virus transfection, pluripotent stem cell differentiation, and gene targeting in human pluripotent stem cells via genome editing (**Figure 3**). The TGTSR can work with the KUCC Biospecimen Shared Resource (BSR) to obtain live tissue biopsies for establishing primary cell cultures. High profile manuscripts reporting mouse models developed by TGTSR human pluripotent stem cell services include Renaud, *Proceedings of the National Academy of Sciences of the United States of America*, 2015.

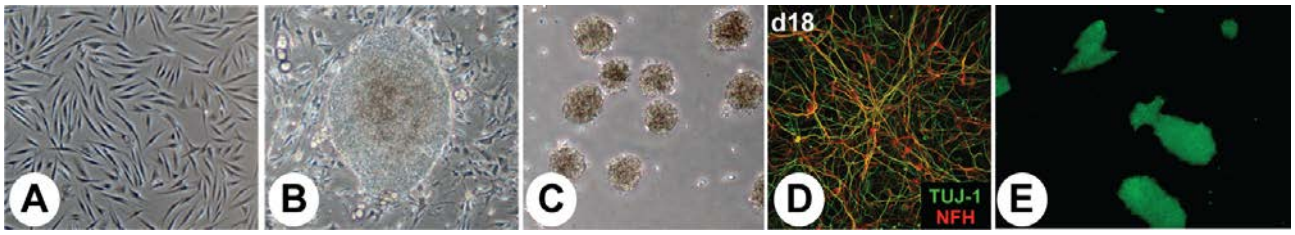


Figure 3. Derivation and differentiation of human induced pluripotent stem cells in TGTSR. A. Primary fibroblasts isolated from patient biopsy. **B**. iPS cell colony from preprogrammed patient-specific cells. **C.** Embryoid body aggregates for differentiation. **E.** Differentiation of human pluripotent stem cells to neural lineages. **F.** Pluripotent stem cells targeted with a ubiquitously expressed GFP transgene to the AAVS1 locus.

Molecular biology services.
Vector backbones. The TGTSR and **Vivian's** lab have several plasmids for generating targeting vectors and other constructs for KUCC member use. Vectors include base plasmids for making conditional alleles, CRE and GFP targeting vectors, and selectable cassettes flanked by piggybac elements. Such plasmids were either developed by **Vivian** or obtained from other investigators and repositories (Addgene, Sanger Centre). The TGTSR will provide guidance on the necessary Material Transfer Agreement to allow individual KUCC member access to plasmids not developed by **Vivian**.

Genome editing. The TGTSR staff can also assist in genome editing design for various projects. **Vivian** can perform oligonucleotide design for use in homology-directed repair with genome editing (CRISPR/Cas9 is the preferred tool), to introduce subtle changes. To avoid duplication, the validation and synthesis of genome editing reagents is not done by the TGTSR, but rather through partnerships with two other core facilities. The TGTSR has partnered with the Genome Engineering core of the Kidney Institute at KUMC, directed by **Ward** (CB) and the Genome Engineering Center at Washington University in St. Louis to serve investigators in the

design and *in vitro* transcription of genome editing tools. These cores provide services including recombinant DNA procedures to clone and validate novel guide RNAs (gRNAs) for specific regions of the mouse or human genome and *in vitro* transcription of Cas9 tools for pronuclear injection. This collaboration of services is an efficient pipeline and avoids unnecessary duplication of effort, and has proven to be highly successful in the generation of novel mouse and rat models in the past two years.

Strain development and genotyping services. The TGTSR offers services for genotyping of founder mice, established stocks, and genotyping of pluripotent stem cell clones after targeting. The current efforts include PCR-based genotyping and gel-based detection of fragments. These methods include qualitative assessment of a transgene via PCR, or using T7 endonuclease or restriction fragment polymorphisms (RFLPs) to identify subtle mutations or small in/dels generated via CRISPR/Cas9. The TGTSR has recently added real-time PCR genotyping of stock mice using TaqMan probes for rapid identification of mutant animals, which is particularly useful for genotyping small deletions and subtle point mutations generated by CRISPR/Cas9 mutagenesis. The TGTSR also offers KUCC members assistance in initial stock establishment and expansion. These mice can then be delivered to the investigators for further expansion and experimental manipulation.

Cryopreservation and rederivation services. The TGTSR has the necessary equipment and expertise for efficient cryopreservation of mouse sperm and embryos and stem cell lines. The cryopreservation service is a convenient cost-saving measure when mouse stocks are no longer being used. As detailed in the Facilities and Other Resources section, the TGTSR has a large (370 liter, 15,600 vial capacity) MVE Eterne nitrogen cryo tank with automated N2 injectors for autofilling. Long-term cryopreservation of sperm, embryos, and pluripotent stem cells is provided to KUCC members at no cost. The TGTSR also has the capability for *in vitro* fertilization (IVF) and intracytoplasmic sperm injection for reconstituting frozen sperm. IVF also can be performed on frozen sperm from other institutions, which allows for rapid transfer of animals strains and importation of animals from institutions with known pathogens. Recently, the TGTSR has successfully reconstituted strains from sperm isolated from fresh epidydimides shipped overnight at room temperature from another institution. All of these services are convenient means of accelerating access to mouse strains for KUCC researchers.

Location

The TGTSR laboratory space consists of three rooms in the Hemenway Life Sciences Innovation Center (HLSIC G020, 558 sq. ft; HLSIC G022, 496 sq. ft.; and HLSIC G021, 110 sq. ft), the newest research building on the KUMC campus, which opened in 2007. HLSIC G020 is the main laboratory for animal surgeries, embryo manipulation, and injections; HLSIC G022 consists of a suite of three interior rooms dedicated to various pluripotent stem cell culture procedures. G021 serves as the molecular biology lab. Additional cell culture, reagent preparation, and general laboratory space is available in HLSIC 3063 (1040 sq. ft.) in **Vivian's** lab. A vivarium room solely for TGTSR mice is within the Hemenway space, which houses stocks for all procedures, and founders and chimeras prior to delivery. This room is within the Specific Pathogen Free environment of the Hemenway vivarium on the same floor as the TGTSR lab space.

Equipment and Instrumentation

The TGTSR has state-of-the-art instrumentation for embryo manipulation, microinjection, pluripotent stem cell culture, and cryopreservation to support all research services. With the opening of the Hemenway Life Sciences Innovation Center in 2007, KUMC invested in a significant enhancement of instrumentation for the TGTSR. Most instrumentation in the TGTSR was upgraded at that time. Thus most of the instrumentation in the TGTSR is less than nine years old, including microscopes, two micromanipulator microinjection stations, three biosafety cabinets, four incubators, a large autofill nitrogen storage tank and an X-ray irradiator. The TGTSR also houses equipment for various molecular biology techniques for genotyping, and has access to a shared ABI7900 real-time PCR machine. Additionally, the Kansas IDeA Network of Biomedical Research Excellence (K-INBRE, P20GM103418, Doug Wright, PhD, PI) Institutional Development Award has provided awards to the TGTSR through competitive application process for new instrumentation. The TGTSR has taken advantage of this funding source the past several years to upgrade and purchase new instrumentation, including a dedicated isofluorane vaporizer anesthesia delivery system and a tattooing workstation for labeling mice prior to delivery to investigators. Details of the TGTSR instrumentation are given in the Facilities and Other Resources section.

Scientific Accomplishments

Several KUCC projects are highlighted below, demonstrating the impact of the novel models developed using the TGTSR services, including support for ongoing grants, newly awarded grants and selected high-profile publications.

Mouse Transgenesis
Raj **Kumar** (CB) has used the TGTSR resources in the generation of several animal models for studying the role of pituitary-derived hormones in the control of ovarian function (Wang, *Molecular and celluar endocrinology*, 2016). In a high-profile paper in *PNAS* and a subsequent follow-up (Wang, *Proceedings of the National Academy of Sciences of the United States of America*, 2014 and Wang, *The Journal of biological chemistry*. 2015). **Kumar** used transgenic mouse lines generated by the TGTSR to understand the pulsatile activity of luteinizing hormone. His results have identified specific amino acids which biochemically control the intracellular trafficking of hormone peptides, and the role of Dicer in fertility. These efforts and models have led to an NCI-funded project examining pituitary gonadotrope tumors (NIH R01 CA166557, *Chemoprevention of pituitary gonadotrope tumors*).

Gene targeting in mouse embryonic stem cells
Vargheese **Chennathukuzhi** (D3ET) has a research interest in uterine fibroids and the molecular control of the progression of these nonmalignant tumors. The TGTSR has generated mouse strains that overexpress or conditionally remove specific regulatory factors identified in **Chennathukuzhi's** studies. These results have highlighted the central role of mTOR signaling in fibroid growth. These studies have led to the publication of a high-profile paper (Varghese, *Proceedings of the National Academy of Sciences of the United States of America*, 2013) and a new R01 grant (NIH R01 HD076450, *The role of REST in the pathogenesis of uterine fibroids*).

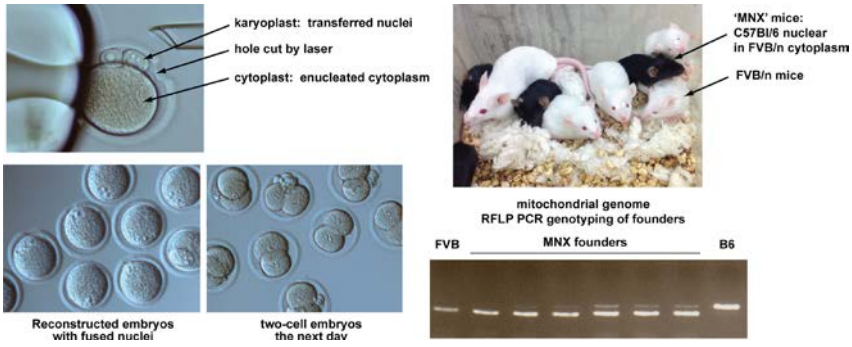
Kristi **Neufeld** (CB) has long-standing research interests in the genes and mutations involved in the progression of colorectal cancer including the role of the tumor suppressor APC (NIH R01 CA109220, *Nuclear functions of the tumor suppressor protein APC*). Using gene targeting in embryonic stem cells and blastocyst injection, the TGTSR generated a novel mouse model harboring subtle mutations producing an APC protein lacking functional nuclear localization sequences (Zeineldin, *Oncogene*, 2012). Her studies with this model have demonstrated a critical role for nuclear APC in control of WNT target genes, intestinal epithelial cell proliferation and polyp formation (Zeineldin, *Carcinogenesis*, 2014).

Genome editing *in vivo*
Michael **Soares** (CB) has a long-standing collaborative interest in studying hormonal influences of cell proliferation and differentiation. As a part of a major new initiative, the TGTSR assisted in the production of several novel mutant rat models of hormonal control, using genome editing approaches *in vivo*. The initial technical assistance in pronuclear injection led to the generation of mutant rat models of estrogen receptors alpha and beta, and progesterone receptor, steroid hormones with important regulatory functions in several types of tumors. These efforts, which are still ongoing, have led to papers describing the *Esr1* and *Pgr* knockout rats (Rumi, *Endocrinology*, 2014 and Kubota, *Proceedings of the National Academy of Sciences of the United States of America*, 2016), two funded R21s (NIH R21 OD010478, *Rat Models for Sex Steroid Action* and NIH R21 HD082535; *Natural Killer Cells and Hemochorial Placentation)* and a P01 (NIH P01 HD079363, *Stem Cells and Epigenetics of Trophoblast Lineage Development*).

Embryo manipulation
Danny **Welch** (CB) has an interest in understanding the role of mitochondria and mitochondrial genetic variants in tumor progression (NIH R01 CA134981 *KISS1: Defining mechanisms for anti-metastatic therapy* and Komen SAC11037). To these ends, **Welch** has been developing mitochondria/nuclear exchange (MNX) strains, in which the nuclear material of one mouse strain has been introduced into the cytoplasmic/mitochondrial environment of another strain (Feeley, *Cancer Research*, 2015). The TGTSR has expanded on the initial models generated by **Welch** and the Transgenic Facility at University of Alabama-Birmingham, and developed novel strategies using a Sendai viral fusion of nucleoplasts into enucleated zygotes to generate novel MNX strains. These TGTSR efforts have resulted in making new MNX founder

strains (**Figure 4**) with no obvious mitochondrial heteroplasmy, which are currently being expanded for future *in vivo* experimentation. Future efforts will develop more MNX strain combinations for **Welch's** studies.

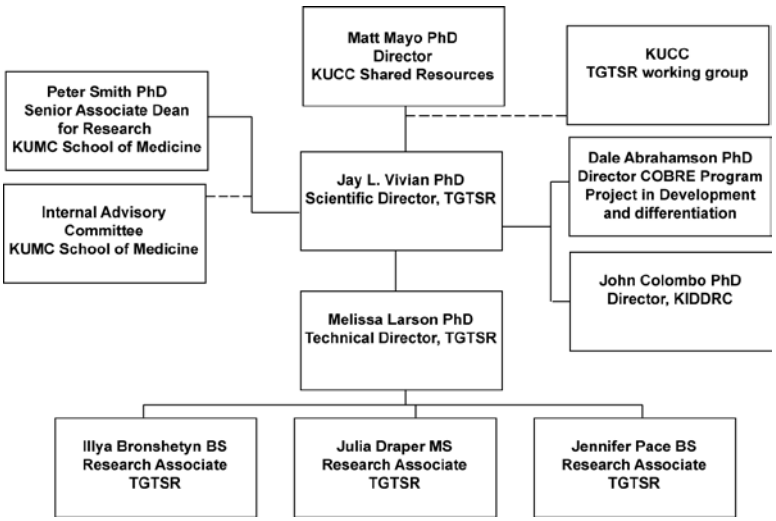
Figure 4. Generation of Mitochondria-nuclear exchange mice. Pronuclei from zygotes are extracted from two strains, then one set ('karyoplasts') are subzonally injected into an enucleated host. Sendai virus is used to fuse the cells and generate reconstituted zygotes. Offspring are genotyped for mitochondrial SNPs between the two strains to identify homoplastic founders.



Management Structure

Vivian serves as the Director of the TGTSR, working closely with the Manager and staff in quality assurance and integration of new methodologies (**Figure 5**). The TGTSR receives support from a variety of sources, including funds from the School of Medicine (Peter **Smith**, Senior Associate Dean for Research), the COBRE program project in Development and Differentiation (Dale Abrahamson, Director), and KUCC (Matt **Mayo**, Associate Director for Shared Resources). **Vivian** meets regularly (at least twice a year) with the leaders of these groups to discuss initiatives, program needs and funding. **Vivian** provides annual fiscal and scientific reports to each of these groups.

Figure 5. Organizational chart



An Internal Advisory Board (IAB), chaired by Ken **Peterson**, meets twice a year to discuss major scientific initiatives and challenges. This board includes **Smith** as an *ex-officio* member and several active users of the TGTSR with research interests and expertise in mouse genetics and pluripotent stem cell biology (**Table 3**). The role of this committee is to provide suggestions to the Scientific Director and Manager, and provide recommendations to the Senior Associate Dean for Research on institutional support. Most of the IAB are KUCC members. The TGTSR also has an external advisory committee consisting of leaders in mouse genetics and cancer biology (**Table 4**).

Table 3. TGTSR Internal Advisory Board

Member	Title	KUCC program
Ken Peterson PhD, Chair	Professor	CB
Matt Mayo PhD, ex officio	Director, KUCC Shared Resources	CB
Peter Smith PhD, ex officio	Senior Assoc. Dean for Research	CPS
Patrick Fields PhD	Assoc. Professor	CB
Leslie Heckert PhD	Professor	-
Tomoo Iwakuma PhD	Assoc. Professor	CB
Soumen Paul PhD	Assoc. Professor	CB
Pamela Tran PhD	Asst. Professor	CB

Table 4. TGTSR External Advisory Board

Member	Title	Institution
Gigi Lozano, PhD	Chair, Dept of Genetics	MD Anderson Cancer Center
David Threadgill, PhD	Director, Whole Systems Genomic Initiative	Texas A&M University

KUCC planning and oversight. A KUCC Mouse Models Strategic Planning Working Group (**Table 5**) was established in Spring 2016 to discuss specific needs for KUCC members. This group will meet twice a year to provide valuable directions for immediate needs of KUCC members, KUCC initiatives and identify venues for further communication of TGTSR efforts and services to KUCC members. This strategic planning group leverages KUCC members with both expertise in mouse models (**Chien, Iwakuma, Neufeld, Welch**) and also program leadership positions in the KUCC (**Mayo, Neufeld, Welch**), and has substantial overlap with the IAB (**Iwakuma, Mayo**).

Table 5. KUCC Mouse Models Strategic Planning Working Group

Member	KUCC Program Affiliation
Jeremy Chien, PhD	CB
Tomoo Iwakuma, PhD	CB
Matt Mayo PhD	CB
Kristi Neufeld, PhD	CB
Danny Welch, PhD	CB

Operations & Policies

Work prioritization and hours of operation. Work is generally performed on a first-come, first served basis. On occasions in which prioritization is required, the following system will be used:

Priority 1 – Cancer Center member with NCI grant support or Cancer Center pilot funds
Priority 2 – Cancer Center member with cancer and/or cancer-related grants funded by NIH (non-NCI) and other peer-reviewed grants as defined by NCI
Priority 3 – Non peer-review funded or unfunded KUCC investigators (e.g., primarily junior investigators)
Priority 4 – NCI/NIH-funded investigators outside of KUCC
Priority 5 – Other funded investigators outside of KUCC
Priority 6 – Unfunded investigators outside of KUCC

Vivian and Larson consult with investigators and staff prior to initiating any new projects, to assess any potential problems or issues with feasibility. An accurate assessment of the current queue, if present, will be provided to an investigator at the time of the work request, along with the expected time of when the work will be performed. If any questions regarding prioritization or scientific feasibility arise, the Internal Advisory Committee is consulted. Scheduling exceptions can be made for investigators who may urgently need cells for completion of a grant submission or for additional experiments requested for a journal publication. Higher priority is also given to researchers for which a previous procedure has not been successful. If this is the case, a detailed analysis will be done on why the procedure 'failed', prior to reinitiating a procedure.

Resolution of disputes relating to core usage. **Vivian**, as the Director of the TGTSR, is the first point of contact when disputes arise. This typically involves **Vivian** having separate discussions with Larson and the TGTSR staff, and the investigator, to determine a possible course of action. If there is no agreed course of action, then the Internal Advisory is consulted and they are the final arbiter of any issues.

Fee-for-service arrangements. All work done by the TGTSR is done on a standard fee-for-service mechanism, and all fees are listed on the TGTSR website. For non-standard services, the TGTSR has in place an hourly rate for staff effort, and customized quotes will be generated to recover staff time and reagent costs. The same fees of all work are applied to all internal investigators, to maintain compliance to NIH policies for costing of NIH-funded core facilities (NIH NOT-OD-13-053).

Hours of operation. TGTSR staff are typically available 8am-5pm during the week for discussions. Major procedures are largely performed during the week, along with weekend preparation work (e.g. superovulations, cell culture, etc). Staff are sufficiently cross-trained so that projects can move forward when assigned staff are on vacation or sick, and this allows for substantial capacity for supporting several projects simultaneously.

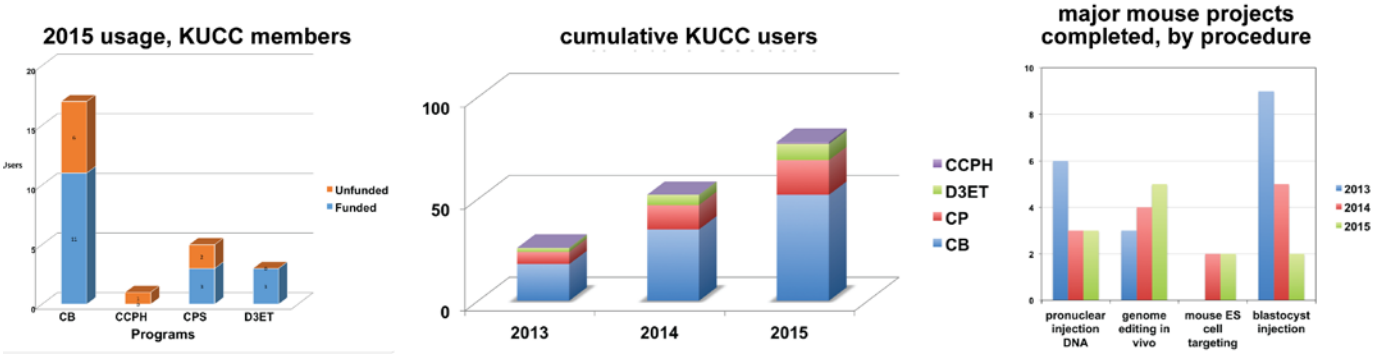
Project management. As part of a KUCC initiative, the TGTSR uses the iLab Solutions online requisition and project management system. iLab Solutions provides users an online system to request work, monitor project progress and approve and process payments. The system allows the TGTSR to assign work duties to specific

staff after a work request is submitted. Over the course of the project, updates in the project progress are input into iLab by the TGTSR staff, such as the completion of an important step in a procedure. The investigator can simply log in to monitor project progress. When a work request is completed, internal accounts and billing are handled by iLabs, allowing for a straightforward means of payment. In addition to individual project management, there are also reporting functions within iLabs, for monitoring the overall activity of the core. For example, reports can be generated at the end of the fiscal year to summarize all activities of the core, including detailed finance information. The iLabs system has become an important tool for accurately tracking all TGTSR services, billing and efficiency.

Usage

In calendar year 2015, the TGTSR supported 64 new and ongoing projects from 43 investigators. This metric includes both hands-on fee-for-service work, as well as, project design meetings and analysis of sequences for construct design. **Figure 1** describes the breakdown of services in terms of TGTSR workload, and is broadly distributed amongst the various services. In CY2015 (**Figure 6**), 26 of the users (61%) of the TGTSR were KUCC members. Most of the projects supported were for funded members (17/26). Of the KUCC users, the program membership is as follows: 65% were in Cancer Biology (CB); 12% in Drug Discovery, Delivery and Experimental Therapeutics (D3ET); 19% in Cancer Prevention and Survivorship (CPS); and 4% were in Cancer Control and Population Health (CCPH). Trends can be observed from this data. First, consistent usage is seen in the past three years. Second, there is a strong trend toward genome editing methods and a concomitant reduction in mouse embryonic stem cell services as expected. The Cancer Biology program is a heavy user, which is expected given the membership of this program and their research interests.

Figure 6. TGTSR Usage



Cost-Effectiveness

The TGTSR has leveraged center, institutional and programmatic support to maintain fees at a low level (**Table 1**) which are competitive with internal pricing at other academic institutions. Although commercial vendors and other academic cores may provide similar services as the TGTSR, these costs tend to be prohibitive to academic researchers. A presence on campus greatly reduces costs associated with otherwise obtaining mice and cell reagents from other sources, including expensive shipping and administrative costs associated with shipping of animals. The generation of animal models in-house also allows researchers immediate access to these animals, in contrast to the restricted quarantine time associated with obtaining animals from external sources. Other services performed by the TGTSR require the lab to be physically near the researchers. For example, the TGTSR currently can collect live biopsies for use in generating primary cell lines from local affiliated hospitals, particularly the University of Kansas Health System and Children's Mercy, and can also leverage tissue collection capacity of the BSR. Finally, the TGTSR leverages the existing expertise in mouse genetics, pluripotent stem cell biology, and novel mutagenesis methods present at KUMC to advance new technologies and making these resources and methodologies immediately available to KUCC researchers. The presence of the TGTSR on the KUMC campus is an important and cost-effective shared resource for all KUCC researchers, and able to quickly provide the necessary novel mouse and stem cell models.

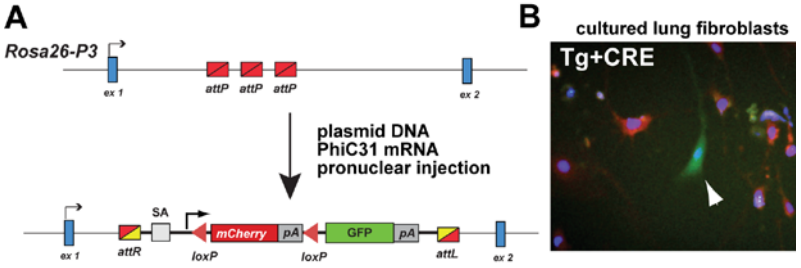
Future Plans

KUCC initiatives. The funding from KUCC to the TGTSR during its participation as a developing shared resource in the previous three years has led to the implementation of several important technological advances. Specifically, the successful CRISPR/Cas9 genome editing pipeline is an excellent example of such a major advancement made possible by Cancer Center support. The participation of the TGTSR as an established shared resource and participant in the CCSG will increase the funding level and allow for the development of new initiatives, and also maintain the low costs of the current services to KUCC members. **Vivian** and the Cancer Center working group have identified several cancer relevant initiatives for the next funding period. Many of these initiatives are directly tied to existing services within the TGTSR. Other procedures leverage the TGTSR's expertise in embryo manipulation, survival surgeries and genetic engineering to develop mouse models in novel ways.

Expanded Molecular Biology services. As part of the TGTSR's participation as a KUCC shared resource, the staff will provide new services in novel DNA construction. This **new service** leverages the expertise in **Vivian's** lab in recombinant DNA techniques. All constructs developed in this service will be plasmid-based, and largely use PCR methods for amplifying elements from BACs and will be cloned into backbone vectors via Gibson Assembly-style cloning (Clontech Infusion), and validated via sequencing. The TGTSR has Geneious DNA annotation software licenses for the design, annotation, and curating of constructs. The cost of vector construction services will depend on the complexity of the construct, but will be approximately $500 per cloning step if the PCR fragments are less than 2kb. As part of the quality assurance function of the shared resource, the staff in the TGTSR handle the preparation of DNA for microinjection, including purification and isolation of DNA fragments, and this is part of the service cost for pronuclear injections.

PhiC31-mediated transgenesis. The TGTSR has incorporated a relatively new technology for targeted integration of transgenes *in vivo*. This work is based on recent efforts by Liqun Luo, PhD, a Howard Hughes Medical Investigator at Stanford University, which relies on the targeted integration of DNA injected into the one cell stage embryo (zygote), catalyzed by the PhiC31 integrase. This exciting new development allows for the insertion of DNA sequences directly into specific locations in the mouse genome *in vivo*. This platform greatly accelerates the production of many new transgenic models that would otherwise require gene targeting in embryonic stem cells. The TGTSR has obtained two mouse strains with the engineered landing sites at the *Rosa26* and *Hipp11* loci for transgene integration using this system (**Figure 7A**). The TGTSR's early efforts using this system for making targeted transgenics for Darren **Wallace** (CB) and Lane **Christenson** (CB) demonstrated an approximately 8-16% targeting efficiency in founder mice after pronuclear injection. Future efforts will include the generation of constructs that allow for the production of mice with conditional transgenes integrated into the endogenous *Rosa26* or *Hipp11* loci (**Figure 7B**), under the control of different promoters. Conditional transgenes are of particular use to KUCC members, as this platform allows for the expression of transgenes in some somatic cells via CRE-mediated recombination.

Figure 7. Transgenes targeted to *Rosa26* locus via pronuclear injection using PhiC31 integrase. A. Targeting of attB flanked conditional construct into strain with engineered *Rosa26* attP docking elements. **B.** Fibroblasts isolated from transgenic mice and transfected with CRE. Note cells with GFP expression (arrowhead), indicating CRE-mediated deletion.



Model development using advanced CRISPR/Cas9 methods. The TGTSR monitors advancements in the use of the CRISPR/Cas9 for the development of novel mouse. Continued efforts will test new methods to enhance the efficiency of the procedure and reduce off- target effects, particularly for the development of more complex alleles such as knock-in alleles and conditional ('floxed') alleles. The TGTSR will explore alternative injection methods, including the use of Cas9 protein/crRNA/tracrRNA co-injections, which may both enhance mutagenesis efficiency and reduce founder mosaicism.

The TGTSR is also working with several KUCC investigators for genome editing in non-standard mouse strains, including mutant mouse lines and atypical strains. The TGTSR is currently working with Mary Markiewicz in the generation of mutations in the NOD/ShiLtJ ('NOD') mouse strain, to understand the effects of specific genes on the control of the immunity system on lymphoma progression. Successful mutagenesis directly into the NOD mice will greatly accelerate the analysis of mutant mice in this immune-compromised background, without having to do the complex backcrosses into this strain. **Neufeld** has interests in using the Diversity Outcross mouse strains to identify novel modulators of the *Apc* mutation in colorectal and small intestine tumorigenesis. These studies will involve the generation of mutations into specific DO haplotypes identified in her studies. The TGTSR has recently participated in **Neufeld's** Provocative Questions grant application to the NCI supporting this effort.

The TGTSR is also interested in advancing novel genome editing approaches by development of novel mouse strains. **Vivian** and **Welch** are exploring the use of MNX strains of mice (**Figure 4**) as potential platforms for enhancing CRISPR/Cas9 mutagenesis. These efforts hypothesize that certain mitochondrial-nuclear combinations will produce a novel strain with enhanced capacity for Cas9 mutagenesis via pronuclear injection methods, including enhanced mutagenesis frequencies and embryo survival. These studies will form the basis of a collaborative grant application in Fall 2016.

Intra-bursal injection. Several KUCC researchers have interests in mouse models of ovarian cancer. Given the TGTSR's expertise in routine survival surgeries for embryo transplantation into the ovarian bursa or anterior uterus, these surgical procedures have been modified to introduce cancer cells into the bursal space of the ovary. This xenograft model more precisely recapitulates the ovarian environment of the ovarian cancer cells. The TGTSR has successfully introduced cells into the ovary for **Godwin** (D3ET) and **Chen** (D3ET). Future efforts in this procedure will assist **Chien** (CB) in intra-bursal injection of virus into a mutant mouse model of ovarian cancer progression. Viral infection will force the expression of genome editing tools (Cas9 and gRNAs) to ablate genes identified in **Chien's** genomic studies as potential modifiers of ovarian cancer progression.

Progress Report Publications

This component has no publications resulting from Cancer Center Support Grant funds.

Vertebrate Animals – TRANSGENIC AND GENE-TARGETING SHARED RESOURCE

Description of Procedures

The Transgenic and Gene-Targeting Shared Resource (TGTSR) conducts studies on vertebrate animals using IACUC approved procedures (current KUMC Animal Care and Use Protocol 2016-2310). All procedures revolve around the generation of mutant and transgenic mice from either pronuclear injection of zygotic embryos or blastocyst embryo injection of targeted embryonic stem cells. As such, the TGTSR maintains stocks of mice for mating to generate embryos for microinjection, which involves cervical dislocation of pregnant females and subsequent embryo harvest. Additionally, mouse stocks are maintained for transfer of embryos into pseudopregnant females via survival surgeries. Finally, a stock of mice are used for harvest of later stage embryos for isolation of fibroblasts for feeder layers for embryonic stem cell culture. Further experimental procedures and matings with the animals will be performed under investigator-initiated protocols approved by the IACUC.

Animal use numbers

Several strains of mice are used for these procedures. Wild-type stocks and the DR4 mice will be purchased from the Jackson laboratories as adult mice only on an as needed basis.

C57Bl6 mice: Wild-type strain for pronuclear and blastocyst injection and stock expansion. Females are superovulated and mated for embryo harvest. Some mice are kept for stock expansion.
20 males per year, 500 females per year. 2600 mice total for 5 year period.

FVBn mice: Wild-type strain for pronuclear injection. Females are superovulated and mated for embryo harvest.
20 males per year, 500 females per year. 2600 mice total for 5 year period.

CD-1 mice: Wild-type strain for embryo transfers. Female mice are mated to vasectomized males for pseudopregnant host females.
20 males per year, 200 females per year. 1100 mice total for 5 year period.

Generation of fibroblasts: Transgenic mice harboring multiple drug resistance markers for feeder layer generation. Two males of the DR4 strain. 5 year timeline. 10 mice total.

Justifications

The mouse has been chosen for our work due to the ability to generate genetically altered mouse strains using advanced transgenic technologies. The use of genome editing has greatly accelerated the capacity to make new mouse models that closely recapitulate the variants identified in human disease. We have leveraged these new methods to both accelerate the generation of these mice, and reducing the number of animals needed to generate these critical models. The procedures for embryo microinjection are well-described, and the staff in the TGTSR have expertise in this procedure. Compared to most mammals, the mouse has a short gestation period and large litter sizes, allowing us to obtain mutant or transgenic offspring quickly without maintaining a large colony of animals. The study of gene function, particularly for physiological and disease studies, requires the use of whole animal models. Although useful for many studies, cell culture and computational models simply cannot provide a complete picture of the complex tissue and organ level organization required for these studies.

Minimization of Pain and Distress

The transfer of microinjected embryos into pseudopregnant females requires the use of survival surgery. This involves a dorsal incision into an anesthetized female (avertin or isofluorane anesthesia) to expose the uterine horn for embryo transfer. Buprenorphine is used presurgically as a prophylactic analgesic. These surgeries are performed by expert staff with over 20 years' experience in this highly standard procedure. Infection is avoided by tip-sterilizing instruments and observing aseptic technique. Anesthetized mice recover on a warming pad

until ambulatory. Should any animals appear distressed after surgery, the vet staff will be consulted with the veterinary staff for treatment.

The identification and maintenance of the mouse lines harboring genetic alterations will require obtaining tissue to isolate DNA from each animal. A highly sensitive PCR-based method of genotyping mice will be used, requiring the isolation of DNA from small amounts of tissue from each mouse, such as an ear clip. Ear clipping will be accomplished a few days prior to mouse weaning (19 days of age) by clipping a disk of outer ear tissue approximately 2 mm in diameter, using an ear clipper specifically designed for this procedure. The resulting ear clip is small enough that no analgesic is required. These procedures will require only limited and transient physical restraint of the mouse, by the scruff of the neck for a total of approximately 15-20 seconds.

Euthanasia

All euthanasia procedures are consistent with the recommendations of the American Veterinary Medical Association Panel on Euthanasia. Euthanasia will be performed only on a small number of mice for embryo harvest, mouse embryo fibroblast isolation, or for culling of offspring that do not carry the indicated mutation. Euthanasia will be performed by CO_2 asphyxiation followed by cervical dislocation or chest cavity opening only by highly skilled staff of the TGTSR. This procedure allows for the rapid loss of consciousness by CO_2 inhalation; the euthanasia is thus performed on an unconscious mouse. This method is used because it is rapid and does not appear to interfere with any subsequent experimental procedures on tissues or embryos derived from the euthanized mouse.

Transgenic and Gene-Targeting Shared Resource – References Cited

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Resource Sharing Plan – TRANSGENIC AND GENE-TARGETING SHARED RESOURCE

Most mouse and stem cell models generated by the TGTSR are delivered to individual investigators, which are responsible for the relevant sharing of these reagents. Over the course of developing novel resources and methods, the TGTSR may produce novel reagents, such as a plasmid, mouse strain, or stem cell line, which would prove to be useful for other investigators. If such reagents are produced, they will either be deposited into an interested resource center (Jackson Labs or a Mutant Mouse Resource Center for mouse strains, WiCell for pluripotent stem cell lines, or Addgene for plasmids) after completion of a standard Material Transfer Agreement with the assistance from the University of Kansas Innovation and Collaboration Center.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 016060860

Legal Name*: University of Kansas Medical Center Research Institute, Inc.
Department:
Division:
Street1*: MSN 1039, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Deborah		Maloney	MSM

Position/Title: Director, Sponsored Programs Administration
Street1*: 3901 Rainbow Boulevard
Street2: Mail Stop 1039
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937
Phone Number*: 913-588-1261 Fax Number: 913-588-3225 Email: spa@kumc.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofit Organization
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Clinical Protocol and Data Management

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2017	06/30/2022

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Medical Center
Duns Number:	016060860
Street1*:	MS 5003, 2330 Shawnee Mission Parkway
Street2:	
City*:	Westwood
County:	Johnson
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66205-2005
Project/Performance Site Congressional District*:	KS-003

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ❍ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number 00003411

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	CPDM_Project_Summary_Final1019469462.pdf
8. Project Narrative*	
9. Bibliography & References Cited	
10.Facilities & Other Resources	
11.Equipment	
12. Other Attachments	CPDM_OtherAttachments_Final1019469461.pdf

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Clinical Protocol and Data Management – Project Summary

The Clinical Protocol and Data Management (CPDM) function at the University of Kansas Cancer Center (KUCC) resides within the Clinical Trials Office (CTO). The CTO, led by Stephen **Williamson,** MD (Medical Director of the CTO and Early Phase Clinical Research Program) and Hobs **Apell**, (Senior Executive Director) provides comprehensive support services that span the life cycle of cancer clinical trials from concept through manuscript. The CTO provides a central location for protocol management and reporting. There is a strong emphasis on assuring data integrity and compliance as well as emphasis on the education and training of CTO staff and investigators. There is also a strong emphasis on achieving timelines for rapid submission and activation of protocols while observing all regulatory requirements. To further translational research and mentorship goals, the Investigator-Initiated Trial Steering Committee (IITSC) was established in 2015. The IITSC, chaired by **Williamson,** and Scott **Weir**, PharmD, PhD (Associate Director for Translational Research), was formed to mentor and educate junior investigators and to support the acceleration of scientific discovery of novel therapeutics through the conduct of investigator-initiated clinical trials.

Over the last four years, substantial progress has been made broadening clinical research partnerships with communities throughout our catchment area. Three major changes have expanded the composition of clinicians participating in the clinical trials process. The first change results from the incorporation of a large private practice oncology group by the University of Kansas Health System, a group now defined as the KUCC community oncology program. The second change is the expansion of the outreach network of KUCC, known as the Midwest Cancer Alliance (MCA), which is a membership fee-based network of hospitals and physician groups located across the KUCC catchment area. Many MCA centers serve as affiliate sites to cooperative group sponsored trials and investigator-initiated trials conducted by KUCC as the Primary Center. The third change results from the 2015 consortium agreement with Children’s Mercy incorporating their clinicians into KUCC programs.

The CTO has enabled a steady increase in clinical trials accrual at KUCC since receiving NCI Designation. Accrual to Intervention clinical trial protocols increased overall by 21% (2,097 accruals in 2012 to 2,544 accruals in 2015). Accrual to Interventional investigator-initiated trials (IIT) increased by 12% (1,140 accruals in 2012 to 1,275 accruals in 2015). Notably, in 2015, institutionally sponsored IITs accounted for nearly 50% of all KUCC intervention clinical trial enrollments. Accrual to Industrial Sponsored Interventional Trials increased more than 160% (96 accruals in 2012 to 256 accruals in 2015). In summary, the CTO has facilitated significant growth of clinical research, while implementing cost-effective processes to ensure that the research activities have scientific merit, protect safety, and maintain scientific integrity.

Clinical Protocol and Data Management – Other Attachments

I. Accrual to Intervention Clinical Trials by Reporting Year and Source of Support*

INTERVENTIONAL CLINICAL TRIAL ENROLLMENT, CALENDAR YEARS 2012-2015					
Reporting Year	**2012**	**2013**	**2014**	**2015**	**TOTAL**
National	136	204	142	208	690
Externally Peer-Reviewed	975	988	660	856	3479
Institutional (Investigator Initiated)	1140	779	1089	1275	4283
Industrial	96	168	138	256	658
TOTAL	**2347**	**2139**	**2029**	**2595**	**9110**

***** This is a summary of Data Table 4 interventional trial data combining primary center and other institution accruals

II. Inclusion of Women and Minorities

								Catchment Area Accrual (% of total treated)					
		Catchment Area Demographics N = 4,446,421		Catchment Area Number of Cancer Cases N=21,831		Treated Patients at KUCC + CMH N = 5,054		Interventional Treatment N = 491 (9.7%)		Interventional Non-Treatment N = 2,104 (41.6%)		Observational/Ancillary N = 932 (18.4%)	
		N	%	N	%	N	%	N	%	N	%	N	%
Gender	Female	2,247,721	51%	10,550	48%	2762	55%	239	49%	1600	76%	615	66%
	Male	2,198,700	49%	11,281	52%	2283	45%	252	51%	501	24%	262	28%
	Unknown	0	0	0	0%	0	0	0	0	3	0%	55	6%
Racial Categories	American Indian/ Alaska Native	44,559	1%	52	0%	16	0.3%	2	0.4%	133	6%	100	11%
	Asian	99,436	2%	197	1%	86	2%	4	1%	18	1%	17	2%
	Native Hawaiian or Other Pacific Islander	7,057	0.2%	0	0%	5	0.1%	0	0%	3	0.1%	0	0%
	Black or African American	377,657	8%	1,474	7%	409	8%	43	9%	434	21%	85	9%
	White	3,802,528	86%	19,637	90%	4407	87%	424	86%	846	40%	571	61%
	Other (>1 race or self-identified as "other")	115,184	3%	471	2%	107	2%	18	4%	595	28%	18	2%
	Unknown or Not Reported	0	0%	0	0%	24	0.5%	0	0%	75	4%	141	15%
Ethnicity Categories	Hispanic or Latino	417,479	9%	568	3%	154	3%	15	3%	711	34%	28	3%
	Not Hispanic or Latino	4,028,942	91%	19,814	91%	4844	96%	475	97%	1320	63%	654	70%
	Unknown or Not Reported	0	0%	1449	6%	47	1%	1	0%	73	3%	250	27%

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Stephen Middle Name Last Name*: Williamson Suffix: MD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Medicine-Clinical Oncology
Division: School of Medicine
Street1*: MS 5003, 2330 Shawnee Mission Parkw
Street2:
City*: Westwood
County: Johnson
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66205-2005

Phone Number*: 913-588-6029 Fax Number: 913-588-4085

E-Mail*: SWILLIAM@kumc.edu

Credential, e.g., agency login: SWILLIAMSON

Project Role*: Other (Specify) Other Project Role Category: Core Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Williamson_Bio_CCSG1019616620.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ❍ Yes ● No

*Agency-Defined Phase III Clinical Trial? ❍ Yes ❍ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ❍ Yes ❍ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

❍ Yes ❍ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

❍ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

☐ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator / Change of Institution Section

☐ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

☐ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	CPDM_Specific_Aims_Final1019469464.pdf
3. Research Strategy*	CPDM_Research_Strategy_Final1019913932.pdf
4. Progress Report Publication List	Progress_Report_Publications_Blank1019754753.pdf
Human Subjects Section	
5. Protection of Human Subjects	Protection_of_Human_Subjects___CPDM1019799868.pdf
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	Inclusion_of_Women_Minorities___CPDM1019799869.pdf
8. Inclusion of Children	Inclusion_of_Children___CPDM1019799870.pdf
Other Research Plan Section	
9. Vertebrate Animals	
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	
14. Resource Sharing Plan(s)	Resource_Sharing_Plan__Generic1019799871.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

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Clinical Protocol and Data Management – Specific Aims

The Clinical Protocol and Data Management (CPDM) function at The University of Kansas Cancer Center (KUCC) resides within the Clinical Trials Office (CTO).

Leveraging the CTO infrastructure, the specific aims include, but are not limited to:

1. Provide comprehensive, centralized support services to KUCC investigators that span the life cycle of cancer clinical trials from protocol concept through manuscript.

2. Provide resources to successfully conduct trials in compliance with federal, state and local regulations.

3. Provide quality control and routine auditing to assure data integrity.

4. Provide ongoing training and education for study staff and investigators.

5. Provide detailed, real-time metric reports on clinical trial accrual and screen failures.

6. Provide detailed, real-time performance metrics on clinical trial activation timelines.

7. Provide a central location for protocol management.

Clinical Protocol and Data Management – Research Strategy

PART I: CLINICAL PROTOCOL AND DATA MANAGEMENT

The CPDM received an "Excellent" rating by NCI Reviewers at the 2012 Site Visit, and was commended for its leadership, organization, planning and overall integration with Cancer Center operations and initiatives. The Clinical Protocol and Data Management (CPDM) function at The University of Kansas Cancer Center (KUCC) resides within the Clinical Trials Office (CTO). Over the past four years, in an effort to further enhance clinical research, the Cancer Center made significant commitment of additional resources to recruit new talent and further refine CTO operations. The following table provides a description of the NCI Reviewer comments regarding areas for improvement, and the actions taken to address them.

RESPONSE TO 2012 NCI REVIEWER COMMENTS

Areas for Improvement	Subsequent Actions
Integrate pharmacokinetics and pharmacodynamics efforts with other research processes	1. Clinical Pharmacology is now represented at the weekly Executive Resource Committee (ERC) assessing every new protocol with respect to correlative laboratory collection requirements. Additionally, the Director of the Clinical Pharmacology shared resource is a standing member of the Investigator-Initiated Trial Steering Committee, receiving early drafts of protocol concepts and providing valuable intellectual input into the design of pharmacokinetic and pharmacodynamics correlative analyses.
Encompass the entire research effort and the clinical trials of the Cancer Center	1. A critical endeavor was initiated in 2012 with the configuration of the centralized KUCC Clinical Trials Management System (CTMS), a web-based database (CRIS/eVELOS) to capture and report on every cancer-related protocol and accrual. This endeavor gained significant momentum with the KUCC-wide policy made fully effective in 2013 which required use of the CRIS centralized database for **all** protocols within KUCC; prior to 2013, the CRIS database was only utilized for treatment intervention trials, while prevention and population science studies utilized several alternative databases. 2. In 2013, a CTMS Database Administrator position was created in the CTO, and that dedicated full-time employment (FTE) position has provided continued enhancement of the centralization and management of KUCC's clinical trial reporting processes. The CTMS Database Administrator position oversees data entry into the CTMS and runs routine reports of protocol status, patient accrual and other important clinical trial performance metrics. In addition, the CTMS Database Administrator trains all Cancer Center clinical research staff on how to use the CTMS so that NCI Data Tables, NCI Clinical Trials Reporting Program (CTRP) and institutional accrual reports are accurate, current and complete.
Enhance CTO auditing and monitoring plans and capabilities	1. New positions (2 FTEs) were added in quality assurance, including a fully dedicated director-level position and an additional Monitoring & Compliance Specialist, focused on routine monitoring, auditing according to KUCC's Data Safety & Monitoring Plan (DSMP), and clinical research training and education of investigators and study team members. 2. In calendar year 2015, the CTO hosted 10 external audits by sponsors (four national sponsors including NRG, SWOG, Alliance, BMT CTN, and six industry sponsors); and one audit by the FDA as a result of being the highest enrolling site on a pivotal industry sponsored clinical trial. All of these 11 audits yielded positive results, attesting to the high quality of clinical research being performed at KUCC.
Convene routine clinical research advisory boards	1. *External* - The Cancer Center's External Advisory Board (EAB) serves as that critical voice in the evaluation of KUCC's focus and direction. The KUCC EAB continues to be led by George J. Weiner, MD, Director of the Holden Comprehensive Cancer Center at the University of Iowa, and is composed of 12 nationally recognized leaders in cancer research and treatment. 2. *External* - CTO leadership are actively engaged participants of, and thus receive routine clinical research guidance from, the American Association of Cancer Institutes (AACI) Clinical Research Initiative (CRI), a national organization comprised of clinical research leaders representing all NCI-designated cancer centers whose objectives include developing better ways to

	disseminate best practices across cancer centers, prioritizing clinical research challenges, and sharing proven means of addressing challenges and measuring progress. The CRI aligns with AACI's strategic goal to stimulate interactions among cancer centers to maximize the use of resources and facilitate research. The individuals involved in CRI possess a comprehensive understanding of their cancer center's entire clinical trials system, and they fill a variety of leadership roles at their centers. At the AACI CRI 2014 national conference, KUCC CTO leadership presented as an invited speaker and presented seven posters. At the AACI CRI 2015 national conference, KUCC CTO leadership members presented as invited speakers, presented two clinical research posters, and most notably, was awarded the prestigious "winning abstract" on the topic "Overcoming Insurance Barriers for Clinical Trials Patients". 3. *Internal* - A KUCC Clinical Research Leadership Committee was formed by the Associate Director of Clinical Research and began in calendar year 2013. Its charge is to review and guide best practices and infrastructure development for conducting the KUCC's clinical research. In addition to Cancer Center and CTO leadership, the committee also includes Rick Barohn, Vice Chancellor, Research Administration for KUMC, President of Research Institute, Principal Investigator of the National Institutes of Health Clinical and Translational Science Award (CTSA) and Director of The Heartland Institute for Clinical and Translational Research.
Enhance clinical trial patient screening processes	1. A Clinical Trial Nurse Navigator position was created and integrated with the hospital system's intake process for newly registered cancer patients. Specifically, this position receives all new patient medical records through the hospital's nurse navigators, pre-screens the patient charts, and then triages potentially eligible participants to the disease-specific clinical research coordinator for further review, consenting, and in-depth screening. In addition, the clinical trial nurse navigator: triages inquiries from medical personnel, patients and the public who are seeking information about clinical trial opportunities; collaborates closely with community oncologists to promote access to Center trials; and serves as a conduit for referral for clinical trials. 2. The KUCC Molecular Tumor Board (KUCC-MTB) was formed in April 2015 to help physicians better maneuver through the complex and ever changing molecular-medicine landscape aimed at matching patients with a given therapy, including clinical trials of targeted agents. The KUCC-MTB, led by Deputy Director, Andrew **Godwin**, is comprised of medical (adult and pediatric) and surgical oncologists, pathologists, clinical geneticists, basic and translational science researchers and bioinformaticians.

OTHER SIGNIFICANT CHANGES SINCE 2012 NCI SITE REVIEW

Over the last four years, substantial progress has been made broadening partnerships with communities throughout our catchment area. Three major changes have expanded the composition of clinicians participating in the clinical trials process. The first change resulted from the incorporation of a large private practice oncology group by the University of Kansas Health System, a group now defined as the KUCC Community Cancer Program (CCP). The second change was the expansion of the outreach network of KUCC, known as the Midwest Cancer Alliance (MCA), which is a membership fee-based network of hospitals and physician groups located across the KUCC catchment area. Many MCA centers serve as affiliate sites to cooperative group sponsored trials and investigator-initiated trials (IITs) conducted by KUCC as the Primary Center. More detail on MCA contributions are outlined in Part III (Inclusion of Women and Minorities). The third change resulted from the 2015 consortium agreement with Children's Mercy, incorporating their clinicians into KUCC programs.

These changes have greatly enhanced the KUCC comprehensive approach to cancer care in our catchment area and extended the reach of KUCC clinical research endeavors. However, with respect to Data Table 3 reporting, KUCC does not including the accruals or index cases associated with the CCP and MCA centers because they are not defined as part of the Primary Center of the KUCC. In the context of Data Table 3 and 4 reporting, the Primary Center is defined as the KUCC Academic Cancer Program (ACP). As a formal consortium partner, Children's Mercy accruals and index cases are reported in a separate Data Table 3.

The ACP defines the KUCC Primary Center and is composed of clinicians practicing at the University of Kansas Health System, including the Westwood (main outpatient facility) and the KU Clinical Research Center (CRC) campuses and Children's Mercy. These clinicians are considered part of the academic practice in that, in addition to patient care, they also have a focus on teaching and/or research. They are on tenured or non-tenured academic tracks with a long-term goal of achieving the rank of Professor. All are involved in clinical research in some way (design of and/or accrual to clinical trials) and a few have lab-based research. The practice includes a diverse array of specialties including, clinical oncology, hematology, BMT, surgical and urologic oncology, neurosurgery, neuro-oncology, radiation oncology, nursing, psychology, radiology and physical medicine. For purposes of the CTO, they are heavily involved in all aspects of clinical trial development and participation. Their focus is on improving the care of cancer patients through clinical translational research. As such, they develop all of the IITs; serve as PIs on cooperative group and other national trials; serve as local PIs on cooperative group and pharmaceutical trials; and enroll the majority of patients on KUCC clinical trials. From 2012 to the present date, 15 investigators have written, and were the principal investigators for, 26 treatment IITs (three of which were Children's Mercy-initiated trials), enrolling 333 patients on these treatment IITs from 2012 through May, 2016. In 2016 they have accrued 56 patients to seven currently enrolling treatment IITs.

The CCP is composed of former private practice clinicians who practice within six community sites. They joined KUCC when the University of Kansas Health System purchased their practice in 2011. For over 30 years, this group of clinicians has provided cancer care for patients within the Kansas City region. They include medical oncologists, hematologists and radiation oncologists and have had an excellent track record for accruing patients onto clinical trials. These clinicians are on the non-tenure track. After the hospital's purchase of the practice, their accruals to clinical trials fell dramatically. This occurred for several reasons: 1) the loss of several clinicians who enrolled significant numbers of patients onto clinical trials; 2) the loss of study coordinators and research personnel during the transition; and 3) in 2013, the conversion to a totally new electronic medical record and ordering system greatly reduced the practice's efficiency. Thus, it is taking time to fully incorporate their clinical research program into the KUCC system. Community Practice Physicians now focus on 1-2 specific organ site(s) facilitating participation in specific DWGs and design of IITs. One benefit of this interaction is that three of the currently enrolling treatment IITs are also open at the community sites (the remaining treatment IITs are early phase trials not suited for the community setting). Through May, 2016, CCP clinicians have accrued 15 of the 56 patients enrolled on KUCC treatment IITs at their centers. Another benefit has been that one of the three treatment IITs was specifically designed to answer a community-based research question (randomized open-label trial of dose dense, fixed dose capecitabine compared to standard dose capecitabine in metastatic breast cancer and advanced/metastatic GI cancers).

Over the past four years, the number of CTO personnel increased from 35.6 FTEs to 91 FTEs to meet continued growth and increasing complexity of cancer trials. The expansion and specialization of CTO staffing positions has enabled the CTO to effectively encompass all of the Cancer Center program's clinical research efforts and facilitate integration of the CCP operations. For instance, at the time of this grant preparation, there are 12 regulatory FTEs and 45 clinical research coordinator FTEs that specialize by disease type and/or clinic location (there are nine geographically distinct Cancer Center clinic locations served by the CTO, including Westwood, CRC, main KU hospital and six CCP sites). There are three quality assurance FTEs that monitor these operations.

Significant changes in the centralizing, managing, and reporting processes

- In 2015, as a result of the new KUCC Consortium partnership with Children's Mercy, the KUCC Protocol Review & Monitoring System (PRMS) now governs both KUCC and Children's Mercy, there is one DSM Plan encompassing both entities, and the KUCC CTO collects all Children's Mercy cancer-related protocol and accrual data. This is achieved by leveraging the KUCC Clinical Trial Management System (CTMS) Database and the CTMS Administrator position. The KUCC CTO leadership is working closely with Children's Mercy CTO leadership to operationalize the standard operating procedures related to PRMS, DSMP, quality assurance, staff training, and centralized reporting.

Significant changes in processes related to trial initiation and completion

- In 2013, CTO Project Director positions were created to lead disease-specific teams with their main focus on protocol activation timelines, facilitating activities across multiple cancer center locations, and oversight of clinical research coordinators.
- In 2013, KUMC IRB executed a reliance agreement with the NCI Central IRB (CIRB) and all National Clinical Trial Network (NCTN) trials eligible for CIRB review have since been submitted to CIRB as the IRB of record.
- In 2014, the regulatory team was re-organized to align regulatory staff by disease specialties such that workloads are distributed according to disease site as much as possible, an organizational design that fosters collaborative and sustained relationships between the regulatory staff and the disease-specialized clinical investigators, CTO project directors and clinical research coordinators. Aligning workloads by disease also has enabled regulatory staff to gain significant knowledge and understanding of the cancer indication of their protocol submissions.
- In 2014, the regulatory team was re-organized to further streamline the study start-up process. The re-organization consisted of creating Regulatory Lead positions to focus on new study submissions and Regulatory Coordinator positions to focus on annual renewal submissions, protocol amendments and essential document collection. This arrangement enabled the Regulatory Lead position to focus on new study submissions without being interrupted by the stream of protocol amendments and annual renewals.
- In 2015, one new FTE regulatory specialist was fully dedicated to institutionally sponsored treatment trials.
- In 2015, an Investigator-Initiated Trial Steering Committee was formulated to provide a forum for consultation and rapid feedback to proposed IITs so that the efficiency of initiating IITs can be significantly improved. The IIT roster is comprised of team members that represent critical expertise concerning different aspects of clinical trial development and implementation.

Significant changes in quality control functions and training services

- In 2013, clinical trial protocol “kick-off meetings” were developed and implemented where study-specific training is conducted for each newly activated trial. Good Clinical Practice (GCP) information is presented at monthly clinical investigator meetings. For ongoing quality control, the CTO Quality Assurance team provides real-time feedback to the Clinical Research Coordinators, Project Directors and Regulatory Associates so that errors can be addressed promptly and corrective plans of action implemented as needed.

Significant changes in CTO organizational structure

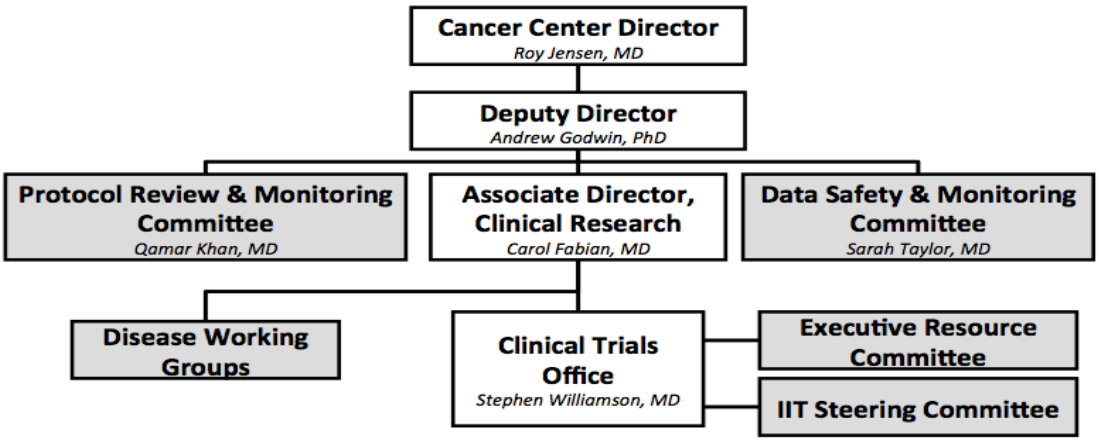
- In 2013, a new CTO Medical Director, Stephen **Williamson**, assumed leadership.
- In June, 2016, a new CTO Senior Executive Director, Hobs Apell, assumed leadership.
- Over the past four years, the number of CTO personnel increased from 35.6 FTEs to 91 FTEs to meet continued growth and complexity of active studies, facilitate patient screening and accrual, help with protocol design and writing of institutionally sponsored trials, IND submissions to FDA, ensure quality assurance and internal monitoring, support clinical research education, provide clinical trial informatics for centralized metric reporting on all cancer-related clinical trials, administer CTO finances, oversee regulatory submissions to PRMC/IRB, provide clinical research coordinators dedicated to community site locations, and clinical trial project management focused on timely initiation of trials. The expansion and specialization of CTO staffing positions has enabled the CTO to effectively encompass all of the Cancer Center programs’ clinical research efforts.

ADMINISTRATIVE STRUCTURE

The CTO is led by **Williamson** who has been involved in clinical trials research since his oncology fellowship in 1984. He has also been active in the Lung, GI and Head and Neck Committees of the Southwest Oncology Group (SWOG) and his first multi-institutional phase II trial through SWOG was initiated in 1986. **Williamson** has been the PI on many IITs developed at KU including the first phase I clinical trial at KU involving a gene therapy trial of irradiated autologous melanoma cells adenovirally transduced with human GM-CSF gene. **Williamson** has been the primary study coordinator for 10 phase II trials, one national phase III clinical trial and a co-investigator and contributor to over 30 trials through SWOG. He has also been the local PI on over 20

multi-institutional pharmaceutical trials conducted at KU. **Williamson** is a member of the GI and Head and Neck Cancer Disease Working Groups and mentors many of the junior faculty on their clinical trials. **Williamson** and Apell (Senior Executive Director) lead the CTO which provides comprehensive support services that span the life cycle of cancer clinical trials from concept through manuscript. The CTO is structured to optimally serve the needs of investigators leading national (cooperative group) trials, industry trials, externally peer-reviewed trials, and especially, trials initiated by KUCC faculty (**Figure 1**). Although each of these trial types has a somewhat different pathway through the development, approval and execution process, the CTO has standardized procedures in place to make each step optimally efficient. There is a strong emphasis on auditing for data integrity and compliance, quality control functions including education and training for study staff and investigators, tracking accrual and screen failures, pre-screening assessment of patient eligibility, timeliness of data availability, safety monitoring, faculty support and high standards for ethics in clinical research. There is also a strong emphasis on achieving timelines for rapid submission and activation of protocols while observing all regulatory requirements. The CTO provides a central location for protocol management and runs routine reports of active protocols and their status via the CTMS, which can be securely accessed by authorized investigators and CTO staff.

Figure 1. Clinical Trials Office Reporting Structure



Below is a detailed table of the CTO comprehensive services and corresponding position descriptions. The CTO services are categorized according to seven major functions: 1) Centralized Reporting, 2) Clinical Research Coordination, 3) Finance Administration, 4) Project Management, 5) Protocol Development, 6) Quality Assurance and 7) Regulatory Affairs.

TABLE OF CTO SERVICES BY FUNCTION

Service	Working Title	Position Summary Description
CENTRALIZED REPORTING		
Clinical Trials Reporting	Clinical Trials Management System (CTMS) Administrator	Information system centralized management and reporting on all KUCC's cancer-related clinical research protocols and patient enrollment. This position generates bi-weekly clinical trial accrual and metric reports, is responsible for submissions to the NCI Clinical Trials Reporting Program (CTRP), and generating Data Tables 3 and 4 for the NCI Cancer Center Support Grant (CCSG) application. **There is 1 CTMS Administrator and 1 part-time Data Manager.**
CLINICAL RESEARCH COORDINATION		
Clinical Research Coordination	Clinical Research Coordinator	Clinical Research Coordinator responsibilities include: pre-screening and screening post-consent, conducting the informed consent process, documenting eligibility of study participants, conducting study visits, obtaining and shipping specimens, completing case report forms, and preparing adverse event forms. They are hired, supervised and trained by CTO Clinical Research Project Directors (see additional detail below under Project Management). Funding support for these positions is provided by clinical trial direct revenue and subsidized as needed by KUCC. **There are 45 Clinical Research Coordinators that specialize by disease type and/or clinic location** (there are nine geographically

		distinct Cancer Center clinic locations part of KUCC, including Westwood, CRC, main hospital and six community sites).
Correlative Laboratory Coordination	Correlative Lab Coordinator	Responsibilities primarily include obtaining, processing and shipping of specimens (blood and tumor tissue), as well as performing study-related EKGs. **There are 4 Clinical Research Laboratory Coordinators and 1 Correlative Laboratory Director.**
Pre-Screening of New Patients	Clinical Trials Nurse Navigator	Receives all new patient medical records and works with hospital nurse navigators to pre-screen patient charts and triage potential participants to the disease-specific Clinical Research Coordinator. Triages inquiries from medical personnel and patients who are seeking information about clinical trial opportunities. Collaborates with community oncologists to promote access to Center trials and serves as conduit for referral for clinical trials. Serves as a central resource to KUCC patients, staff and physicians as well as to Midwest Cancer Alliance's clinical trial network. Communicates widely about clinical trials availability, including inter-institutional and across entire catchment area through websites, networking agencies and print media. **There is 1 Clinical Trial Nurse Navigator.**
FINANCE ADMINISTRATION		
Budget Negotiation and Contract Liaison (Pre-Award)	Clinical Trials Budget Analyst	Prepares coverage and cost analysis and negotiates budget with Sponsor. Acts as interface with University of Kansas Medical Center's Research Institute's legal department to expedite contracts and facilitate study activation. **There is 1 pre-award Clinical Trials Budget Analyst.** To keep pace with ebb and flow of workload demands and timelines, the CTO also works with independent contractor(s) to develop and negotiate budgets for industry trials on a per-project basis.
Clinical Research Billing Reconciliation (Post-Award)	Clinical Research Billing Specialist	Monitors accuracy of charges billed to the clinical trial accounts and interfaces with hospital billing staff to ensure correction. Invoices clinical trial sponsors for research costs according to executed contract. **There are 2 post-award Research Billing Specialists and 1 Finance Manager.**
PROJECT MANAGEMENT		
Clinical Research Project Management	Clinical Research Project Director	Project Directors and Associate Project Directors supervise the Clinical Research Coordinators, conduct feasibility review of protocol requirements, update team members of study status and approval, liaison with finance team on trial financial aspects and facilitate partnerships with departments and collaborators. Project Directors lead weekly meetings focused on timeline metrics documenting milestones. Project Directors administratively support the physician-led Disease Working Groups (DWG). At the time of this application, **there are 3 Clinical Research Project Directors and 8 Associate Project Directors that specialize by disease type and/or clinic location.**
PROTOCOL DEVELOPMENT		
Protocol Design and Development	Protocol Development Manager	Develops concept of a treatment trial into a comprehensive protocol, including facilitating biostatistical input, initiating budget development, and defining timelines for accrual and execution in collaboration with the PI and study team. Serves a pivotal role in the Investigator-Initiated Trial Steering Committee. **There is 1 Protocol Development Manager.**
QUALITY ASSURANCE		
Clinical Research Education	Quality Assurance Director/Compliance & Monitoring Specialist	Conduct monthly education series with expert guest speakers and professional webinars presenting on Good Clinical Practice (GCP), clinical research ethics, and preparation for FDA audits, among many other topics. Additionally, ongoing real-time education occurs with internal monitoring of files.

Quality Assurance and Internal Monitoring	Quality Assurance Director/Compliance & Monitoring Specialist	Responsible for reviewing data collection accuracy and completeness, training clinical research personnel in protocol procedures and implementation, identifying problems in protocol implementation/conduct and resolving regulatory issues. The quality assurance and internal monitoring team provides real time feedback to the Clinical Research Coordinators, Project Directors, Study Investigators and CTO leadership so that isolated and systemic errors can be addressed promptly and corrective plans of action implemented if need be. **There are 2 Monitoring & Compliance Specialists and 1 Quality Assurance Director.**
REGULATORY AFFAIRS		
FDA Submissions	Regulatory Leads & Associates	Responsible for managing IRB/PRMC and FDA submissions for treatment clinical trials that are institutionally sponsored. Responsible for clinicaltrials.gov registrations and updates.
IRB/PRMC Submissions	Regulatory Leads & Coordinators	Regulatory Leads are responsible for study pre-activation activity (e.g. submitting new study protocols to PRMC and IRB), and regulatory coordinators are responsible for post-activation activity by maintaining current approvals and essential documents (e.g. 1572, Financial Disclosures, etc.). Additionally, the Regulatory Leads continuously advise investigators and Clinical Study Coordinators on how best to comply with FDA/OHRP/NIH and local IRB regulations. **There are 12 Regulatory Associates.**

OPERATIONS AND POLICIES

CTO services are available to all KUCC members and CTO operations are administered according to well-defined, standardized procedures. The CTO maintains all Standard Operating Policies (SOPs), guidance documents and work instructions in SharePoint, a secure, web-based platform that is readily accessible to all CTO staff and is utilized to electronically document their training. CTO staff are located throughout the Cancer Center's multiple sites based on the service they provide and the clinical population they serve.

ONGOING PROGRESS TOWARDS GOALS (BASED ON 2012 COMPETITIVE APPLICATION)

SCIENTIFIC GOALS

1. Continue to focus on and prioritize IIT development and Phase I clinical trials aligning with KUCC research programs, including biomarker correlatives;
2. Support clinical investigators in preparing applications for peer-reviewed funding for translational research;
3. Increase training, mentoring and educational opportunities for KUCC faculty and staff; and
4. Increase clinical trial accrual at KUCC community sites and more fully incorporate the community sites into the KUCC clinical trials research program.

To further the scientific goals outlined above, the Investigator-Initiated Trial Steering Committee (IITSC) was established. In 2015, the IITSC was formed to mentor and educate junior investigators and to support the acceleration of scientific discovery of novel therapeutics through the conduct of IITs. Scott **Weir** (Associate Director for Translational Research) and **Williamson** serve as co-chairs. Specifically, the IITSC provides an interactive venue for basic and clinical researchers to present IIT concepts arising from laboratory and bedside discoveries, as well as a structure for defining and refining IIT concepts prior to and following discussion. Investigators receive instant feedback from clinical researchers, representatives from relevant KUCC shared resources (i.e., Biospecimen, Lead Development & Optimization, Clinical Pharmacology and Biostatistics & Informatics) and the CTO. The full IITSC roster (listed below) is comprised of team members that represent critical, multidisciplinary expertise concerning different aspects of clinical trial development and implementation. Additionally, as part of KUCC's efforts to increase and broaden research program influence and interaction in the clinical trials enterprise, at least one co-leader from the relevant research program will be asked to attend when a proposal from their research program is presented to the IITSC. The IITSC typically meets the first and third Thursday of every month at the CRC. The meeting day/time/location is adjusted as needed to accommodate IIT presenter(s). Presenters are provided a power point template to customize with their IIT proposal content prior to their scheduled meeting date. Agenda and slides are issued to the attendees prior to the meeting.

IITSC Roster and Represented Expertise

Stephen Williamson, MD, Co-chair – Clinical Trials Office Medical Director, IIT Physician (Solid Tumors)
Scott Weir, PharmD/PhD, Co-chair – Associate Director Translational Research (Drug Development)
Carol Fabian, MD – Associate Director of Clinical Research, IIT Physician (Prevention and Survivorship)
Sid Ganguly, MD – IIT Physician (Hematological Malignancies)
Priyanka Sharma, MD – Assistant Director Clinical Research, IIT Physician (Solid Tumor)
Qamar Khan, MD – Chairman of PRMC, IIT Physician (Solid Tumor)
Andrew Godwin, PhD – Deputy Director, Biorepository/Biomarkers
Gregory Reed, PhD – Clinical Pharmacology Shared Resource, Correlative Studies (PK/PD)
Brooke Fridley, PhD (or alternate, Milind Phadnis, PhD) – Biostatistics/Data Management
Keith August, MD – Pediatric Oncology Phase I Director (Children's Mercy)
Hobs Apell – Clinical Trials Office, Senior Executive Director
Carolyn Foster – Clinical Trials Office, IIT Protocol Development
Kevin Schorno – Institute for Advancing Medical Innovation, IIT Project Management

EDUCATIONAL AND TRAINING EFFORTS

The IITSC works with KUCC members to generate pilot clinical data by conducting pilot IITs that enable significant, impactful and fundable cancer therapeutic clinical trials. Multidisciplinary teams support KUCC members to advance IITs from concept to clinic with the assistance of a dedicated IIT project manager and writer. This initiative is contributing to an increase in the number of IITs and contributes to the ongoing education of participating junior investigators. Since forming the IITSC in 2015, 15 IIT concepts from 20 investigators have been presented and most are moving forward with full proposals. KUCC leadership made the strategic decision to designate $500,000 and **Godwin** (Deputy Director) obtained an additional $100,000 from Radiation Oncology (matching funds for two IITs for Radiation Oncology faculty) to support the prioritized pilot IITs in CY16. Others are being supported by pharma sponsors or departmental resources.

OPERATIONAL GOALS

1) Address improvements of the design, launch and conduct of KUCC clinical trials based on review of the Institute of Medicine's Report: "A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program." This operational initiative is primarily related to internal processes and IITs. Performance metrics will be developed and tracked.
2) Support the enhancement of the clinical trial informatics system (CRIS) to streamline operations and support increased use by research teams to enhance the reporting and output of data. The CTO will improve processes to assure case report form (CRF) readiness at study activation, by development of standard form sets.
3) Expand staff to meet continued growth in the number of active studies and accrual. Continue staff development through internal education and support of external continuing education activities.
4) Incorporate the KU Community Cancer Program clinical research activities and practice into KUCC clinical research efforts.

To further the operational goals outlined above, a significant re-engineering of the clinical research infrastructure, primarily focusing on the CTO, was initiated in 2012. Innovative upgrades to clinical research informatics systems have also been made, effectively leveraging technology platforms to improve efficiencies and operationalize meaningful metric tracking. As a result, major advancements have been achieved:

- Significant strides were made when the institution migrated from a paper-based IRB submission system to an electronic-based IRB in calendar year 2013.
- Another efficiency initiative leveraging technology included the transition from a paper-based system to an electronic filing system for collection and distribution of essential documents and study-related documents. As a result, when external monitors visit the site, the regulatory office provides a flash drive containing the study history of documents. Going "electronic" in regulatory has resulted in significantly reduced paper burden, increased efficiency for communications and usage of storage space, improved timeliness of review and enhanced, cost-efficient regulatory compliance.
- A third notable achievement resulting from a process improvement initiative since the 2012 NCI site review includes providing electronic access to the medical records for external monitors. Over the past four years, concomitant with increased clinical trial accruals by the cancer center, the CTO has hosted a significant increase of sponsor monitoring visits. For instance, in 2015, the CTO hosted nearly 600 monitoring visits,

representing a 33% increase from 2014. To facilitate monitor access to the electronic medical record, the CTO developed the infrastructure, operational guidance documents and invested in laptop computers for on-site monitoring activity resulting in measurable cost reduction in terms of employee time and supplies.
- Beginning in 2012 and continuing through calendar year 2013, the re-engineering initiative resulted in re-aligning regulatory staff by disease specialties and focused newly created "Lead" positions on new study submissions *versus* "Coordinator" positions focused on maintenance of activated studies. This arrangement enables the Regulatory Lead position to devote their time solely on new study submissions without being interrupted by the stream of protocol amendments and annual renewals.
- As a result of these advancements, the CTO regulatory leads and coordinators are managing more volume, on increasingly complex protocols, with overall improved efficiency.

In 2013 and 2014, major progress was attained in assuring case report form (CRF) readiness at study activation for IITs, by successfully transitioning to an electronic data capture system. To achieve this, an electronic Case Report Form (eCRF) Content Toolkit was developed at the field-level using Clinical Data Acquisition Standards Harmonization (CDASH) standards published by the Clinical Data Interchange Standards Consortium (CDISC), when available, and inter-disciplinary collaboration with KUCC senior physician investigators when CDASH standards were not available. Researchers now use the tool to design study eCRFs by selecting the fields they want included, indicating whether they are mandatory or optional, and dictating the order of presentation. In addition to improving the quality of data collected in each study, and making the data easily combined with, and compared to, existing data, the time and money required for eCRF creation is drastically reduced, thereby speeding up the time to activation for IITs. The Biostatistics & Informatics shared resource and the CTO have implemented the use of the eCRF Content Toolkit for use in all new cancer IITs.

EARLY PHASE CLINICAL TRIAL (EPCT) GOALS

Details on KUCC goals and progress for early phase clinical research is now included as part of the Early Phase Clinical Research Support (EPCRS) section of this CCSG submission (this is KUCC's first year requesting EPCRS funding).

PART II: DATA AND SAFETY MONITORING

Significant changes were made to the KUCC Data Safety Monitoring Plan (DSMP) in 2015 as a result of the new KUCC Consortium partnership with Children's Mercy. Most notably, the DSMP revisions reflect a single DSMP encompassing both KUCC and Children's Mercy while defining the overall structure of the monitoring entity and the mechanisms for reporting adverse events.

Other DSMP updates included revised audit ratings and recommendation outcomes established by the KUCC DSM Committee (DSMC) for each protocol reviewed, revised definitions for levels of risk established by the PRMC (and related sections throughout the document), and increasing the quorum from four to seven standing members. Administrative revisions to the DSMP document were also made, including a new document section entitled "Document History" to catalog and clearly identify the changes throughout the plan. Additional administrative revisions include the addition of the following: "Abbreviation" and "Overview" sections; section entitled "Studies Requiring DSMC Monitoring" to clarify the clinical trials targeted with this procedure; other minor changes throughout to reflect current practice and to add clarity to current procedures; addition of an appendix to expand upon description of reporting requirements for Serious Adverse Events; addition of an appendix to include a table of DSMC membership; and other updates and deletions to appendices as applicable. The revised DSMP has been reviewed and approved by the NCI Office of Cancer Centers.

PART III: INCLUSION OF WOMEN AND MINORITIES

The KUCC catchment area (105 counties in Kansas and 18 counties in Western Missouri) has a surprisingly diverse population including a rapidly growing Hispanic community, African-American urban poor, Native American communities, immigrant Asia populations associated with the meatpacking industry, and largely elderly rural whites. KUCC is committed to addressing the challenges and meeting the needs of these populations and other underserved minorities, indeed we see our strong relationship to these communities as a differentiating asset for our center.

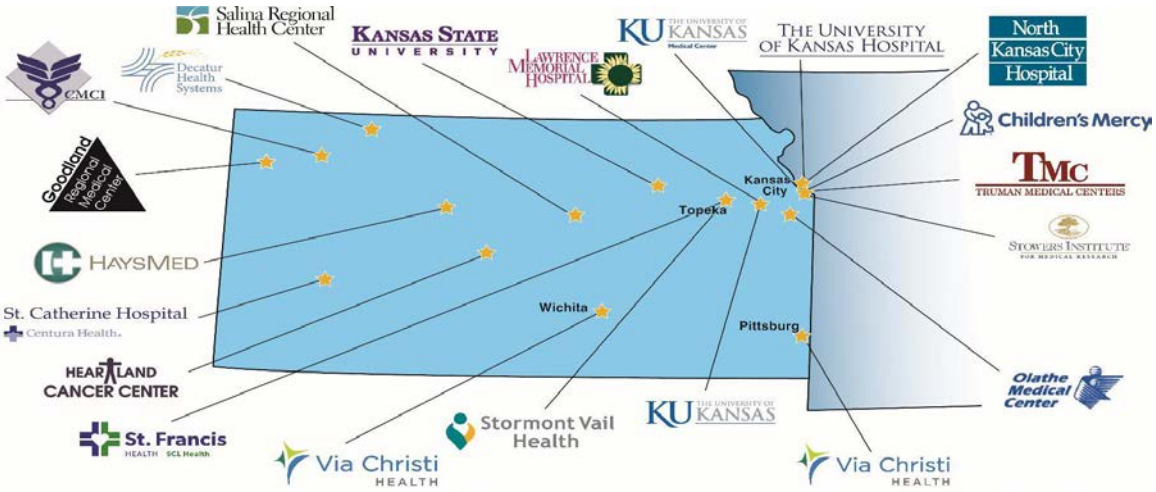
Below is a high level summary of demographic data presented in the CPDM Table II, representing the KUCC catchment area along with the treated patients at KUCC and Children's Mercy as well as demographic data for enrolled patients.

Minority distribution in catchment area: A lower percentage of Hispanics (3%) than the catchment area demographic (9%) are treated at KUCC. This is largely explained by the fact that the Hispanic population is dramatically younger and has a much lower crude cancer rate than the White population in the KUCC catchment area. According to the Kansas Cancer Registry, the prevalence of invasive cancers from 2003-2012 was 2.4% among Hispanics compared to Whites at 91.3%.

Gender distribution in clinical trials: The higher number of females who enroll in Interventional Non-treatment studies compared to males is largely due to the highly active and longstanding breast cancer prevention and survivorship program under the direction of **Fabian**.

Minority distribution in clinical trials: The higher percentages of American Indian/Alaska Native, Black, and Hispanic accruals to Intervention, Non-Treatment trials can be largely attributed to the efforts of the Cancer Control and Population Health (CCPH) program conducting community-based trials in tobacco cessation, colorectal cancer prevention, breast cancer screening, and exercise interventions specifically targeted to these minority populations. The higher percentage of "Other" in the Racial Categories can be explained in large part to a few studies with high accrual conducted by CCPH where participants self-reported "Other" or identified with more than one race; one example is a breast cancer early detection study aimed at the Hispanic/Latina population with a target enrollment of over 600 participants, many of which self-reported "Other" for race.

As part of the KUCC comprehensive plan to address disparities in the catchment area with respect to inclusion of women and minorities in clinical research, processes for monitoring and improving recruitment of minorities and women are continually underway. To address specific population-based needs, the MCA, was created in 2007 as a network of state and regional hospitals to ensure the latest clinical discoveries were extended to patients throughout the KUCC catchment area, particularly in rural and low socio-economic communities. Improving recruitment of traditionally underrepresented populations is reflected in the notable expansion of the MCA since its inception. The current MCA members include those institutions depicted in the map below.



The MCA has built the infrastructure at 18 community cancer centers across the state creating a culture of clinical research among the providers, administrators and the community. As a result, 11 of the 18 MCA centers have been successfully set up as KUCC affiliate sites to accrue to cancer treatment trials. At the close of 2015, MCA members had access to 37 clinical trials, including 32 National Clinical Trial Network (NCTN) trials, one industry trial, two IITs, and five population health studies. Additional trials are made available when researchers engage with the MCA and/or members of the MCA express an interest in a study or research idea for their patients or community. MCA staff and members collaborate closely with the KUCC CTO, as MCA sites utilize the KUCC CTO Clinical Research Information Service (CRIS) for data management and rely on the IRB of record (KUCC IRB or NCI Central IRB), with the KUCC CTO performing all regulatory submissions. In addition to accruing to clinical trials at their own location, the MCA members have developed a strong understanding of KUCC's clinical trial portfolio, including early phase research. Performance metrics were recently developed to measure this increased awareness and referral activity. To date, from when metrics started being captured, MCA members have

referred 198 patients for eligibility screening to KUCC treatment trials with 14 patients enrolled on trials and the successful enrollment of nine patients to early phase trials being conducted at the CRC.

To prime wider acceptance and future accrual to proposed KUCC clinical research, the MCA convenes a monthly Disease Working Group via interactive televideo with physicians located at the distant MCA sites. This collaboration has also enabled KUCC researchers to expand their research opportunities by presenting emerging research ideas as well as funded projects. MCA physician investigators and research teams have provided critical insight into the development of KUCC IITs. To increase patient engagement with research, MCA has launched PIVOT (Patient and Investigator Voices Organizing Together), which serves as the venue to support research through insight from patients regarding study questions, accrual promoters/barriers, and communicating results back to the community (an expanded description can be found in Planning and Evaluation). In addition, MCA and Kansas Patients and Providers Engaged in Prevention Research (KPPEPR) members extend the reach of KUCC research by opening clinical studies at their community practices which are located throughout the KUCC catchment area. The MCA Partner's Advisory Board (PAB) members also supports collaborative research, by providing financial support to KUCC and PAB member's research efforts through a total of $8,750,000 in membership fees from 2012-2016. Examples of some of the projects supported by PAB funds are detailed below.

Accrual for Cancer Clinical Trials - A Strategic Communication Campaign to Increase Knowledge and Change Attitudes and Beliefs. This project, sponsored by MCA and executed by the developing Health Communications Research Shared Resource (HCRSR) of the KUCC, aims at developing an evidence-based, tailored communication campaign to address accrual for cancer clinical trials. The primary study objectives, which were completed in 2015, are: 1) Understanding and assessing current knowledge and beliefs about cancer clinical trials among health care providers, patients and the general public; 2) Identifying and understanding motivators and barriers for participation in cancer clinical trials; 3) Develop preliminary tailored communication messages. These objectives were met by conducting focus groups, in-person and telephone interviews as well as online surveys with the target audience. Providers and patients were recruited from two MCA member clinics, an urban center and a cancer center serving a primarily rural area.

Biobank. One of the strongest demonstrations of change in culture and infrastructure for clinical trials is demonstrated through the MCA partnership with Truman Medical Centers (TMC). This organization is the largest provider of safety net medical care for uninsured and under-insured patients in the Kansas City metropolitan area. TMC handles over 329,000 outpatient visits annually. In 2012, TMC provided $125 million in uncompensated primary, specialty and inpatient care to the uninsured and many other lower-income people, serving a diverse group of vulnerable populations. In collaboration with MCA, TMC designed and constructed an area to function specifically as the oncology research lab with primary use as the biobank. With the guidance and cooperation from the KUCC Biospecimen shared resource (BSR), TMC's Pathology and Surgery department and KUMC IRB, protocols were developed and implemented to standardize the consenting of patients, interdepartmental notifications, tissue processing, and delivery of tissue to KUCC. For the first twelve months of operating (12/2014 – 11/2015), TMC's biobank collected 170 blood specimens (African American = 74, Caucasian = 54, Hispanic = 8 and Other = 1) and 137 tissue specimens (African American = 87, Caucasian = 74, Hispanic = 7 and Other = 2).

Make It Your Own. The MCA has partnered with researchers from Health Communication Impact at Washington University in St. Louis (WUSTL) to develop a product to support clinical trials accrual. An NCI Small Business Innovation Research award funds the project. Researchers from WUSTL have created an on-line tool called Make It Your Own (MIYO), which helps organizations create their own versions of evidence-based health communication materials for the specific populations they serve. Users "build" materials by choosing from a menu of evidence-based approaches recommended by the *Guide to Community Preventive Services*, and then customize them by choosing from a library of images, messages and graphic designs. MIYO renders their creations into electronic documents that can be printed, e-mailed, texted, used online or distributed in other ways to target audiences. MIYO applies strong scientific evidence and theoretical models from communication, marketing and cancer control. It allows health care organizations to readily create a wide range of educational and promotional resources and customize them to very specific patient profiles (e.g., African American men with colon cancer) and provider profiles (e.g., physicians who perceive their patients may not be interested in clinical trials) by choosing from tested messages, images and designs. Each of these

content modules includes up to six customization elements. The researchers have developed MIYO products for tobacco quit lines, colorectal cancer screenings, and HPV vaccination. KUCC partnered with researchers in 2010 to develop the HPV modules and are now partnering to expand the product to address clinical trials accrual. The aims for the study: 1) Develop and refine MIYO content for increasing cancer clinical trials participation and 2) Conduct a group randomized treatment-delayed control study to test effects of MIYO on provider referrals to, and patient enrollment in, *Pioneers*, a KUMC research participant registry.

The CCPH research program has also played a significant role in advancing outreach and recruitment of minorities and women. CCPH strategic priority has been focused on increasing the recruitment of investigators with a research focus on health disparities among minorities. Efforts by the CCPH program to reach underserved populations through its research portfolio are exemplified by its collaboration with Community Partnership for Health program, a part of the Clinical and Translational Science Award at KUMC and its extension of clinical research unit activities to a local Federally Qualified Health Center that cares for predominantly underrepresented minority populations, which greatly facilitate recruitment of African American participants into cancer control studies. Additionally, CCPH members have held numerous community events to address barriers to research participation in minority communities.

In 2016, Sally J. **Maliski**, RN, PhD, FAAN, was named the KUCC Associate Director for Health Equity. **Maliski** has had a distinguished career focusing on cancer disparities in the Hispanic community particularly as it relates to men with prostate cancer. Since her arrival, she has been working to develop a comprehensive program that will identify, implement, and fund research that is critical to reducing cancer-related health disparities as well as coordinate efforts across programs to increase recruitment of underrepresented populations into cancer research.

PART IV: INCLUSION OF CHILDREN IN CLINICAL RESEARCH

Significant advancements have been achieved with respect to the plans and mechanisms to include children in clinical trials. Highlights of such are listed below:

- **In 2015, a formalized consortium partnership between KUCC and Children's Mercy was executed.** KUCC's request for consortium status with Children's Mercy grew out of Children's Mercy founding membership in the MCA. The increasing collaboration between KUCC and Children's Mercy led to a formal consortium agreement in April 2015. This agreement was reviewed for content by NCI program officials to ensure that all stipulations outlined in the CCSG RFA were adequately addressed.
- Children's Mercy cares for over 2,000 cancer patients each year with 168 index cases in the tumor registry calendar year 2015. Of these 168 cases, 23.2% (n=39) were enrolled onto cancer treatment trials.
- Children's Mercy has a number of nationally recognized pediatric oncologists and a robust clinical research program, as witnessed by their participation and leadership in multiple Children's Oncology Group initiatives.
- As part of the consortium agreement, Children's Mercy researchers engaged in cancer research are eligible to be KUCC members and serve in leadership roles. As such, **Jensen** designated Alan **Gamis**, MD, MPH, as the co-leader of the KUCC Drug Discovery, Delivery and Experimental Therapeutics research program following signing of the agreement. **Gamis** is the Associate Division Director for the Section of Oncology at Children's Mercy.
- As a result of the consortium agreement, Children's Mercy cancer clinical trial protocols are now subject to the KUCC Protocol Review and Monitoring System and the KUCC Data Safety Monitoring Institutional Plan. Along these lines, Children's Mercy researchers have been added to the KUCC Protocol Review and Monitoring Committee and KUCC Data Safety and Monitoring Board.
- A significant portion of the Children's Mercy MCA Partners Advisory Board membership fees are directly invested into collaborative pediatric cancer research projects across KUCC campuses. From 2012-2015, 12 research projects were funded for a total of $1,902,559 through these membership dollars. Areas of research include drug development for pediatric cancers, immunotherapy, stem cell research and care for the pediatric cancer survivor.
- Children's Mercy provides $500,000 to support the expansion of KUCC bioinformatics and personalized medicine capabilities, the development of a biospecimen repository for pediatric cancers and other collaborative research initiatives.

Progress Report Publications

This component has no publications resulting from Cancer Center Support Grant funds.

Protection of Human Subjects – CLINICAL PROTOCOL and DATA MANAGEMENT

The Human Subjects Committee (HSC) is designated as the Institutional Review Board (IRB) for the University of Kansas Medical Center, as required by 45 CFR 46 and 21 CFR 56. The HSC is responsible for reviewing, approving, modifying, rejecting and monitoring research involving human subjects. The University of Kansas Cancer Center Support Grant is an umbrella grant to the institution and therefore not reviewed by the IRB. However, all clinical trials must obtain appropriate IRB review and approval prior to initiation. Any human subjects research project at the University of Kansas Medical Center is subject to regulatory requirements for legally effective informed consent and ongoing IRB oversight. Human subjects research is conducted under FWA#00003411 and complies with DHHA and FDA standards.

Inclusion of Women & Minorities – CLINICAL PROTOCOL and DATA MANAGEMENT

The University of Kansas Cancer Center is committed, along with the NIH, to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study. As such, KUCC will adhere to the NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research. Specifically, in the case of any clinical trial in which women or members of minority groups will be included as subjects, KUCC will ensure that the trial is designed and carried out in a manner sufficient to provide for valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

OMB Number:0925-0001 and 0925-0002
Expiration Date: 10/31/2018

***Study Title:** Clinical Protocol and Data Management- Any human subject study funded by CCSG funds will be required to submit a PHS inclusion enrollment report.

***Delayed Onset Study?** ☑ Yes ❑ No

If study is not delayed onset, the following selections are required:

Enrollment Type ❑ Planned ❑ Cumulative (Actual)

Using an Existing Dataset or Resource ❑ Yes ❑ No

Enrollment Location ❑ Domestic ❑ Foreign

Clinical Trial ❑ Yes ❑ No

NIH-Defined Phase III Clinical Trial ❑ Yes ❑ No

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/Alaska Native										
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More than One Race										
Unknown or Not Reported										
Total										

Inclusion of Children – CLINICAL PROTOCOL and DATA MANAGEMENT

In the same manner, The University of Kansas Cancer Center will adhere to the guidelines set forth by the NIH for the Inclusion of Children as Participants in Research Involving Human Subjects. KUCC understands the goal of this policy is to increase the participation of children in research so that adequate data will be developed to support the treatment modalities for disorders and conditions that affect adults and may also affect children.

Resource Sharing Plan

The University of Kansas Cancer Center (KUCC) and its scientific community understands its responsibility to comply with the instructions for the Resource Sharing Plans provided within the SF 424 (R&R) Application General Instructions and Supplemental Grant Application Instructions. When resources are developed with NIH funds via this Cancer Center Support Grant P30 mechanism, KUCC will ensure findings are made readily available to the NIH and the scientific community in a timely manner.

Data Sharing Plan

KUCC will adhere to the Final NIH Statement on Sharing Research Data and refer to the National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research. KUCC encourages the free flow of information and ideas while recognizing the timeliness of data sharing, the rights and privacy of human subjects and issues related to proprietary data. KUCC encourages data documentation, using a data-sharing agreement and selecting an appropriate method for sharing; considering the sensitivity of the data, the size of the dataset and the volume of requests anticipated.

Additionally, KUCC encourages any user of a CCSG-supported shared resource to acknowledge the source of data upon which their manuscript is based either in the Acknowledgments section or with authorship on the paper. Furthermore, any research project that received direct cost support from the CCSG is encouraged to cite the P30 CA168524. In both cases, citing the P30 CA168524 grant number and then being compliant with the NIH Public Access Policy is required.

Sharing Model Organisms

In the event that a model organism is developed, KUCC will comply with the NIH Policy on Sharing of Model Organisms for Biomedical Research. KUCC will work with the NIH/NCI to share and disseminate the critical model organism in a timely manner.

Genome Wide Associate Studies

When applicable, KUCC will comply with the NIH Genomic Data Sharing Policy. KUCC supports the sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. All research studies funded through the CCSG involving genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data will be submitted in a timely manner.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 016060860

Legal Name*: University of Kansas Medical Center Research Institute, Inc.
Department:
Division:
Street1*: MSN 1039, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Deborah		Maloney	MSM

Position/Title: Director, Sponsored Programs Administration
Street1*: 3901 Rainbow Boulevard
Street2: Mail Stop 1039
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937
Phone Number*: 913-588-1261 Fax Number: 913-588-3225 Email: spa@kumc.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofite Organization

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Protocol Review and Monitoring System

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2017	06/30/2022

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Medical Center
Duns Number:	016060860
Street1*:	MSN 2029, 3901 Rainbow Blvd
Street2:	
City*:	Kansas City
County:	Wyandotte
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66160-8500
Project/Performance Site Congressional District*:	KS-003

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ❍ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number 00003411

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	PRMS_Project_Summary_Final1019428411.pdf
8. Project Narrative*	
9. Bibliography & References Cited	
10.Facilities & Other Resources	
11.Equipment	
12. Other Attachments	PRMS_Other_Attachments_FINAL1019428415.pdf

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Protocol Review and Monitoring System – Project Summary

The Protocol Review and Monitoring System (PRMS) oversees and ensures the scientific merit, appropriate resourcing and progress of all clinical studies at KUCC. KUCC received conditional approval of PRMS at the 2012 NCI site visit and have made multiple personnel and process changes since that time resulting in full approval in August 2016. The KUCC Clinical Trials Office (CTO) may support the Center's cancer clinical trials that are approved by the PRMS. The PRMS evaluation occurs prior to submission to the institutional review board called the Human Subjects Committee (HSC) and does not overlap with HSC responsibilities. The three components of the PRMS are the Disease Working Groups (DWG; reporting to Associate Director (AD) of Clinical Research; Carol Fabian, MD, 2016), the Executive Resourcing Committee (ERC; Stephen Williamson, MD, Chair, 2013, also reporting to AD of Clinical Research), and the Protocol Review and Monitoring Committee (PRMC; Qamar Khan, MD, Chair 2013, reporting to the Deputy Director). Although each component has a unique role, these are aligned to ensure protocols are efficiently moved through the system, receive high-quality peer-review and monitoring, and that the research portfolio is consistent with KUCC clinical research priorities. The DWGs, which meet monthly, are charged with initial review of clinical trial merit and feasibility, and with prioritizing by disease-site. Highest priority is given to investigator initiated peer-reviewed funded trial proposals. DWG co-chairs are appointed by the AD for Clinical Research. Although the DWG composition is rich in clinicians focused on treatment trials and primarily D3ET members, representatives of CPS and CCPH are also DWG members. DWGs with significant prevention and survivorship components have formal liaisons from CPS and CCPH, and this is likely to extend to CB in the future. To further increase interaction with KUCC programs and translational research, each DWG has one of their meetings per year replaced by a Clinical Translational Research Meeting focused on their area but chaired by the AD of Clinical Research with at least 1 basic or behavioral scientist presenting a relevant proposal or ongoing project along with 1-2 clinical projects. All KUCC members are invited and KUCC program leaders and ADs are expected to attend. DWGs are evaluated yearly by the AD for proportion of trials that are IIT and/or national, quality and translational nature of interventional trials, trial accrual, and national meeting presentations and publications. The ERC reviews protocol resource requirements, available funding, and alignment with KUCC research programs as defined by the Leadership Council (ADs and Program Leaders); CTO sends ERC approved studies to the PRMC for Scientific Review. The PRMC performs independent scientific merit and bio-statistical reviews, including rationale, design, statistical analysis plan, and adequacy of the data safety monitoring. The PRMC also monitors active protocols at least annually for continued scientific merit, clinical appropriateness, progress toward completion of scientific objectives, accrual status, and terminates studies as appropriate.

Protocol Review and Monitoring System - Other Attachments **P30CA168524**

Table 1 - Institutional Protocols Reviewed and Monitored
Reporting period: 01/01/2015 - 12/31/2015
Report Prepared: 08/04/2015

Interventional:

INSTITUTIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	PRMS Status
The SWOG/Hope Foundation Impact Award	Multiple	NCT02087657	Auto-HBO	Aljitawi, O	D3ET	3/13/2014	01/22/2015	Device	Tre	Pilot Study Exploring the Use of Hyperbaric Oxygen in Autologous PBSC Transplantation	N	20	20	0	23	0	0	Closed
KU Endowment Association Frontiers	Multiple	NCT02099266	BMT-2011-08-01	Aljitawi, O	D3ET	6/4/2013	02/23/2015	Device	Tre	A Pilot Study to Determine the Safety and Efficacy of Using Hyperbaric Oxygen Therapy to Improve Umbilical Cord Blood Stem Cell Homing and Subsequent Engraftment	N	15	15	3	15	0	0	Closed
KU Endowment Association U-Systems	Breast-Female	NCT02488187	KUMC 12801	Amin, A	CPS	12/17/2012	07/27/2016	Feasibility/Pilot	Dia	Comparison of Preoperative Automated Breast Ultrasound and MRI to Determine Therapeutic Management of Newly Diagnosed Breast Cancer Patients	N	200	200	65	97	0	0	Closed
Thomas Jefferson University	Multiple	NCT01833351	KUMC 12680	Drisko, J	D3ET	7/1/2011	09/11/2015	I	Tre	Pharmacokinetic Evaluation of Intravenous Ascorbic Acid	N	66	66	4	34	0	0	Closed
Investigator	Breast-Female	NCT00291096	KUMC 4601	Fabian, C	CPS	7/25/1989		N/A	Pre	High Risk Breast Clinic - Breast Tissue Biomarkers Predicting Short Term Risk of Breast Cancer	N	3000	3000	82	2668	0	0	Approved and Activated
Investigator	Breast-Female	NCT02101970	STUDY00000703	Fabian, C	CPS	3/24/2014	04/23/2015	II	Pre	Randomized Pilot Trial of Omega-3 Fatty Acids or Placebo in Peri- or Post-menopausal Women at High Risk For Breast Cancer Undergoing a Weight Loss Intervention	N	50	50	10	46	0	0	Closed
Breast Cancer Research Foundation	Breast-Female	NCT02517502	STUDY00002415	Fabian, C	CPS	8/18/2015		Feasibility/Pilot	Sup	Docosahexaenoic Acid (DHA) To Prevent Development of Cognitive Dysfunction Due to Chemotherapy	Y	50	40	3	3	0	0	Approved and Activated
Celgene University of Nebraska	Non-Hodgkins Lymphoma	NCT01035463	RV-LYM-PI-0328	Ganguly, S	D3ET	3/10/2015	07/14/2015	I/II	Tre	Phase I/II Study of Lenalidomide Maintenance Following BEAM (+/- Rituximab) for Chemo-Resistant or High Risk Non-Hodgkin's Lymphoma	Y		20	4	4	0	0	Closed
University of Kansas Cancer Center	Multiple Myeloma	NCT02703779	2015-IIT-LQT-BMT-MM-AutoSCT	Ganguly, S	D3ET	3/2/2016		II	Tre	An exploratory trial to estimate the proportion of patients with tumor cell contaminated, flow positive leukapheresis products collected with and without bortezomib as in-vivo purging prior to autologous stem cell harvest for multiple myeloma.	N	100	100	0	4	0	0	Approved and Activated
Cancer Prevention and Survivorship Pilot Project	Cancer Prevention		STUDY00002779	Gibson, C	CPS	9/10/2015	06/01/2016	Feasibility/Pilot	Sup	Televideo Exercise and Nutrition Program for Adult Survivors of Pediatric Cancer	N	24	24	9	9	0	0	Closed
GlaxoSmithKline	Breast-Female	NCT01283789	2010-IIT-Novartis-RAD-001	Khan, Q	D3ET	2/22/2011		II	Tre	Phase II Trial of Lapatinib and RAD-001 for HER2 Positive Metastatic Breast Cancer	N	45	45	0	20	0	0	Approved and Activated

University of Kansas Cancer Center	Multiple	NCT02595320	2015-X7-7-LQT	Khan, Q	D3ET	10/1/2015		II	Tre	Randomized open-label trial of dose dense, fixed dose capecitabine compared to standard dose capecitabine in metastatic breast cancer and advanced/metastatic GI cancers.	Y	183	183	9	9	6	6	Approved and Activated
Novartis Pharmaceuticals	Breast-Female	NCT02712723	CLEE011XUS10T	Khan, Q	D3ET	2/16/2016		II	Tre	Femara (Letrazole)Plus Ribociclib (LEE011) or Placebo as Neo-adjuvant Endocrine Therapy for Women with ER-positive, HER2-negative Early Breast Cancer	Y	120	24	0	8	0	0	Approved and Activated
University of Kansas Cancer Center	Prostate	NCT02678520	2015-IIT-RT-IMRT	Kumar, P	D3ET	2/16/2016	03/04/2016	II	Tre	Phase II Randomized Clinical Trial Comparing 3-D Conformal Radiation Therapy (RT) vs. Intensity Modulated Radiation Therapy in Post- Prostatectomy Prostate Cancer Patients	N	100	100	0	0	0	0	Closed
FRONTIERS	Urinary Bladder	NCT02716623	STUDY00001802	Lee, E	CB			Feasibility/Pilot	Pre	The Feasibility of a Diet and Exercise Intervention in Diabetics During Treatment for Non-muscle Invasive Bladder Cancer (DEAL)	N	5	5	0	0	0	0	Approved by not yet activated
AngioDynamics University of Arkansas	Breast-Female	NCT01420380	104603	McGinness, M	D3ET	4/12/2011	07/26/2016	N/A	Tre	ABLATE Trial: Radiofrequency Ablation After Breast Lumpectomy (eRFA) Added To Extend Intraoperative Margins in the Treatment of Breast Cancer	Y		40	8	34	0	0	Closed
FRONTIERS	Prostate	NCT02198859	KUMC 13582	Mirza, M	D3ET	4/11/2014		I	Tre	Phase 1 Study of Evaluation of Lithium and its effect on clinically localized prostate cancer	N	18	18	3	9	0	0	Approved and Activated
Cedars-Sinai Medical Center	Breast-Female	NCT02360917	IIT 2014-01	Myers, J	CPS	7/29/2015		N/A	Sup	Emerging from the Haze™ – A multi-center, wait-list controlled trial to measure impact of a multi-dimensional psycho-educational program on subjective cognitive complaints after breast cancer treatment using virtual technology	Y		35	7	7	0	0	Approved and Activated
University of Chicago	Head and Neck	NCT01111058	09-266-B	Neupane, P	D3ET	6/8/2012	04/01/2015	II	Tre	Randomized Double-Blind Phase II Trial of Everolimus versus Placebo as Adjuvant Therapy in Patients with Locally Advanced Squamous Cell Cancer of the Head and Neck (SCCHN)	Y		10	2	9	0	0	Closed
Univ. of Kansas Cancer Center	Breast-Female	NCT02413320	2014-BRST-TNBC-LQT	Sharma, P	D3ET	7/9/2015		II	Tre	Randomized open label Phase II trial of neoadjuvant Carboplatin plus Docetaxel or Carboplatin plus Paclitaxel followed by Adriamycin plus Cyclophosphamide in stage I-III triple-negative breast cancer.	Y	100	100	6	6	6	6	Approved and Activated
Novartis Pharmaceuticals	Breast-Female	NCT02379247	CBYL719XUS06T	Sharma, P	D3ET	3/3/2015		I/II	Tre	Phase I/II study of BYL719 and Nab-Paclitaxel (Abraxane) in patients with locally recurrent or metastatic HER-2 negative breast cancer	Y	54	34	9	9	0	0	Approved and Activated
Celgene	Multiple	NCT02393794	RM-CL-PI-002783	Sharma, P	D3ET	7/17/2015		I/II	Tre	Phase I/II trial of Cisplatin + Romidepsin in locally recurrent or metastatic triple negative breast cancer or BRCA 1/BRCA 2 mutation associated locally recurrent or metastatic breast cancer	N	54	54	4	4	0	0	Approved and Activated

Lineberger Comprehensive Cancer Center	Lung	NCT02276560	LCC 1407	Veeramachaneni, N	D3ET	3/8/2016	04/12/2016	II	Tre	Multicenter Phase II Trial of Neoadjuvant Cisplatin and Nab-paclitaxel for (N2) Defined Stage IIIA Non-Small Cell Lung Cancer (NSCLC)	Y	51	10	0	0	0	0	Closed
Weill Cornell Medical College	Prostate	NCT00859781	0810010067 (J591+Ketoconazole)	Williamson, S	D3ET	12/14/2012	04/28/2015	II	Tre	A Randomized Phase 2 Trial of 177Lu Radiolabeled Monoclonal Antibody HuJ591 (177Lu-J591) and Ketoconazole in Patients with High-Risk Castrate Biochemically Relapsed Prostate Cancer After Local Therapy	Y		10	1	3	0	0	Closed
Albert Einstein College of Medicine of Yeshiva University	Myelodysplastic Syndrome	NCT01772420	2012-407	Yacoub, A	D3ET	7/31/2015		II	Tre	Phase II Study of Lenalidomide and Eltrombopag in Patients with Symptomatic Anemia in Low or Intermediate I Myelodysplastic Syndrome (MDS)	Y		15	5	5	0	0	Approved and Activated

Observational:

INSTITUTIONAL												**Total Targeted Accrual**		**Cancer Center Primary Accrual Institution**		**Other Accrual Institutions(s)**		
Specific Funding Source	**Anatomic Site**	**NCT Number**	**Protocol ID**	**PI**	**Prog Code**	**Date Opened**	**Date Closed**	**Phase**	**Primary Purpose**	**OfficialTitle**	**Multi-Inst study?**	**Entire Study**	**Your Center**	**12 Months**	**To Date**	**12 Months**	**To Date**	**PRMS Status**
Investigator	Breast-Female		KUMC 12614	Sharma, P	CPS	3/22/2011		N/A	Oth	Prospective evaluation of GErmline mutations, Cancer outcome and Tissue biomarkers (P.R.O.G.E.C.T.): A registry for patients with triple negative breast cancer and germline mutations	Y	N/A	N/A	133	421	98	269	Approved and Activated

Ancillary/Correlative:

INSTITUTIONAL												**Total Targeted Accrual**		**Cancer Center Primary Accrual Institution**		**Other Accrual Institutions(s)**		
Specific Funding Source	**Anatomic Site**	**NCT Number**	**Protocol ID**	**PI**	**Prog Code**	**Date Opened**	**Date Closed**	**Phase**	**Primary Purpose**	**Official Title**	**Multi-Inst study?**	**Entire Study**	**Your Center**	**12 Months**	**To Date**	**12 Months**	**To Date**	**PRMS Status**
Thomas Jefferson University	Multiple Sites		KUMC 12845	Drisko, J	D3ET	11/7/2011	09/11/2015	N/A	Bas	Evaluation of Intravenous Ascorbic Acid: Imaging with MRI-Spectroscopy	N	10	10	4	10	0	0	Closed
KUCC Pilot Award	Colorectal		KUMC 13370	Greiner, A	CCPH	5/1/2013		N/A	Oth	A Translational Approach to Understanding African American Colorectal Cancer Health Disparities	N	40	40	20	39	0	0	Approved and Acitivated

Table 2. Number of Trials Reviewed or Prioritized by Source of Support and Year

Reporting Year (calendar year)	2013	2014	2015	Total
National Group	69	55	58	182
Externally Peer-Reviewed	3	3	4	10
Institutional (Investigator-Initiated)	39	33	27	99
Industry	90	84	82	256
Total	**201**	**175**	**171**	**547**

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: Dr First Name*: Qamar Middle Name Jamal Last Name*: Khan Suffix: MD

Position/Title*:	Assistant Professor
Organization Name*:	University of Kansas Medical Center
Department:	Medicine-Clinical Oncology
Division:	School of Medicine
Street1*:	MS 5003 Kansas University Medical Center
Street2:	2330 Shawnee Mission Parkway
City*:	Westwood
County:	Johnson
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66205-0000

Phone Number*: 913-588-3375 Fax Number: 913-588-3679

E-Mail*: QKHAN@kumc.edu

Credential, e.g., agency login: QJKHAN

Project Role*: Other (Specify) Other Project Role Category: Core Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: KHAN_BIOSKETCH1019428422.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: James Middle Name Last Name*: Coster Suffix: MD

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Radiation Oncology
Division: Medicine
Street1*: MS 4033, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-8500

Phone Number*: 913-574-2650 Fax Number:

E-Mail*: jcoster@kumc.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: COSTER_BIOSKETCH1019483468.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Bruce Middle Name F Last Name*: Kimler Suffix: PhD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Radiation Oncology
Division: School of Medicine
Street1*: MS 4033, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-3660 Fax Number: 913-588-3663

E-Mail*: bkimler@kumc.edu

Credential, e.g., agency login: BKIMLER

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: KIMLER_BIOSKETCH1019428423.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Kevin Middle Name Fate Last Name*: Ginn Suffix: MD

Position/Title*: Assistant Professor, Pediatrics
Organization Name*: The Children's Mercy Hospital
Department: Director, Brain Tumor Program
Division: Mediine
Street1*: 2401 Gillham Rd
Street2:
City*: Kansas City
County:
State*: MO: Missouri
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 64108-4619

Phone Number*: 816-234-3265 Fax Number:

E-Mail*: kginn@cmh.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: GINN___BIOSKETCH1019428419.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Jianghua Middle Name Last Name*: He Suffix: Ph.D.

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Biostatistics
Division: School of Medicine
Street1*: MS 1026, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-2985 Fax Number: 913-588-0252

E-Mail*: jhe@kumc.edu

Credential, e.g., agency login: hejiang

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Amanda Middle Name Last Name*: August Suffix: PharmD

Position/Title*: Clinical Pharmacist
Organization Name*: The Children's Mercy Hospital
Department: Pediatric Heme/Onc, Pharmacy
Division: Medicine
Street1*: 2401 Gilham Road
Street2:
City*: Kansas City
County:
State*: MO: Missouri
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 64108-4619

Phone Number*: 816-234-3055 Fax Number:

E-Mail*: aaugust@cmh.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: AUGUST_A_BIOSKETCH1019483470.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Chris Middle Name Last Name*: Lominska Suffix: MD

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Radiation Oncology
Division: Medicine
Street1*: MS 4033, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66103-0000

Phone Number*: 913-588-3600 Fax Number:

E-Mail*: clominska@kumc.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: LOMINSKA_BIOSKETCH1019857908.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Cory Middle Name Last Name*: Bivona Suffix: PharmD

Position/Title*: Clinical Pharmacist
Organization Name*: University of Kansas Medical Center
Department: KUCC SW-Pharmacy
Division: Medicine
Street1*: 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-8500

Phone Number*: 913-588-7747 Fax Number:

E-Mail*: cbivona@kumc.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: BIVONA_BIOSKETCH1019483472.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Diana Middle Name Last Name*: Hoelscher Suffix: PharmD

Position/Title*: Clinical Pharmacist
Organization Name*: University of Kansas Medical Center
Department: Outpatient CC Pharmacy
Division: Medicine
Street1*: 2330 Shawnee Mission Parkway
Street2:
City*: Westwood
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66205-0000

Phone Number*: 913-588-7747 Fax Number:

E-Mail*: dsvoboda@kumc.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: HOELSCHER_BIOSKETCH1019483473.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Fariba Middle Name Last Name*: Behbod Suffix: PhD

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Pathology & Lab Medicine
Division: School of Medicine
Street1*: MS 3045, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-7070 Fax Number: 913-588-7073

E-Mail*: fbehbod@kumc.edu

Credential, e.g., agency login: FBEHBOD

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: BEHBOD_BIOSKETCH1019428417.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Fen Middle Name Last Name*: Wang Suffix: MD

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Radiation Oncology
Division: School of Medicine
Street1*: MS 4033, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-3619 Fax Number: 913-588-3663

E-Mail*: FWANG1@kumc.edu

Credential, e.g., agency login: FENWANG

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: WANG_BIOSKETCH1019483474.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Francisco Middle Name J. Last Name*: Diaz Suffix: PhD

Position/Title*: Associate Professor
Organization Name*: University of Kansas Medical Center
Department: Biostatistics
Division: School of Medicine
Street1*: MSN 1026, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66103-0000

Phone Number*: 913-620-1541 Fax Number: 913-588-0252

E-Mail*: fdiaz@kumc.edu

Credential, e.g., agency login: FJDIAZ

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: James Middle Name Last Name*: Coulter Suffix: BSN

Position/Title*: MCA Clinical Director
Organization Name*: University of Kansas Medical Center
Department: Midwest Cancer Alliance
Division: Cancer Center
Street1*: MS 6003, 4350 Shawnee Mission Parkway
Street2:
City*: Fairway
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66205-0000

Phone Number*: 913-945-6834 Fax Number:

E-Mail*: jcoulter@kumc.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: COULTER_BIOSKETCH1019483466.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Jan Middle Name Last Name*: Ward Suffix: LPN

Position/Title*: Clinical Research Coordinator
Organization Name*: University of Kansas Medical Center
Department: Cancer Center
Division: Medicine
Street1*: MS 6009, 4350 Shawnee Mission Parkway
Street2:
City*: Fairway
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66205-0000

Phone Number*: 913-574-2372 Fax Number:

E-Mail*: jward3@kumc.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: WARD_BIOSKETCH1019483467.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Jennifer Middle Name Rose Last Name*: Klemp Suffix: PhD

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Medicine-Clinical Oncology
Division: School of Medicine
Street1*: MS 5015
Street2: 2330 Shawnee Mission Parkway
City*: Westwood
County: Johnson
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66205-0000

Phone Number*: 913-588-3662 Fax Number: 913-588-1455

E-Mail*: JKLEMP@kumc.edu

Credential, e.g., agency login: JKLEMP

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Joshua Middle Name M Last Name*: Mammen Suffix: MD

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Surgery
Division: School of Medicine
Street1*: MSN 2005, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-0022 Fax Number: 913-588-7450

E-Mail*: jmammen2@kumc.edu

Credential, e.g., agency login: JMAMMEN

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: MAMMEN_BIOSKETCH1019483477.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Julia Middle Name A Last Name*: Chapman Suffix: MD

Position/Title*: Associate Professor
Organization Name*: University of Kansas Medical Center
Department: Gynecology & Obstetrics
Division: School of Medicine
Street1*: MS 2028 Kansas University Medical Center
Street2: 3901 Rainbow Boulevard
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-6225 Fax Number: 913-588-6244

E-Mail*: JCHAPMAN2@kumc.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: CHAPMAN_BIOSKETCH1019428418.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Keith Middle Name Last Name*: August Suffix: MD

Position/Title*: Associate Director, Pediatrics
Organization Name*: The Children's Mercy Hospital
Department: Exp Therp Ped Cancer
Division: Medicine
Street1*: 2401 Gilham Road
Street2:
City*: Kansas City
County:
State*: MO: Missouri
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 64108-0000

Phone Number*: 816-234-3265 Fax Number:

E-Mail*: kaugust@cmh.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: AUGUST_K_BIOSKETCH1019428416.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Leyla Middle Name Last Name*: Shune Suffix: MD

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Hematologic Malignancies
Division: Medicine
Street1*: MS 5003, 2330 Shawnee Mission Parkway
Street2:
City*: Westwood
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66205-0000

Phone Number*: 913-588-6030 Fax Number:

E-Mail*: lshune@kumc.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: SHUNE_BIOSKETCH1019483479.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Moben Middle Name Last Name*: Mirza Suffix: MD

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Urology Surgery
Division: Medicine
Street1*: MS 3016, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-8500

Phone Number*: 913-945-6432 Fax Number:

E-Mail*: mmirza@kumc.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: MIRZA_BIOSKETCH1019483480.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Nikki Middle Name Last Name*: Ogle Suffix: PharmD

Position/Title*: Clinical Pharmacist
Organization Name*: University of Kansas Medical Center
Department: Outpatient CC Pharmacy
Division: Medicine
Street1*: MS 5022, 2330 Shawnee Mission Parkway
Street2:
City*: Westwood
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66205-0000

Phone Number*: 913-588-7747 Fax Number:

E-Mail*: nogle@kumc.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: OGLE_BIOSKETCH1019483481.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: Dr First Name*: Prakash Middle Name Chandra Last Name*: Neupane Suffix: MD

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Medicine-Clinical Oncology
Division: School of Medicine
Street1*: MS 5003 Kansas University Medical Center
Street2: 2330 Shawnee Mission Parkway
City*: Westwood
County: Johnson
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66205-0000

Phone Number*: 913-588-6029 Fax Number: 913-588-4085

E-Mail*: pneupane@kumc.edu

Credential, e.g., agency login: pneupane

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: NEUPANE_BIOSKETCH1019483478.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Raed Middle Name Last Name*: Al-Rajabi Suffix: MD

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Medical Oncology
Division: Medicine
Street1*: MS 5003, 2330 Shawnee Mission Parkway
Street2:
City*: Westwood
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66205-0000

Phone Number*: 913-588-6029 Fax Number:

E-Mail*: ral-rajabi@kumc.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: AL_RAJABI_BIOSKETCH1019659741.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Robin Middle Name Last Name*: Ryan Suffix: MPH

Position/Title*: Research Program Manager
Organization Name*: The Children's Mercy Hospital
Department: Pediatric Heme/Oncology
Division: Medicine
Street1*: 2401 Gilham Rd
Street2:
City*: Kansas City
County:
State*: MO: Missouri
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 64108-4619

Phone Number*: 816-701-1345 Fax Number:

E-Mail*: rryan@cmh.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: RYAN_BIOSKETCH1019483483.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Sharon Middle Name Last Name*: Lewis Suffix: RN

Position/Title*: Nurse Practitioner Coordinator
Organization Name*: University of Kansas Medical Center
Department: KU Clinical Research Center
Division: Medicine
Street1*: MS 6007, 4350 Shawnee Mission Parkway
Street2:
City*: Fairway
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66205-0000

Phone Number*: 913-945-7641 Fax Number:

E-Mail*: slewis@kumc.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: LEWIS_BIOSKETCH1019483484.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Stella Middle Name Last Name*: Baccaray Suffix: MSN

Position/Title*: Research Nurse Clinician
Organization Name*: University of Kansas Medical Center
Department: Cancer Ctr Clinical Trials
Division: Medicine
Street1*: MS 5005, 2330 Shawnee Mission Pkwy
Street2:
City*: Westwood
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66203-0000

Phone Number*: 913-588-2437 Fax Number:

E-Mail*: sbaccaray@kumc.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: BACCARAY_BIOSKETCH1019483485.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: William Middle Name R Last Name*: Jewell Suffix: MD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Surgery General
Division: School of Medicine
Street1*: MS 1027 Kansas University Medical Center
Street2: 3901 Rainbow Boulevard
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-6112 Fax Number: 913-945-6650

E-Mail*: wjewell@kumc.edu

Credential, e.g., agency login: WJEWELL1

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: JEWELL_BIOSKETCH1019428420.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Barry Middle Name Last Name*: Skikne Suffix: MD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Heme/Oncology
Division: Medicine
Street1*: MS 5003, 2330 Shawnee Mission Parkway
Street2:
City*: Westwood
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66205-0000

Phone Number*: 913-588-6078 Fax Number:

E-Mail*: bskikne@kumc.edu

Credential, e.g., agency login: bskikne

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Skikne_Bio_CCSG1019799876.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Debra Middle Name Kay Last Name*: Sullivan Suffix: PhD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Dietetics and Nutrition
Division: School of Health Professions
Street1*: MS 4013, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-5357 Fax Number: 913-588-7685

E-Mail*: dsulliva@kumc.edu

Credential, e.g., agency login: DKSULLIVAN

Project Role*: Other (Specify) Other Project Role Category: PRMC committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: SULLIVAN_BIOSKETCH1019857909.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Shrikant Middle Name Last Name*: Anant Suffix: PhD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Molec and Integr Physiology
Division: School of Medicine
Street1*: MSN 3040, 3901 Rainbow Boulevard
Street2: 4019 Wahl East
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-945-6334 Fax Number: 913-945-6327

E-Mail*: sanant@kumc.edu

Credential, e.g., agency login: SANANT3

Project Role*: Other (Specify) Other Project Role Category: PRMC Committee

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ○ Yes ● No

*Agency-Defined Phase III Clinical Trial? ○ Yes ○ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator / Change of Institution Section

❑ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	PRMS_SpecificAims_Final1019428413.pdf
3. Research Strategy*	PRMS_ResearchStrategy_Final1019496489.pdf
4. Progress Report Publication List	Progress_Report_Publications_Blank1019754754.pdf
Human Subjects Section	
5. Protection of Human Subjects	Protection_of_Human_Subjects___PRMS1019799872.pdf
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	Inclusion_of_Women_Minorities___PRMS1019799873.pdf
8. Inclusion of Children	Inclusion_of_Children___PRMS1019799874.pdf
Other Research Plan Section	
9. Vertebrate Animals	
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	
14. Resource Sharing Plan(s)	Resource_Sharing_Plan__Generic1019799875.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Protocol Review and Monitoring System – Specific Aims

The University of Kansas Cancer Center (KUCC) Protocol Review and Monitoring System (PRMS) ensures that cancer clinical research conducted at the Cancer Center supports the development of novel clinical research in concert with KUCC overall goals, is of high scientific quality and is adequately resourced.

Specifically, the PRMS:

1. Prioritizes competing studies and resources based upon the KUCC institutional prioritization plan;

2. Reviews all proposed cancer-related protocols for merit of scientific rationale and adequacy of patient population;

3. Reviews the statistical analysis plan and appropriateness of trial design;

4. Reviews the adequacy of the data safety monitoring plan to assure oversight of patient safety; and

5. Monitors the accrual and scientific progress of studies.

Protocol Review and Monitoring System – Research Strategy

The Protocol Review and Monitoring System (PRMS) received a "Conditional Approval" by NCI reviewers at the 2012 site visit. As a result, significant leadership changes were implemented between 2013 to present, including the Protocol Review and Monitoring Committee (PRMC) chair (Qamar **Khan**, 2013), Executive Resourcing Committee (ERC) chair (Stephen **Williamson**, 2013) and Associate Director for Clinical Research (Carol **Fabian**, 2016), as well as multiple procedural changes. As a result of these changes, KUCC received "Full Approval" by the NCI in August, 2016. The following table provides a description of the NCI reviewer comments regarding areas for improvement and the specific actions taken to address them.

RESPONSE TO 2012 NCI REVIEWER COMMENTS

Areas for Improvement	Response
Need for an enhanced and more organized "paper trail" leading to approval/disapproval of a protocol.	1. The PRMS Coordinator's responsibility transitioned into a position fully dedicated to the PRMC ensuring proper documentation of the process from initial application to approval/disapproval. Specifically, in 2013, the time-consuming function of coordinating the Disease Working Groups was removed from the PRMS Coordinator role and re-assigned to the respective disease-specific Clinical Trials Office (CTO) Project Directors. 2. Further delineation and enforcement of the documentation trail at each critical step in the PRMS approval pathway was implemented as follows: • First step - Disease Working Group (DWG) protocol review and approval. • Second step - Executive Resource Committee (ERC) review and approval for trials using CTO resources. For those trials, review documentation and ERC approval is required for a complete submission to, and decision by, the Protocol Review and Monitoring Committee (PRMC). Trials not using CTO resources go straight to PRMC. • Third step - PRMC review. Once a decision on a protocol is made by the PRMC, the decision, and any necessary correspondence, is communicated via email between the committee and the PI. This correspondence, along with PRMC and ERC meeting minutes, are recorded and maintained on the KUCC SharePoint for electronic archiving and accessibility.
Need for strict enforcement of accrual progress rules for study continuation or closure	Strict enforcement rules are being followed as shown below: • In CY 2015, 83 cancer protocols were reviewed by PRMC for their annual continuing review. • Four trials were closed by PRMC due to insufficient enrollment without granting probation. Specifically, o One trial was terminated by PRMC for zero patient accrual within the first year of trial activation; and o Three trials were closed to enrollment because the accrual was so slow that the studies would either not be scientifically valid or were not worth the cancer center resources. • 17 trials were placed on probation by PRMC for not meeting at least 50% of their accrual goal (note that trials involving rare diseases and/or rare molecular targets were excluded). • 13 trials reached the end of their probation period. Of these: o Five studies were closed; o One study was granted an additional six-month probation (plan for increasing accrual was in place); o One was granted an additional three-month probation (patients in the screening process); and o Six were removed from probation because the accrual goal set during probation was met.
Establishment and documentation of a sufficiently large multidisciplinary committee meeting quorum to ensure rigorous reviews.	• The PRMC is chaired by Qamar **Khan**, Associate Professor and a board certified hematologist and oncologist, with expertise in investigator-initiated trials in breast cancer. • A dedicated PRMS Coordinator, Molly Shugrue, assures and documents meeting quorum of at least 75%. • If the meeting quorum is projected to be less than 75%, then a meeting is convened by email and quorum confirmed electronically. • Currently, the PRMC is comprised of 30 voting members and one coordinator.

	The physician members are Medical Hematologist/Oncologists, Surgical Oncologists, Radiation Oncologists and Pediatric Hematologist/Oncologists. • In addition, there are members who are basic scientists, biostatisticians, Board Certified Hematology/Oncology clinical pharmacists, Pediatric Hematology/Oncology clinical pharmacists and Hematology/Oncology Research Nurses.
Appointment of an adequate number of senior (more experienced) investigators.	• The Chair of the PRMC identifies and invites new members to serve on the committee. The Deputy Director may also suggest members for the PRMC. The Chair, who reports to the Deputy Director, monitors the composition of PRMC membership on an ongoing basis to ensure the committee is well balanced in terms of seniority and multidisciplinary expertise. Currently, 18 of the 30 members have more than 10 years of experience in various disciplines of cancer care. The PRMC membership table can be found later in this section.

OTHER SIGNIFICANT CHANGES TO PRMS SINCE 2012 NCI SITE REVIEW

In 2015, Children's Mercy became a consortium partner of KUCC, and as a result, the KUCC PRMC now governs all cancer-related clinical trial protocols across both institutions, with the authority described above, and so the PRMC charter outlining PRMC authority, charter and bylaws was revised. The PRMC charter provides a standardized guideline for evaluation of protocols for scientific merit, scientific priorities and accrual. Specifically, the following updates were made in the PRMC charter document:

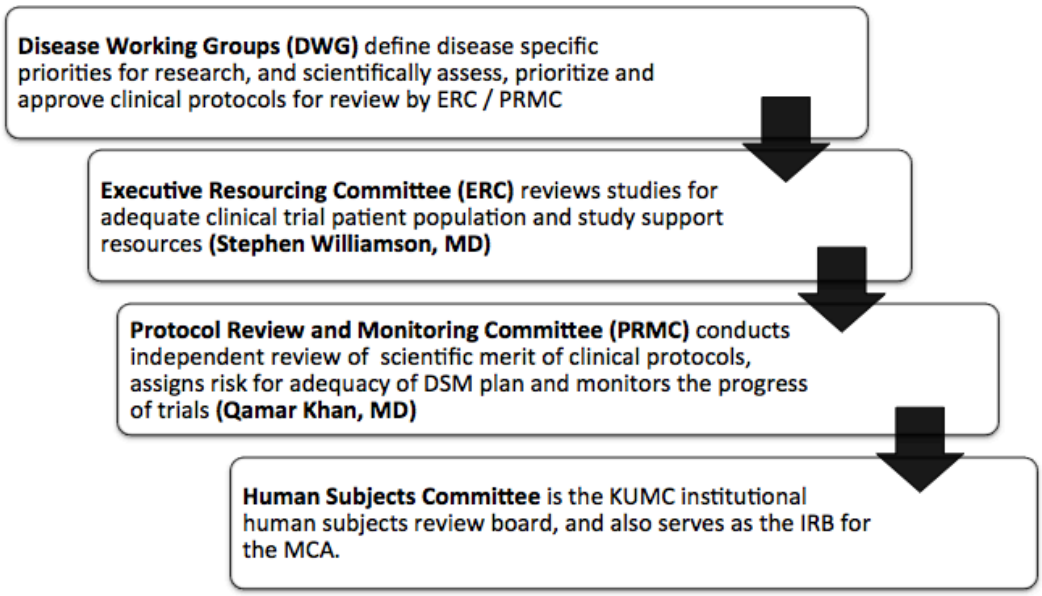
- Added reference to Children's Mercy to reflect consortium partnership;
- Added new sections of "Document History" and "Abbreviations";
- Added a section for "Risk Assignment" with new definitions;
- Added language providing exception to accrual goal requirements for trials involving narrower molecular subtypes; and
- Other minor changes made throughout to reflect current practices and clarify current procedures.

The PRMC consists of 30 voting members and one administrative coordinator. Of the four new voting members from Children's Mercy, one has been designated as a co-chair of the PRMC. In selecting the replacement members, particular attention was paid to identifying individuals who would consistently be free of potential conflicts at regular meeting dates/times, who had significant scientific and clinical expertise and who represented the community cancer program.

PRMS CLINICAL TRIAL SUBMISSION WORKFLOW

As shown in **Figure 1**, the PRMS involves three committees established to ensure adequate internal oversight of the scientific aspects of cancer clinical studies: 1) the Disease Working Groups (DWGs), 2) Executive Resourcing Committee (ERC) and 3) Protocol Review and Monitoring Committee (PRMC). The 13 DWGs and the ERC chair (**Williamson**) report to the AD for Clinical Research (**Fabian**). The PRMC Chair (**Khan**) reports to the Deputy Director (Andrew **Godwin**). **Fabian** reports to the Director (**Jensen**). Concepts for clinical trials originate and/or are reviewed in the DWGs. Promising investigator-initiated treatment trials with peer-reviewed funding and investigator-initiated treatment concepts, for which KUCC will likely have subjects and resources, are given highest priority. Prioritized trials are cleared by the DWG members after discussion at the monthly meetings and are then submitted to the ERC for review based on the Cancer Center prioritization order (see below) and availability of adequate patient and study support resources. The ERC meets weekly and is chaired by the Medical Director of the CTO (**Williamson**). Adequately resourced national trial protocols as well as industry protocol trials of interest to the DWGs are also submitted to the ERC for review. For clinical trials not using any CTO resources, the ERC step may be skipped. Once approved by the ERC, PRMC reviews the protocol and performs a detailed and independent scientific and statistical review of the protocol.

Figure 1. KUCC Protocol Review & Monitoring System



If approved, the PRMC will issue a letter to the investigator indicating that the study may proceed to the University of Kansas Medical Center institutional review board, called the Human Subjects Committee (HSC). PRMC approvals must be in place before HSC will issue full approval. The PRMC is complementary to the HSC review and does not overlap or duplicate the responsibilities of the HSC. For national [cooperative group] trials, particularly those that utilize the NCI Central IRB, the PRMC submission and review process may begin in parallel with the HSC submission, but HSC approval will be held until documentation of PRMC approval is provided to the HSC.

KUCC leadership has defined clinical research priorities in order to focus decisions about research conducted across campuses. These priorities are communicated to the DWGs and discussed in the monthly meetings. Each clinical research trial is evaluated in the PRMS according to the following order of priority (high to low).

1. NCI grants/contracts for investigator-initiated research
2. Cancer and/or cancer-related grants funded by NIH and other peer-reviewed grants as defined by NCI for investigator-initiated trials (IITs)
3. KUCC sponsored investigator-initiated research
4. Investigator-initiated research funded by other sources
5. Other grants, contracts that are non-peer reviewed
   a. SWOG and SWOG-endorsed trials
   b. Other Cooperative Group trials
   c. Pharmaceutical/Industry
   d. Non-profit
   e. Unfunded or underfunded projects from KUCC research programs with scientific merit

Substantial collaborations between the cancer clinical research activity and any three of the four research programs (Cancer Control & Population Health, Cancer Prevention & Survivorship or Drug Discovery, Delivery & Experimental Therapeutics) are also considered strongly. Early phase cancer treatment clinical trials are given priority consideration over trials in the later phases, which allows KUCC to be involved in the investigation of new and experimental cancer treatments, novel combinations of drugs and other therapeutic options at their earliest stages. Additional considerations include availability of patients to accrue to trials. Unique research needs of the KUCC catchment area such as those patient populations served by the Midwest Cancer Alliance and community cancer centers are considered in PRMS review. Additionally, each trial must be carefully evaluated for resource utilization and support.

Disease Working Groups (DWGs)

The Disease Working Groups (DWGs) provide a forum for exchange of research ideas and an opportunity to identify potential collaborative opportunities between clinical and basic science research investigators. Meetings include review of the trial portfolio and accrual activity, investigator presentations on new clinical and translational trial concepts and brainstorming sessions. The AD for Clinical Research oversees and coordinates the DWGs and appoints co-chairs. DWG co-chairs have, to date, been largely appointed on the basis of their clinical expertise and likelihood of stimulating new concepts for clinical trial and clinical trial accrual. In as much as possible one or more co-chairs are selected on the basis of complementary disciplines (e.g. surgery, medical oncology, radiation). Membership in DWGs include clinical, behavioral and laboratory investigators. Membership in DWGs include clinical, behavioral and laboratory investigators. Recent administrative changes in Medical Oncology encouraging community practice physicians to subspecialize in no more than two disease site areas has increased their attendance at DWGs, and influenced the design of IIT research as well as the selection of national and industry sponsored trials that the DWG adopts for its use. This increasing participation by community physicians has also helped develop important IIT protocols that encompass broader patient populations across the KUCC catchment area.

To improve DWG and KUCC research program interaction and translational research, starting in the last half of 2016, a Clinical Translational Research Meeting replaced at least one of the monthly meetings for each DWG. This meeting is chaired by the AD for Clinical Research with at least one basic or behavioral scientist presenting a relevant proposal or ongoing project along with one or two clinical projects. All Cancer Center members are invited and at least one research program co-leader and other Associate Directors are expected to attend. Furthermore, for those DWGs with a current significant prevention or survivorship component, formal liaison designations have been added in these areas and more are expected in the future.

The DWGs define the clinical research priorities respective to their disease site, but it is KUCC policy that IITs that have externally peer-reviewed funded protocols are given first priority. All potential clinical trials must be presented to the DWG. The Clinical Trials Office provides significant administrative support to the DWGs, with a team consisting of a disease-specialized CTO Project Director (who helps prepare the agenda), a Regulatory Lead (who prepares the listing of pending and active trials along with the protocol status and accrual updates), and a Clinical Research Coordinator (who provides input on active clinical trial patients).

<u>DWG Activities</u>

- Review of current studies, accrual and any outstanding issues related to accrual, data management, study coordination, safety for clinical trials, and additional study concerns
- Discussion and decision about termination of studies
- Review of current status of pending studies
- Development, review and discussion of IIT concepts that focuses on identification of unmet needs
- Review, discussion and approval of new study proposals including investigator-initiated trial concepts and protocols, cooperative group and industry studies
- The interested principal investigator submits a DWG evaluation form that includes:
    - Brief description of the concept/hypothesis/objectives/aims and study type (treatment, prevention, supportive care, screening, diagnostic, basic science, health services)
    - Proposed accrual and timeline for accrual (including current data/information about relevant patient population in catchment area)
    - Level of resource support needed for the study
    - Budget and/or funding source discussion
- DWG co-chairs and staff then complete these sections of the DWG Evaluation Form:
    - Evaluation of scientific merit
    - Justification for the trial and its relationship to current open and pending studies
    - Prioritization of the study to the DWG, as well as priority relative to other potential clinical studies or studies that are open or in the process of opening
- To assist in evaluation of scientific merit and study prioritization, in the last quarter of 2016, a formal scoring process by DWG faculty was added.

As shown in the table below, there are 13 Disease Working Groups: 10 disease-specific and 3 non-disease-specific but focused more broadly to identify clinical research to meet the needs of the patient population in their unique settings. These three non-disease specific DWGs include: 1) Pediatric Oncology, 2) Early Phase Clinical Trials, and 3) Midwest Cancer Alliance.

Disease Working Group	Name of Chair (s)	Title, Department
Brain	Sarah Taylor, MD Roukoz Chamoun, MD	Professor, Internal Medicine Assistant Professor, Neurosurgery
Breast	Priyanka Sharma, MD Melissa Mitchell, MD, PhD Jamie Wagner, DO, FACOS Bruce Kimler PhD (*Liaison, CPS translational trials* Fariba Behbod, PharmD, PhD (*Liaison, CPS Pre-Cancerous Biology)*	Associate Professor, Medical Oncology Assistant Professor, Radiation Oncology Assistant Professor, Surgery Professor Radiation Biology, Breast Cancer Prevention Associate Professor, Pathology
Gastrointestinal	Mazin Al-Kasspooles, MD, FACS Raed Al-Rajabi, MD Arvind Sugumar, MD Dan Dixon, PhD *(Liaison, CPS Pre-cancerous biology)*	Associate Professor, Surgery Assistant Professor, Medical Oncology Assistant Professor, Gastroenterology Associate Professor, Cancer Biology
Genitourinary	Jeffrey Holzbeierlein, MD, FACS Xinglei Shen, MD Jill Hamilton-Reeves PhD *(Liaison, CPS translational trials)*	Associate Professor, Urology Assistant Professor, Radiation Oncology Associate Professor, Dietetics and Nutrition
Gynecological	Julia Chapman, MD, FACOG	Associate Professor, Obstetrics/Gynecology
Head & Neck	Lisa Shnayder, MD, FACS/ Prakash Neupane, MD Chris Lominska, MD	Associate Professor, Otolaryngology Assoc. Professor, Medical Oncology Medicine Assistant Professor, Radiation Oncology
Leukemia/Myeloid	Sunil Abhyankar, MD Tara Lin, MD	Professor, Hematology Assistant Professor, Internal Medicine
Lung	Chao Huang, MD, FACP Fen Wang, MD, PhD Nirmal Veeramachaneni, MD	Associate Professor, Internal Medicine Associate Professor, Radiation Oncology Associate Professor, Cardiothoracic Surgery
Lymphoma/Myeloma	Sid Ganguly, MD, FACP	Professor, Internal Medicine
Melanoma/Sarcoma	Joshua Mammen, MD, PhD, FACS Howard Rosenthal, MD Gary Doolittle, MD	Associate Professor, Surgery Assistant Professor, Orthopedic Surgery Professor, Medical Oncology
Pediatric Oncology	Doug Meyers, MD Keith August, MD	Assoc. Professor, Children's Mercy Asst. Professor, Children's Mercy
Early Phase Clinical Trials	Raymond Perez, MD	Professor, Medical Oncology
Midwest Cancer Alliance	Gary Doolittle, MD	Professor, Medical Oncology

Evaluation of the DWGs

DWGs are currently evaluated yearly by the AD for Clinical Research with input from Program Leaders for: a) proportion of trials that are IIT and/or national; b) quality and translational nature of interventional trials; c) trial accrual and national meeting presentations and publications; and d) relevance to the three programs conducting clinical research. Evaluations are submitted to the Director and Deputy Director who along with the AD and CTO/ERC Director make decisions regarding any actions needed including resource re-allocation.

Executive Resource Committee (ERC)

The mission of the ERC is to critically review studies recommended by each of the DWGs to ensure that resources are available to appropriately support the proposed research. The DWG evaluation form and the protocol along with related documents (investigator brochure, laboratory manual, study budget) are submitted to the ERC. The proposed studies are reviewed for adequate funding and whether there are the necessary resources to provide quality support for study conduct, to include regulatory, research coordination, clinical

data management and correlative components. The committee meets weekly to consider the ability to effectively support proposed studies and make recommendations.

The ERC may take the following action for studies submitted: approve, conditionally approve (pending additional information or changes), deferral back to the PI, or table until resources are available. Once approved by the ERC, the protocols are assigned to a CTO Regulatory Lead for submission to the PRMC. The table below outlines the current ERC membership. For projects involving prevention or survivorship, at least one of the research program co-leaders or the AD for Clinical Research will attend the session in person or by phone or appoint a surrogate to do so depending on the study type and degree of support being requested.

Name of ERC Member	Title, Department
Stephen Williamson, MD (Chair)	Professor, Medical Oncology; Medical Director, Clinical Trials Office
Tara Lin, MD (Co-chair)	Associate Professor, Hematologic Malignancies & Cellular Therapeutics, Director, Acute Leukemia Program
Hobs Apell	Senior Executive Director, Clinical Trials Office
Melissa Daniels, BBA, CCRP	Dir. of Regulatory Affairs, Clinical Trials Office
LaToya Berry	Correlative Lab Director, Clinical Pharmacology Shared Resource
Leslie Curtis, PharmD	Pharmacy Manager, Investigational Drug Services
Matt Mayo, PhD	Professor and Chair, Biostatistics
Chris Mackay, RN, MSA, CCRP	Site Development Director, Clinical Trials Office
Sherri Miller	Project Director; Community Cancer Program, Clinical Trials Office
Dianna Link	Project Director, Clinical Trials Office
Julie Collins	Project Director, Clinical Trials Office
Kelly Daniels	Project Director, Clinical Trials Office
Jecinta Scott, MS	Project Director, Clinical Trials Office
Chris Baierl	Assoc. Project Director, Clinical Trials Office
Renee Sol, MS	Assoc. Project Director, Clinical Trials Office
Sharon Lewis, DNP, APRN-NP, AOCNP	Nurse Practitioner, University of Kansas Health System
Molly Shugrue, BA	PRMS Coordinator, Clinical Trials Office

Protocol Review and Monitoring Committee (PRMC)

The PRMC reviews the scientific merit of proposed research, prioritizes studies, and monitors the progress of the clinical research being conducted by the Cancer Center and its consortium partners, which now includes Children's Mercy. Importantly, the PRMC has the authority to open protocols that meet the center's rigorous standards and to terminate protocols that fail to meet accrual goals or demonstrate scientific progress. The PRMC chair, Qamar **Khan**, MD, is an Associate Professor and a board-certified hematologist and oncologist with expertise developing and conducting investigator-initiated trials in breast cancer, and reports directly to the Deputy Director of the Cancer Center, Andrew **Godwin**, PhD.

The PRMC is complementary to the IRB review and does not overlap or duplicate the responsibilities of the IRB. Final IRB approval will not be granted unless PRMC approval is in place. The PRMC meets two times each month and meetings are scheduled in coordination with IRB meetings to assure minimal time between reviews. The PRMC chair attends all meetings or occasionally may be represented by a co-chair. The PRMS Coordinator administratively supports the PRMC.

Over the grant period, 18% of trials reviewed or prioritized by the PRMC were IIT not peer-reviewed funded, 2% were IIT peer-reviewed funded and 34% were national trials.

Protocol Review by PRMC

New Studies Requiring Full Review

A study that is cancer-related and requires any patient intervention or is requesting Cancer Center resources requires review. Cancer Center resources include the CTO and the Biostatistics & Informatics, Biospecimen, Lead Development & Optimization and Clinical Pharmacology shared resources. This includes investigator-initiated (interventional and non-interventional), co-operative group trials and industry-sponsored trials. For

retrospective/chart review studies, no PRMC submission is necessary unless the study is using one of the KUCC shared resources. If the study is planning on using one of the KUCC shared resources, only review of initial/new submission will be required. Since achieving accrual goals is not an issue and monitoring of these studies by PRMC is not needed, annual/subsequent reviews are not necessary.

A review of a new study consists of four PRMC members assigned to complete an online review of the study. One biostatistician, one physician or basic scientist and two additional committee members must review the study. The Chair will review the DSM plan for all new studies. The Pediatric Co-Chair will review the DSM plan for all new pediatric studies. The PRMC coordinator will review the studies before assigning them to the reviewers to ensure no conflict exists with the PRMC members assigned to review. The committee members present at the meeting discuss the scientific merit of the study being reviewed. The Chair makes a motion to the committee after the discussion from the group and committee members vote on their recommendation. PRMC members assigned to complete an online review of a new protocol are required to address specific questions for each study submitted. The committee reviews according to the following criteria:

Criteria	Evaluation Questions
Scientific rationale	• Are the objectives reasonable? • Is there sufficient justification for the objectives? • Is the methodology appropriate to accomplish the objectives?
Agent/device information	• Is there adequate toxicity information? • Is there sufficient storage, handling, and preparation information? • Is efficacy data provided?
Subject population	• Is this the appropriate patient population to study? • Are the inclusion/exclusion criteria complete? • Was adequate documentation provided to support accrual goals?
Exclusions of special population	• Are populations at increased risk excluded or included? • Is a population unduly excluded?
Enrollment procedure	• Is the enrollment procedure clearly described? • Are screening logs required?
Description of study intervention	• Is the description of the study intervention clear and concise? • Are dose modifications included?
Description of study procedures	• Are all necessary study procedures included? • Are there too many or too few? • Is the timetable reasonable? • Is the study calendar correct? • Are ancillary studies well described and easily executed?
Projected accrual rate and enrollment period	• Can the accrual be completed in the proposed time frame? • Is the accrual rate adequate and justified?
Adverse event reporting	• Is the AE reporting clearly defined? • Are all necessary KUCC, IRB and FDA guidelines included per the KUCC institutional DSM plan?
Data and safety monitoring plan (reviewed by PRMC chair)	• Does the DSMB plan follow the KUCC, IRB and FDA guidelines per the KUCC institutional DSM plan?
Biostatistical analysis (reviewed by biostatistician)	• Study design? • Sample size? • Data collection and analysis? • Interim analysis? • Data and Safety Monitoring Plan? • Qualified biostatistician investigator for locally-initiated studies?

The committee, based on a majority vote after the group has discussed the trial and the results of the online reviews conducted by the PRMC members, makes the final determination. The numeric results of the vote at the meeting are documented in the meeting minutes. Individual votes at the meeting are not documented in the minutes unless someone specifically abstains from voting due to conflict or must step out of the room prior to the vote if the committee member is the PI for the study.

The committee will vote on motions recommending one of the following actions:

1. **Approved** – Scientifically sound and acceptable as written; PI may forward to IRB without modifications, or minor modifications, to IRB forms prior to submission to IRB may be necessary.
2. **Conditionally Approved** – Clarifications must be provided; full approval will be held until the necessary modifications are made, or questions are answered and reviewed by the initial reviewers and the Chair via email.
3. **Tabled** – Must be re-submitted to the PRMC for full-committee review with significant modifications and responses to the questions raised by the PRMC during its initial review.
4. **Disapproved** – Not scientifically sound, not ethical, or not within the mission of The University of Kansas Cancer Center.
5. **Terminated** – due to quality assurance, inadequate accrual, competing protocols or safety issues. Studies can also be terminated by PRMC if there is no accrual for the life of the study. For studies with some accrual, termination would mean that the study will be closed to new enrollment but patients will still be followed.

New Studies or Other Research Eligible for Chair Review/Administrative Review

Studies eligible for Chair or Chair-designee review include all cooperative group trials or studies that have prior approval by CTEP/NCI, or one of the NCI-approved external peer-review organizations. If the Chair is unable, due to conflict or unavailable to complete the Chair review, the Chair may identify a designee to complete the review. This is typically the co-chair of the committee unless a conflict exists in which case the Chair may designate a physician or basic scientist from the committee. In the event the Chair is unavailable to designate a committee member to review, the Chair review defaults to the co-chair. Chair or Chair-designee review is documented in the minutes of the meeting.

Studies that are low risk and fall into one of the six categories of research activities that are exempt from the federal regulations are also exempt from PRMC review *(http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html).* The PRMS Coordinator (with consultation of the PRMC chair if needed) will determine if PRMC exempt status applies to studies submitted. Studies that are closed to enrollment are not reviewed on a continuous basis by the PRMC since monitoring of accrual goals is not an issue. A study closed to accrual will however be reviewed by the PRMC if there is an amendment or the study is re-opened to enrollment.

<u>Assessing Level of Risk</u>

For every institutional trial, PRMC chair will assign a level of risk based on the guidelines stated below. The purpose of assigning a level of risk (see below) is to determine the minimal required frequency of data and safety monitoring activities (frequency of an audit and frequency of review of the protocol by DSM committee).

Levels of Risk

- **Very High Risk:** Studies involving recombinant DNA molecules (gene transfer), and/or the first use of the drug in humans, in which case the investigator may have the only relevant knowledge regarding the use of such new drugs.
- **High Risk:** Any institutional Phase I, II, or III trials using investigational agents not yet approved by the FDA, institutional multi-center trials, all intuitional IND trials.
- **Moderate Risk:** Most institutional Phase II trials and Phase I trials using FDA-approved, commercially available compounds.
- **Low Risk:** Most non-treatment trials.

Types of trials specified above may be assigned a higher, but not a lower risk category. Any types of trials not specifically listed have risk determined by the PRMC chair, and are peer-reviewed during regular committee meetings.

This risk determination is utilized by the PRMC when assessing DSM plans for adequacy relative to the level of risk for specific trials, and also when determining whether or not a given protocol potentially qualifies for expedited review by PRMC and/or IRB. Further detail is included in the DSM plan.

Protocol Amendments

Amendments that impact change in study objectives, change local or total accrual goal, change the analysis plan, change the treatment plan, or change the eligibility criteria must be reviewed by PRMC prior to IRB review. Any amendments that do not meet any of those criteria do not have to be reviewed by PRMC prior to IRB review. The coordinator assigns an amendment online review to two reviewers with a minimum of one physician or basic scientist. The second reviewer assigned can be any other voting PRMC member without a conflict of interest. The Chair makes a motion to the committee after the discussion within the group, and committee members vote on their recommendation. All cooperative group amendments will be Chair-review only. All pediatric cooperative group amendments will be Chair-review only by the pediatric Co-Chair.

Protocol Monitoring by PRMC

In addition, the PRMS monitors the progress of clinical research and terminates studies as necessary. Studies are required to be renewed annually by the Institutional Review Board. Part of the renewal process is a review by PRMC to monitor scientific relevance and accrual. Review for annual renewal is required for all active cancer-related research that required PRMC review at new submission. The coordinator assigns annual renewal review to two online reviewers, with a minimum of one physician or basic scientist. The second reviewer assigned can be any other PRMC member without a conflict of interest. The Chair makes a motion to the committee after the discussion within the group, and committee members vote on their recommendation.

If a study is closed to enrollment it should still be submitted to PRMC. Although the committee will not review the study, a letter will be sent out stating that the study will not require future PRMC reviews unless there is an amendment to the study or the study is re-opened to enrollment.

Trials not enrolling at least 50% of the stated annual accrual goal must provide written documentation to justify their continuation and provide strategies to improve accrual. Accrual for trials that do not meet the stated annual accrual goal will be placed on a six-month probation and re-evaluated after a six-month probation period. Trials that continue to show accrual less than 50% of the annual accrual goal will be closed by the PRMC unless there is compelling annual justification for continuation and there is appropriate modification of the accrual goals. Modification of the accrual goal requires approval by the PRMC following full-committee review.

Any trial that accrues no subjects in the first year of activation will be closed by PRMC unless there is a specific approval from the Director or Deputy Director of the KUCC for continuation. Trials may also be closed for lack of scientific relevance, patient safety, and changes in clinical practice, where completion of the trial is not possible, or other reasons identified by the PRMC or the KUCC Leadership.

The committee will allow a study to remain open to allow access to a clinical trial for a rare disease (PRMC uses the NCI definition of a rare cancer: any cancer types with an incidence rate of three or less per 100,000 person population per year, including all pediatric cancers). These cancers will get an exception to accrual goal requirements. With a better understanding of molecular basis of cancer, it is now recognized that common solid cancers and hematologic malignancies harbor relatively rare actionable mutations, providing an opportunity to individualize potentially highly effective therapy based on molecular changes in cancer. Smaller, but more likely to respond, patient populations will likely become a norm in clinical trials. Many institutions, each accruing small numbers of patients, will be required to complete these studies. Because of this change in the therapy of cancers, PRMC will make exceptions for accrual goals for trials involving narrower molecular subtypes will be treated like rare diseases and will be granted exception to the accrual goal requirements. The final decision to classify a trial as a rare molecular subtype for the purpose of accrual exception will be made by the PRMC Chair. When IRB terminates studies due to completion, no action is required by the PRMC.

PRMC Membership

The Director or Deputy Director of KUCC assigns the Chair of the PRMC. The PRMC members are selected and invited to participate by the Chair. The Deputy Director may also suggest potential members to the Chair. The committee members should have research experience and include senior Cancer Center Members as well as those who are involved in the implementation and conduct of research. Members are representatives from medical oncology, hematology, radiation oncology, surgical oncology, basic science research, biostatistics, preventive medicine and public health, pediatric oncology, oncology nursing and pharmacology/pharmacy. Membership may include any other representatives from any other disciplines based on determination of need by the Chair. The PRMC chair designates two members as co-chairs of the PRMC, and one co-chair to represent pediatric oncology and KUCC PRMC consortium oversight of Children's Mercy. In the event the Chair is unavailable to attend meetings or conduct reviews, one of the co-chairs will serve as the acting PRMC Chair.

Table of PRMC Membership

Member	Title, Department	Expertise
Qamar Khan, MD (chair)*	Associate Professor, Medicine	Investigator-initiated Trials, Breast Cancer
James Coster, MD (co-chair)*	Asst. Professor, Radiation Oncology	Radiation Oncology (stereotactic, brachytherapy, intensity-modulated)
Bruce Kimler, PhD (co-chair)*	Professor, Radiation Oncology	Basic and Translational Science (Biology and Breast Cancer Prevention); Radiation Biology
Kevin Ginn, MD (pediatric co-chair)	Director, Brain Tumor Program Asst. Professor, Pediatrics	Pediatric Brain Tumors, Experimental Therapeutics
Molly Shugrue, BA	Coordinator, CPDM	
Jianghua He, PhD*	Associate Professor, Biostatistics	Biostatistics
Amanda August, PharmD*	Clinical Pharmacist, Pediatrics	Pediatric Hematology Oncology Pharmacy
Chris Lominska, MD	Asst. Professor, Radiation Oncology	Radiation Oncology (head/neck, GI)
Cory Bivona, PharmD	Clinical Pharmacist – Hem	Oncology Pharmacy
Diana Hoelscher, PharmD	Clinical Pharmacist – Heme-Onc board certified	Oncology Pharmacy
Fariba Behbod, PhD, PharmD*	Associate Professor, Pathology	Basic scientist, DCIS models
Fen Wang, MD, PhD*	Associate Professor, Radiation Oncology	Radiation Oncology
Francisco Diaz, PhD*	Associate Professor, Biostatistics	Biostatistics (Trial design, modeling, genetics, pharmacokinetics)
James Coulter, RN*	Oncology Research nurse	Regional/community trials
Jan Ward, LPN	Research nurse, CPDM	Oncology nursing
Jennifer Klemp, PhD*	Associate Professor, Medicine	Genetics, cancer risk, survivorship
Joshua Mammen, MD	Associate. Professor, Surgery	Surgical Oncology (breast, melanoma)
Julia Chapman, MD*	Associate Professor, Ob-Gyn	Gyn Onc
Keith August, MD	Director, Leukemia and Lymphoma Program Asst. Professor, Pediatrics	Pediatric Leukemia, Lymphoma and Experimental Therapeutics
Leyla Shune, MD	Asst. Professor, Medicine	BMT and hematological malignancies and cellular therapeutics
Moben Mirza, MD	Asst. Professor, Surgery	Surgical Oncology (Urology)
Nikki Ogle, PharmD	Clinical Pharmacist – Heme-Onc	Oncology Pharmacy
Prakash Neupane, MD*	Associate Professor, Medicine	Head and neck and lung cancer
Raed Al-Rajabi, MD	Asst. Professor, Medicine	Gastrointestinal cancer
Robin Ryan, MPH*	Research Program Manager	Pediatric Hematology/Oncology/Stem Cell Transplant
Sharon Lewis, RN	Heme Onc Nurse Practitioner	Oncology nursing Early Phase Trials
Stella Baccaray, MSN*	Nursing	Oncology nursing, patient advocacy
William Jewell, MD*	Professor, Surgery; Assoc. Director of Education, KUMC	Surgical Oncology

Barry Skikne, MD*	Professor of Medicine, Division of Hematologic Malignancies and Cellular Therapeutics	Malignant and benign hematology
Debra Sullivan, PhD, RD*	Professor and Chair/Dietetics and Nutrition	Clinical nutrition, prevention and treatment of obesity/chronic disease
Shrikant Anant, PhD*	Professor of Surgery, Associate Director for Cancer Prevention & Control	Basic scientist and cancer cell biology

Of the 30 members, 18 members (denoted with an *) have more than 10 years of cancer experience.

PRMC Meetings

The PRMC meets twice per month. Materials for review must be submitted two weeks prior to the meeting date to provide adequate time for PRMC members to complete online reviews. A minimum of 75% voting members of the committee must be present for the meeting and vote to represent a quorum. If a member of the committee has a conflict of interest, that member is asked to leave the room during the voting process. This is documented in the minutes from the meeting. PRMC recommendations are sent to the PI and study contact the day following the meeting unless additional review and discussion is required. In that case, the PRMC recommendation will be provided to the PI and study contact upon completion of review and discussion.

If the committee has provisos before the study can be approved, they will be detailed in the PRMC letter to the PI and study contact. The PI will have 30 days to respond to the committee addressing the provisos. If the committee does not receive a response within the 30 days, PRMC will disapprove or close the study to accrual.

PRMC members are given the opportunity to discuss any comments or questions they have for the study at the meeting, including comments from the online reviews. PRMC members who are assigned reviews for the meeting and are unable to attend are asked to provide detailed comments regarding their review findings for discussion by the remaining committee members in attendance at the meeting. The committee, when taking a final vote, will consider the online reviews, but PRMC members not in attendance will not have an opportunity to vote.

The PI of the study may attend either by request of the committee or at the request of the PI to help explain the trial and answer questions from the Committee. The PI will not be present during final PRMC comments and voting. All PRMC members vote on the decision, unless they have a conflict of interest related to the project.

Minutes are recorded at every PRMC meeting and retained as the official record of the PRMC meeting discussions and votes. The PRMS coordinator is responsible for recording the minutes, providing the minutes for the PRMC Chair to review and approve, and retaining the minutes in the PRMC records.

Conflict of Interest

A committee member must abstain from vote if a conflict of interest exists. All committee members are expected to follow the university Individual Conflict of Interest Policy. See Conflict of Interest Policies and Procedures: *http://www.kumc.edu/compliance/conflict-of-interest/policies-and-procedures.html*

Progress Report Publications

This component has no publications resulting from Cancer Center Support Grant funds.

Protection of Human Subjects – PROTOCOL REVIEW and MONITORING SYSTEM

In accordance with federal and institutional regulations, all investigators are required to submit and obtain appropriate IRB review and approval for any proposed human subjects research study.

Inclusion of Women & Minorities – PROTOCOL REVIEW and MONITORING SYSTEM

In accordance with federal and institutional regulations, any proposed clinical trial would be required to be designed and carried out in a manner sufficient to provide for valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

OMB Number:0925-0001 and 0925-0002
Expiration Date: 10/31/2018

***Study Title:** Protocol Review and Monitoring System- Any human subject study funded by CCSG funds will be required to submit a PHS inclusion enrollment report.

***Delayed Onset Study?** ☑ Yes ❑ No

If study is not delayed onset, the following selections are required:

Enrollment Type ❑ Planned ❑ Cumulative (Actual)

Using an Existing Dataset or Resource ❑ Yes ❑ No

Enrollment Location ❑ Domestic ❑ Foreign

Clinical Trial ❑ Yes ❑ No

NIH-Defined Phase III Clinical Trial ❑ Yes ❑ No

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/Alaska Native										
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More than One Race										
Unknown or Not Reported										
Total										

Inclusion of Children – PROTOCOL REVIEW and MONITORING SYSTEM

In accordance with federal and institutional regulations, any proposed clinical trial would be required to be developed to support the treatment modalities for disorders and conditions that affect adults and may also affect children.

Resource Sharing Plan

The University of Kansas Cancer Center (KUCC) and its scientific community understands its responsibility to comply with the instructions for the Resource Sharing Plans provided within the SF 424 (R&R) Application General Instructions and Supplemental Grant Application Instructions. When resources are developed with NIH funds via this Cancer Center Support Grant P30 mechanism, KUCC will ensure findings are made readily available to the NIH and the scientific community in a timely manner.

Data Sharing Plan

KUCC will adhere to the Final NIH Statement on Sharing Research Data and refer to the National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research. KUCC encourages the free flow of information and ideas while recognizing the timeliness of data sharing, the rights and privacy of human subjects and issues related to proprietary data. KUCC encourages data documentation, using a data-sharing agreement and selecting an appropriate method for sharing; considering the sensitivity of the data, the size of the dataset and the volume of requests anticipated.

Additionally, KUCC encourages any user of a CCSG-supported shared resource to acknowledge the source of data upon which their manuscript is based either in the Acknowledgments section or with authorship on the paper. Furthermore, any research project that received direct cost support from the CCSG is encouraged to cite the P30 CA168524. In both cases, citing the P30 CA168524 grant number and then being compliant with the NIH Public Access Policy is required.

Sharing Model Organisms

In the event that a model organism is developed, KUCC will comply with the NIH Policy on Sharing of Model Organisms for Biomedical Research. KUCC will work with the NIH/NCI to share and disseminate the critical model organism in a timely manner.

Genome Wide Associate Studies

When applicable, KUCC will comply with the NIH Genomic Data Sharing Policy. KUCC supports the sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. All research studies funded through the CCSG involving genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data will be submitted in a timely manner.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 016060860

Legal Name*: University of Kansas Medical Center Research Institute, Inc.
Department:
Division:
Street1*: MSN 1039, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Deborah		Maloney	MSM

Position/Title: Director, Sponsored Programs Administration
Street1*: 3901 Rainbow Boulevard
Street2: Mail Stop 1039
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937
Phone Number*: 913-588-1261 Fax Number: 913-588-3225 Email: spa@kumc.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofit Organization
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Early Phase Clinical Research Support

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2017	06/30/2022

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Medical Center
Duns Number:	016060860
Street1*:	MSN 2029, 3901 Rainbow Blvd
Street2:	
City*:	Kansas City
County:	Wyandotte
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66160-8500
Project/Performance Site Congressional District*:	KS-003

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ❍ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number 00003411

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	EPCRS_Project_Summary1019496482.pdf
8. Project Narrative*	
9. Bibliography & References Cited	
10.Facilities & Other Resources	
11.Equipment	
12. Other Attachments	EPCRS_Other_Attachments1019496481.pdf

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Early Phase Clinical Research Support – Project Summary

This renewal is the first time that KUCC is requesting Early Phase Clinical Research Support (EPCRS) funds and undergoing formal evaluation as a CCSG component. Although this is the first year to request CCSG support, KUCC has been investing heavily to build the infrastructure, facilities, staffing and capabilities for a successful early phase clinical research program. Stephen **Williamson**, MD, leads the Early Phase Clinical Research program.

Long-range strategic planning is focused on short-term, pilot (pre-phase I) and phase I clinical research studies originating from KUCC scientific investigators. Preliminary data generated from these studies are typically challenged by shortages in funding, yet have great potential to serve as the foundation for later phase studies through competitive grants or industry.

The Investigator-Initiated Trial Steering Committee will score and prioritize proposed studies for EPCRS funding based on whether the new compound was invented by a KUCC member, a repurposed drug with KUCC pre-clinical data and highly likely to provide preliminary data for further clinical development.

In order to be considered, the proposals requesting EPCRS funds must be: 1) high priority, innovative, pilot and phase 0 or I institutional clinical studies focusing on initial testing of a candidate agent or device for the diagnosis, prevention, detection or treatment of cancer; 2) conceptualized/designed by KUCC members; and 3) of short duration (*e.g.*, 1-2 years). If the proposal is selected for EPCR support, the Protocol Review and Monitoring System must approve the study before funding will be released.

Early Phase Clinical Research Support – Other Attachments

Table 1 is not applicable as this is the first time KUCC is requesting funds for EPCRS.

Table 2. List of proposed pilot/phase I projects

Study Title #1	**Safety, Dose Tolerance, Pharmacokinetics and Pharmacodynamics of Ciclopirox Prodrug (CPX-POM) in Bladder Cancer Patients**
PI	Eugene K. **Lee**, MD, University of Kansas Cancer Center
Sub-investigators	Jeffrey M. **Holzbeierlein**, MD, University of Kansas Cancer Center Moben **Mirza**, MD, University of Kansas Cancer Center Hadley Wyre, MD, University of Kansas Cancer Center
Collaborators	Shrikant **Anant**, PhD, University of Kansas Cancer Center Greg **Reed**, PhD, University of Kansas Cancer Center Scott **Weir**, Pharm D, PhD, University of Kansas Cancer Center
Study Objective	Evaluate the safety, toxicity, serum and urine pharmacokinetics and pharmacodynamics of CPX-POM
EPCRS Specific Aims Being Met	✓ Scott **Weir** (D3ET) and Shrikant **Anant** (CPS) discovered and developed Ciclopirox Prodrug (CPX-POM), a potential breakthrough treatment in the management of high-grade non-muscle invasive bladder cancer NMIBC (Issued US Patent 8,609,637). ✓ CPX-POM represents the first KU-invented anticancer agent advanced from the bench to the bedside at our institution. ✓ CPX-POM will represent one of the first new agents directed at NMIBC in decades.
Study Title # 2	**Phase I Study to Evaluate the Safety and Efficacy of Umbilical Cord-Derived, Ex-Vivo Cultured and Expanded Wharton's Jelly Mesenchymal Stem Cells (MSCTC-0010) for the Treatment of De Novo High Risk Acute or Steroid Refractory Acute Graft Versus Host Disease (GVHD) in Subjects who have undergone Allogeneic Hematopoietic Stem Cell Transplantation**
PI	Joel **McGuirk**, DO, University of Kansas Cancer Center
Sub-investigators	Sunil **Abyhankar**, MD, University of Kansas Cancer Center
Study Objective	To evaluate the safety and efficacy of MSCTC-0010 administered to subjects with de novo high risk (HR) acute or steroid refractory (SR) acute GVHD, post-allogeneic stem cell transplantation.
EPCRS Specific Aims Being Met	✓ Joel **McGuirk**, DO and Sunil **Abyhankar**, MD are collaborating with the Midwest Stem Cell Therapy Center at KUMC to develop MSCTC-0010 for the treatment of de novo high risk acute or steroid refractory acute Graft Versus Host Disease (GVHD). ✓ MSCTC-0010 is an allogeneic, unmatched, tissue-derived cell product. MSCTC-0010 is a suspension of mesenchymal stem cells (WJMSC) isolated from the Wharton's Jelly (WJ) fraction of human umbilical cords. WJMSCs are obtained under Good Manufacturing Practice/Good Tissue Practice (GTP) conditions at the MSCTC. ✓ Proof of concept has been established as a treatment for GVHD based on research on mesenchymal stem cells described in the literature as well as in vitro immunosuppression studies conducted at the MSCTC. ✓ On February 4, 2016, KUCC and MSCTC participated in Type B Pre-IND meeting with the Food and Drug Administration (FDA) to discuss chemistry, manufacturing, preclinical and clinical issues for a Phase I Investigational New Drug (IND) submission. As a result of the Pre-IND meeting with FDA, GLP preclinical safety studies are ongoing with an IND submission planned for early 2017.
Study Title #3	**Pilot Trial of Heated Intraperitoneal Chemotherapy at Initial Surgical Debulking for Ovarian Cancer**
PI	Andrea **Jewell**, MD, University of Kansas Cancer Center Julia **Chapman**, MD, University of Kansas Cancer Center
Sub-investigators	Robert **Pleunneke**, MD, University of Kansas Cancer Center
Study Objective	To determine the surgical morbidity associated with HIPEC in this setting and whether or not there will be any delays in starting and completing 6 cycles of standard post - operative chemotherapy.
EPCRS Specific Aims Being Met	✓ Concept developed by junior investigator – Andrea **Jewell**, MD ✓ Innovative concept to fill an unmet need – attempt to utilize a new strategy for incorporating IP therapy as part of standard treatment of ovarian cancer as recommended in various treatment guidelines.

	✓ Pilot concept, if feasible and acceptable toxicity, plan to propose phase III trial to cooperative group
Study Title #4	**A Phase I Study of Pyrimethamine, a STAT3 Inhibitor, for the Treatment of Intermediate/ High-risk MDS that has Relapsed or is Refractory to Azanucleosides**
PI	Tara **Lin**, MD, University of Kansas Cancer Center Amit Verma, MD, Albert Einstein College of Medicine
Sub-investigators	Suman Kambhampati, MD, Sarah Cannon Cancer Center Aditi Shastri, MD, Albert Einstein College of Medicine Ulrich G. Steidl, MD, PhD Albert Einstein College of Medicine Scott **Weir**, PharmD, PhD - University of Kansas Cancer Center
Study Objectives	Determine the safety, tolerance and clinical activity of pyrimethamine in MDS Determine whether pyrimethamine inhibits STAT3 *in vivo* Describe the toxicity profile of the agent in this population Describe the initial and steady-state pharmacokinetics of study drug in this patient population Determine correlation of MDS stem and progenitor alterations in response to study drug
EPCRS Specific Aims Being Met	✓ Collaborative effort between KUCC and Albert Einstein College of Medicine ✓ Clinical proof of concept trial ✓ STAT3 activity to be evaluated by investigators at Albert Einstein ✓ Pharmacokinetic analysis performed by KUCC
	Experimental Therapeutics Clinical Trials Network (ETCTN) Trials to be Opened at KUCC CRC with partial funding through 4 P30 CA168524-05 (EDDOP)*
Study Title #A	**9706: Randomized Phase II Study to Assess the Role of Nivolumab as Single Agent to Eliminate Minimal Residual Disease and Maintain Remission in Acute Myelogenous Leukemia (AML) Patients After Chemotherapy**
PI	Study Chair: Dr. Hongtao Liu at University of Chicago Cancer Center
Sub-investigators	Multiple sites
EPCRS Specific Aims Being Met	✓ Participation in ETCTN through EDDOP ✓ Trial is currently being amended to allow EDDOP sites, once amended will proceed with opening at KUCC
Study Title #B	**9855: A Phase 2 Study of CDX-011 (Glembatumumab Vedotin) for Metastatic Uveal Melanoma**
PI	Study Chair: Dr. Sapna Patel at MD Anderson Cancer Center
Sub-investigators	Multiple sites
EPCRS Specific Aims Being Met	✓ Participation in ETCTN through EDDOP ✓ Trial is proceeding through regulatory start up and should open at KUCC October 1, 2016.

*While the Phase II studies listed in Table 2 WILL NOT be supported via the EPCRS mechanism, they do illustrate KUCC's active participation in ETCTN and desire to identify ETCTN trial opportunities that meet EPCRS criteria (pilot/Phase I) that could potentially qualify for support.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Roy Middle Name A Last Name*: Jensen Suffix: MD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Pathology & Lab Medicine
Division: School of Medicine
Street1*: MS 3045, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-4700 Fax Number: 913-588-4701

E-Mail*: RJENSEN@kumc.edu

Credential, e.g., agency login: JENSENRA

Project Role*: Other (Specify) Other Project Role Category: Core Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ❍ Yes ● No

*Agency-Defined Phase III Clinical Trial? ❍ Yes ❍ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ❍ Yes ❍ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

❍ Yes ❍ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

❍ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator / Change of Institution Section

❑ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	EPCRS_Specific_Aims1019496484.pdf
3. Research Strategy*	EPCRS_ResearchStrategy_final1019913934.pdf
4. Progress Report Publication List	Progress_Report_Publications_Blank1019754755.pdf
Human Subjects Section	
5. Protection of Human Subjects	Protection_of_Human_Subjects___EPCRS1019799877.pdf
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	Inclusion_of_Women_Minorities___EPCRS1019799878.pdf
8. Inclusion of Children	Inclusion_of_Children___EPCRS1019799879.pdf
Other Research Plan Section	
9. Vertebrate Animals	
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	
14. Resource Sharing Plan(s)	Resource_Sharing_Plan__Generic1019799880.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Early Phase Clinical Research Support – Specific Aims

1. **Design and complete early phase clinical research studies originating from scientific investigations within the Cancer Center based on discoveries made by KUCC basic, clinical and translational scientists. This includes:**
   a. Clinical proof of concept trials evaluating new cancer therapeutic strategies arising from KUMC, consortium members, and national collaborators; and
   b. Developing new therapeutic strategies through the proof of concept and toxicity phases, then turning them over to the broader research community for further development.

2. **Partner with the Target Acceleration Group and The Institute for Advancing Medical Innovation to design and enable innovative investigator-initiated clinical trials with new, repurposed or abandoned drugs discovered by the four KUCC research programs.**
   a. Provide project management and infrastructure support to allow investigators to pursue and complete innovative early phase studies with significant potential to move to a national stage.
   b. Provide practical advice and industry experience via interaction with **Williamson**, **Weir** and Schorno via monthly meetings to critique and develop robust and scientifically valid studies.

3. **Develop the clinical research expertise of junior investigators as it relates to early phase clinical trials.**
   a. Provide pilot grant awards to promote the development of junior investigators who are capable of developing high quality, innovative clinical trials.
   b. Mentor junior investigators through the Investigator-Initiated Trials Steering Committee which provides a structure to define and refine IIT concepts arising from laboratory and bedside discoveries.

4. **Aggressively pursue trials from industry and other NCI-designated cancer centers to expand KUCC's portfolio of innovative early phase trials and make them available to our catchment area**
   a. Initiate and maintain relationships with industry and other NCI-designated cancer centers to promote KUCC investigator's roles in the design of multi-institutional trials.
   b. Leverage the CCSG P30 administrative supplement to support KUCCs participation in the Experimental Therapeutics Clinical Trials Network (ETCTN) through the Early Drug Development Opportunity Program (EDDOP), which is for NCI-designated sites who are not part of ETCTN to participate in selected ETCTN trials.
   c. Initiate efforts to join the WINS (University of Wisconsin and Rutgers Cancer Institute) UM1 Consortium of the ETCTN with the goal of being a sub-award site as part of an expanded WINS Consortium when the UM1 grant is submitted for renewal in 2018. This initiative was started in July 2016 and a formal memorandum of understanding between the institutions is being developed to allow sharing of clinical trial data and subject accrual.

Early Phase Clinical Research Support – Research Strategy

Operations and Infrastructure in Support of Early Phase Clinical Research

The University of Kansas Cancer Center (KUCC) infrastructure to facilitate the development and implementation of high-priority, pilot, phase 0 or I Institutional Investigator-Initiated Trials (IITs) of novel and targeted agents is embedded within the Clinical Trials Office (CTO). Stephen **Williamson** serves as the Medical Director of the CTO and Director of the early phase clinical working group. **Williamson** has been involved in clinical trials research since his oncology fellowship in 1984. He has been actively involved in clinical trial development locally and nationally through the Southwest Oncology Group (SWOG). He has also been active in the Lung, GI and Head and Neck Committees of the SWOG since 1986 and his first multi-institutional phase II trial through SWOG was initiated in 1986. **Williamson** has been the PI on multiple IITs developed at KU including the first phase I clinical trial at KU involving a gene therapy trial of irradiated autologous melanoma cells adenovirally transduced with human GM-CSF gene. He successfully submitted the IND to the FDA for this product and assisted with developing the quality assurance guidelines for manufacture of the investigational product.

Early phase clinical trials are designed and implemented by the resident expertise in KUCC's tumor-specific, multidisciplinary Disease Working Groups (DWGs) and the early phase clinical trial leadership, faculty and research staff. CTO resources allocated specifically for protocols designated to receive Early Phase Clinical Research Support (EPCRS) will include clinical research nurses and coordinators directly involved in the conduct of these studies.

Briefly, Research Study and Data Coordinators are responsible for managing a caseload of clinical trial participants during screening, enrollment and follow-up. Research Study Coordinators provide guidance to the KU Clinical Research Center (KU CRC - the dedicated, state-of-the-art early phase clinical trial facility) nursing and support staff, and work closely with the PIs to coordinate study activities. Clinical Research Study and Data Coordinators are primarily responsible for study coordination, data management, monitoring and submission of adverse event reports. The KU CRC employs the nursing and support staff that provide the clinical care and investigational treatment for trial participants. These hospital employees are specifically recruited and trained in early phase protocol conduct, in addition to Human Subjects and Good Clinical Practice training, and are involved in all protocol specific training – their only focus is on managing patients on early phase trials. One full-time nurse practitioner (KUCC is currently recruiting a second full-time nurse practitioner) provides support for the early phase physicians and insures continuity and adherence to protocol therapy.

Management of the early phase clinical trials primarily occurs at the monthly Early Phase Disease Working Group meeting in addition to biweekly team meetings, led by **Williamson**. Progress of all open early phase trials and enrolled active patients is discussed at these meetings, including treatment-related toxicities, responses, cohort performance, dose escalations and patient accruals. Issues related to real time sample and data collection are also discussed.

The KUCC Clinical Pharmacology shared resource (CPSR) is located on the 2nd floor of the KU CRC, optimally positioned to support early phase clinical research. This shared resource provides trained staff and equipment for the acquisition, processing, storage and shipment of biological samples generated from clinical studies, including blood, urine, ascites fluid and tissue samples. The correlative laboratory provides critical support for more than 130 (early and late phase) cancer clinical trials.

Also part of the CPSR is the bioanalytical laboratory that develops, optimizes, validates and applies various methods to the identification and quantitation of drugs, drug metabolites and other small molecules from clinical samples to generate data for assessment of either pharmacokinetics or for examination of biomarkers of effect. The Director of the CPSR, Greg **Reed**, is a standing member of the IIT Steering Committee and is also readily available *ad hoc* to consult with investigators on the incorporation of PK/PD to add value to clinical studies and to guide the experimental design to maximize this value. This includes the optimization of dosing and sampling protocols.

To ensure that KUCC is meeting the needs of cancer patients throughout the catchment area and building upon a longstanding tradition at KUCC of community engagement and local partnerships to improve the health of our patients, KUCC has a number of effective strategies to systematically bring patients' perspectives into early phase clinical research. One example is the PIVOT program (Patient and Investigator Voices Organizing Together), which expands on KUCC's mission to empower patients and advance quality cancer research. The PIVOT program provides resources to expand the Cancer Center's focus on patient-centered research and care by offering an engagement venue and framework for patients and researchers, encouraging a culture that welcomes diverse patient perspectives and experiences across the research spectrum from early development of ideas through returning results back to the communities. The PIVOT program will provide KUCC early phase clinical research with opportunities to engage patients in the design and execution of early phase cancer clinical trials.

EPCRS funds will be allocated according to the criteria and processes outlined herein, and effectively leveraged to support innovative early clinical investigations that employ assets highly unique to the KUCC environment. Most notably:

Johnson County Education & Research Triangle (JCERT). An early phase clinical research facility was key to the KUCC's director's vision to focus on drug discovery and development to translate basic and clinical research at the Cancer Center into tangible benefits to the catchment area. In November 2008, the citizens of Johnson County, Kansas passed a 1/8th cent sales tax ballot initiative in support of research and education, specifically cancer clinical research for KUCC. To our knowledge, it is the only county-supported cancer research tax in the country. Johnson County has 544,000 residents with the 19th highest median household income (2000) and 46th highest per capita income in the country (2005). **Jensen** played a pivotal role working with civic leaders to champion the initiative. To date, the sales tax has generated $30.5M in support of the KU Clinical Research Center with annual support eclipsing $5.6M in 2016. The 82,400 sq. ft. facility was donated by the Hall Family Foundation and completely renovated ($19.4M) to support research and KUCC's early phase working group. To date, KUCC has invested over $50.6M in the early phase program, including the facility renovation. Support also includes an endowed professorship for the Phase I program and a dedicated business development resource.

The 82,400 square-foot KU Clinical Research Center (KU CRC). Opened in January 2012, the KU CRC is equipped with state-of-the-art features designed to make efficient use of space and resources to optimally serve patients and clinical researchers. At full capacity, this facility can accommodate approximately 400 new phase I subjects per year. It includes an outpatient oncology early phase and longer-term observation rooms (overnight) for phase I patients. It also contains specialized facilities for specimen collection (including a procedure room for bone marrow biopsies), GCP-compliant correlative laboratory for sample acquisition and processing, a GLP-compliant bioanalytical laboratory for sample analysis, investigational pharmacy, clinical chemistry and hematology, biostatistical support, physiological assessments, a metabolic food kitchen and ample administration office space for CTO staff and investigators.

Target Acceleration Group (TAG). To assist KU investigators and consortium members, Stowers Institute for Medical Research and Children's Mercy, in advancing new cancer therapeutic concepts to the clinic, the TAG enables, facilitates and accelerates collaborative projects that span from the chemistry/biology interface through *in vivo* preclinical proof of principle. New cancer therapeutic strategies include the discovery of novel drugs, repurposing of FDA-approved and abandoned drugs, reformulation strategies to improve delivery, as well as clinical pharmacology approaches that integrate pharmacokinetics and pharmacodynamics, biomarker discovery and validation, genetics and epigenetics, genomics and pharmacogenomics.

The Institute of Advancement in Medical Innovation (IAMI). Serving as the product development-focused translational research engine for KUCC, IAMI is focused on transforming laboratory and bedside discoveries into new drug and diagnostic/biomarker medical innovations, and then advancing those innovations into the clinic. Established in 2009 based on a $16.1M co-investment by the Ewing Marion Kauffman Foundation and the University of Kansas Endowment Association, IAMI invests to advance projects to *in vivo* preclinical proof of principle. IAMI is already seen as a national model for commercialization of academic research. IAMI looks to creatively advance the most promising new cancer therapeutic strategies to clinical proof of concept through innovative collaborations with industry, academia, government, disease philanthropy and investment partners.

The Investigator-Initiated Trial Steering Committee (IITSC). The IITCS was formed in 2015 and is comprised of team members that represent critical, multidisciplinary expertise concerning different aspects of clinical trial development and implementation (see roster below). With the IIT Steering Committee co-chairs **Williamson** and **Weir**, as well as Children's Mercy Phase I Director, **August**, participating on the TAG, new cancer therapeutic strategy discoveries are well integrated with early phase clinical research to accelerate bench-to-bedside translation.

IITSC Roster and Represented Expertise

Stephen Williamson, MD, Co-chair – Clinical Trials Office Medical Director, IIT Physician (Solid Tumors)
Scott Weir, PharmD/PhD, Co-chair – Associate Director Translational Research (Drug Development)
Carol Fabian, MD – Associate Director of Clinical Research, IIT Physician (Prevention and Survivorship)
Sid Ganguly, MD – IIT Physician (Hematological Malignancies)
Priyanka Sharma, MD – Assistant Director Clinical Research, IIT Physician (Solid Tumor)
Qamar Khan, MD – Chairman of PRMC, IIT Physician (Solid Tumor)
Andrew Godwin, PhD – Deputy Director, Biorepository/Biomarkers
Gregory Reed, PhD – Clinical Pharmacology Shared Resource, Correlative Studies (PK/PD)
Brooke Fridley, PhD (or alternate, Milind Phadnis, PhD) – Biostatistics/Data Management
Keith August, MD – Pediatric Oncology Phase I Director (Children's Mercy)
Hobs Apell – Clinical Trials Office, Senior Executive Director
Carolyn Foster – Clinical Trials Office, IIT Protocol Development
Kevin Schorno – Institute for Advancing Medical Innovation, IIT Project Management

A primary objective of the IITSC is to mentor and educate junior investigators and to support the acceleration of scientific discovery of novel therapeutics through the conduct of IITs. Specifically, the IITSC provides an interactive venue for basic and clinical researchers to present IIT concepts arising from laboratory and bedside discoveries, as well as a structure for defining and refining IIT concepts prior to and following discussion. Investigators receive instant feedback during the meeting from the committee members. The IITSC works with KUCC members to generate pilot clinical data by conducting pilot IITs that enable significant, impactful and fundable cancer therapeutic clinical trials.

Immediately following an investigator(s) presentation, the IITSC holds an Executive Session comprised of a subset of the IIT Steering Committee members representing Cancer Center Senior Leadership (see list below).

IIT Steering Committee Executive Session

Stephen Williamson, MD, Co-chair – Clinical Trials Office Medical Director, IIT Physician (Solid Tumors)
Scott Weir, PharmD/PhD, Co-chair – Associate Director Translational Research (Drug Development)
Andrew Godwin, PhD – Deputy Director, Biorepository/Biomarkers
Carol Fabian, MD – Associate Director of Clinical Research, IIT Physician (Prevention and Survivorship)
Priyanka Sharma, MD – Assistant Director Clinical Research, IIT Physician (Solid Tumor)

Hobs Apell – Clinical Trials Office, Senior Executive Director

The process for reviewing, selecting, prioritizing and overseeing the funds, will occur by way of the Investigator-Initiated Trial Steering Committee. As Deputy Director of the Cancer Center, Andrew **Godwin**, has final decision-making authority. Ongoing oversight of funded projects also occurs during the Executive Session of the IIT Steering Committee.

Selection & Prioritization Process

Scoring and prioritizing proposed studies for EPCRS funding will be based on the following:
1. New compound invented by KU (4 points)
2. Repurposed drug with KU pre-clinical data (2 points)
3. Highly likely to provide preliminary data for further clinical development (0-10 points)
4. Scored by IIT Steering Committee Executive Session Members (see below)

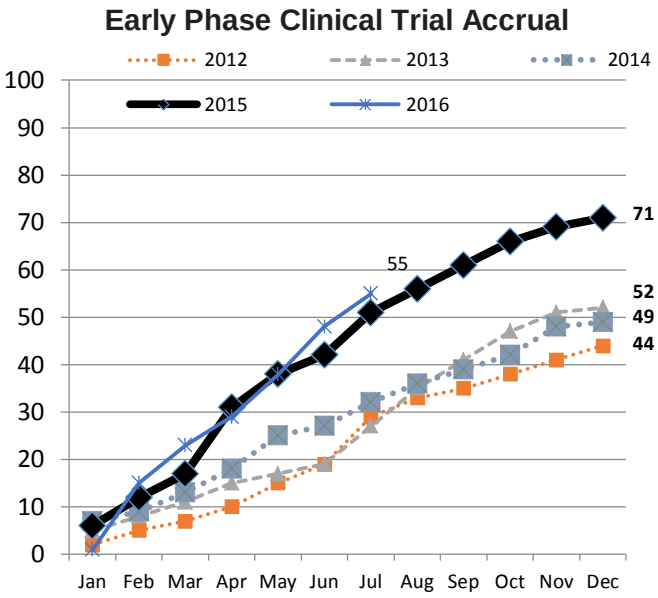
In order to be considered, the proposals requesting EPCRS funds must meet the following criteria:

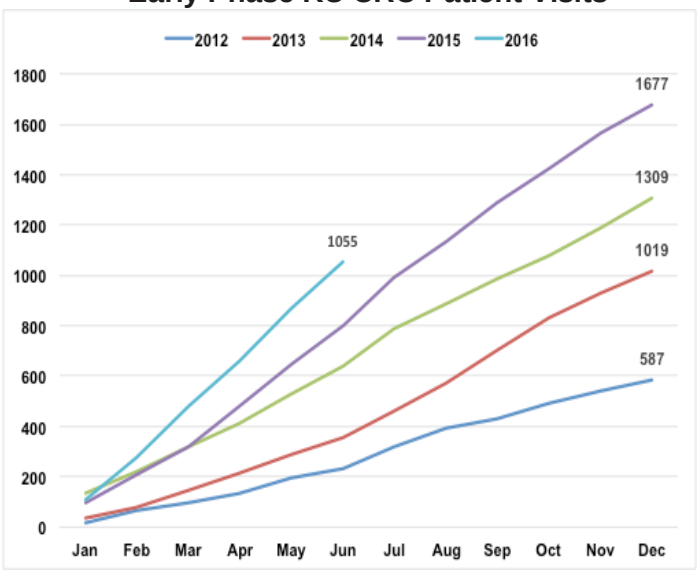
- High priority, innovative, pilot and phase 0 or I institutional clinical studies focusing on initial testing of a candidate agent or device for the diagnosis, prevention, detection or treatment of cancer;
- Conceptualized/designed by KUCC members; and
- Short duration (*e.g.*, 1-2 years).

If the proposal is selected for EPCR support, the study must be approved by the PRMS before funding will be released.

Early Phase Accrual Performance

The early phase clinical research program at KUCC currently has eight physicians who see and enroll patients on clinical trials at the KU CRC. The program currently has 32 active clinical trials in its clinical trial portfolio. These include five investigator-initiated trials, two targeted-marker trials (two other trials have recently closed to accrual), five PD1/PDL1 combination trials, 10 novel agent trials and 10 single agent drug-to-drug pharmacokinetic trials. There are currently seven trials in the start-up submission pipeline. There are 15 investigator-initiated trials currently in some phase of development, seven of which are based on basic science work through KUCC. The graphs below demonstrate the continued growth of the early phase program.





It is worthwhile to note that in February of 2015, KUCC leadership initiated a top-to-bottom review of the early phase clinical trials working group. This was prompted by the observation that KUCC had devoted a significant amount of resources to the early phase working group but assessed that accruals in 2013 and 2014 had

plateaued and were not commensurate with the level of institutional investment. To understand the issues contributing to this situation, an early phase summit was convened, involving nearly 20 individuals who had a direct or indirect role in our early phase working group. This group met multiple times over a six-month period and made a number of recommendations to the Associate Director's Council. As a result, **Williamson** was appointed as the new director of the early phase clinical trials program in 2015. Since then, we have seen nearly 50% expansion of our early phase clinical trial accruals.

The early phase summit committee members also advocated for increased support for investigator-initiated clinical trials, and this resulted in the development of an RFA and the commitment of $400,000 of resources to fund IIT's. Since then, a number of studies have been funded and we have seen a corresponding increase in our accruals to such trials.

Additional signals of success in building an early phase clinical research program and in demonstrating readiness to leverage EPCRS funding are shown below in the list of examples of early phase trials completed during the last funding period that met the EPCRS eligibility criteria.

Early Phase Clinical Trials Completed During Last Funding Period

Study Title	**A Phase I Study of Intraperitoneal Nanoparticle Paclitaxel in Patients With Peritoneal Malignancies**	
Award Period	2007-2013	
PI	Stephen K. **Williamson**, MD, University of Kansas Cancer Center (KUCC)	
Sub-Investigators	Gary **Johnson**, MD, KUCC Holly A. Maulhardt, US Biotest, Inc. Kathleen Moore, Stephenson Cancer Ctr D.S. McMeekin, Stephenson Cancer Ctr Thomas K. **Schulz**, MD, Cancer Center of Kansas at Wichita Gregory A. **Reed**, PhD, KUCC Katherine R. **Roby**, PhD, KUCC Christine B. Mackay, RN, KUCC Holly J. Smith, Quintiles	Scott J. **Weir**, PhD, KUCC Jo **Wick**, KUMC Maurie Markman, Cancer Treatment Centers of America; Drexel University Gere diZerega, US Biotest, Inc.; Keck School of Medicine at USC Michael **Baltezor**, KU; CritiTech, Inc. Jahna Espinosa, CritiTech, Inc. Charles Decedue, CritiTech, Inc.
Return on Investment	PMID: 25898813 and Patent submitted	
Sponsor Name	KU Endowment; CritiTech, Inc.	
NCT Number	NCT00666991	

Study Title	**A Pilot trial to Assess mobilization of hematopoietic progenitor cells with a combination of Bortezomib and G-CSF in patients undergoing autologous transplant for myeloma and lymphoma**	
Award Period	2010-2013	
PI	Sunil **Abhyankar**, MD, KUCC	
Sub-Investigators	Joseph P. **McGuirk**, DO, KUCC Siddhartha **Ganguly**, MD, KUCC	Omar S **Aljitawi**, MD, KUCC
Return on Investment	PMID: 26939585	
Sponsor Name	Millenium Pharmaceuticals	
NCT Number	NCT01171092	

Study Title	**A phase I study evaluating the efficacy of 5-Azacitidine and Bevacizumab in advanced renal cell carcinoma**	
Award Period	2009-2013	
PI	Peter J. **Van Veldhuizen**, MD, KUCC	
Sub-Investigators	Jeffrey **Holzbeierlein**, MD, KUCC	Suman **Kambhampati**, MD, KUCC
Return on Investment	Completed, analysis ongoing	
Sponsor Name	Celgene Corporation	
NCT Number	NCT00934440	

Study Title	**Adequacy of Peripheral Blood Stem Cell mobilization in Patients with Relapsed Lymphoma Treated with Bendamustine: A Pilot Project and a Proof of Concept Study**	
Award Period	2010-2014	
PI	Siddhartha **Ganguly**, MD, KUCC	
Sub-Investigators	Omar **Aljitawi**, MD, KUCC Sunil **Abhyankar**, MD, KUCC	Joseph **McGuirk**, DO, KUCC
Return on Investment	PMID: 26294340	
Sponsor Name	Cephalon, Inc.	
NCT Number	NCT01022021	

Study Title	**Phase I Open-Label Study of Decitabine in Combination with Midostaurin (PKC412) for Elderly (Age ≥ 60) Newly Diagnosed or Relapsed/Refractory Adult Patients with Acute Myeloid Leukemia**	
Award Period	2010-2013	
PI	Casey Williams, PharmD, KU Medical Center	
Sub-Investigators	Joseph **McGuirk**, DO, KUCC Sunil **Abhyankar**, MD, KUCC Siddartha **Ganguly**, MD, KUCC Omar **Aljitawi**, MD, KUCC	Suman **Kambhampati**, MD, KUCC Ruben **Reyes**, MD, KUCC Allan Fleming, MD, KUCC
Return on Investment	PMID:23798029	
Sponsor Name	Novartis Pharmaceuticals	
NCT Number	NCT01130662	

Study Title	**STALLO: PILOT STUDY OF ALLOGENEIC STEM CELL TRANSPLANTATION FOR ADVANCED NEUROBLASTOMA USING MCH MISMATCHED RELATED DONORS AND A SUB-MYELOABLATIVE REGIMEN**	
Award Period	2010-2014	
PI	G. Douglas **Myers**, MD, Children's Mercy	
Sub-Investigators	Jignesh Dalal, MD, CMH Mohamed Radhi, MD, CMH Carla McCrave, MD, CMH Joseph **McGuirk**, DO, KUCC	Sunil **Abhyankar**, MD, KUCC Siddhartha **Ganguly**, MD, KUCC Omar **Aljitawi**, MD, KUCC
Return on Investment	Completed, presented: Tri-virus Specific Cytotoxic T-Lymphocytes Redirected Toward Neuroblastoma with a GD2-specific CAR After Allogeneic Transplant ASGCT 16th Annual Meeting 2013	
Sponsor Name	MCA Partners Advisory Board; **We did not support this trial, included as example of potential future collaboration with CMH**	
NCT Number	NCT01462396	

Study Title	**A Phase I Trial of Irinotecan and BKM120 in Previously Treated Advanced Colorectal Cancer**	
Award Period	2011-2014	
PI	Joaquina **Baranda**, MD, KUCC	
Sub-Investigators	Gregory **Reed**, PhD, KUCC Bruno Hagenbuch, PhD, KUMC Maxine, Stoltz, PhD, KUCC Stephen **Williamson**, MD, KUCC Rashna **Madan**, MD, KUMC Qamar **Khan**, MD, KUCC Prakash Neupane, MD, KUCC Andrew **Godwin**, PhD, KUCC	Ruben **Reyes**, MD, KUCC Sarah **Taylor**, MD, KUCC Raymond **Perez**, MD, KUCC Sharon Lewis, NP, KUMC Rowena Henderson, NP, KUMC Christine Mackay, RN, KUCC Jecinta Scott, KUCC
Return on Investment	Presented at ESMO 2014 and submitted for publication	
Sponsor Name	Novartis Pharmaceuticals	
NCT Number	NCT01304602	

Study Title	**Translation of *in vitro* and *in vivo* ascorbate research into a new treatment option for pancreatic cancer: Phase I/Ib clinical trial**

Award Period	2011-2014	
PI	Jeanne Drisko, MD, University of Kansas Cancer Center (KUCC)	
Sub-Investigators	Stephen **Williamson**, MD, KUCC	Gregory **Reed**, PhD, KUCC
Return on Investment	Completed, Manuscript pending	
Sponsor Name	Hecht Foundation	
NCT Number	NCT01364805	

Study Title	**Phase I Study of Donor Derived, Gene Modified, Multi-virus-specific, Cytotoxic T-Lymphocytes Redirected to the Tumor Marker GD2 for Relapsed/Refractory Neuroblastoma Post-allogeneic Stem Cell Transplantation With a Submyeloblative Conditioning Regimen**	
Award Period	2011-2014	
PI	G. Douglas **Myers**, MD, Children's Mercy	
Sub-Investigators	Jignesh Dalal, MD, CMH Mohamed Radhi, MD, CMH Carla McCrave, MD, CMH Joseph **McGuirk**, DO, KUCC	Sunil **Abhyankar**, MD, KUCC Siddhartha **Ganguly**, MD, KUCC Omar **Aljitawi**, MD, KUCC
Return on Investment	Completed, manuscript pending	
Sponsor Name	PACT/NHLBI/Childrens Mercy Hospital Kansas City; **We did not support this trial, included as example of potential future collaboration with CMH**	
NCT Number	NCT01460901	

Study Title	**A Phase 1 Study of the Oral Gold Compound Auranofin in Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)/Prolymphocytic Lymphoma (PLL)**	
Award Period	2011-2014	
PI	Suman **Kambhampati**, MD, University of Kansas Cancer Center (KUCC) Kami Maddocks, MD, The Ohio State University Adrian Wiestner, MD, PhD, National Heart, Lung & Blood Institute	
Sub-Investigators	Sunil **Abhyankar**, MD, KUCC Omar **Aljitawi**, MD, KUCC Siddartha **Ganguly**, MD, KUCC Rowena Henderson, NP, KUCC Sharon Lewis, NP, KUMC Tara **Lin**, MD, KUCC Brea **Lipe**, MD, KUCC Joseph **McGuirk**, DO, KUCC Raymond **Perez**, MD, KUCC Ruben **Reyes**, MD, KUCC Abdulraheem **Yacoub**, MD, KUCC Leslie Andritsos, MD, OSU John C. Byrd, MD, OSU	Joseph Flynn, DO, OSU Amy Johnson, PhD, OSU Jeffery Jones, MD, OSU Michael Grever, MD, OSU Jennifer Woyach, MD, OSU Samantha Jaglowski, MD, OSU Mohammen Z. Farooqui, DO, NHLBI Georg Aue, MD, NHLBI Leodayan Bojanowski, DNP, RN, NHLBI Susan Soto, RN, NHLBI Janet Valdez, PA, NHLBI Thomas Hughes, PharmD, NHLBI
Return on Investment	Completed, manuscript pending; Manuscripts in support of the trial: PMID: 22246671; PMID: 24599128	
Sponsor Name	Multiple	
NCT Number	NCT01419691	

Study Title	**A Phase I Trial of Post-Prostatectomy Radiation Therapy, Hormonal Therapy and Concurrent Docetaxel for High Risk Pathologic T2-T3N0M0 Prostate Cancer**
Award Period	2011-2015
PI	Parvesh **Kumar**, MD, University of Kansas Cancer Center (KUCC)
Sub-Investigators	Peter **Van Veldhuizen**, MD, KUCC
Return on Investment	Completed, Manuscript pending
Sponsor Name	Department of Defense (DOD)
NCT Number	NCT00669162

Study Title	**Phase I study evaluating the tolerance and biologic activity of intravenous infusions of tigecycline in patients with relapsed or refractory AML**

Award Period	2012-2014
PI	Suman **Kambhampati**, MD, University of Kansas Cancer Center (KUCC)
Sub-Investigators	Martin Tallman, MD, Memorial Sloan Kettering Gary Schiller, MD, UCLA Andre Schuh, MD, Princess Margaret Hospital (overall PI)
Return on Investment	Manuscript pending
Sponsor Name	University Health Network and LLS
NCT Number	NCT01332786

Study Title	**A Pilot Study to Determine the Safety and Efficacy of Using Hyperbaric Oxygen Therapy to Improve Umbilical Cord Blood Stem Cell Homing and Subsequent Engraftment**	
Award Period	2013-2015	
PI	Omar **Aljitawi**, MD, University of Kansas Cancer Center (KUCC)	
Sub-Investigators	Joseph **McGuirk**, DO, KUVC Siddartha **Ganguly**, MD, KUCC Sunil **Abhyankar**, MD, KUCC	Tara **Lin**, MD, KUCC Dennis Allin, KUCC
Return on Investment	Presentations: 12th International Cord Blood Symposium 2014 ASH Annual Meeting 2015 IBC Annual Meeting 2015 Manuscript pending	
Sponsor Name	KU Endowment Association Frontiers Pilot Grant	
NCT Number	NCT02099266	

Study Title	**Pilot Study Exploring the Use of Hyperbaric Oxygen in Autologous PBSC Transplantation**	
Award Period	2014-2015	
PI	Omar **Aljitawi**, MD, University of Kansas Cancer Center (KUCC)	
Sub-Investigators	Joseph **McGuirk**, DO, KUCC Siddartha **Ganguly**, MD, KUCC Sunil **Abhyankar**, MD, KUCC Tara **Lin**, MD, KUCC	Anurag Singh, MD, KUCC Dennis Allin, KUCC Brea **Lipe**, MD, KUCC
Return on Investment	Presentations: ASBMT Tandem Meeting 2015 ASCO 2015 Manuscript pending	
Sponsor Name	The SWOG/Hope Foundation Impact Award	
NCT Number	NCT02087657	

It should be noted that KUCC did not request funding for EPCPS in the last grant period, because KUCC was just initiating the early phase clinical trials working group and wanted to demonstrate KUCC's ability to develop and successfully execute these studies prior to requesting funds for this component of the CCSG. With this consideration in mind, a number of the studies listed above had an accrual period that extended beyond the optimal 1-2 year enrollment criteria for EPCRS trials. In some cases the enrollment was slower than expected, but in others KUCC felt it was important to open the trial because it represented a critical example of KUCC science being translated into the clinic. These trials also represented a key opportunity to train early phase faculty and staff coincident with opening of the KU CRC facility and demonstrate progress to the voters of Johnson County who funded the KU CRC facility. For current trials listed below, KUCC has more strongly emphasized the necessity of a 1-2 year timeframe for enrollment and will ensure that for trials that extend beyond this enrollment period, EPCRS support will be withdrawn from the study.

Active Early Phase Clinical Trials that meet the EPCRS eligibility criteria

Study Title	**Pilot Study of Vaccine Enriched, Autologous, Activated T-Cells Redirected to the Tumor Marker GD2 in Patients with Relapsed/Refractory Melanoma**
PI	Gary **Doolittle**, MD, University of Kansas Cancer Center
Sub-investigators	Joy **Fulbright**, MD, Children's Mercy G. Douglas **Myers**, MD, Children's Mercy Sunil **Abhyankar** MD, University of Kansas Cancer Center

	Sid **Ganguly** MD, University of Kansas Cancer Center Hongying Dai, PhD, Children's Mercy (statistician)
Accrual Target	3 patients
Accrual Window	1 year
Study Objectives	1. To evaluate the safety and persistence of autologous, 14g2a.zeta chimeric receptor transduced, activated T-cells, enriched for vaccine specific cytotoxic T-lymphocytes (tvs-CTL) that are administered to patients with progressive, relapsed, or refractory high-risk melanoma. 2. To determine the expansion of infused tvs-CTL in response to repeat vaccination with previously administered vaccines 3. To compare the frequency of tvs-CTL in the peripheral blood, after revaccination, to the frequency noted in the prior study of autologous activated, CAR transduced T-cells infused in patients with relapsed, refractory neuroblastoma 4. Evaluate tumor response to infusion of tvs-CTL and repeat vaccination post-infusion.
Statistical Methodology	This is a pilot, phase I study. Descriptive statistics (means, ranges and standard deviations or standard errors) will be used to summarize datasets.
EPCRS Specific Aims Being Met	✓ Collaboration with KUCC Consortium partner, Children's Mercy ✓ Based on preliminary work by Drs. Myers and Fulbright ✓ Collaboration with Baylor College of Medicine Center for Cell and Gene Therapy GMP facility (CAGT), performing cell culture and gene transfer manipulations ✓ High priority, innovative, pilot institutional clinical study focusing on initial early phase testing of a candidate agent or device for the treatment of cancer ✓ Conceptualized/designed by KUCC members ✓ Short duration (*e.g.*, 1-2 years)

Study Title	**Pilot Study of Ethacrynic Acid Elimination in Non-Muscle Invasive Bladder Cancer Patients undergoing Transurethral Resection Pharmacokinetic trial**
PI	Eugene K. **Lee**, MD, University of Kansas Cancer Center
Sub-Investigators	Jeffrey M. **Holzbeierlein**, MD, University of Kansas Cancer Center Moben **Mirza**, MD, University of Kansas Cancer Center Hadley Wyre, MD, University of Kansas Cancer Center
Collaborators	Shrikant **Anant**, PhD, University of Kansas Cancer Center Greg **Reed**, PhD, University of Kansas Cancer Center Scott **Weir**, Pharm D, PhD, University of Kansas Cancer Center
Accrual Target	12 patients
Study Duration	1 year
Study Objectives	1. The primary objective of the study is to provide quantitative characterization of the renal elimination of ethacrynic acid and metabolites in patients with non-muscle invasive bladder cancer (NMIBC) at the time of transurethral resection of bladder tumor 2. To determine the safety of Ethacrynic acid in patients undergoing standard of care Transurethral Resection of Bladder Tumor (TURBT) 3. To determine recurrence/non-recurrence of disease at 3 months post-treatment 4. To identify potential biomarkers of response to the combination of study drug Ethacrynic acid
Statistical Methodology	This is a pilot study designed to provide preliminary metabolite measures at four time points after administration in order to establish adequate dosing, optimal administration care, optimal timing of resection to ensure that the most efficacious dosage is present in the bladder at the time of the procedure. This study is not powered to identify significant differences in metabolites across time points, between routes, or to test if the peak metabolite is significantly different than a targeted threshold. The analysis is exploratory with a sample size of 12 participants assigned to receive the study drug (oral 50 mg of ethacrynic acid).
EPCRS Specific Aims Being Met	✓ Based on D3ET discovery ✓ High priority, innovative, pilot institutional clinical study focusing on initial early phase testing of a candidate agent or device for the treatment of cancer ✓ Conceptualized/designed by KUCC members ✓ Short duration (*e.g.*, 1-2 years)

Study Title	**A Pilot Study of Low-Dose Daunorubicin (DNR) in Patients with Relapsed/Refractory Acute Leukemia**
PI	Raymond **Perez**, MD, PhD, University of Kansas Cancer Center
Sub-Investigator	Tara **Lin**, MD, University of Kansas Cancer Center

Collaborators	Linheng **Li**, PhD, Stowers Institute John Perry, PhD, Stowers Institute Gregory A. **Reed**, PhD, University of Kansas Cancer Center Mark Cunningham, MD, KUMC Milind Phadnis, PhD, University of Kansas Cancer Center
Accrual Target	12 patients
Study Duration	1 year
Study Objectives	*Primary Objective* 1. Investigate the correlation of PI3K aberration with response to determine the molecular pharmacodynamic effects of low dose daunorubicin on β-catenin phosphorylation in serial bone marrow samples of patients with relapsed leukemia. *Secondary Objectives* 2. To demonstrate the safety and feasibility of low-dose DNR administration in patients with relapsed/refractory acute leukemia 3. To measure the pharmacokinetics of low dose DNR 4. To demonstrate the feasibility of measuring β-catenin expression by flow cytometry on bone marrow and peripheral blood samples at serial time points 5. To demonstrate the feasibility of measuring β-catenin expression by flow cytometry on bone marrow and peripheral blood samples at serial time points *Exploratory Objectives* 6. To observe treatment effects on the leukemia stem cell population in serial bone marrow specimens 7. To observe treatment effects over a 2-fold dose range 8. To observe the relationship between pretreatment MDR1/Pgp protein levels by IHC and treatment effects. 9. To quantify daunorubicin-induced DNA damage on serial marrows specimens by IHC of p-gH2Ax foci
Statistical Methodology	Each dose cohort tested independently for PD effect. No formal/quantitative comparison between dose levels is planned. Study sample size is 12 patients (6 patients per cohort). Power is = 93%, to detect a standardized effect size of magnitude 1.25 or more.
EPCRS Specific Aims Being Met	✓ Based on collaborative basic research with Stower's Institute (Consortium Partner) ✓ High priority, innovative, pilot institutional clinical study focusing on initial early phase testing of a candidate agent or device for the treatment of cancer ✓ Conceptualized/designed by KUCC members ✓ Short duration (*e.g.*, 1-2 years)

Study Title	**Phase I study of BYL719 and Nab-Paclitaxel (Abraxane) in patients with locally recurrent or metastatic HER-2 negative breast cancer**
PI	Priyanka **Sharma**, MD, University of Kansas Cancer Center
Sub-Investigators	Andrew **Godwin**, Ph.D, University of Kansas Cancer Center Qamar **Khan**, M.D., University of Kansas Cancer Center Raymond **Perez**, M.D., University of Kansas Cancer Center Takefumi **Komiya**, M.D., University of Kansas Cancer Center Greg **Reed**, Ph.D, University of Kansas Cancer Center
Collaborators	Vandana Abramson, M.D., **Vanderbilt-Ingram Cancer Center**
Accrual Target	18 patients in phase I
Study Duration	1 to 2 years for phase I enrollment
Study Objectives	*Primary Objective* 1. For Phase I, determine the recommended phase II dose (RPTD) of BYL719 + Nab-Paclitaxel to be used in combination for treatment of advanced HER-2 negative breast cancer *Secondary Objectives* 2. Assess pharmacokinetics of BYL719 when administered with Nab-Paclitaxel 3. Assess pharmacokinetics of Nab-Paclitaxel when administered with BYL719 *Exploratory Objectives* 4. Investigate the correlation of PI3K aberration with response
Statistical Methodology	Standard 3+3 design for Phase I portion with three dose levels of BYL719 (250 mg, 300 mg, 350 mg) and one level of Nab-Paclitaxel (100 mg/m2)
EPCRS Specific Aims Being Met	✓ Collaboration with other NCI-designated Cancer Center (Vanderbilt-Ingram) ✓ High priority, innovative, phase I institutional clinical trial focusing on initial early phase testing of a candidate agent or device for the treatment of cancer

	✓ Conceptualized/designed by KUCC members ✓ Short duration (*e.g.*, 1-2 years)

Study Title	**Phase I trial of Cisplatin + Romidepsin in locally recurrent or metastatic triple negative breast cancer or BRCA 1/BRCA 2 mutation associated locally recurrent or metastatic breast cancer**
PI	Priyanka **Sharma**, MD, University of Kansas Cancer Center
Sub-Investigators	Qamar **Khan**, MD, University of Kansas Cancer Center Raymond **Perez**, MD, University of Kansas Cancer Center Takefumi **Komiya**, MD, University of Kansas Cancer Center Andrew **Godwin**, PhD, University of Kansas Cancer Center Roy **Jensen**, MD, University of Kansas Cancer Center Greg **Reed**, PhD, University of Kansas Cancer Center
Accrual Target	18 patients in phase I
Study Duration	1 to 2 years for phase I enrollment
Study Objectives	*Primary Objective* 1. Determine the recommended phase II dose (RPTD) of romidepsin + cisplatin to be used in combination for treatment of advanced TNBC *Secondary Objectives* 2. Assess pharmacokinetics of BYL719 when administered with Nab-Paclitaxel 3. Assess pharmacokinetics of Nab-Paclitaxel when administered with BYL719 *Exploratory Objective* 4. Investigate the correlation of PI3K aberration with response
Statistical Methodology	Standard 3+3 design for Phase I portion with three dose levels of romidepsin (8 mg/ m2, 10 mg/ m2, 12 mg/ m2) and one level of cisplatin (75 mg/m2)
EPCRS Specific Aims Being Met	✓ High priority, innovative, phase I institutional clinical trial focusing on initial early phase testing of a candidate agent or device for the treatment of cancer ✓ Conceptualized/designed by KUCC members ✓ Short duration (*e.g.*, 1-2 years)

Study Title	**Phase I Study of Evaluation of Lithium and its effect on clinically localized prostate cancer**
Award Period	2014-Present
PI	Moben **Mirza**, MD, KU Medical Center
Sub-Investigators	Jeffrey **Holzbeierlein**, MD, KUMC J. Brantley **Thrasher**, MD, KUMC David Duchene, MD, KUMC Benyi **Li**, MD, PhD, KUMC Gregory **Reed**, PhD, KUMC
Sponsor Name	Frontiers Pilot Grant
EPCRS Specific Aims Being Met	✓ High priority, innovative, phase I institutional clinical trial focusing on initial early phase testing of a candidate agent or device for the treatment of cancer ✓ Conceptualized/designed by KUCC members ✓ Short duration (*e.g.*, 1-2 years)

Study Title	**An exploratory trial to estimate the proportion of patients with tumor cell contaminated, flow positive leukapheresis products collected with and without bortezomib as *in vivo* purging prior to autologous stem cell harvest for multiple myeloma.**
PI	Siddhartha **Ganguly**, MD, KU Medical Center
Sub-Investigators	Joseph **McGuirk**, DO, KUMC Sunil **Abhyankar**, MD, KUMC Tara **Lin**, MD, KUMC Anurag Singh, MD, KUMC Leyla Shune, MD, KUMC
Sponsor Name	University of Kansas Cancer Center
EPCRS Specific Aims Being Met	✓ High priority, innovative, phase I institutional clinical trial focusing on initial early phase testing of a candidate agent or device for the treatment of cancer ✓ Conceptualized/designed by KUCC members ✓ Short duration (*e.g.*, 1-2 years)

Summary

The EPCRS component of this CCSG application is a critical aspect of KUCC. This results from the strong focus that KUCC has on drug discovery and development, and the opportunity to leverage the rich history of research from the KU Lawrence School of Pharmacy and the pharmaceutical industry in the Kansas City metropolitan area. KUCC is committed to establishing an outstanding early phase clinical research group that is focused on providing access to the most promising therapeutic advances to KUCC patients. In many respects, the EPCRS represents the crown jewel of KUCC's efforts to build a nationally significant clinical research and developmental therapeutics program, as it embodies a number of key components that are central to the stated vision as a cancer center. Specifically, KUCC has committed to developing, promoting and implementing a cancer center culture whose highest priority is to foster the discovery and advancement of new and more effective therapeutic and prevention options for the benefit of KUCC patients. This was an important guiding principal in the development of the Target Acceleration Group and the Investigator-Initiated Trial Steering Committee. Both of these entities bring together multidisciplinary expertise intended to establish a strong culture of translational research and clinical investigation that KUCC believes is critical to have a successful developmental therapeutics program.

KUCC also worked with the leadership of Johnson County to pass a ballot initiative that strongly supports KUCC's ability to turn cancer research discoveries into new therapeutic and prevention approaches that could quickly benefit the patients within our catchment area. The Johnson County Education and Research Tax is a unique partnership between an NCI-designated cancer center and a county government that directly supports early phase clinical research and KUCC is humbled to be its beneficiary. The proceeds from the sales tax have enabled KUCC to build a state-of-the-art facility that allows the development of paradigm changing therapeutic advances in a compassionate and caring manner. This initiative also enables the training and mentoring of junior faculty and fellows in translational and clinical research, and will prepare them for a career as an academic clinical investigator.

Finally, KUCC believes that there is a significant opportunity to involve patients and their advocates in the developmental therapeutic pipeline therefore recently developed the PIVOT initiative. PIVOT is an evolving community of patient research advocates learning and working with our academic research stakeholders to enhance research to more effectively address patients' needs and desired outcomes (more details about PIVOT can be found in Planning and Evalution). For too long, the patient voice has been inadequately represented in this process and KUCC believes that patients have much to contribute. Indeed without their input KUCC will not be able to reach its potential.

Progress Report Publications

This component has no publications resulting from Cancer Center Support Grant funds.

Protection of Human Subjects – EARLY PHASE CLINICAL RESEARCH SUPPORT

The Human Subjects Committee (HSC) is designated as the Institutional Review Board (IRB) for the University of Kansas Medical Center, as required by 45 CFR 46 and 21 CFR 56. The HSC is responsible for reviewing, approving, modifying, rejecting and monitoring research involving human subjects. The University of Kansas Cancer Center Support Grant is an umbrella grant to the institution and therefore not reviewed by the IRB. However, all clinical trials must obtain appropriate IRB review and approval prior to initiation. Any human subjects research project at the University of Kansas Medical Center is subject to regulatory requirements for legally effective informed consent and ongoing IRB oversight. Human subjects research is conducted under FWA#00003411 and complies with DHHA and FDA standards.

Inclusion of Women & Minorities – EARLY PHASE CLINICAL RESEARCH SUPPORT

The University of Kansas Cancer Center is committed, along with the NIH, to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study. As such, KUCC will adhere to the NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research. Specifically, in the case of any clinical trial in which women or members of minority groups will be included as subjects, KUCC will ensure that the trial is designed and carried out in a manner sufficient to provide for valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

OMB Number:0925-0001 and 0925-0002
Expiration Date: 10/31/2018

***Study Title:** Early Phase Clinical Research Support- Any human subject study funded by CCSG funds will be required to submit a PHS inclusion enrollment report.

***Delayed Onset Study?** ☑ Yes ❑ No

If study is not delayed onset, the following selections are required:

Enrollment Type ❑ Planned ❑ Cumulative (Actual)

Using an Existing Dataset or Resource ❑ Yes ❑ No

Enrollment Location ❑ Domestic ❑ Foreign

Clinical Trial ❑ Yes ❑ No

NIH-Defined Phase III Clinical Trial ❑ Yes ❑ No

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/Alaska Native										
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More than One Race										
Unknown or Not Reported										
Total										

Inclusion of Children – EARLY PHASE CLINICAL RESEARCH SUPPORT

In the same manner, The University of Kansas Cancer Center will adhere to the guidelines set forth by the NIH for the Inclusion of Children as Participants in Research Involving Human Subjects. KUCC understands the goal of this policy is to increase the participation of children in research so that adequate data will be developed to support the treatment modalities for disorders and conditions that affect adults and may also affect children.

Resource Sharing Plan

The University of Kansas Cancer Center (KUCC) and its scientific community understands its responsibility to comply with the instructions for the Resource Sharing Plans provided within the SF 424 (R&R) Application General Instructions and Supplemental Grant Application Instructions. When resources are developed with NIH funds via this Cancer Center Support Grant P30 mechanism, KUCC will ensure findings are made readily available to the NIH and the scientific community in a timely manner.

Data Sharing Plan

KUCC will adhere to the Final NIH Statement on Sharing Research Data and refer to the National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research. KUCC encourages the free flow of information and ideas while recognizing the timeliness of data sharing, the rights and privacy of human subjects and issues related to proprietary data. KUCC encourages data documentation, using a data-sharing agreement and selecting an appropriate method for sharing; considering the sensitivity of the data, the size of the dataset and the volume of requests anticipated.

Additionally, KUCC encourages any user of a CCSG-supported shared resource to acknowledge the source of data upon which their manuscript is based either in the Acknowledgments section or with authorship on the paper. Furthermore, any research project that received direct cost support from the CCSG is encouraged to cite the P30 CA168524. In both cases, citing the P30 CA168524 grant number and then being compliant with the NIH Public Access Policy is required.

Sharing Model Organisms

In the event that a model organism is developed, KUCC will comply with the NIH Policy on Sharing of Model Organisms for Biomedical Research. KUCC will work with the NIH/NCI to share and disseminate the critical model organism in a timely manner.

Genome Wide Associate Studies

When applicable, KUCC will comply with the NIH Genomic Data Sharing Policy. KUCC supports the sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. All research studies funded through the CCSG involving genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data will be submitted in a timely manner.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 076248616

Legal Name*: University of Kansas Center for Research, Inc.
Department:
Division:
Street1*: 2385 Irving Hill Road
Street2: Youngberg Hall
City*: Lawrence
County: Douglas
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66045-7568

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Alicia		Reed	MAS

Position/Title: Interim Assistant Vice Chancellor
Street1*: Youngberg Hall
Street2: 2385 Irving Hill Road
City*: Lawrence
County:
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66045-7568
Phone Number*: 785-864-3441 Fax Number: 785-864-5025 Email: kures@ku.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofit Organization
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Cancer Biology Research Program

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2017	06/30/2022

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Center for Research, Inc.
Duns Number:	076248616
Street1*:	2385 Irving Hill Road
Street2:	Youngberg Hall
City*:	Lawrence
County:	Douglas
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66045-7568
Project/Performance Site Congressional District*:	KS-002

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ❍ **Yes** ● **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ❍ No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	CB_ProjectSummary_Final1019616614.pdf
8. Project Narrative*	
9. Bibliography & References Cited	CB_ReferencesCited_Final_Fife_edits1019754778.pdf
10.Facilities & Other Resources	
11.Equipment	
12. Other Attachments	CB_Other_Attachments_Final1019857903.pdf

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Cancer Biology – Project Summary

The scientific goal of the Cancer Biology research program (CB) is to understand the molecular mechanisms that define normal and neoplastic cell growth in order to identify and characterize molecules, pathways and processes that are involved in tumor development, growth and progression that can serve as useful biomarkers and/or as new cellular targets for cancer therapeutics and prevention. CB represents the basic science initiatives of The University of Kansas Cancer Center (KUCC) and is unified by member utilization of molecular, biochemical and cell-based approaches to understand normal and cancer cell behavior. The Specific Aims of CB are: 1) to promote collaboration that enhances discovery of the mechanisms underlying tumor development, progression and malignant behavior; and 2) to leverage basic science discoveries to inspire pre-clinical and clinical development of novel cancer therapies.

CB has 49 full members and 12 associate members from 17 departments located at KUMC, KU-Lawrence and Stowers. In 2015, CB garnered nearly $17M in cancer-related, peer-reviewed funding ($2M from NCI, $12.2M other NIH). CB members have published 617 articles since 2012 of which 144 (23%) had intra-programmatic, 128 (21%) had inter-programmatic and 315 (51%) had inter-institutional collaborations. These publications have been cited over 5,600 times, have an average journal impact factor (JIF) of 7.3 and 167 (27%) have a JIF≥8.

CB is jointly led by Kristi **Neufeld** (KU-Lawrence) and Linheng **Li** (Stowers), who bring complementary scientific expertise in cell biology, stem cell biology, biochemistry and translational research, leadership experience and diverse institutional representation. Danny **Welch**, Associate Director for Basic Science & Education and Jim **Calvet**, KUCC Research Staff Investigator, round out the leadership team and represent KUMC. Intra- and inter-programmatic collaborations are fostered by research retreats, seminars, research symposia and targeted pilot funding. CB has taken advantage of historical strengths in the study of three tumor sites over-represented in either incidence or mortality rate in the KUCC catchment area population (GI, kidney and hematopoietic). But rather than a disease-based thematic organization, CB members have expertise that can be organized into four discipline-based themes: 1) Cancer Cell Biology and Stem Cell Biology; 2) Cell Proliferation, Differentiation and Death; 3) Chromatin Organization and Transcriptional Regulation; and 4) Signaling Pathways and Development.

Cancer Biology – Other Attachments

Table 1 – Externally Funded, Cancer-Related Research Projects
Table 2 – Program Members
Table 3 – Shared Resource Usage
Table 4 – Programmatic Activities
Table 5 – Publications
Table 6 – Clinical Research*

***There are no clinical research protocols to report for the Cancer Biology research program**

Table 1. Externally Funding, Cancer-Related Research Projects as of 12/31/2015 - Cancer Biology

Table 1. Program Funding											
PI	**Specific Funding Source**	**Project Number**	**Project Start Date**	**Project End Date**	**Project Title**	**Annual Project Direct Costs**	**Annual Project Total Costs**	**Program Code**	**Percent**	**Annual Program Direct Costs**	**Annual Program Total Costs**
PEER-REVIEWED PROJECTS											
Abrahamson DR	NIGMS	5P20GM104936-09	9/27/2007	6/30/2017	MOLECULAR REGULATION OF CELL DEVELOPMENT AND DIFFERENTIATION	$437,447	$660,546				
Abrahamson DR Krieg AJ	NIGMS	5P20GM104936-09	7/1/2015	6/30/2016	MOLECULAR REGULATION OF CELL DEVELOPMENT AND DIFFERENTIATION (FUNCTIONAL ANALYSIS OF HISTONE DEMETHYLASE ACTIVITY IN HYPOXIC CANCER CELLS)			CB	100%	$150,000	$226,500
Abrahamson DR Slawson CE	NIGMS	5P20GM104936-09	7/1/2015	6/30/2016	MOLECULAR REGULATION OF CELL DEVELOPMENT AND DIFFERENTIATION (TARGETING AND REGULATION OF O-GLCNAC TRANSFERASE AT M PHASE)			CB	100%	$150,000	$226,500
Apte UM	NIDDK	5R01DK098414-03	4/1/2013	3/31/2018	MECHANISMS OF LIVER REGENERATION AFTER ACETAMINOPHEN-INDUCED ACUTE LIVER FAILURE	$217,500	$328,425	CB	100%	$217,500	$328,425
Cancer Relevance (DK098414): *The mechanisms of liver regneration closely parallel proliferative states in human cancer. This proposal studies canonical and non-canonical Wnt signaling cascades and biomarkers associated with hepatocyte growth.*											
Azuma Y Clarke DJ (Univ Minnesota)	NIGMS	5R01GM112793-02	1/12/2015	12/31/2018	REGULATION OF KINETOCHORE FUNCTION BY TOPOISOMERASE II	$226,800	$265,300	CB	100%	$113,400	$132,650
Cheng N	ACS	RSG-13-182-01-CSM	7/1/2013	6/30/2017	BARRIERS TO BREAST CANCER TREATMENT DUE TO CCL2/CCR2 CHEMOKINE SIGNALING	$150,000	$180,000	CB	100%	$150,000	$180,000
Cheng N	Susan G. Komen Foundation	CCR13261859	8/16/2013	8/15/2016	MOLECULAR SWITCHING OF DCIS TO INVASIVE CARCINOMAS BY CCR2 CHEMOKINE RECEPTORS	$120,000	$150,000	CB	100%	$120,000	$150,000
Cheng N Behbod F	NCI	5R01CA172764-03	9/1/2013	6/30/2018	PROGRESSION OF DCIS TO INVASIVE BREAST CANCER THROUGH CCR2 CHEMOKINE SIGNALING	$274,254	$414,124	CB	100%	$137,127	$207,062
Chien JR	ACS	RSG-14-067-01-TBE	7/1/2014	6/30/2018	MECHANISM OF CARBOPLATIN RESISTANCE IN OVARIAN CANCER	$163,958	$196,750	CB	100%	$163,958	$196,750
Chien JR	DOD	W81XWH-14-1-0116	5/15/2014	5/14/2016	TARGETING FOXM1 PATHWAY IN OVARIAN CANCER	$113,565	$171,483	CB	100%	$113,565	$171,483
Ding WX	NIAAA	5R01AA020518-05	8/1/2011	7/31/2016	MECHANISMS REGULATING AUTOPHAGY IN ALCOHOL-INDUCED LIVER INJURY	$218,250	$327,375	CB	100%	$218,250	$327,375
Cancer Relevance (AA020518): *Fundamental insights into mechanisms of autophagy have been determined in the alcohol-induced liver injury model. The data are being used to guide research regarding metabolism relationships between autophagy and cancer cell growth.*											
Ding WX Jaeschke HW	NIDDK	5R01DK102142-02	9/25/2014	5/31/2018	AUTOPHAGY AND DRUG-INDUCED LIVER INJURY	$225,000	$339,750	CB	100%	$225,000	$339,750
Cancer Relevance (DK102142): *Fundamental insights into mechanisms of autophagy have been determined in the drug-induced liver injury model. The data are being used to guide research regarding metabolism relationships between autophagy and cancer cell growth.*											
Fields PE	NIDDK	5R01DK091277-04	4/15/2012	3/31/2017	THE ROLE OF THE HISTONE METHYLTRANSFERASE DOT1L IN ERYTHROPOIESIS	$217,500	$328,425	CB	100%	$217,500	$328,425
Cancer Relevance (DK091277): *Insights related to erythropoiesis epigenetic regulation are helping guide bone marrow transplant research.*											
Freudenthal BD	NIEHS	4R00ES024431-02	9/30/2015	8/31/2018	DNA REPAIR STRATEGIES THAT IMPACT GENOMIC STABILITY DURING OXIDATIVE STRESS	$184,249	$249,000	CB	100%	$184,249	$249,000
Cancer Relevance (ES024431): *Oxidative stress results from many environmental agents and promotes deleterious DNA modifications, ultimately leading to cancer.*											

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Gibson MC	NIGMS	1R01GM111733-01A1	8/1/2015	7/31/2020	MITOTIC ROUNDING AND PLANAR SPINDLE ALIGNMENT IN PROLIFERATING EPITHELIA	$176,000	$290,400	CB	100%	$176,000	$290,400
Cancer Relevance (GM111733): *Disorientation of mitotic spindle alignment can lead to randomized cell devision, thus resulting in epithelial neoplasia.*											
Gudima SO	NCI	5R01CA166213-04	4/1/2012	3/31/2017	SUPER-INFECTION AND VIRUS SPREAD DURING CHRONIC HEPADNAVIRAL INFECTION	$265,339	$319,945	CB	100%	$265,339	$319,945
Hagan CR	NCI	4R00CA166643-03	9/23/2012	3/31/2018	CK2-DEPENDENT PHOSPHORYLATION OF PROGESTERONE RECEPTORS MEDIATES PROLIFERATIVE SI	$164,900	$249,000	CB	100%	$164,900	$249,000
Iwakuma T	NCI	5R01CA174735-02	5/1/2014	4/30/2019	THE ROLE OF MDM2-MTBP AXIS IN CANCER METASTASIS	$207,500	$313,325	CB	100%	$207,500	$313,325
Jaeschke HW	NIGMS	5P20GM103549-10	6/1/2006	6/30/2016	NUCLEAR RECEPTORS IN LIVER HEALTH AND DISEASE	$1,309,790	$1,977,783	CB	100%	$1,309,790	$1,977,783
Koestler DC	NCI Tufts University	5R01CA166150-04	7/1/2015	6/30/2016	MICROBIOMES IN HUMAN PANCREATIC CANCER	$22,200	$33,522	CB	100%	$22,200	$33,522
Kulsea P	NINDS	5R21NS092001-02	2/1/2015	1/31/2017	IN VIVO ANALYSIS OF TRKB SIGNALING DURING SYMPATHETIC NERVOUS SYSTEM DEVELOPMENT AND NEUROBLASTOMA PATHOGENESIS	$125,000	$206,250	CB	100%	$125,000	$206,250
Kumar TR	NCI	4R01CA166557-04	1/1/2013	12/31/2017	CHEMOPREVENTION OF PITUITARY GONADOTROPE TUMORS	$186,750	$281,992	CB	100%	$186,750	$281,992
Kumar TR	NICHD University of Colorado Denver	1R01HD081162-01A1	8/28/2015	5/31/2020	DYSREGULATION OF FSH IN OBESITY: FUNCTIONAL AND STATISTICAL ANALYSIS	$242,440	$343,237	CB	100%	$242,440	$343,237
Li L	NIDDK	5U01DK085507-07	9/30/2009	8/31/2019	CELLULAR, MOLECULAR, AND FUNCTIONAL CHARACTERIZATION OF QUIESCENT/ACTIVE INTESTIN	$220,905	$364,493	CB	100%	$220,905	$364,493
Cancer Relevance (DK085507): *To distinguish the role of quiescent and active intestinal stem cells can help to understand drug-sensitivity and resistance of cancer stem cells.*											
Li L	NIDDK	3U01DK085507-07S1	9/30/2009	8/31/2019	CELLULAR, MOLECULAR, AND FUNCTIONAL CHARACTERIZATION OF QUIESCENT/ACTIVE INTESTIN	$35,080	$57,882	CB	100%	$35,080	$57,882
Lundquist EA	NINDS	5R01NS040945-12	1/18/2001	5/31/2016	CYTOSKELETAL SIGNALING AND AXON GUIDANCE	$206,872	$296,452	CB	100%	$206,872	$296,452
Cancer Relevance (NS040945): *Many axon guidance molecules also regulate tumor vascularization and cell migration and apoptosis in normal and tumor tissues.*											
Lunte SM Azuma M	NIGMS	5P20GM103638-04	7/1/2015	6/30/2016	MOLECULAR ANALYSIS OF DISEASE PATHWAYS (FUNCTIONAL ANALYSIS OF EWING SARCOMA PROTEINS EWS/FLI1 AND EWS IN ZEBRAFISH)			CB	100%	$122,884	$184,326
Moise AR	NICHD	5R01HD077260-02	4/17/2014	3/31/2019	MOLECULAR DETERMINANTS OF RETINOID METABOLISM IN EMBRYONIC TISSUES	$264,170	$306,111	CB	100%	$264,170	$306,111
Cancer Relevance (HD077260): *Vitamin A metabolite, all-trans-retinoic acid (ATRA) is currently being used to treat acute promyelocytic leukemia and is being studies in the prevention and treatment of other types of cancer. The long-term goal of this project is to develop therapies based on the manipulation of the endogenous levels and activity of ATRA in diseased tissues.*											
Mure M	NIGMS	5R01GM113101-02	9/22/2014	7/31/2018	UNDERSTANDING THE ROLES OF PTM'S IN MODULATING MOLECULAR FUNCTIONS OF LYSYL OXIDASE-LIKE 2 IN BREAST CANCER CELLS	$195,000	$287,219	CB	100%	$195,000	$287,219
Neufeld K	NSF	1456538	4/15/2015	3/31/2018	COLLABORATIVE RESEARCH: BETA-CATENIN REGULATION DURING ASYMMETRIC STEM CELL DIVISIONS	$266,666	$400,000	CB	100%	$266,666	$400,000
Cancer Relevance (1456538): *Please also note multi-PI grant 5R01CA178831 listed under contact PI, Xu, L*											
Nicot CP	NCI	5R01CA106258-11	4/1/2004	5/31/2016	HTLV-I TAX INDUCES DNA BREAKS AND INHIBITS HR REPAIR THROUGH ACTIVATION OF NF-KB	$149,339	$224,009	CB	100%	$149,339	$224,009

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Peterson KR	NHLBI	5R01HL111264-03	8/15/2013	5/31/2017	MECHANISMS OF HBF ACTIVATION BY NON-DELETIONAL HPFH	$246,250	$371,837	CB	100%	$246,250	$371,837
Cancer Relevance (HL111264): *Using a model of hemaglobin switching, this grant studies fundamental aspects of gene rearrangements, which model analogous events taking place in cancer genome instability.*											
Peterson KR Slawson CE	NIDDK	5R01DK100595-03	1/1/2014	12/31/2016	REGULATION OF GLOBIN GENE SWITCHING BY O-GLCNAC POST-TRANSLATIONAL MODIFICATION	$156,600	$236,466	CB	100%	$156,600	$236,466
Cancer Relevance (DK100595): *Globin gene regulation by O-GlcNAc epigenetic marks is a model for how the same marks regulate cancer genes.*											
Soares MJ	NICHD	5P01HD079363-02	7/1/2015	6/30/2019	STEM CELLS AND EPIGENETICS OF TROPHOBLAST LINEAGE DEVELOPMENT: RESEARCH PROJECT III: HISTONE H3K9 METHYLATION AND TROPHOBLAST LINEAGE DEVELOPMENT			CB	100%	$179,178	$270,558
Cancer Relevance (HD079363): *Abnormalities in proliferation and differentiation are key features in cancer.*											
Soares MJ	NICHD	1R21HD082535-01	4/1/2015	3/31/2017	NATURAL KILLER CELLS AND HEMOCHORIAL PLACENTATION	$125,000	$188,750	CB	100%	$125,000	$188,750
Cancer Relevance (HD082535): *Natural killer cells play a critical role in distinguishing self vs. pathogen including cancer cells.*											
Soares MJ	NIH Office of Director	5R21OD010478-02	5/27/2013	4/30/2016	RAT MODELS FOR SEX STEROID ACTION	$142,650	$215,402	CB	100%	$142,650	$215,402
Cancer Relevance (OD010478): *Estrogen and androgens are key signals in development of breast and prostate cancers. The rat model to study sex steroid action can provide insight for understanding breast and prostate cancers.*											
Soares MJ	NICHD	5R01HD020676-27	7/1/1986	4/30/2017	TROPHOBLAST DIFFERENTIATION	$255,114	$385,221	CB	100%	$255,114	$385,221
Cancer Relevance (HD020676): *Sex steroid action can provide insight for understanding breast and prostate cancers.*											
Soares MJ	NICHD	5P01HD079363-02	7/1/2015	6/30/2019	STEM CELLS AND EPIGENETICS OF TROPHOBLAST LINEAGE DEVELOPMENT (RESEARCH PROJECT III: HISTONE H3K9 METHYLATION AND TROPHOBLAST LINEAGE DEVELOPMEN)			CB	100%	$179,178	$270,558
Cancer Relevance (HD079363): *Abnormalities in proliferation and differentiation are key features in cancer.*											
Soares MJ Paul S	NICHD	5P01HD079363-02	7/1/2015	6/30/2019	STEM CELLS AND EPIGENETICS OF TROPHOBLAST LINEAGE DEVELOPMENT (RESEARCH PROJECT I: TEAD4 ORCHESTRATION OF TROPHOBLAST DEVELOPMENT)			CB	100%	$182,534	$275,627
Cancer Relevance (HD079363): *Abnormalities in proliferation and differentiation are key features in cancer.*											
Soares MJ Rumi M AK	NICHD	5P01HD079363-02	7/1/2015	6/30/2019	STEM CELLS AND EPIGENETICS OF TROPHOBLAST LINEAGE DEVELOPMENT (RESEARCH PROJECT II: SATB REGULATION OF THE TROPHOBLAST STEM CELL STATE)			CB	100%	$184,448	$278,516
Cancer Relevance (HD079363): *Abnormalities in proliferation and differentiation are key features in cancer.*											
Staudinger JL	NIDDK	5R01DK090558-04	7/6/2011	4/30/2016	INFLAMMATION, PXR MODIFICATION AND DRUG DISPOSITION	$217,500	$315,780	CB	100%	$217,500	$315,780
Cancer Relevance (DK090558): *This research seeks to understand the mechanistic basis for clinically observed altered drug metabolism pathways that occur in liver during inflammatory-related disease, such as haptocellular carcinoma.*											
Tang L	NIGMS	5R01GM090010-05	9/1/2010	8/31/2016	GENOME PACKAGING IN DNA VIRUSES	$188,100	$270,426	CB	100%	$188,100	$270,426
Cancer Relevance (GM090010): *Human herpesviruses are linked to cancer and the majority of individuals in most human populations are infected by several herpesviruses. This proposal investigates a common molecular mechanism in herpesvirus life cycle, in search of new measures to control and prevent infection and diseases caused by the viral pathogen.*											
Thyfault J	NIDDK	7R01DK088940-05	7/25/2011	3/31/2016	AEROBIC FITNESS, MITOCHONDRIAL DYSFUNCTION, AND FATTY LIVER DISEASE	$187,500	$283,125	CB	100%	$187,500	$283,125

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Cancer Relevance (DK088940): *Metabolic changes in cancer are being interpreted in light of the mitochondrial functional changes observed in metabolic disease.*											
Tran PV	NIDDK	1R01DK103033-01A1	4/1/2015	3/31/2020	HEDGEHOG SIGNALING AS A THERAPEUTIC TARGET FOR CYSTIC KIDNEY DISEASE	$234,611	$348,755	CB	100%	$234,611	$348,755
Cancer Relevance (DK103033): *This is a cancer-PKD project examining hedgehog inhibitors on neoplastic cyst growth in PKD genetic models.*											
Tran PV	NIGMS	5P20GM104936-09	7/1/2015	6/30/2016	MOLECULAR MECHANISM OF THM1-MEDICATED RENAL CYSTOGENESIS	$150,000	$226,500	CB	100%	$150,000	$226,500
Cancer Relevance (GM104936): *This is a cancer-PKD study to investigate the mechanism of ciliary IFT in a THM1 mutant mouse model.*											
Wallace DP	NIDDK	2R01DK081579-06A1	7/1/2008	4/30/2019	ROLE OF PERIOSTIN IN POLYCYSTIC KIDNEY DISEASE	$225,000	$339,750	CB	100%	$225,000	$339,750
Cancer Relevance (DK081579): *This is a cancer-PKD project to determine how the cancer-associated tumorigenic protein, periostin, stimulates cell proliferation in PKD kidneys.*											
Ward CJ	NIDDK	5R01DK080688-05	12/3/2013	5/31/2016	FUNCTIONAL ANALYSIS OF PKD PROTEINS IN URINARY EXOSOMES	$217,500	$328,425	CB	100%	$217,500	$328,425
Cancer Relevance (DK080688): *This is a cancer-PKD investigation that is assessing the functional roles of exosome proteins in PKD proliferative disorders.*											
Weinman SA	NIAAA	5R01AA012863-15	9/27/2000	2/28/2017	MECHANISMS OF LIVER INJURY BY HEPATITIS C AND ALCOHOL	$331,842	$501,081	CB	100%	$331,842	$501,081
Cancer Relevance (AA012863): *Hepatitis C and chronic alcoholism are risk factors for liver cancer development. This project studies early changes in cells under both stresses.*											
Welch DR	NCI	5R01CA134981-06	9/1/2009	5/31/2016	KISS1: DEFINING MECHANISMS FOR ANTIMETASTATIC THERAPY	$186,243	$281,227	CB	100%	$186,243	$281,227
Welch DR	Susan G. Komen Foundation	SAC110037	7/28/2011	9/27/2016	Regulation of Metastasis by Mitochondrial DNA	$160,000	$200,000	CB	100%	$160,000	$200,000
Workman JL	NIGMS	5R01GM047867-23	8/1/1992	7/31/2016	MECHANISMS OF TRANSCRIPTIONAL REGULATION IN CHROMATIN	$200,000	$318,000	CB	100%	$200,000	$318,000
Cancer Relevance (GM047867): *Abnormal transcriptional regulation of oncogenic or tumor suppressor genes often lead to over proliferation and impaired differentiation.*											
Workman JL Abmayr SM	NIGMS	5R01GM099945-04	5/1/2012	4/30/2016	ANALYSIS OF METAZOAN SAGA COMPLEX FUNCTION IN GENE EXPRESSION	$190,000	$307,800	CB	100%	$190,000	$307,800
Cancer Relevance (GM099945): *A SAGA complex mediates HAT function in recruiting transcriponal machinary to the promoter. Changes of proteins in this complex can result in abnormal transcriptional regulation, and thus abnormal cell proliferation and differentiation.*											
Xu L Neufeld KL Aube J (UNC)	NCI				SMALL MOLECULES MODULATING RNA-BINDING PROTEIN MSI1			CB	100%	$97,221	$144,164
			Peer-Reviewed Research Subtotals			$10,000,384	$14,681,343			**$10,557,853**	**$15,557,834**

NON-PEER-REVIEWED PROJECTS											
Aljitawi OS	Medtronic Inc				A PHASE IIB, MULTICENTER, OPEN-LABEL, SAFETY AND EFFICACY STUDY OF HIGH DOSE MELPHALAN HCL FOR INJECTION (PROPYLENE GLYCOL-FREE) FOR MYELOABLATIVE CONDITIONING IN MULTIPLE MYELOMA PATIENTS UNDERGOING AUTOLOGOUS TRANSPLANTATION	$42,149	$56,058	CB	100%	$42,149	$56,058
Aljitawi OS	Hope Foundation				PILOT STUDY EXPLORING THE USE OF HYPERBARIC OXYGEN IN AUTOLOGOUS PBSC TRANSPLANTATION	$108,883	$129,854	CB	100%	$108,883	$129,854
Calvet JP	Polycystic Kidney Disease Foundation		3/1/2014	2/28/2016	ROLE OF CFTR AND NKCC1 IN POLYCYSTIC KIDNEY DISEASE	$80,000	$80,000	CB	100%	$80,000	$80,000
Cancer Relevance: *This is a cancer-PKD study using mouse models of PKD to investigate the role of chloride transport in regulating cell proliferation and fluid secretion.*											

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Fields TA	Polycystic Kidney Disease Foundation		3/1/2014	2/28/2016	PRE-CLINICAL ASSESSMENT OF MCP-1/CCR2 INHIBITION AS TREATMENT FOR ADPKP	$80,000	$80,000	CB	100%	$80,000	$80,000
Cancer Relevance: *This is a cancer-PKD project to study elevated cytokine expression and function in PKD and to determine the effects of inhibiting these pathways.*											
Ganguly S	Sanofi-Aventis US Inc		7/17/2012	12/31/2020	A PHASE 2 STUDY OF SAR245409 IN PATIENTS WITH RELAPSED OR REFRACTORY MANTLE CELL LYMPHOMA, FOLLICULAR LYMPHOMA, OR CHRONIC LYMPHOCYTIC LEUKEMIA/SMALL LYMPHOCYTIC LYMPHOMA	$25,137	$33,432	CB	100%	$25,137	$33,432
Ganguly S	Ambit Biosciences Corporation		9/12/2014	12/31/2020	A PHASE 3 OPEN-LABEL RANDOMIZED STUDY OF QUIZARTINIB (AC220) MONOTHERAPY VERSUS SALVAGE CHEMOTHERAPY IN SUBJECTS WITH FLT3-ITD POSITIVE ACUTE MYELOID LEUKEMIA (AML) REFRACTORY TO OR RELAPSED AFTER FIRST-LINE TREATMENT WITH OR	$14,728	$19,589	CB	100%	$14,728	$19,589
Ganguly S	Janssen Research and Development, L.L.C.		2/5/2013	12/31/2020	RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE 3 STUDY OF IBRUTINIB, A BRUTON'S TYROSINE KINASE (BTK) INHIBITOR, IN COMBINATION WITH BENDAMUSTINE AND RITUXIMAB (BR) IN SUBJECTS WITH RELAPSED OR REFRACTORY CHRONIC LYMPHOCYTIC	$83,975	$111,687	CB	100%	$83,975	$111,687
Hagan CR	V Foundation for Cancer Research		1/1/2015	12/31/2017	PROGESTERONE RECEPTOR PROMOTES INFLAMMATION IN BREAST CANCER	$100,000	$100,000	CB	100%	$100,000	$100,000
Jaeschke HW	Hubert and Richard Hanlon Trust		1/6/2014	12/31/2016	MECHANISMS OF ALCOHOLIC HEPATITIS IN HUMANS	$50,000	$50,000	CB	100%	$50,000	$50,000
Cancer Relevance: *Alcohol-induced hepatitis is a precursor for hepatocellular carcinoma. This grant studies early events in hepatocyte growth following ethanol exposure.*											
Soares MJ	Lalor Foundation Inc		6/1/2015	5/31/2016	EPIGENETIC REGULATION OF TROPHOBLAST DEVELOPMENT	$45,000	$50,000	CB	100%	$45,000	$50,000
Cancer Relevance: *Abnormal proliferation and differentiation are key features of cancer development.*											
Staudinger JL Azuma Y	Inez Jay Fund		7/1/2015	6/30/2016	SUMOYLATION OF BAG3 IN HEPATOCYTES AND HEPATOMA CELL LINES	$20,000	$20,000	CB	100%	$20,000	$20,000
Cancer Relevance: *The goal of this project is to provide new molecular insights regarding the underlying biology of chronic inflammation which, in turn, may provide new opportunities to develop novel pharmacological strategies for addressing multiple diseases, including cancer, that are related to chronic inflammation.*											
Thyfault J	Veteran Affairs Medical Center	12402	10/1/2015	9/30/2017	MITOCHONDRIAL MITOPHAGY IN THE DEVELOPMENT AND TREATMENT OF NAFLD	$85,800	$85,800	CB	100%	$85,800	$85,800
Cancer Relevance: *Mitophagy, as a subtype of autophagy, is increasingly recognized as a modification in tumor cells. This application studies fundamental mechanisms of the process in the context of fatty liver and metabolic syndome, which are both risk factors for many types of cancer.*											
Thyfault J	Veteran Affairs Medical Center	12326	8/1/2015	7/31/2017	MITOCHONDRIAL MITOPHAGY IN THE DEVELOPMENT AND TREATMENT OF NAFLD	$39,409	$39,409	CB	100%	$39,409	$39,409
Cancer Relevance: *Mitophagy, as a subtype of autophagy, is increasingly recognized as a modification in tumor cells. This application studies fundamental mechanisms of the process in the context of fatty liver and metabolic syndome, which are both risk factors for many types of cancer.*											
Wallace DP	Polycystic Kidney Disease Foundation		4/1/2012	3/31/2016	PKD RESEARCH BIOMATERIALS AND CELLULAR MODELS CORE	$50,000	$50,000	CB	100%	$50,000	$50,000
Cancer Relevance: *This is a cancer-PKD related core that collects primary cyst tissue for cell culture phenotyping and molecular studies.*											

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Wallace DP	Allen Foundation		2/1/2014	1/31/2017	ROLE OF PHOSPHODIESTERASES IN CYST GROWTH IN AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD)	$75,000	$90,000	CB	100%	$75,000	$90,000
Cancer Relevance: *This is a cancer-PKD investigational grant to study how cAMP levels are abnormally regulated in PKD cells, tissues, and mouse models, and how this cAMP drives abnormal cyst cell proliferation.*											
Wallace DP	NovaTarg		9/21/2015	8/31/2017	SYNTHESIZE AND EVALUATE NOVEL, POTENT AND OCT2-SELECTIVE BIGUANIDES FOR LEAD OPTIMIZATION	$86,610	$130,781	CB	100%	$86,610	$130,781
Cancer Relevance: *This is a cancer-PKD related project to develop new small molecule compounds to inhibit the abnormal neoplastic cell proliferation in cystic kidneys.*											
Welch DR	National Foundation for Cancer Research		1/1/2014	12/31/2016	NFCR CENTER FOR METASTASIS RESEARCH	$130,435	$150,000	CB	100%	$130,435	$150,000
			Non-Peer-Reviewed Rearch Subtotals:			$1,117,126	$1,276,610			**$1,117,126**	**$1,276,610**
								CB Grand Totals		**$11,674,979**	**$16,834,444**

PEER-REVIEWED TRAINING PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Gomez C *(Mentor: Neufeld KL)*	DOD	W81XWH-16-1-0115	8/1/2016	7/31/2017	A ROLE FOR APC IN GOBLET CELL FUNCTION AND THE UNFOLDED PROTEIN RESPONSE (UPR)	$108,000	$108,000	CB	100%	$108,000	$108,000
Koestler DC Barohn RJ	NCATS	5KL2TR000119-05	3/1/2014	2/28/2017	HEARTLAND INSTITUTE FOR CLINICAL AND TRANSLATIONAL RESEARCH (INTEGRATIVE GENOMICS FOR UNDERSTANDING THE DEVELOPMENT AND PROGRESSION OF EPITHELIAL OVARIAN CANCER)	$92,742	$92,742	CB	100%	$92,742	$92,742
Pruitt M *(Mentor: Baumann P)*	NCI	1F31CA200228-01	9/1/2015	8/31/2019	THE RANDOMIZATION OF THE TELOMERASE RNA TEMPLATE TO DEFINE THE ROLE OF TELOMERE SEQUENCE IN TELOMERE STRUCTURE, FUNCTION, AND CELLULAR SURVIVAL	$30,188	$30,188	CB	100%	$30,188	$30,188
Zhang Y	NCI	5K22CA184146-02	9/18/2014	8/31/2017	METABOLIC REPROGRAMMING IN LIVER CANCER CELLS BY A NOVEL TUMOR SUPPRESSOR	$31,650	$34,182	CB	100%	$31,650	$34,182
					Peer-Reviewed Training Totals:	$262,580	$265,112			**$262,580**	**$265,112**

Table 2 – Program Members

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Aljitawi	Omar	Internal Medicine - Clinical Oncology	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme II Clinician
Apte	Udayan	Pharmacology, Toxicology & Therapeutics	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full Theme IV
Azuma	Mizuki	Molecular Biosciences	University of Kansas, Lawrence, KS	Associate Professor	Full Theme I & IV
Azuma	Yoshiaki	Molecular Biosciences	University of Kansas, Lawrence, KS	Associate Professor	Full Theme III & IV
Calvet	James	Biochemistry & Molecular Biology	University of Kansas Medical Center, Kansas City, KS	Professor	Full Theme II & IV
Cheng	Nikki	Pathology & Laboratory Medicine	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme II & III
Chien	Jeremy	Cancer Biology	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full Theme IV
Christenson	Lane	Molecular & Integrative Physiology	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme II
Conaway	Joan	Biochemistry & Molecular Biology	Stowers Institute of Medical Research, Kansas City, MO	Professor	Full Theme II & III
Conaway	Ron	Biochemistry & Molecular Biology	Stowers Institute of Medical Research, Kansas City, MO	Professor	Full Theme II & III
Csanaky	Ivan	Division of Clinical Pharmacology, Toxicology and Therapeutic Innovation	Children's Mercy Hospital & Clinics	Research Assistant Professor	Associate Theme IV Clinician
Davido	David	Molecular Biosciences	University of Kansas, Lawrence, KS	Associate Professor	Associate Theme IV
Ding	Wen-Xing	Pharmacology, Toxicology & Therapeutics	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme II & III
Fields	Patrick	Pathology & Laboratory Medicine	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme I & II
Fields	Timothy	Pathology & Laboratory Medicine	University of Kansas Medical Center, Kansas City, KS	Professor	Associate Theme IV

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Freudenthal	Bret	Biochemistry & Molecular Biology & Department of Cancer Biology	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full Theme I
Ganguly	Siddhartha	Internal Medicine - Hematology/Oncology	University of Kansas Medical Center, Kansas City, KS	Professor	Full Theme I Clinician
Gerton	Jennifer	Department of Biochemistry & Molecular Biology	Stowers Institute of Medical Research, Kansas City, MO	Associate Professor	Full Theme IV
Gibson	Matthew		Stowers Institute of Medical Research, Kansas City, MO	Associate Investigator	Full Theme II & IV
Gudima	Severin	Microbiology, Molecular Genetics & Immunology	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full Theme IV
Hagan	Christy	Biochemistry & Molecular Biology	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full Theme III & IV
Hawley	R. Scott		Stowers Institute of Medical Research, Kansas City, MO	Investigator	Full Theme III
Iwakuma	Tomoo	Cancer Biology	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme I, II & III
Jaeschke	Hartmut	Pharmacology, Toxicology & Therapeutics	University of Kansas Medical Center, Kansas City, KS	Professor & Chair	Full Theme II
Jaspersen	Sue		Stowers Institute of Medical Research, Kansas City, MO	Associate Investigator	Full Theme III
Koestler	Devin	Biostatistics	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full Theme III
Krumlauf	Robb		Stowers Institute of Medical Research, Kansas City, MO	Scientific Director	Associate Theme III & IV
Kulesa	Paul	Department of Anatomy & Cell Biology	Stowers Institute of Medical Research, Kansas City, MO	Director of Imaging; Professor	Full Theme IV
Kumar	T. Rajendra	Molecular & Integrative Physiology	University of Kansas Medical Center, Kansas City, KS	Professor	Full Theme I
Lee	Eugene	Urology	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full Theme I & II Clinician

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Lewis-Wambi	Joan	Cancer Biology	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full Theme I & II
Li	Linheng		Stowers Institute of Medical Research, Kansas City, MO	Investigator	Full Theme I
Li	Xiaogang	Internal Medicine/Nephrology	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme I & III
Lundquist	Erik	Molecular Biosciences	University of Kansas Medical Center, Lawrence, KS	Professor	Full Theme I
Mayo	Matthew	Biostatistics	University of Kansas Medical Center, Kansas City, KS	Professor & Chair; Associate Director Shared Resources	Full Theme I
Moise	Alexander	Pharmacology & Toxicology	University of Kansas, Lawrence, KS	Assistant Professor	Full Theme III & IV
Mure	Minae	Chemistry	University of Kansas, Lawrence, KS	Associate Professor	Full Theme I & II
Neufeld	Kristi	Molecular Biosciences	University of Kansas, Lawrence, KS	Associate Professor	Full Theme II & IV
Nicot	Christophe	Center for Viral Oncology	University of Kansas Medical Center, Kansas City, KS	Professor and Director	Full Theme IV
Parnell	Stephen	Biochemistry & Molecular Biology	University of Kansas Medical Center, Kansas City, KS	Research Assistant Professor	Associate Theme III
Paul	Soumen	Pathology & Laboratory Medicine	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Associate Theme IV
Peterson	Kenneth	Biochemistry & Molecular Biology	University of Kansas Medical Center, Kansas City, KS	Professor; Director and Vice Chair	Associate Theme III
Rao	Reena	Nephrology & Hypertension	University of Kansas Medical Center, Kansas City, KS	Assistant Professor of Medicine	Full Theme II
Saadi	Irfan	Anatomy & Cell Biology	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Associate Theme IV
Shnayder	Yelizaveta	Otolaryngology	University of Kansas Medical Center, Kansas City, KS	Associate Professor, ENT	Associate Theme I Clinician

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Slawson	Chad	Biochemistry & Molecular Biology	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full Theme IV
Soares	Michael	Pathology & Laboratory Medicine	University of Kansas Medical Center, Kansas City, KS	University Distinguished Professor	Full Theme IV
Staudinger	Jeff	Pharmacology & Toxicology	University of Kansas, Lawrence, KS	Professor	Associate Theme I
Thomas	Sufi	Otolaryngology & Cancer Biology	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Associate Theme I & IV
Thyfault	John	Molecular & Integrative Physiology	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Associate Theme I
Tran	Pamela	Anatomy & Cell Biology	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full Theme IV
Tsue	Terance	Otolaryngology; Radiation Oncology	University of Kansas Medical Center, Kansas City, KS	Physician-in-Chief, KUCC; Professor, Interim Chair	Full Theme II Clinician
Vivian	Jay	Pathology & Laboratory Medicine	University of Kansas Medical Center, Kansas City, KS	Research Associate Professor	Full Theme I & III
Wallace	Darren	Nephrology & Hypertension	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme I
Ward	Christopher	Medicine-Nephrology	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme IV
Washburn	Michael	Pathology & Laboratory Medicine	Stowers Institute of Medical Research, Kansas City, MO	Director of Proteomics Center; Professor	Full Theme III
Weinman	Steven	Gastroenterology and Hepatology	University of Kansas Medical Center, Kansas City, KS	Professor; Director Liver Center	Full Theme IV Clinician
Welch	Danny	Cancer Biology	University of Kansas Medical Center, Kansas City, KS	Chair & Professor	Full Theme I, II & III
Workman	Jerry		Stowers Institute of Medical Research, Kansas City, MO	Investigator	Full Theme III
Yankee	Thomas	Microbiology, Molecular Genetics & Immunology	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme I & IV

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Zhang	Yuxia (Lisa)	Pharmacology, Toxicology & Therapeutics	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full Theme III

Table 3 – Program Shared Resource Usage

Shared Resource	Number of program members using the shared resource	Percentage of shared resource usage by program members
Biospecimen (BSR)	10	23%
Biostatistics & Informatics (BISR)	15	26%
Lead Development & Optimization (LDOSR)	12	29%
Transgenic & Gene-Targeting (TGTSR)	17	65%
Clinical Pharmacology (CPSR)	4	19%

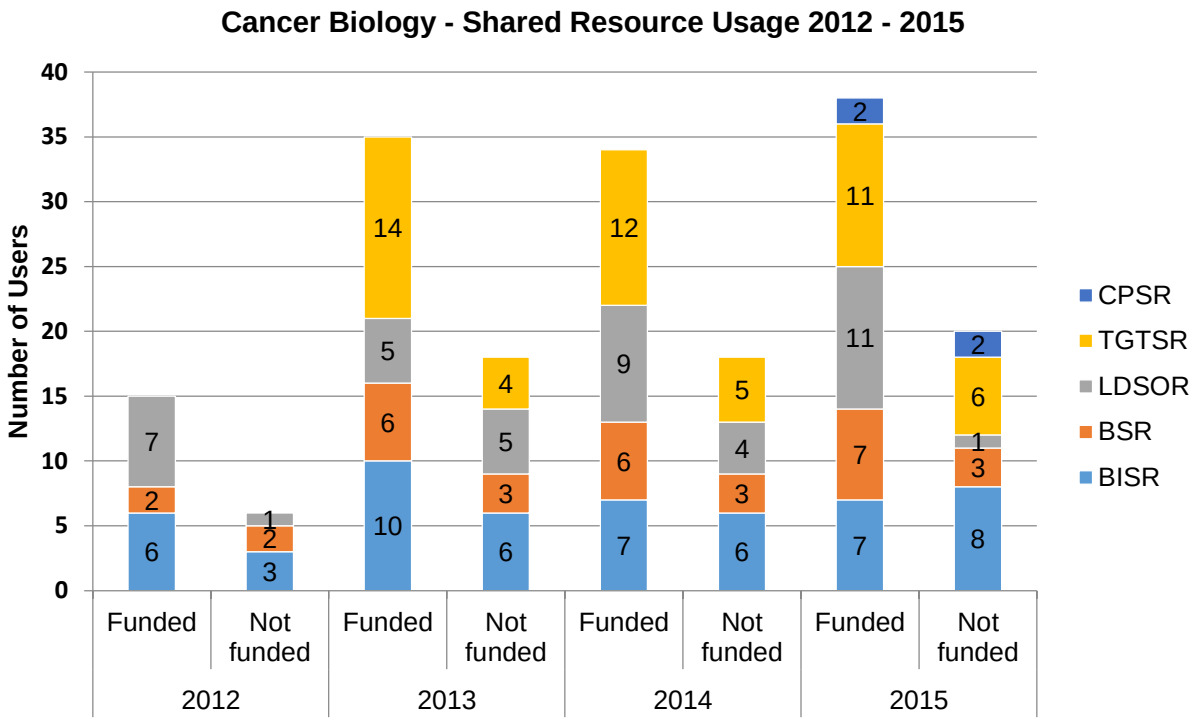


Table 4 – Programmatic Activities

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
2012				
Workgroup	2012 Quarterly	Stowers IAMI KUCC LDOSR	Li (CB) Perry (CB) Sittampalam, Roy, Weir, Broward	Wnt-PTEN target and KBA hit screening compounds
Grant Rounds	Quarterly		KUCC members	Presentation of Specific Aims page for targeted grant submission
Rehearsal Site Visit	1/9/12	Multiple CB	Neufeld, Li, Calvet and other Program Leaders, Jensen	Dress Rehearsal Site Visit
EAB Meeting with CB Researchers	1/24/12		EAB Meeting with CB Researchers	CB Progress and Future Directions
Seminar, KUMC/KU-L (Lawrence)	1/31/12		Animesh Dhar (CPS)	Pancreatic Cancer Stem Cells
Seminar, Lawrence	2/3/12		Erick Lundquist (CB)	UNC-40 control of cell migration
Seminar, Lawrence	2/3/12		Emily Scott (D3ET)	CYP45017A1 in prostate cancer
Seminar, Lawrence	2/3/12		Jeff Staudinger (CB)	Nuclear Receptors
Seminar, Lawrence	2/29/12		Yinghao Wu	Cadherin-mediated cell adhesion
Seminar, KUMC/KU- L	3/6/12		David Albertini	DNA Damage Response
Seminar, KUMC/KU- L	3/13/12		Liang Xu (D3ET)	Cancer Therapeutic Drug Discovery
Leadership Council	3/16/12	Kristi Neufeld, Linheng Li and KUCC Leadership	Roy Jensen	Leadership Council
Cross discipline Research Cancer Prevention Survivorship	3/19/12	Danny Welch	Carol Fabian	Potential projects Between Cancer Biology and CPS (Kiss-1) Recruitment Joan Lewis-Wambi
Seminar, KUMC/KU- L	3/27/12		Mark T. Fisher	Identifying broad based protein binding ligands under physiological conditions
Seminar, Lawrence	3/27/12		Ed Sansville	Drug Development
Workgroup	3/21/12	Liang Xu (D3ET)	Kristi Neufeld (CB)	Joint planning meeting for grant development
Seminar, Lawrence	4/9/12		David Ballou	Drug Discovery
Seminar, Lawrence	4/11/12		Ross Stein (D3ET)	High throughput screening
KUCC Pilot Reviews	4/13/12	Kristi Neufeld and other Program Leaders	Roy Jensen	Review CCSG factual comments
Program Leadership	4/27/12	Kristi Neufeld and Leadership	Roy Jensen	Program Leadership Meeting
Seminar, KUMC/KU- L	4/24/12		Kristi Neufeld (CB)	
Program Leadership	4/27/12	Kristi Neufeld and Leadership	Roy Jensen	Program Leadership Meeting
Seminar, KUMC/KU- L	5/1/12		Nikki Cheng (CB)	CCL2 chemokine signaling in breast tumor microenvironment
CB Seminar, Lawrence	5/8/12		Charlotte Vines (CB)	CCR7 Regulation of Metastasis in breast cancer
Recruitment Committee Meeting	5/8/12	Danny Welch Kristi Neufeld	Jim Calvet	Recruitment for Cancer Center Cancer Biology Department
Strategic Planning	5/9/12		Matt Mayo (CB)	KUCC Shared Resources
CB Seminar, Lawrence	5/9/12	Liang Xu, Jeff Aube (D3ET) Kristi Neufeld (CB)	Lan Lan	Musashi1 project
Workgroup	5/10/12	Liang Xu (D3ET) Anu Roy (D3ET)	Kristi Neufeld	Meeting to discuss HTS for Musashi project
Recruitment Interview	5/14/12	Jeremy Graff	Kristi Neufeld, Jim Calvet, Danny Welch	Recruitment for Cancer Center, Cancer Biology Department

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Seminar, KUMC/KU- L	5/15/12		Jeremy Graff	Translation initiation complex as cancer target
Program Leadership	5/18/12	Kristi Neufeld and Leadership	Roy Jensen	Program Leadership Meeting
Recruitment Committee Meeting	5/22/12	Danny Welch Kristi Neufeld	Jim Calvet	Recruitment for Cancer Center Cancer Biology Department
Seminar, KUMC/KU- L	5/22/12		Ed Ellerbeck (CCPH)	Smoking Cessation
Workgroup	5/23/12	Mizuki Azuma, Kristi Neufeld, Liang Xu (D3ET)	Yoshi Azuma, David Davido (CB)	Strategic Planning CB-Lawrence
Recruitment Committee Meeting	6/5/12	Danny Welch Kristi Neufeld	Jim Calvet	Recruitment for Cancer Center Cancer Biology Department
Seminar, KUMC/KU- L	6/5/12			
CB Seminar, Lawrence	6/7/12		Liang Xu (D3ET)	Animal imaging capabilities
Seminar, KUMC/KU- L	6/12/12			
Seminar, KUMC/KU- L	6/19/12			
Recruitment Committee Meeting	6/19/12	Danny Welch Kristi Neufeld	Jim Calvet	Recruitment for Cancer Center Cancer Biology Department
Program Leadership	6/20/12	Kristi Neufeld and Leadership	Roy Jensen	Program Leadership Meeting
Workgroup	6/22/12	Liang Xu (D3ET) Kristi Neufeld John Karanicolas (D3ET)	Audrey Lamb (D3ET)	Musashi Project
Presentation	6/22/12	Matt Mayo and Kristi Neufeld (CB) Blake Peterson (D3ET)	Byron Gajewski	KUCC Facility Parental Oversight Committee
President's National Cancer Advisory Board	6/26/12	Kristi Neufeld, other leadership	NCAB	Conference Call
Seminar, KUMC/KU- L	6/26/12			
Recruitment Committee Meeting	6/26/12 7/2/12 7/5/12	Danny Welch Kristi Neufeld Jim Calvet		Recruitment for Cancer Center Cancer Biology Department
Planning	7/10/12	Leanne Wiedemann, Kristi Neufeld	Roy Jensen (CPS)	Cancer Biology course planning
Cancer Center Wide Meeting	7/12/12	Kristi Neufeld and CB members	Roy Jensen, Others	Announcement CCSG Designation, News Conference
CB Seminar, Lawrence	7/13/12		Kristi Neufeld (CB)	Musashi Project
Recruitment Committee Meeting	7/17/12 7/19/12 7/20/12	Danny Welch Kristi Neufeld Jim Calvet		Recruitment for Cancer Center Cancer Biology Department
Seminar, CB Department	7/19/12		Naveen Said	Bladder cancer metastasis, integrating omics with therapeutics
Recruitment Committee Meeting	7/24/12 7/30/12 7/31/12	Danny Welch Kristi Neufeld Jim Calvet		Recruitment for Cancer Center Cancer Biology Department
Leadership Council	7/20/12	Kristi Neufeld and others	Roy Jensen	Administrative Issues
Seminar, CB Department	7/20/12		Jason Heschkowitz	Claudin in breast cancers
Seminar, CB Department	7/30/12		Xin Tong	Apigenin inhibits UVB-induced skin cancer: critical role of AMPK and RNA binding proteins
Seminar, KUMC/KU- L	7/31/12		Raju Kucherlapati	Cancer Genomics

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Recruitment Committee Meeting	8/1/12 8/8/12 8/15/12	Danny Welch Kristi Neufeld Jim Calvet		Recruitment for Cancer Center Cancer Biology Department
Seminar, CB Department	8/1/12		Rob Roundbehler	
CB Seminar, Lawrence	8/3/12		Yoshi Azuma (CB)	SUMOylation screen
Strategic Planning	8/3/12		Dan Welch (CB)	
Seminar, KUMC/KU- L	8/7/12		Jeremy Chien (CB)	Genetics and Genomics of Ovarian Cancer
Seminar, CB Department	8/8/12		Dhyan Chandra	XIAP and nucleotide regulation of apoptosome function and caspase activation
Retreat Planning	8/14/12	Kristi Neufeld, Danny Welch, Jim Calvet, Linheng Li	Lisa Harlan-Williams	
Seminar, KUMC/KU- L	8/14/12		Kathleen O'Connor	Modulation of RhoA GTPase function for breast carcinoma invasion
Symposium, KU-L	8/17/12		Jim Calvet (CB)	PKD-a calcium signaling disorder
Seminar, KUMC/KU- L	8/21/12		Dan Dixon (CPS)	New Ways to Control COX-2 in Cancer
Program Leadership	8/24/12	Kristi Neufeld and other leadership	Roy Jensen and others	KUCC Administrative issues
Research Overview	8/27/12	Jeff Aube (D3ET), Ross Stein (D3ET), Kristi Neufeld, Barbara Timmerman (D3ET)	John Karanicolas (D3ET) Anu Roy (D3ET)	COBRE project review
Seminar, KUMC/KU- L	8/28/12		Ossama Tawfik	What does a pap smear have to do with telepathology?
Workgroup	8/31/12	Liang Xu, Kristi Neufeld		Musashi project
Seminar, KUMC/KU- L	9/4/12		Roy Jensen (CPS)	BRCA1: A Mystery Solved and a Path Forward
CB Seminar, Lawrence	9/6/12		David Davido (CB)	Developing method to identify targets of E3 ubiquitin ligases such as BRCA1
Seminar, KUMC/KU- L	9/11/12		Udayan Apte (CB)	Role of nuclear receptors in pathogenesis of hepatocellular carcinoma
KUCC Strategic Plan Meeting	9/13/12	CPS CB	Dan Dixon Tomoo Iwakuma Susan Harp	KUCC Education Strategic Planning and Goals planning meeting
Seminar, KUMC/KU- L	9/18/12		Guillermina Lozano, MD Anderson	Thep53 tumor suppressor pathway in development and tumorigenesis
Retreat Planning	9/19/12	Kristi Neufeld, Danny Welch, Jim Calvet, Linheng Li	Lisa Harlan-Williams (CPS)	
Seminar, KU- L	9/24/12		Katsura Asano	Translational Control
Seminar, KUMC/KU- L	9/25/12		Benyi Li (D3ET)	Nanotech-based tissue specific targeting of PI3K/p110beta for prostate cancer therapy
Strategic Planning	9/27/12			Scientific and Clinical Research Initiatives
Seminar, KUMC/KU- L	10/2/12		Larry Sklar	Analysis of leukocyte integrin function and discovery of regulatory small molecules and repurposed drugs by flow cytometry

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
CB Seminar, Lawrence	10/4/12		Mizuki Azuma (CB)	Ewing Sarcoma
Seminar, Stowers	10/5/12		Harold Varmus	Cancer as a Rare Disease
KUCC Strategic Plan Meeting	10/10/12	CPS CB	Dan Dixon Tomoo Iwakuma Susan Harp	KUCC Education Strategic Planning and Goals planning meeting
KUCC Strategic Plan Meeting	10/12/12	KUCC Executive Team	Dan Dixon Tomoo Iwakuma Susan Harp	KUCC Education Strategic Planning and Goals
Seminar, KU- L	10/15/12		Jeroen Roelofs	Chaperone-assisted assembly of proteasomes
Seminar, KUMC/KU- L	10/16/12		Bruno Hagenbuch	Organic anion transporting polypeptide 1B3, a potential target for cancer diagnosis and therapy
Seminar, KU-L	10/22/12		Mark Fisher	Catching protein transformers and partially folded transitions
Seminar, KUMC/KU- L	10/23/12		Susan Bates	HDAC inhibitors
Seminar, KUMC/KU- L	10/30/12		Adam Krieg (CB)	Hypoxic regulation of histone demethylase mediate cellular response to the tumor microenvironment
Research Overview	10/30/12	Jeff Aube, Barbara Timmerman, Anu Roy, John Karanicolas (D3ET)	Jerry Reeck and Duy Hua	COBRE project review
CB Seminar, Lawrence	11/1/12		John Karanicolas	Disruption of protein-protein interactions: Mcl-1 and Msi-1
KUCC annual symposium	11/8/12	CPS, CCPH CB, D3ET	Len Neckers; Brian Blagg; Kristi Neufeld (CB) Jeffrey Holzbeirlein	
Seminar, KU-L	11/5/12		Erika Geisbrecht	Proteomic and genetic approaches to understand myofiber attachment and stability
Seminar, KUMC/KU- L	11/13/12		T. Rajendra Kumar	Genetics and pathophysiology of gonadotrope tumors
Leadership Council	11/16/12	CPS,CCPH, CB,D3ET	Roy Jensen	Administrative and Research Issues
Seminar, KUMC/KU- L	11/20/12		Prunit Prakash	Thermally triggered drug delivery
Seminar, KU-L	11/26/12		Bryan Phillips	Asymmetric Cell Division: Role of Wnt
Seminar, KUMC/KU- L	11/27/12		Satish Ramalingam	Role of RNA binding protein CELF2 in colon cancer
Seminar, KU-L	12/3/12		Matthew Antonik	DNA damage
Seminar, KUMC/KU- L	12/4/12		Greg Reed	Bioanalysis and pharmacokinetics in drug development:cancer chemotherapy clinical trials
Seminar, KUMC/KU- L	12/11/12		Mridul Mukherji	Role of dioxygenases in HIF signaling
CB Seminar, Lawrence	12/12/12		Tomoo Iwakuma	MDM2 Binding Protein
KUCC Program Leaders Meeting	12/17/12	Kristi Neufeld and other leadership CPS, CB, D3ET	Roy Jensen	Multiple Planning and Administrative Issues

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Research Overview	12/12/12	Kristi Neufeld (CB) Jeff Aube, Barbara Timmerman, Anu Roy, John Karanicolas (D3ET)	Qi Chen, Liang Xu	COBRE project review
Workshop	12/18-19/12	Kristi Neufeld (CB)	Michner; Prisanzano	Contemporary Medicinal Chemistry
2013				
Workgroup	1/13, 12/13	KUCC IAMI LDOSR	Chien (CB) Godwin, Roby, Johnson, G, Weir (D3ET) Fridley (CCPH)	Ovarian Cancer Learning Collaborative
Grant Rounds	17 times in 2013		KUCC members	Presentation of Specific Aims page for targeted grant submission
Workgroup	1/13, 6/13-12/13 Monthly	Stower's IAMI CMH KUCC LDOSR	Li (CB) Weir, Gamis, August (D3ET) Erin Quest (CMH collaborator)	KUCC Pilot Program for Hematological Cancers – to advance target of leukemic stem cell concept to the clinic, translation of target to preclinical proof of concept and early work for Phase I clinical trial
Seminar, KUMC/KU- L	1/8/13		Paul Kulesa (CB)	Reprograming the metastatic phenotype with the embryonic microenvironment
CB Seminar, Lawrence	1/10/13		Minae Mure (CB)	Lysyl Oxidase
Seminar, KUMC/KU- L	1/15/13		Weston Porter	A singleminded effect on tumor metabolism and diet in breast cancer progression
KUCC Leadership Council Meeting	1/18/13	CPS, CCPH CB, D3ET	Kristi Neufeld Linheng Li	KUCC leadership meeting and program updates
Seminar, KUMC/KU- L	1/22/13		Dev Karan	Immune Surveillience
Multi-PI Project Planning Meeting	1/24/13		Kristi Neufeld Jeff Aube, Liang Xu (D3ET)	Planning meeting on omega-3 fatty acids MPI project
Seminar, KU- L	1/28/13		Jeffry Toretsky	EWS-FLI1 sarcoma
Seminar, KUMC/KU- L	1/29/13		Chand Khanna	A comparative approach to metastasis biology and therapy
Seminar, KUMC/KU- L	2/5/13		Stefan Bossmann	Cancer-mediated therapy
CB Seminar, Lawrence	2/6/13		Jeff Aube (D3ET)	Medicinal Chemistry collaborations
Seminar, KUMC/KU- L	2/12/13		Yasuyoshi Ueki	Molecular and cellular pathogenesis of the human craniofacial disorder, Cherubism
Seminar, KU- L	2/18/13		Shrikant Anant (CPS)	Tumor in a Dish and DCAMK
Workgroup	2/21/13	Audrey Lamb, Liang Xu (D3ET) Kristi Neufeld John Karanicolas (D3ET)	Jeff Aube (D3ET)	Musashi Project
Seminar, KUMC/KU- L	2/19/13		Jennifer Klemp (CCPH)	
Program Leadership	2/22/13	CPS, CCPH CB, D3ET	Roy Jensen	KUCC leadership meeting and program updates
Seminar, KUMC/KU- L	2/26/13		Stuart Macdonald	
Seminar, KU- L	3/4/13		Thomas Meek, Glaxo Smith Kline	Drug Discovery
Seminar, KUMC/KU- L	3/5/13		Jonathan Brody	HuR in Pancreatic Cancer

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Seminar, KU-L	3/7/13		Chuabin Mao, U. Oklahoma	Genetic engineering bionanostructures to develop nanobiotechnology and nano medicine
Workgroup	3/7/13	Jeff Aube, Audrey Lamb, Liang Xu (D3ET) Kristi Neufeld (CB)	John Karanicolas (D3ET)	Musashi Project
Seminar, KUMC/KU- L	3/12/13		Minae Mure (CB)	
Seminar, KU- L	3/25/13		Yong Zeng	Microfluidic Biomolecular Analysis
Seminar, KUMC/KU- L	3/26/13		T. Raj Kumar	Estrogens and pituitary null cell tumors
Research Overview	3/19/13	Jeff Aube, Barbara Timmerman(D3ET)	John Karanicolas, Anu Roy (D3ET), Kristi Neufeld, Minae Mure (CB)	COBRE project review
Collaboration	4/1-12/13 Monthly	CM CSU IAMI	Iwakuma (CB) Fulbright, Neville, Weir, Thamm, Roy, Broward, Bruns (D3ET)	Osteosarcoma Midwest Cancer Alliance Project Sarcoma Learning Collaborative
Seminar, KUMC/KU- L	4/2/13		Nita Maihle, Yale	Her2, Her3 and EGFR in ovarian cancer
Workgroup	4/2/13	Jeff Aube, Steve Rogers	Kristi Neufeld (CB)	Musashi Project
CB Seminar, Lawrence	4/4/13		Berl Oakley (D3ET)	A. nidulans as model to study mitosis
Seminar, KUMC/KU- L	4/16/13		David Cheresh, UCSF	Reversing tumor stemness and drug resistance
Seminar, KU-L	4/18/13		Chuabin Mao	Genetic engineering bionanostructures to develop nanobiotechnology and nano medicine
Seminar, KU-L	4/18/13		Rebecca Marquez	Epigenetic regulation of miRNAs in Breast Cancer
Drug Discoveries Working Group	4/22/13	PKD/IAMI/D3ET	Katherine Swenson-Fields	In vivo models of PKD – treatment with oral CCR2 inhibitors -- bioavailability
Seminar, KU-L	4/25/13		Zhijie Chang	CREPT promotes Cyclin D1 expression oppositely to its homologue p15R5
Seminar, KU-L	4/28/13		Raymond Habas	Wnt in Development
Seminar, KUMC/KU- L	4/30/13		Fernando Blanco (CPS)	Anti-tumor role of TGFbeta through TTP
CB Seminar, Lawrence	5/2/13		Dan Dixon (CPS)	Aberrant translational control in cancer as therapeutic target
Seminar, KUMC/KU- L	5/7/13		Chad Slawson (CB)	The)-GlcNAc post-translational modification: New insights into cellular function
EAB Meeting with CB Researchers	5/9/13		Kristi Neufeld Linheng Li	CB Progress and Future Directions
KUCC Leadership Council Meeting	5/17/13	CPS, CCPH CB, D3ET	Kristi Neufeld Linheng Li	KUCC leadership meeting and program updates
Workgroup	5/24/13	Yoshi Azuma, David Davido, Kristi Neufeld,	Mizuki Azuma (CB), Liang Xu (D3ET)	Strategic Planning CB-Lawrence
Seminar, KUMC/KU- L	5/28/13		Paula Cupertino (CCPH)	Minority participation and community partnership in cancer research studies in rural southwest Kansas
Workgroup	6/6/13	Audrey Lamb, Liang Xu (D3ET)	Kristi Neufeld (CB)	Musashi Project

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
CB Seminar, Lawrence	6/6/13		Erik Lundquist (CB)	Worm neurons and melanoma: Rho GTPases in the driver's seat
Seminar, KUMC/KU- L	6/11/13		Julia Zeitlinger, Stowers	Genomics and development
Drug Discoveries Working Group	6/24/13	PKD/IAMI/D3ET	Peter Rowe/James Calvet	BRAF & mTOR Pathways & SPR4 Peptides PKD/H2-GMX Progress
Seminar, KUMC/KU- L	6/25/13		Kimber Richter (CCPH)	An informed decisionmaking tool for increasing access to cessation medications
KUCC Program Meeting	6/28/13	CPS, CCPH CB, D3ET	Kristi Neufeld	KUCC program meeting and updates
Workgroup	7/2/13		Shrikant Anant, Dan Dixon, Shihad Umar (CPS), Liang Xu, Jeff Aube (D3ET), Kristi Neufeld (CB)	KUCC Pilot funded, Strategic Planning for PPG on RNA Binding Proteins
CB Seminar, Lawrence	7/11/13		Blake Peterson (D3ET)	Developing fluorescent chemical probes for cancer targets
CB Retreat Planning	7/11/13	Kristi Neufeld (CB)	Danny Welch (CB)	Brainstorm retreat ideas
Workgroup	7/18/13		Shrikant Anant, Dan Dixon, Shihad Umar (CPS), Liang Xu, Jeff Aube (D3ET), Kristi Neufeld (CB)	KUCC Pilot funded, Strategic Planning for PO1 on RNA Binding Proteins
Drug Discoveries Working Group	7/22/13	PKD/IAMI/D3ET	James Calvet	Presentation – Lonidamine Derivatives Have Properties Expected of Effective Drugs for Treating ADPKD
Membership committee meeting	7/25/13		KUCC leadership	KUCC membership
Workgroup	8/13 11/13	Stowers, IAMI KUCC, LDOSR	Shilatifard (CB) Roy, Weir (D3ET) Erin Quest (CMH collaborator)	KUCC Pilot Program Pediatric Hematological Cancers – Developmental Funds to Identify MLL Drug Target and HTS Assay.
CB Seminar, Lawrence	8/1/13		Yoshi Azuma (CB)	Role of mitotic SUMOylation on the regulation of centrosomeric function
Seminar, KUMC/KU- L	8/6/13		Jeff Rosen, Baylor	EMT programs, therapeutic resistance and cancer stem cells
Seminar, KUMC/KU- L	8/13/13		Jeff Aube (D3ET)	Chemistry and the cancer biologist
Seminar, KU-L	8/20/13		Peter Jones, USC	Cancer epigenome
Workgroup	8/21-22/13	Jeff Aube, Liang Xu, Audrey Lamb (D3ET)	John Karanicolas (D3ET); Kristi Neufeld (CB)	Musashi Project monthly meeting
Kidney Institute Seminar & Drug Discoveries	8/26/13	PKD/IAMI/D3ET	Scott Weir	Sullivan Conference "Drug Discovery & Development Overview"
Seminar, KUMC/KU- L	8/27/13		David Curiel, Wash. U	Strategies to adapt adenovirus for cancer therapy
CB graduate student seminar, KUMC/KU-L	8/28/13			Opportunity for graduate students in CB to present to their peers without faculty
Seminar, KUMC/KU- L	9/3/13		Sushanta Banerjee	Phenotype switching in human pancreatic cancer
CB Seminar, Lawrence	9/5/13		Alex Moise (CB)	Molecular determinants of retinoic acid
Workgroup	9/5/13	Jeff Aube, Liang Xu, Audrey Lamb (D3ET)	John Karanicolas (D3ET); Kristi Neufeld (CB)	Musashi Project monthly meeting
Seminar, KUMC/KU- L	9/17/13		Dan Theodorescu, U. Colorado	Translating metastasis biology into cancer therapy

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Kidney Institute Seminar & Drug Discoveries	9/20/13	Laboratory for Early Stage Translational Research (LESTR)	David Wilson, Director	Sullivan Conference "Target Identification & Validation Early Assay Development"
Mason's Day	9/21/13	Masons	Jill Hamilton-Reeves Roy Jensen (CPS) Ed Ellerbeck (CCPH) Danny Welch	Role of KUCC in addressing cancer control needs in the catchment area
Drug Discoveries Working Group	9/23/13	PKD/IAMI/D3ET	James Calvet (CB) & Alan Yu	General Drug Discovery, Development Discussion (PKD mouse model, H2-GMZ animal dosing, nicotinamide regulatory aspects and patient study design)
Seminar, KUMC/KU- L	9/24/13		Stuart Macdonald	Genomics and systems biology of complex traits in the drosophila model system
CB graduate student seminar, KUMC/KU-L	9/25/13			Opportunity for graduate students in CB to present to their peers without faculty
Workgroup	10/13-11/13 Every 2 weeks	KUCC, IAMI, Kidney Institute, Cardinal Health, Beckloff Assoc, LDOSR	Calvet (CB) Weir (D3ET)	Nicotinamide PKD pilot clinical trial application Data resulted in R21 award for 10 patient PKD clinical trial
Seminar, KUMC/KU- L	10/1/13		Michele Pritchard	The role of Egr-1 in liver regeneration and fibrosis:implications for the development of hepatocellular carcinoma
CB Seminar, Lawrence	10/3/13		Sufi Thomas (CB)	Tumor associate fibroblasts in head and neck cancer
Workgroup	10/4/13	Jeff Aube, Liang Xu, Audrey Lamb (D3ET)	John Karanicolas (D3ET); Kristi Neufeld (CB)	Musashi Project monthly meeting
Seminar, KU-L	10/7/13		Aaron Ciechanover, Nobel laureate; Israel	Ubiquitin-mediated proteolysis
Seminar, KUMC/KU- L	10/8/13		Scott Weir (D3ET)	Our patients are waiting! Product development-focused translational research in academia
Seminar, KUMC/KU- L	10/15/13		Qi Chen	Losing and finding way at C: the role of vitamin C in cancer treatment
CPS-CB Breast Research Discussions	10/21/13		Danny Welch Joan Lewis-Wambi Carol Fabian Pepper Schedin	Discussions
Seminar, KUMC/KU- L	10/22/13		Pepper Schedin, U. Colorado	NSAID-based chemoprevention of postpartum breast cancer
Workgroup	10/23/13		Shrikant Anant, Dan Dixon, Shihad Umar (CPS), Liang Xu, Jeff Aube (D3ET), Kristi Neufeld (CB)	KUCC Pilot funded, Strategic Planning for PO1 on RNA Binding Proteins
Research Overview	10/24/13	Jeff Aube, Barbara Timmerman, Anu Roy, John Karanicolas (D3ET) Kristi Neufeld (CB)	Steve Rogers; Yong Zeng	COBRE project review
Drug Discoveries Working Group	10/28/13	PKD/IAMI/BiOC/ LDO/D3ET	Alan Yu	Nicotinamide Experimental Therapeutics Trial in PKD

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Seminar, KUMC/KU- L	10/29/13		Robert Hines (CCPH)	Rural vs. urban disparities in CRC
Workgroup	11/1/13	Jeff Aube, Liang Xu, Audrey Lamb (D3ET)	John Karanicolas (D3ET); Kristi Neufeld (CB)	Musashi Project monthly meeting
KUCC annual symposium	11/7/13			
Drug Discoveries Working Group	11/11/13	PKD/IAMI/HTS/ LDO/D3ET	Anuradha Roy	Sullivan Conference "Method Optimization, Validation and Large Compound Screens, Confirming Hits, HTS
Drug Discoveries Working Group	11/12/13	PKD/IAMI, Cardinal Health Regulator- Winchell, Holly	Alan Yu	Nicotinamide PKD IND Inquiry
Seminar, KUMC/KU- L	11/12/13		Amato Glaccia, Stanford	Targeted therapies directed against hypoxia-induced genes
Seminar, KUMC/KU- L	11/19/13		Brooke Fridley and Jo Wick (CPS)	Biostatistics, bioinformatics and statistical genomics in medical research
Drug Discoveries Working Group	11/22/13	PKD/BIOC/IAMI	Mike Baltezor (D3ET)	Sullivan Conference "Pharmacokinetics/eADME, in vitro and in vivo formulations"
CB graduate student seminar, KUMC/KU-L	11/27/13			Opportunity for graduate students in CB to present to their peers without faculty
Seminar, KU- L	12/2/13		Eric Baehrecke, UMass Med	Function and regulation of autophagy during cell death
Seminar, KUMC/KU- L	12/3/13		Jason Zell, UC-Irvine	Colorectal cancer risk reduction through polyamine inhibition
CB Seminar, Lawrence	12/5/13		Rebecca Marquez, Liang Xu lab (D3ET)	Epigenetic dysregulation of miRNAs in breast cancer
Seminar, KUMC/KU- L	12/10/13		Prajna Dhar	Understanding lipid-protein interactions in disease: A bioengineering perspective
CB Retreat Planning	12/18/13	Kristi Neufeld, Danny Welch, Jim Calvet, Linheng Li	Lisa Harlan-Williams (CPS)	
Workgroup	12/20/13	Jeff Aube, Liang Xu, Audrey Lamb (D3ET)	John Karanicolas (D3ET); Kristi Neufeld (CB)	Musashi Project monthly meeting
2014				
Grant Rounds	15 times in 2014		KUCC members	Presentation of Specific Aims page for targeted grant submission
Collaboration	1/14- 12/14 Monthly	CMH, CSU, IAMI, LDOSR, TAG, KUCC	Iwakuma (CB) Neville, Weir, Roy (D3ET)	Osteosarcoma Midwest Cancer Alliance Project Sarcoma Learning Collaborative
Workgroup	1/14- 12/14 Quarterly	KUCC IAMI LDOSR Kidney Institute	Calvet, Wallace (CB) Baltezor, Weir, Roy (D3ET)	D3ET and PKD therapeutics-Monthly meetings enabled collaboration to facilitate and advance drug discovery and repurposing projects targeting PKD
Seminar, KUMC/KU- L	1/7/14		John Perry, Linheng Li lab (CB)	Pharmacological inhibition of Wnt and PI3K interaction targets cancer stem cells
1st Annual CB Program meeting	1/9/14		Jason Mills (Wash U.); Paul Kulesa, Hans-Martin Herz, Sufi Thomas, Jeremy Chien, Minae Mure, Udayan Apte, (CB)	Offsite all day retreat for CB program members

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Seminar, KUMC/KU- L	1/14/14		Stephen Kingsmore (CB)	Sequencing pediatric genomes, exomes and TaGSCANs for diagnosis and management guidance
Seminar, KUMC	1/13/14		Kristi Neufeld (CB)	Mouse model reveals roles for nuclear Apc in regulation of differentiation, inflammation & tumor suppression
Seminar, KUMC/KU- L	1/21/14		Yong Zeng (D3ET)	Microfluidic technology: from “omics” to diagnostics
Seminar, KUMC/KU- L	1/28/14		Joseph McGuirk (D3ET)	The evolution of stem cell transplantation and personalized medicine
Collaboration	2/14-4/14	Kidney Institute, KUCC, LDOSR, TAG	Wallace (CB) Weir (D3ET)	resulted in service contract for In vivo models of PKD for preclinical compound testing to be conducted at KUMC
Workgroup	2/14-12/14 Monthly	Stower’s IAMI CMH KUCC LDOSR	Li (CB) Weir, Gamis, August (D3ET) Erin Quest (CMH collaborator)	KUCC Pilot Program for Hematological Cancers – to advance target of leukemic stem cell concept to the clinic, translation of target to preclinical proof of concept and early work for Phase I clinical trial
Seminar, KUMC/KU- L	2/4/14		Ray Perez (D3ET)	Sprouty2 feedback inhibition of PTK signaling
Seminar, KUMC/KU- L	2/11/14		Christina Hester	What can gut microbiota and metabolites reveal about colon pathology
Drug Discoveries Working Group	2/13/14	PKD/IAMI/Thrasos	Darren Wallace (CB)	In vivo models of PKD in preclinical compound testing
Seminar, KUMC/KU- L	2/18/14		Soumen Paul (CB)	Atypical PKC in breast cancer
ACS IRG	2/19/14	CPS, CCPH CB, D3ET	Bruce Kimler, Ajay Bansal, Qi Chen, Ed Ellerbeck, Kimberly Engelman, Brooke Fridley, Heather Gibbs Severin Gudima, Satish Ramalingam, Megha Ramaswamy, Aravind Sugumar, Danny Welch	Review of internal ACS grant applications
Seminar, KU- L	2/24/14		Jim Amos-Landgraf, UM-Columbia	Rat models of Colon Cancer
Seminar, KUMC/KU- L	2/25/14		Stephen Parnell (CB)	Missense mutations in polycystin-1 signaling domains cause polycystic kidney disease
Workgroup	3/14-4/14	Stower’s, Univ of Conn, IAMI, LDOSR TAG, Clin Bioanlyt	Li, Lu (CB) Weir, Lin, Perez, Reed, Baltezor (D3ET)	Nanoparticle formulation low dose Daunorubicin for Leukemia Treatment
Seminar, KUMC/KU- L	3/4/14		Makoto Senoo, U. of Pennsylvania	Stem cells and niche in the epidermis
CB Seminar, Lawrence	3/5/14		Udayan Apte	HHF4alpha in liver cancer
Research Overview	3/6/14	Jeff Aube, Barbara Timmerman, Anu Roy, John Karanicolas (D3ET)	Kristi Neufeld (CB) Liang Xu (D3ET)	COBRE project review

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Seminar, KUMC/KU- L	3/11/14		Lisa VanHoose	Physical and psychosocial predictors of high distress in cancer survivors
Seminar, KUMC/KU- L	3/18/14		Yoshiaki Azuma (CB)	The role of mitotic SUMOylation on the regulation of centromeric functions
Seminar, KUMC/KU- L	3/25/14		Yang Shi, Harvard	A histone methylation network regulates transgenerational epigenetic inheritance
Research Overview	3/28/14	Jeff Aube, B. Timmerman, Anu Roy, L. Xu J. Karanicolas (D3ET) Kristi Neufeld (CB)	Minae Mure (CB) Dan Dixon (CPS)	COBRE project review
Workgroup	4/14-12/14 Monthly	KUCC IAMI LDOSR TAG	Chien (CB) Godwin, Johnson, G, Roby, Weir, Fridley (CCPH)	Ovarian Cancer Learning Collaborative
Workgroup	4/14-12/14 Monthly	Stower's, LDOSR, TAG, KUCC, KUMC, Clin Bioanlyt	Li (CB) Weir, Lin, Perez, Reed, Baltezor (D3ET)	Low dose Daunorubicin for Leukemia treatment, D3ET and LDOSR supported translation of target to preclinical proof of concept and early work for Phase I clinical trial application to start 2nd quarter 2016
Seminar, KUMC/KU- L	4/1/14		Ken Peterson (CB)	Basic science to drug discovery: novel fetal hemoglobin inducers for treatment of sickle cell disease
CB Seminar, Lawrence	4/4/14		Xiao-Feng Sun, Linköping University, Sweden	Risk factors of rectal cancer
Lawrence	4/14/14	All programs	KUCC leadership	Francis Collins Award Ceremony
Seminar, KUMC/KU- L	4/15/14		Edus Warren, U. of Washington	Dissecting GVL and GVHD with 21st century tools
Drug Discoveries Working Group	4/18/14	PKD/IAMI/Thrasos	Darren Wallace (CB)	Thrasos PKD study timelines
Seminar, KUMC/KU- L	4/22/14		Hari Koul	Androgen receptor signaling in prostate cancer
Seminar, KUMC/KU- L	4/29/14		Bhaskar Das	Boron containing retinoids as potential therapeutics for glioblastoma
EAB Content Discussion Meeting	4/30/14		Kristi Neufeld, Linheng Li, Jim Calvet, Dan Welch, Lisa Harlan-Williams, Teresa Christenson	EAB meeting planning
CB Seminar meetings and core facility tour, Lawrence	5/1/14		Joan Lewis-Wambi (CB)	Endocrine resistant breast cancer
Seminar, KUMC/KU- L	5/6/14		Ray Perez (D3ET)	Breaking up is hard to do: disrupting SPRY2-Cbl complexes as an anticancer therapeutic target
EAB Practice Session	5/13/14		Kristi Neufeld, Linheng Li, and others	
Seminar, KUMC/KU- L	5/13/14		Ashim Mitra, UMKC	Novel molecular strategies to improve therapy in drug resistant patients
Drug Discoveries Working Group	5/19/14	PKD/IAMI/D3ET	Peter Rowe	ASARM and SPR4 peptide in vivo and in vitro and impacts on renal phosphate handling

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Seminar, KUMC/KU- L	5/20/14		Jim McCarthy, U. Minnesota	Hyaluronan, the prostate tumor microenvironment and malignant progression
KUCC EAB Meeting	5/22/14	Webster Cavanee	Kristi Neufeld, Linheng Li	CB progress and future directions
Seminar, KUMC/KU- L	5/27/14		Bret Flanders, K-State U.	Nanofabricatiton new tools and adhesion by fast-migrating cells
Seminar, KUMC/KU- L	6/3/14		Mizuki Azuma (CB)	Function of Ewing's Sarcoma EWS protein in skeletogenesis
CB Seminar, Lawrence	6/5/14		Blake Peterson (D3ET)	Synthetic lethal delivery system for targeting cancer
Meeting, CMH and UMKC	6/13/14		Tomoo Iwakuma (CB) Thomas Yankee (CB)	Child Discovery Forum "Advances in Pediatric Cancer Research"
Seminar, KUMC/KU- L	6/10/14		Takefumi Komiya	Development of biomarker to guide treatment in medical oncology
Seminar, KUMC/KU- L	6/17/14		Blake Peterson (D3ET)	Synthetic lethal delivery system for targeting cancer
Seminar, KUMC/KU- L	6/24/14		Ajay Bansal	Role of microRNA in Barrett's esophagus and associated neoplasia
CB Seminar, Lawrence	7/3/14		Animesh Dhar (CPS)	Cumarin compounds in cancer therapy
Workgroup	7/9/13	Kristi Neufeld (CB); Rebecca Marquez	John Karanicolas (D3ET)	Musashi Project monthly meeting
KUCC Leadership Council Meeting	7/18/14	CPS, CCPH CB, D3ET	Kristi Neufeld Linheng Li	KUCC leadership meeting and program updates
Kidney Institute Planning Meeting	7/28/14	PKD/IAMI/D3ET	Alan Yu, James Calvet	P30 Application-PKD -Integrating Drug Discovery & Development
Seminar, KUMC/KU- L	8/5/14		Babalola Faseru	Integrating smoking cessation into routine inpatient service: implications for cancer prevention and control
Seminar, KUMC/KU- L	8/12/14		Jeffrey Miller, U. Minnesota	NK Cells in cancer and transplantation
Seminar, KUMC/KU- L	8/15/14		Naoto Ueno (MD Anderson)	Targeted therapy for triple negative and inflammatory breast cancer
Seminar, KUMC/KU- L	8/19/14		Sami Malek, U. Mich.	CLL
Seminar, KUMC/KU- L	8/22/14		Gary Piazza	Phosphodiesterase 10, a novel cancer target
Seminar, KUMC/KU- L	8/26/14		Joshua Mammen	The beginnings of the journey to the bedside from the bench
Seminar, KUMC/KU- L	8/2/14		Byron Gajewski	KUCC pilot of Bayesian prediction for interim review of studies with slow patient accrual
CB Seminar, Lawrence	9/4/14		Val Stella (D3ET)	A case for prodrugs
Seminar, KUMC/KU- L	9/9/14		Jennifer Rubin Grandis, U. Pittsburg	Precision head and neck cancer medicine
Seminar, KU- L	9/15/14		Mizuki Azuma	Ewings Sarcoma EWS in skeletogenesis
Drug Discoveries Working Group	9/15/14	PKD/IAMI/D3ET	James Calvet	Review on-going drug development projects in PKD group & resources – How can IAMI help with the PKD P30?
Research Overview	9/18/14	Dan Dixon (CPS), B. Timmerman, Anu Roy, L. Xu J. Karanicolas (D3ET) Kristi Neufeld (CB)	Minae Mure (CB) David Weiss	COBRE project review

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Seminar, KUMC/KU- L	916/14		Christina Ciaccio, UMKC	Indoor tobacco legislation and pediatric emergency department
Seminar, KUMC/KU- L	9/23/14		Stephen Fawcett	Participatory research and action with community health partnerships
Workgroup	9/26/13	Jeff Aube, Liang Xu, (D3ET) Kristi Neufeld (CB) Steve Rogers		Musashi Project monthly meeting
KUCC Leadership Council Meeting	9/26/14	CPS, CCPH CB, D3ET	Kristi Neufeld, Linheng Li	KUCC leadership meeting and program updates
Seminar, KUMC/KU- L	9/30/14		Crystal Lumpkins (CCPH)	Conducting transdisciplinary research with faith based organizations
Seminar, KUMC/KU- L	10/2/14		Yoshi Azuma (CB)	Mitotic SUMOylation regulation of centrisomes
CB Seminar, Lawrence	10/6/14		Richard Halberg, U. Wisconsin	APC mutant mouse models
Seminar, KUMC/KU- L	10/7/14		Richard Halberg, U. Wisconsin	Polyclonal intestinal tumors: formation and significance
Seminar, KUMC/KU- L	10/14/14		Ester Chang, Georgetown	Cancer drug delivery challenges
Seminar, KUMC/KU- L	10/21/14		Jonathan Mahnken	Statistical methods for grants and protocols: what information should be conveyed
Seminar, KUMC/KU- L	10/28/14		Anil Rustgi, U. Penn.	Pancreatic regeneration and carcinogenesls
Seminar, KUMC/KU- L	11/4/14		Nabeel Bardessy, Mass. General	Functions of mutant IDH in biliary cancer
CB Seminar, Lawrence	11/6/14		Liang Xu (D3ET)	Fragment based drug discovery of HuR inhibitors
Seminar, KU-Lawrence	11/10/14		Jeremy Chien (CB)	Ovarian Cancer
Fight Colorectal Cancer Research Advocate Training	11/12-13/14	Fight CRC National Advocacy Foundation	Dan Dixon, Shrikant Anant (CPS) Tomoo Iwakuma, Danny Welch (CB) Andy Godwin (D3ET) Kim Engleman (CCPH)	Educational event for Fight CRC research advocates
KUCC annual symposium	11/14/14			
Seminar, KUMC/KU- L	11/18/14		Andy Chan, MIT	Can combination agents enhance the effect of aspirin on CRC
Seminar, KU-Lawrence	12/1/14		Duncan Clark, U. Minn.	Topoisomerase II
Seminar, KUMC/KU- L	12/2/14		Joseph Fontes	Coding and non-coding output of the transcription factor gene ZXDC
CB Seminar, Lawrence	12/4/14		Fariba Behbod (CPS)	Identification of the molecular and cellular basis for the invasive phenotype in human ductal carcinoma in situ
Seminar, KUMC/KU- L	12/9/14		Kim Richter (CCPH)	Tobacco and obesity project
Seminar, KUMC/KU- L	12/16/14		Daniel Aires (CB)	Injectable targeted chemotherapy for locally advanced squamous cell cancer
2015				
Grant Rounds	Monthly (11 times)		KUCC members	Presentation of Specific Aims page for targeted grant submission

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Collaboration	1/15-12/15 Monthly	CMH, CSU, IAMI, LDOSR, TAG, KUCC	Iwakuma (CB) Neville, Weir, Roy (D3ET)	Osteosarcoma Midwest Cancer Alliance Project Sarcoma Learning Collaborative
Seminar, KUMC/KU- L	1/6/15		Mary Markiewicz, KUMC	Novel mouse models give new insight into the role of NKG2D and its ligands in immunity
CB Seminar, Lawrence	1/8/15		Kristi Neufeld (CB)	Insights from animal models: Inflammation control as a new facet on the tumor suppressor APC gem
Seminar, KUMC/KU- L	1/13/15		Wen Liu, KUMC	Pilot data using a mind-body intervention on quality of life in cancer survivors
KUCC Leadership Council Meeting	1/16/15	CPS, CCPH CB, D3ET	Kristi Neufeld	KUCC leadership meeting and program updates
Seminar, KUMC/KU- L	1/20/15		Zigang Dong	Can with win the war against cancer by prevention?
Seminar, KUMC/KU- L	2/3/15		Stefen Bossman, K-State	Protease Signatures in Cancer Diagnosis
CB Seminar, Lawrence	2/5/15		Rick Dobrowsky	Pharmacologic Treatment of Insensate Diabetic Neuropathy: Can a Chaperone Help this Disease Behave?
Seminar, KUMC/KU- L	2/10/15		Animesh Dhar (CPS)	Lysine histone demthylase 3A (KDM3A):Novel epigenetic target for pancreatic cancer progression and metastasis
Seminar, KUMC/KU- L	2/17/15		Omar Aljitawi (CB)	EPO modulation using hyperbaric oxygen to improve engraftment post-hematopoietic stem cell transplantation
Collaboration	2/17/15	Kidney Institute, KUCC, LDOSR, TAG	Wallace, Parnell (CB) Weir (D3ET)	resulted in service contract for In vivo models of PKD for preclinical compound testing to be conducted at KUMC
Seminar, KUMC/KU- L	2/24/15		Tomoo Iwakuma (CB)	Metabolic regulation of mutant p53 stability
Seminar, KUMC/KU- L	2/27/15		Xiushi Sun, K-State	High performance 3D peptide hydrogel matrix and applications
ACS IRG	2/27/15	CPS, CCPH CB, D3ET	Bruce Kimler, Ajay Bansal, Kimberly Engelman, Brooke Fridley, Heather Gibbs Jill Hamilton-Reeves Robin Hines, William Jewell, & Severin Gudima, Eugene Lee, Satish Ramalingam, Danny Welch (CB)	Review of internal ACS grant applications
Seminar, KUMC/KU- L	3/3/15		Peter Nelson	The prostate cancer genome: lessons for precision oncology
CB Seminar, Lawrence	3/5/15		Berl Oakley	γ-tubulin: a Multitasking Cell Organizer
Workgroup	3/5/15		Shrikant Anant, Dan Dixon, Shihad Umar (CPS), Liang Xu, Jeff Aube (D3ET), Kristi Neufeld (CB)	KUCC Pilot funded, Strategic Planning for PPG on RNA Binding Proteins

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
EAB Content Discussion Meeting	3/5/15		Kristi Neufeld, Linheng Li, Danny Welch, Jim Calvet, Lisa Harlan-Williams, Roy Jensen Teresa Christenson	EAB meeting planning
Research Overview	3/10/15	Jeff Aube, B. Timmerman, L. Xu J. Karanicolas (D3ET) Kristi Neufeld (CB)	Anu Roy, (D3ET) Dan Dixon (CPS)	COBRE project review
Seminar, KUMC/KU- L	3/10/15		Thomas Yankee (CB)	The Ikaros family of transcription factors in T-Cell development and leukemogenesis
Seminar, KUMC/KU- L	3/17/15		Scott Weir (D3ET) Shrikant Anant (CPS)	CPX-POM- a novel, promising treatment for non-muscle invasive bladder cancer
EAB Practice Session	3/24/15	CB program	Kristi Neufeld Linheng Li and others	
EAB Practice Session	4/7/15	CB program	Kristi Neufeld Linheng Li and others	
Seminar, KUMC/KU- L	4/7/15		Craig Cameron, Penn State	Misregulated mitochondrial transcription and disease
Workgroup	4/9/15		Shrikant Anant, Dan Dixon, Shihad Umar (CPS), Liang Xu, Jeff Aube (D3ET), Kristi Neufeld (CB)	KUCC Pilot funded, Strategic Planning for PPG on RNA Binding Proteins
CB Seminar, Lawrence	4/13/15		David Drubin, UC Berkeley	Harnessing actin dynamics for endocyte trafficking
Seminar, KUMC/KU- L	4/14/15		Wen-Xing Ding (CB)	Autophagy and Nrf-2: two double-edged swords in cancer
Seminar, KUMC/KU- L	4/20/15		Mark Hixon, Takeda	Drug Discovery
Seminar, KUMC/KU- L	4/24/15		Gloria Su, Columbia	Pancreatic Cancer
Seminar, KUMC/KU- L	4/28/15		John Karanicolas (D3ET)	New computational approaches for addressing non-traditional drug targets
Seminar, KUMC/KU- L	5/5/15		Udayan Apte	Role of hepatocyte nuclear factor 4 alpha in hepatocellular carcinoma
Research Overview	5/7/15	Jeff Aube, Anu Roy, B. Timmerman, L. Xu J. Karanicolas (D3ET) Kristi Neufeld (CB) Dan Dixon (CPS)	Tomoo Iwakuma (CB) Steve Rogers, KU-Lawrence	COBRE project review
CB Seminar, Lawrence	5/7/15		David Davido (CB)	Develop in vitro assay to detect ICP0 HSV-1 E3 ligase substrates
Seminar, KUMC/KU- L	5/11/15		Raelene Wouda, K-State	Companion animals as cancer research models: Comparative Oncology
KUCC Leadership Council Meeting	5/15/15	CPS, CCPH CB, D3ET	Kristi Neufeld, Linheng Li, Jim Calvet	KUCC leadership meeting and program updates

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
ACS IRG	5/15/15	CPS, CCPH CB, D3ET	Bruce Kimler, Ajay Bansal, Kimberly Engelman, Brooke Fridley, Heather Gibbs Jill Hamilton-Reeves Robin Hines, William Jewell, Severin Gudima, Eugene Lee, Satish Ramalingam, Danny Welch (CB)	Review of internal ACS grant applications
Seminar, KUMC/KU- L	6/2/15		David Davido (CB)	Regulation of the HSV-1 Life Cycle: Role of virulence host factors
Seminar, KUMC/KU- L	6/23/15		Barry Skikne, Celgene Corp	Performing clinical studies in hematology/oncology: a pharmaceutical perspective
Meeting	7/7/15		Neufeld (CB) Weir, Schoenen, Godwin, McGuirk (D3ET) Ramalingam (CPS) Kimminau (CCPH) Chastain, Rosenthal (CMH)	D3ET Project and Program presentations
KUCC Leadership Council Meeting	7/10/15	CPS, CCPH CB, D3ET	Kristi Neufeld, Linheng Li, Jim Calvet	KUCC leadership meeting and program updates
KUCC Membership Committee Meeting	7/15/15	CPS, CCPH CB, D3ET	Kristi Neufeld, Linheng Li, Jim Calvet	Discussion of current and new member applications
Presentation	7/16/15	KUCC IAMI Novation IQ	Welch (CB) Weir, Kumar (D3ET) Jensen (CPS)	Presentation/ introduction of Novation IQ technology for ablation of cancerous cells
Seminar, KUMC/KU- L	8/4/15		Ashim Mitra, University of Missouri Kansas City	Novel Prodrug Strategies to Overcome Cancer
Seminar, KUMC/KU- L	8/11/15		Jeremy Chien (CB)	Ovarian Cancer Genomics: Peering through the forest in search of trees
Seminar, KUMC/KU- L	8/18/15		Roy Jensen (CPS)	Global Cancer Issues
Seminar, KUMC/KU- L	8/25/15		Liang Xu (D3ET)	“Drug the undruggable”: Molecular cancer therapy targeting RNA-binding protein HuR
Meeting to Discuss Increasing Interaction between Cancer Biology and CPS Breast Investigators	8/26/15	CB-CPS	Carol Fabian Christy Hagan	Decision to Start a Translational Research Conference monthly meeting.
Seminar, KUMC/KU- L	9/15/15		Shellie Ellis (CCPH)	Physician Decision Making in Low-Risk Prostate Cancer
Seminar, KUMC/KU- L	9/11/15		Adam Krieg (CB)	Hypoxia, histone demethylases, and ovarian cancer
KUCC Leadership Council Meeting	9/18/15	CPS, CCPH CB, D3ET	Kristi Neufeld, Linheng Li, Jim Calvet	KUCC leadership meeting and program updates
CB Seminar, Lawrence	10/1/15		Mizuki Azuma (CB)	O-GlcNAcylation of Ewing sarcoma proteins
Seminar, KUMC/KU- L	10/13/15		Anna Zolkiewska, K-State	ADAM12: a new modulator of breast cancer stem cell signaling pathways
Seminar, KU-L	10/19/15		Andrew Byrd, NCI	Allostery and Dynamics of Ubiquitination
Seminar, KUMC/KU- L	10/20/15		Sufi Thomas (CB)	Disrupting tumor-stroma metabolic symbiosis for head and neck cancer therapy

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Collaboration	10/20/15	Stower's NCATS KUCC TAG Univ of Conn	Li,L (CB), Weir, Sittampalam, (D3ET) Baltezor (core), Reed (Core)	Doxorubicin nanoparticle formulation
Drug Discoveries Working Group	10/23/15	PKD/D3ET/TAG	PKD Kidney Group	General Drug Discovery, Development Discussion (KU Med Chemistry Overview, Grant Opportunities, Screening Targets)
Seminar, KUMC/KU- L	10/27/15		James Brooks, Stanford University	Genomic data for clinical management of genitourinary cancer
Seminar, KUMC/KU- L	11/3/15		Fariba Behbod (CPS)	The identification of molecular and cellular basis for the invasive phenotype in human ductal carcinoma in situ
D3ET Webinar	11/6/15		Linheng Li (CB)	Project Discussion
Seminar, KU-L	11/16/15		Bret Freudenthal (CB)	Clarity through resolution: DNA damage processing
Seminar, KUMC/KU- L	11/17/15		Joan Lewis-Wambi (CB)	Dysregulation of type I interferon signaling in hormone-resistant breast cancer
KUCC Leadership Council Meeting	11/20/15	CPS, CCPH CB, D3ET	Kristi Neufeld, Linheng Li, Jim Calvet	KUCC leadership meeting and program updates
Seminar, KUMC/KU- L	12/1/15		Devin Koestler (CB)	DNA methylation biomakers for estimating the cell composition of whole blood: the rich get richer and the poor get poorer
CB Seminar, Lawrence	12/3/15		James Calvet	Lonidamine derivatives as single compound therapy for PKD
Seminar, KUMC/KU- L	12/8/15		Lisa Zhang (CB)	Nutrient sensing in liver cancer
Drug Discoveries Working Group	12/14/15	PKD/D3ET/TAG	James Calvet	H2-GMZ Endpoint Data for PKD Mice
Seminar, KUMC/KU- L	12/15/15		Eduardo Rosa-Molinar, KU-Lawrence	Microscopy Core Facility Technologies

Table 5 – Cancer Biology

The CB program had 617 publications from 2012-2015; 128 (21%) inter-programmatic, 144 (23%) intra-programmatic, 315 (51%) inter-institutional, and 167 (27%) of these publications were high impact (JIF ≥ 8).

Table 5. Program Publications			
Inter	**Intra**	**External**	**Publication**
With PMCID			
	x	**x**	Agarwal N, Adhikari AS, Iyer SV, Hekmatdoost K, **Welch** DR, **Iwakuma** T. MTBP suppresses cell migration and filopodia formation by inhibiting ACTN4. Oncogene. 2013;32(4):462-70. Epub 2012/03/01. doi: 10.1038/onc.2012.69. PubMed PMID: 22370640; PMCID: PMC3742333.
		x	Agrawal A, Civantos FJ, Brumund KT, Chepeha DB, Hall NC, Carroll WR, Smith RB, Zitsch RP, Lee WT, **Shnayder** Y, Cognetti DM, Pitman KT, King DW, ccc, Lai SY. [(99m)Tc]Tilmanocept Accurately Detects Sentinel Lymph Nodes and Predicts Node Pathology Status in Patients with Oral Squamous Cell Carcinoma of the Head and Neck: Results of a Phase III Multi-institutional Trial. Annals of surgical oncology. 2015;22(11):3708-15. Epub 2015/02/12. doi: 10.1245/s10434-015-4382-x. PubMed PMID: 25670018; PMCID: Pmc4565859.
x		**x**	**Aires** DJ, Rockwell G, Wang T, Frontera J, **Wick** J, Wang W, Tonkovic-Capin M, Lu J, E L, Zhu H, Swerdlow RH. Potentiation of dietary restriction-induced lifespan extension by polyphenols. Biochim Biophys Acta. 2012;1822(4):522-6. Epub 2012/01/24. doi: 10.1016/j.bbadis.2012.01.005. PubMed PMID: 22265987; PMCID: PMC3643308.
			Alan JK, Struckhoff EC, **Lundquist** EA. Multiple cytoskeletal pathways and PI3K signaling mediate CDC-42-induced neuronal protrusion in C. elegans. Small GTPases. 2013;4(4):208-20. Epub 2013/10/24. doi: 10.4161/sgtp.26602. PubMed PMID: 24149939; PMCID: PMC4011816.
			Al-Ani G, Briggs K, Malik SS, Conner M, **Azuma** Y, Fischer CJ. Quantitative determination of binding of ISWI to nucleosomes and DNA shows allosteric regulation of DNA binding by nucleotides. Biochemistry. 2014;53(27):4334-45. Epub 2014/06/06. doi: 10.1021/bi500224t. PubMed PMID: 24898734; PMCID: PMC4100786.
		x	Aleksunes LM, Yeager RL, Wen X, Cui JY, **Klaassen** CD. Repression of hepatobiliary transporters and differential regulation of classic and alternative bile acid pathways in mice during pregnancy. Toxicol Sci. 2012;130(2):257-68. Epub 2012/08/21. doi: 10.1093/toxsci/kfs248. PubMed PMID: 22903823; PMCID: PMC3498745.
x	**x**		Alhafez A, **Aljitawi** OS, **Lin** TL, **Ganguly** S, **Abhyankar** S, **McGuirk** JP. Bendamustine associated with irreversible ascending paralysis. Case reports in hematology. 2013;2013:931519. doi: 10.1155/2013/931519. PubMed PMID: 23533850; PubMed Central PMCID: PMC3600208.
x	**x**		**Aljitawi** OS, Li D, Xiao Y, Zhang D, Ramachandran K, Stehno-Bittel L, **Van Veldhuizen** P, Lin TL, **Kambhampati** S, **Garimella** R. A novel three-dimensional stromal-based model for in vitro chemotherapy sensitivity testing of leukemia cells. Leuk Lymphoma. 2014;55(2):378-91. Epub 2013/04/10. doi: 10.3109/10428194.2013.793323. PubMed PMID: 23566162; PMCID: PMC4090917.
x	**x**		**Aljitawi OS**, Li D, Xiao Y, Zhang D, Ramachandran K, Stehno-Bittel L, **Van Veldhuizen** P, **Lin** TL, **Kambhampati** S, Garimella R. A novel three-dimensional stromal-based model for in vitro chemotherapy sensitivity testing of leukemia cells. Leukemia & lymphoma. 2014;55(2):378-91. doi: 10.3109/10428194.2013.793323. PubMed PMID: 23566162; PubMed Central PMCID: PMC4090917.

Inter	Intra	External	Publication
		x	Antignac C, **Calvet** JP, Germino GG, Grantham JJ, Guay-Woodford LM, Harris PC, Hildebrandt F, Peters DJ, Somlo S, Torres VE, Walz G, Zhou J, Yu AS. The Future of Polycystic Kidney Disease Research--As Seen By the 12 Kaplan Awardees. Journal of the American Society of Nephrology : JASN. 2015;26(9):2081-95. Epub 2015/05/09. doi: 10.1681/asn.2014121192. PubMed PMID: 25952256; PMCID: Pmc4552123.
		x	Antoine DJ, Jenkins RE, Dear JW, Williams DP, McGill MR, Sharpe MR, Craig DG, Simpson KJ, **Jaeschke** H, Park BK. Molecular forms of HMGB1 and keratin-18 as mechanistic biomarkers for mode of cell death and prognosis during clinical acetaminophen hepatotoxicity. J Hepatol. 2012;56(5):1070-9. Epub 2012/01/24. doi: 10.1016/j.jhep.2011.12.019. PubMed PMID: 22266604; PMCID: PMC4127883.
		x	Avena JS, Burns S, Yu Z, Ebmeier CC, Old WM, **Jaspersen** SL, Winey M. Licensing of yeast centrosome duplication requires phosphoregulation of sfi1. PLoS genetics. 2014;10(10):e1004666. Epub 2014/10/24. doi: 10.1371/journal.pgen.1004666. PubMed PMID: 25340401; PubMed Central PMCID: PMCPmc4207612.
		x	Bachanova V, Burns LJ, Ahn KW, Laport GG, Akpek G, Kharfan-Dabaja MA, Nishihori T, Agura E, Armand P, Jaglowski SM, Cairo MS, Cashen AF, Cohen JB, D'Souza A, Freytes CO, Gale RP, **Ganguly** S, Ghosh N, Holmberg LA, Inwards DJ, Kanate AS, Lazarus HM, Malone AK, Munker R, Mussetti A, Norkin M, Prestidge TD, Rowe JM, Satwani P, Siddiqi T, Stiff PJ, William BM, Wirk B, Maloney DG, Smith SM, Sureda AM, Carreras J, Hamadani M. Impact of Pretransplantation (18)F-fluorodeoxy Glucose-Positron Emission Tomography Status on Outcomes after Allogeneic Hematopoietic Cell Transplantation for Non-Hodgkin Lymphoma. Biology of blood and marrow transplantation : journal of the American Society for Blood and Marrow Transplantation. 2015;21(9):1605-11. Epub 2015/05/20. doi: 10.1016/j.bbmt.2015.05.007. PubMed PMID: 25983043; PMCID: Pmc4558181.
		x	Bae KT, Sun H, Lee JG, Bae K, Wang J, Tao C, Chapman AB, Torres VE, **Grantham** JJ, Mrug M, Bennett WM, Flessner MF, Landsittel DP. Novel methodology to evaluate renal cysts in polycystic kidney disease. American journal of nephrology. 2014;39(3):210-7. Epub 2014/03/01. doi: 10.1159/000358604. PubMed PMID: 24576800; PubMed Central PMCID: PMCPmc4020571.
			Bai XT, Moles R, Chaib-Mezrag H, **Nicot** C. Small PARP inhibitor PJ-34 induces cell cycle arrest and apoptosis of adult T-cell leukemia cells. Journal of hematology & oncology. 2015;8:117. Epub 2015/10/27. doi: 10.1186/s13045-015-0217-2. PubMed PMID: 26497583; PMCID: Pmc4619390.
			Bai XT, **Nicot** C. miR-28-3p is a cellular restriction factor that inhibits human T cell leukemia virus, type 1 (HTLV-1) replication and virus infection. The Journal of biological chemistry. 2015;290(9):5381-90. Epub 2015/01/09. doi: 10.1074/jbc.M114.626325. PubMed PMID: 25568327; PubMed Central PMCID: PMC4342455.
			Bai XT, Sinha-Datta U, Ko NL, Bellon M, **Nicot C**. Nuclear Export and Expression of Human T-Cell Leukemia Virus Type 1 tax/rex mRNA Are RxRE/Rex Dependent. J Virol. 2012;86(8):4559-65. PMCID: 3318616.
		x	Balgkouranidou I, Chimonidou M, Milaki G, Tsarouxa EG, Kakolyris S, **Welch** DR, Georgoulias V, Lianidou ES. Breast cancer metastasis suppressor-1 promoter methylation in cell-free DNA provides prognostic information in non-small cell lung cancer. British journal of cancer. 2014;110(8):2054-62. Epub 2014/03/20. doi: 10.1038/bjc.2014.104. PubMed PMID: 24642624; PubMed Central PMCID: PMCPmc3992488.
			Banks CA, Boanca G, Lee ZT, Florens L, **Washburn** MP. Proteins interacting with cloning scars: a source of false positive protein-protein interactions. Scientific reports. 2015;5:8530. Epub 2015/02/24. doi: 10.1038/srep08530. PubMed PMID: 25704442; PMCID: Pmc4336944.

Inter	Intra	External	Publication
x	x	x	**Bansal** A, Hong X, Lee IH, Krishnadath KK, Mathur SC, Gunewardena S, **Rastogi** A, **Sharma** P, **Christenson** LK. MicroRNA Expression can be a Promising Strategy for the Detection of Barrett's Esophagus: A Pilot Study. Clinical and translational gastroenterology. 2014;5:e65. Epub 2014/12/17. doi: 10.1038/ctg.2014.17. PubMed PMID: 25502391; PMCID: PMC4274369.
		x	Belinsky MG, Rink L, Cai KQ, Capuzzi SJ, Hoang Y, **Chien** J, **Godwin** AK, von Mehren M. Somatic loss of function mutations in neurofibromin 1 and MYC associated factor X genes identified by exome-wide sequencing in a wild-type GIST case. BMC cancer. 2015;15:887. Epub 2015/11/12. doi: 10.1186/s12885-015-1872-y. PubMed PMID: 26555092; PMCID: Pmc4641358.
		x	Bellon M, Ko NL, Lee MJ, Yao Y, Waldmann TA, Trepel JB, **Nicot** C. Adult T-cell leukemia cells overexpress Wnt5a and promote osteoclast differentiation. Blood. 2013;121(25):5045-54. doi: 10.1182/blood-2012-07-439109. PubMed PMID: 23660959; PubMed Central PMCID: PMC3689251.
			Bellon M, **Nicot** C. Multiple Pathways Control the Reactivation of Telomerase in HTLV-I-Associated Leukemia. International journal of cancer and oncology. 2015;2(2). Epub 2015/10/03. doi: 10.15436/2377-0902.15.017. PubMed PMID: 26430700; PMCID: Pmc4587533.
			Belousov AB, **Fontes** JD. Neuronal gap junction coupling as the primary determinant of the extent of glutamate-mediated excitotoxicity. J Neural Transm. 2014;121(8):837-46. Epub 2013/11/02. doi: 10.1007/s00702-013-1109-7. PubMed PMID: 24178243; PMCID: Pmc4007417.
			Belousov AB, **Fontes** JD. Neuronal gap junctions: making and breaking connections during development and injury. Trends in neurosciences. 2013;36(4):227-36. doi: 10.1016/j.tins.2012.11.001. PubMed PMID: 23237660; PubMed Central PMCID: PMC3609876.
			Belousov AB, Wang Y, Song JH, Denisova JV, Berman NE, **Fontes JD**. Neuronal gap junctions play a role in the secondary neuronal death following controlled cortical impact. Neurosci Lett. 2012;524(1):16-9. PMCID: 3414632.
x		x	Berg CJ, **Cox** LS, **Choi** WS, **Mayo** MS, Krebill R, Bronars CA, Ahluwalia JS. Assessment of depression among African American light smokers. J Health Psychol. 2012;17(2):197-206. Epub 2011/07/22. doi: 10.1177/1359105311414953. PubMed PMID: 21775497; PMCID: PMC4268862.
		x	Bhushan B, Walesky C, Manley M, Gallagher T, Borude P, Edwards G, Monga SP, **Apte** U. Pro-regenerative signaling after acetaminophen-induced acute liver injury in mice identified using a novel incremental dose model. Am J Pathol. 2014;184(11):3013-25. doi: 10.1016/j.ajpath.2014.07.019. PubMed PMID: 25193591; PMCID: PMC4215032.
	x	x	Bi Q, Ranjan A, Fan R, Agarwal N, **Welch** DR, **Weinman** SA, Ding J, **Iwakuma** T. MTBP inhibits migration and metastasis of hepatocellular carcinoma. Clinical & experimental metastasis. 2015;32(4):301-11. Epub 2015/03/12. doi: 10.1007/s10585-015-9706-5. PubMed PMID: 25759210; PMCID: Pmc4510982.
		x	Bilal MY, Zhang EY, Dinkel B, Hardy D, **Yankee** TM, Houtman JC. GADS is required for TCR-mediated calcium influx and cytokine release, but not cellular adhesion, in human T cells. Cellular signalling. 2015;27(4):841-50. Epub 2015/02/01. doi: 10.1016/j.cellsig.2015.01.012. PubMed PMID: 25636200; PMCID: Pmc4339522.
			Blanco G, **Wallace** DP. Novel role of ouabain as a cystogenic factor in autosomal dominant polycystic kidney disease. American journal of physiology Renal physiology. 2013;305(6):F797-812. doi: 10.1152/ajprenal.00248.2013. PubMed PMID: 23761677; PubMed Central PMCID: PMC3761286.
		x	Bodenstine TM, Vaidya KS, Ismail A, Beck BH, Diers AR, Edmonds MD, Kirsammer GT, Landar A, **Welch DR**. Subsets of ATP-sensitive potassium channel (KATP) inhibitors increase gap junctional intercellular communication in metastatic cancer cell lines independent of SUR expression. FEBS Lett. 2012;586(1):27-31. PMCID: 3249498.

Inter	Intra	External	Publication
			Bohl CR, Harihar S, Denning WL, Sharma R, **Welch** DR. Metastasis suppressors in breast cancers: mechanistic insights and clinical potential. Journal of molecular medicine (Berlin, Germany). 2014;92(1):13-30. Epub 2013/12/07. doi: 10.1007/s00109-013-1109-y. PubMed PMID: 24311119; PubMed Central PMCID: PMCPmc3923422.
x		x	Bojesen SE, Pooley KA, Johnatty SE, ..., **Fridley** BL, ..., Easton DF, Berchuck A, Antoniou AC, Chenevix-Trench G, Dunning AM. Multiple independent variants at the TERT locus are associated with telomere length and risks of breast and ovarian cancer. Nature genetics. 2013;45(4):371-84, 84e1-2. doi: 10.1038/ng.2566. PubMed PMID: 23535731; PubMed Central PMCID: PMC3670748.
		x	Boutell C, **Davido** DJ. A quantitative assay to monitor HSV-1 ICP0 ubiquitin ligase activity in vitro. Methods (San Diego, Calif). 2015;90:3-7. Epub 2015/04/12. doi: 10.1016/j.ymeth.2015.04.004. PubMed PMID: 25862948; PMCID: Pmc4655872.
x	x		Bray WM, Bivona C, Rockey M, Henry D, Grauer D, **Abhyankar** S, **Aljitawi** O, **Ganguly** S, **McGuirk** J, Singh A, **Lin** TL. Outcomes for newly diagnosed patients with acute myeloid leukemia dosed on actual or adjusted body weight. Cancer chemotherapy and pharmacology. 2015;76(4):691-7. Epub 2015/08/02. doi: 10.1007/s00280-015-2829-1. PubMed PMID: 26231954; PMCID: Pmc4725583.
x	x	x	Bronars CA, **Faseru** B, Krebill R, **Mayo** MS, Snow TM, Okuyemi KS, Ahluwalia JS, **Cox** LS. Examining Smoking Dependence Motives among African American Light Smokers. Journal of smoking cessation. 2015;10(2):154-61. Epub 2015/11/12. doi: 10.1017/jsc.2014.7. PubMed PMID: 26557184; PMCID: Pmc4635476.
x	x		Brownback KR, Simpson SQ, **McGuirk** JP, **Lin** TL, **Abhyankar** S, **Ganguly** S, **Aljitawi** OS. Pulmonary manifestations of the pre-engraftment syndrome after umbilical cord blood transplantation. Annals of hematology. 2014;93(5):847-54. doi: 10.1007/s00277-013-1981-0. PubMed PMID: 24346710; PubMed Central PMCID: PMC4109706.
x	x	x	Buchanan TS, **Sanderson Cox** L, Thomas JL, **Nollen** NL, Berg CJ, **Mayo** MS, Ahluwalia JS. Perceived treatment assignment and smoking cessation in a clinical trial of bupropion versus placebo. Nicotine Tob Res. 2013 Feb;15(2):567-71. doi: 10.1093/ntr/nts143. Epub 2012 Sep 4. PubMed PMID: 22949570; PubMed Central PMCID:PMC3611997.
		x	Burns S, Avena JS, Unruh JR, Yu Z, Smith SE, Slaughter BD, Winey M, **Jaspersen** SL. Structured illumination with particle averaging reveals novel roles for yeast centrosome components during duplication. eLife. 2015;4. Epub 2015/09/16. doi: 10.7554/eLife.08586. PubMed PMID: 26371506; PMCID: Pmc4564689.
x		x	Cai S, Alhowyan AA, Yang Q, Forrest WC, **Shnayder** Y, **Forrest** ML. Cellular uptake and internalization of hyaluronan-based doxorubicin and cisplatin conjugates. Journal of drug targeting. 2014;22(7):648-57. Epub 2014/06/04. doi: 10.3109/1061186X.2014.921924. PubMed PMID: 24892741; PMCID: PMC4620033.
		x	Cao Z, Carey TS, Ganguly A, Wilson CA, **Paul** S, Knott JG. Transcription factor AP-2gamma induces early Cdx2 expression and represses HIPPO signaling to specify the trophectoderm lineage. Development (Cambridge, England). 2015;142(9):1606-15. Epub 2015/04/11. doi: 10.1242/dev.120238. PubMed PMID: 25858457; PubMed Central PMCID: PMCPmc4419278.
		x	Cardenas A, **Koestler** DC, Houseman EA, Jackson BP, Kile ML, Karagas MR, Marsit CJ. Differential DNA methylation in umbilical cord blood of infants exposed to mercury and arsenic in utero. Epigenetics. 2015;10(6):508-15. Epub 2015/04/30. doi: 10.1080/15592294.2015.1046026. PubMed PMID: 25923418; PMCID: Pmc4622995.

Inter	Intra	External	Publication
		x	Carey TS, Cao Z, Choi I, Ganguly A, Wilson CA, **Paul** S, Knott JG. BRG1 Governs Nanog Transcription in Early Mouse Embryos and Embryonic Stem Cells via Antagonism of Histone H3 Lysine 9/14 Acetylation. Molecular and cellular biology. 2015;35(24):4158-69. Epub 2015/09/30. doi: 10.1128/mcb.00546-15. PubMed PMID: 26416882; PMCID: Pmc4648823.
		x	Chaib-Mezrag H, Lemacon D, Fontaine H, Bellon M, Bai XT, Drac M, Coquelle A, **Nicot** C. Tax impairs DNA replication forks and increases DNA breaks in specific oncogenic genome regions. Molecular cancer. 2014;13:205. Epub 2014/09/05. doi: 10.1186/1476-4598-13-205. PubMed PMID: 25185513; PubMed Central PMCID: PMCPmc4168069.
x			**Chalise** P, **Koestler** DC, Bimali M, Yu Q, **Fridley** BL. Integrative clustering methods for high-dimensional molecular data. Translational cancer research. 2014;3(3):202-16. Epub 2014/09/23. doi: 10.3978/j.issn.2218-676X.2014.06.03. PubMed PMID: 25243110; PubMed Central PMCID: PMCPmc4166480.
		x	Chavan H, Khan MM, Tegos G, **Krishnamurthy** P. Efficient purification and reconstitution of ATP binding cassette transporter B6 (ABCB6) for functional and structural studies. The Journal of biological chemistry. 2013;288(31):22658-69. doi: 10.1074/jbc.M113.485284. PubMed PMID: 23792964; PubMed Central PMCID: PMC3829351.
		x	Chavan H, **Krishnamurthy P.** Polycyclic Aromatic Hydrocarbons (PAHs) Mediate Transcriptional Activation of the ATP Binding Cassette Transporter ABCB6 Gene via the Aryl Hydrocarbon Receptor (AhR). J Biol Chem. 2012;287(38):32054-68. PMCID: 3442536.
			Chen G, Bradford WD, Seidel CW, **Li R.** Hsp90 stress potentiates rapid cellular adaptation through induction of aneuploidy. Nature. 2012;482(7384):246-50. PMCID: 3276732.
		x	Chen G, Mulla WA, Kucharavy A, Tsai HJ, Rubinstein B, Conkright J, McCroskey S, Bradford WD, Weems L, Haug JS, Seidel CW, Berman J, **Li** R. Targeting the adaptability of heterogeneous aneuploids. Cell. 2015;160(4):771-84. Epub 2015/02/14. doi: 10.1016/j.cell.2015.01.026. PubMed PMID: 25679766; PubMed Central PMCID: PMCPmc4328141.
			Chen G, Rubinstein B, **Li** R. Whole chromosome aneuploidy: big mutations drive adaptation by phenotypic leap. BioEssays: News And Reviews In Molecular, Cellular And Developmental Biology. 2012;34(10):893-900. Epub 2012/08/29. PubMed PMID: 22926916; PubMed Central PMCID: PMC3526072.
			Chen J, Smoyer CJ, Slaughter BD, Unruh JR, **Jaspersen** SL. The SUN protein Mps3 controls Ndc1 distribution and function on the nuclear membrane. The Journal of cell biology. 2014;204(4):523-39. Epub 2014/02/12. doi: 10.1083/jcb.201307043. PubMed PMID: 24515347; PubMed Central PMCID: PMCPmc3926959.
	x		Chen L, Ooi SK, **Conaway** JW, **Conaway** RC. Biochemical assays for analyzing activities of ATP-dependent chromatin remodeling enzymes. Journal of visualized experiments : JoVE. 2014(92):e51721. Epub 2014/11/20. doi: 10.3791/51721. PubMed PMID: 25407555; PMCID: PMC4356568.
	x	x	Chen L, Zhou X, Fan LX, Yao Y, Swenson-Fields KI, Gadjeva M, **Wallace** DP, Peters DJ, Yu A, Grantham JJ, **Li** X. Macrophage migration inhibitory factor promotes cyst growth in polycystic kidney disease. The Journal of clinical investigation. 2015;125(6):2399-412. Epub 2015/05/12. doi: 10.1172/jci80467. PubMed PMID: 25961459; PMCID: Pmc4497763.
			Chen S, Lewallen M, Xie T. Adhesion in the stem cell niche: biological roles and regulation. Development. 2013;140(2):255-65. doi: 10.1242/dev.083139. PubMed PMID: 23250203; PubMed Central PMCID: PMC3597204.
			Cheng X, **Klaassen CD**. Hormonal and chemical regulation of paraoxonases in mice. J Pharmacol Exp Ther. 2012;342(3):688-95. PMCID: 3422525.

Inter	Intra	External	Publication
			Chien J, Kuang R, Landen C, Shridhar V. Platinum-Sensitive Recurrence in Ovarian Cancer: The Role of Tumor Microenvironment. Frontiers in oncology. 2013;3:251. doi: 10.3389/fonc.2013.00251. PubMed PMID: 24069583; PubMed Central PMCID: PMC3781360.
		x	**Chien** J, Sicotte H, Fan JB, Humphray S, Cunningham JM, Kalli KR, Oberg AL, Hart SN, Li Y, Davila JI, Baheti S, Wang C, Dietmann S, Atkinson EJ, Asmann YW, Bell DA, Ota T, Tarabishy Y, Kuang R, Bibikova M, Cheetham RK, Grocock RJ, Swisher EM, Peden J, Bentley D, Kocher JP, Kaufmann SH, Hartmann LC, Shridhar V, Goode EL. TP53 mutations, tetraploidy and homologous recombination repair defects in early stage high-grade serous ovarian cancer. Nucleic acids research. 2015;43(14):6945-58. Epub 2015/04/29. doi: 10.1093/nar/gkv111. PubMed PMID: 25916844; PMCID: Pmc4538798.
		x	Chimonidou M, Kallergi G, Georgoulias V, **Welch** DR, Lianidou ES. Breast cancer metastasis suppressor-1 promoter methylation in primary breast tumors and corresponding circulating tumor cells. Molecular cancer research : MCR. 2013;11(10):1248-57. doi: 10.1158/1541-7786.MCR-13-0096. PubMed PMID: 23744981; PubMed Central PMCID: PMC3868947.
		x	Chipps E, Protzman A, Muhi MZ, Ando S, **Calvet** JP, Islam MR. Nuclear Localization Signal and p53 Binding Site in MAP/ERK Kinase Kinase 1 (MEKK1). Journal of cellular biochemistry. 2015;116(12):2903-14. Epub 2015/05/29. doi: 10.1002/jcb.25238. PubMed PMID: 26018553; PMCID: Pmc4600025.
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Inter	Intra	External	Publication
x			Nazzaro JM, **Klemp** JA, Brooks WM, Cook-Wiens G, **Mayo** MS, Van Acker GM, 3rd, Lyons KE, Cheney PD. Deep brain stimulation lead-contact heating during 3T MRI: single- versus dual-channel pulse generator configurations. The International journal of neuroscience. 2013. doi: 10.3109/00207454.2013.840303. PubMed PMID: 24000873.
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x	x		Rao R, Fiskus W, **Ganguly** S, **Kambhampati** S, **Bhalla** KN. HDAC inhibitors and chaperone function. Advances in cancer research. 2012;116:239-62. Epub 2012/10/24. PubMed PMID: 23088873.
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Inter	Intra	External	Publication
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Inter	Intra	External	Publication
		x	Zhao M, Perry JM, Marshall H, Venkatraman A, Qian P, He XC, Ahamed J, **Li** L. Megakaryocytes maintain homeostatic quiescence and promote post-injury regeneration of hematopoietic stem cells. Nature medicine. 2014. Epub 2014/10/20. doi: 10.1038/nm.3706. PubMed PMID: 25326798.
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OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Kristi Middle Name Last Name*: Neufeld Suffix:

Position/Title*: Associate Professor
Organization Name*: University of Kansas
Department: Molecular Biosciences
Division:
Street1*: Haworth Hall
Street2: 1200 Sunnyside Ave
City*: Lawrence
County: Douglas
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66045-7563

Phone Number*: 785-864-5079 Fax Number:

E-Mail*: klneuf@ku.edu

Credential, e.g., agency login: KNEUFELD

Project Role*: Other (Specify) Other Project Role Category: Project Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Neufeld_Bio_CCSG1019616621.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Linheng Middle Name Last Name*: Li Suffix: PhD

Position/Title*: Senior Investigator
Organization Name*: Stowers Institute for Medical Research
Department:
Division:
Street1*: 1000 E. 50th Streer
Street2:
City*: Kansas City
County: Jackson
State*: MO: Missouri
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 64110-0000

Phone Number*: (816) 926-4000 Fax Number: (816) 926-2000

E-Mail*: lil@stowers.org

Credential, e.g., agency login: LINHENGL

Project Role*: Other (Specify) Other Project Role Category: Project Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Li_L_bio_CCSG1019616622.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ❍ Yes ❍ No

*Agency-Defined Phase III Clinical Trial? ❍ Yes ❍ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ❍ Yes ❍ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

❍ Yes ❍ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

❍ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator / Change of Institution Section

❑ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	CB_Specific_Aims_Final1019616616.pdf
3. Research Strategy*	CB_Research_Strategy_Final1019616615.pdf
4. Progress Report Publication List	Progress_Report_Publications_Blank1019754756.pdf
Human Subjects Section	
5. Protection of Human Subjects	
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	
8. Inclusion of Children	
Other Research Plan Section	
9. Vertebrate Animals	
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	
14. Resource Sharing Plan(s)	Resource_Sharing_Plan__Generic1019913981.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Cancer Biology – Specific Aims

Development of new approaches to cancer treatment is driven by understanding the underlying biology of tumor cells and their surrounding microenvironments. The goal of the Cancer Biology (CB) research program is to understand the molecular mechanisms that define normal and neoplastic cell growth in order to identify and characterize molecules, pathways and processes that are involved in tumor development, growth and progression that can serve as useful biomarkers and/or as new cellular targets for cancer therapeutics and prevention. CB represents the basic science initiatives of The University of Kansas Cancer Center (KUCC) and is unified by member utilization of molecular, biochemical, model organism and cell-based approaches to study the aberrant behavior of cancer cells.

CB members include investigators from multiple disciplines and departments at KUMC, KU-Lawrence and Stowers. CB members have expertise in a wide range of biological, biochemical, molecular biological and genetic methods, all of which are being used to dissect fundamental processes related to the genesis or progression of cancer. CB has taken advantage of historical strengths in liver, gastrointestinal, kidney and the hematopoietic system tumors. Recent recruitments have further strengthened those initiatives as well as efforts in other tumor types (e.g., breast, sarcoma). Rather than a disease-based thematic organization, CB members have expertise that can be organized into four discipline-based themes:

- **Theme I: Cancer Cell Biology and Stem Cell Biology** – These investigators utilize *in vivo* and *in vitro* models to explore intrinsic and extrinsic factors that affect cancer cell behavior. There is increasing appreciation that tumor cell behavior is determined by interactions between intrinsic characteristics of tumor cells and interactions with their microenvironment. This area is especially coming into focus with regard to how tumor stem cells control and are controlled by their niche.
- **Theme II: Cell Proliferation, Differentiation and Death** – Investigators in this theme study mechanisms involved in deregulated cell proliferation, death and differentiation, de-differentiation and trans-differentiation in normal and neoplastic cells. These studies provide a fundamental understanding of cellular responses to anti-cancer therapies as well.
- **Theme III: Chromatin Organization and Transcriptional Regulation** – Investigators in this theme are primarily interested in the mechanisms that contribute to dysregulated expression of wild-type or aberrant oncogenic or tumor suppressing genes. There is considerable enthusiasm related to the therapeutic potential of chromatin modifications.
- **Theme IV: Signaling Pathways and Development** – Investigators in this theme study intracellular signaling pathways that control cellular behavior in normal cells, including embryologic development, and neoplastic cells. Recent development and introduction of drugs that target cancer-related signaling cascades (e.g., BRAF inhibitors for melanoma) have re-ignited enthusiasm for selective agents to treat key signaling pathways. Likewise, recent data highlight the importance of cancer cell metabolism as a driver for neoplastic cell behavior and differential response to therapy. CB investigators are applying their expertise in metabolic syndrome to alterations of cancer cell metabolism.

CB program members' research spans the topics of cancer prevention, tumor progression and treatment. In the past funding period, KUCC supported recruitment of five current CB members to the KUMC faculty. A major goal during the proposed funding period will be to continue strategic recruitment of exceptional, collaborative researchers who have a passion to see discoveries applied to clinical practice and who will contribute to the critical mass with regard to moving the science forward in the most rapid timeframe possible. CB will also support the development of, and introduction of technologies (e.g., shRNA libraries, next generation sequencing, ChIP-sequencing) that will enable identification of cancer causing molecules that would represent novel biomarkers and/or therapeutic targets.

The Specific Aims of CB are to: 1) to promote collaboration that enhances discovery of the mechanisms underlying tumor development, progression and malignant behavior; and 2) to leverage basic science discoveries to inspire pre-clinical and clinical development of novel cancer therapies. To accomplish these initiatives, CB will seek to engage basic researchers and clinical researchers, facilitate sharing of information and ideas, promote synergistic, interdisciplinary collaborations within and between KUCC programs and foster translational research programs that elucidate the causes and progression of cancer and the development of therapies.

Cancer Biology – Research Strategy

Overview

The Cancer Biology (CB) program focuses on understanding the molecular mechanisms that define normal and neoplastic cell growth in order to identify and characterize molecules, pathways and processes that are involved in tumor development, growth and progression that can serve as useful biomarkers and/or as new cellular targets for cancer therapeutics and prevention. CB represents the basic science initiatives of The University of Kansas Cancer Center (KUCC) and is unified by member utilization of molecular, biochemical and cell-based approaches to understand normal and cancer cell behavior. CB has 49 full and 12 associate members representing 17 departments on four campuses. Between 2012 and 2015, CB members had 617 publications (128 inter- and 144 intra-program) with an average impact factor of 7.3. In 2015, CB members had a total of $16.8M in cancer relevant funding including $2M from NCI and $12.2M from other NIH institutes. Grants from the American Cancer Society (ACS), Susan G. Komen Foundation, National Science Foundation (NSF) and the Department of Defense (DoD) contribute to nearly $1.3M from other peer reviewed sources (**Table 1**).

Table 1. Program Metrics

Members (2015)		
Total	**Full**	**Associate**
61	49 (80%)	12 (20%)

Funding (2015)		
Type	**# of grants**	**$ (total costs)**
NCI	9	2,054,246
Other NIH	37	12,205,355
Other Peer Reviewed	6	1,298,233
Total Peer Reviewed	**52**	**15,557,834**
Other	17	1,276,610
Total Funding	**69**	**16,834,444**

Publications (2012-2015)	
Total	**617**
High Impact (JIF ≥ 8)	167 (27%)
Inter-programmatic	128 (21%)
Intra-programmatic	144 (23%)
External collaborative	315 (51%)

Program Development in Response to NCI Site Visit Review and EAB Input

Table 2. Program Development in Response to Prior Critiques

2011 NIH critique	Program Response
Inter-programmatic publications have been limited	CB has provided opportunities to foster collaboration including annual CB program research meetings (Pecha Kucha style presentations by all program members), program meetings in conjunction with the annual KUCC research symposium, monthly interactive research presentations by KUMC and Stowers investigators for the KU-L campus and pilot funding for collaborative research. Inter-programmatic publications have increased from 9% (2011) to 21% (2015).
CB should discover multiple targets for drug development by D3ET program	This remains a long term goal and CB now has several examples of basic science discoveries leading to drug development by the D3ET program including: **Neufeld** (Msi1), **Li**/**Aljitawi** (phospho-β-catenin/AKT),**Yankee** (CAR T-cell therapy), as well as three investigator-initiated trials: **Lee** (Ethacrynic acid), **Li** (low dose daunorubicin) and **Iwakuma** (auranofin)
Cancer focus in some areas is uncertain – some concern that PKD is not cancer-related	Since the original CCSG site visit, two CB member publications greatly strengthen the relationship between PKD and cancer. When **Ward** was at the Mayo Clinic, he showed protection from colon cancer in persons with germline PKHD1 mutations (Ward, *Hum Genet,* 2011). More recently, **Calvet** collaborated with Eric Engels (NCI) and others in an epidemiological study showing a decreased overall incidence of cancer in ADPKD patients (Wetmore, *J. Am. Soc. Nephrol,* 2014). These two papers suggest that there may be interesting cancer-relevant protective mechanisms associated with PKD mutations that could involve metastatic mechanisms or the tumor microenvironment in PKD patients.

Program Leadership

The CB program is co-led by Kristi **Neufeld** and Linheng **Li.** The leadership, in conjunction with Jim **Calvet**, KUCC Staff Scientist representing KUMC, and Danny **Welch**, Associate Director for Basic Science and Education, has identified a clear research agenda that continues to support fundamental research discovery while promoting opportunities for collaborative, translational research. A portfolio of activities and strategies has been implemented and is planned to achieve the initiatives set forth in this document.

Kristi **Neufeld**, PhD is Professor of Molecular Biosciences at KU-Lawrence. **Neufeld** has been an active member of KUCC since 2005 and has served as a CB program co-leader since 2009. Prior to her relocation to KU in 2003, she was a research assistant professor in the Department of Oncological Sciences at the

Huntsman Cancer Institute. **Neufeld's** laboratory studies the tumor suppressor protein adenomatous polyposis coli (APC) to understand how mutations in the APC gene lead to colon carcinogenesis. In more than a decade of APC research, **Neufeld** has demonstrated that nuclear-cytoplasmic shuttling of APC is critical for its function, with recent identification of roles for nuclear APC in intestinal inflammation and cellular differentiation. Her research now aims to further define both upstream triggers and downstream consequences of nuclear APC. **Neufeld** is the recipient of numerous honors, including the University of Kansas William T. Kemper Fellowship for Teaching Excellence, the Grant K. Goodman Undergraduate Mentor Award, the Leading Light Award for Research and the Steeples Service to Kansans Award. She regularly reviews manuscripts for multiple journals, serves as an *ad hoc* member of various NIH study sections and as Scientist Peer Reviewer for Cancer Research Program Proposals for the DoD. **Neufeld** has served as Principal Investigator and Co-Investigator for R01 Grants and as a Subproject Leader for a Program Project Grant, all from the National Institutes of Health/National Cancer Institute. She currently is Principal Investigator for a multi-PI R01 from NCI and for a grant from the NSF and one of her graduate students was recently awarded funding by the DoD.

Linheng **Li**, PhD is a Senior Investigator at The Stowers Institute for Medical Research and holds an appointment in the Department of Pathology and Laboratory Medicine at KUMC. Currently, his laboratory is focused on hematopoietic and intestinal stem cell compartments and tumors. **Li** is best known for his leadership in the elucidation of the cellular and molecular basis of stem cell niches. His research program spans from understanding the roles of normal stem cells in development and tissue homeostasis to regeneration in the context of signaling from the microenvironment. His group has demonstrated that the Notch, Wnt, BMP and PTEN signaling pathways are involved in developmental regulation and tumorigenesis. He recently proposed the co-existence of active and quiescent adult stem cells in the same tissue in mammals and applied this model to cancer, thus providing a potential mechanism underlying the drug-resistance of cancer, and with it a novel strategy for treatment called the ADAPT method that targets the duality of active and quiescent cancer stem cells. **Li** has received many awards and recognitions including the Missouri Biotechnology Association Excellence in Life Sciences Award, Hudson Prize for excellence in basic biomedical research and election to Fellow of the American Association for the Advancement of Science in 2011 and Fellow of American Gastroenterological Association in 2013. He also serves on the editorial boards of *Cell Stem Cell, Cancer Research, Journal of Biological Chemistry* and *Stem Cells*. **Li** is on the program committee of the International Society for Stem Cell Research. **Li** is uniquely positioned to provide leadership across several disciplines represented within CB.

Together, **Neufeld** and **Li** bring complementary areas of scientific expertise and inter-institutional focus to their position. **Li** is responsible for coordinating and facilitating activities within Themes I (Cancer Cell and Stem Cell Biology) and III (Chromatin Organization and Transcriptional Regulation), while **Neufeld** oversees activities within Themes II (Cell Proliferation, Differentiation and Death) and IV (Signaling Pathways & Development). **Calvet, Li, Neufeld** and **Welch** meet at least semi-annually to evaluate scientific directions, to identify emerging fields and technologies and to recommend directions for CB. This committee also plans seminars, retreats and data exchange venues to promote intra- and inter-programmatic collaborations.

Program Scientific Quality and Cancer Focus

CB is focused on understanding the genetic and cellular networks that control complex biological processes involved in controlling cancer development and progression. It is through this type of basic research that most of the known tumor suppressor genes, oncogenes and other genes related to cancer development have been identified. Research from CB guides the work of translational scientists in our program and in the D3ET program toward the biomolecules and cellular processes that can be monitored to diagnose cancer and/or serve as targets to prevent and treat cancer and other neoplastic diseases.

To decipher the underlying mechanisms of cancer, a variety of model organisms are utilized by CB members. Powerful genetic manipulation afforded by yeast *S. cerevisiae* facilitates the study of chromatin modification and regulation of gene transcription (**Workman**) and chromosome positioning, cohesion and segregation (**Gerton**). The fruit fly *Drosophila melanogaster* has long been used as a genetic model organism to understand interactions between molecules and pathways. Using Drosophila, CB researchers analyze meiosis and meiotic recombination (**Hawley**) and mechanisms controlling signal transduction, cell proliferation and epithelial morphogenesis during organismal development (**Gibson**). Zebrafish provide an *in vivo* whole animal model amenable to genetic screening for second hit mutations or suppressor genes in the study of Ewing

sarcoma (M. **Azuma**). The nematode *C. elegans* is being used as a model to study the normal roles of signaling molecules in cell migration (**Lundquist**) and Xenopus egg extracts are used to study protein complexes that regulate mitosis (Y. **Azuma**). Chick embryos provide a model system to explore tumor cell reprogramming and metastatic ability (**Kulesa**). Finally, mice are used by many of our investigators to study gene regulation and signal transduction (**Apte**, **Calvet**, **Cheng**, **Christenson**, **Csanaky**, **Neufeld**, **Vivian**, **Wallace**, **Welch**, **Zhang**), tissue development (**Kumar**, **Neufeld**), cancer metastases (**Iwakuma**, **Welch**) and stem cell homeostasis (L. **Li**). In addition to organism-based models, CB members utilize a number of cell lines and other experimental models: organoids (**Calvet,** L. **Li, Neufeld**); tumor-to-culture (**Wallace**).

Scientific Highlights

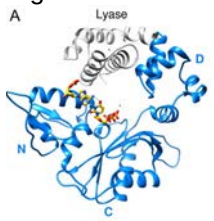
<u>Theme I: Cancer Cell Biology and Stem Cell Biology</u> - To study intrinsic and extrinsic factors that affect cancer cell behavior

Members: KU-Lawrence: Azuma-M, Lundquist, Mure, Staudinger; **KUMC**: Fields-P, Freudenthal, Ganguly, Iwakuma, Jaeschke, Kumar, Lee, Lewis-Wambi, Li-X, Shnayder, Thomas, Thyfault, Tsue, Vivian, Wallace, Welch, Yankee; **Stowers**: Li-L

DNA Repair Strategies that Impact Genomic Stability During Oxidative Stress (**Freudenthal,** R00ES024431)

Significance: Oxidative stress results from many environmental agents and promotes deleterious DNA modifications, ultimately leading to cancer. This negative cellular impact is mediated by DNA polymerases. **Research Description:** Combining enzymology with time-lapse crystallography, **Freudenthal** defines key intermediates during proofreading by DNA polymerase (**Fig.1**). **Innovation:** To understand the origin of these harmful effects, **Freudenthal** uses novel approaches to determine how DNA polymerases process DNA damage, and the influence this has on larger repair complexes. **Impact:** Understanding how oxidative DNA damage arising from environmental exposure is processed identifies novel steps that can be exploited to modulate repair and intervene to enhance human health. **Key Findings** include:

Figure 1. DNA pol β domain/sub-domain organization



- Time-lapse crystallography revealed how oxidized nucleoside 8-oxo-dGTP escapes general discrimination checkpoints by human pol β to be inserted opposite adenine or cytosine and thus drive mutagenesis (**Freudenthal**, *Nature,* 2015)
- A primary defense mechanism employed during the repair of oxidative DNA damage is base excision repair (BER). BER involves the removal of the damaged base and subsequent processing by a multi-protein complex that protects the cell from toxic DNA intermediates. (**Freudenthal**, *Nat Struct Mol Biol,* 2015)
- Published a detailed structural analysis on an impressive list of proteins involved in DNA repair including (Perera, *PNAS*, 2015; Fedeles, *PNAS,* 2015).

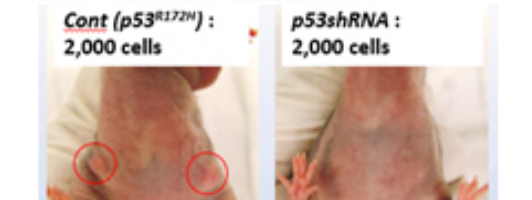
Value Added Aspects: Resources from KUCC were utilized to recruit **Freudenthal** to the Departments of Biochemistry and Molecular Biology and Cancer Biology (KUMC) in 2015. **Freudenthal** is already a valued and strategic collaborator on work testing novel therapeutics addressing this candidate vulnerability of cancers and will exploit this potential through targeted and strategic fostered collaborations.

Mutant p53 as a Therapeutic Target and The Role of MDM2-MTBP Axis in Cancer Metastasis (**Iwakuma**: CA174735)

Significance: Over 50% of human cancers have mutations in the tumor suppressor p53 which regulates cell cycle progression, cell death, senescence, chromosome integrity, DNA repair, and metastasis. **Research Description: Iwakuma** and his group dissect the mechanism of cancer progression using genetically engineered mice, as well as tumor transplantation models. Increased expression of oncoprotein MDM2 which targets p53 for destruction and decreased expression of MTBP, an MDM2 binding partner, are each associated with metastasis of hepatocellular carcinoma and other types of human cancer. **Innovation:** Completion of this NCI funded project will fill the knowledge gaps pertaining to the mechanisms by which MTBP inhibits cancer metastasis and MDM2 promotes tumor progression through inhibition of MTBP. **Impact:** Given that metastasis is the major cause of cancer mortality, this study should provide new insights into mechanisms of metastasis that will significantly contribute to the improved survival and quality of life of many cancer patients. **Key Findings** include:

- MTBP suppresses cancer migration and metastasis independently of p53 (Bi, *Clinical & Experimental Metastasis,* 2015)
- A luciferase-based high throughput screen has identified compounds that reduce the level of mutant p53 (decrease protein stability) but do not affect wild-type p53. (Parrales, *Frontiers in Onc,* 2015).
- Allele-specific silencing of mutant p53 with p53 shRNAs attenuates dominant-negative and gain-of-function activities and provides a novel strategy toward targeted cell therapies (**Fig. 2**; Iyer, *Oncotarget,* 2016)

Figure 2. HTS for destabilizers of mutant p53



shRNA	Cont (p53R172H)		p53shRNA	
Cell number	2,000	5,000	2,000	5,000
Tumor formation	2/3	3/3	0/3	1/3

Tumor formation 70 days after subcutaneous injection into

Transdisciplinary, Collaborative and Value Added Aspects: **Iwakuma** led a collaborative study with **Welch** and clinician **Weinman** which showed that a metastasis suppressor termed MTBP selectively inhibited hepatocellular carcinoma metastasis, but not primary tumor growth (Bi, *Clinical & Experimental Metastasis*, 2015). Regarding mechanism of action, MTBP was found to bind alpha-actinin 4, which resulted in decreased motility, but in a context-dependent manner. These findings emphasize the notion that metastasis suppressors are mediators of cellular responses to different microenvironments, which explains differential effects on cells in orthotopic and ectopic sites. **Iwakuma** also collaborated with **Welch** to identify shRNAs that suppress pancreatic cancer growth and metastasis (Kurahara, *International Journal of Cancer,* 2016) and with **Welch** and **Dhar** (CPS) to reveal an unexpected connection between the metastasis suppressor, KISS1 and metabolism. Re-expression of KISS1 in multiple cell lines reversed the Warburg effect by increasing expression of PPAR-gamma-co-activator 1-alpha (Liu, *Cancer Res,* 2014). Finally, in collaboration with CPS member **Tawfik**, **Iwakuma** established a new orthotopic osteosarcoma mouse model by combining intrafemoral injection of osteosarcoma cells and minimized leakage (Sasaki, *Analytical Biochemistry,* 2015). **Iwakuma** received pilot funds from KUCC prior to his obtaining NCI funding.

Intrinsic and Extrinsic Regulation of Stem Cells (**Li,** Linheng**:** 5U01DK085507)
Significance: Understanding how stem cells are maintained and regulated extrinsically and intrinsically under homeostasis and/or stress will provide insight into cancer stem cell behavior *in vivo*, particularly in response to chemo and radio therapy, thus revealing potential new therapeutic targets and/or elucidating the molecular basis of treatment resistance. **Research Description:** The **Li** group uses a genomics approach to reveal critical genes involved in stem cell regulation and further applies genetics tools in mouse models to show how disturbing the genes or the related pathway affects stem cell function and properties. **Innovation:** The concept that non-coding RNAs serve as intrinsic signaling molecules that play a role in controlling metabolic activity of stem cells, thus preserving stem cells is innovative. **Impact**: Non-canonical Wnt has been shown to be involved in drug resistance (Wnt receptor Frizzled 8 is enriched in therapy-resistant chronic myelogenous leukemia). Megakaryocytes play a role in expanding hematopoietic stem cells (HSCs), which impact bone marrow derived HSC transplantation practice. Both *H19* and *Gtl2* genes were viewed as tumor suppressors, and the related insulin like growth factor (IGF) and mTOR pathways are involved in tumorigenesis and development. **Key Findings**:

- While canonical Wnt signaling is a hot topic in stem cell and cancer research, **Li** was the first to report that non-canonical Wnt signaling plays a critical role in maintaining quiescent adult stem cells (Sugimura, *Cell*, 2012).
- Published first evidence that megakaryocytes, as stem cell progeny, can function as a niche to provide a negative-feedback signal (TGFβ) to maintain hematopoietic stem cells. In response to stress, mega-karyocytes downregulate TGFβ and upregulate FGF to promote stem cell expansion (**Fig. 3**; Zhao, *Nat Med,* 2014).
- First to reveal that imprinted gene loci, such as *H19*, function to control the IGF2-IGF1R pathway via *H19*-derived miR475, thus maintaining the quiescent state of stem cells (Venkatraman, *Nature,* 2013).

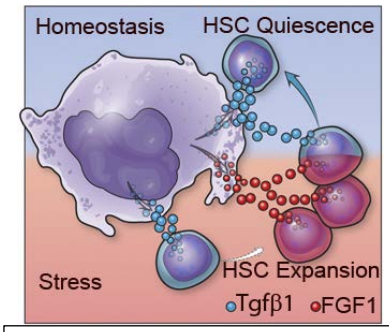


Figure 3.HSC niche stress

- A team led by **Li** and which included **Ding** discovered that the largest miRNA cluster (46 miRNAs) in the mammalian genome located at the imprinted *Gtl2* locus plays a role in suppressing the entire mTOR

pathway, thus controlling biogenesis and metabolism of mitochondria and by doing so protects stem cells (Qian, *Cell Stem Cell,* 2016).

Transdisciplinary and Collaborative Aspects: Li leads a multidisciplinary, multi-organizational team of basic, translational (**Weir**, D3ET) and clinical (**McGuirk**, D3ET; **Aljitawi**) scientists to advance one of his basic research discoveries to a clinical proof of concept trial in acute myeloid leukemia. **Li** demonstrated that β-catenin phosphorylation of serine 552 by Akt is critical for cooperation between the PI3K/Akt and Wnt/β-catenin pathways to drive long-term hematopoietic stem cell expansion including proliferation of leukemia stem cells (Perry, *Genes Dev,* 2011). **Roy** (D3ET) used high throughput screening to identify anthracyclines as inhibitors of Akt/β-catenin cooperation *in vitro* and **Li** showed that anthracyclines, administered at 1/40th the cytotoxic dose, depleted leukemia-initiating stem cells in a validated mouse model. Following this *in vivo* proof of principle, **Lin** (D3ET) and **Li** established the presence of β-catenin with phosphorylated Ser^{552} in 6/10 AML patients, 5/10 B-ALL patients and 7/10 T-ALL patients. As a result, **Lin** and **Perez** (D3ET) have initiated a hypothesis-driven investigator-initiated clinical trial that is enrolling AML and ALL patients to evaluate low-dose daunorubicin as an inhibitor of β-catenin Ser^{552} phosphorylation.

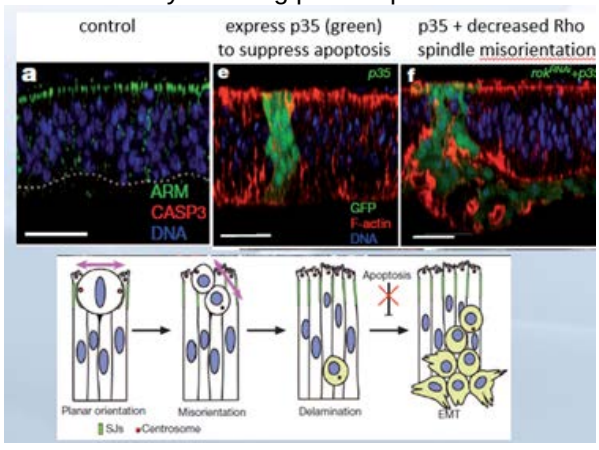
<u>Theme II: Cell Proliferation, Differentiation and Death</u> - To understand the mechanisms controlling tissue homeostasis

Members: KUMC: Aljitawi, Calvet, Cheng, Christenson, Ding, Fields-P, Iwakuma, Jaeschke, Lee, Lewis-Wambi, Rao, Tsue, Welch; **Stowers**: Conaway-J, Conaway-R, Gibson; **KU-Lawrence**: Mure, Neufeld

Mitotic Rounding and Planar Spindle Alignment in Proliferating Epithelia (**Gibson**, R01GM111733)
Significance: The vast majority of metastatic cancers originate from epithelial cells that proliferate excessively and escape their sites of origin through a process known as epithelial-to-mesenchymal transition (EMT). During epithelial cell proliferation, planar alignment of the mitotic spindle coordinates the local process of symmetric cell cleavage with the global maintenance of polarized tissue architecture. Although the disruption of planar spindle alignment is proposed to cause epithelial to mesenchymal transition and cancer, the *in vivo* mechanisms regulating mitotic spindle orientation remain elusive. **Research Description:** Using a genetically tractable model organism, **Gibson** at Stowers studies the molecular mechanisms that coordinate cell division with the maintenance of tissue architecture in healthy epithelia, as well as the pathological process by which defects in these mechanisms result in EMT. **Innovation: Gibson** uses the developing wing epithelia in the genetic model *Drosophila* to dissect mitotic spindle orientation regulation *in vivo*. Further, **Gibson** is developing a model for abnormal EMT events that result from defective spindle orientation *in vivo*, and will provide detailed mechanistic insight into the molecular genetic control of both of these processes. **Impact:** These studies will lead to potential avenues for the early detection and treatment of cancer. **Key Findings**:

- In epithelial tissue, suppression of apoptosis and misdirecting mitotic spindle orientation drove the formation of basally localized tumor-like masses (**Fig. 4**; Nakajima, *Nature*, 2013; Nakajima, *Current Biol,* 2016).
- On the basis of these findings, **Gibson** proposes that the deleterious effects of aberrant spindle alignment are typically corrected by apoptosis, and that suppression of this corrective mechanism could be a common initial driver of epithelial dysplasia and tumorigenesis *in vivo* (**Gibson**, *Theoretical Biology and Medical Modeling*, 2014).

Figure 4. Epithelial junctions maintain tissue architecture by directing planar spindle orientation



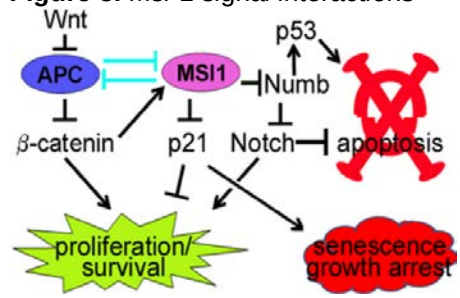
Value Added Aspects: Gibson was awarded an R01 in 2015 and gave the opening research presentation at the 2016 CB retreat to facilitate interaction and collaboration with other CB members.

Exploring Novel Roles for Tumor Suppressor APC (**Neufeld**, multi-PI R01CA178831; NSF- IOS-1456538)
Significance: Over 80% of all colorectal cancers are initiated by mutation of the *Adenomatous polyposis coli (APC)* tumor suppressor gene. Although most commonly recognized as a Wnt signal antagonist, APC has emerging roles in other areas critical for maintaining normal colonic epithelial homeostasis. **Research**

Description: Neufeld and her group use mouse models and cultured cells to decipher novel roles for APC. **Innovation:** Several of the mouse models used were developed by the Neufeld group and represent a unique resource (Zeineldin, *Oncogene*, 2012). **Impact:** Identification of novel roles for Apc might lead to new therapeutic avenues for preventing colon cancer in patients with inflammatory bowel disease. **Key Findings** from this work include:

- Identification of novel roles for nuclear APC in promoting cell differentiation and regulating inflammation (Zeineldin, *Carcinogenesis*, 2014).
- A novel double negative feedback loop between APC and RNA binding protein Musashi-1 (Msi-1) was identified and is expected to impact colon cell homeostasis through interaction with p21, Notch, and p53 pathways (**Fig. 5**; Spears, *J. Biol. Chem*, 2011).
- The APC/ Msi-1 interaction is being examined for efficacy as a potential therapeutic target (Lan, *Mol. Oncology*, 2015).
- Identification and characterization of a gene that modifies tumorigenesis in mice with mutant *Apc*. Results also illustrated the potential for confounding results when using outbred mice for tumorigenicity studies.

Figure 5. Msi-1 signal interactions



Transdisciplinary, Collaborative and Value Added Aspects:
Neufeld collaborated with former D3ET member, Vielhauer, for the *Apc* modifier study, which was further enhanced by KUCC funding of a summer undergraduate scholar (Zeineldin, *Genetics*, 2014). Following up on the biological finding that Msi-1 inhibits translation of APC, and APC suppresses Msi-1 transcription, **Neufeld** began a collaboration with **Xu, Aubé,** and **Karanicolas** (D3ET) to identify small molecule Msi-1 inhibitors using high throughput screening and computer modeling. This collaboration resulted in obtaining a multi-PI R01 from NCI to support this work and publications including (Smith, *Oncotarget*, 2015).

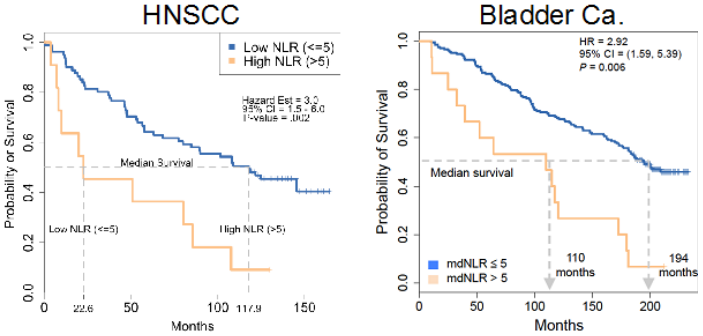
<u>Theme III: Chromatin Organization and Transcriptional Regulation</u> - To understand the biochemical and molecular basis of gene expression and chromatin structure

Members: KU-Lawrence: Azuma-Y, Moise; **KUMC**: Cheng, Cui, Ding, Hagan, Iwakuma, Koestler, Li-X, Peterson, Vivian, Welch, Zhang; **Stowers**: Conaway-J, Conaway-R, Hawley, Herz, Jaspersen, Krumlauf, Washburn, Workman

Interdisciplinary Application of Genomic and Bioinformatics Methods to Describe Cell Heterogeneity and Identify Diagnostic and Prognostic Cancer Biomarkers
Significance: With an eye toward precision oncology, development and application of bioinformatics/ statistical methodologies for analyzing high-throughput 'omic' data is becoming increasingly important. **Research Description: Koestler**, who joined the CB program in 2013, developed and validated a new methodology for analyzing time-course gene expression data (**Koestler**, *Translational Cancer Research*, 2014). He also used statistical and experimental methodologies that he previously developed to identify DNA methylation markers to understand their functional role in the context of colon adenomas and epithelial ovarian cancer (**Koestler**, *Epigenetics*, 2013; **Koestler**, *Modern Pathology,* 2014; **Koestler**, *BMC Medical Genomics,* 2014; **Koestler**, *BMC Bioinformatics*, 2016). **Key Findings** from this research include:

- **Koestler's** team has begun to apply his statistical methods to monitor cell heterogeneity to the identification of diagnostic and prognostic cancer biomarkers. Utilizing the diagnostic epigenomic features of normal circulating neutrophils and lymphocytes in concert with novel bioinformatic algorithms, **Koestler's** team has created a DNA methylation-derived neutrophil-to-lymphocyte ratio (mdNLR) that is significantly associated with cancer occurrence and survival, paralleling what has been reported for the cytological NLR (**Fig. 6**).
- These results mean that our current understanding of mature leukocyte methylomes

Figure 6. DNA methylation-derived neutrophil-to-lymphocyte ratio associates with cancer survival



is sufficient to allow researchers and clinicians to apply epigenetically-based analyses of NLR in clinical and epidemiologic studies of cancer risk and survival.
- Collectively, **Koestler's** work in the area of statistical/bioinformatic epigenomics has resulted in three NIH R01 submissions in 2015-2016, one of which recently scored in the 4th percentile: "*Prospective Immune Profiling Using Methylation Markers and Risk of Pancreatic Cancer*" (**Koestler**, Co-I).

Transdisciplinary, Collaborative and Value Added Aspects: Koestler regularly collaborates with **Chien**, **Fridley** (CCPH) and **Chalise** (CPS). **Koestler** joined forces with faculty from CCPH (**Fridley** and **Ellis**) to respond to the *Prostate Cancer Challenge* organized by the Prostate Cancer Foundation and focused on the development of improved prediction models for survival and toxicity of docetaxel treatment in patients with metastatic castrate resistant prostate cancer (mCRPC) (http://dreamchallenges.org/). The Jayhawk team submitted an ensemble model as a prediction model and were co-winners of 2 out of the 3 challenge questions.

CK2-Dependent Phosphorylation of Progesterone Receptor (PR) Mediates Proliferative Signaling in Breast Cancer (**Hagan**, R00CA166643)
Significance: Progesterone is an ovarian steroid hormone essential for breast development. Different PR isoforms are most often co-expressed in the same tissues, and cells that express only a single PR isoform are rare, except in breast cancer where the normal 1:1 ratio is frequently altered. The goal of this research proposal is to determine how proteins that interact with the PR regulate its direct phosphorylation, thereby dictating PR isoform-specific transcriptional events at genes important for breast cancer cell proliferation, pro-survival, and expansion of the stem cell compartment (**Hagan**, *BMC Med,* 2014). **Research Description:** Preliminary data from the **Hagan** lab suggests that PR, together with the potent pro-inflammatory signaling molecule STAT5A, may drive pro-inflammatory gene signatures in breast cancer. **Innovation:** Understanding how PR isoform-specific regulation is achieved may allow one to modulate/inhibit the proliferative actions of PR in the breast, while preserving protective anti-proliferative activities in other tissues. **Impact:** These studies could open the way to new treatments that may prevent or reverse the development of early cancerous steroid receptor-positive breast lesions and/or provide novel PR-based additions to the current repertoire of largely estrogen receptor-based endocrine therapies. **Key Findings** from this project include:
- PR-B CD domain-dependent recruitment of phosphatase DUSP6 and CK2 is required for PR-B phosphorylation on Ser81 (**Hagan**, *Nucleic Acids Res,* 2013). This complex is required for PR-B–dependent expression of STAT5A. STAT5A then complexes with Ser81-phosphorylated PR-B on a specific-subset of PR-target genes, such as Wnt1.
- JAK/STAT-dependent control of phospho-Ser81 PR-B target genes regulates critical genes involved in mammary gland development, stem cell maintenance/expansion and early breast cancer progression.

Collaborative and Value Added Aspects: Hagan joined the faculty in the Departments of Biochemistry and Molecular Biology and Cancer Biology (KUMC) in 2015 with KUCC funds to support her recruitment package. Since her arrival, **Hagan** has been successful in obtaining additional research funding from the V Foundation for Cancer Research, the DoD and Komen. Breast cancer research is expanding in CB and as such, we planned the 2016 Program meeting to emphasize this theme including Dr. Sukumar (Johns Hopkins) as the keynote speaker. In addition to a talk by **Hagan**, other CB speakers included a graduate student from the **Lewis-Wambi** lab who described her efforts to determine whether abnormal interferon signaling might be the cause of aromatase inhibitor-resistance in breast cancers. (Choi, *Breast Cancer Res,* 2015). A postdoc from **Cheng's** lab also spoke at the CB meeting and described how breast carcinoma associated fibroblasts (CAFs), which show increased expression of numerous soluble factors including growth factors and cytokines, overexpress the chemokine CXCL1, a key regulator of tumor invasion and chemo-resistance. The **Cheng** group found that TGFβ negatively regulates CXCL1 expression in CAFs through Smad2/3 binding to its promoter, and through suppression of hepatocyte growth factor (HGF)/c-Met autocrine signaling (Fang, *PLoS One,* 2015). We anticipate future interactions between these labs as well as other breast cancer researchers **Fabian, Jensen,** and **Behbod** in the CPS program.

Regulation of Metastasis by Mitochondrial DNA (**Welch**, Komen SAC110037; NFCR, R01CA134981)
Significance: Metastasis is responsible for >90% of cancer morbidity and mortality. And some patients are more susceptible to metastasis than others, based not only on the type of tumor they have, but also to underlying genetics. **Research Description:** Previous publications from Kent Hunter's lab at NCI have mapped metastasis modifier loci for mouse mammary tumors and have identified syntenic regions in humans. The **Welch** lab identified an alternative genetic explanation involving mitochondrial polymorphisms and

developed a new mouse model in which nuclei were placed onto different mitochondrial backgrounds (termed MNX for mitochondrial-nuclear exchange). **Innovation:** The MNX mouse represents an unprecedented way to examine the contributions of mitochondrial genetics to complex diseases. **Impact:** These studies have the potential to stratify patients' risk for developing metastases as well as mapping anterograde and retrograde nuclear-mitochondrial signaling that controls metastasis. **Key Findings** from this research include:

- In collaboration with colleagues at the University of Alabama-Birmingham Comprehensive Cancer Center (UAB CCC), **Welch** has determined that mitochondrial DNA polymorphisms present in the MNX mice can replicate the changes in metastatic efficiency.
- Preliminary data show that the MNX mice show selective nuclear DNA epigenetic changes associated with specific mitochondrial polymorphisms (Feeley, *Cancer Res*, 2015).

Transdisciplinary, Collaborative, and Value Added Aspects: To date, this project has been performed in collaboration with colleagues at UAB CCC, where **Welch** and colleagues developed the mice. Since moving to KUMC in 2011, Welch has been working with **Vivian** and the Transgenic & Gene-Targeting shared resource to develop new MNX mice, freeze embryos, and characterize the existing strains. New initiatives are underway with **Umar** (CPS) to examine whether the microbiome is altered in MNX mice; and **Dixon** (CPS) and **Neufeld** to assess whether mitochondrial polymorphisms alter the aggressiveness in tumors arising in Apc^{Min} mice. In addition, **Welch** and **Mure** received CB program pilot funding to demonstrate that expression of lysyl oxidase-like 2 (LOXL2) in a variety of cell types was associated with initiation of epithelial-to-mesenchymal transition, a process involved in metastasis (Moon, *J. Biol. Chem,* 2013). This work led to a successful R01 application for **Mure** (5R01GM113101). **Welch, Iwakuma** and **Dhar** (CPS) also collaborated to study the role of metastasis suppressor, KISS1 and metabolism as described in Theme I (Liu, *Cancer Res,* 2014).

<u>Theme IV: Signaling Pathways and Development</u> - To understand cellular signaling pathways involved in cancer cell behavior

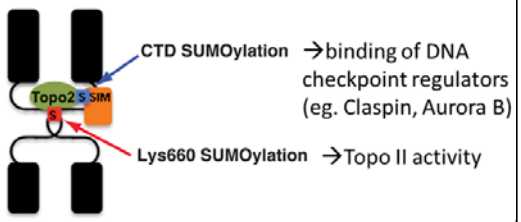
Members: KUMC: Apte, Calvet, Chien, Csanaky, Fields-T, Gudima, Hagan, Nicot, Parnell, Paul, Saadi, Slawson, Soares, Thomas, Tran, Ward, Weinman, Yankee**; KU-Lawrence**: Azuma-M, Azuma-Y, Davido, Moise, Neufeld; **Stowers**: Gerton, Gibson, Krumlauf, Kulesa

Regulation of Kinetochore Function by Topoisomerase II (Yoshi **Azuma**, R01GM112793)
Significance: Faithful segregation of chromosomes is the key event of mitosis, and its dysregulation can lead to aneuploidy and genomic instability, both hallmarks of cancer cells. However, an unanswered question is whether Topo II has additional functions at the kinetochores of chromosomes, where Topo II is most abundant in mitosis and where cell cycle checkpoint signals are generated. **Research Description:** Yoshi **Azuma** has demonstrated specific sites on topoisomerase II that are post-translationally modified by SUMOylation – one site regulates topoisomerase activity and the other regulates binding to DNA checkpoint regulators Claspin and Aurora B (**Fig. 7**; Ryu, *Cell Cycle,* 2015; Ryu, *J. Cell Biol,* 2010). **Innovation**: Combining yeast genetics, Xenopus egg extract cell-free assays, and genetically modified human cell lines, the SUMOylation status of Topo II will be manipulated to control interaction with these regulators. **Impact:** Elucidating the mechanism of faithful segregation of the genome in mitosis is important for determining the molecular basis of human cancers caused by genomic instability. Understanding the novel role of Topo II in maintenance of genomic stability via regulation of Aurora B kinase, could lead to the development of therapeutics targeting this function of Topo II.
Key Findings:

- Elucidate the regulation of checkpoint helicase PICH by SUMO -ylation during mitosis (Sridharan, *J Biol Chem,* 2015).
- Determine a role for SUMO ligase PIAS1 in UV-induced apoptosis (Sudharsan, *J Cell Sci*, 2012).

Transdisciplinary, Collaborative and Value Added Aspects: In 2008, **Azuma** was co-I on a KUCC pilot grant awarded to **Neufeld** to study Topoisomerase IIα. After meeting at the first CB program retreat, Azuma initiated collaboration with **Lewis-Wambi** to determine the role of SUMOylation in hormone-resistant breast cancer. Duncan Clarke (UMN Masonic Comprehensive Cancer Center) is co-PI on **Azuma**'s R01.

Figure 7. Regulation of Chromosome segregation by Topo II

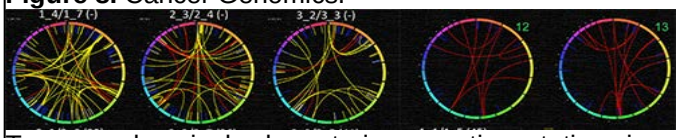


SUMOylation of topoisomerase II α C-terminal domain (CTD) regulates centromeric localization of DNA checkpoint regulators Claspin and Aurora B.

Understanding the genetic basis of ovarian cancer (**Chien**, ACS Research Scholar, multiple DoD)
Significance: Ovarian cancer has a high-mortality rate. **Research Description: Chien** led a multi-investigator team from Mayo, Cambridge, Washington U., U. Minnesota and U. Washington to define the early somatic changes in high-grade serous ovarian cancers (HGSOC). This particular ovarian cancer subtype is the most lethal because it develops from an undefined precursor lesion and may progress rapidly without obvious intermediate steps. **Innovation:** Their study aimed to elucidate early events in this lethal disease, determine whether the pathogenesis of early stage disease is the same or different from more advanced disease, and accelerate the development of genome-based biomarkers for early detection. **Impact:** Advances in the identification of "driver" genetic alterations in cancer will lead to the development of novel therapeutic targets to effectively treat cancer, a prerequisite for "Precision Cancer Medicine." **Key findings** include:

- Analysis of whole cancer genomes for 44 low stage and 316 late stage HGSOCs identified *TP53* mutations, tetraploidy and homologous recombination repair defects in early stage cancers (**Fig. 8**; **Chien**, *Nucl. Acids Res,* 2015).
- **Chien** proposes a similar approach could be applied to identify molecular determinants of chemotherapy resistance in ovarian cancer (Cooley, *Pharmacogenomics,* 2015).

Figure 8. Cancer Genomics.

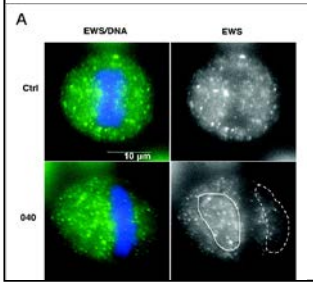


To comprehensively characterize somatic mutations in ovarian cancer genomes, Chien analyzed novel fusion transcripts that are detected in patient-matched primary and recurrent tumor samples (red lines across the circos image) as well as fusion transcripts that are unique to recurrent tumor samples (yellow lines in circos image).

Transdisciplinary, Collaborative and Value Added Aspects: Chien was given CB program pilot funds in 2013 that led to several publications (he has 28 publications since his KUMC arrival in 2012) and his success in obtaining funding from the DoD. **Chien** has teamed with **Godwin** (D3ET) on five published studies, including one aimed to enhance carboplatin sensitivity in cancer cells by targeting mutant p53-induced FoxM1 transcription factor with thiostrepton (Zhang, *Oncotarget,* 2014). Two genomic methodologies were reported by **Chien** and **Godwin**: with CB member **Koestler**, a method for targeted or whole genome sequencing of formalin fixed tissue samples (Munchel, *Oncotarget,* 2015) and with **Fridley** (CCPH), a method for robust gene expression and mutation analyses of RNA-sequencing of formalin-fixed diagnostic tumor samples (Graw, *Sci. Rep,* 2015). Most recently, **Chien** and **Slawson** demonstrated that changes in protein modification by the sugar O-GlcNAc can activate the p53 pathway in ovarian cancer cells (de Queiroz, *J Biol Chem,* 2016); and along with clinician **Tsue** and **Thomas,** found the degree of intra-tumor mutational heterogeneity varies by primary tumor sub-site in head and neck cancers (Ledgerwood, *Oncotarget*, 2016).

The Function of Ewing's Sarcoma Proteins in Mitosis (Mizuki **Azuma**, P20GM103638)
Significance: Ewing's sarcoma, the second most common form of bone cancer in children and adolescents is distinguished by expression of an aberrant chimeric EWS/FLI1 protein containing EWS-derived sequences fused with a portion of the ETS transcription factor FLI1. **Research Description:** The normal role of EWS during development is not well understood. Mizuki **Azuma** and her group recently reported that both the knockdown of EWS, and expression of the EWS/FLI1 fusion protein in zebrafish embryos and HeLa cells leads to mitotic defects (Park, *Cell Cycle,* 2014). **Innovation:** Establishing a mutant EWS zebrafish line will allow **Azuma** to elucidate the molecular mechanism whereby the fusion protein EWS/FLI1 leads to malignant transformation in an animal model. **Impact:** Introducing EWS/FLH into zebrafish at the DNA level will generate a model that can be used to find drugs and therapies for the treatment of Ewing's sarcoma. **Key findings:**

Figure 9. EWS spindle localization is disrupted in OGA knockdown (040) cells.



- EWS regulates the Sox 9 transcription factor to promote development of the Meckel's cartilage which is later ossified to form the lower jaw bone (Merkes, *PLoS One,* 2015).
- EWS participates in organizing the chromosomal passenger protein complex and has been shown to be modified by the sugar O-GlcNAc. **Azuma** collaborated with **Slawson** to examine the relationship between this sugar modification and EWS spindle localization (Lanza, *Cell Cycle,* 2016).
- When the enzyme that removes O-GlcNAc was knocked down in HeLa cells (**Fig. 9**), EWS O-GlcNAcylation was significantly increased, promoting uneven localization of the mitotic midzone. These data suggest that O-GlcNAc cycling is essential for proper mitotic signaling and spindle formation, and alterations in the cycling rate produce aberrant spindles and promote aneuploidy.

Transdisciplinary, Collaborative and Value Added Aspects: Were it not for KUCC, a collaboration between **Azuma** (KU-L) and **Slawson** (KUMC), who met at the first annual CB program meeting in 2013, seems unlikely. **Azuma** and **Slawson** were given pilot funds in 2015 to support their collaboration and have already published a paper together (Lanza, *Cell Cycle*, 2016).

Conducting Cancer Research Relevant to the Needs of the KUCC Catchment Area
CB members conduct basic research which impacts our fundamental understanding of neoplasia. Of note, there are several cancers for which incidence or mortality rate in the KUCC catchment area population falls in the top quartile of all US states and which are represented by research in CB. In this report, we highlighted research studies directly relating to some of these tissues: **Li, Aljitawi**, **Nicot** (Non-Hodgkin Lymphoma); **Calvet**, **Wallace**, **Ward** and **Li-X** (kidney, death rates, males; incidence, females); **Li, Ward** and **Neufeld** (Colorectal, incidence and death rates, males <50yr); M-**Azuma** (childhood cancers). Of all states, Kansas had the lowest rate of females age 13-15 receiving three doses of HPV vaccination (2014 National Immunization Survey). CB clinicians **Shnayder** and **Tsue** and basic scientists **Chien** and **Thomas** all publish in this area (Ledgerwood, *Oncotarget,* 2016; Rasband-Lindquist, *Ear Nose Throat J*, 2016; Rodgers, *Front Oncol,* 2013; Kumar, *JAMA Otolaryn. Head Neck Surg,* 2015).

Transdisciplinary Research Collaboration
Seminars, Workshops and Symposia
In addition to the annual KUCC research symposium and annual CB program retreat, KU-Lawrence, KUMC and Stowers host a number of seminars. All KUCC members are invited to attend, either live or via state-of-the-art videoconferencing facilities. All of the educational efforts of KUCC have been aided by upgrading video conferencing equipment at the KU-Lawrence and KUMC campuses with funds from KUCC to facilitate seminar and classroom transmission by Zoom®, a web-based video service. Besides departmental seminars, CB has taken the lead role in coordinating and advertising a weekly KUCC seminar series with both extramural and intramural speakers from all of the KUCC programs which is broadcast from the KUMC campus. CB also sponsors a monthly seminar series at KU-Lawrence where KUCC members from different programs give more informal presentations of preliminary results. Smaller project-focused meetings are listed in Table 4 in Other Attachments.

Graduate and Post-graduate Education
Since many collaborations are spawned by trainees and since well-trained investigators contribute to exceptional, groundbreaking scientific discovery, **Neufeld** and **Jensen** (CPS) spearheaded the development of a semester long course (Carcinogenesis and Cancer Biology) that has been offered eight times since 2006 to trainees at KUMC, KU-Lawrence and Stowers utilizing video conferencing technology. This course bridges basic research efforts with the educational objectives of KUCC and departments on all campuses. Students participating in this course are contributing to research projects that are both intra-programmatic and inter-programmatic in nature. Faculty from CB at KUMC, KU-Lawrence and Stowers have served on graduate and postdoctoral advisory committees on all three campuses (i.e., KU-Lawrence faculty serve on Stowers and KUMC committees and all possible other permutations). **Welch** served as President for the Cancer Biology Training Consortium (CABTRAC) from 2015-16, which is setting national standards for pre-and post-doctoral education and the criteria for obtaining T32 grants in cancer biology. This course includes faculty from all campuses, integration of clinical faculty and accommodates all of the CABTRAC recommendations. **Welch** and **Jensen** led a national effort to help define the education criteria for CCSG grants (**Welch**, *Cancer Research*, 2015). In January 2016, the Kansas Board of Regents approved MS and PhD programs in cancer biology (CBIO). In addition, **Welch** and **Godwin** (D3ET) have been leaders in developing a postdoctoral affairs office on the KUMC campus.

CB members are strongly encouraged to participate in the training of pre- and post-doctoral and clinical fellows. The annual KUCC research symposium provides an opportunity for students, post-doctoral fellows, and junior faculty to present their research findings in a poster format. At the 2015 retreat, 40 students and postdoctoral fellows, and 24 junior faculty members from CB competed for three KUCC-funded travel awards in each category (CB students won all three places). In addition, four CB graduate students were chosen from submitted abstracts to give short oral presentations to program members at a lunch break-out session. Other opportunities for graduate student and postdoctoral fellow engagement were provided at the annual CB program retreat February, 2015, where two postdoctoral fellows and two graduate students were invited to give

oral research presentations and all students and postdoctoral fellows were invited to join the keynote speaker for a lunchtime discussion about research and career development. KUCC also sponsors a research training program that provides stipends for undergraduate students to work in cancer research labs over the summer. Since 2011, 20 students have participated in this program, nine of the students have chosen mentors from the CB program on the KUMC and KU-Lawrence campuses.

Interactions of Clinicians with Basic Researchers

CB membership includes seven clinicians (**Aljitawi, Csanaky, Ganguly, Lee, Shnayder, Tsue, Weinman**) who have contributed to 75 publications (12% total) since 2012. In addition, CB members collaborate frequently with clinicians from other programs such as **Tawfik** (CPS) and **McGuirk** (D3ET).

Inter-Programmatic Presentations/Target Acceleration Group (TAG)

Since many CB members work on projects that identify potential therapeutic targets, CB and D3ET program leaders thought it would be useful to have a series of presentations to: (1) inform D3ET of potential targets very early in the discovery cycle; and (2) to educate CB members about the capabilities and processes of the D3ET program. Some recent examples include: **Weir** (D3ET) has made several presentations to CB program theme groups. In February 2016, **Weir** presented an overview of the TAG program at the lunch breakout session of the CB annual program meeting. At the D3ET program meeting July 17, 2015, **Neufeld** gave an overview of her experience moving from basic biological studies to an NCI-funded collaborative drug development project with D3ET members **Xu** and **Aubé** (R01CA178831). The PKD group meets in the Kidney Institute with **Weir** and the IAMI and D3ET teams on a monthly basis to discuss ideas for the development of new PKD therapies.

Cancer-PKD Group Interactions

In 2015, **Calvet** and colleagues at The Kidney Institute were awarded a 5-year $5.4M P30 grant to develop the Kansas PKD Research and Translation Core Center. This P30 supports four cores, three of which are led by CB members, Gene Targeting (**Ward**), Epigenetics (**Li, Peterson**), Biomarkers (**Wallace**), and Clinical Research, plus five pilot & feasibility grants per year. KUCC committed to fund one pilot & feasibility grant per year to stimulate further research that proposes to investigate the relationship between PKD and cancer with grant ideas solicited from KUCC program members, as well as from PKD investigators. This program shows strong synergy between the KUCC and PKD research community, and will help PKD investigators focus research on this interesting, but understudied area. The Drug Development component of the P30 currently has three active PKD therapy projects: H2-gamendazole (**Calvet**, Tash), CCR2 antagonists (Swenson-Fields, **Fields**) and nicotinamide (**Li**, Yu), and can support other newly emerging cancer therapies.

Value Added by KUCC to Programmatic Efforts

Targeted recruitment

KUCC support (approx. $3.2M total) was critical for recruiting five current CB members (**Lewis-Wambi**, **Hagan**, **Freudenthal**, **Saha**, **Thomas**) to the KUMC faculty.

Shared Resource Utilization

In 2015, 15 CB members had new or revised grant applications supported by the Biostatistics & Informatics shared resource; 10 had projects supported by the Biospecimen shared resource. CB members accounted for 29% of the overall usage of the Lead Development and Optimization shared resource. Seventeen projects from CB members accounted for 65% of the overall usage of the Transgenic and Gene-Targeting shared resource. Four CB members used the Clinical Pharmacology shared resource.

Faculty Development

As a growing program within an expanding cancer center, CB leadership is keenly aware of the need to promote and nurture young investigators. Professional development of junior faculty will be held to the highest standards and will place the faculty member in a favorable position with respect to promotion and tenure expectations. Junior faculty members are mentored to understand how to develop an appropriate balance between research, teaching, and service. In 2012, **Welch** established “Grant Rounds” in which junior investigators throughout KUCC present ideas for grant applications to each other and more senior faculty for critique and advice. To date, the program has met 50 times and has been very successful. For example, **Cheng** and **Behbod** (CPS) received funding from NIH, DoD and Komen. **Chien** has received multiple grants

from DoD and ACS. **Iwakuma**, initially funded by ACS, was awarded a five-year and **Mure** was awarded a four-year RO1 grant. **Hagan** was recently awarded grants from Komen, DoD and the V Foundation.

Pilot Funding

Since 2012, nine CB members have received 11 KUCC Pilot Project Awards ($35K each) as PI or Co-investigator. Investment in CB investigators and projects is beginning to yield fruit. For example, the seed grant received by **Neufeld** and **Xu** resulted in a new multi-PI NCI R01 grant in 2014. **Iwakuma's** R01 grant success was bolstered by prior KUCC pilot funds. Beyond these bi-annual KUCC awards, for the past two years, CB has used over $30,000 of program development funds to support its members with smaller awards. So far, this funding mechanism has led to an NCI/RO1 (**Mure**), a DoD grant (**Chien**), multiple collaborative publications (including by M. **Azuma** and **Slawson**) and grant applications.

Consortium Partners

CB is excited to welcome Children's Mercy (CM) as a new consortium member. Former CM faculty Stephen **Kingsmore** contributed to CB initiatives and CB looks forward to collaborating with the new Director of The Children's Research Institute at CM, Tom **Curran**. CB immunologist **Yankee** and CM pediatric hematologist-oncologist **Myers** (D3ET) use chimeric antigen receptor (CAR) technology to modify T cells such that they are more potent tumor killers in a protocol in trials in pediatric and adult patients. **Yankee's** student presented this work at the 2016 CB program retreat. The annual KUCC research symposium provides another great opportunity for CB members from KU-Lawrence, KUMC, Stowers and CM to talk to each other and form collaborations. There is ongoing collaboration between investigators among the three main campuses to conduct drug screening for oncogenic pathways originally discovered at Stowers and CM will be actively integrated into this process. In 2015, Scott **Hawley**, Investigator at Stowers, was recognized with a research service award from the regional chapter of the ACS to acknowledge his dedication and service to the ACS and cancer research. **Hawley** has held 32 years of continuous ACS funding, with 18 grants totaling over $2.1M and he has served as an ACS Research Professor for the past ten years.

Future Plans

In the next five years, the Cancer Biology program will continue to serve as the major portal for basic science researchers throughout the University of Kansas by positioning itself to be a key pipeline to early stages of the translational continuum, such as those represented in other KUCC programs.

- KUCC leadership plans to develop a center-wide database of validated cell lines and models that can be used to facilitate research. CB will link this inventory to an investment of effort to uncover resources in specific cancer areas currently lacking, but which can be targeted for development in collaboration with clinician-researchers for translational impact.
- Strategically engage basic cancer biologists with medical oncologists and pathologists to elevate and energize the lab studies for clinical trajectory using strategic pilot funding with an eye towards securing extramural support.
- Integration of our most recent CB recruits from Stowers (**Gerton** and **Washburn**) and CM (**Curran**) with speaking invitations in the weekly seminar series, the KU-Lawrence informal monthly series and annual CB retreat and with targeted pilot funding to encourage collaborations across institutes.
- CB themes are continually revisited to best encompass the common research goals of members. To continue to improve the depth of the already existing scientific themes at KUCC, especially with regard to cancer focus, tumor microenvironment is considered a future research priority. To this end, **Welch** and **Anant** (CPS) applied for a COBRE to develop a Center for Tumor Microenvironment Research and recruit new faculty in this strategic priority for KUCC
- With CB member research productivity in the area of metabolism already demonstrated (**Apte, Chien, Csanaky, Ding, Staudinger, Thyfault, Washburn, Workman**), this is also an emerging theme. Finally, current strength of the CB program in cancer cell genetics and epigenetics (**Chien**, **Gerton**, **Koestler**, **Neufeld**, **Thomas**, **Ward**) sets the stage for prioritizing this initiative for future expansion.
- In addition to developing our research pipeline, we recognize that trainees are a natural mechanism to develop and expand interactions between labs and programs. Therefore, CB, in conjunction with the Department of Cancer Biology will develop a robust degree-granting training program for pre- and postdoctoral fellows throughout the KUCC and will submit applications for The Ruth L. Kirschstein NRSA Institutional Research Training Grant (T32) for Pre and Postdoctoral fellows.

Progress Report Publications

This component has no publications resulting from Cancer Center Support Grant funds.

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Resource Sharing Plan

The University of Kansas Cancer Center (KUCC) and its scientific community understands its responsibility to comply with the instructions for the Resource Sharing Plans provided within the SF 424 (R&R) Application General Instructions and Supplemental Grant Application Instructions. When resources are developed with NIH funds via this Cancer Center Support Grant P30 mechanism, KUCC will ensure findings are made readily available to the NIH and the scientific community in a timely manner.

Data Sharing Plan

KUCC will adhere to the Final NIH Statement on Sharing Research Data and refer to the National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research. KUCC encourages the free flow of information and ideas while recognizing the timeliness of data sharing, the rights and privacy of human subjects and issues related to proprietary data. KUCC encourages data documentation, using a data-sharing agreement and selecting an appropriate method for sharing; considering the sensitivity of the data, the size of the dataset and the volume of requests anticipated.

Additionally, KUCC encourages any user of a CCSG-supported shared resource to acknowledge the source of data upon which their manuscript is based either in the Acknowledgments section or with authorship on the paper. Furthermore, any research project that received direct cost support from the CCSG is encouraged to cite the P30 CA168524. In both cases, citing the P30 CA168524 grant number and then being compliant with the NIH Public Access Policy is required.

Sharing Model Organisms

In the event that a model organism is developed, KUCC will comply with the NIH Policy on Sharing of Model Organisms for Biomedical Research. KUCC will work with the NIH/NCI to share and disseminate the critical model organism in a timely manner.

Genome Wide Associate Studies

When applicable, KUCC will comply with the NIH Genomic Data Sharing Policy. KUCC supports the sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. All research studies funded through the CCSG involving genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data will be submitted in a timely manner.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 016060860

Legal Name*: University of Kansas Medical Center Research Institute, Inc.
Department:
Division:
Street1*: MSN 1039, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Deborah		Maloney	MSM

Position/Title: Director, Sponsored Programs Administration
Street1*: 3901 Rainbow Boulevard
Street2: Mail Stop 1039
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937
Phone Number*: 913-588-1261 Fax Number: 913-588-3225 Email: spa@kumc.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofit Organization

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Cancer Control & Population Health Research Program

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2017	06/30/2022

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Medical Center
Duns Number:	016060860
Street1*:	MS 1008, 3901 Rainbow Boulevard
Street2:	
City*:	Kansas City
County:	Wyandotte
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66160-0000
Project/Performance Site Congressional District*:	KS-003

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ❍ **Yes** ● **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ❍ No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	CCPH_ProjectSummary_Final1019659694.pdf
8. Project Narrative*	
9. Bibliography & References Cited	CCPH_ReferencesCited_Final1019659695.pdf
10.Facilities & Other Resources	
11.Equipment	
12. Other Attachments	CCPH_Other_Attachments_Final21019857899.pdf

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Cancer Control and Population Health – Project Summary

The Cancer Control and Population Health (CCPH) research program in The University of Kansas Cancer Center (KUCC) brings together an interdisciplinary team of researchers focused on: 1) identifying new strategies to improve smoking cessation and enhance the capability of clinical systems to deliver proven smoking cessation services; and 2) advancing the science of translating cancer control into communities and clinical practice, with a particular emphasis on addressing the needs of the KUCC catchment area. The 35 members of the CCPH program come from 14 departments in six schools across four campuses. These members represent a rich mix of expertise, including psychologists, sociologists, neuroscientists, primary care physicians, oncologists, epidemiologists, biostatisticians, anthropologists, economists, pharmacists, communication specialists and health services researchers. Program members are supported by $13.4M in total annual funds, including $3.6M from the National Cancer Institute. CCPH members have published 341 articles since 2012 of which 111 (33%) had intra-programmatic, 69 (20%) had inter-programmatic and 243 (71%) had inter-institutional collaborations.

Since the creation of CCPH, program members have made remarkable progress in developing the infrastructure to conduct cancer control research in our region among underserved, rural, American Indian, African American and Latino communities. With this infrastructure in place, in 2015 CCPH members enrolled 1,929 people, including those from underserved communities in the KUCC catchment area, into cancer control research studies. Specifically, 1,603 to interventional research studies. Paralleling this growth in infrastructure has been a significant growth in cancer control funding, program membership and scholarly productivity. CCPH program activities support both intra- and inter-programmatic interactions through translational research seminars, a visiting scholars program, research symposia and research working groups. A strong mentoring program has helped junior faculty procure training grants and minority supplements. CCPH research efforts have led to a better understanding of the cancer control needs in the KUCC catchment area, improved capacity to analyze the needs of affected and at-risk populations, better strategies for the design and delivery of cancer control messages and improvements in the delivery of tobacco control, cancer screening, physical activity and obesity treatment programs at the level of both the clinical practice and the community at large.

Cancer Control and Population Health – Other Attachments

Table 1 – Externally Funded, Cancer-Related Research Projects
Table 2 – Program Members
Table 3 – Shared Resource Usage
Table 4 – Programmatic Activities
Table 5 – Publications
Table 6 – Clinical Research

Table 1. Externally Funded, Cancer-Related Research Projects as of 12/31/2015 – Cancer Control & Population Health

Table 1. Program Funding											
PI	**Specific Funding Source**	**Project Number**	**Project Start Date**	**Project End Date**	**Project Title**	**Annual Project Direct Costs**	**Annual Project Total Costs**	**Program Code**	**Percent**	**Annual Program Direct Costs**	**Annual Program Total Costs**
PEER-REVIEWED PROJECTS											
Befort C	PCORI	OB-1402-09413	1/1/2015	12/31/2019	MIDWESTERN COLLABORATIVE FOR TREATING OBESITY IN RURAL PRIMARY CARE	$1,542,640	$2,003,429	CCPH	100%	$1,542,640	$2,003,429
Cancer Relevance (OB-1402-09413): *Obesity contributes to increased risk for at least eight types of cancer and up to 20% of all cancer-related deaths. People in rural communities, which account for nearly 20% of the United States population, have higher rates of obesity. Re-Power (Rural Engagement in Primary Care for Optimizing Weight Reduction) is a pragmatic implementation trial targeting cancer control in follow-up to 5R01CA155014 conducted in rural breast cancer survivors. The trial is comparing three models for integrating weight control strategies into primary care practices in underserved rural settings.*											
Caburnay CA Doolittle GC	NCI Health Communication Impact, LLC	1R44CA192442-01	9/1/2015	7/31/2017	RECRUITING UNDERSERVED POPULATIONS INTO CLINICAL TRIALS WITH CUSTOMIZABLE MEDIA	$62,593	$62,593	CCPH	100%	$62,593	$62,593
Chen YC	NCI VIRGINIA POLYTECHNIC INST	5R01CA154364-05	7/1/2013	4/30/2016	SIPSMARTER: A NUTRITION LITERACY APPROACH TO REDUCING SUGAR-SWEETENED BEVERAGES	$34,566	$51,790	CCPH	100%	$34,566	$51,790
Choi WS	NCI	5R01CA174481-03	4/1/2013	3/31/2018	WEB-BASED SMOKING CESSATION PROGRAM FOR TRIBAL COLLEGE STUDENTS	$416,590	$565,964	CCPH	100%	$416,590	$565,964
Collie-Akers VL	NCCDPHP	1U58DP005806-01	9/30/2014	9/29/2017	HEALTH FOR ALL: HEALTHY PLACES THAT PROMOTE HEALTH EQUITY AMONG LATINOS IN KANSAS CITY, KS	$569,137	$723,299	CCPH	100%	$569,137	$723,299
Cox LS	NIDA Pinnacle Technology Inc	5R01DA035796-02	6/1/2014	3/31/2019	ADVANCING TOBACCO USE TREATMENT FOR AFRICAN AMERICAN SMOKERS	$427,801	$631,776	CCPH	100%	$427,801	$631,776
Cupertino AP Ellerbeck EF	NIMHD Agile Heatlh	1R41MD010318-01	8/1/2015	7/31/2016	LATINOS KICK BUTS: MOBILE ENGAGEMENT AND CESSATION SUPPORT FOR LATINO SMOKERS	$149,688	$149,688	CCPH	100%	$149,688	$149,688
Cupertino AP	NIH Office of Director	1R25OD020214-01	9/3/2015	8/31/2020	S.C.O.R.E: STUDENTS FOR COMMUNITY-ORIENTED RESEARCH AND EDUCATION	$213,995	$231,007	CCPH	100%	$213,995	$231,007
Daley CM	NCI	1R21CA191158-01A1	4/1/2015	3/31/2017	DEVELOPMENT OF A TOBACCO HEALTH LITERACY INSTRUMENT	$140,250	$211,778	CCPH	100%	$140,250	$211,778
Daley CM	NIMHD	5R01MD007800-02	7/10/2014	4/30/2017	SMOKELESS TOBACCO CESSATION AMONG AMERICAN INDIANS USING IN-PERSON GROUPS	$250,000	$377,500	CCPH	100%	$250,000	$377,500
Doolittle GC	CDC Kansas Dept of Health & Environment	U58DP003889-04	6/30/2012	6/29/2017	CANCER PREVENTION AND CONTROL PROGRAMS FOR STATE, TERRITORAL AND TRIBAL ORGANIZATIONS	$50,770	$50,770	CCPH	100%	$50,770	$50,770
Ellerbeck EF	PCORI	CER-1306-02901	4/1/2014	3/31/2017	SMOKING CESSATION VERSUS LONG-TERM NICOTINE REPLACEMENT AMONG HIGH-RISK SMOKERS	$498,964	$698,550	CCPH	100%	$498,964	$698,550
Fawcett SB Collie-Akers VL	NIH Battelle Memorial Institute	268201000041C-13-0-1	8/15/2011	8/14/2016	STUDYING COMMUNITY PROGRAMS TO REDUCE CHILDHOOD OBESITY: TASK 1 - SCIENTIFIC LEADERSHIP & PROJECT MANAGEMENT	$209,845	$306,978	CCPH	100%	$209,845	$306,978
Fawcett SB Collie-Akers VL	NIH Battelle Memorial Institute	268201000041C-13-0-1	8/15/2011	8/14/2016	STUDYING COMMUNITY PROGRAMS TO REDUCE CHILDHOOD OBESITY: TASK 8 - DATA ANALYSIS AND DISSEMINATION OF RESULTS	$256,098	$373,411	CCPH	100%	$256,098	$373,411

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Gajewski BJ	NINR	5R03NR013236-02	5/21/2014	4/30/2016	A NOVEL METHOD FOR EXPEDITING THE DEVELOPMENT OF PATIENT REPORTED OUTCOME MEASURES	$48,500	$73,235	CCPH	100%	$48,500	$73,235
Gibbs H	NICHD	5R03HD081730-02	8/1/2014	7/31/2016	ADAPTATION AND VALIDATION OF A NUTRITION LITERACY ASSESSMENT INSTRUMENT	$53,693	$80,082	CCPH	100%	$53,693	$80,082
Greiner KA	NCI	5U54CA154253-05	9/17/2010	8/31/2016	KANSAS COMMUNITY CANCER HEALTH DISPARITIES NETWORK	$565,498	$814,582	CCPH	100%	$565,498	$814,582
Greiner KA	NCI	3U54CA154253-05S1	9/17/2010	8/31/2016	KANSAS COMMUNITY CANCER HEALTH DISPARITIES NETWORK	$66,225	$100,000	CCPH	100%	$66,225	$100,000
Greiner KA	NCI	3U54CA154253-05S2	9/17/2010	8/31/2016	KANSAS COMMUNITY CANCER HEALTH DISPARITIES NETWORK	$213,346	$322,152	CCPH	100%	$213,346	$322,152
Greiner KA	NCI	5R01CA158238-04	9/15/2011	7/31/2016	TAILORED TOUCHSCREEN COLORECTAL CANCER PREVENTION IN AMERICAN INDIAN COMMUNITIES	$338,264	$504,749	CCPH	100%	$338,264	$504,749
Jensen RA Ellerbeck EF Cupertino AP	NCI	3P30CA168524-04S1	7/11/2012	6/30/2017	CANCER CENTER SUPPORT GRANT (E-DECIDETE: MOBILE CESSATION SUPPORT FOR LATINO SMOKERS IN MEXICO)	$134,239	$179,698	CCPH	100%	$134,239	$179,698
Jiao L Chen GJ	NCI BAYLOR COLLEGE OF MEDICINE	5R01CA172880-03	9/20/2013	7/31/2016	ADVANCED GLYCATION END-PRODUCTS AND RISK OF PANCREATIC CANCER	$25,086	$37,881	CCPH	100%	$25,086	$37,881
Landau MJ	NCI	5R01CA185378-02	6/1/2014	5/31/2018	COGNITIVE AND EMOTIONAL PROCESSES OF METAPHORIC CANCER COMMUNICATIONS	$305,663	$327,411	CCPH	100%	$305,663	$327,411
Martin LE	NCI University of Missouri Kansas City	5R21CA184834-02	5/19/2014	8/31/2016	(PQA3) NEURAL PREDICTORS OF SELF-REGULATION OF SMOKING URGES AT A STRESSFUL MOMEN	$122,361	$164,213	CCPH	100%	$122,361	$164,213
Nollen NL	PCORI	AD-1310-08709	10/1/2014	9/30/2017	INFORMING TOBACCO-TREATMENT GUIDELINES FOR AFRICAN AMERICAN NON-DAILY SMOKERS	$497,976	$680,971	CCPH	100%	$497,976	$680,971
Nollen NL	NIDA Pinnacle Technology Inc	5R01DA031815-04	5/1/2012	4/30/2017	UNDERSTANDING DISPARITIES IN QUITTING IN AFRICAN AMERICAN AND WHITE SMOKERS	$486,405	$666,846	CCPH	100%	$486,405	$666,846
Ramaswamy M	NCI	5R01CA181047-02	4/1/2014	3/31/2019	SEXUAL HEALTH EMPOWERMENT FOR CERVICAL HEALTH LITERACY AND CANCER PREVENTION	$218,527	$313,325	CCPH	100%	$218,527	$313,325
Savage CR Donnelly JE	NIDDK	5R01DK085605-05	4/1/2010	1/31/2016	NEUROIMAGING STUDIES OF REWARD, IMPULSIVITY, AND ADHERENCE TO AN EXERCISE PROGRAM	$488,003	$576,124	CCPH	65%	$351,906	$376,062
			Peer-Reviewed Rearch Subtotals:			$8,386,723	$11,279,802			**$8,250,626**	**$11,079,740**

NON-PEER-REVIEWED PROJECTS											
Ablah E	Kansas Health Foundation		1/1/2015	12/31/2017	WORKWELL KANSAS: PHASE II	$1,000,000	$1,000,000	CCPH	100%	$1,000,000	$1,000,000
Cancer Relevance: *Research directed at implementing worksite wellness programs for employees, including smoking cessation, nutrition, physical activity, and screening.*											
Chen GJ	Veteran Affairs Medical Center		3/1/2014	9/30/2016	VALUE OF DELIVERY OF TARGETED THERAPY FOR VETERANS WITH ADVANCED LUNG CANCER	$61,459	$61,459	CCPH	100%	$61,459	$61,459

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Collie-Akers VL	KS Health Foundation		6/1/2014	5/31/2016	CREATING HEALTHY PLACES AND SPACES TO PROMOTE HEALTHY EATING AND ACTIVE LIVING AMONG LATINOS IN KANSAS CITY, KANSAS	$90,764	$99,842	CCPH	100%	$90,764	$99,842
Collie-Akers VL	Robert Wood Johnson Univ of California - Berkeley		6/1/2014	5/31/2016	IN-DEPTH EXAMINATION OF DIVERSE SCHOOLS WITH DECLINING BMIS	$53,572	$60,000	CCPH	100%	$53,572	$60,000
Lai SM	KANSAS DEPT OF HEALTH AND ENVIRONMENT		8/15/2015	8/14/2016	KANSAS CANCER REGISTRY	$831,402	$831,402	CCPH	100%	$831,402	$831,402
Cancer Relevance: *In addition to supporting the state cancer control plan, registry activities include collaborative work with other cancer centers and hypothesis driven studies related to CRC screening, breast cancer prevalence, and registry reporting/completeness.*											
Pacheco CM	Robert Wood Johnson Foundation		9/1/2014	8/31/2016	SMOKING RESTRICTIVE POLICIES AND ITS IMPACTS ON SMOKING AT TRIBAL	$46,146	$51,683	CCPH	100%	$46,146	$51,683
					Non-Peer-Reviewed Research Subtotals:	$2,083,343	$2,104,386			**$2,083,343**	**$2,104,386**
								CCPH Grand Totals		**$10,333,969**	**$13,184,126**

PEER-REVIEWED TRAINING PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Daley CM	Susan G. Komen Foundation	GTDR15333785	8/13/2015	8/12/2018	CONTINUING AN AMERICAN INDIAN BREAST CANCER DISPARITIES TRAINING PROGRAM	$135,000	$135,000	CCPH	100%	$135,000	$135,000
Lumpkins CY	NCI	5K01CA164009-06	9/22/2011	8/31/2016	COMMUNICATING COLORECTAL CANCER PREVENTION THRU URBAN AFRICAN AMERICAN CHURCHES	$102,159	$110,332	CCPH	100%	$102,159	$110,332
					Peer-Reviewed Training Totals:	$237,159	$245,332			**$237,159**	**$245,332**

CHILDREN'S MERCY PEER-REVIEWED PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Myers A	PCORI	7954291	5/1/2015	2/28/2016	ENGAGING COMMUNITIES IN INFECTIOUS DISEASES RESEARCH AND INTERVENTION DEVELOPMENT	$13,500	$15,000	CCPH	100%	$13,500	$15,000
					Peer-Reviewed Training Totals:	$13,500	$15,000			**$13,500**	**$15,000**

Table 2 – Program Members

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Ablah	Elizabeth	Preventive Medicine and Public Health	University of Kansas, Wichita, KS	Associate Professor	Full
Ault	Kevin	Dept of Obstetrics and Gynecology	University of Kansas Medical Center, Kansas City, KS	Professor & Chair	Full
Befort	Christie	Preventive Medicine & Public Health	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full
Carlson	Jordan	Director, Community Engaged Research	Children's Mercy Kansas City, Kansas City, MO	Research Assistant Professor	Associate
Catley	Delwyn	Pediatrics	Children's Mercy Kansas City, Kansas City, MO	Professor	Associate
Chen	Guoqing "John"	Internal Medicine	University of Kansas Medical Center, Kansas City, KS	Director	Full
Chen	Yvonnes	School of Journalism & Mass Communications	University of Kansas, Lawrence, KS	Associate Professor	Full
Choi	Won	Preventive Medicine & Public Health	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full
Collie-Akers	Vicki	Work Group for Community Health and Development, Life Span Institute	University of Kansas, Lawrence, KS	Assistant Research Professor	Full
Cox	Lisa	Preventive Medicine and Public Health	University of Kansas Medical Center, Kansas City, KS	Research Associate Professor	Full
Cupertino	Ana	Preventive Medicine & Public Health	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full
Daley	Christine	Preventive Medicine & Public Health	University of Kansas Medical Center, Kansas City, KS	Professor	Full
Doolittle	Gary	Center for Telemedicine & Telehealth	University of Kansas Medical Center, Kansas City, KS	Professor	Full
Ellerbeck	Edward	General and Geriatric Medicine; Preventive Medicine and Public Health	University of Kansas Medical Center, Kansas City, KS	Professor; Professor, Chairman Preventive Medicine	Full
Ellis	Shellie	Health Policy & Management	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Associate

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Faseru	Babalola	Preventive Medicine and Public Health	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full
Fawcett	Steve	Applied Behavioral Science	University of Kansas, Lawrence, KS	Professor-Senior Scientist	Full
Fridley	Brooke	Biostatistics	University of Kansas Medical Center, Kansas City, KS	Professor	Full
Gajewski	Byron	Biostatistics	University of Kansas Medical Center, Kansas City, KS	Professor	Full
Geana	Mugur	School of Journalism and Mass Communications/ School of Medicine – Department	University of Kansas, Lawrence, KS	Assistant Professor	Associate
Gibbs	Heather	Dietetics & Nutrition	University of Kansas Medical Center, Kansas City, KS	Clinical Assistant Professor	Full
Greiner	K. Allen	Family Medicine Research Division	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full
Hines	Robert	Preventive Medicine & Public Health	University of Kansas, Wichita, KS	Assistant Professor	Full
Kimminau	Kim	Family Medicine	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Associate
Koestler	Devin	Biostatistics	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Associate
Lai	Sue	Preventive Medicine and Public Health	University of Kansas Medical Center, Kansas City, KS	Professor, Director KCR	Full
Landau	Mark	Psychology	University of Kansas, Lawrence, KS	Associate Professor	Full
Lumpkins	Crystal	Family Medicine	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Associate
Mahnken	Jonathan	Biostatistics	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full
Martin	Laura	Preventive Medicine and Public Health	University of Kansas Medical Center, Kansas City, KS	Assistant Professor & Associate Director of Functional MRI	Full

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Myers	Angela	Pediatrics/Infectious Diseases	Children's Mercy Kansas City, Kansas City, MO	Associate Professor of Pediatrics	Associate
Nollen	Nicole	Preventive Medicine and Public Health	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full
Ramaswamy	Megha	Preventive Medicine and Public Health	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full
Richter	Kimber	Preventive Medicine and Public Health	University of Kansas Medical Center, Kansas City, KS	Professor	Full
Savage	Cary	Center for Health Behavior Neuroscience	University of Kansas Medical Center, Kansas City, KS	Director	Full
Scheuermann	Taneisha	Preventive Medicine & Public Health	University of Kansas Medical Center, Kansas City, KS	Research Instructor	Associate

Table 3 – Shared Resource Usage

Shared Resource	Number of program members using the shared resource	Percentage of shared resource usage by program members
Biospecimen (BSR)	4	9%
Biostatistics & Informatics (BISR)	20	35%
Lead Development & Optimization (LDOSR)	1	2%
Transgenic & Gene-Targeting (TGTSR)	1	4%
Clinical Pharmacology (CPSR)	3	14%

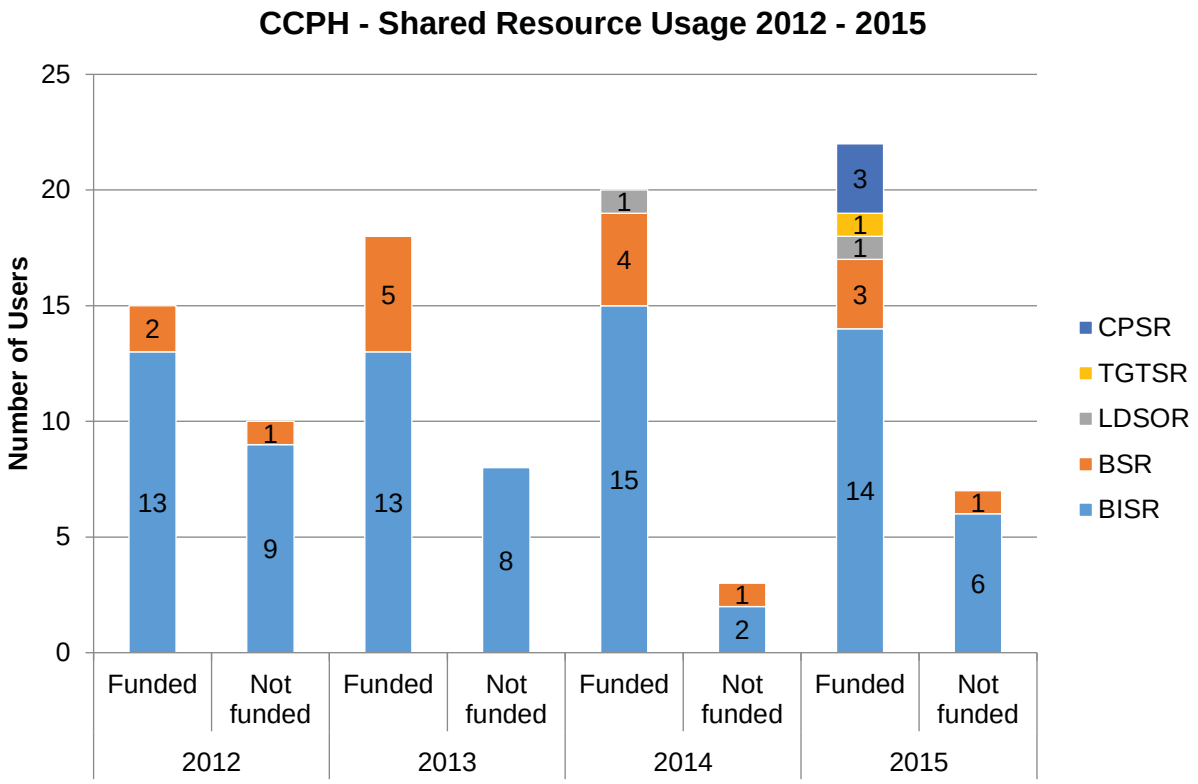

Table 4 – Programmatic Activities

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
2012				
Workgroup	1/3/12		Jean Rumbaugh	Lung Cancer Screening workgroup/planning
TRG Meeting	1/5/12		Laura Martin	Role of f-MRI in characterizing cue reactivity to smoking
MCA Meeting	1/9/12		Ed Ellerbeck	Research priorities and opportunities with the MCA
Workgroup	2/8/12	Jasjit Ahluwalia	Lisa Cox	Strategic planning for research on light AA smokers
CTRS Seminar	2/9/12		Lisa Cox	Findings from KIS-3 and implications for future research
CTRS Seminar	2/23/12		Michael Rappof	E-health interventions
EAB Meeting with CCPH Researchers	2/24/12		Kim Engelman	
International visit	3/6/12	MOH Mexico	Paula Cupertino	Addressing the health care needs of the Mexican immigrant community
Workgroup	3/13/12		Tracey Campbell	Development of a lung cancer screening database
MCA Meeting	5/2/12		Hope Krebill	Research priorities and opportunities with the MCA
KUCC Seminar Series	5/22/12		Ed Ellerbeck	Chronic disease management and smoking cessation in rural Kansas
International visit	6/7/12	MOH Mexico	Paula Cupertino	Addressing the health care needs of the Mexican immigrant community
Workgroup	6/19-20/12	Jasjit Ahluwalia	Nikki Nollen Lisa Cox	Joint planning meeting for grant development
TRG Meeting	7/12/12		Jamie Hunt	
CTRS Seminar	8/23/12		Byron Gajewski	Expediting Clinical and Translational Research via Bayesian Instrument Development
CCPH-CPS joint program meeting	9/7/12	CPS	Brian Petroff Jennifer Klemp Cary Savage Theresa Shireman	Focus on Energy Balance Interventions; fMRI and diet and exercise; comparative effectiveness research
Healthy Kansans	9/27/12	KDHE	Paula Clayton	Strategic planning meeting in collaboration in KDHE on 2020 health priorities
CTRS Seminar	9/27/12		Bill Brooks	From Animal Models to Clinical Trials: Imaging in Clinical and Translational Research
CTRS Seminar	10/4/12		Laura Martin	Winning or Losing: Cognitive Neuroscience Studies of Addiction and Obesity
Cerner Health Conference	10/9/12	Elliot Fisher	John Spertus Patrick James	Variations in health care services and implications for quality improvement and informed choice
Shared Resources Strategic Planning	10/10/12		Andrew Godwin Brooke Fridley Shrikant Anant Matt Mayo Ed Ellerbeck	Shared Resources Strategic Planning
CTRS Seminar	10/25/12		Crystal Lumpkins	Communicating Cancer Risk and Prevention Through African American Churches
CTRS Seminar	11/1/12		Christie Befort	Breast Cancer Prevention through Weight Contorl and Exercise
Healthy Kansans	11/2/12	KDHE	Robert Moser	National Public Health Performance Standards

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Program Meeting	11/8/12		Kim Engelman Ed Ellerbeck	KUCC Research Symposium, poster exhibit and program planning
2013				
ACS IRG	1/16/13	CPS	Bruce Kimler	Review of internal ACS grant applications
CTRS Seminar	2/7/13		Catherine Satterwhite	The Role of School Based Health Centers in Delivering Adolescent Health Care
CTRS Seminar	3/7/13	JCHD	Barbara Mitchell	Community Health Assessment/Improvement Plan in Johnson County
International Visit	4/15/13	UNAM	Paula Cupertino	Conclusion of Memorandum of Agreement for collaborative work with medical school in Morelos, MX
PH Grand Rounds	4/17/13			State Employee Wellness Program
KUCC Seminar Series	4/23/13		Lisa Cox	Promoting cessation among light AA smokers
CTRS Seminar	4/25/13		Cathy Davis	Progress to Quality: KCQIC using a registry for Quality Improvement
EAB Meeting with CCPH Researchers	5/9/13	Al Neugut Mark Clanton	Ed Ellerbeck Kim Engelman	CCPH Progress and Future Directions
Program Meeting	5/15/13		Ed Ellerbeck	CCPH member meeting to review and address EAB feedback
CCPH Executive Team Meeting	5/17/13		Ed Ellerbeck Kim Engelman	Development of video to describe CCPH with partners
TRG meeting	6/6/13		Seung Lark Lim	Grant review and feedback – imaging and smoking cues
Healthy Kansans	6/11/13	KDHE	Robert Moser	Integrating public health and primary care
KUCC Seminar Series	6/23/13		Kimber Richter	An informed decision-making tool for increasing access to cessation medications
ACS IRG	7/17/13	CPS	Bruce Kimler	Review of internal ACS grant applications
CTRS Seminar	9/5/13		Manoj Mittal	Smoking Cessation after Ischemic Stroke
KUCC Seminar Series	9/10/13		Megha Ramaswamy	Understanding the cervical health gap for women in jail
CTRS Seminar	9/12/13	Univ. New Mexico	Carolina NKouaga Juliana Anastasoff	CTSC and Health Extension in New Mexico
Mason's Day	9/21/13	Masons	Ed Ellerbeck Dan Welch Roy Jensen	Role of CCPH and KUCC in addressing cancer control needs in the catchment area
CTRS Seminar	10/3/15		Babalola Faseru	Why Should We Care About Menthol in Cigarettes?
CTRS Seminar	10/10/15		Laura Martin	Neuroimaging: A Tool to Understand Health Behaviors
Workgroup	10/14/13	Jasjit Ahluwalia	Nikki Nollen	Grant development meeting
KCP meeting	10/29/13	KCP	Gary Doolittle	Meeting of Kansas Cancer Partnership with joint research priority setting
KUCC Seminar Series	10/29/13		Robert Hines	Rural vs. Urban disparities in colorectal cancer outcomes
CTRS Seminar	11/14/13		Kim Richter	Telemedicine for Health Behavior Change: Helping Rural Smokers Quit
KUCC Seminar Series	11/19/13	Jo Wick	Brooke Fridley	Bioinformatics and Statistical Genomics in Medical Research

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
CTRS Seminar	12/5/13		Julie Christianson	The Painful Consequences of Early Life and Adult Stress
CCPH-CPS joint program meeting	12/6/13	CPS	Andy Godwin Shahid Umar Carol Fabian Jill Hamilton-Reeves	Cancer Prevention Research Retreat; Core facilities; New developments in GI, GU, and breast cancer prevention
Workgroup	12/9/13		Kim Engelman Tami Gurley-Calvez	Implications of Medicaid Expansion on Tobacco Control
2014				
Program Meeting	1/4/14	CPS	Allen Greiner Won Choi Heather Gibbs Yvonnes Chen	CCPH Science Friday: Nutrition Literacy; Media Literacy; Tobacco use among AIs; Implementation Intentions & CRC screening
CTRS Seminar	1/23/14		Taneisha Buchanan	Nondaily smoking in a Tri-Ethnic Population
CCPH Executive Team Meeting	1/28/14		Ed Ellerbeck	Identifying strategies to address the needs of CCPH researchers
CTRS Seminar	2/6/14	UMKC	Seung-Lark Lim	Neural and Computational Mechanisms of Value-Based Decision-Making and Their Clinical Implications
KUCC Seminar Series	2/11/14		Christina Hester	What can gut microbiota and metabolites reveal about colon pathology?
CTRS Seminar	2/27/14		Robert Hines	Rural vs. Urban Disparities in Colorectal Cancer Outcomes
CTRS Seminar	3/6/14	KC Care	Craig Dietz	Medically Underserved and Access to Clinical Trials
CCPH Executive Team Meeting	3/24/14		Ed Ellerbeck	Identifying strategies to address the needs of CCPH researchers
Program Meeting	4/4/14		Brooke Fridley Crystal Lumpkins Ed Ellerbeck Allen Greiner	CCPH Science Friday: Big data and molecular epidemiology; Faith, churches & CRC screening; PCORI
CTRS Seminar	4/10/14		Amanda Szabo	Win, Lose, or Draw: Interventions to Increase Weight Loss and Maintenance Success
Tobacco Research Group	5/1/2014		Dr. Won Choi, KUMC	Impact of Home Assessments and Biomarker feedback to Reduce Second hand Smoke Exposure among American Indians
EAB Meeting with CCPH Researchers	5/23/14	Al Neugut Mark Clanton	Ed Ellerbeck Kim Engelman	CCPH Progress and Future Directions
CCPH Executive Team Meeting	6/2/14		Kim Engelman	Research meeting program planning
Tobacco Research Group	6/5/2014		Dr. Ed Ellerbeck, KUMC	Kan Quit II
Program Meeting	7/11/14		Joe Lemaster Kim Engelman Tamara Robinson Devin Koestler	CCPH Science Friday: KPEPR Network; CRC in rural practice; ACS health systems focus; Prediction models for bladder cancer recurrence
KUCC Seminar Series	8/5/14		Babalola Faseru	Integrating smoking cessation into routine inpatient service: Implications for cancer prevention and control
Tobacco Research Group	8/7/2014		Dr. Babalola Faseru, KUMC	Tobacco Treatment in Patient Centered Medical Homes

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
KUCC Seminar Series	9/2/14		Byron Gajewski	The beginnings of the journey to the bedside from the bench: Modulating Notch Isoforms in Melanoma
Tobacco Research Group	9/4/2014		Dr. Laura Martin, KUMC	Neuroimaging Studies of Smoking
KUCC Seminar Series	9/16/14		Christina Ciaccio	Indoor tobacco legislation and pediatric emergency department visits for asthma
KUCC Seminar Series	9/23/14		Stephen Fawcett	Participatory research and action with community health partnerships
KUCC Seminar Series	9/30/14		Crystal Lumpkins	Conducting transdisciplinary research with faith-based organizations
Tobacco Research Group	10/2/2014		Dr. Ed Ellerbeck, KUMC	Smoking Cessation in Rural Primary Care Practicies
Program Meeting	10/3/14		Roy Jensen Kim Kimminau Kim Richter Hope Krebill	CCPH Science Friday: NCI Comprehensive status; AAFP PBRN; Tobacco and obesity treatment in Safety nets; KCP efforts
Tobacco Research Group	11/6/2014		Dr. Paula Cupertino, KUMC	eDecídete: Mobile Cessation Support for Latino Smokers
KUCC Seminar Series	10/21/14		Jonathan Mahnken	Statistical Methods for Grants and Protocols: What information should be conveyed?
Tobacco Research Group	12/4/2014		Dr. Taneisha Scheuermann, KUMC	Pregnant and Postpartum Smokers
2015				
Tobacco Research Group	1/8/15		Dr. Susan Carlson, KUMC	Omega-3 Supplementation for Smoking Cessation
Program Meeting	1/9/15		Mugur Geana Mark Landau Christina Pacheco Byron Gajewski	CCPH Science Friday: Communications Shared Resource; Metaphoric Cancer Messages; CBPR among AIs; Adaptive designs
Visiting Professor	1/21-1/22/15	Jack Westfall	Jack Westfall	***Mystery of the Blue Highway. Engaging Community in Research***
Tobacco Research Group	2/3/15	Jody Brook	Jody Brook	***Substance Use and Abuse in the Foster Care System***
Tobacco Research Group	3/2/15		Dr. Yvonnes Chen, KU	E-cigarette Marketing through Social Media
Visiting Professor	3/22 – 3/23/15	Lisa Saldana	Lisa Saldana	Implementation Research with focus on Cancer Control
KUCC Seminar Series	3/31/15	KDHE	Austin Rogers	Cancer Surveillance & Opportunities for Academic-PH Collaboration
Tobacco Research Group	4/2/2015		Dr. Kim Richter, KUMC	Tobacco Use and People with Mental Illness/Substance Abuse
CCPH Executive Team Meeting	4/10/15		Ed Ellerbeck Kim Engelman	Research meeting program planning
Program Meeting	4/10/15		Christine Daley Melissa Filippi Megha Ramaswamy Barbara Pahud	CCPH Science Friday: ANBL; Tobacco health literacy; Cervical health literacy; KAP of HPV among peds hospital workers
EAB Meeting with CCPH Researchers	4/16/15	Al Neugut Mark Clanton	Ed Ellerbeck Kim Engelman	CCPH Progress and Future Directions
Visiting Professor	5/5 – 5/6/15	Melinda Wharton – CDC	Melinda Wharton	You are the Key to HPV Cancer Prevention
Tobacco Research Group	5/7/15		Dr. Jarron Saint Onge, KUMC	Social Stress and Home Smoking Rules

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Tobacco Research Group	6/2/15		Jennifer Church, Becky Ross, Kansas Department of Health and Environment	White Paper: Best Clinical Practices for Tobacco Cessation Treatments in the Medicaid Program
Program Meeting	7/10/15		Shellie Ellis Tami Gurley-Calvez Kevin Ault Jarron Saint Onge	CCPH Science Friday: Physician decisions on low-risk prostate CA; Economics of cancer clinical trials; HPV vaccine development; Social stressors and home smoking
CPS-CCPH Joint Program Meeting	7/24/15			
CCPH Executive Team Meeting	8/4/15		Ed Ellerbeck Christie Befort	Strategic Planning
Tobacco Research Group	8/6/2015		Dr. Andrew Fox, KUMC	Smoking Cessation, Cognitive Control and Reward Processing: an fMRI Pilot study
Tobacco Research Group	9/3/2015		Dr. Nikki Nollen, KUMC	Biomarkers of Toxicant Exposure among Cigarette Only and Cigarette and Other Tobacco Product Users
KUCC Seminar Series	9/15/15		Shellie Ellis	Physician Decision-Making in Low-Risk Prostate Cancer
Visiting Professor	9/18/15	Barbara McCrady; Univ New Mexico	Barbara McCrady	Alcoholism, substance abuse, and addictions – lessons for treating couples with smoking cessation
Tobacco Research Group	10/6/2015	Agile Health	Dr. Paula Cupertino, KUMC	Latino Kick Buts: Smoking Cessation via Text Messaging.
Tobacco Research Group	11/13/2015	Univ of Michigan	Laura Damschroder, MS, MPH, VA Ann Arbor Healthcare System	Implementation Research
KUCC Seminar Series	12/1/15		Devin Koestler	DNA methylation biomarkers for estimating the cell composition of whole blood
Tobacco Research Group	12/1/2015	KCAAP	Dr. Taneisha Scheuermann, KUMC and Melissa Hudelson, KCAAP	Smoke Free for Kansas Kids: KUMC Pediatric Clinics

Table 5 – Drug Discovery, Delivery and Experimental Therapeutics
The CCPH program 341 publications from 2012-2015; 69 (20%) inter-programmatic, 111 (33%) intra-programmatic, 243 (71%) inter-institutional, and 28 (8%) of these publications were high impact (JIF ≥ 8).

Table 5. Program Publications			
Inter	**Intra**	**External**	**Publication**
With PMCID			
x		**x**	**Aljitawi OS**, Xiao Y, Eskew JD, Parelkar NK, Swink M, Radel J, **Lin** TL, **Kimler** BF, **Mahnken** JD, **McGuirk** JP, Broxmeyer HE, Vielhauer G. Hyperbaric oxygen improves engraftment of ex-vivo expanded and gene transduced human CD34(+) cells in a murine model of umbilical cord blood transplantation. Blood cells, molecules & diseases. 2014;52(1):59-67. doi: 10.1016/j.bcmd.2013.07.013. PubMed PMID: 23953010; PubMed Central PMCID: PMC4075130.
	x	**x**	Allen AM, **Scheuermann** TS, **Nollen** N, Hatsukami D, Ahluwalia JS. Gender Differences in Smoking Behavior and Dependence Motives Among Daily and Nondaily Smokers. Nicotine Tob Res. 2016;18(6):1408-13. Epub 2015/07/03. doi: 10.1093/ntr/ntv138. PubMed PMID: 26136526; PMCID: PMC4906260.
		x	Amankwah EK, Lin HY, Tyrer JP, Lawrenson K, Dennis J, Chornokur G, Aben KK, Anton-Culver H, Antonenkova N, Bruinsma F, Bandera EV, Bean YT, Beckmann MW, Bisogna M, Bjorge L, Bogdanova N, Brinton LA, Brooks-Wilson A, Bunker CH, Butzow R, Campbell IG, Carty K, Chen Z, Chen YA, Chang-Claude J, Cook LS, Cramer DW, Cunningham JM, Cybulski C, Dansonka-Mieszkowska A, du Bois A, Despierre E, Dicks E, Doherty JA, Dork T, Durst M, Easton DF, Eccles DM, Edwards RP, Ekici AB, Fasching PA, **Fridley** BL, Gao YT, Gentry-Maharaj A, Giles GG, Glasspool R, Goodman MT, Gronwald J, Harrington P, Harter P, Hasmad HN, Hein A, Heitz F, Hildebrandt MA, Hillemanns P, Hogdall CK, Hogdall E, Hosono S, Iversen ES, Jakubowska A, Jensen A, Ji BT, Karlan BY, Jim H, Kellar M, Kiemeney LA, Krakstad C, Kjaer SK, Kupryjanczyk J, Lambrechts D, Lambrechts S, Le ND, Lee AW, Lele S, Leminen A, Lester J, Levine DA, Liang D, Lim BK, Lissowska J, Lu K, Lubinski J, Lundvall L, Massuger LF, Matsuo K, McGuire V, McLaughlin JR, McNeish I, Menon U, Milne RL, Modugno F, Moysich KB, Ness RB, Nevanlinna H, Eilber U, Odunsi K, Olson SH, Orlow I, Orsulic S, Weber RP, Paul J, Pearce CL, Pejovic T, Pelttari LM, Permuth-Wey J, Pike MC, Poole EM, Risch HA, Rosen B, Rossing MA, Rothstein JH, Rudolph A, Runnebaum IB, Rzepecka IK, Salvesen HB, Schernhammer E, Schwaab I, Shu XO, Shvetsov YB, Siddiqui N, Sieh W, Song H, Southey MC, Spiewankiewicz B, Sucheston-Campbell L, Teo SH, Terry KL, Thompson PJ, Thomsen L, Tangen IL, Tworoger SS, van Altena AM, Vierkant RA, Vergote I, Walsh CS, Wang-Gohrke S, Wentzensen N, Whittemore AS, Wicklund KG, Wilkens LR, Wu AH, Wu X, Woo YL, Yang H, Zheng W, Ziogas A, Kelemen LE, Berchuck A, Georgia Chenevix-Trench on behalf of the Amg, Schildkraut JM, Ramus SJ, Goode EL, Monteiro AN, Gayther SA, Narod SA, Pharoah PD, Sellers TA, Phelan CM. Epithelial-Mesenchymal Transition (EMT) Gene Variants and Epithelial Ovarian Cancer (EOC) Risk. Genetic epidemiology. 2015;39(8):689-97. Epub 2015/09/25. doi: 10.1002/gepi.21921. PubMed PMID: 26399219; PMCID: PMC4721602.
		x	**Baker TA**, O'Connor ML, Krok JL. Experience and knowledge of pain management in patients receiving outpatient cancer treatment: what do older adults really know about their cancer pain? Pain medicine. 2014;15(1):52-60. doi: 10.1111/pme.12244. PubMed PMID: 24118873; PubMed Central PMCID: PMC3947025.
		x	Bartlett TE, Jones A, Goode EL, **Fridley** BL, Cunningham JM, Berns EM, Wik E, Salvesen HB, Davidson B, Trope CG, Lambrechts S, Vergote I, Widschwendter M. Intra-Gene DNA Methylation Variability Is a Clinically Independent Prognostic Marker in Women's Cancers. PLoS One. 2015;10(12):e0143178. Epub 2015/12/03. doi: 10.1371/journal.pone.0143178. PubMed PMID: 26629914; PMCID: PMC4667934.
x			**Befort** CA, Bennett L, Christifano D, **Klemp** JR, **Krebill** H. Effective recruitment of rural breast cancer survivors into a lifestyle intervention. Psycho-oncology. 2015;24(4):487-90. Epub 2014/06/24. doi: 10.1002/pon.3614. PubMed PMID: 24953687; PMCID: Pmc4272910.

Inter	Intra	External	Publication
x	x	x	**Befort CA**, **Klemp** JR, **Fabian** C, Perri MG, **Sullivan** DK, Schmitz KH, **Diaz** FJ, **Shireman** T. Protocol and recruitment results from a randomized controlled trial comparing group phone-based versus newsletter interventions for weight loss maintenance among rural breast cancer survivors. Contemporary clinical trials. 2014;37(2):261-71. doi: 10.1016/j.cct.2014.01.010. PubMed PMID: 24486636; PubMed Central PMCID: PMC3992482.
x			**Befort** CA, Nazir N, Engelman K, **Choi** W. Fatalistic cancer beliefs and information sources among rural and urban adults in the USA. Journal of cancer education : the official journal of the American Association for Cancer Education. 2013;28(3):521-6. doi: 10.1007/s13187-013-0496-7. PubMed PMID: 23813489; PubMed Central PMCID: PMC3768251.
		x	Bellettiere J, **Carlson** JA, Rosenberg D, Singhania A, Natarajan L, Berardi V, LaCroix AZ, Sears DD, Moran K, Crist K, Kerr J. Gender and Age Differences in Hourly and Daily Patterns of Sedentary Time in Older Adults Living in Retirement Communities. PloS one. 2015;10(8):e0136161. Epub 2015/08/22. doi: 10.1371/journal.pone.0136161. PubMed PMID: 26296095; PMCID: Pmc4546658.
	x	x	Berg CJ, **Daley CM,** Nazir N, Kinlacheeny JB, Ashley A, Ahluwalia JS, **Greiner KA, Choi WS**. Physical activity and fruit and vegetable intake among American Indians. J Community Health. 2012;37(1):65-71. PMCID: 3259287.
	x	x	Berg CJ, Ling PM, Hayes RB, Berg E, **Nollen** N, Nehl E, **Choi** WS, Ahluwalia JS. Smoking frequency among current college student smokers: distinguishing characteristics and factors related to readiness to quit smoking. Health Educ Res. 2012;27(1):141-50. Epub 2011/12/14. doi: 10.1093/her/cyr106. PubMed PMID: 22156071; PMCID: PMC3605919.
		x	Birken SA, **Ellis** SD, Walker JS, DiMartino LD, Check DK, Gerstel AA, Mayer DK. Guidelines for the use of survivorship care plans: a systematic quality appraisal using the AGREE II instrument. Implementation science : IS. 2015;10:63. Epub 2015/05/04. doi: 10.1186/s13012-015-0254-9. PubMed PMID: 25935752; PMCID: Pmc4425878.
		x	Birken SA, Presseau J, **Ellis** SD, Gerstel AA, Mayer DK. Potential determinants of health-care professionals inverted question mark use of survivorship care plans: a qualitative study using the theoretical domains framework. Implementation science : IS. 2014;9(1):167. Epub 2014/11/16. doi: 10.1186/s13012-014-0167-z. PubMed PMID: 25398477; PubMed Central PMCID: PMCPmc4236456.
	x	x	Black WR, Lepping RJ, Bruce AS, Powell JN, Bruce JM, **Martin** LE, Davis AM, Brooks WM, **Savage** CR, Simmons WK. Tonic hyper-connectivity of reward neurocircuitry in obese children. Obesity (Silver Spring, Md). 2014;22(7):1590-3. Epub 2014/03/19. doi: 10.1002/oby.20741. PubMed PMID: 24634397; PubMed Central PMCID: PMCPmc4077951.
		x	Block MS, Charbonneau B, Vierkant RA, Fogarty Z, Bamlet WR, Pharoah PD, Rossing MA, Cramer D, Pearce CL, Schildkraut J, Menon U, Kjaer SK, Levine DA, Gronwald J, Culver HA, Whittemore AS, Karlan BY, Lambrechts D, Wentzensen N, Kupryjanczyk J, Chang-Claude J, Bandera EV, Hogdall E, Heitz F, Kaye SB, Fasching PA, Campbell I, Goodman MT, Pejovic T, Bean YT, Hays LE, Lurie G, Eccles D, Hein A, Beckmann MW, Ekici AB, Paul J, Brown R, Flanagan JM, Harter P, du Bois A, Schwaab I, Hogdall CK, Lundvall L, Olson SH, Orlow I, Paddock LE, Rudolph A, Eilber U, Dansonka-Mieszkowska A, Rzepecka IK, Ziolkowska-Seta I, Brinton LA, Yang H, Garcia-Closas M, Despierre E, Lambrechts S, Vergote I, Walsh CS, Lester J, Sieh W, McGuire V, Rothstein JH, Ziogas A, Lubinski J, Cybulski C, Menkiszak J, Jensen A, Gayther SA, Ramus SJ, Gentry-Maharaj A, Berchuck A, Wu AH, Pike MC, Van Den Berg D, Terry KL, Vitonis AF, Ramirez SM, Rider DN, Knutson KL, Sellers TA, Phelan CM, Doherty JA, Johnatty SE, deFazio A, Song H, Tyrer J, Kalli KR, **Fridley** BL, Cunningham JM, Goode EL. Variation in NF-kappaB signaling pathways and survival in invasive epithelial ovarian cancer. Cancer Epidemiol Biomarkers Prev. 2014;23(7):1421-7. Epub 2014/04/18. doi: 10.1158/1055-9965.epi-13-0962. PubMed PMID: 24740199; PMCID: Pmc4082406.

Inter	Intra	External	Publication
x		x	Bojesen SE, Pooley KA, Johnatty SE, Beesley J, Michailidou K, Tyrer JP, Edwards SL, Pickett HA, Shen HC, Smart CE, Hillman KM, Mai PL, Lawrenson K, Stutz MD, Lu Y, Karevan R, Woods N, Johnston RL, French JD, Chen X, Weischer M, Nielsen SF, Maranian MJ, Ghoussaini M, Ahmed S, Baynes C, Bolla MK, Wang Q, Dennis J, McGuffog L, Barrowdale D, Lee A, Healey S, Lush M, Tessier DC, Vincent D, Bacot F, Vergote I, Lambrechts S, Despierre E, Risch HA, Gonzalez-Neira A, Rossing MA, Pita G, Doherty JA, Alvarez N, Larson MC, **Fridley** BL, Schoof N, Chang-Claude J, Cicek MS, Peto J, Kalli KR, Broeks A, Armasu SM, Schmidt MK, Braaf LM, Winterhoff B, Nevanlinna H, Konecny GE, Lambrechts D, Rogmann L, Guenel P, Teoman A, Milne RL, Garcia JJ, Cox A, Shridhar V, Burwinkel B, Marme F, Hein R, Sawyer EJ, Haiman CA, Wang-Gohrke S, Andrulis IL, Moysich KB, Hopper JL, Odunsi K, Lindblom A, Giles GG, Brenner H, Simard J, Lurie G, Fasching PA, Carney ME, Radice P, Wilkens LR, Swerdlow A, Goodman MT, Brauch H, Garcia-Closas M, Hillemanns P, Winqvist R, Durst M, Devilee P, Runnebaum I, Jakubowska A, Lubinski J, Mannermaa A, Butzow R, Bogdanova NV, Dork T, Pelttari LM, Zheng W, Leminen A, Anton-Culver H, Bunker CH, Kristensen V, Ness RB, Muir K, Edwards R, Meindl A, Heitz F, Matsuo K, du Bois A, Wu AH, Harter P, Teo SH, Schwaab I, Shu XO, Blot W, Hosono S, Kang D, Nakanishi T, Hartman M, Yatabe Y, Hamann U, Karlan BY, Sangrajrang S, Kjaer SK, Gaborieau V, Jensen A, Eccles D, Hogdall E, Shen CY, Brown J, Woo YL, Shah M, Azmi MA, Luben R, Omar SZ, Czene K, Vierkant RA, Nordestgaard BG, Flyger H, Vachon C, Olson JE, Wang X, Levine DA, Rudolph A, Weber RP, Flesch-Janys D, Iversen E, Nickels S, Schildkraut JM, Silva Idos S, Cramer DW, Gibson L, Terry KL, Fletcher O, Vitonis AF, van der Schoot CE, Poole EM, Hogervorst FB, Tworoger SS, Liu J, Bandera EV, Li J, Olson SH, Humphreys K, Orlow I, Blomqvist C, Rodriguez-Rodriguez L, Aittomaki K, Salvesen HB, Muranen TA, Wik E, Brouwers B, Krakstad C, Wauters E, Halle MK, Wildiers H, Kiemeney LA, Mulot C, Aben KK, Laurent-Puig P, Altena AM, Truong T, Massuger LF, Benitez J, Pejovic T, Perez JI, Hoatlin M, Zamora MP, Cook LS, Balasubramanian SP, Kelemen LE, Schneeweiss A, Le ND, Sohn C, Brooks-Wilson A, Tomlinson I, Kerin MJ, Miller N, Cybulski C, Henderson BE, Menkiszak J, Schumacher F, Wentzensen N, Le Marchand L, Yang HP, Mulligan AM, Glendon G, Engelholm SA, Knight JA, Hogdall CK, Apicella C, Gore M, Tsimiklis H, Song H, Southey MC, Jager A, den Ouweland AM, Brown R, Martens JW, Flanagan JM, Kriege M, Paul J, Margolin S, Siddiqui N, Severi G, Whittemore AS, Baglietto L, McGuire V, Stegmaier C, Sieh W, Muller H, Arndt V, Labreche F, Gao YT, Goldberg MS, Yang G, Dumont M, McLaughlin JR, Hartmann A, Ekici AB, Beckmann MW, Phelan CM, Lux MP, Permuth-Wey J, Peissel B, Sellers TA, Ficarazzi F, Barile M, Ziogas A, Ashworth A, Gentry-Maharaj A, Jones M, Ramus SJ, Orr N, Menon U, Pearce CL, Bruning T, Pike MC, Ko YD, Lissowska J, Figueroa J, Kupryjanczyk J, Chanock SJ, Dansonka-Mieszkowska A, Jukkola-Vuorinen A, Rzepecka IK, Pylkas K, Bidzinski M, Kauppila S, Hollestelle A, Seynaeve C, Tollenaar RA, Durda K, Jaworska K, Hartikainen JM, Kosma VM, Kataja V, Antonenkova NN, Long J, Shrubsole M, Deming-Halverson S, Lophatananon A, Siriwanarangsan P, Stewart-Brown S, Ditsch N, Lichtner P, Schmutzler RK, Ito H, Iwata H, Tajima K, Tseng CC, Stram DO, van den Berg D, Yip CH, Ikram MK, Teh YC, Cai H, Lu W, Signorello LB, Cai Q, Noh DY, Yoo KY, Miao H, Iau PT, Teo YY, McKay J, Shapiro C, Ademuyiwa F, Fountzilas G, Hsiung CN, Yu JC, Hou MF, Healey CS, Luccarini C, Peock S, Stoppa-Lyonnet D, Peterlongo P, Rebbeck TR, Piedmonte M, Singer CF, Friedman E, Thomassen M, Offit K, Hansen TV, Neuhausen SL, Szabo CI, Blanco I, Garber J, Narod SA, Weitzel JN, Montagna M, Olah E, **Godwin** AK, Yannoukakos D, Goldgar DE, Caldes T, Imyanitov EN, Tihomirova L, Arun BK, Campbell I, Mensenkamp AR, van Asperen CJ, van Roozendaal KE, Meijers-Heijboer H, Collee JM, Oosterwijk JC, Hooning MJ, Rookus MA, van der Luijt RB, Os TA, Evans DG, Frost D, Fineberg E, Barwell J, Walker L, Kennedy MJ, Platte R, Davidson R, Ellis SD, Cole T, Bressac-de Paillerets B, Buecher B, Damiola F, Faivre L, Frenay M, Sinilnikova OM, Caron O, Giraud S, Mazoyer S, Bonadona V, Caux-Moncoutier V, Toloczko-Grabarek A, Gronwald J, Byrski T, Spurdle AB, Bonanni B, Zaffaroni D, Giannini G, Bernard L, Dolcetti R, Manoukian S, Arnold N, Engel C, Deissler H, Rhiem K, Niederacher D, Plendl H, Sutter C, Wappenschmidt B, Borg A, Melin B, Rantala J, Soller M, Nathanson KL, Domchek SM, Rodriguez GC, Salani R, Kaulich DG, Tea MK, Paluch SS, Laitman Y, Skytte AB, Kruse TA, Jensen UB, Robson M, Gerdes AM, Ejlertsen B, Foretova L, Savage SA, Lester J, Soucy P, Kuchenbaecker KB, Olswold C, Cunningham JM, Slager S, Pankratz VS, Dicks E, Lakhani SR, Couch FJ, Hall P, Monteiro AN, Gayther SA, Pharoah PD, Reddel RR, Goode EL, Greene MH, Easton DF, Berchuck A, Antoniou AC, Chenevix-Trench G, Dunning AM. Multiple independent variants at the TERT locus are associated with telomere length and risks of breast and ovarian cancer. Nat Genet. 2013;45(4):371-84, 84e1-2. Epub 2013/03/29. doi: 10.1038/ng.2566. PubMed PMID: 23535731; PMCID: Pmc3670748.

Inter	Intra	External	Publication
x		x	Bolton KL, Chenevix-Trench G, Goh C, Sadetzki S, Ramus SJ, Karlan BY, Lambrechts D, Despierre E, Barrowdale D, McGuffog L, Healey S, Easton DF, Sinilnikova O, Benitez J, Garcia MJ, Neuhausen S, Gail MH, Hartge P, Peock S, Frost D, Evans DG, Eeles R, **Godwin** AK, Daly MB, Kwong A, Ma ES, Lazaro C, Blanco I, Montagna M, D'Andrea E, Nicoletto MO, Johnatty SE, Kjaer SK, Jensen A, Hogdall E, Goode EL, **Fridley** BL, Loud JT, Greene MH, Mai PL, Chetrit A, Lubin F, Hirsh-Yechezkel G, Glendon G, Andrulis IL, Toland AE, Senter L, Gore ME, Gourley C, Michie CO, Song H, Tyrer J, Whittemore AS, McGuire V, Sieh W, Kristoffersson U, Olsson H, Borg A, Levine DA, Steele L, Beattie MS, Chan S, Nussbaum RL, Moysich KB, Gross J, Cass I, Walsh C, Li AJ, Leuchter R, Gordon O, Garcia-Closas M, Gayther SA, Chanock SJ, Antoniou AC, Pharoah PD, Embrace, kConFab I, Cancer Genome Atlas Research N. Association between BRCA1 and BRCA2 mutations and survival in women with invasive epithelial ovarian cancer. JAMA. 2012;307(4):382-90. Epub 2012/01/26. doi: 10.1001/jama.2012.20. PubMed PMID: 22274685; PMCID: PMC3727895.
x	x	x	Bronars CA, **Faseru** B, Krebill R, **Mayo** MS, Snow TM, Okuyemi KS, Ahluwalia JS, **Cox** LS. Examining Smoking Dependence Motives among African American Light Smokers. Journal of smoking cessation. 2015;10(2):154-61. Epub 2015/11/12. doi: 10.1017/jsc.2014.7. PubMed PMID: 26557184; PMCID: Pmc4635476.
	x	x	Bruce AS, Bruce JM, Black WR, Lepping RJ, Henry JM, Cherry JB, **Martin** LE, Papa VB, Davis AM, Brooks WM, **Savage** CR. Branding and a child's brain: an fMRI study of neural responses to logos. Social cognitive and affective neuroscience. 2014;9(1):118-22. Epub 2012/09/22. doi: 10.1093/scan/nss109. PubMed PMID: 22997054; PubMed Central PMCID: PMCPmc3871732.
x	x	x	Bruce AS, Bruce JM, Ness AR, Lepping RJ, Malley S, Hancock L, Powell J, Patrician TM, Breslin FJ, **Martin** LE, **Donnelly** JE, Brooks WM, **Savage** CR. A comparison of functional brain changes associated with surgical versus behavioral weight loss. Obesity (Silver Spring, Md). 2014;22(2):337-43. Epub 2013/10/12. doi: 10.1002/oby.20630. PubMed PMID: 24115765; PubMed Central PMCID: PMCPmc3946492.
x	x	x	Buchanan TS, **Sanderson Cox** L, Thomas JL, **Nollen** NL, Berg CJ, **Mayo** MS, Ahluwalia JS. Perceived treatment assignment and smoking cessation in a clinical trial of bupropion versus placebo. Nicotine Tob Res. 2013 Feb;15(2):567-71. doi: 10.1093/ntr/nts143. Epub 2012 Sep 4. PubMed PMID: 22949570; PubMed Central PMCID:PMC3611997.
	x	x	Campos Tda S, **Richter** KP, **Cupertino** AP, Galil AG, Banhato EF, Colugnati FA, Bastos MG. Cigarette smoking among patients with chronic diseases. Int J Cardiol. 2014;174(3):808-10. Epub 2014/05/08. doi: 10.1016/j.ijcard.2014.04.150. PubMed PMID: 24801077; PMCID: PMC4568820.
		x	Candido-dos-Reis FJ, Song H, Goode EL, Cunningham JM, **Fridley** BL, ..., Gayther SA, Bowtell D, Pharoah PD. Germline mutation in BRCA1 or BRCA2 and ten-year survival for women diagnosed with epithelial ovarian cancer. Clinical cancer research : an official journal of the American Association for Cancer Research. 2015;21(3):652-7. Epub 2014/11/16. doi: 10.1158/1078-0432.ccr-14-2497. PubMed PMID: 25398451; PMCID: Pmc4338615.
		x	**Carlson** JA, Schipperijn J, Kerr J, Saelens BE, Natarajan L, Frank LD, Glanz K, Conway TL, Chapman JE, Cain KL, Sallis JF. Locations of Physical Activity as Assessed by GPS in Young Adolescents. Pediatrics. 2016;137(1). Epub 2015/12/10. doi: 10.1542/peds.2015-2430. PubMed PMID: 26647375; PMCID: PMC4702023.
x		x	**Carlson** SE, Colombo J, **Gajewski** BJ, Gustafson KM, Mundy D, Yeast J, Georgieff MK, Markley LA, Kerling EH, Shaddy DJ. DHA supplementation and pregnancy outcomes. The American journal of clinical nutrition. 2013;97(4):808-15. doi: 10.3945/ajcn.112.050021. PubMed PMID: 23426033; PubMed Central PMCID: PMC3607655.

Inter	Intra	External	Publication
		x	Carvajal-Carmona LG, O'Mara TA, Painter JN, Lose FA, Dennis J, Michailidou K, Tyrer JP, Ahmed S, Ferguson K, Healey CS, Pooley K, Beesley J, Cheng T, Jones A, Howarth K, Martin L, Gorman M, Hodgson S, National Study of Endometrial Cancer Genetics G, Australian National Endometrial Cancer Study G, Wentzensen N, Fasching PA, Hein A, Beckmann MW, Renner SP, Dork T, Hillemanns P, Durst M, Runnebaum I, Lambrechts D, Coenegrachts L, Schrauwen S, Amant F, Winterhoff B, Dowdy SC, Goode EL, Teoman A, Salvesen HB, Trovik J, Njolstad TS, Werner HM, Scott RJ, Ashton K, Proietto T, Otton G, Wersall O, Mints M, Tham E, Rendocas, Hall P, Czene K, Liu J, Li J, Hopper JL, Southey MC, Australian Ovarian Cancer S, Ekici AB, Ruebner M, Johnson N, Peto J, Burwinkel B, Marme F, Brenner H, Dieffenbach AK, Meindl A, Brauch H, Network G, Lindblom A, Depreeuw J, Moisse M, Chang-Claude J, Rudolph A, Couch FJ, Olson JE, Giles GG, Bruinsma F, Cunningham JM, **Fridley** BL, Borresen-Dale AL, Kristensen VN, Cox A, Swerdlow AJ, Orr N, Bolla MK, Wang Q, Weber RP, Chen Z, Shah M, Pharoah PD, Dunning AM, Tomlinson I, Easton DF, Spurdle AB, Thompson DJ. Candidate locus analysis of the TERT-CLPTM1L cancer risk region on chromosome 5p15 identifies multiple independent variants associated with endometrial cancer risk. Hum Genet. 2015;134(2):231-45. doi: 10.1007/s00439-014-1515-4. PubMed PMID: 25487306; PMCID: PMC4291520.
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		x	Charbonneau B, Block MS, Bamlet WR, Vierkant RA, Kalli KR, Fogarty Z, Rider DN, Sellers TA, Tworoger SS, Poole E, Risch HA, Salvesen HB, Kiemeney LA, Baglietto L, Giles GG, Severi G, Trabert B, Wentzensen N, Chenevix-Trench G, Whittemore AS, Sieh W, Chang-Claude J, Bandera EV, Orlow I, Terry K, Goodman MT, Thompson PJ, Cook LS, Rossing MA, Ness RB, Narod SA, Kupryjanczyk J, Lu K, Butzow R, Dork T, Pejovic T, Campbell I, Le ND, Bunker CH, Bogdanova N, Runnebaum IB, Eccles D, Paul J, Wu AH, Gayther SA, Hogdall E, Heitz F, Kaye SB, Karlan BY, Anton-Culver H, Gronwald J, Hogdall CK, Lambrechts D, Fasching PA, Menon U, Schildkraut J, Pearce CL, Levine DA, Kjaer SK, Cramer D, Flanagan JM, Phelan CM, Brown R, Massuger LF, Song H, Doherty JA, Krakstad C, Liang D, Odunsi K, Berchuck A, Jensen A, Lubinski J, Nevanlinna H, Bean YT, Lurie G, Ziogas A, Walsh C, Despierre E, Brinton L, Hein A, Rudolph A, Dansonka-Mieszkowska A, Olson SH, Harter P, Tyrer J, Vitonis AF, Brooks-Wilson A, Aben KK, Pike MC, Ramus SJ, Wik E, Cybulski C, Lin J, Sucheston L, Edwards R, McGuire V, Lester J, du Bois A, Lundvall L, Wang-Gohrke S, Szafron LM, Lambrechts S, Yang H, Beckmann MW, Pelttari LM, Van Altena AM, van den Berg D, Halle MK, Gentry-Maharaj A, Schwaab I, Chandran U, Menkiszak J, Ekici AB, Wilkens LR, Leminen A, Modugno F, Friel G, Rothstein JH, Vergote I, Garcia-Closas M, Hildebrandt MA, Sobiczewski P, Kelemen LE, Pharoah PD, Moysich K, Knutson KL, Cunningham JM, **Fridley** BL, Goode EL. Risk of ovarian cancer and the NF-kappaB pathway: genetic association with IL1A and TNFSF10. Cancer Res. 2014;74(3):852-61. Epub 2013/11/26. doi: 10.1158/0008-5472.can-13-1051. PubMed PMID: 24272484; PMCID: Pmc3946482.

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		x	Charbonneau B, Moysich KB, Kalli KR, Oberg AL, Vierkant RA, Fogarty ZC, Block MS, Maurer MJ, Goergen KM, **Fridley** BL, Cunningham JM, Rider DN, Preston C, Hartmann LC, Lawrenson K, Wang C, Tyrer J, Song H, deFazio A, Johnatty SE, Doherty JA, Phelan CM, Sellers TA, Ramirez SM, Vitonis AF, Terry KL, Van Den Berg D, Pike MC, Wu AH, Berchuck A, Gentry-Maharaj A, Ramus SJ, Diergaarde B, Shen H, Jensen A, Menkiszak J, Cybulski C, Lubilski J, Ziogas A, Rothstein JH, McGuire V, Sieh W, Lester J, Walsh C, Vergote I, Lambrechts S, Despierre E, Garcia-Closas M, Yang H, Brinton LA, Spiewankiewicz B, Rzepecka IK, Dansonka-Mieszkowska A, Seibold P, Rudolph A, Paddock LE, Orlow I, Lundvall L, Olson SH, Hogdall CK, Schwaab I, du Bois A, Harter P, Flanagan JM, Brown R, Paul J, Ekici AB, Beckmann MW, Hein A, Eccles D, Lurie G, Hays LE, Bean YT, Pejovic T, Goodman MT, Campbell I, Fasching PA, Konecny G, Kaye SB, Heitz F, Hogdall E, Bandera EV, Chang-Claude J, Kupryjanczyk J, Wentzensen N, Lambrechts D, Karlan BY, Whittemore AS, Culver HA, Gronwald J, Levine DA, Kjaer SK, Menon U, Schildkraut JM, Pearce CL, Cramer DW, Rossing MA, Chenevix-Trench G, Pharoah PD, Gayther SA, Ness RB, Odunsi K, Sucheston LE, Knutson KL, Goode EL. Large-scale evaluation of common variation in regulatory T cell-related genes and ovarian cancer outcome. Cancer immunology research. 2014;2(4):332-40. Epub 2014/04/26. doi: 10.1158/2326-6066.cir-13-0136. PubMed PMID: 24764580; PMCID: Pmc4000890.
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		x	Chen P, Hinote D, **Chen** G. A rule based solution to co-reference resolution in clinical text. J Am Med Inform Assoc. 2013 Sep-Oct;20(5):891-7. doi: 10.1136/amiajnl-2011-000770. Epub 2012 Oct 11. PubMed PMID: 23059732; PubMed Central PMCID: PMC3756251.
		x	Cheng TH, Thompson D, Painter J, O'Mara T, Gorman M, Martin L, Palles C, Jones A, Buchanan DD, Ko Win A, Hopper J, Jenkins M, Lindor NM, Newcomb PA, Gallinger S, Conti D, Schumacher F, Casey G, Giles GG, Pharoah P, Peto J, Cox A, Swerdlow A, Couch F, Cunningham JM, Goode EL, Winham SJ, Lambrechts D, Fasching P, Burwinkel B, Brenner H, Brauch H, Chang-Claude J, Salvesen HB, Kristensen V, Darabi H, Li J, Liu T, Lindblom A, Hall P, de Polanco ME, Sans M, Carracedo A, Castellvi-Bel S, Rojas-Martinez A, Aguiar Jnr S, Teixeira MR, Dunning AM, Dennis J, Otton G, Proietto T, Holliday E, Attia J, Ashton K, Scott RJ, McEvoy M, Dowdy SC, **Fridley** BL, Werner HM, Trovik J, Njolstad TS, Tham E, Mints M, Runnebaum I, Hillemanns P, Dork T, Amant F, Schrauwen S, Hein A, Beckmann MW, Ekici A, Czene K, Meindl A, Bolla MK, Michailidou K, Tyrer JP, Wang Q, Ahmed S, Healey CS, Shah M, Annibali D, Depreeuw J, Al-Tassan NA, Harris R, Meyer BF, Whiffin N, Hosking FJ, Kinnersley B, Farrington SM, Timofeeva M, Tenesa A, Campbell H, Haile RW, Hodgson S, Carvajal-Carmona L, Cheadle JP, Easton D, Dunlop M, Houlston R, Spurdle A, Tomlinson I. Meta-analysis of genome-wide association studies identifies common susceptibility polymorphisms for colorectal and endometrial cancer near SH2B3 and TSHZ1. Scientific reports. 2015;5:17369. Epub 2015/12/02. doi: 10.1038/srep17369. PubMed PMID: 26621817; PMCID: PMC4664893.

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		x	Cooperman NA, **Richter** KP, Bernstein SL, Steinberg ML, Williams JM. Determining Smoking Cessation Related Information, Motivation, and Behavioral Skills among Opiate Dependent Smokers in Methadone Treatment. Subst Use Misuse. 2015;50(5):566-81. Epub 2015/01/07. doi: 10.3109/10826084.2014.991405. PubMed PMID: 25559697; PMCID: Pmc4646090.
			Cruvinel E, **Richter** KP, Bastos RR, Ronzani TM. Screening and brief intervention for alcohol and other drug use in primary care: associations between organizational climate and practice. Addict Sci Clin Pract. 2013 Feb 11;8(1):4. doi: 10.1186/1940-0640-8-4. PubMed PMID: 23399417; PubMed Central PMCID:PMC3598982.

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	x	x	**Cupertino** AP, Hunt JJ, **Gajewski** BJ, Jiang Y, Marquis J, Friedmann PD, **Engelman** KK, **Richter** KP. The index of tobacco treatment quality: development of a tool to assess evidence-based treatment in a national sample of drug treatment facilities. Substance abuse treatment, prevention, and policy. 2013;8(1):13. doi: 10.1186/1747-597X-8-13. PubMed PMID: 23497366; PubMed Central PMCID: PMC3704700.
	x	x	**Cupertino** AP, Saint-Elin M, de Los Rios JB, **Engelman** KK, **Greiner** KA, **Ellerbeck** EF, Napoles AM. Empowering Promotores de Salud as partners in cancer education and research in rural southwest Kansas. Oncology nursing forum. 2015;42(1):15-22. Epub 2014/12/30. doi: 10.1188/15.onf.15-22. PubMed PMID: 25542317; PMCID: Pmc4349504.
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		x	DeRycke MS, Gunawardena SR, Middha S, Asmann YW, Schaid DJ, McDonnell SK, Riska SM, Eckloff BW, Cunningham JM, **Fridley** BL, Serie DJ, Bamlet WR, Cicek MS, Jenkins MA, Duggan DJ, Buchanan D, Clendenning M, Haile RW, Woods MO, Gallinger SN, Casey G, Potter JD, Newcomb PA, Le Marchand L, Lindor NM, Thibodeau SN, Goode EL. Identification of novel variants in colorectal cancer families by high-throughput exome sequencing. Cancer Epidemiol Biomarkers Prev. 2013 Jul;22(7):1239-51. doi: 10.1158/1055-9965.EPI-12-1226. Epub 2013 May 1. PubMed PMID: 23637064; PubMed Central PMCID: PMC3704223.
		x	Duffy SA, Cummins SE, Fellows JL, Harrington KF, Kirby C, Rogers E, **Scheuermann** TS, Tindle HA, Waltje AH. Fidelity monitoring across the seven studies in the Consortium of Hospitals Advancing Research on Tobacco (CHART). Tobacco induced diseases. 2015;13(1):29. Epub 2015/09/04. doi: 10.1186/s12971-015-0056-5. PubMed PMID: 26336372; PMCID: Pmc4557818.
		x	Dusetzina SB, **Ellis** S, Freedman RA, Conti RM, Winn AN, Chambers JD, Alexander GC, Huskamp HA, Keating NL. How Do Payers Respond to Regulatory Actions? The Case of Bevacizumab. J Oncol Pract. 2015;11(4):313-8. Epub 2015/06/11. doi: 10.1200/jop.2015.004218. PubMed PMID: 26060224; PMCID: Pmc4507391.
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		x	Liu M, Ingle JN, **Fridley** BL, Buzdar AU, Robson ME, Kubo M, Wang L, Batzler A, Jenkins GD, Pietrzak TL, Carlson EE, Goetz MP, Northfelt DW, Perez EA, Williard CV, Schaid DJ, Nakamura Y, Weinshilboum RM. TSPYL5 SNPs: association with plasma estradiol Concentrations and aromatase expression. Mol Endocrinol. 2013 Apr;27(4):657-70. doi: 10.1210/me.2012-1397. Epub 2013 Mar 21. PubMed PMID: 23518928; PubMed Central PMCID: PMC3607698.
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	x		**Mahnken** JD, Chen X, Brown AR, Vidoni ED, Billinger SA, **Gajewski** BJ. Evaluating Variables as Unbiased Proxies for Other Measures: Assessing the Step Test Exercise Prescription as a Proxy for the Maximal, High-intensity Peak Oxygen Consumption in Older Adults. Int J Stat Probab. 2014;3(4):25-34. Epub 2014/12/17. doi: 10.5539/ijsp.v3n4p25. PubMed PMID: 25505498; PubMed Central PMCID: PMCPmc4258696.

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		x	Matimba A, Li F, Livshits A, Cartwright CS, Scully S, **Fridley** BL, Jenkins G, Batzler A, Wang L, Weinshilboum R, Lennard L. Thiopurine pharmacogenomics: association of SNPs with clinical response and functional validation of candidate genes. Pharmacogenomics. 2014;15(4):433-47. Epub 2014/03/15. doi: 10.2217/pgs.13.226. PubMed PMID: 24624911; PubMed Central PMCID: PMCPmc4027966.
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	x	x	Wetmore JB, **Mahnken** JD, Rigler SK, **Ellerbeck** EF, Mukhopadhyay P, Spertus JA, Hou Q, **Shireman** TI. The prevalence of and factors associated with chronic atrial fibrillation in Medicare/Medicaid-eligible dialysis patients. Kidney Int. 2012;81(5):469-76. Epub 2011/12/23. doi: 10.1038/ki.2011.416. PubMed PMID: 22189842; PMCID: Pmc3891593.
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		x	**Steele** RG, Wu YP, Cushing CC, Jensen CD. Evaluation of child health matters: a web-based tutorial to enhance school nurses' communications with families about weight-related health. The Journal of school nursing : the official publication of the National Association of School Nurses. 2013;29(2):151-60. Epub 2012/05/18. doi: 10.1177/1059840512446070. PubMed PMID: 22592540.
x		x	Thompson L, Wang S, **Tawfik** O, Templeton K, Tancabelic J, Pinson D, Anderson HC, **Keighley** J, **Garimella** R. Effect of 25-hydroxyvitamin D3 and 1 alpha,25 dihydroxyvitamin D3 on differentiation and apoptosis of human osteosarcoma cell lines. J Orthop Res. 2012;30(5):831-44. Epub 2011/11/02. doi: 10.1002/jor.21585. PubMed PMID: 22042758.
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			Vacek JL, Vanga SR, Good M, **Lai** SM, Lakkireddy D, Howard PA. Vitamin D deficiency and supplementation and relation to cardiovascular health. Am J Cardiol. 2012;109(3):359-63. Epub 2011/11/11. doi: 10.1016/j.amjcard.2011.09.020. PubMed PMID: 22071212.
		x	Van Allen J, Borner KB, Gayes LA, **Steele** RG. Weighing Physical Activity: The Impact of a Family-Based Group Lifestyle Intervention for Pediatric Obesity on Participants' Physical Activity. Journal of pediatric psychology. 2014. Epub 2014/09/23. doi: 10.1093/jpepsy/jsu077. PubMed PMID: 25241402.
		x	Walsh M, Plein LC, Fitzgerald MP, **Gurley-Calvez** T, Pellillo A. Opting to opt-in: policy choice, program expectations and results in West Virginia's Medicaid reform initiative. Journal of health care for the poor and underserved. 2014;25(3):1449-71. Epub 2014/08/19. doi: 10.1353/hpu.2014.0150. PubMed PMID: 25130251.
		x	Wu YP, **Steele** RG. Predicting health-related quality of life from the psychosocial profiles of youth seeking treatment for obesity. Journal of developmental and behavioral pediatrics : JDBP. 2013;34(8):575-82. Epub 2013/10/18. doi: 10.1097/DBP.0b013e3182a509a6. PubMed PMID: 24131880.
		x	Young R, Willis E, Cameron G, **Geana** M. "Willing but unwilling": attitudinal barriers to adoption of home-based health information technology among older adults. Health informatics journal. 2014;20(2):127-35. Epub 2013/09/24. doi: 10.1177/1460458213486906. PubMed PMID: 24056750.

Table 6 – Cancer Control and Population Health – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

Interventional:

EXTERNALLY PEER-REVIEWED												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
NIH	Lung	NCT02050308	KUMC 13613	Choi, W	CCPH	5/12/2015		III	Pre	Web-Based Smoking Cessation Program for Tribal College Students	N		300	87	87	0	0	Protocol enrollment and activities are all web-based. All subjects are from Salish Kootenai College in Montana
NIH	Smoking Cessation	NCT02360631	STUDY00000721	Cox, L	CCPH	7/21/2015		N/A	Pre	Advancing Tobacco Use Treatment for African American Smokers	N	500	500	68	111	0	0	
NIH	Smoking Cessation		STUDY00002725	Cupertino, P	CCPH	9/9/2015		N/A	Pre	Latinos Kick Buts: Mobile Engagement and Cessation Support for Latino Smokers	N	100	100	56	56	0	0	
PCORI	Smoking Cessation	NCT02148445	STUDY00000666	Ellerbeck, E	CCPH	5/15/2014	11/30/2015	N/A	Pre	Smoking Cessation versus Long-term Nicotine Replacement among High-risk Smokers	N	400	400	245	398	0	0	
St. Baldricks Foundation	Lymphoid Leukemia		STUDY00000227	Gibson, C	CCPH	9/30/2013	09/01/2015	N/A	Sup	Telephonic Health Coaching for Children with Acute Lymphoblastic Leukemia	Y	24	12	3	15	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
NIH NCI	Cancer Prevention		KUMC 12873	Greiner, A	CCPH	12/24/2012		N/A	Pre	Tailored Touchscreen Colorectal Cancer Prevention in American Indian Communities	N	460	460	38	202	0	0	
NCI	Cancer Prevention		KUMC 13509	Greiner, A	CCPH	2/1/2014		N/A	Pre	Latino and American Indian Health Workers Promoting Healthy Diets	N	120	120	0	60	0	0	Protocol is a small pilot study linked to our U54 Community Networks Program Center grant which is in its final year. We have been analyzing data to build a pilot intervention this year and that is why no one was recruited this last year. In 2016 we anticipate recruiting participants for the intervention.
NCI	Cancer Prevention		STUDY00000316	Lumpkins, C	CCPH	4/14/2014		N/A	Hsr	Communicating Colorectal Cancer Prevention Through Urban African American Churches - The Pilot Intervention	N	240	240	114	168	0	0	
NIH Pfizer	Smoking Cessation	NCT01836276	KUMC 12990	Nollen, N	CCPH	2/1/2013	12/10/2015	IV	Pre	Understanding Disparities in Quitting in African American and White Smokers	Y	448	448	19	449	0	0	
Patient-Centered Outcomes Research Institute (PCORI)	Smoking Cessation	NCT02244918	STUDY00001602	Nollen, N	CCPH	5/15/2015		IV	Pre	Informing Tobacco Treatment Guidelines for African American Non-Daily Smokers	N	384	384	86	124	0	0	
NIDDKD	Cancer Prevention	NCT02010463	KUMC 11951	Savage, C	CCPH	11/1/2011	04/28/2015	N/A	Pre	Neuroimaging Studies of Reward, Impulsivity, and Adherence to an Exercise Program	N	200	200	22	181	0	0	

Table 6 – Cancer Control and Population Health – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

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Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
American Cancer Society	Breast-Female		STUDY00000502	Cupertino, P	CCPH	1/31/2014		N/A	Pre	ACS-NFL A.M.I.G.A. (Helping Women with Information, Generosity and Support) for Breast Cancer Early Detection	N	1500	1500	661	1312	0	0	
Investigator	Cancer Prevention		STUDY00001320	LeMaster, J	CCPH	1/22/2015		Feasibility/Pilot	Pre	A Touch-to-Screen Implementations Intentions intervention to increase colonoscopy screening rates among Bhutanese refugees	N	20	20	10	10	0	0	
Investigator	Smoking Cessation		STUDY00001782	Martin, L	CCPH	12/2/2014		N/A	Pre	Smoking Cessation, Cognitive Control and Reward Processing: An fMRI Pilot study	N	50	50	39	50	0	0	
Investigator	Cervix	NCT02128659	KUMC 13559	Ramaswamy, M	CCPH	3/26/2013		N/A	Pre	Sexual Health Empowerment for Cervical Health Literacy and Cancer Prevention	N	200	200	155	223	0	0	

Observational:

INSTITUTIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	OfficialTitle	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
University of Kansas Cancer Center	Multiple		STUDY00002442	Geana, M	CCPH	09/25/2015	02/29/2016	N/A	Oth	Accrual for Cancer Clinical Trials - A Strategic Communication Campaign to Increase Knowledge and Chage Attitudes and Beliefs	Y	200	0	0	0	165	167	Recruitment occurred at sites affiliated with our primary insitution/Midwest Cancer Alliance members
Investigator	Colorectal		STUDY00001172	Hines, R	CCPH	8/7/2014	05/01/2015	Feasibility/Pilot	Oth	Pilot testing a patient questionnaire in colorectal cancer (CRC) patients	Y	100	100	4	4	37	43	
Investigator	Cancer Prevention		KUMC 11930	Martin, L	CCPH	9/8/2009		N/A	Oth	fMRI Studies of Decision-Making	N	96	96	0	107	0	0	Temporary suspension due to funding. Enrollment to resume in 2016

Ancillary/Correlative:

INSTITUTIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
KUCC Pilot Award	Colorectal		KUMC 13370	Greiner, A	CCPH	5/1/2013		N/A	Oth	A Translational Approach to Understanding African American Colorectal Cancer Health Disparities	N	40	40	20	39	0	0	
American Cancer Society	Lung		STUDY00000888	Pacheco, C	CCPH	11/1/2014	08/31/2015	N/A	Oth	American Indian Comprehension of Informed Consent and Trust of Medical Researchers	N	170	170	100	153	0	0	

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Edward Middle Name F Last Name*: Ellerbeck Suffix: MD

Position/Title*:	Professor
Organization Name*:	University of Kansas Medical Center
Department:	Preventive Med and Public Hlth
Division:	School of Medicine
Street1*:	MS 1008, 3901 Rainbow Boulevard
Street2:	
City*:	Kansas City
County:	Wyandotte
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66160-0000

Phone Number*: 913-588-2829 Fax Number: 913-588-2780

E-Mail*: eellerbe@kumc.edu

Credential, e.g., agency login: EELLERBECK

Project Role*: Other (Specify) Other Project Role Category: Project Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Ellerbeck_bio_CCSG1019857850.pdf

Attach Current & Pending Support: File Name:

Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Christie Middle Name Ann Last Name*: Befort Cardador Suffix: PhD

Position/Title*: Assistant Professor
Organization Name*: University of Kansas Medical Center
Department: Preventive Medicine
Division: School of Medicine
Street1*: MS 1008, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-3338 Fax Number: 913-588-2780

E-Mail*: cbefort@kumc.edu

Credential, e.g., agency login: CBEFORT

Project Role*: Other (Specify) Other Project Role Category: Project Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Befort_Bio_CCSG1018883933.pdf

Attach Current & Pending Support: File Name:

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ❍ Yes ❍ No

*Agency-Defined Phase III Clinical Trial? ❍ Yes ❍ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ❍ Yes ❍ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

❍ Yes ❍ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

❍ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

☐ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator / Change of Institution Section

☐ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

☐ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	CCPH_SpecificAims_Final1019659696.pdf
3. Research Strategy*	CCPH_ResearchStrategy_Final1019857901.pdf
4. Progress Report Publication List	Progress_Report_Publications_Blank1019754757.pdf
Human Subjects Section	
5. Protection of Human Subjects	
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	
8. Inclusion of Children	
Other Research Plan Section	
9. Vertebrate Animals	
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	
14. Resource Sharing Plan(s)	Resource_Sharing_Plan__Generic1019913982.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Cancer Control and Population Health – Specific Aims

The Cancer Control and Population Health (CCPH) research program within The University of Kansas Cancer Center (KUCC) was established to advance scientific knowledge related to cancer control with a particular emphasis on addressing the needs within the KUCC catchment area. CCPH research is focused on addressing issues related to tobacco control and translation of cancer control strategies to patients and communities in need. CCPH researchers work closely with patients, providers, advocacy groups and public health programs to ensure the ongoing support and relevance of their work to the KUCC catchment area. CCPH research is concentrated in five domains of study within two thematic areas:

Theme 1: Tobacco Control

- Develop behavioral interventions for smokers not ready to quit;
- Meet the sociocultural and biologic needs of diverse groups of smokers; and
- Integrate cessation tools into clinical settings to connect smokers with effective cessation options.

Theme 2: Translating Cancer Control into Clinics and Communities

- Implement cancer control strategies in clinical settings; and
- Develop tools to support translational research for cancer control.

The work in CCPH begins and ends with the cancer control needs of the KUCC communities. CCPH works to address these needs through outstanding interdisciplinary research. CCPH researchers use their skills in community-based participatory research and health services research to identify the needs and priorities of KUCC communities. CCPH has built on its historical strengths in community engagement to expand the scientific impact and launch innovative pragmatic cancer control trials. CCPH tobacco control research addresses the number one cause of cancer mortality in the KUCC catchment area and uses a combination of descriptive research, clinical trials and pharmacogenomics studies to advance smoking cessation research. This has led to some of the most extensive efforts in the country to advance tobacco control among African American, American Indian and rural smokers and expand access to treatment for Latino smokers both here and internationally. CCPH tobacco control work helped develop outstanding relationships with health care providers, patients and community members throughout the KUCC catchment area. These strong relationships have created an excellent environment for extending the translational tobacco control efforts to address other cancer control needs in KUCC communities and clinical settings, including cancer screening, immunizations, nutrition and physical activity.

With strong support from KUCC, including start-up funds, pilot projects, and programmatic support, CCPH is recruiting and developing cancer control researchers who are equipped to address the needs of the KUCC catchment area. In turn, the CCPH program has provided critical benefits to KUCC, particularly in terms of faculty development and community engagement. CCPH future plans are guided by extensive internal deliberations among the CCPH membership with critical input from the KUCC External Advisory Board and the patients and providers in the KUCC communities. These plans are integrated within the overall strategic plans of KUCC and supported by strategic investments that will allow CCPH to accelerate the growth of its research programs and enhance the relevance and impact of this research on cancer control in the KUCC catchment area.

Cancer Control and Population Health (CCPH) – Research Strategy

Overview

The CCPH program brings together 35 researchers at The University of Kansas Cancer Center (KUCC) to advance scientific knowledge related to cancer control with a particular emphasis on answering questions relevant to the KUCC catchment area. CCPH interdisciplinary research teams are addressing translational research problems related to tobacco control, nutrition, physical activity, obesity, cancer screening and HPV prevention. These efforts are particularly focused on translating cancer control strategies to benefit underserved minority and rural communities.

Table 1. Program Metrics

Members (2015)		
Total	**Full**	**Associate**
35	27	8

Funding (2015)		
Type	**# of grants**	**$ (total costs)**
NCI	13	3,656,136
Other NIH	11	3,989,884
Other Peer Reviewed	4	3,433,720
Total Peer Reviewed	**28**	**11,079,740**
Other	6	2,104,386
Total Funding	**34**	**13,184,126**

Publications (2012-2015)	
Total	**341**
High Impact (JIF ≥ 8)	28 (8%)
Inter-programmatic	69 (20%)
Intra-programmatic	111 (33%)
External collaborative	243 (71%)

Trial Accrual (2015)		
Type of trial	**# of trial(s)**	**# participants**
Health Services Research	1	114
Prevention	13	1,486
Supportive Care	1	3
Observational	3	206
Ancillary/Correlative/Other	2	120

CCPH program metrics are summarized in **Table 1**. Since the time of the initial CCSG award in 2012, CCPH has grown from 19 to 35 members and annual funding has grown by 74% from $7.7M in 2011 to $13.4M in 2015, with an average, per member funding of $376,690/year. At this time 66% of CCPH members are principal investigators on externally-funded cancer control research. The NCI funding has also increased 33% over the award period, even though some of the tobacco control grants, previously funded by the NCI, are now funded by NIDA. Meanwhile, CCPH members have been able to take advantage of almost $3M/year in PCORI funding to advance its cancer control research. The scientific output has also grown from 54 publications (2.8/member/year) in 2011 to 119 (3.4/member/year) in 2015. CCPH research benefits from a high degree of inter- and intra-programmatic collaborations along with extensive collaborations with other cancer centers. CCPH programmatic activities have benefited from strong use of shared resources, including Biostatistics and Informatics, Biospecimen and the developing Health Communications Research shared resource, as well as $80,000/year for programmatic expenses, faculty start-up and retention packages, pilot funding and grant writing support.

Program Development in Response to NCI Review and EAB Input

The KUCC External Advisory Board (EAB) and program leadership have helped CCPH leadership use the 2011 NCI critiques to identify ways in which CCPH could improve the quality and productivity of the program. The EAB, in particular, has identified ways to improve the organization of the thematic areas and enhance responsiveness to the needs of the KUCC catchment area. CCPH leaders have used program meetings and KUCC program leadership meetings to identify additional areas for improvement. Patients, providers, and other stakeholders have also provided valuable input, primarily through a rural practice-based research network (Kansas Physicians and Patients Engaged in Prevention Research (KPPEPR)) and the Midwest Cancer Alliance (MCA). Program improvements to major critiques are outlined in **Table 2**.

Table 2. CCPH Program Development in Response to Prior Critiques

2011 NIH critiques	Program Response
Increase number of publications	Increased annual publication productivity by 120%.
Need genetic epidemiology	Recruited **Fridley** and **Koestler** (CB) with expertise and funded research in biostatistical genetics. As their work progresses, this may become a separate thematic area, but may not be housed in the CCPH program.
Improve per member funding	Average funding now > $376,000/year with 66% of members funded as PI.
Expand inter-programmatic interactions	Joint program meetings, joint pilot funds, and interdisciplinary, team-building meetings have resulted in collaborative publications and research efforts with each of the other programs, but especially with the Cancer Prevention and Survivorship (CPS) program.

CCPH received excellent reviews for its efforts to engage underrepresented and rural communities. CCPH has built on this strength by moving beyond engagement to more innovative pragmatic trials and translational (T3) research. These transformations were facilitated by outstanding advice from selected visiting consultants and by the transfer of Christie **Befort** with her rural/pragmatic trial expertise from CPS to CCPH.

Program Leadership
The CCPH program is co-led by Edward **Ellerbeck** and **Befort**. These accomplished researchers provide complementary roles in the development and successful execution of this program. **Ellerbeck** provides a background in clinical medicine and health services research and provides cross-cutting support for both of our thematic areas. **Befort** brings expertise in implementation research, behavioral interventions and obesity treatment to lead a thematic group focused on improving the quality and delivery of cancer control services in both community and clinical settings. Both of these program leaders have worked extensively on developing community-based sites for CCPH. **Ellerbeck** and **Befort** meet regularly with Shrikant **Anant**, the Associate Director for Cancer Prevention and Control. **Anant** provides additional expertise in strategic planning and invaluable assistance in developing new inter-programmatic collaborations and effective utilization of shared resources.

Edward Ellerbeck, MD, MPH, has led the CCPH program since its inception in 2006. Since his arrival at KUMC, **Ellerbeck** has been the principal investigator on more than $11M in extramural funding addressing research related to cancer prevention and improving the quality of medical care. He has also served as a deputy editor for the *Journal of General Internal Medicine*, president of the Board of Governors for the *American Journal of Preventive Medicine* and a member of the Dissemination and Implementation Research in Health Study Section. **Ellerbeck's** research is devoted to T2/T3 translational research, developing new strategies for cancer control and moving established clinical innovations into the community. His group developed and tested a novel disease-management approach for enhancing the delivery of smoking cessation services into rural primary care practices. They demonstrated the feasibility of addressing nicotine dependence as a chronic disease, linking smokers, regardless of their readiness to quit, to effective pharmacotherapy and counseling resources. His current PCORI-funded work is assessing the impact of long-term nicotine replacement in the treatment of highly dependent smokers. **Ellerbeck** was the first to initiate NCI-funded research into our rural practice-based research network (KPPEPR) and the first to make use of our I2B2 interface for recruiting participants into clinical trials. **Ellerbeck** brings extensive experience in analysis of large datasets to identify 'opportunities for improvement' and the use of observational datasets to analyze the impact of interventions. **Ellerbeck** also leads the Frontiers clinical research training program, playing a critical role in the development of fellows and junior faculty. His current and recent mentees have received NIH K awards, American Cancer Society career development grants, Komen Foundation grants, PCORI funding, R21s and NCI-funded R01s.

Christie Befort, PhD became the co-leader of the CCPH program in 2015. **Befort** directs a research program focused on cancer control and survivorship through weight loss. Her work, funded by the NCI, ACS, Komen, and PCORI, is focused on delivering weight-loss interventions tailored to survivorship and primary care needs in rural settings. She has had continuous funding since her ACS postdoctoral fellowship in 2005, securing more than $13M in extramural funding. Befort has developed a keen interest in enhancing the impact of behavioral science by developing interventions that are scalable and have a market demand. While in the midst of conducting her first NCI R01 among overweight/obese rural breast cancer survivors she learned first-hand the benefits to individual patients, but noted the lack of infrastructure threaten the sustainability of the intervention. As a result, she became dedicated to focusing her work on pragmatic research promoting sustainable models of preventive care guided by direct input from patients, providers and system stakeholders. **Befort's** PCORI-funded, large, multi-site, pragmatic clinical trial addressing obesity treatment models in heterogeneous rural primary care settings (from FQHCs to physician-owned solo practices) is testing the limits of both engaging rural providers in implementing an intensive behavioral intervention as well as designing trial elements to promote real-time clinical adoption. **Befort** is also the Co-Director of the KUCC Breast Cancer Survivorship Center and a standing member of the NIH Psychosocial Risk and Disease Prevention Study Section.

Ellerbeck and **Befort** work together to enhance the growth, productivity and scientific rigor of the CCPH program. While **Ellerbeck's** primary focus has been on tobacco control (Theme 1), he has fostered

transdisciplinary interactions across both thematic areas. He participates in monthly meetings of the Tobacco Control group and has used this as an opportunity to connect these researchers with potential opportunities or parallel work being conducted within our translational research theme. **Befort** leads efforts to enhance translating cancer control into practices and communities (Theme 2). In addition, she works closely with researchers in both CCPH and CPS on weight management issues in cancer prevention and survivorship. **Ellerbeck** and **Befort** meet monthly to plan program activities. Both mentor junior faculty, lead grant-development brainstorming sessions and review grant applications. **Befort** and **Ellerbeck** work together to recruit and select program members.

CCPH Executive Committee and Theme Co-leaders: Ellerbeck and **Befort** call upon the assistance and advice of an executive committee that helps with program planning and stimulating intra-programmatic interactions. The CCPH Executive Committee meets quarterly and includes: **Richter** and **Nollen** as the theme co-leaders for Tobacco Control; **Greiner** and **Befort** as theme co-leaders for Translating Cancer Control into Practices and Communities; and **Cupertino** and **Daley** who provide cross-cutting support on community-engagement research.

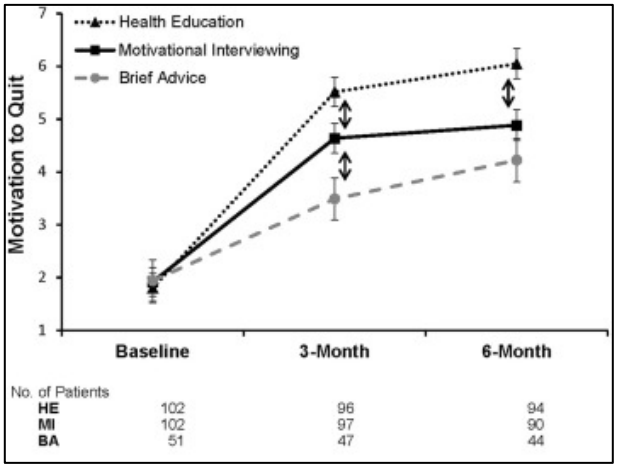
Program Membership
The 35 members of CCPH come from 14 departments in six schools. They represent a rich mix of expertise, including psychology, sociology, neuroscience, primary care, oncology, epidemiology, anthropology, economics, pharmacology, communications, biostatistics and health services research. Membership is reviewed annually. All members must demonstrate the ability to make scientific contributions to the program as demonstrated by either significant cancer-related publications and/or cancer-related, peer-reviewed funding. CCPH members are expected to participate actively in KUCC and CCPH program activities. Active participation is demonstrated by regular participation in program meetings and seminars, contributions to research interest groups and grant brainstorming sessions or peer review of grants and protocols. Of the current members, five (**Befort**, **Catley**, **Cupertino**, **Faseru, Scheuermann**) received support from KUCC to help launch their careers. Over the past four years, CCPH targeted recruitment of new members to address specific needs identified in the catchment area. In response to concerns raised from the first review, CCPH recruited **Fridley** and **Koestler** (CB), both with expertise and funding in biostatistical genetics. It is anticipated that their work may develop into a distinct thematic area. In response to low HPV immunization rates seen in Kansas, CCPH leaders recruited **Myers** and **Ault** and launched a PCORI-funded HPV vaccination initiative that would: a) enhance the understanding of the problem; b) raise community awareness of the issue; and c) foster research that could help address the problem. The new affiliation with Children's Mercy not only provided CCPH members with more resources for addressing HPV vaccinations, but also integrated **Carlson** who will facilitate extension of obesity-related interventions into younger age groups. CCPH integrated **Geana** to improve efforts to integrate communications technology into various interventions and **Ellis** to provide additional support in cancer-related decision science.

Member development and mentorship
The future of CCPH is dependent upon the development and retention of a skilled team of researchers, and CCPH is particularly proud of the accomplishments that have been made in the area of faculty development. Senior CCPH members have devoted hours to mentoring junior CCPH members. **Koestler** (CB), **Ramaswamy** and **Hamilton-Reeves** (CPS) were all supported by the institutional KL2 and worked directly with **Ellerbeck** on their career development. **Koestler** (CB) and **Ramaswamy** have both transitioned their KL2 support into independently funded R01s. **Ellerbeck** and **Richter** mentored **Cupertino**, and **Greiner** mentored **Lumpkins** on their NCMHD K01s. **Nollen** used a diversity supplement to launch **Scheuermann's** career. **Richter** has co-mentored two K23 awardees at the Montefiore Medical Center (Montefiore is a key collaborator on **Richter's** research on smoking cessation and drug dependency). **Befort** mentored Fazzino as a post-doctoral fellow and helped her secure an F32. **Befort** and **Ellerbeck** have also provided mentorship to **Ellis**, **Gibbs** and **Hamilton-Reeves** (CPS) for obtaining independent funding.

Program Scientific Research
THEME 1. Tobacco Control
KUCC is a national leader in tobacco control research. CCPH has worked with researchers at Children's Mercy to test psychosocial principles that underlie current smoking cessation guidelines. Under the leadership of **Richter** and in close alignment with Theme 2, CCPH members are identifying better ways to link smokers to

evidence-based treatments, with a particular focus on identifying better ways to integrate tobacco treatment into different health care systems and within underrepresented minority communities. Under the leadership of **Nollen**, CCPH is describing patterns of tobacco use among African-Americans and identifying biological and pharmacological correlates of treatment success.

Subtheme 1a. Developing Behavioral Treatment for Smokers Not Ready to Quit (R01CA133068; R01HL131512)

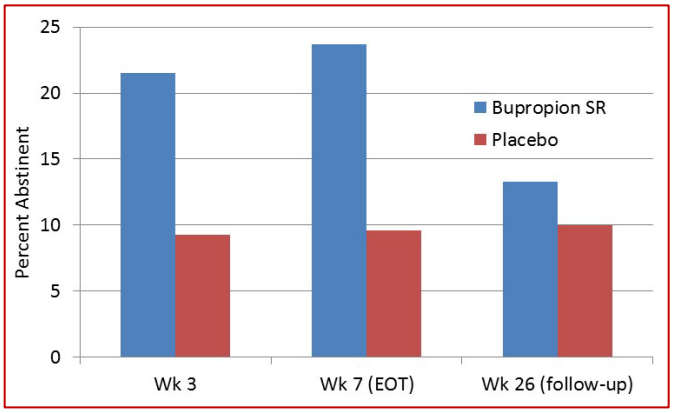


The vast majority of smoking cessation efforts are focused on the small minority (~20%) of smokers that indicate that they are ready to initiate a quit attempt, but there is a paucity of empiric data on the best way to approach smokers that aren't immediately ready to quit. Current treatment guidelines recommend that counseling for these patients should focus on motivation counseling strategies. **Catley's** work is challenging this long-held assumption. In his recent trial, **Catley** along with **Richter** and **Ellerbeck** randomized unmotivated smokers to receive either motivational interviewing, health education or brief advice (R01CA133068). He closely monitored counselors to assure fidelity to the counseling protocols. He showed that health education actually outperformed motivational interviewing in terms of motivation to quit smoking, and resulted in higher abstinence at 6 months (15% vs. 6%; p = 0.04) (**Cately**, *Am J Prev Med*, 2016). This work led to a formal 'debate' in *Addiction* by **Richter** and **Ellerbeck** on the need to revise current treatment guidelines and offer specific treatment options (health education) to all smokers regardless of their initial readiness to quit. **Richter** is following up on this work with a study to test an 'opt-out' approach in which all smokers, regardless of their initial motivation to quit, would be enrolled in a smoking cessation program unless they 'opted out' (R01HL131512) (**Richter**, *Addiction*, 2015).

Subtheme 1b. Meeting the Sociocultural and Biologic Needs of Diverse Groups of Smokers

Biology and pharmacology of tobacco control among African Americans (R01CA091912; R01DA035796; AD-1310-08709)

African Americans (AA) smoke fewer cigarettes per day than the general population, but experience disproportionately greater smoking-related morbidity and mortality. KUCC researchers along with collaborators from the US and Canada (Ahluwalia, Benowitz and Tyndale) are leading efforts to understand the interplay of biology, behavior and pharmacology as it relates to smoking cessation among AAs. This KUCC-led team has received federal funding (NIH or PCORI) for seven clinical trials, enrolling more than 3,000 AA smokers, resulting in more than 50 publications, including work supporting a report to the FDA on the hazards of menthol in tobacco products.



Cox and **Nollen** are leading efforts to identify the harms of 'light' and non-daily smoking among AA smokers and testing alternative treatment strategies. Their team demonstrated extensive use of alternative tobacco products among AAs (cigars, cigarillos, pipes), high secondary dependence motives among light and non-daily smokers and much higher levels of carcinogen exposure among AA compared to white non-daily smokers (**Nollen**, *Nicotine & Tobacco Res*, 2016; **Scheuermann**, Addict Behav, 2015; Khariwala, *Nicotine & Tobacco Res*, 2014). **Cox** completed the first controlled clinical trial of bupropion for smoking cessation among African American light smokers (R01CA091912). She demonstrated significant, short-term treatment effects from bupropion, which unfortunately, were not sustained (**Cox**, *JNCI*, 2012). Expanded analysis of this work, using reliable methods of

adherence described by this team, demonstrated that adherence to treatment was critical to supporting sustained abstinence (Buchanan, *Nicotine Tob Res*, 2012; **Nollen**, *Annals of Behavioral Med*, 2013). With important implications for the FDA and regulation of cigarette additives, they also showed that menthol was a deterrent to cessation, even among light smokers (**Faseru**, *Addictive Behaviors*, 2013).

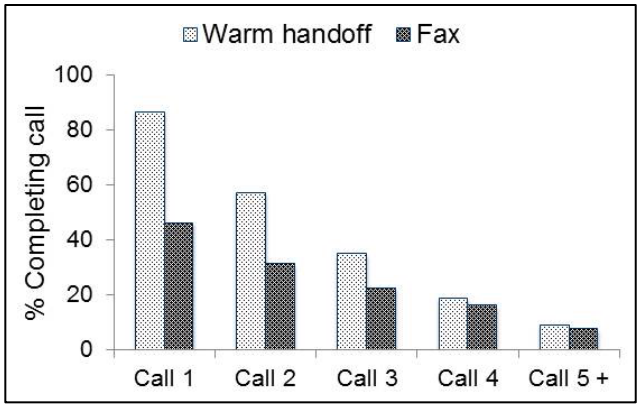
CCPH researchers are also examining genetic polymorphisms contributing to smoking behavior, treatment response and cessation outcomes, including some of the first work of this type conducted with light smokers. **Cox** combined data from two of her clinical trials with African American smokers to examine the implications of genetic variability in the nicotinic cholinergic receptor. While multiple select independent single-nucleotide polymorphisms (SNPs) were not associated with baseline smoking behavior among African Americans, CHRNA5-A3-B4 SNP rs2036527 (which codes for subunits of the nicotinic acetylcholine receptor) was associated with poorer response to treatment (Zhu, *Clin Pharmacol Ther*, 2014). These findings suggest that pharmacogenetic approaches might be useful for optimizing treatment for subsets of AA smokers. Her team further showed that genetic polymorphisms in CYP2B6, responsible for metabolizing bupropion to its major metabolite, hydroxybupropion influenced the effects of bupropion on smoking cessation (Zhu, *Clin Pharmacol Ther*, 2012). Such findings suggest that clinical adjustment of bupropion dose based on achieving a specific level of hydroxybupropion, or increasing bupropion dose for slow metabolizers, might improve cessation outcomes. **Future:** Given the limitations of nicotine gum and bupropion for treatment of light smokers, **Cox** is now conducting the first placebo-controlled trial of varenicline for the full spectrum of light, moderate, and heavy smokers in our urban African American community (R01DA035796). Meanwhile, **Nollen** is leading the first ever randomized cessation trial for African American non-daily smokers (AD-1310-08709).

Linking Latino smokers to effective cessation treatment (K01CA136993; R41MD010318; P30CA168524-S1)
Latinos represent the most rapidly growing population of new smokers in the KUCC catchment area, yet they are the least likely to access evidence-based treatment services. **Cupertino** developed and tested a computer-based decision support tool (*Decídete*) designed to present Latino smokers with evidence-based care options and help them develop an individualized treatment plan (K01CA136993, **Ellerbeck** - mentor). The *Decídete* program was very popular with users and resulted in high rates of initiation of evidence-based cessation therapy, leading to the submission of an R01 for a full-scale trial. Participants in her study expressed interest in text messaging to support them in implementing their treatment plan. However, the existing Spanish language text messaging programs in the United States did not reflect the needs of our regional Latino smokers either culturally or linguistically. **Cupertino** and **Ellerbeck**, therefore, partnered with Agile Health to procure an STTR to create a more culturally tailored and linguistically appropriate version of their KickButs text messaging program (R41MD010318). This study demonstrated 80% retention in the program at 12 weeks with an end-of-treatment cessation rate of 33%. This work with Latino smokers has resulted in important international collaborations. **Cupertino** guided the development of the Vivo Sem Fumar text message-based smoking cessation program in Brazil. Currently, more than 20,000 Brazilian smokers are using this pre-paid text messaging program with a withdraw rate of less than 10%. **Cupertino** worked with two national leaders in tobacco control in Mexico, Drs. Reynales and Ponciano, to implement and test *Decídete* in primary care clinics in Mexico. This program is now operational in Mexico, and **Cupertino** and **Ellerbeck** are using a CCSG supplement (P30CA168524-S1) to develop a text messaging program that will be integrated with the *Decídete* software. This program will not only create the first text message-based smoking cessation program in Mexico, but also the first one to be guided by an electronic decision support platform. **Future:** With her pending R01 **Cupertino** will now test her integrated cessation program in a randomized, controlled clinical trial among Latino smokers. A phase 2 STTR application will be submitted in January, the results of which will provide critical information on how to expand the reach of text-based smoking cessation programs for Latinos. In 2017, **Cupertino** will use results from the CCSG supplement to submit an application for a collaborative, hybrid type III implementation trial in Mexico.

Culturally tailored smoking cessation for American Indians (R01CA141618; P20MD004895)
Traditional smoking cessation programs developed primarily among majority-white smokers have not performed well among American Indians (AI) who have the highest cigarette smoking prevalence of any racial/ethnic group in the U.S. **Choi** and **Daley** worked extensively with AI tribes in the KUCC catchment area to develop the "All Nations Breath of Life" (ANBL), a culturally tailored smoking cessation program that supports smoking cessation while still recognizing the importance of tobacco in traditional and ceremonial practices. AI smokers from reservations and rural communities in the southern and northern plains regions (n = 624) were randomized to either the culturally tailored ANBL group-based treatment or a non-tailored individually delivered cessation program of comparable intensity. The ANBL was well accepted by AI smokers and resulted in significantly higher retention in treatment ($p < 0.05$) and higher abstinence rates at six months (20.1% vs. 12.0% p=0.03) (**Choi**, *Am J Prev Med*, 2016). **Future:** This work led to two additional trials designed to address the expressed needs of the AI community: 1) addressing smokeless tobacco cessation in American Indians (**Daley** R01MD007800) and 2) web-based ANBL for tribal college students (**Choi** R01CA174481). Enrollment for both of these trials is currently underway.

Subtheme 1c. Integrating Smoking Cessation Tools into Clinical Settings

Connecting hospitalized smokers to evidence-based cessation treatment (U01HL105232; R01CA101963)
Evidence-based cessation treatments are severely underutilized in the KUCC catchment area (Ku, *Health Aff,* 2016). This has been particularly problematic for hospitalized smokers. **Richter** and her team of co-investigators (**Faseru**, **Ellerbeck**) joined smoking cessation researchers across the country to form CHART, a multi-institutional collaboration supporting a series of implementation studies to evaluate real-world methods for connecting hospitalized smokers with treatment post-discharge (U01HL105232). **Richter** enrolled 1,054 hospitalized smokers in a randomized trial to test the theory that 'warm handoffs' from hospital staff to quitline personnel would enhance the therapeutic alliance with quitline staff and improve counseling adherence. She showed that warm handoffs, compared to fax referrals, resulted in greater quitline enrollment (99.6% vs. 59.6%; $p < 0.01$) and a greater number of quitline calls completed (2.08 vs. 1.25; $p < 0.01$). However, she also showed that standard quitline protocols were associated with long delays in post-discharge counseling and poor coordination of treatment services (**Richter**, *AJPM* 2016 in press). These findings demonstrate the potential to use warm-handoffs to connect patients to treatment, but highlight the need for radical changes in quitline protocols to improve the timeliness and relevance of post-discharge counseling. Meanwhile, in a study of 487 smokers discharged from rural Kansas hospitals throughout the catchment area, many of whom were uninsured, (R01CA101963) **Ellerbeck** showed that the presence of either Medicaid (OR 2.29; 95% CI: 1.32-4.02) or other insurance (OR 1.69; 95% CI: 1.01 – 2.86) was highly correlated with use of pharmacotherapy post-discharge (Tague, *Nicotine Tob Res*, 2016). These findings underscore the difficulties in getting cessation therapy to smokers hospitalized in states like Kansas or Missouri that have not expanded Medicaid coverage. **Future: Richter** is following up on this work with a study to test an 'opt-out' approach in which hospitalized smokers, regardless of their initial motivation to quit, would be enrolled in a smoking cessation program unless they opt out (R01HL131512). **Ellerbeck** is using PCORI funding to focus more specifically on patients with COPD, examining the impact of long-term nicotine replacement on cessation and carcinogen exposure (CER-1306002901).



Expanding the reach and efficacy of smoking cessation to smokers in drug treatment (R21 DA020489; Kansas Health Foundation)
The prevalence of smoking has become increasingly concentrated among those with addictions and other mental health disorders. Practitioners in the mental health community have been slow to address this problem, in part due to a belief that cigarettes might be 'the lesser of two evils.' But smoking is the #1 cause of death among people with mental illness or drug addiction. To address this concern, **Richter** helped found the Association for Medical Education and Research on Substance Abuse (AMERSA, www.amersa.org), a

national organization of interdisciplinary leaders in substance abuse education, research, care and policy. As president of AMERSA, **Richter** secured a subcontract with the American Association of Addiction Psychiatry to conduct interdisciplinary training on medication-assisted substance abuse treatment (http://pcssmat.org) along with a 5-year NIDA conference grant for AMERSA, to train under-represented minorities in addiction treatment.

In this role, **Richter** has led the way in studying smoking cessation activities and barriers within the context of drug treatment. **Richter's** nationwide survey of drug treatment facilities demonstrated that most facilities had the requisite skills for tobacco treatment, but few had the policies, leadership, or financial resources to provide cessation services (Hunt, *Am J Public Health*, 2013). Further analysis of facility-level tobacco treatment practices resulted in the development of the 7-item Index of Tobacco Treatment Quality (ITTQ) which showed that most facilities identify clients who smoke (87.7%), but less than half (48.6%) advised smokers to quit. Fewer, yet (23.3%) provided cessation counseling to most of their smoking clients and even fewer (18.3%) advised clients to use quit smoking medications. **Richter** and **Cupertino** further showed that clients had to specifically request tobacco treatment in order to receive it. Moreover, systems to facilitate consistent, evidence-based tobacco treatment were nonexistent (Hunt, *J Subst Abuse Treat*, 2012). **Richter** also developed the 14-item Tobacco Treatment Commitment Scale (TTCS), and showed that three factors: "tobacco is less harmful than other drugs," "it's not our job to treat tobacco," and "tobacco treatment will harm clients" emerged as the major constructs driving staff commitment, or lack of commitment, to provide tobacco treatment services. This scale has been translated into other languages and incorporated into national treatment guidelines (Hunt, *Psychology of Addictive Behaviors*, 2014). **Richter** has co-mentored two NIH K-Awardees addressing tobacco control in the context of drug treatment: Shadi Nahvi MD at the Albert Einstein College of Medicine (K23DA025736); and Nina Cooperman, PsyD at the Robert Wood Johnson Medical School (K23DA025049). She helped Nahvi establish the safety and short-term efficacy of varenicline for smoking cessation among methadone-maintained smokers (Nahvi, *Drug Alcohol Depend*, 2013) and assisted Cooperman in developing an Information-Motivation-Behavioral Skills (IMB) Model of smoking cessation for methadone-maintained smokers (Cooperman, *Subst Use Misuse*, 2015). **Richter's** experiences with tobacco control and drug treatment led to her critical editorial in the *New England Journal of Medicine* comparing the history of big tobacco to the emerging marijuana industry (**Richter**, *N Engl J Med,* 2014). **Future:** With support from the Kansas Health Foundation, **Richter** and **Faseru** are now translating the results of their findings into mental health treatment facilities in Kansas. In addition to addressing system-support issues, they are also aiming to uncover and address systemic problems that smokers have encountered in taking advantage of treatments that are supposed to be covered by Medicaid.

THEME 2. Translating Cancer Control into Clinics and Communities

With leadership from **Befort** and **Greiner**, CCPH researchers are advancing the research needed to translate cancer control interventions to the populations at risk. The work in this thematic area has benefited from community-based participatory research (CBPR) conducted by CCPH members, research that has built the infrastructure and relationships required to conduct high quality translational research (see Catchment Area section below). CCPH is paving new paths for pragmatic clinical trials that advance clinical translation of cancer control interventions in primary care settings, the criminal justice system and communities at large. CCPH members are also developing new tools to measure the impact of these interventions and to make clinical trials more efficient. This work is grounded in CCPH's commitment to address the needs of the KUCC catchment area and is facilitated by the MCA and the KPPEPR network.

<u>Subtheme 2a.</u> Implementing Cancer Control Strategies in Clinical Settings

Using 'Implementation Intentions' to advance colorectal cancer screening in safety-net clinics
(R01CA158238; R01CA1888898)

Low-income and racial/ethnic minority populations have lower screening rates and experience disproportionate morbidity and mortality related to colorectal cancer (CRC). Implementation Intentions is a theory-driven approach to behavioral interventions that holds great promise for addressing the barriers faced by low-income and minority populations. **Greiner**, assisted by **Daley** and **Ellerbeck**, used the Precaution-Adoption Process Model and the Theory of Implementation Intentions to develop an interactive, touchscreen CRC screening support tool in clinic waiting rooms. This tool was designed to elicit a patient's decisional stage, preferred screening method and screening barriers, and then provide the patient with personalized, step-by-step guidance on how to 'implement' their planned screening. They conducted a RCT where this CRC screening

support tool was offered in nine area safety net clinics and among 470 low-income patients (42% African American, 27% Hispanic). They showed that patients were more likely to complete CRC screening after navigating the touchscreen tool vs. an attention-control intervention (AOR = 1.83 [1.23-2.73]). Participants selecting fecal immunochmicale (FIT) testing were also significantly more likely to complete their CRC screening (AOR = 4.07 [1.89-8.80]) (**Greiner**, *Am J Prev Med*, 2014). These findings provide strong support for incorporating 'how-to' elements and deliberative planning within clinic-based cancer screening interventions while also indicating the need to include alternatives to colonoscopy as an option for CRC screening among low-income patients. **Greiner** is also coordinating efforts to identify biological factors that could account for disparities in CRC among AAs. He identified associations between race/ethnicity and short chain fatty acid levels and 16S microbial profiles in the stool of patients participating in his CRC screening study (Hester, *World J Gastroenterol*, 2015). This led to work with **Umar** (CPS) that demonstrated the role that intestinal bacteria can play in the epigenetic regulation of Wnt antagonist WIF1 (Roy, *Oncogene*, 2015). **Future:** Despite the success of the implementation intentions intervention, 46% of patients in the active intervention arm still failed to complete screening. **Greiner** is now using a Bayesian adaptive design to examine alternative strategies for repeat 'dosing' of interventions to further enhance cancer screening rates (R01CA188898).

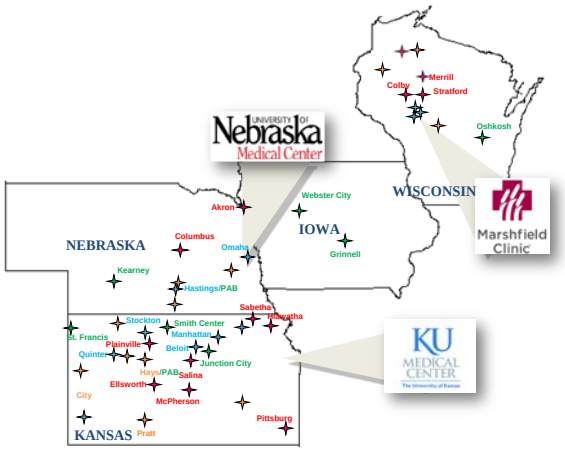
Cervical cancer prevention and control for women in the criminal justice system (ACS-IRG pilot, R03CA162869, UL1TR000119 (KL2); R01CA181047; R21CA204767)
Women with criminal justice histories bear the burden of multiple risk factors for cervical cancer, including multiple sex partners, sexually transmitted infections, and trading sex for drugs, money, or life's necessities. Women with a history of incarceration have higher rates of HPV infection and 4-5 times the rates of cervical cancer compared to women without these histories, but little has been done to address this health disparity. **Ramaswamy** surveyed 290 women leaving Kansas City jails to identify risk factors for cervical cancer and barriers to cervical cancer screening and follow-up care (**Ramaswamy**, *Women Health*, 2011). These women frequently reported a history of abnormal pap smears (40% compared to 6% nationwide) with even higher rates among women with a history of physical abuse (OR=6.05; CI 2.36, 15.54). Follow-up for cervical cancer screening was limited by low rates of health insurance coverage (45%) and lack of a primary care physician (57%). **Ramaswamy** developed a conceptual model for cervical health literacy that was designed to reveal opportunities for intervention. This model was refined and tested in 45 women revealing major barriers related to knowledge, beliefs and self-efficacy for cervical health promotion (**Ramaswamy**, *J Health Care Poor Underserved*, 2015). This preliminary work was used to develop a brief, jail-based cervical health promotion intervention (the Sexual Health Empowerment (SHE) program), based on a social-feminist approach to enhancing both knowledge and empowerment (**Table 3**) (**Ramaswamy**, *Health Promot Pract* 2015). In a randomized, wait-list control trial among 188 incarcerated women, the SHE program led to significant gains in 7 of 8 domains of cervical health literacy, including improvements in knowledge, motivation, and self-efficacy, and reductions in perceived barriers ($p < 0.01$ on all domains) (**Ramaswamy**, 2016; under review) **Future:** Ongoing tracking of this cohort will examine changes in cervical cancer screening behaviors. **Ramaswamy** and **Ault** are currently using the Consolidated Framework for Implementation Research to develop and test the clinical implementation of HPV immunization of incarcerated youth by placing regular health department-run vaccine clinics within juvenile detention facilities (R21CA204767). The mixed-methods approach to their implementation strategy is designed to facilitate future dissemination. **Ramaswamy's** extensive work in jails and prisons will facilitate future cancer control efforts related to hepatitis screening and smoking cessation in this high risk population (**Ramaswamy**, *Subst Abuse Treat Prev Policy*, 2013).

Table 3. Sexual Health Empowerment (She) Intervention Content

DOMAINS	CONTENT
Knowledge	Female anatomy, familiarity with reproductive health "terms," screening procedures
Beliefs	Sex, trauma, family perspectives, "if it ain't broke," HPV vaccine, perceived susceptibility
Self-Efficacy	Interpreting the Pap test, navigating local resources, "risks" – balancing health risks against life circumstances
Confidence	Trust, jail and prison health care, stigma, ER care, social support

Implementing obesity treatment options into rural primary care (PCORI OTO-1402-09413)
Befort was the first to show a national rural-urban disparity in obesity prevalence using objectively measured height and weight from the National Health and Nutrition Examination Survey (40% of rural vs. 33% of urban adults; $p = 0.006$) (**Befort**, *J Rural Health*, 2012). She demonstrated that rural residence contributes to obesity prevalence even after controlling for demographic, socioeconomic and lifestyle determinants. In a state-wide

survey assessing supportive care needs among rural women with a history of breast cancer, **Befort** and **Klemp** (CPS) found the number one supportive care need was for weight loss and physical activity interventions. Building from her obesity treatment trials among rural breast cancer survivors and collaborations

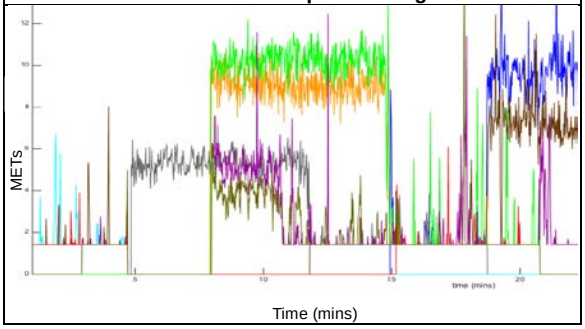


with CPS investigators, **Befort** is now collaborating with **Ellerbeck, Greiner** and **Gajewski** to test real-world clinical implementation of three models of care delivery for obesity treatment in rural primary care settings. This 36-site trial is being implemented throughout our rural catchment area in Kansas as well as in rural Nebraska, Iowa, and Wisconsin. The implementation plans are driven by patient advisors and provider stakeholders at the local community level. Primary care practices are randomized to one of three real-world models of care: fee-for-service (traditional 15 min office visits), patient centered medical home (care coordination and enhanced access with after-hours group visits) or disease management (phone-based group visits delivered centrally). Existing local practice personnel, rather than research-hired personnel, implement an intensive behavioral weight loss intervention into their clinical routine with payment systems based on current payer models. Using the Consolidated Framework for Implementation Research, baseline interviews of practice personnel revealed that enthusiasm and willingness to participate was driven primarily by Intervention and Inner Setting characteristics, such as lack of bias regarding which arm is most likely to succeed, and the physicians' self-reflection that they can no longer ignore obesity in their clinical practice (**Befort**, *Contemp Clin Trials*, 2016). **Future:** The MCA and KPPEPR networks have helped **Befort** develop essential clinical collaborations for this landmark rural primary care obesity treatment trial. **Befort** will build on the infrastructure, training protocols and data collection processes developed for this current trial to conduct future primary care implementation trials focused on cancer control as well as cancer survivorship. **Befort** is continuing to collaborate with CPS investigators, **Klemp** and **Fabian**, on obesity treatment trials among cancer survivors and to explore novel cancer risk biomarkers (e.g. miRNA-21, PAI-1) from samples collected in her clinical weight loss trials.

<u>Subtheme 2b</u>. Developing Tools to Support Translational Research for Cancer Control

Tools for physical activity and nutrition assessment (R21CA194492, R03HD081730)
Successful translational research is dependent upon tools that can measure the impact of interventions. **Carlson's** work is focused on location-based determinants of physical activity. Using accelerometers paired

Video-based estimates of PA intensity (METs) for color-coded individuals in a park setting



with GPS devices among youth, he found that the proportion of location time spent in physical activity was twice as high in neighborhoods surrounding schools (10.5%) than inside schools (4.8%; $p < 0.001$) (**Carlson**, *Pediatrics*, 2016). **Carlson** has since developed an Ecological Video Identification system to capture location-based physical activity levels. This novel tool provides automated, continuous and cost-effective PA assessment in parks, schools and other locations (R21CA194492). Building on technology for scene classification, people detection and crowd counting, **Carlson** has successfully developed algorithms for quantifying population-level MET-minutes accumulated in different locations. The ultimate goal is to inform physical activity environmental policy and programming. **Future: Carlson** is developing novel computational approaches for improving assessment of sedentary behavior from hip-worn accelerometers. In a pending R01 application, he has proposed to use machine learning techniques in three existing large datasets with a gold standard comparison to establish criterion validity, and apply the developed algorithms to four large cohort studies in youth, adults and older adults to test construct validity with metabolic health markers. This new method will allow researchers to validly assess both physical activity and sedentary patterns from the same device.

Gibbs is working to improve nutrition literacy assessment. In collaboration with **Befort, Ellerbeck, Gajewski** and **Sullivan** (CPS), she adapted her novel nutrition literacy instrument for breast cancer survivors enrolled in

Befort's lifestyle intervention trial (R01CA155014). **Gibbs** demonstrated significant relationships between five domains of nutrition literacy (e.g. consumer skills, food label and numeracy and macronutrients) and diet quality (measured by Healthy Eating Index-2010) among overweight/obese breast cancer survivors (**Gibbs**, *J Cancer Educ,* 2015). **Future: Gibbs** is testing the validity of the NLit tool in primary care patients and aims to expand the use of her tool into other clinical settings (R03HD081730).

Tools for promoting translation of cancer control strategies into communities (R24MD0027800)
KUCC researchers are collaborating beyond academic cancer center walls to build tools that enhance community partnerships for cancer control efforts. **Fawcett** and **Collie-Akers** used a CBPR approach to better understand and improve conditions that affect community health and health equity. Their Latino Health for All initiative (R24MD002780) takes place in Wyandotte County, Kansas, the most disadvantaged county in the state of Kansas where 26% of residents are Latino and over half live below the federal poverty level. They worked with community partners including churches, parks, and safety net clinics to test a community coalition/mini-grant model to promote healthy nutrition, physical activity, and access to health services and evaluate a novel system for numerically coding and scoring programs by the type of strategy used, the duration, and the reach within the targeted population (**Fawcett**, *Am J Prev Med*, 2015). **Future:** A total of 55 mini-grants have resulted in 65 discrete new programs ranging from community gardens to youth soccer programs. A controlled evaluation, by zip code, is currently underway to evaluate the impact of the Latino Health for All initiative while simultaneously evaluating the merits of the evaluation model.

Tools for conducting cancer control clinical trials (R03NR013236)
The CCPH program also is working to improve the efficiency and quality of clinical trials. With support from a KUCC pilot grant and R03NR013236, **Gajewski** developed and tested novel statistical models using the Bayesian paradigm that allowed the integration of prior information into all phases of the clinical trial. He showed that these models provide better predictions of accrual and produce clinical trials that are much more efficient, or require fewer participants for optimal statistical power. These novel clinical trials designs were more optimal, stronger (more powerful), faster to finish, and smaller in size while preserving well calibrated operating characteristics (**Gajewski**, *Stat Med*, 2015; Jiang, *Stat Med*, 2015; Wick, *J Biopharm Stat*, 2016). **Future: Gajewski** is further developing response adaptive randomization (RAR) applications for sequential, multiple assignment, randomized trials (SMART). He aims to combine the strengths of both methods to promote efficient pragmatic clinical trials.

Conducting Cancer Research Relevant To the Needs of the KUCC Catchment Area
CCPH researchers work closely with patients, providers, public health officials and other community stakeholders to link their research with the needs of the community and help convert research into practice and policy. CCPH members connect with area providers and other stakeholders through KPPEPR, the Kansas Cancer Partnership and the MCA. Community partners helped CCPH researchers prioritize work on e-cigarettes, age of tobacco sales, HPV immunizations and rural obesity.

Greiner in collaboration with **Cupertino** and **Engelman** led the Kansas Community Cancer Disparities Network (U54CA154253). This program used CBPR methods to engage rural dwelling American Indians and Latinos to enhance access to cancer control research and strategies. The network continues to grow and includes hospitals, safety-net and Indian Health Service clinics, churches, schools, the regional Mexican consulate and sovereign tribal entities. Creation of these partnerships has helped ensure a broad and inclusive representation of rural Latino and American Indians in our cancer control programs and supports the dissemination of cancer information through our Promotores de Salud training program for community health workers (**Cupertino**, *Oncology Nursing Forum*, 2015). This work provided a critical foundation for **Greiner**'s work on CRC screening in American Indian communities (R01CA158238) and **Cupertino**'s development of culturally and linguistically appropriate smoking cessation interventions for Latinos (R41MD010318).

Lai, Director of the Kansas Cancer Registry since 1994, has helped establish changes in state statutes that now allow registry-Medicaid linkages thereby opening new avenues for health services research in the KUCC catchment area. Under her guidance, the Kansas Cancer Registry has achieved GOLD level designation. She has used the registry to support more than 150 cancer cluster investigations and more than 100 peer-reviewed publications. In the KUCC catchment area, her findings also support the work of the Kansas Cancer Partnership along with the development of the state cancer control plan.

Faseru's work on the epidemiology of electronic cigarettes (Christensen, *Preventive Medicine,* 2014) along with grassroots efforts by **Nollen** and **Kimminau** have helped get language banning indoor use of electronic cigarettes passed in multiple Kansas City metropolitan communities. Work by **Faseru**, **Richter**, **Ellerbeck**, **Martin**, **Catley**, and **Cupertino** was used to inform the Healthy KC initiative and launch the Tobacco 21 effort. This legislation raised the age of tobacco and e-cigarette sales from age 18 to 21, impacting 16 regional municipalities covering 1.4M people on both sides of the state line of the KUCC catchment area.

In 2013, Kansas was identified as having the lowest HPV vaccination rates in the country. This led to the recruitment of new faculty to the CCPH program (**Myers** and **Ault**) and the development of an HPV immunization action team. CCPH members are now working with the Kansas Department of Health and the Environment (KDHE) and the Immunize Kansas Children coalition to identify research needs specific to the KUCC catchment area. **Mahnken** and **Ellerbeck** recently teamed together and used Medicaid data from the Kansas Health Insurance Information System to develop alternative strategies to track HPV immunizations. Using a novel HPV/tdap immunization ratio, they were able to profile HPV immunization delivery by school district, demonstrating a more than 4-fold variation in HPV delivery in school districts across the state. This work has highlighted the importance of linking HPV immunization to the required 7th grade TDAP immunization. With support of PCORI and KUCC pilot funds, they are now using these data in work with pediatricians, school nurses and public health professionals in both Kansas and Missouri to lay out the critical groundwork needed for HPV vaccine implementation research.

Befort, with the help of patient and physician stakeholders, developed the RePOWER cluster randomized trial designed to improve implementation of obesity treatment in rural primary care throughout KUCC's geographically dispersed rural catchment area. **Befort** and **Greiner,** with the support of KPPEPR, will continue to work with these primary care sites after completion of the trial to help them sustain the intervention they initially adopted during the trial. Meanwhile, **Kimminau**, **Fawcett**, and **Collie-Akers** are working with community leaders to change policies and provide access to good nutrition and physical activity in Latino neighborhoods in the Kansas City region. Finally, **Doolittle** has leveraged KUCC's long-standing telehealth infrastructure to establish effective outreach and cancer control educational programs for rural patients and providers throughout the catchment area.

Intra- and Inter-Programmatic Interactions and External Collaborations

Regular program meetings have fostered strong collaborations among CCPH members as evidenced by the large number of intra-programmatic collaborations on publications and grants. Monthly tobacco control working group meetings bring together members from other thematic areas, KUCC research programs and cancer centers to foster new, innovative ideas and stimulate new interdisciplinary collaborations. With KUCC support, CCPH has launched a research action team to respond to the low rate of HPV immunizations in the state. This team has held joint program meetings with CPS and currently collaborate on a variety of activities at the intersection of cancer and nutrition (**Befort**, **Gibbs**, **Ellerbeck** with **Fabian**, **Sullivan**, **Donnelly, Hamilton-Reeves** from CPS). **Greiner** is working with **Koestler** and other researchers in CB to address cancer risk and disparities related to microbial profiles from patients undergoing CRC screening. Meanwhile, **Ellerbeck** and **Fridley** are working with **Weir** (D3ET) and **Godwin** (D3ET) on a variety of issues ranging from entrepreneurship to biobanking to personalized medicine.

CCPH's extensive external collaborations were only partly described among the scientific accomplishments. 'Visiting professors' like Saldana and Damschroeder have had a substantial impact on the implementation research efforts. **Fridley's** collaborations with the Mayo Clinic have resulted in important discoveries related to treatment response in ovarian cancer. **Befort** has collaborated with researchers across the Midwest and Florida to improve treatment of rural obesity. **Richter** has worked with researchers across the country to improve treatment of hospitalized smokers and advance training on addictions treatment and research. **Cox's** work with Benowitz, Ahluwalia, and Tyndale, has advanced our understanding of smoking patterns and treatment implications for African American smokers, and **Cupertino** is expanding international collaborations.

Value Added By the CCPH Program

CCPH workshops, visiting professor programs, formal courses, mock grant reviews and training in grant writing have been particularly valuable for KUCC junior faculty and post-doctoral fellows. CCPH members (**Ellerbeck, Choi**, **Richter**) have used the CTSA Frontiers Scholars training programs to create training opportunities for all

KUCC members while also stimulating interdisciplinary collaborations. CCPH members have played a critical role in defining the needs of the KUCC catchment area and have opened new venues for KUCC members to engage patients in underserved minority and rural communities. CCPH quantitative scientists have also developed new analytic methods that are being implemented in the conduct of clinical trials in other areas of KUCC (Staggs, *Stat Methods Med Res*, 2015). Experts on state healthcare policy and advocates for patient-centered research, most notably **Kimminau**, have transformed a long-standing tradition in community engagement into new infrastructure to support KPPEPR and PIVOT (Patient and Investigator Voices Organizing Together). KUCC members are able to connect with members of underserved Latino, American Indian, African American and rural communities through resources developed by CCPH researchers, including the JUNTOS Center for Advancing Latino Health (**Cupertino**), the Center for Advancing American Indian Community Health (**Daley**), the Frontiers Community Partnerships for Health (**Kimminau**) and the Kansas Patients and Physicians Engaged in Prevention Research (**Greiner**).

Value Added By KUCC to Programmatic Efforts

CCPH and KUCC leadership have worked together to increase the capacity and productivity of the CCPH program. CCPH has received $50,000 each year to support visiting professors, mini-grants, strategic planning meetings and external consultations. Many of these investments in the program were quickly followed by external funding. KUCC also provided support for recruiting new members, start-up support for new and emerging members (**Faseru, Cupertino, Scheuermann**, **Corriveau**), and funds to retain established researchers (**Cupertino**, **Befort**, **Choi)**. Pilot funds from KUCC have led to subsequent grant funding for **Martin** (ACS). CCPH members have also made extensive use of KUCC shared resources as shown in Table 3 (Other Attachments). KUCC created the Grants Development Office which provides two grant specialists to assist KUCC members in grant submissions; this assistance was instrumental in successful grant submissions by a number of CCPH members. Perhaps most importantly, KUCC support of KPPEPR and the MCA has stimulated new research in rural communities and provided critical support to both PCORI and NIH-funded projects (OB-1402-09413, R01CA101963 and R01HL087643).

Future Plans

The CCPH program enjoys strong relationships with community organizations, stakeholders and health care providers throughout the region. A recent $5M endowment from the Kansas Masonic Foundation places us in a much stronger position to capitalize on these relationships with new resources to grow the size and level of engagement from oncology and primary care providers and patients throughout the KUCC catchment area. Other recent KUCC investments position CCPH to make major contributions to advancing implementation science while simultaneously addressing critical cancer control needs in the KUCC catchment area. These investments include the appointment of Sally **Maliski** as Associate Director for Health Equity and the creation of the patient engagement PIVOT initiative. In addition, PCORNet, the Greater Plains Collaborative, facilitates new national and regional collaborations in cancer control. CCPH leadership has worked with CCPH members, KUCC leadership and key stakeholders to craft a plan for the future of CCPH, including:

- Stimulate implementation research within primary care communities (particularly rural communities) through specifically targeted pilot grants and development funds;
- Use the KPPEPR network and regional health information networks to support trials on implementation of tobacco control into rural primary care and other settings with high concentrations of smokers;
- Leverage the addition of Children's Mercy to KUCC to extend cancer control research into pediatric settings, advancing translational and implementation research related to childhood nutrition, adolescent and parental tobacco use and HPV immunizations;
- Build upon **Befort's** PCORI experience and take advantage of the PCORNet infrastructure to support development of multi-institutional, pragmatic cancer control research studies with regional partners;
- Accelerate the implementation of cancer genomics into communities by forming a new research action team that will bring CCPH researchers together with cancer prevention (**Fabian** and **Klemp** (CPS)), clinical informatics (**Waitman** (CPS)) and personalized medicine (**Godwin** (D3ET)) experts. With this team, launch new systems to track the clinical uptake of cancer genomic technologies in the KUCC catchment area and develop implementation strategies to ensure that new technologies reach rural, AI, AA and Latino patients.
- Work with from **Weir** (D3ET) to advance training in entrepreneurship and SBIR/STTR grant writing to help CCPH researchers develop technology driven population-health interventions with potential for commercialization. This builds on **Cupertino** and **Ellerbeck's** STTR success and **Befort's** participation in the NCI's Speeding Research-tested INTerventions [SPRINT] program.

Progress Report Publications

This component has no publications resulting from Cancer Center Support Grant funds.

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Resource Sharing Plan

The University of Kansas Cancer Center (KUCC) and its scientific community understands its responsibility to comply with the instructions for the Resource Sharing Plans provided within the SF 424 (R&R) Application General Instructions and Supplemental Grant Application Instructions. When resources are developed with NIH funds via this Cancer Center Support Grant P30 mechanism, KUCC will ensure findings are made readily available to the NIH and the scientific community in a timely manner.

Data Sharing Plan

KUCC will adhere to the Final NIH Statement on Sharing Research Data and refer to the National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research. KUCC encourages the free flow of information and ideas while recognizing the timeliness of data sharing, the rights and privacy of human subjects and issues related to proprietary data. KUCC encourages data documentation, using a data-sharing agreement and selecting an appropriate method for sharing; considering the sensitivity of the data, the size of the dataset and the volume of requests anticipated.

Additionally, KUCC encourages any user of a CCSG-supported shared resource to acknowledge the source of data upon which their manuscript is based either in the Acknowledgments section or with authorship on the paper. Furthermore, any research project that received direct cost support from the CCSG is encouraged to cite the P30 CA168524. In both cases, citing the P30 CA168524 grant number and then being compliant with the NIH Public Access Policy is required.

Sharing Model Organisms

In the event that a model organism is developed, KUCC will comply with the NIH Policy on Sharing of Model Organisms for Biomedical Research. KUCC will work with the NIH/NCI to share and disseminate the critical model organism in a timely manner.

Genome Wide Associate Studies

When applicable, KUCC will comply with the NIH Genomic Data Sharing Policy. KUCC supports the sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. All research studies funded through the CCSG involving genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data will be submitted in a timely manner.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 016060860

Legal Name*: University of Kansas Medical Center Research Institute, Inc.
Department:
Division:
Street1*: MSN 1039, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Deborah		Maloney	MSM

Position/Title: Director, Sponsored Programs Administration
Street1*: 3901 Rainbow Boulevard
Street2: Mail Stop 1039
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937
Phone Number*: 913-588-1261 Fax Number: 913-588-3225 Email: spa@kumc.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofit Organization

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
CPS-Cancer Prevention & Survivorship Research Program

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2017	06/30/2022

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Medical Center
Duns Number:	016060860
Street1*:	MS1027,3901 Rainbow Boulevard
Street2:	
City*:	Kansas City
County:	Wyandotte
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66103-0000
Project/Performance Site Congressional District*:	KS-003

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ❍ **Yes** ● **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ❍ No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	CPS_ProjectSummary_final1019659660.pdf
8. Project Narrative*	
9. Bibliography & References Cited	CPS_ReferencesCited_Final1019659661.pdf
10.Facilities & Other Resources	
11.Equipment	
12. Other Attachments	CPS_Other_Attachments_Final21019857897.pdf

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Cancer Prevention and Survivorship – Project Summary

Cancer Prevention and Survivorship (CPS) focuses on pre-cancerous biology and its translation into initial testing of new prevention strategies, as well as interventions aimed at improving the quality of life for cancer survivors. In the Pre-Cancerous Biology and Risk Biomarkers theme, research centers on tissue changes that serve as indicators or predictors of malignant transformation and potential targets for developing new preventive strategies. In the Prevention and Survivorship Translational Research theme, basic scientists from the Pre-Cancerous Biology and Risk Biomarkers theme work with behavioral and clinical researchers for early testing of new strategies. CPS is unique from Cancer Control and Population Control (CCPH) in that CPS focuses on the discovery of new biomarkers and early phase testing of prevention and survivorship interventions using high-risk individuals, whereas CCPH focuses on implementation of known effective strategies. CPS has 21 full and 10 associate members from 16 departments/divisions with expertise in cancer biology, medical and surgical oncology, radiation biology, gastroenterology, nursing, clinical health psychology, nutrition, exercise physiology and biomedical informatics. In 2015, CPS increased the number of NCI (12) and total peer-reviewed (29) funded grants from 6 and 24 since 2011, the previous CCSG submission. Seven of the peer-reviewed grants are multi-PI awards, up from one. NCI and total peer-reviewed funding increased from $1,804,303 and $6,244,484 to $3,098,479 and $11,890,377. From 2012-2015, over 800 patients were accrued to 15 intervention trials. Twelve of these trials were investigator-initiated and three peer-reviewed funded. Kansas and Missouri have high rates of adult obesity. Thus, many of the CPS interventional trials focus on physical activity and weight reduction, in close collaboration with catchment area partners. CPS members have published 382 articles since 2012 of which 164 (43%) had intra-programmatic, 127 (33%) had inter-programmatic and 204 (54%) had inter-institutional collaborations. Forty-five publications (12%) had a journal impact factor ≥ 8. CPS contributes to KUCC with significant leadership (Director and three ADs, Chair PRMC, Co-chair SWOG Survivorship Committee) and highly translational biomarker based early phase prevention and survivorship trials often with parallel animal studies. The SWOG chair position helps move promising pilots into larger co-operative group trials. KUCC contributes to CPS both through shared resources and pilot funding. In the future, CPS will continue to build on its strengths of novel pre-cancerous models, new risk and response biomarkers, high-risk cohorts for early phase trials, energy balance and natural products in chemoprevention trials. CPS will increase collaborations with CB to expand biomarker research in metabolomics, with D3ET to develop natural product analogues for primary prevention and with CCPH to increase disparity and catchment area-relevant research, as well as educational initiatives and mentoring.

Cancer Prevention and Survivorship – Other Attachments

Table 1 – Externally Funded, Cancer-Related Research Projects
Table 2 – Program Members
Table 3 – Shared Resource Usage
Table 4 – Programmatic Activities
Table 5 – Publications
Table 6 – Clinical Research

Table 1. Externally Funded, Cancer-Related Reseach Projects as of 12/31/2015 - Cancer Prevention & Survivorship

Table 1. Program Funding											
PI	**Specific Funding Source**	**Project Number**	**Project Start Date**	**Project End Date**	**Project Title**	**Annual Project Direct Costs**	**Annual Project Total Costs**	**Program Code**	**Percent**	**Annual Program Direct Costs**	**Annual Program Total Costs**
PEER-REVIEWED PROJECTS											
Anant S Umar S	NCI	5R01CA190291-02	8/1/2014	7/31/2019	BITTER MELON COMPONENT AND COLON CANCER PREVENTION	$360,735	$544,710	CPS	100%	$360,735	$544,710
Anant S Weir SJ	NCI	5R01CA182872-02	1/1/2014	12/31/2018	NOVEL DUAL NOTCH/PXR TARGETING FOR COLON CANCER THERAPY	$416,214	$628,483	CPS	100%	$208,107	$314,242
Banerjee S	VA	1BX001989A	11/20/2012	12/31/2016	THE ROLE OF CCN5 IN PROGRESSION OF BREAST CANCER	$227,848	$227,848	CPS	100%	$227,848	$227,848
Banerjee SK	VA	2I01BX001002-05	10/30/2015	11/30/2019	ROLE OF CYR61/CCN1 IN PANCREATIC CANCER PROGRESSION AND THERAPY	$238,772	$238,772	CPS	100%	$238,772	$238,772
Befort C	NCI	5R01CA155014-05	8/1/2011	5/31/2016	GROUP PHONE-BASED WEIGHT CONTROL AMONG RURAL BREAST CANCER SURVIVORS	$347,308	$510,955	CCPH	100%	$347,308	$510,955
Behbod F	NCI	5R21CA185460-02	5/1/2014	4/30/2016	(PQC3) ESSENTIAL ROLE OF BCL9 IN PROMOTION OF HUMAN DCIS TO INVASIVE DUCTAL CARCI	$108,750	$164,213	CPS	100%	$108,750	$164,213
Behbod F	NCI	5R21CA187890-02	9/1/2014	8/31/2016	ELUCIDATING CELLULAR HETEROGENEITY AMONG CANCER STEM CELLS BY RAMAN SPECTROSCOPY	$112,314	$145,059	CPS	100%	$112,314	$145,059
Behbod F	AACR		8/1/2014	7/31/2016	ESSENTIAL ROLE OF BCL9 IN DCIS PROGRESSION TO INVASIVE BREAST CANCER	$82,273	$90,500	CPS	100%	$82,273	$90,500
Carlson SE	NICHD	5R01HD047315-09	7/1/2004	1/31/2017	DHA SUPPLEMENTATION AND PREGNANCY OUTCOME	$311,002	$463,431	CPS	100%	$311,002	$463,431
Cancer Relevance (HD047315): *We have a number of ongoing studies prevention and survivorship studies with omega-3 fatty acids for and including DHA in prevention of cognitive dysfunction in women undergoing chemotherapy for breast cancer. Dr. Carlson is involved in these and uses the methods in outlined in this project for fatty acid.*											
Cheng N Behbod F	NCI	5R01CA172764-03	9/1/2013	6/30/2018	PROGRESSION OF DCIS TO INVASIVE BREAST CANCER THROUGH CCR2 CHEMOKINE SIGNALING			CPS	100%	$137,127	$207,062
Dhar A	NCI	5R01CA125262-06	9/15/2008	7/31/2016	CHEMOPREVENTION OF PANCREATIC CANCER BY EGCG	$187,120	$280,680	CPS	100%	$187,120	$280,680
Donnelly JE	NHLBI	5R01HL111842-04	5/4/2012	4/30/2017	A RANDOMIZED TRIAL OF RECOMMENDATIONS FOR EXERCISE TO PREVENT WEIGHT REGAIN	$460,645	$677,148	CPS	100%	$460,645	$677,148
Donnelly JE	NICHD	1R01HD079642-01A1	3/6/2015	2/28/2020	WEIGHT MANAGEMENT FOR ADOLESCENTS WITH IDD	$363,841	$549,400	CPS	100%	$363,841	$549,400
Cancer Relevance (HD079642): *Intellectual developmental disorder or IDD is defined as an IQ score below 70 and 2 or more adaptive behavioral or learning deficiencies. This disorder affects 2-3% of the US population and the intellectual disability is mild in 75-90% of cases. Intellectual disability affects about 2–3% of the general population. Donnelly and Sullivan have found that the majority of adults with IDD have an excess caloric intake and poorer dietary quality than average Americans. IDD in young adult or adolescent cancer survivors may further impact weight gain common in these individuals and these investigators are exploring exercise and simple dietary interventions which may be effective.*											
Fabian CJ	NCI Oregon Health and Science University	5UG1CA189974-02	8/1/2014	7/31/2019	SWOG NCORP RESEARCH BASE	$18,790	$28,374	CPS	100%	$18,790	$28,374
Fabian CJ	Susan Komen Foundation	SAC110051	9/22/2010	9/21/2016	DEVELOPMENT OF BIOMARKERS OF RESPONSE TO PREVENTION INTERVENTIONS WITH LIGNANS.	$51,000	$51,000	CPS	100%	$51,000	$51,000
Fabian CJ	Susan Komen Foundation	KG 101039	9/24/2010	10/1/2016	FLAXSEED LIGNAN AS A PREVENTION STRATEGY FOR PRE-MENOPAUSAL WOMEN AT HIGH RISK FOR DEVELOPMENT OF BREAST CANCER.	$863,000	$863,000	CPS	100%	$863,000	$863,000
Kimler BF	ACS	IRG-09-062-04	1/1/2013	12/31/2016	INSTITUTIONAL RESEARCH GRANT	$90,000	$90,000	CPS	100%	$90,000	$90,000

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Klemp J	CDC Kansas Dept of Health & Environment	U58DP006113-01	9/30/2015	9/29/2018	INCREASING THE IMPLEMENTATION OF EVIDENCE-BASED CANCER SURVIVORSHIP INTERVENTIONS TO INCREASE QUALITY AND DURATION OF LIFE AMONG CANCER PATIENTS	$262,500	$262,500	CPS	100%	$262,500	$262,500
Kluding PM	NIDDK University of Utah	3R01DK064814	4/1/2015	3/31/2020	ACTIVITY FOR DIABETIC POLYNEUROPATHY: THE "ADAPT STUDY"	$112,626	$154,938	CPS	100%	$112,626	$154,938
Cancer Relevance (DK064814): *The investigator is assessing effects of exercise on diabetics with peripheral neuropathy. Experience should be translatable to individuals with chemotherapy induced neuropathy and safety of the exercise regimen.*											
Lunte SM Dhar P	NIGMS	5P20GM103638-04	7/1/2015	6/30/2016	MOLECULAR ANALYSIS OF DISEASE PATHWAYS (DETERMINING THE PHYSIOLOGICAL OPTIMAL SURFACE VISCOSITY)			CPS	100%	$122,236	$183,354
Lunte SM	NSF	1411993	9/1/2014	8/31/2017	MICROANALYTICAL TECHNIQUES TO STUDY SINGLE CELL BIOCHEMICAL PROCESSES	$503,210	$650,000	CPS	100%	$503,210	$650,000
Cancer Relevance (1411993): *This may be useful in studying exosomes.*											
Savage CR Donnelly JE	NIDDK	5R01DK085605-05	4/1/2010	1/31/2016	NEUROIMAGING STUDIES OF REWARD, IMPULSIVITY, AND ADHERENCE TO AN EXERCISE PROGRAM			CPS	35%	$136,097	$200,062
Cancer Relevance (DK085605): *This project developed the fMRI neuroimaging studies used in the DHA vs placebo to prevent cognitive dysfunction during chemotherapy study as well as the omega-3 vs placebo weight loss study.*											
Smith PG	NICHD	5R01HD049615-09	4/16/2006	6/30/2017	IDENTIFYING THERAPEUTIC TARGETS FOR VULVODYNIA	$246,189	$349,752	CPS	100%	$246,189	$349,752
Cancer Relevance (HD049615): *Vulvodynia is a common complaint for women with treatment induced menopause/estrogen deprivation and/or pelvic cancer surgery. This work looks at the biologic basis of hormonal deprivation and pelvic pain.*											
Sullivan DK Donnelly J	NIDDK	5R01DK094833-04	9/25/2012	6/30/2016	A VIRTUAL REALITY INTERVENTION (SECOND LIFE) TO IMPROVE WEIGHT MAINTENANCE	$411,268	$611,139	CPS	100%	$411,268	$611,139
Cancer Relevance (DK094833): *These investigators are assessing a virtual reality intervention to help improve food selection and portion size in the grocery store, restaurants etc. This is very applicable to cancer prevention and survivorship weight loss interventions.*											
Umar S	NCI	5R01CA185322-02	1/5/2015	12/31/2019	EPIGENETICS AND INFECTION-INDUCED EMT OF COLONIC CRYPTS - TARGET FOR CHEMOPREVENTION	$263,084	$380,222	CPS	100%	$263,084	$380,222
Van Veldhuizen PJ	NCI Southwest Oncology Group (SWOG)	3969	8/5/2004	12/31/2020	SWOG: SOUTHWEST ONCOLOGY GROUP- UNIVERSITY OF KANSAS	$38,798	$38,798	CPS	100%	$38,798	$38,798
Van Veldhuizen PJ	NCI Southwest Oncology Group (SWOG)	10867	10/30/2013	12/31/2020	SWOG: SOUTHWEST ONCOLOGY GROUP- UNIVERSITY OF KANSAS	$409,164	$409,164	CPS	100%	$409,164	$409,164
Waitman RL	PCORI	CDRN-1306-04631 MC	4/1/2015	9/30/2016	THE GREATER PLAINS COLLABORATIVE	$2,044,128	$2,879,054	CPS	100%	$2,044,128	$2,879,054
Zeng Y Lunte S	NCI Univ of KS Med Ctr Research Institute	5R21CA186846-02	7/1/2015	6/30/2016	INTEGRATED MICROFLUIDIC EXOSOME PROFILING FOR EARLY DETECTION OF CANCER: DEVELOPMENT OF A LIVER-ON-A-CHIP TECHNOLOGY FOR STUDY OF LIVER DISEASE			CPS	100%	$50,000	$75,000
					Peer-Reviewed Research Subtotals:	$8,530,579	$11,289,140			**$8,767,932**	**$11,640,377**

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
NON-PEER-REVIEWED PROJECTS											
Fabian CJ	Breast Cancer Research Foundation		10/1/2014	9/30/2016	WILL THE OMEGA-3 FATTY ACID DHA PREVENT DEVELOPMENT OF COGNITIVE DYSFUNCTION DUE TO CHEMOTHERAPY?	$208,000	$250,000	CPS	100%	$208,000	$250,000
					Non-Peer-Reviewed Research Subtotals:	$208,000	$250,000			**$208,000**	**$250,000**
								CPS Grand Totals		**$8,975,932**	**$11,890,377**

PEER-REVIEWED TRAINING PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Hamilton-Reeves J Barohn RJ	NCATS	5KL2TR000119-05	3/1/2014	2/28/2017	HEARTLAND INSTITUTE FOR CLINICAL AND TRANSLATIONAL RESEARCH (PREVENTING THE PROGRESSION OF CACHEXIA IN BLADDER CANCER PATIENTS)	$88,223	$88,223	CPS	100%	$88,223	$88,223
					Peer-Reviewed Training Totals:	$88,223	$88,223			**$88,223**	**$88,223**

Table 2 – Program Members

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Anant	Shrikant	General Surgery	University of Kansas Medical Center, Kansas City, KS	Professor, Associate Director Cancer Prevention & Control	Full Theme 1 and 2
Banerjee	Snigdha	Internal Medicine – Medical Oncology	University of Kansas Medical Center, Kansas City, KS	Research Associate Professor	Full Theme 1
Banerjee	Shushanta	Internal Medicine – Medical Oncology	University of Kansas Medical Center, Kansas City, KS	Professor	Full Theme 1
Bansal	Ajay	Internal Medicine – Gastroenterology/ Hepatology/Motility	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Associate Theme 1 and 2
Behbod	Fariba	Pathology and Laboratory Medicine	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme 1 and 2
Carlson	Susan	Dietetics and Nutrition	University of Kansas Medical Center, Kansas City, KS	Professor	Full Theme 2
Dhar	Animesh	Cancer Biology	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme 1
Dixon	Dan	Cancer Biology	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme 1 and 2
Donnelly	Joseph	Internal Medicine – Cardiovascular Diseases	University of Kansas, Lawrence, KS	Professor/Director Energy Balance Lab & Center for Physical Activity & Weight Management	Full Theme 2
Fabian	Carol	Internal Medicine – Medical Oncology	University of Kansas Medical Center, Kansas City, KS	Distinguished Professor, AD Clinical Research, Director Breast Cancer Prevention and Survivorship Research Center	Full Theme 2 and 1
Hamilton-Reeves	Jill	Dietetics and Nutrition	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Associate Theme 2
Harlan-Williams	Lisa	Anatomy and Cell Biology	University of Kansas Medical Center, Kansas City, KS	Research Assistant Professor	Associate Theme 1

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Jensen	Roy	Pathology and Laboratory Medicine	University of Kansas Medical Center, Kansas City, KS	Professor, Director, University of Kansas Cancer Center	Full Theme 1
Khan	Qamar	Internal Medicine – Medical Oncology	University of Kansas Medical Center, Kansas City, KS	Associate Professor, Chair PRMC	Full Theme 2
Kimler	Bruce	Radiation Oncology	University of Kansas Medical Center, Kansas City, KS	Professor	Full Theme 2 and 1
Klemp	Jennifer	Internal Medicine – Medical Oncology	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme 2
Kluding	Patricia	Physical Therapy and Rehabilitation Sciences	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme 2
Lunte	Susan	Chemistry	University of Kansas, Lawrence, KS	Distinguished Professor	Full Theme 1
Maliski	Sally	School of Nursing	University of Kansas Medical Center, Kansas City, KS	Professor, Dean School of Nursing, AD Health Disparities	Full Theme 2
Rastogi	Amit	Medicine – Gastroenterology and Hepatology	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Associate Theme 2
Sharma	Prateek	Medicine – Gastroenterology/ Hepatology/Motility	University of Kansas Medical Center, Kansas City, KS	Professor	Associate Theme 2
Smith	Peter	Molecular and Integrative Physiology	University of Kansas Medical Center, Kansas City, KS	Associate Dean Research, Professor, Director Institute for Neurological Discoveries	Full Theme 1
Subramaniam	Dharmalingam	General Surgery	University of Kansas Medical Center, Kansas City, KS	Research Assistant Professor	Associate Theme 1
Sullivan	Debra	Dietetics and Nutrition	University of Kansas Medical Center, Kansas City, KS	Professor and Chair	Full Theme 2
Tawfik	Ossama	Pathology and Laboratory Medicine	University of Kansas Medical Center, Kansas City, KS	Professor and Director, Anatomic and Surgical Pathology	Associate Theme 1 and 2
Umar	Shahid	General Surgery	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full Theme 1 and 2

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Valdez	Kelli	Pathology and Laboratory Medicine;	University of Kansas Medical Center, Kansas City, KS	Research Assistant Professor	Associate Theme 1
Van Veldhuizen Left KUMC 2016	Peter	Internal Medicine – Medical Oncology;	University of Kansas Medical Center, Kansas City, KS	Professor	Full Theme 2
Wagner	Jamie	General Surgery	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Associate Theme 2
Waitman	Russ	Internal Medicine – Medical Informatics	University of Kansas Medical Center, Kansas City, KS	Professor, Associate Vice Chancellor for Enterprise Analytics, Director Medical Informatics	Full Theme 2
Yeh Left KUMC 2016	Hung-Wen (Henry)	Biostatistics	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Associate Theme 2 and 1

Table 3 – Shared Resource Usage

Shared Resource	Number of program members using the shared resource	Percentage of shared resource usage by program members
Biospecimen Repository Core Facility (BRCF)	11	25%
Biostatistics & Informatics (BISR)	10	18%
Lead Development & Optimization (LDOSR)	6	14%
Transgenic & Gene-Targeting (TGTSR)	5	19%
Clinical Pharmacology (CPSR)	3	14%

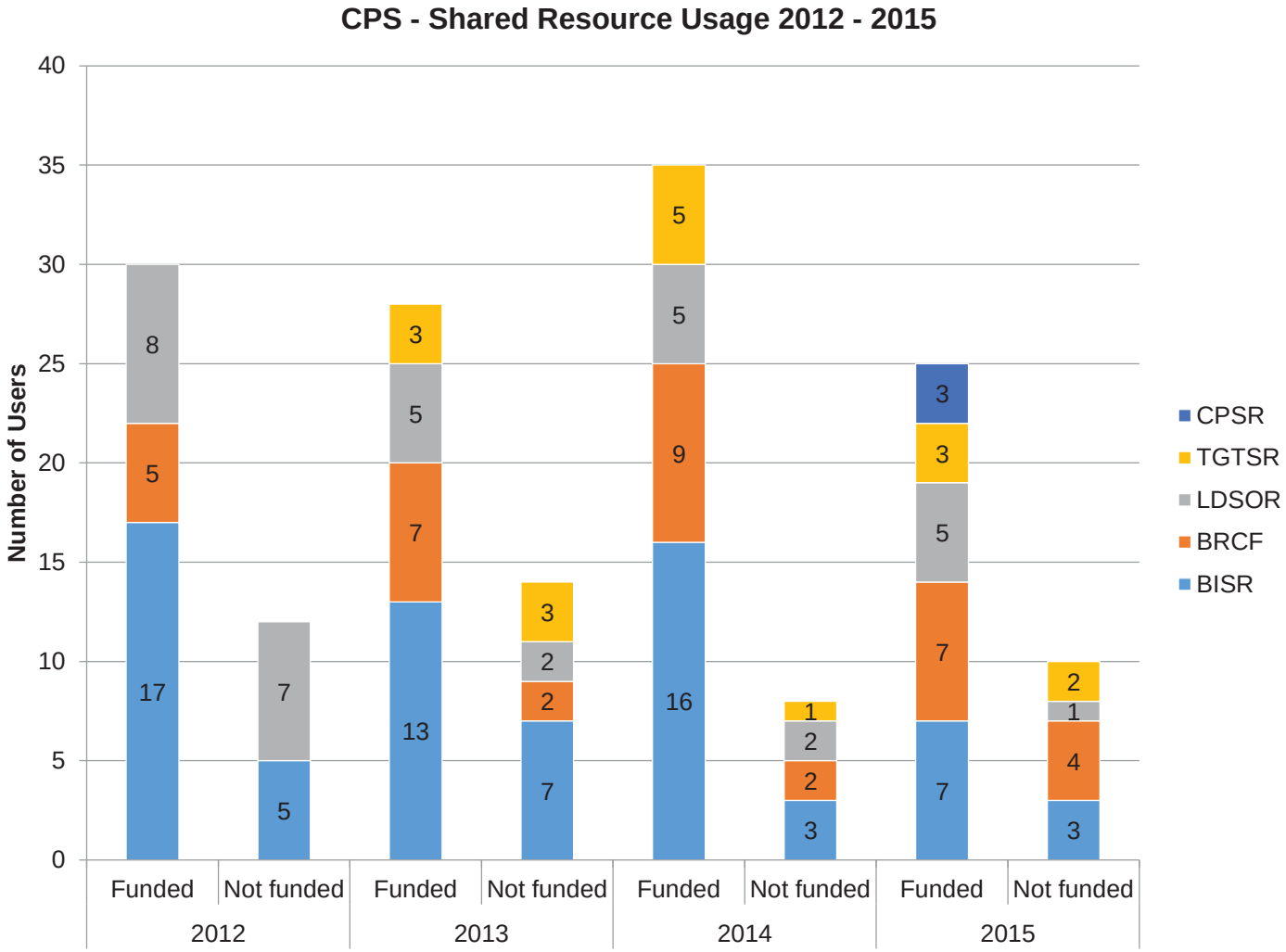

Table 4 – Programmatic Activities

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
2012				
Multi-Disciplinary Research Planning	1/13/12	Carol Fabian Susan Carlson Bruce Kimler	Brandon Hidaka	Effect of Fatty Acids on Breast Tissue Cytolomorphology. Support MD PhD Student
Leadership Council	1/20/12	Carol Fabian and KUCC Leadership	Roy Jensen	Leadership Council
EAB Meeting with CPS Researchers	1/24/12	Ernie Hawk Larry Baker	Carol Fabian	CPS Progress and Future Directions
Feedback +EAB	1/27/12	KUCC Leadership	Roy Jensen	EAB Critique Discussion
Planning Multi-PI Grant	2/7/2012	Steve Hursting Bruce Kimler Brian Petroff	Carol Fabian	Discussion omega-3 fatty acid results to date. Planning pilot multi-PI grant
Hispanic Minority Recruitment Techniques	2/10/12	Jennifer Klemp	Paula Cupertino (CCPH) Carol Fabian	Hispanic Recruitment into Prevention Trials
Rehearsal Site Visit	2/15/12	Multiple CPS	Carol Fabian and other Program Leaders, Jensen	Dress Rehearsal Site Visit
Meeting AD Cancer Control	2/20/12	Shri Anant Brian Petroff	Carol Fabian	Prep for Site Visit and Administrative Issues
Multi-Disciplinary Research Planning	2/20/12 2/27/12 3/19/12	Fabian Susan Carlson Bruce Kimler	Brandon Hidaka	Effect of Fatty Acids on Breast Tissue Cytomorphology. Support MD PhD Student
Board of Regents Presentation	4-18-12	Kansas Board of Regents	Carol Fabian	Translational Prevention Research and the Cancer Center
Cross discipline Research Cancer Biology	3/19/12	Carol Fabian	Danny Welch	Potential projects Between Cancer Biology and CPS (Kiss-1) Recruitment Joan Lewis-Wambi
CPS Advocate Meeting	4-9-2016	Cheryl Jernigan lead	Carol Fabian	Advocate recruitment for CPS projects especially basic science
Program Leadership	4/27/12	Carol Fabian and Leadership	Roy Jensen	Program Leadership Meeting
KUCC Pilot Reviews	5/04/12	Carol Fabian and other Program Leaders	Roy Jensen	Review pilots for funding
Recruitment Interview	5/14/12	Brooke Fridley PhD, Dir Biostat	Carol Fabian	Recruitment for Cancer Center. Biomarker Analysis Studies
KUCC Membership	6/11/12	Carol Fabian, other co-leaders programs	Matt Mayo	Membership and Program Assignment Decisions
President's National Cancer Advisory Board	6/26/12	Carol Fabian Brian Petroff	NCAB	Conference Call
Cancer Center Wide Meeting	7/1212	Carol Fabian and CC members	Roy Jensen, Others	Announcement CCSG Designation, News Conference
Meeting CPS Investigators Research Issues	7/16/12	Fariba Behbod Mark Cohen	Carol Fabian	Barriers to Current Translational Research Projects
KUCC Town Hall	7/16/12	C Fabian and B Petroff and CPS, CB, D3ET members	Roy Jensen	Cancer Center Announcements and Discussion
Leadership Council	7/20/12	Carol Fabian, Brian Petroff and others	Roy Jensen	Administrative Issues

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
CPS and CPPH Collaboration	7/23/12	Ed Ellerbeck	Carol Fabian	Opportunities for collaboration
KUCC Strategic Plan Meeting	8/3/12	KUCC Executive Team	Dan Dixon Tomoo Iwakuma	KUCC Education Strategic Planning and Goals
KUCC Strategic Plan Meeting	8/7/12	CPS CB	Dan Dixon Tomoo Iwakuma Danny Welch	KUCC Education Strategic Planning and Goals
Rural Weight Loss Project	8/13/12	Carol Fabian Jennifer Klemp	Christie Befort	Discussion of involvement MCA, accrual, barriers, assessment of AEs
KUCC Strategic Plan Meeting	8/16/12	CPS CB	Dan Dixon Tomoo Iwakuma	KUCC Education Strategic Planning and Goals
KUCC Seminar Series	8/21/12		Dan Dixon	New ways to control COX-2 in cancer
Program Leadership	8/24/12	Carol Fabian, Brian Petroff from CPS, CB, D3ET	Roy Jensen and others	KUCC Administrative issues
Obesity Research Meeting	8/27/12	Carol Fabian Jennifer Klemp Bruce Kimler	Travis Williams	Obesity Research in CPS
KUCC Seminar Series	8/28/12		Ossama Tawfik	What Does a Pap Smear Have to Do with Telepathology?
KUCC Seminar Series	9/4/12		Roy Jensen	BRCA1: A Mystery Solved and A Path Forward
Planning Meeting for San Antonio Breast Cancer Review	9/7/12	Jennifer Klemp, Continuing Education Reps	Carol Fabian	Plan for post-San Antonio Review
CCPH-CPS joint program meeting	9/7/12	CPS and CCPH	Brian Petroff Jennifer Klemp Cary Savage Theresa Shireman	Focus on Energy Balance Interventions; fMRI and diet and exercise; comparative effectiveness research
KUCC Pilot Project Meeting	9/12/12	CB D3ET	Dan Dixon Ray Perez Anuradha Roy	Planning meeting for joint CPS/D3ET pilot project
KUCC Strategic Plan Meeting	9/13/12	CPS CB	Dan Dixon Tomoo Iwakuma Susan Harp	KUCC Education Strategic Planning and Goals planning meeting
KUCC Pilot Application	9/17/12	Carol Fabian Jennifer Klemp	Christie Befort	Planning for a multi-investigator pilot grant
CPS Grant Planning Meeting	9/21/12	CPS CCPH	Carol Fabian Bruce Kimler Dan Dixon Jennifer Klemp Brian Petroff Cary Savage	Follow-up meeting on combined diet and exercise and omega-3 fatty acids Multi-PI Pilot Study
Shared Resources Strategic Planning	10/10/12		Andrew Godwin Brooke Fridley Shrikant Anant Matt Mayo Ed Ellerbeck	Shared Resources Strategic Planning
KUCC Strategic Plan Meeting	10/10/12	CPS CB	Dan Dixon Tomoo Iwakuma Susan Harp	KUCC Education Strategic Planning and Goals planning meeting
KUCC Strategic Plan Meeting	10/12/12	KUCC Executive Team	Dan Dixon Tomoo Iwakuma Susan Harp	KUCC Education Strategic Planning and Goals
Educational Outreach Symposium	10/24/12	Breast Cancer Survivors	Jennifer Klemp Carol Fabian, others	Educational Program for Breast Cancer Survivors on Multiple topics

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Cancer Prevention Cabinet Meeting	11/5/12		Carol Fabian, Dan Dixon, Brian Petroff, Fariba Behbod, Bruce Kimler, Jennifer Klemp	
KUCC Annual Symposium	11/8/12	CPS, CCPH CB, D3ET	Multiple	Program member meeting
CPS Multi-Discipline Research Planning	11/16/12		Jill Hamilton Reeves Bruce Kimler Brian Petroff Lisa Harlan-Williams	Discussion of Research Interests and Opportunities new faculty with interest in Prostate Cancer and Weight Control
Leadership Council	11/16/12	CPS,CCPH, CB,D3ET	Roy Jensen	Administrative and Research Issues
CPS Executive Team Meeting	11/16/12		Lisa Harlan-Williams Brian Petroff Carol Fabian Dan Dixon	Research meeting program planning Strategic Planning
KUCC Seminar Series	11/27/12		Satish Ramalingam	Role of RNA Binding Protein CELF2 in Colon Cancer
Recruitment CPS	12/10/12	Holly Pederson Cleveland Clinic	Carol Fabian Klemp Kimler	Potential Recruitment for Fabian Replacement
KUCC Seminar Series	12/11/12	Animesh Dhar	Mridul Mukherji (UMKC)	Role of dioxygenases in HIF signaling
CPS co-leader Meeting	12/13/12		Dan Dixon Carol Fabian Brian Petroff	Co-Leader Discussion and Planning meeting
CPS Cabinet Meeting	12/14/12		Carol Fabian Dan Dixon Brian Petroff Fariba Behbod Jennifer Klemp Christie Befort	CPS Cabinet Program planning
KUCC Program Leaders Meeting	12/17/12	Carol Fabian and Dan Dixon CPS, CB, D3ET	Roy Jensen	Multiple Planning and Administrative Issues
U10 Planning Meeting	12/21/12	Carol Fabian	Peter Van Veldhuizen Division Director, SWOG PI	Planning and Writing Responsibilities, KUCC contribution
2013				
KUCC Pilot Project Meeting	1/7/13	CPS D3ET	Dan Dixon Ray Perez Anuradha Roy	Joint CPS/D3ET project progress reporting
CPS Cabinet Meeting	1/14/13		Carol Fabian Dan Dixon Bruce Kimler Brian Petroff	Program planning
CPS-CCPH Meeting			Carol Fabian and Ed Ellerbeck	Exploration of Possible Collaborations
CPS Sponsored Seminar	1/15/12	Cancer Center	Weston Porter	Tumor Metabolism and Diet

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
ACS IRG	1/16/13	CPS, CCPH CB, D3ET	Bruce Kimler Ajay Bansal Qi Chen Ed Ellerbeck Kimberly Engelman Brooke Fridley William Jewell Satish Ramalingam Megha Ramaswamy Kathy Roby Danny Welch	Review of internal ACS grant applications
KUCC Leadership Council Meeting	1/18/13	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	KUCC leadership meeting and program updates
Planning Meeting San Antonio Breast Cancer Review	1/18/13		Carol Webb Carol Fabian Continuing Education	Planning for Post San Antonio Breast Cancer Review
Post SABCS Symposium	2/9/13	(125 participants including community and catchment physicians)	Carol Fabian Qamar Khan Jennifer Klemp Others	Review and Critique of Studies Presented at SABCS
Program Leadership	2/22/13	CPS, CCPH CB, D3ET	Roy Jensen	KUCC leadership meeting and program updates
KUCC Seminar Series	2/19/13		Jennifer Klemp	Cardiovascular Exercise and Biomarkers in Cancer Survivors
Multi-PI Project Planning Meeting	2/22 and 3/4/13 and 3/35		Carol Fabian Brian Petroff Bruce Kimler Dan Dixon Susan Carlson Steve Hursting (UNC0	Planning meeting on omega-3 fatty acids MPI project
KUCC Seminar Series	3/5/12	Dan Dixon	Jonathan Brody (Thomas Jefferson University)	The RNA Binding Protein HuR plays a Critical Role in Pancreatic Tumorigenesis and Chemotherapeutic Efficacy
Multi-PI Project Planning Meeting	3/25/13		Carol Fabian Brian Petroff Bruce Kimler Dan Dixon Susan Carlson	Planning meeting on omega-3 fatty acids MPI project
KUCC Seminar Series	3/26/13		T. Rajendra Kumar	Estrogens and pituitary null cell tumors
EAB Content Discussion Meeting	4/25/13		Carol Fabian Dan Dixon Brian Petroff Danny Welch Lisa Harlan-Williams Shrikant Anant Teresa Christenson	EAB meeting planning
KUCC Leadership Council Meeting	4/26/13	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	KUCC leadership meeting and program updates
CPS-Bio-specimen Bank	4/29/13		Carol Fabian Andrew Godwin	Blood banking for high risk women for Breast Cancer
EAB Practice Session	5/6/13		Carol Fabian Dan Dixon Brian Petroff Lisa Harlan-Williams Shrikant Anant	EAB presentation CPS practice and discussion
EAB Meeting with CPS Researchers	5/9/13	Ernie Hawk Larry Baker	Carol Fabian Dan Dixon	CPS Progress and Future Directions

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Outreach Pink Promise Brunch	5/11/13		Carol Fabian	Booth Presentations of Prevention Trials in KUCC
Multi-PI Project Planning Meeting	5/13/13		Carol Fabian Brian Petroff Bruce Kimler Dan Dixon Susan Carlson	Planning meeting on omega-3 fatty acids MPI project
KUCC Leadership Meeting	5/15/13	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	EAB Review & Strategic Planning
KUCC Leadership Council Meeting	5/17/13	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	KUCC leadership meeting and program updates
Junior Member Development	5/20/130		Carol Fabian Jill Hamilton Reeves	
KUCC Pilot Project Meeting	6/10/13	CPS D3ET	Dan Dixon Ray Perez Anuradha Roy	Meeting to discuss moving joint CPS/D3ET KUCC pilot project into a COBRE project
CPS Executive Team Meeting	6/14/13		Carol Fabian Dan Dixon Bruce Kimler Brian Petroff	Program planning
KUCC Program Meeting	6/28/13	CPS, CCPH CB, D3ET	Dan Dixon	KUCC program meeting and updates
Outreach Pink Promise Wichita	6/28/13		Carol Fabian	KUCC Research Breast Ca Prev and Surviorship-Keynote Speaker
Multi-PI Project Planning Meeting	7/1/13		Carol Fabian Brian Petroff Bruce Kimler Dan Dixon Susan Carlson Christie Befort	Planning meeting on omega-3 fatty acids MPI project
ACS IRG	7/17/13	CPS, CCPH CB, D3ET	Bruce Kimler Ajay Bansal Qi Chen Ed Ellerbeck Kimberly Engelman Brooke Fridley Severin Gudima Greg Reed Danny Welch	Review of internal ACS grant applications
KUCC Membership Committee	7/25/13		Carol Fabian and other program leaders Matt Mayo Roy Jensen	Determine membership and program assignment
KUCC Membership Committee Meeting	7/25/13	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	Discussion of current and new member applications
CPS Executive Team Meeting	7/29/13		Lisa Harlan-Williams Brian Petroff Carol Fabian Dan Dixon Bruce Kimler Fariba Behbod Jennifer Klemp Christie Befort	Review of EAB Comments on CPS Program
GI High Risk Cancer Group	8/5/13		Dan Dixon Mojtaba Olyaee Shrikant Anant	Meeting to discuss the formation of a GI high risk clinic
KUCC Seminar Series	8/6/13	Fariba Behbod Carol Fabian	Jeffrey M. Rosen (Baylor)	EMT programs, Therapeutic Resistance and Cancer Stem Cells

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Colon Cancer Prevention Meeting	8/23/13		Dan Dixon Bruce Kimler Carol Fabian Debra Collins Joaquina Baranda Lori Reeves Scott Grisolano Shrikant Anant	Meeting to discuss colon cancer prevention topics
Meeting with CPS Theme 2 and Biostats	8/23/13		Byron Gajewski Carol Fabian, Bruce Kimler, Matt Mayo (CB)	Predicting Patient Accrual in Clinical Trials
Biostats and Biomarkers Analysis	8/26/13		Carol Fabian Brooke Fridley (CCPH)	
Research Retreat	9/13/13	CPS, Multiple Oncologists	Carol Fabian	Omega-3 in Prevention and Survivorship
Mason's Day	9/21/13	Masons	Jill Hamilton-Reeves Roy Jensen Ed Ellerbeck Danny Welch	Role of CPS and KUCC in addressing cancer control needs in the catchment area
Joint Mentoring MS Clinical Research Student Michaels-Hensing	9/24		Carol Fabian Andy Godwin (D3ET)	SNP s Predictive of atypical hyperplasia with HRT use in High Risk Women
CPS Executive Team Meeting	9/27/13		Carol Fabian Dan Dixon Lisa Harlan-Williams	Program planning
GI High Risk Cancer Group	10/4/13		Dan Dixon Shrikant Anant Roy Jensen Aravind Sugumar	Meeting to discuss the formation of a GI high risk clinic
CPS-CB Breast Research Discussions	10/21/13		Danny Welch Joan Lewis-Wambi Carol Fabian Pepper Schedin	Discussions
KUCC Seminar Series	10/22/13	Carol Fabian Danny Welch	Pepper Schedin (Univ of Colorado)	Advancements in understanding NSAID-based chemoprevention of postpartum breast cancer
KUCC Program Meeting	10/25/13	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	KUCC program meeting and updates
KUCC Annual Symposium	11/7/13	CPS, CCPH CB, D3ET	Anand Venugopal (CPS trainee) Nikki Cheng	Program member meeting
KUCC Leadership Council Meeting	11/15/13	CPS,CCPH CB, D3ET	Carol Fabian Dan Dixon	KUCC leadership meeting and program updates
KUCC Seminar Series	12/3/13	Carol Fabian Multiple CPS, D3ET, CB	Jason Zell (UC-Irvine)	Colorectal Cancer Risk Reduction through Polyomine Inhibition
Cancer Prevention Pilot Reviews	12/5/13		Carol Fabian Bruce Kimler Dan Dixon	
CPS-CCPH Joint Program Meeting	12/6/13	CCPH	Andy Godwin Shahid Umar Carol Fabian Jill Hamilton-Reeves	Cancer Prevention Research Retreat; Core facilities; New developments in GI, GU, and breast cancer prevention
2014				

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
CPS Executive Team Meeting	1/27/14		Carol Fabian Dan Dixon Lisa Harlan-Williams Andrew Godwin Brian Petroff Roy Jensen Shrikant Anant Teresa Christenson	Program report content meeting
CPS Executive Team Meeting	1/31/14		Carol Fabian Dan Dixon Brian Pettroff Seth Septer	Opportunities for GI Prevention Using Cohorts from Children's Mercy Hospital
KUCC Seminar Series	2/4/14		Arindam Paul	Atypical PKC signaling in Breast Cancer
ACS IRG	2/19/14	CPS, CCPH CB, D3ET	Bruce Kimler Ajay Bansal Qi Chen Ed Ellerbeck Kimberly Engelman Brooke Fridley Heather Gibbs Severin Gudima Satish Ramalingam Megha Ramaswamy Aravind Sugumar Danny Welch	Review of internal ACS grant applications
GI High Risk Cancer Group	2/19/14		Aravind Sugumar Dan Dixon Debra Collins Jennifer Klemp Shrikant Anant	Meeting to discuss genetic counseling for high risk GI clinic
Omega-3 Multi-PI Study	2/21		Christie Befort Bruce Kimler Jennifer Klemp	Behavioral Intervention Issues and Data Capture
KUCC Program Meeting	2/27/14	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon Brian Petroff	KUCC program meeting and updates
Cancer Prevention Symposium Internal Planning Committee	3/3/14	CPS D3ET CCPH	Carol Fabian Dan Dixon Krista Allen Roy Jensen Scott Weir Shrikant Anant	Discussion of cancer prevention symposium
CPS-D3ET Research Discussion	3/7/14		Priyanka Sharma Carol Fabian	Joint Research Opportuniteis Triple Negative Registry
Sarcoma Survivorship Research Clinic Seminar	3/21/14	Larry Baker (Mich)	Carol Fabian Gary Doolittle	
Replacement for Fabian Recruitment	3/25/-3/27/15	Erin Hofstatter (Yale Cancer Center)	Carol Fabian Roy Jensen	Recruitment Interviews and Seminar
EAB Content Discussion Meeting	4/21/14		Carol Fabian Dan Dixon Brian Petroff Lisa Harlan-Williams Shrikant Anant Teresa Christenson	EAB meeting planning
KUCC Seminar Series	4/22/14		Sushanta Banerjee	Phenotype Switching in Human Pancreatic Cancer: A Tale of Two Sister Genes

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
EAB Practice Session	5/12/14		Carol Fabian, Dan Dixon CPS, others	
KUCC Seminar Series	5/13/14	Shrikant Anant	Ashim Mitra (UMKC)	Novel molecular strategies to improve therapy in drug resistant patients
CPS Executive Team Meeting	5/16/14		Carol Fabian Dan Dixon Shrikant Anant	Program planning meeting
EAB Meeting with CPS Researchers	5/23/14	Ernie Hawk Larry Baker	Carol Fabian Dan Dixon	CPS progress and future directions
KUCC Program Meeting	6/13/14	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	KUCC program meeting and updates
Integration Genetic and Risk Counseling and Research	6/23/13		Carol Fabian Jennifer Klemp Terry Tsue Jeff Wright	
Weight Loss +/- Omega-3 Multi-PI Project	6/24/14	CPS, CCPH	Carol Fabian Christy Befort Dan Dixon Carry Savage Bruce Kimler	
KUCC Seminar Series	6/24/14		Ajay Bansal	Role of MicroRNA in Barrett's esophagus and Associated Neoplasia
Recruitment Visit Fabian Replacement	6/25 and 6/26/14		Carol Fabian Dan Dixon Jennifer Klemp Bruce Kimler Roy Jensen and others	2nd recruiting visit and meeting
KUCC Leadership Council Meeting	7/18/14	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	KUCC leadership meeting and program updates
KUCC Program Meeting	8/22/14	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	KUCC program meeting and updates
KUCC Seminar Series	9/9/14	Roy Jensen Sufi Thomas	Jennifer Rubin Grandis (U Pitt)	Precision Head and Neck Cancer Medicine
KUCC Leadership Council Meeting	9/26/14	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	KUCC leadership meeting and program updates
CPS Program Meeting	9/26/14		Russ Waitman Sue Lunte Dan Dixon Prateek Sharma	CPS program member meeting and presentations
Joint Program Meeting	10/3/14	CCPH	Roy Jensen Kim Kimminau Kim Richter Hope Krebill	CCPH Science Friday: NCI Comprehensive status; AAFP PBRN; Tobacco and obesity treatment in Safety nets; KCP efforts
KUCC Seminar Series	10/7/14	Dan Dixon Kristi Neufeld	Richard Halberg (Wisc)	Polyclonal Intestinal Tumors: Formation and Significance
Cancer Prevention Symposium Internal Planning Committee	10/21/14	CPS D3ET CCPH	Dan Dixon Krista Allen Jean Peat Scott Weir Shrikant Anant	Discussion of cancer prevention symposium
KUCC Program Meeting	10/24/14	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	KUCC program meeting and updates
KUCC Seminar Series	10/28/14	Shrikant Anant	Anil Rustgi (U Penn)	Pancreatic Regeneration and Carcinogenesis

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Fight Colorectal Cancer Research Advocate Training	11/12-13/14	Fight CRC National Advocacy Foundation	Dan Dixon Tomoo Iwakuma Kim Engleman Danny Welch Andy Godwin Shrikant Anant	Educational event for Fight CRC research advocates
KUCC Annual Symposium	11/14-15/14	CPS, CCPH CB, D3ET	Joaquina Baranda Qamar Khan Jamie Wagner	Program member meeting
KUCC Seminar Series	11/18/14	Shrikant Anant Dan Dixon	Andy Chan (Harvard)	Can combination agents enhance the effect of aspiring on colorectal cancer?
KUCC Seminar Series	12/9/14	Jennifer Klemp	Florence Ndikum-Moffor (KUMC)	Assessment of Knowledge of Hereditary Breast and Ovarian Cancer and Interest in Genetic Testing Among African American Women
O'Sullivan Foundation Meeting	12/9/14		Dan Dixon Shrikant Anant Roy Jensen Krista Allen	Meeting and presentations with O'Sullivan CRC Foundation
2015				
CPS Executive Team Meeting	1/5/15		Carol Fabian Dan Dixon Lisa Harlan-Williams Andrew Godwin Brian Petroff Roy Jensen Shrikant Anant Teresa Christenson	EAB progress report content meeting
Recruitment Fabian Replacment	1/22/15	Banu Arun (MD Anderson)	Carol Fabian Jennifer Klemp Roy Jensen Dan Dixon Jamie Wagner	Discussion Recruitment as Program Leader and Director - Breast Cancer Prevention Center
Cognition Study Variables and Biostats	1/21/15	CPS, CCPH	Carol Fabian Bruce Kimler Brooke Fridley (CCPH)	
Incorporating fMRI into Prevention and Survivorship Studies	1/26/15	CPS, CCPH	Carol Fabian Bruce Kimler William Brooks Cary Savage (CCPH) Laura Martin	
KUCC Seminar Series	1/13/15		Wen Liu	Pilot data using a mind-body intervention on quality of life in cancer survivors
KUCC Leadership Council Meeting	1/16/15	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	KUCC leadership meeting and program updates
CPS Leadership Meeting	1/21/15		Carol Fabian Dan Dixon Bruce Kimler	Program planning meeting
KUCC Seminar Series	1/20/15	Shrikant Anant	Zigang Dong (U Minn)	Can We Win the War Against Cancer by Prevention?
KUCC Seminar Series	2/10/15		Animesh Dhar	Lysine Histone Demethylase 3A (KDM3A): Novel Epigenetic Target for Pancreatic Cancer Progression and Metastasis

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
ACS IRG	2/27/15	CPS, CCPH CB, D3ET	Bruce Kimler Ajay Bansal Kimberly Engelman Brooke Fridley Heather Gibbs Severin Gudima Jill Hamilton-Reeves Robin Hines William Jewell Eugene Lee Satish Ramalingam Danny Welch	Review of internal ACS grant applications
EAB Content Discussion Meeting	3/2/15		Carol Fabian Dan Dixon Lisa Harlan-Williams Shrikant Anant Roy Jensen Teresa Christenson	EAB meeting planning
CRC PCORI Proposal Meeting	3/9/15	Fight CRC National Advocacy Foundation	Dan Dixon Allen Greiner	Discussion of collaborative PCORI proposals
Bio-specimen analysis from Befort R01	3/18/15 and 4/22 and 5/13		Christie Befort Carol Fabian Bruce Kimler Dan Dixon	Discuss analysis of blood specimens for cytokines and miRNA by Fabian and Dixon Labs
EAB Practice Session	3/23/15	CPS program	Carol Fabian Dan Dixon and others	
KUCC Seminar Series	3/24/15		Shrikant Anant Scott Weir	CPX-POM: A Novel, Promising Treatment for Non-Muscle Invasive Bladder Cancer
EAB Content Discussion Meeting	4/3/15		Carol Fabian Dan Dixon Lisa Harlan-Williams Shrikant Anant Andy Godwin Teresa Christenson	EAB meeting planning and presentation
EAB Meeting with CPS Researchers	4/16/15	Larry Baker Mark Clanton	Carol Fabian Dan Dixon	CPS Progress and Future Directions
Outreach Komen Pink Promise Brunch			Carol Fabian	Presentation KUCC Research
Clinical Research and Translational Meeting	4/22/15		Qamar Kahn	Randomized Trial of Capecitabine in Metastatic Breast Cancer and Advanced GI Malignancies
Recruitment Anne O'Dea Clinical Replacement for Fabian	5/8/15		Carol Fabian Jennifer Klemp Bruce Kimler and others	
Meeting with fMRI group	5/8/13		Carol Fabian Bruce Kimler William Brooks Carry Savage Laura Martin Rebecca Lepping	Issues with fMRI Weight Loss prevention and Cognition Survivorship Studies.
Meeting with Associate Member Kelly Valdez, Discussion of Research Opportunities	5/13/15		Bruce Kimler Carol Fabian Kelly Valdez	Presentation and discussion of pilot project

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
KUCC Leadership Council Meeting	5/15/15	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	KUCC leadership meeting and program updates
ACS IRG	5/15/15	CPS, CCPH CB, D3ET	Bruce Kimler Ajay Bansal Kimberly Engelman Heather Gibbs Severin Gudima Jill Hamilton-Reeves Robin Hines William Jewell Eugene Lee Satish Ramalingam Danny Welch	Review of internal ACS grant applications
KUCC Seminar Series	5/26/15		Francisco Diaz	Statistical Modeling
CPS-CCPH Joint Program Meeting	6/12/15	CPS CCPH	Carol Fabian Dan Dixon Ed Ellerbeck Lisa Harlan-Williams	Joint CPS-CCPH planning meeting
KUCC Leadership Council Meeting	7/10/15	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	KUCC leadership meeting and program updates
KUCC Membership Committee Meeting	7/15/15	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	Discussion of current and new member applications
CPS-CCPH Joint Program Meeting	7/24/15	CPS CCPH	Carol Fabian Dan Dixon Ed Ellerbeck Megha Ramaswamy Nikki Nollen Joe Donnelly	Joint program updates and presentations
KUCC Seminar Series	8/4/15	Animesh Dhar	Ashim Mitra (UMKC)	Novel Prodrug Strategies to Overcome Cancer Drugs Resistance
Recruitment to Replace Fabian	8/4/15 and 8/5/15		Carol Fabian Roy Jensen Bruce Kimler Dan Dixon Jennifer Klemp Others	Seminar and recruitment visit for medical oncologist who will eventually take over the Breast Cancer Prevention Center
NCI - PREVENT Cancer Meeting	8/5/15	CPS D3ET	Carol Fabian Dan Dixon Bruce Kimler Frank Schoenen Lisa Harlan-Williams Michael Baltezor Scott Weir Anuradha Roy	Meeting to discuss feasibility NCI - PREVENT Cancer Preclinical Drug Development Program proposal
Survivorship MPI-R01 Planning Meeting	8/7/15	CPS CCPH	Bruce Kimler Carol Fabian Dan Dixon Joseph Donnelly Jennifer Klemp Christie Befort	Planning meeting for MPI-R01: Physical Activity and Weight Control Interventions Among Cancer Survivors: Effects on Biomarkers of Prognosis and Survival
Survivorship MPI-R01 Planning Meeting	8/14/15	CPS CCPH	Bruce Kimler Carol Fabian Dan Dixon Joseph Donnelly Jennifer Klemp Christie Befort	Planning meeting for MPI-R01: Physical Activity and Weight Control Interventions Among Cancer Survivors: Effects on Biomarkers of Prognosis and Survival
KUCC Seminar Series	8/18/15		Roy Jensen	Control of Gene Expression on BRCA1: The Role of Micro RNA's

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Survivorship MPI-R01 Planning Meeting	8/21/15	CPS CCPH	Bruce Kimler Carol Fabian Dan Dixon Joseph Donnelly Jennifer Klemp Christie Befort	Planning meeting for MPI-R01: Physical Activity and Weight Control Interventions Among Cancer Survivors: Effects on Biomarkers of Prognosis and Survival
CB-CPS	8-26		Carol Fabian Christy Hagan	Meeting to Discuss Increasing Interaction between Breast Cancer Biology and CPS Breast Investigators. Decision to Start a Translational Research Conference meeting Monthly.
Survivorship MPI-R01 Planning Meeting	8/26/15	CPS CCPH	Bruce Kimler Carol Fabian Dan Dixon Joseph Donnelly Jennifer Klemp Christie Befort	Planning meeting for MPI-R01: Physical Activity and Weight Control Interventions Among Cancer Survivors: Effects on Biomarkers of Prognosis and Survival
PIVOT Project Meeting	9/1/15	CPS, CCPH CB, D3ET	Kim Kimminau Scott Weir Cheryl Jernigan Dan Dixon Gary Doolittle Hope Krebill	Meeting to Discuss patient/ community engagement (PIVOT) project
Program Leadership meeting		CPS, CCPH CB, D3ET	Roy Jensen	Administrative Program Meeting
Survivorship MPI-R01 Planning Meeting	9/4/15	CPS CCPH	Bruce Kimler Carol Fabian Dan Dixon Joseph Donnelly Jennifer Klemp Christie Befort	Planning meeting for MPI-R01: Physical Activity and Weight Control Interventions Among Cancer Survivors: Effects on Biomarkers of Prognosis and Survival
GI High Risk Cancer Group	9/4/15		Dan Dixon Bruce Kimler Jennifer Klemp Joaquina Baranda	Meeting to discuss omega-3 fatty acids prevention trial for high risk GI clinic
Survivorship MPI-R01 Planning Meeting	9/11/15	CPS CCPH	Bruce Kimler Carol Fabian Dan Dixon Joseph Donnelly Jennifer Klemp Christie Befort	Planning meeting for MPI-R01: Physical Activity and Weight Control Interventions Among Cancer Survivors: Effects on Biomarkers of Prognosis and Survival
KUCC Leadership Council Meeting	9/18/15	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	KUCC leadership meeting and program updates
Survivorship MPI-R01 Planning Meeting	9/25/15	CPS CCPH	Bruce Kimler Carol Fabian Dan Dixon Joseph Donnelly Jennifer Klemp Christie Befort	Planning meeting for MPI-R01: Physical Activity and Weight Control Interventions Among Cancer Survivors: Effects on Biomarkers of Prognosis and Survival
KUCC Seminar Series	9/29/15	Shrikant Anant	Shivendra Singh	Cancer Chemoprevention
Survivorship MPI-R01 Planning Meeting	10/2/15	CPS CCPH	Bruce Kimler Carol Fabian Dan Dixon Joseph Donnelly Jennifer Klemp Christie Befort	Planning meeting for MPI-R01: Physical Activity and Weight Control Interventions Among Cancer Survivors: Effects on Biomarkers of Prognosis and Survival
KUCC Seminar Series	10/6/15	Carol Fabian Andy Godwin Jim Calvert	Henry Lynch (Creighton)	Explosive Developments in Cancer Epidemiology and Genetics

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
KUCC Seminar Series	10/20/15	Fariba Behbod	Anna Zolkiewska (K-State)	ADAM12: a new modulator of breast cancer stem cell signaling pathways
Microbiome in Weight Loss Projects	11/2/15		Shahid Umar Carol Fabian Bruce Kimler	Discussion of results
KUCC Seminar Series	11/3/15		Fariba Behbod	The identification of molecular and cellular basis for the invasive phenotype in human ductal carcinoma in situ
GI High Risk Cancer Group	11/5/15		Dan Dixon Bruce Kimler Jennifer Klemp Joaquina Baranda	Meeting to discuss omega-3 fatty acids prevention trial for high risk GI clinic
KUCC Annual Symposium	11/13-14/15	CPS, CCPH CB, D3ET	Dan Dixon Parthasarathy Rangarajan (CPS trainee) Joaquina Baranda	Program member meeting with Victoria Seewalt (Duke)
KUCC Leadership Council Meeting	11/20/15	CPS, CCPH CB, D3ET	Carol Fabian Dan Dixon	KUCC leadership meeting and program updates
Planning Meeting Prevention Spore	11/25/15		Dean Brenner University of Michigan Steve Hursting UNC Carol Fabian Bruce Kimler	Discussion of Possibility of Prevention Spore utilizing several KUCC CPS members and faculty from U of Michigan
GI High Risk Cancer Group	11/30/15		Dan Dixon Bruce Kimler Jennifer Klemp Raed Al-Rajabi	Meeting to discuss omega-3 fatty acids prevention trial for high risk GI clinic
EAB Content Discussion Meeting	11/30/15		Carol Fabian Dan Dixon Andy Godwin Lisa Harlan-Williams Shrikant Anant Teresa Christenson	EAB meeting planning
PIVOT Project Meeting	11/30/15	CPS CCPH D3ET	Kim Kimminau Scott Weir Cheryl Jernigan Dan Dixon Gary Doolittle Hope Krebill	Meeting to Discuss patient/ community engagement (PIVOT) project
High Risk Colon Clinic and Lynch Syndrome Trial	12/7/15		Carol Fabian Jennifer Klemp Dan Dixon Raed Al-Rajabi (GI Faculty)	Meeting to Discuss Take-Over of Lynch Syndrome Proposal with Omega-3 FA with Dr. Baranda's departure

Table 5 – Cancer Prevention and Survivorship Publications

The CPS program had 382 publications from 2012-2015; 127 (33%) inter-programmatic, 164 (43%) intra-programmatic, 205 (54%) inter-institutional, and 45 (12%) of these publications were high impact (JIF ≥ 8).

Table 5. Program Publications

Inter	Intra	External	Publication
With PMCID			
		x	Aguado A, Fischer T, Rodriguez C, Manea A, Martinez-Gonzalez J, Touyz RM, Hernanz R, Alonso MJ, **Dixon** DA, Briones AM, Salaices M. Hu antigen R is required for NOX-1 but not NOX-4 regulation by inflammatory stimuli in vascular smooth muscle cells. J Hypertens. 2016;34(2):253-65. Epub 2015/12/20. doi: 10.1097/hjh.0000000000000801. PubMed PMID: 26682942; PMCID: PMC4947528.
		x	Aguado A, Rodríguez C, Martínez-Revelles S, Avendaño MS, Zhenyukh O, Orriols M, Martínez-González J, Alonso MJ, Briones AM, **Dixon** DA, Salaices M. HuR mediates the synergistic effects of angiotensin II and interleukin 1β on vascular COX-2 expression and cell migration. British journal of pharmacology. 2015;172(12):n/a-n/a. doi: 10.1111/bph.13103. PubMed PMID: 25653183; PubMed Central PMCID: PMC4459021.
	x	x	Ahmed I, Chandrakesan P, **Tawfik O**, Xia L, **Anant S, Umar S**. Critical roles of Notch and Wnt/beta-catenin pathways in the regulation of hyperplasia and/or colitis in response to bacterial infection. Infect Immun. 2012;80(9):3107-21. PMCID: 3418747.
	x	x	Ahmed I, Roy B, Chandrakesan P, Venugopal A, Xia L, **Jensen** R, **Anant** S, **Umar** S. Evidence of functional cross talk between the Notch and NF-kappaB pathways in nonneoplastic hyperproliferating colonic epithelium. American journal of physiology Gastrointestinal and liver physiology. 2013;304(4):G356-70. doi: 10.1152/ajpgi.00372.2012. PubMed PMID: 23203159; PubMed Central PMCID: PMC3566617.
x	x		**Aljitawi OS**, Li D, Xiao Y, Zhang D, Ramachandran K, Stehno-Bittel L, **Van Veldhuizen** P, **Lin** TL, **Kambhampati** S, Garimella R. A novel three-dimensional stromal-based model for in vitro chemotherapy sensitivity testing of leukemia cells. Leukemia & lymphoma. 2014;55(2):378-91. doi: 10.3109/10428194.2013.793323. PubMed PMID: 23566162; PubMed Central PMCID: PMC4090917.
x		x	**Aljitawi OS**, Xiao Y, Eskew JD, Parelkar NK, Swink M, Radel J, **Lin** TL, **Kimler** BF, **Mahnken** JD, **McGuirk** JP, Broxmeyer HE, Vielhauer G. Hyperbaric oxygen improves engraftment of ex-vivo expanded and gene transduced human CD34(+) cells in a murine model of umbilical cord blood transplantation. Blood cells, molecules & diseases. 2014;52(1):59-67. doi: 10.1016/j.bcmd.2013.07.013. PubMed PMID: 23953010; PubMed Central PMCID: PMC4075130.
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x	x		Dubey S, **Vanveldhuizen** P, **Holzbeierlein** J, **Tawfik** O, **Thrasher** JB, **Karan** D. Inflammation-associated regulation of the macrophage inhibitory cytokine (MIC-1) gene in prostate cancer. Oncology letters. 2012;3(5):1166-70. Epub 2012/07/12. doi: 10.3892/ol.2012.635. PubMed PMID: 22783412; PMCID: PMC3389684.
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		x	Goldkorn A, Ely B, Quinn DI, Tangen CM, Fink LM, Xu T, Twardowski P, **Van Veldhuizen** PJ, Agarwal N, Carducci MA, Monk JP, 3rd, Datar RH, Garzotto M, Mack PC, Lara P, Jr., Higano CS, Hussain M, Thompson IM, Jr., Cote RJ, Vogelzang NJ. Circulating tumor cell counts are prognostic of overall survival in SWOG S0421: a phase III trial of docetaxel with or without atrasentan for metastatic castration-resistant prostate cancer. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2014;32(11):1136-42. Epub 2014/03/13. doi: 10.1200/jco.2013.51.7417. PubMed PMID: 24616308; PubMed Central PMCID: PMCPmc3970171.
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		x	**Sharma** P, Brill J, Canto M, DeMarco D, Fennerty B, Gupta N, Laine L, Lieberman D, Lightdale C, Montgomery E, Odze R, Rex D, Tokar J, Kochman M. Advanced Imaging in Barrett's Esophagus. Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association. 2015. Epub 2015/10/16. doi: 10.1016/j.cgh.2015.09.017. PubMed PMID: 26462567.
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		x	**Sharma** P, Gupta N, Kuipers EJ, Repici A, Wallace M. Advanced imaging in colonoscopy and its impact on quality. Gastrointestinal endoscopy. 2014;79(1):28-36. Epub 2013/10/15. doi: 10.1016/j.gie.2013.08.020. PubMed PMID: 24119713.
	x	x	**Sharma** P, Hawes RH, **Bansal** A, Gupta N, Curvers W, **Rastogi** A, Singh M, Hall M, Mathur SC, Wani SB, Hoffman B, Gaddam S, Fockens P, Bergman JJ. Standard endoscopy with random biopsies versus narrow band imaging targeted biopsies in Barrett's oesophagus: a prospective, international, randomised controlled trial. Gut. 2013;62(1):15-21. doi: 10.1136/gutjnl-2011-300962. PubMed PMID: 22315471.
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x	x	x	Singh M, Gupta N, Gaddam S, Balasubramanian G, Wani S, Sinh P, Aghaie K, Higbee AD, **Rastogi** A, Kanakadandi V, **Bansal** A, **Sharma** P. Practice patterns among U.S. gastroenterologists regarding endoscopic management of Barrett's esophagus. Gastrointestinal endoscopy. 2013;78(5):689-95. doi: 10.1016/j.gie.2013.05.002. PubMed PMID: 23769458.
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Inter	Intra	External	Publication
	x	x	Sinh P, Gupta N, Rao DS, Wani S, **Sharma** P, **Bansal** A, Allen J, Ketover SR, **Rastogi** A. Community gastroenterologists can learn diminutive colon polyp histology characterization with narrow band imaging by a computer-based teaching module. Digestive endoscopy : official journal of the Japan Gastroenterological Endoscopy Society. 2015;27(3):374-80. Epub 2014/11/11. doi: 10.1111/den.12403. PubMed PMID: 25382541.
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	x	x	**Sullivan** DK, Goetz JR, Gibson CA, **Washburn** RA, Smith BK, Lee J, Gerald S, Fincham T, **Donnelly** JE. Improving weight maintenance using virtual reality (Second Life). Journal of nutrition education and behavior. 2013;45(3):264-8. doi: 10.1016/j.jneb.2012.10.007. PubMed PMID: 23622351.
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Inter	Intra	External	Publication
	x		Tofteland N, Singh M, Gaddam S, Wani SB, Gupta N, **Rastogi** A, **Bansal A**, Kanakadandi V, McGregor DH, Ulusarac O, Cherian R, Mathur SC, **Sharma** P. Evaluation of the updated confocal laser endomicroscopy criteria for Barrett's esophagus among gastrointestinal pathologists. Diseases of the esophagus : official journal of the International Society for Diseases of the Esophagus / ISDE. 2014;27(7):623-9. doi: 10.1111/dote.12121. PubMed PMID: 24006939.
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		x	Van Zee KJ, Hansen NM, Barrio AV, **Connor** CS, Danforth DN, Euhus DM, Kulkarni SA, McCready DR, McLaughlin S, Wilke LG. Commentary on the canadian national breast screening study. Annals of surgical oncology. 2014;21(13):4397-8. Epub 2014/05/27. doi: 10.1245/s10434-014-3789-0. PubMed PMID: 24859935.
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x			Walmann T, Kilgore L, Meadows L, McGinness M, **Connor** C, **Mammen** JM. Accurate Preoperative Axillary Biopsies for Breast Cancer May Mitigate the Need for Sentinel Lymph Node Biopsy in Selected Patients. Journal of Surgical Research. 2014;186(2):504. doi: 10.1016/j.jss.2013.11.195.
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Inter	Intra	External	Publication
		x	Wani S, Mullady D, Early DS, **Rastogi** A, Collins B, Wang JF, Marshall C, Sams SB, Yen R, Rizeq M, Romanas M, Ulusarac O, Brauer B, Attwell A, Gaddam S, Hollander TG, Hosford L, Johnson S, Kushnir V, Amateau SK, Kohlmeier C, Azar RR, Vargo J, Fukami N, Shah RJ, Das A, Edmundowicz SA. The clinical impact of immediate on-site cytopathology evaluation during endoscopic ultrasound-guided fine needle aspiration of pancreatic masses: a prospective multicenter randomized controlled trial. The American journal of gastroenterology. 2015;110(10):1429-39. Epub 2015/09/09. doi: 10.1038/ajg.2015.262. PubMed PMID: 26346868.
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x			Woodruff DY, **Van Veldhuizen** P, Muehlebach G, Johnson P, Williamson T, **Holzbeierlein** JM. The perioperative management of an inferior vena caval tumor thrombus in patients with renal cell carcinoma. Urologic oncology. 2013;31(5):517-21. doi: 10.1016/j.urolonc.2011.03.006. PubMed PMID: 21514183.
		x	Xia CQ, **Smith** PG. Drug efflux transporters and multidrug resistance in acute leukemia: therapeutic impact and novel approaches to mediation. Mol Pharmacol. 2012;82(6):1008-21. Epub 2012/07/25. doi: 10.1124/mol.112.079129. PubMed PMID: 22826468.
x		x	Zhao M, Tang SN, Marsh JL, **Shankar** S, **Srivastava** RK. Ellagic acid inhibits human pancreatic cancer growth in Balb c nude mice. Cancer letters. 2013;337(2):210-7. doi: 10.1016/j.canlet.2013.05.009. PubMed PMID: 23684930.

Table 6 – Cancer Prevention and Suvivorship – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

Interventional:

NATIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
SWOG	Colon	NCT01349881	SWOG S0820	Williamson, S	CPS	3/20/2013		III	Pre	A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon Cancer, Phase III - Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)	Y		10	0	1	0	1	

EXTERNALLY PEER-REVIEWED												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
Susan G. Komen for the Cure	Breast-Female	NCT01276704	KUMC 12377	Fabian, C	CPS	11/9/2010		II	Pre	Flaxseed Lignan as a Prevention Strategy for Pre-Menopausal Women at High Risk for Development of Breast Cancer	Y	231	121	27	105	17	61	

INSTITUTIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
KU Endowment Association U-Systems	Breast-Female	NCT02488187	KUMC 12801	Amin, A	CPS	12/17/2012		Feasibility/Pilot	Dia	Comparison of Preoperative Automated Breast Ultrasound and MRI to Determine Therapeutic Management of Newly Diagnosed Breast Cancer Patients	N	200	200	65	97	0	0	
Investigator	Breast-Female	NCT00291096	KUMC 4601	Fabian, C	CPS	7/25/1989		N/A	Pre	High Risk Breast Clinic-Breast Tissue Biomarkers Predicting Short Term Risk of Breast Cancer	N	3000	3000	82	2668	0	0	
Investigator	Breast-Female	NCT02101970	STUDY00000703	Fabian, C	CPS	3/24/2014	04/23/2015	II	Pre	Randomized Pilot Trial of Omega-3 Fatty Acids or Placebo in Peri- or Post-menopausal Women at High Risk For Breast Cancer Undergoing a Weight Loss Intervention	N	50	50	10	46	0	0	
Breast Cancer Research Foundation	Breast-Female	NCT02517502	STUDY00002415	Fabian, C	CPS	8/18/2015		Feasibility/Pilot	Sup	Docosahexaenoic Acid (DHA) To Prevent Development of Cognitive Dysfunction Due to Chemotherapy	Y	50	40	3	3	0	0	

Table 6 – Cancer Prevention and Suvivorship – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

Interventional:

INSTITUTIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
Cancer Prevention and Survivorship Pilot Project	Cancer Prevention		STUDY00002779	Gibson, C	CPS	9/10/2015		Feasibility/Pilot	Sup	Televideo Exercise and Nutrition Program for Adult Survivors of Pediatric Cancer	N	24	24	9	9	0	0	
NIH Pilot Grant	Prostate	NCT02252484	STUDY00001274	Hamilton-Reeves, J	CPS	10/21/2014		Feasibility/Pilot	Pre	Energy Balance for Prostate Cancer Survivorship	N	40	40	17	20	0	0	
American Cancer Society and Nestle HealthCare Nutrition	Urinary Bladder	NCT01868087	KUMC 13730	Hamilton-Reeves, J	CPS	8/15/2013	04/14/2015	Feasibility/Pilot	Sup	Impact Advanced Recovery® for Radical Cystectomy Patients	N	30	30	1	30	0	0	
Cedars-Sinai Medical Center	Breast-Female	NCT02360917	IIT 2014-01	Myers, J	CPS	7/29/2015		N/A	Sup	Emerging from the Haze™ – A multi-center, wait-list controlled trial to measure impact of a multi-dimensional psycho-educational program on subjective cognitive complaints after breast cancer treatment using virtual technology	Y		35	7	7	0	0	

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
ImpediMed Limited	Multiple	NCT02167659	L-DEX	Wagner, J	CPS	5/20/2015		Device	Sup	A Randomized Trial Evaluating Bioimpedance Spectroscopy Versus Tape Measurement in the Prevention of Lymphedema Following Locoregional Treatment for Breast Cancer	Y		100	42	42	0	0	

Observational:

INSTITUTIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	OfficialTitle	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
Investigator	Breast-Female		KUMC 12614	Sharma, P	CPS	3/22/2011		N/A	Oth	Prospective evaluation of GErmline mutations, Cancer outcome and Tissue biomarkers (P.R.O.G.E.C.T.): A registry for patients with triple negative breast cancer and germline mutations	Y	N/A	N/A	133	421	98	269	

Table 6 – Cancer Prevention and Suvivorship – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

Ancillary/Correlative:

INSTITUTIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
NCI	Breast-Female		KUMC 11513	Behbod, F	CPS	11/4/2008		N/A	Bas	The study of molecular and cellular basis for the invasive phenotype in human ductal carcinoma in situ	Y	600	600	28	388	55	161	

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Dan Middle Name A. Last Name*: Dixon Suffix: PhD

Position/Title*: Associate Professor
Organization Name*: University of Kansas Medical Center
Department: Cancer Biology
Division: School of Medicine
Street1*: MS1027,3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66103-0000

Phone Number*: 913-945-7501 Fax Number: 913-945-6650

E-Mail*: ddixon3@kumc.edu

Credential, e.g., agency login: DIXON00

Project Role*: Other (Specify) Other Project Role Category: Project Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Dixon_Bio_CCSG1018883931.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Jennifer Middle Name Rose Last Name*: Klemp Suffix: PhD

Position/Title*:	Assistant Professor
Organization Name*:	University of Kansas Medical Center
Department:	Medicine-Clinical Oncology
Division:	School of Medicine
Street1*:	MS 5015
Street2:	2330 Shawnee Mission Parkway
City*:	Westwood
County:	Johnson
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66205-0000

Phone Number*: 913-588-3662 Fax Number: 913-588-1455

E-Mail*: JKLEMP@kumc.edu

Credential, e.g., agency login: JKLEMP

Project Role*: Other (Specify) Other Project Role Category: Project Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: KLEMP_BIOSKETCH1019799881.pdf

Attach Current & Pending Support: File Name:

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ❍ Yes ❍ No

*Agency-Defined Phase III Clinical Trial? ❍ Yes ❍ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ❍ Yes ❍ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

❍ Yes ❍ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

❍ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator / Change of Institution Section

❑ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
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Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	CPS_SpecificAims_final1019659663.pdf
3. Research Strategy*	CPS_ResearchStrategy_Final1020031041.pdf
4. Progress Report Publication List	Progress_Report_Publications_Blank1019754758.pdf
Human Subjects Section	
5. Protection of Human Subjects	
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	
8. Inclusion of Children	
Other Research Plan Section	
9. Vertebrate Animals	
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	
14. Resource Sharing Plan(s)	Resource_Sharing_Plan__Generic1019913983.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

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Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Cancer Prevention and Survivorship – Specific Aims

Cancer Prevention and Survivorship (CPS) focuses on pre-cancerous biology and its translation into initial testing of new prevention strategies, as well as interventions aimed at improving the quality of life for cancer survivors. As the most common cancers in the KUCC catchment area are breast, prostate and colon much of CPS's research focuses on these disease sites. The KUCC catchment area also has one of highest proportions of obese adolescents and adults in the nation. Thus, one of the areas of emphasis is developing successful weight loss interventions for primary and secondary prevention, as well as developing biomarkers that can be used as surrogates to predict the success of these interventions in preventing cancer development or recurrence.

Theme 1: Pre-Cancerous Biology and Risk Biomarkers

- Study of molecular events associated with development and/or progression of breast, prostate, pancreas and colon cancer.
- Development of natural product derivatives for use in pre-clinical models and, if promising, in prevention intervention trials.
- Adaptation and testing of risk and response biomarkers likely to be useful in predicting short-term risk in clinical cohorts and/or as response biomarkers in interventional trials.

Theme 2: Prevention and Survivorship Translational Research

- Conduct of early phase primary prevention trials (with biomarker modulation as outcome) using drugs or natural products or behaviors (such as weight loss and physical activity) with minimal side effects.
- Conduct of survivorship trials to prevent or reduce common side effects from local or systemic therapy (cognitive dysfunction, cardiac dysfunction) and/or improve the quantity or quality of life with both objective and patient reported outcomes. Interventions should be applicable to underserved populations (rural catchment area) and/or those with co-morbidities (i.e. peripheral neuropathy).

Cancer Prevention and Survivorship – Research Strategy

Overview

The CPS program focuses on translation of precancerous biology to develop targets and risk biomarkers that are then used in early phase prevention and survivorship trials. CPS has 21 full and 10 associate members and 30 active peer-reviewed grants with a 47% increase in overall funding from CY2011. Between 2012 and 2015 CPS members had 382 publications (127 inter- and 164 intra-program) and 827 accruals to interventional prevention or survivorship trials (**Table 1**).

Program Development in Response to NCI Review and EAB Input

In 2012, CPS received an overall merit rating of 'excellent to outstanding' for leadership, intra-program interactions, junior member mentoring and the translational nature of its research. Two of its three themes (pre-cancerous biology and translational prevention trials) were thought to be particularly strong and are now the primary program themes. Suggestions for improvement and response are detailed in **Table 2**.

Table 1. Program Metrics

Members (2015)		
Total	**Full**	**Associate**
31	21	10
Funding (2015)		
Type	**# of grants**	**$ (total costs)**
NCI	12	$3,098,479
Other NIH	8	$3,189,224
Other Peer Reviewed	9	$5,352,674
Total Peer Reviewed	**29**	**$11,640,377**
Other	1	$250,000
Total Funding	**30**	**$11,890,377**
Publications (2012-2015)		
Total		**382**
High Impact (JIF ≥ 8)		45 (12%)
Inter-programmatic		127 (33%)
Intra-programmatic		164 (43%)
External collaborative		204 (54%)
Trial Accrual (2012-2015)		
Type of trial	**# trials**	**# participants**
Prevention Intervention	6	529
Survivorship Intervention	9	298
Prevention Non-Intervention	2	340
Survivorship Non-Intervention	8	936

Table 2. CPS Program Development in Response to Prior Critiques

2011 NIH critiques	Program Response
Recruit a co-leader with expertise in molecular aspects of pre-cancerous biology and prevention, in addition, recruit an individual who can eventually take over **Fabian's** role.	Dan **Dixon**, PhD was recruited as the basic science program co-leader in 2013. **Dixon's** research focus is in post-transcriptional regulation of oncogenic mRNAs by RNA binding proteins and microRNAs in colon. In April 2016, Jennifer **Klemp**, MPH, PhD, a clinical health psychologist, with research interests in cancer survivorship, replaced co-leader **Fabian** who became AD for Clinical Research. **Fabian** remains active in the program as co-leader of translational trials. Two junior breast cancer medical oncologists (O'Dea and Nye) have been recruited (2015, 2016) and will eventually take over the clinical/translational aspects of breast cancer prevention trials from **Fabian** and collaborate on survivorship clinical research with **Klemp**.
Expand research in risk and response biomarkers for prevention trials to other areas besides breast.	CPS has dramatically expanded risk and response biomarker research for colon and prostate cancer (while continuing efforts in breast cancer) to include biomarkers of gene expression, cancer stem cell markers, pro-inflammatory and obesity markers, changes in gut microbiome and extracellular vesicles.
Expand translational intervention trials in prevention to other organ sites.	CPS has increased efforts to expand primary prevention in sites other than breast, to include Barrett's Esophagus and the development of a high-risk cohort in GI including those with a family history or genetic predisposition. This clinic is supported in part by KUCC and has grown rapidly, with plans for initiation of an interventional trial in 2017 with the recruitment of a GI clinical researcher. With the new emphasis on bladder cancer in D3ET and recruitment of an expert in bladder cancer, CPS plans to make bladder a focus of prevention and survivorship in the near future.
Improve the quantity and quality of survivorship research (at the time a developing theme area).	CPS has increased investigator-initiated survivorship research in multiple organ sites including breast, colon, prostate and bladder largely related to nutrition, weight loss and quality of life. One of these was an R01-supported weight loss and maintenance trial in rural breast cancer survivors (R01CA155014) using the Midwest Cancer Alliance (MCA) and other rural practices across the catchment area for participants. **Befort**, a former CPS focus group leader and now co-leader of CCPH, led the trial which provided the basis for her current PCORI award which aims to train rural primary care providers to provide weight loss interventions. **Klemp** was awarded a CDC grant in partnership with the Kansas Department of Health and Environment that addresses quality of life and access to survivorship care for cancer survivors across the KUCC catchment area. One of the projects in the PCOR NET Greater

	Plains Collaborative (Waitman PCORI PI, **Klemp** Project PI) is devoted to determining survivorship experiences after a breast cancer diagnosis. An ongoing investigator-initiated trial funded by the Breast Cancer Research Foundation (**Fabian**) is assessing the ability of high dose DHA vs. placebo to prevent cognitive dysfunction during chemotherapy. CPS has also been active in cooperative group research. **Klemp** was the institutional PI of SWOG S1008, behavioral weight loss and exercise intervention in female breast and colon cancer survivors. **Fabian** and **Godwin** will provide central laboratory assessments of two of the translational endpoints in SWOG S150 - Carvedilol vs. no treatment for prevention of cardiac dysfunction in women with HER-2 metastatic breast cancer.
Increase the proportion of full members who are PIs on peer-reviewed grants, the amount of NCI-funded research, and interaction with other programs, especially CCPH.	Since 2011, NCI funding has modestly increased and the number of NCI-funded investigators has increased. The number of investigators with peer-reviewed funding has increased from 15 in 2011 to 19 in 2015 and total cost peer-reviewed funding has increased 56% over the past four years. Both intra- and inter-programmatic interactions have increased as evidenced by new multi-PI grants and manuscript authorship. Multi-PI grants include: **Anant** and **Weir** (D3ET) (R01CA182872) assessing potential agents that target Notch signaling for GI tract cancers; **Anant** and **Umar** (R01CA190291) to study a bitter melon component for colon cancer prevention; **Behbod** and **Cheng** (CB) (R01CA172764) to study role of microenvironment in progression of DCIS; **Savage** (CCPH) and **Donnelly** (R01DK085605) and **Sullivan** and **Donnelly** (DK094833) to study aspects of weight loss and maintenance. A listing of CPS grant, trial and publication interactions with other programs is provided in **Table 3**.

Table 3. CPS Program Interactions

Interaction	Number	Type (with Grant Number and Protocol ID)
Funding	# of grants = 30 (as of 12-2015) (29 peer-reviewed)	With CCPH Co-PI: R01CA155014 and R01DK085605 With CB Co-PI: R01CA172764 With D3ET Co-PI: R01CA190291
Prevention Intervention Trials accruing 2012-2015	# of trials = 6 (1 colon, 5 breast) 5 IIT, 1 SWOG 2 peer-reviewed funded 1 National	With CCPH Investigators: 12350,703, With CB Investigators: 10587,12377,4601 With D3ET Investigators: S0820
Survivorship Intervention Trials accruing 2012-2015	# of trials = 9 (1 colon and breast), 2 prostate, 1 bladder, 5 breast) 7 IIT, 2 SWOG 1 peer-reviewed funded 2 National	With CCPH Investigators: 12633, 2415, 00002779,13700 With D3ET Investigators: 00001274, 13730
Publications	# of publications = 382	13% with CB, 10% with CCPH, 14% with D3ET

Program Leadership

CPS is co-led by Dan **Dixon** and Jennifer **Klemp**. Leadership has changed since the last site visit as **Dixon** was added in 2013 and **Klemp** replaced **Fabian** as co-leader when **Fabian** transitioned to the AD for Clinical Research in April, 2016. **Fabian** continues to be active in CPS as she remains as co-leader of Theme 2 Translational Trials. In her new role she is helping to expand Cancer Center support for prevention and survivorship clinical trials. CPS leadership supports a research agenda that continues to develop pre-cancerous targets, drugs, and biomarkers that can be incorporated into translational trials for high-risk individuals and cancer survivors. A portfolio of research activities and strategies has been implemented to continue our ongoing initiatives and address new areas of prevention within our catchment area.

Dan A. **Dixon**, PhD is an Associate Professor of Cancer Biology at KUMC. He was a Research Assistant Professor at Vanderbilt University Medical Center (2001-2004) and Associate Professor at the University of South Carolina (2004-2012) where he served as Associate Director of the Center for Colon Cancer Research, prior to joining the KUMC Cancer Biology Department in 2012. **Dixon's** laboratory is internationally recognized for their research in post-transcriptional gene regulation and COX-2 regulation in colon cancer. He currently serves as a standing member of NCI Subcommittee J - Career Development Panel and the USAMRMC (DOD) Peer-Reviewed Cancer Research Program Programmatic Panel. He serves on the Research Awards Panel

and as Councilor for the Gastrointestinal Oncology Section for the American Gastroenterological Association Institute, along with AACR Colorectal Cancer Research Fellowships Scientific Review Committee. **Dixon** recently served as the Principal Investigator for an R01, and currently serves as Principal Investigator of an AACR grant, and Co-Investigator on three NCI R01 and R21 grants. **Dixon** has been an active member of KUCC since 2012 and has served as CPS co-leader since 2013. Within the School of Medicine, **Dixon** is an active leader in defining the Cancer Biology component of the new ACE Curriculum and has developed course content for the SOM, along with Cancer Biology Graduate Program course development. He also currently serves as Chair of the SOM Research Committee. Through his interactions with Fight Colorectal Cancer Foundation, where he serves on their Medical Advisory Board, Dixon developed a two-day educational training course for CRC survivors/care-givers. This course brought CRC research advocates to KUCC where guest lecturers and hands-on lab tours from KUCC members as part of CPS's educational outreach efforts.

Jennifer R. **Klemp**, PhD, MPH is a clinical health psychologist whose research focus is in cancer genetics and survivorship. She was promoted to the co-leader role in 2016. **Klemp**'s research centers on quality of life, quality improvement and technology, cancer genetics, and behavioral interventions in primary and secondary prevention populations. As part of her research program, she coordinates a multi-disciplinary program that serves cancer survivors across the KUCC catchment area. She serves as a member on the NCI Community Oncology COPTRG Community Oncology Cardiotoxicity Task Force and on the Academy of Oncology Nurse & Patient Navigators (AONN+) Leadership Council. She is the Founder and CEO of Cancer Survivorship Training, Inc., an eLearning solutions company accelerating education and training to healthcare providers. She currently serves as Co-Principal Investigator with Krebill (MCA) of a CDC National Comprehensive Cancer Control Program (NCCCP) cooperative agreement "Increasing the Implementation of Evidence- Based Cancer Survivorship Interventions to Increase Quality and Duration of Life among Cancer Patients", and Co-Investigator on a National Cancer Institute R01. **Klemp** also serves as Co-Investigator on PCORI (**Waitman** PI) and Komen Promise (**Fabian** PI) grants.

Together, **Dixon** and **Klemp** bring complementary areas of scientific expertise in basic and translational research to their position. **Dixon**, **Klemp**, and **Fabian** meet on a regular basis to transition administrative duties, discuss program priorities, recruitment and translational projects. Other members of the leadership team include **Behbod** who along with **Dixon** co-leads Theme 1 and **Kimler**, a biologist, who along with **Fabian**, a breast medical oncologist, and **Klemp**, a behavioral scientist, co-lead Theme 2. Theme leaders meet on a regular basis to assess pilot studies and award program specific pilot monies and plan seminars and data exchange venues to promote intra- and inter-programmatic collaborations. They interact with the other members of the leadership team including **Anant** (AD for Cancer Prevention and Control) to evaluate chemoprevention drug identification and novel biomarker development.

Program Scientific Quality and Cancer Focus

Theme 1: Pre-Cancerous Biology and Risk Biomarkers; Co-Leaders: Dixon and Behbod
A major strength of the CPS program is that it relies on discoveries of basic cancer researchers particularly in the area of pre-cancerous biology with subsequent application of findings to: 1) risk stratification and response biomarkers for early phase trials and 2) development of natural product derivatives for use in pre-clinical models and if successful, eventually into clinical prevention and survivorship trials. Theme 1 investigators often participate in investigations led by clinicians and vice versa (see membership table). Theme 1 investigations also are fertile training grounds for basic science and MD/PhD students.

Molecular Events Associated With Invasive Breast Cancer Development
Background and Significance: Phenotypic and molecular events which result in progression of atypical hyperplasia and carcinoma in situ (DCIS) into invasive cancer are not well defined and as result, a substantial number of these precancerous conditions are likely over-treated. **Behbod** (R21CA185460, R21CA187890) has

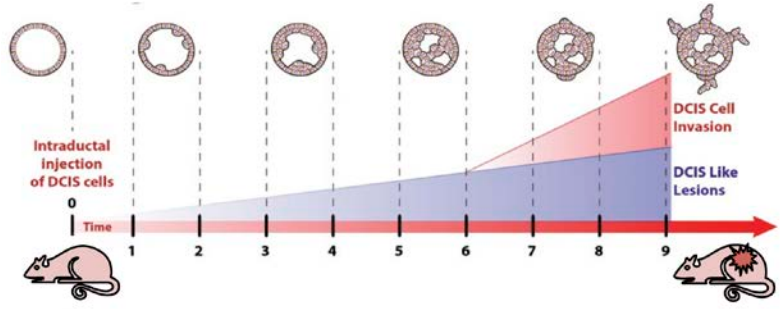

Figure 1. DCIS progression to IDC using the MIND pre-clinical model.

developed a novel model called MIND (mouse-intraductal) in which human epithelial cells from pre-cancerous biopsies are injected intraductally into immunocompromised mice. Xenografts are allowed to progress over the following 9-12 months and mice are sacrificed. Human histopathology is generally recapitulated in the mouse ductal lesions, but about 20% exhibit invasive cancer (**Fig. 1**) (Valdez, *J Pathol,* 2011). Gene expression analysis suggests significant elevated expression of B cell lymphoma-9 (BCL9) with a transition from DCIS to invasive ductal cancer (IDC) (Elsarraj*, Can Res,* 2015; Osuala*, BMC Cancer,* 2015; Kittrell, *Bioprotocol,* 2016*).* Breast chemokine signaling (CCR2) is also likely to play a role in progression to invasive cancer (R01CA172764 **Cheng** (CB) and **Behbod**). **Impact**: These findings need to be tested further in a cohort study where both initial DCIS and cancer specimens are available. If these biomarkers are validated as indicating a high risk of subsequent invasion then overtreatment for DCIS could be avoided. **Future: Behbod** along with breast surgeons (Amin, **Wagner**) and investigators in the Breast Cancer Prevention Center (**Fabian,** Nye, O'Dea) are determining the feasibility of invasive cancer development in the MIND model after injection of benign tissue from *BRCA*1/2 carriers as predicting invasive carcinoma development.

New Response Biomarkers for Weight Loss Trials in High Risk Women and Breast Cancer Survivors
Background and Significance: Obesity increases the risk for breast cancer development, recurrence, and overall mortality. Trials with response biomarkers as endpoints are needed to efficiently begin to address questions of dose, method and duration of weight loss needed to significantly impact on primary breast cancer risk and recurrence. Epithelial cell atypia and proliferation (Ki-67) as well as mammographic density are often used in early phase chemoprevention trials as indicators of response. However, obese postmenopausal women, frequently have low epithelial density and Ki-67 as much of the breast volume has been replaced by fat. Furthermore % mammographic density actually increases with weight loss. In a pilot study of a behavioral weight loss intervention (R21CA121106 and Breast Cancer Research Foundation, **Fabian**) we demonstrated that several serum as well as tissue biomarkers were favorably modulated by >10% but not by <10% weight loss. Markers modulated included serum insulin, bioavailable hormones, and pro-inflammatory factors and cytokines including high sensitivity CRP, PAI-1, HGF, and the ratio of adiponectin to leptin. A >10% weight loss was also associated with favorable modulation (increase) of adiponectin: leptin ratio in tissue obtained by random peri-areolar fine needle aspiration (RPFNA) (**Fig. 2**) which in turn was correlated with both the serum ratio and fat mass loss. We also observed significant down modulation of the estrogen inducible gene pS2 (qPCR), the proliferation associated proteins Cyclin B1, and phosphorylated Rb as well as S6 (downstream of mTOR) in reverse phase protein arrays (Mills, MD Anderson) performed on benign breast tissue before and after the 6 month intervention (**Fabian**, *Breast Ca Res Treat,* 2013). A progressive increase in activated macrophage (CD68+) infiltration into breast tissue is associated with proliferative breast disease and in situ cancer. Obesity is associated with an increase in crown-like structures consisting of dying adipocytes surrounded by macrophages. These crown like structures are a biomarker of adipose dysfunction, increased inflammation and aromatase and therefore useful in Phase IIB studies of effects of weight loss on breast cancer risk and recurrence. However it is difficult to get repeated large core needle biopsies containing this material. **Fabian, Kimler**, and **Tawfik** are performing a pilot study (BCRF) which aims to assess CD68+ macrophages in the fat layer from RPFNA (**Fig. 3**). Repeated RPFNA is quite acceptable to women since the average pain score is only 1-2 on a 0-10 scale. Although we have been successful, we are refining our methodology to facilitate quantitative assessment with an image analyzer both alone and in combination with an activated T cell antibody (PD1). Adipose stromal cells are the source of many cytokines, and circulating adipose stromal cells both increase with fat mass and increase the potential for metastases. Preliminary studies in obese high-risk women by

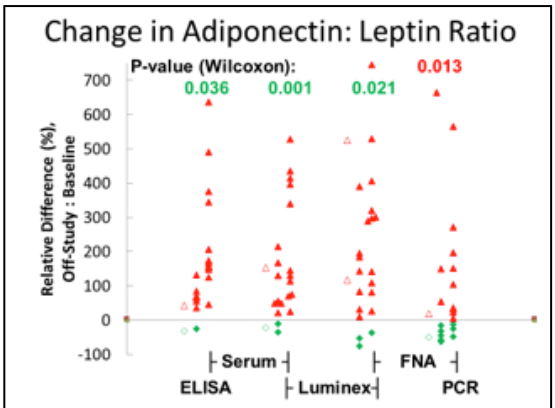

Figure 2. Association of breast tissue adiponectin:leptin ratio increase with weight loss.

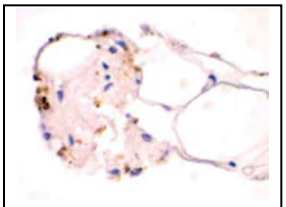

Figure 3. Adipocytes and stroma with CD68+ macrophages within a RPFNA fat layer.

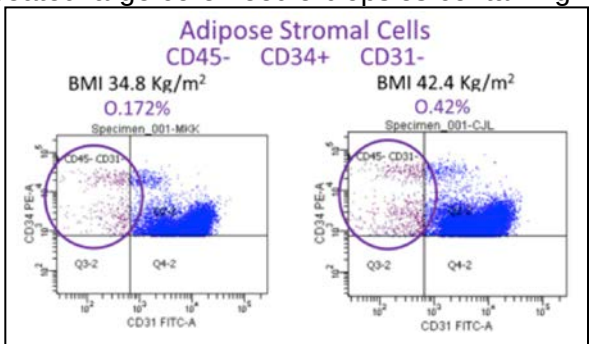

Figure 4. Identification and quantification of Adipose Stromal Cells (ASCs) by flow cytometry.

Fabian, **Kimler**, **Dixon** and medical student Hailey Baker, working on her MS of Clinical Research, have shown an increase in circulating adipose stromal cells (**Fig. 4**). This group is also assessing change in circulating miRNAs implicated in cancer development with weight loss and/or improved fitness in high risk (**Fabian**) and cancer cohorts (**Befort**). **Impact and Future**: These biomarkers may facilitate answering weight loss dose questions in early Phase weight loss and physical activity trials.

"Tumor in a Dish" Methodology for Chemopreventive Compound Screening

Background and Significance: As a means to accelerate drug discovery, **Anant** and **Ramamoorthy** (CPS postdoctoral trainee) have developed a novel multicellular spheroid culture method termed "Tumor in a Dish" (TiD) where, the effect of compounds on tumor cells can be determined in their native environment that includes normal fibroblasts, epithelial cells and lymphatic and heme endothelial cells (**Fig. 5**). In addition to monitoring specific cancer cell inhibition, anti-angiogenic properties can be assessed though neovascularization of blood and lymphatic vessels (Anant, Patent: 20130316392). **Impact**: A major obstacle in the discovery of new cancer therapies is that current *in vitro* culture and *in vivo* animal screening methods are poorly predictive of the clinical efficacy and safety of drug candidates. The TiD offers an alternative. Several natural products and their derivatives have been identified by this method. **Future**: This methodology for compound screening has expanded to include breast, head and neck, bladder, sarcoma and glioblastoma tumors from the Biospecimen Repository.

Figure 5 Example of a TiD including colon cancer cells expressing GFP.

Natural Product Based Chemoprevention of GI Cancers

Background and Significance: A major focus of the CPS program has been determining mechanisms by which dietary phytochemicals and the microbiome regulate gene expression and cancer stem cell signaling pathways in colorectal and pancreatic tumors. Efforts to identify the chemopreventive component from the medicinal plant *Aegle marmelos* by **Anant** and **Weir** (D3ET) have isolated marmelin and demonstrated its chemopreventive activity in colon cancer preclinical models through inhibition of the cancer stem cell marker kinase DCLK1 (**Fig. 6**) (**Subramaniam**, *Cancer Res,* 2008). Further work in collaboration with the LDO Shared Resource has optimized this compound and increased its bioavailability. This work has resulted in a MPI R01 (R01CA182872). Similarly, studies on Charantin (Bitter melon) and honokiol (Magnolia) have shown chemoprevention in colon cancer models (Kwatra, *Evid Based Complement Alternat Med,* 2013; Ponnurangam, *Mol Cancer Ther*, 2012). **Anant** and **Umar**, in collaboration with Subhash Padhye (Director, ISTRA, Pune, India), have now developed analogs of these compounds and are determining their effect on cancer stem cells *in vitro* and in animal models. This work has also resulted in a multi-PI R01 (R01CA190291). In pancreatic cancer, preclinical work by **Dhar**, **Tawfik**, **Umar**, **Weir** (D3ET), **Sugumar**, **Jensen**, **Subramaniam** and **Anant** has demonstrated chemopreventive effects with Quinomycin A and Crocetinic acid, along with showing their inhibitory effects on cancer stem cell pathways (Ponnurangam, *Oncotarget,* 2015; Rangarajan, *Oncotarget,* 2015). To better understand the protective role the gut microbiome serves against GI cancer, **Umar**, **Ramamoorthy**, **Subramaniam**, **Tawfik** and **Anant**, along with **Hester** and **Greiner** (CCPH) made key observations (**Fig. 7**) that demonstrate bacterial infection can influence intestinal gene expression through epigenetic mechanisms (Roy,

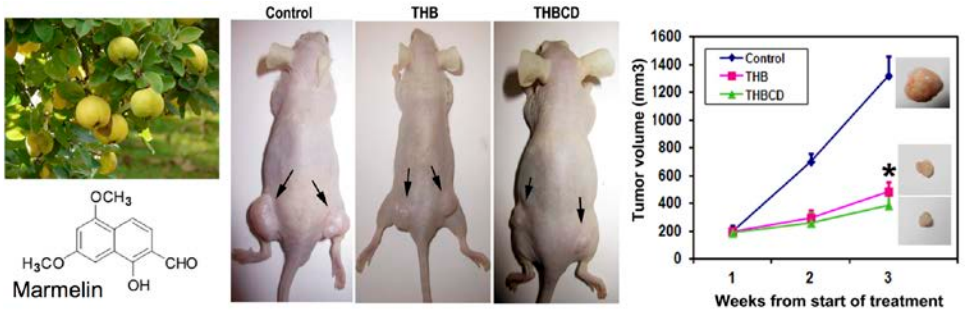

Figure 6. Marmelin isolated from *A. marmelos* was optimized into the lead compounds THB and THBCD that show chemoprevention of CRC xenograft growth at 2 mg/kg bw.

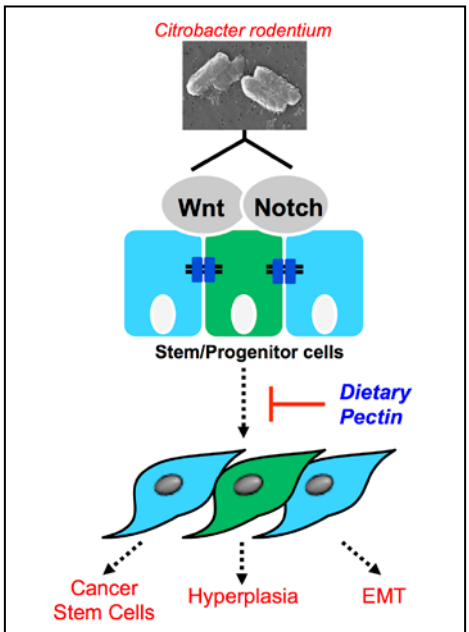

Figure 7. Alterations in the microbiome from *C. rodentium* infection, can promote colon hyperplasia and tumorigenesis by altering Wnt and Notch signaling pathways. Dietary pectin and short chain fatty acids can control these changes to establish gut-microbiome symbiosis.

Oncogene, 2015). This can result in phenotypic changes of intestinal hyperplasia, increased stem cells, and epithelial-to-mesenchymal transition that are observed during CRC tumorigenesis (Chandrakesan, *Oncotarget,* 2014). Importantly, they demonstrate that these changes can be reversed with dietary pectin supplementation and short chain fatty acids (i.e., butyrate) to control epithelial cell hyperplasia and re-establish the gut-microbiome symbiotic relationship (**Greiner**, *Am J Physiol Gastrointest Liver Physiol,* 2014). **Impact**: While providing the necessary mechanistic insights underlying the chemopreventive effects of dietary natural products, these efforts by CPS researchers allow complementary and alternative approaches for KUCC GI cancer patients. **Future**: Novel derivatives of marmelin, honokiol, and crocetinic acid that show greater bioactivity and availability have been developed and are being assessed in preclinical studies with the aim of moving them into Phase I trials. Recent work by **Dixon**, **Weir** (D3ET) and **Roy** (D3ET) using the high throughput screening (HTS) facility has identified flavonoid compounds as modulators of mRNA decay and shown their chemoprevention ability to target the COX2/PGE_2 pathway in colon cancer preclinical models. Planning for a NCI PREVENT grant to facilitate moving gingerols into early human trials for breast and colon cancer is underway (**Fabian**, **Dixon**, **Weir** (D3ET), **Timmerman** (D3ET)).

Post-transcriptional Regulators as Novel Prevention Targets and Biomarkers

Background and Significance: Factors that regulate post-transcriptional gene expression such as microRNAs (miRNAs) and RNA-binding proteins are gaining clinical utility as biomarkers of cancer incidence/progression and therapeutic targets for chemoprevention. Kumaraswamy and **Jensen** have demonstrated a novel post-transcriptional mechanism by which BRCA1 regulates EGFR expression through the induction of miR-146a and identified this miRNA as a biomarker of TNBC patient survival (Kumaraswamy, *Oncogene,* 2014) (**Fig. 8**). Another member of the miR-146 family (miR-146b) has been show by **Behbod, Valdez** and **Christenson** (CB) to be involved in hormonal maintenance of breast alveolar cells and may provide a missing link in the molecular pathways implicated in hormonal regulation of breast cancer (Elsarraj, *J Cell Sci,* 2013). In the GI tract, **Bansal**, **Rastogi**, **Sharma** and **Christenson** (CB) have identified miRNAs associated with Barrett's Esophagus progression and demonstrated their feasibility in a phase II biomarker study (**Bansal**, *Clin Transl Gastroenterol,* 2014). **Subramaniam** and **Anant** have identified chemoprevention dietary interventions that modulate miRNA expression in colorectal cancer patients (Ramalingam, *Curr Pharmacol Rep,* 2015), along with work by **Dixon** who identified a common COX-2 polymorphism that interferes with miRNA regulation and serves as a biomarker of COX-2 overexpression (Moore, *Oncogene,* 2012). In an effort to increase multi-PI R01 submissions, a GI cancer group (**Anant**, **Dixon**, **Umar; Weir, Xu** (D3ET); **Neufeld** (CB)) was initiated in 2014 and supported by KUCC programmatic funds to coordinate efforts utilizing RNA-binding proteins as new prevention targets for drug discovery in colorectal cancer (**Fig 9**). This new area of emphasis has led to group publications showing the role of RBM3 in promoting colon cancer stem cell characteristics (Venugopal, *Mol Carcinog*, 2015), discovery and characterization of novel small molecule inhibitors of HuR and Msi1 (Wu, *ACS Chem Biol,* 2015) and RNA-binding protein control of TGF-β signaling in intestinal epithelium (Blanco, *Mol Cell Biol,* 2014), along with providing CPS-based training to MD/PhD student Anand Venugopal and postdoctoral fellow Fernando Blanco. **Impact**: miRNAs and RNA-binding proteins are recognized for their ability to influence early progression of various tumor types. Utilizing the discoveries of CPS members, KUCC is well poised to advance new biomarkers and future new inhibitors into the clinic that will allow for screening advances and new chemopreventive approaches. **Future**: New inhibitors of RNA-binding proteins are currently being evaluated with *in vitro* TiD models and preclinical animal models. miRNAs associated with clinical outcomes are being evaluated for detection as circulating biomarkers. **Dixon**, **Godwin** (D3ET), **Christenson** (CB) and **Fridley** (CCPH), have initiated a KUCC pilot supported study of RNA-binding proteins as serum-based exosomal biomarkers

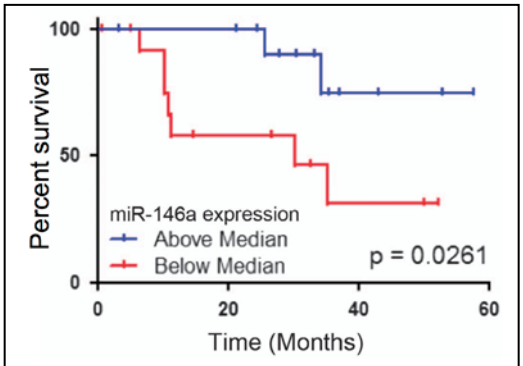

Figure 8. miR-146a is a clinical marker of triple negative breast cancer patient survival.

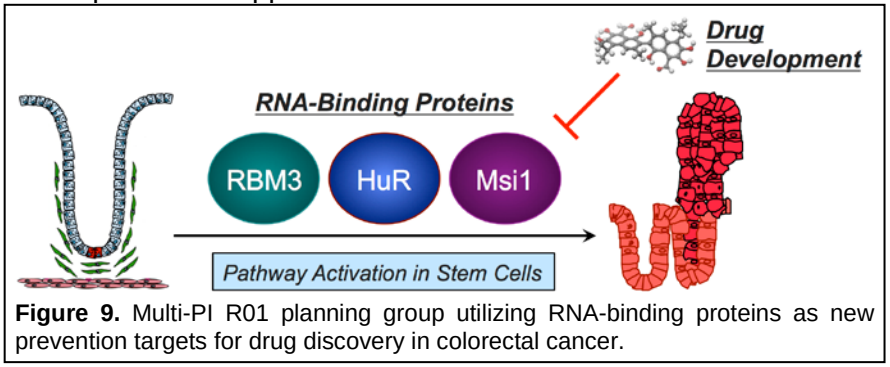

Figure 9. Multi-PI R01 planning group utilizing RNA-binding proteins as new prevention targets for drug discovery in colorectal cancer.

for early detection of colon cancer.

Theme 2: Prevention and Survivorship Translational Research; Co-Leaders: Fabian, Kimler, Klemp
A hallmark of CPS is the trans-disciplinary emphasis of its interventional trials in primary prevention and survivorship with basic behavioral and clinical scientists playing substantial roles in trial designs that often utilize biomarkers as response predictors and indicators. Cross fertilization between disease site areas, particularly breast and colon (*e.g.,* miRNAs, microbiome) is increasing. Between 2012 and 2015, CPS had over 800 accruals to 15 interventional trials at KUMC, in breast, prostate, colon and bladder disease sites of which 13 were KUCC investigator-initiated and three were external peer-reviewed funded. In addition, the Barrett's Esophagus group at the VA conducted early detection and prevention studies. The decrease in survivorship accrual beginning in 2014 was due to closure of a large R01-supported diet and exercise study. Increased clinical trial office support for prevention and survivorship studies beginning in 2016 and launch of new IIT and SWOG survivorship trials combined with community physician enthusiasm will help reverse this recent trend. Results/progress of key trials during the grant period are detailed below.

Phase II Breast Cancer Prevention Trials using Drugs/Natural Products
Background and Significance: The majority of women at elevated risk for breast cancer will not take standard drugs for primary prevention (such as tamoxifen) because of concerns about peri-menopausal symptoms and more serious side effects, combined with a lack of a demonstrated survival advantage. The strategy of our CPS trial group (**Fabian, Kimler, Petroff** (now at Michigan State University), **Yeh, Klemp**, **Befort** (CCPH), **Carlson, Sullivan,** and **Donnelly**) along with lead advocate Cheryl Jernigan has been to assess interventions with few menopausal symptoms in early phase studies lasting 6-12 months using RPFNA as a minimally invasive means of repeated breast tissue sampling for biomarker evaluation (**Fabian***, JNCI,* 2000). Single-arm pilots are completed prior to larger placebo controlled phase IIB trials to establish a likely effect size, with the randomized studies often performed across a network of institutions using a change in Ki-67 in women with RPFNA evidence of hyperplasia/ +/- atypia as the primary endpoint. For most trials women must have a minimal Ki-67 to be enrolled on the intervention.

Results Phase II Pilot Trials EPA and DHA: Omega-3 fatty acids have been shown to resolve inflammation in pre-clinical models, although human observational data is conflicting. CPS investigators **Fabian**, **Kimler**, **Carlson** (fatty acid analysis) and **Sullivan** (diet composition), teamed up with University of North Carolina and University of Texas/MD Anderson investigators, Steve Hursting, Linda de Graffenreid (preclinical) and Gordon Mills (reverse phase protein array) to assess their potential for breast cancer prevention. In an initial cross sectional study, we found that women with lower levels of serum omega-3 fatty acids were more likely to have hyperplasia with atypia on RPFNA (Hidaka, *Cancer Prev Res,* 2015). Separate pilot trials of six months of 3.4 g EPA and DHA combined (4g Lovaza), in pre- and post-menopausal women (funded by Kansas Bioscience Authority and BCRF) showed a significant decrease in Ki-67, and in the premenopausal study, a significant decrease in atypical cytomorphology. Substantial tissue proteomic effects were observed with omega-3 fatty acids (Mills MD, Anderson) (Fabian*, Cancer Prev Res,* 2015, 8:912 and 8:922). Collaborating basic science investigators at the University of Texas Austin demonstrated similar effects at a bioequivalent dose in an obese triple negative animal model (Ford*, Cancer Prev Res,* 2015). **Impac**t: High-dose omega-3 fatty acids appear well tolerated in postmenopausal women and improve breast cytology. **Future**: Omega-3 fatty acids have been incorporated into the multi-PI project of omega-3 fatty acids vs. placebo during weight loss and maintenance influenced in part by preclinical findings of greater impact of DHA and EPA (Lovaza) in a diet induced obese mouse model. If omega-3 fatty acids favorably impact biomarkers, weight loss or avoidance of weight regain, a multi-PI R01 is planned.

Results Phase II Pilot of the SERM Acolbifene (no endometrial agonist activity) in pre-menopausal women was associated with a reduction in benign issue Ki-67 and less hot flashes than anticipated (**Fabian***, Cancer Prev Res,* 2015). **Future:** Consider a randomized trial in SWOG.

Results Phase IIB Trial of Letrozole vs. Placebo in Women on HRT. Based on intriguing preclinical findings, a positive single arm pilot was undertaken showing reduction in Ki-67 with letrozole in women on a stable dose of HRT (**Fig 10**) (**Fabian***, Breast Cancer Res Treat,* 2007). The randomized study (R01CA122577 **Fabian**, **Kimler**, **Mayo** (CB)) was stopped after 53/108 accruals to the intervention portion (265 underwent screening RPFNAs) due to low probability of reaching the goal within a reasonable time frame. Although

KUMC reached its target enrollment, other sites did not contribute significantly as many women stopped HRT subsequent to the results of the Women's Health Initiative. The majority of the rest were prescribed lower dose estrogen alone such that most screened by RPFNA had a baseline Ki-67 lower than our pilot and lower than the cutoff of 1.5% and could not participate. Despite these limitations, women randomized to letrozole showed a significant reduction in median Ki-67 from baseline to 6 months ($p = 0.004$) and from baseline to 12 months ($p = 0.015$). However, the placebo group also showed a reduction from 0-6 months. Between groups there was no significant difference in change in Ki-67 at 6 months or difference in secondary endpoints (blood hormones, cytomorphology, mammographic density and side effects). **Impact**: Study underscores the difficulty in using Ki-67 as a response biomarker in benign breast tissue of postmenopausal women given the number of women who must be screened to find those with a minimal level of Ki-67. **Future**: Menopause symptoms in high and moderate risk women remain a problem. Now exploring Duavee, the combination of low dose equine estrogen and a SERM bazedoxifene, for women at increased risk of breast cancer who also have both a uterus and hot flashes (BCRF **Fabian** PI).

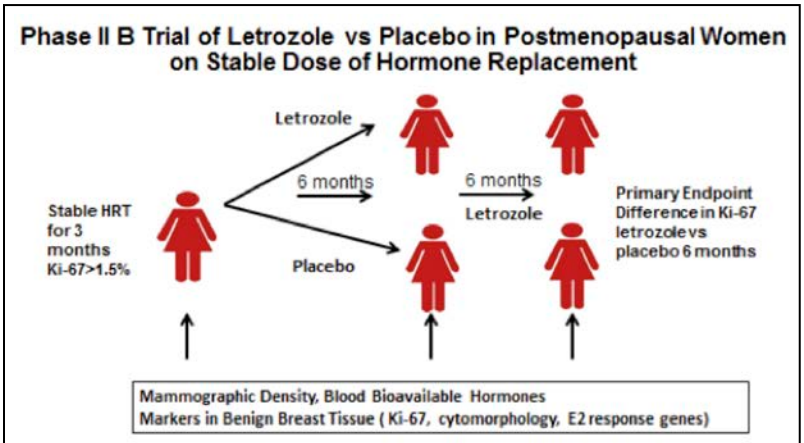

Figure 10. Schema for Phase IIB letrozole study.

Phase IIB Trial of Lignans vs. Placebo for Primary Prevention in Premenopausal Women. Associational and preclinical studies suggest that the lignan secoisoresinol (SDG) found in greatest concentrations in flaxseed may reduce risk for breast cancer. An NCI funded pilot (R21CA117847 **Fabian**) of 12-months of SDG 50 mg/day indicated reduction in Ki67, decrease in pS2 and increase in BRCA1 mRNA in benign breast tissue obtained from high risk premenopausal women by RPFNA (**Fabian**, *Breast Cancer Res, 2010*). We were subsequently awarded a multi-PI Komen Promise grant (KG101039) in which 12 months of SDG was compared to placebo with a primary endpoint of change in Ki-67 in a multisite trial (**Fabian,** Hursting**, Petroff, Kimler, Klemp, Yeh**). Parallel animal studies were conducted (**Petroff,** Hursting) in which a portion of the animals were sacrificed at 6 months for biomarker assessment and the remainder were allowed to go on to 12 months for cancer incidence. This will allow change in biomarker expression to be correlated with change in cancer incidence that would not be possible in the short term human trial (**Fig 11**). **Progress**: In the ER+ studies at the University of Kansas, ACI rats received several doses of SDG with the highest (~10mg/kg) producing similar blood lignan levels as observed in our pilot. SDG normalized several markers in mammary gland tissue (dysplasia, cell number, ER beta and N-cadherin) that had been altered by carcinogen (Delman, *Nutr Cancer*, 2015), but did not alter pre-neoplastic progression in the ovarian epithelium. ER negative mouse studies at UNC are still ongoing. The randomized trial is the product of a large number of CPS program members and KUCC Shared Resources, as well as outside collaborators. KUCC with 115 entrants exceeded its original accrual goal of 77 subjects, but accrual was limited at most non-KUCC sites (total 65). Because of funding limitations, accrual was stopped in April 2016 at 180, short of the 231 originally planned. **Future:** Un-blinding the clinical trial is expected in 2017. A manuscript is currently being prepared detailing challenges of this type of a study requiring tissue screening (495 women by RPFNA), and a minimum level of cytomorphology abnormality and Ki-67 in young, highly premenopausal women. SDG is commercially available as Brevail® and if this study appears promising the findings could actually be adopted without an expensive

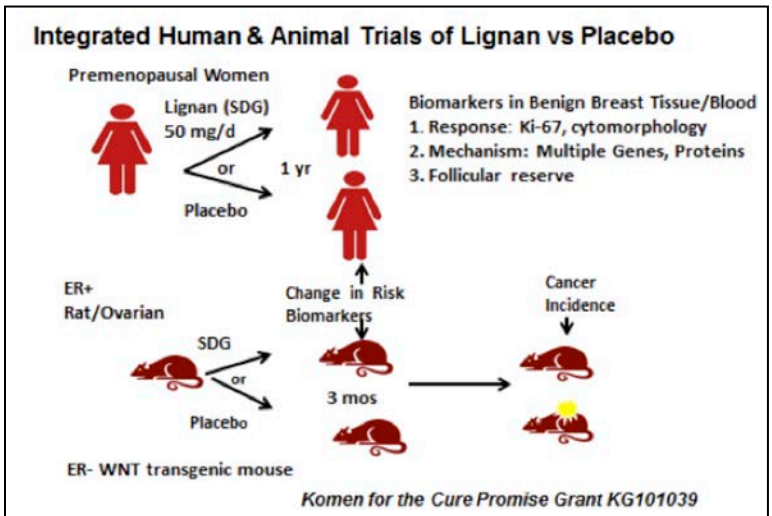

Figure 11. Schema for Phase IIB lignan vs. placebo trial in premenopausal women and Phase II-III trial in animals.

Phase III cancer incidence trial.

Phase II trials of Imaging and Phase II trials of Primary Prevention in Barrett's Esophagus
Background and Significance: High-grade Barrett's is associated with development of esophageal adenocarcinoma (EAC). Early detection and treatment of Barrett's is essential to impact the incidence of esophageal carcinoma which has a survival rate of <3% when symptomatic. Guidelines generally recommend surveillance endoscopy every 3-5 years in individuals with Barrett's as the progression rate is estimated at 0.1 to 0.6 %/year. However, small lesions can be difficult to detect. Treatment for Barrett's once recognized consists of proton pump inhibitors to reduce acid reflux and aspirin. **Progress: Sharma** has been at the forefront in developing guidelines recommendations for Barrett's. He and his group (**Rastogi, Bansal**) have been instrumental in developing and testing narrow band imaging that provides greater mucosal detail than traditional white light endoscopy (**Fig 12**) (**Sharma**, *Gastroenterology,* 2016; Singh, *Endosc Int Open,* 2015). Their findings were also pivotal in assessing radiofrequency ablation as treatment of high grade Barrett's (Saligram, *Endosc Int Open,* 2015). **Sharma** also participated in trials establishing proton pump inhibitors and aspirin as standard of care for Barrett's (Falk, *Gastroenterology,* 2012). Noting that central adiposity associated with insulin resistance seems to be associated with an increased risk of Barrett's our Barrett's group (**Sharma, Rastogi, Bansal**) participated in a National Phase II B trial of metformin 2000 mg/day vs. placebo in Barrett's (Chak, *Clin Gastroenterol Hepatol,* 2015). No changes were observed in proliferation (Ki-67), apoptosis (activated caspase 3), or a biomarker of insulin pathway activation (mTOR) despite an improvement in the blood homeostatic model assessment of insulin resistance. **Impact**: This group has had a tremendous impact in the establishment of the standard of care for surveillance and optimal type of endoscopy for Barrett's. **Future**: Plans are to continue efforts in early diagnosis and increase the development and participation in prevention trials.

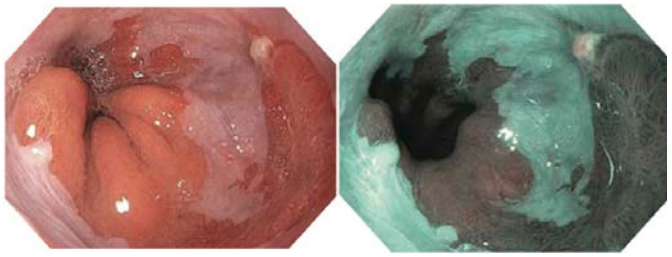

Figure 12. Difference in clarity of Barrett's lesions in the esophagus with white light and narrow band imaging.

Nutrition and Exercise Interventions in Prevention and Survivorship
Background and Significance: Obesity, weight gain and sedentary behavior increase cancer risk and result in poorer outcomes after diagnosis for several common cancers including breast, colon, and prostate. CPS experts in exercise physiology and nutrition (**Donnelly, Sullivan, Carlson**) have developed interventions in average cancer risk adolescents and adults (R01HL111842, R01HD079642) which have then been adapted for prevention in high risk (**Fabian, Kimler, Klemp, Sullivan, Donnelly** R21CA121106) and cancer survivor (**Befor**t, **Klemp, Fabian**, R01CA155014) (**Klemp, Hamilton-Reeves,** pilot funding) cohorts. Key principals are use of pre-packaged portion controlled meals, self-monitoring exercise, and regular small group behavioral interventions producing 11-13% loss at 6 months and improved diet quality (**Fabian**, *Breast Ca Res,* 2013; **Befort,** *Obesity,* 2016; Ptomey, *J Hum Nutr Diet*, 2016). Importantly, significant modulation of both serum and benign breast tissue risk biomarkers for breast cancer were observed with 10% or greater but not less than 10% weight loss. (See Theme 1). A group telephone behavioral intervention was shown to be as successful as an in-person intervention in the general population (**Donnelly**, *Obesity,* 2013) and has been used in the majority of our recent weight loss interventions in high risk and cancer cohorts. Collaborative studies between **Donnelly, Sullivan**, **Befort**, **Yeh, Savage** (CCPH) and **Martin** (CCPH) (R01DK085605) showed functional MRI (fMRI) change with weight loss (Bruce, *Obesity,* 2014) and are being explored in high-risk cohort studies. Current investigations involve higher volume exercise (**Donnelly** R01HL111842) and a virtual reality tool to improve weight maintenance (**Sullivan**, **Donnelly** R01DK094833). **Fabian**, **Kimler**, **Klemp**, and **Befort** (CCPH) are exploring greater expenditure of energy from exercise and physical activity with modest calorie restriction in a pilot study of obese sedentary breast cancer survivors. **Carlson** is an expert in omega-3 fatty acids and cognition in infants and children as well as omega-3 fatty acid analysis. This expertise has been invaluable in CPS investigations of omega-3 fatty acids for primary prevention in breast cancer, immunomodulation prior to cystectomy in bladder cancer, an adjunct to calorie restriction during weight loss and maintenance, or prevention of cognitive dysfunction during chemotherapy.

Rural Weight Loss Study in Breast Cancer Survivors: Rural residents often have poor access to weight control services (**Befort***, J Women's Health*, 2011). To date, weight loss studies (predominately in breast

cancer survivors) suggest an average loss of 5-6% at 6 months decreasing to 3-4% at 2 years. While this amount of weight loss may be associated with improvement in some cardiovascular parameters it is unclear whether risk of cancer or cancer recurrence are favorably impacted. Via R01CA15504, PI **Befort** (CCPH), along with other CPS members **Klemp**, **Fabian** and **Sullivan,** targeted overweight/obese breast rural cancer survivors in both our catchment and adjacent areas to deliver a phone based behavioral weight loss intervention. This interventional trial performed in collaboration with MCA demonstrated substantial weight loss (median 13%) in a rural cohort (**Fig 13**). Regain was less in the group who continued the behavioral group phone intervention through the 12-month maintenance period compared to newsletter only (**Befort**, *Obesity*, 2016). **Impact on our Catchment Area:** A group phone behavioral intervention combined with calorie restriction and targeted at breast cancer survivors demonstrated that a >10% loss is readily achievable (**Befort**, *Breast Cancer Res Treat*, 2012). Assessment of risk biomarkers on serum collected as part of this trial is pending (**Fabian, Kimler, Dixon**). **Impact and Future**: This study capitalized on KUCC start-up funds and demonstrated brisk accrual in a hard to reach population (**Befort**, *Psycho-oncology,* 2014) that was instrumental in facilitating a PCORI grant (**Befort**, CCPH) to implement weight loss interventions in primary care offices across the catchment area.

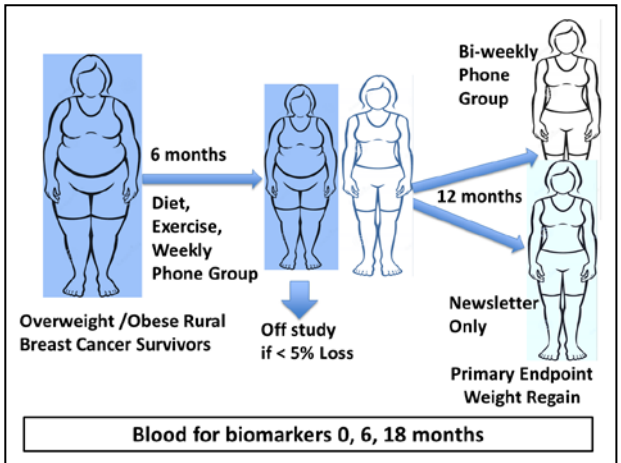

Figure 13. Schema for rural weight loss study in breast cancer survivors.

Pre-operative Weight Loss in Prostate Cancer: Hamilton-Reeves, Klemp, Befort (CCPH), and **Thrasher** (D3ET) have assessed the impact of weight loss *before* and weight maintenance *after* prostate cancer surgery on obesity-driven prostate cancer biomarkers (**Fig 14**). This KUCC pilot of a weight-loss intervention administered prior to surgery led to 12 pounds of weight loss (95% CI, 6−19 pounds; $p < 0.001$) and nine pounds of fat loss (95% CI, 4−13 pounds; $p < 0.001$) among 20 overweight and obese men. Moreover, the intervention significantly reduced immune suppressive myeloid derived suppressor cells (MDSCs) in our weight management arm ($p = 0.02$) before prostatectomy compared to the prospective control arm. This weight loss intervention emphasizes competition, autonomy, technology, cost savings, and male-specific barriers to change--factors that prior studies have found to be important to successful weight loss interventions (Diggett, *J Cancer Educ,* 2014). **Hamilton-Reeves** was also the PI on a pilot study of high dose omega-3 fatty acids and arginine supplementation on individuals undergoing radical cystectomy for bladder cancer. Patients receiving the supplement had a reduction in myeloid derived suppressor cells, a 33% reduction in postoperative complication rate and a 39% reduction in infections (95% CI, 8-70; $p = 0.027$) (**Hamilton-Reeves**, *Eur Urol,* 2015). An R01 submitted to support the translational aspects, with a decision on funding, is pending. **Future:** SWOG multi-institutional pilot studies are being considered for both of these concepts based on these KUCC findings.

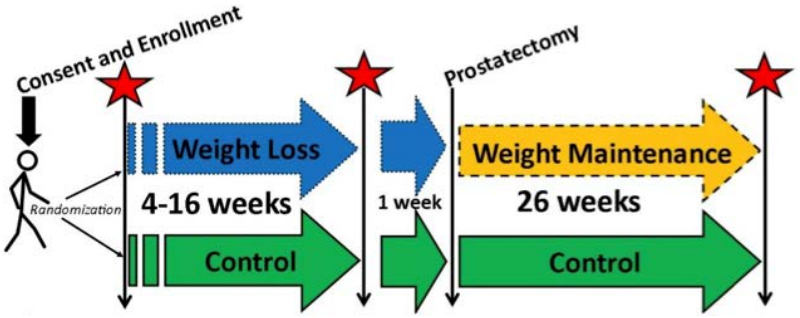

Figure 14. Schema of weight loss in newly diagnosed prostate cancer patients in interval between biopsy and prostatectomy followed by post-prostatectomy weight maintenance. Stars indicate assessment points for medical anthropometrics, blood biomarkers, and QOL.

Weight Loss +/- Omega-3 Fatty Acids Results from the R21 funded weight loss pilot in high risk women and our omega-3 fatty acid pilot trials was used in the design of a multi-PI pilot of a 12 month weight loss and maintenance intervention with high dose omega-3 fatty acids vs. placebo. This collaborative trial between CPS and CCPH investigators (**Fabian, Kimler, Klemp, Dixon, Carlson, Umar** (CPS); **Savage, Martin, Befort, Fridley** (CCPH) has completed accrual. Primary endpoints are feasibility, weight loss induced biomarker modulation, reduction in weight re-gain, and differences in fMRI at six months between omega-3 fatty acids and placebo. After the first two weeks of diet and exercise prior to study drug start we observed favorable modulation of stool microbiome phyla in women who went on to lose > 10% of their initial weight at 6 months.

Impact and Future: Un-blinding is expected in fall 2016 with submission of a multi-PI R01 in 2017.

Neurotoxicity and Cognitive Function in Cancer Survivors

Background and Significance: Preventing and managing side effects of treatment are developing areas of emphasis for our program group and of tremendous interest to community physicians in our catchment area. **Carlson's** expertise in omega-3 fatty acids and cognition (R01HD047315) (Brenna, *J Hum Evol*, 2014) has been combined with the functional brain imaging expertise of **Savage** and **Martin** (CCPH), cognitive testing training expertise of Wefel and Kessler (MD Anderson), and trial experience of Fabian to assess the feasibility of high dose DHA vs. placebo to protect against chemotherapy induced cognitive dysfunction. This pilot trial (**Fabian** PI) funded by BCRF has accrued 14/40 anticipated patients in six months with community physicians making a substantial contribution. **Lunte** from the KU-Lawrence campus along with Jarmolowicz and **Johnson** (D3ET) are assessing changes in brain neurotransmitters resulting from chemotherapy (Shin, *Analyst,* 2015; Saylor, *Electrophoresis,* 2015). Preliminary findings showing that oxidation resulting from chemotherapy may affect neurotransmitter levels will be leveraged in our DHA vs. placebo cognition study. Exercise is associated with improved outcomes for several common malignancies including breast, colon and prostate but is often a challenge in cancer survivors due to other co-morbidities including treatment induced or pre-existing peripheral neuropathies. **Kluding**, an exercise physiologist, is examining the effects of exercise on diabetics with peripheral neuropathy (R01DK064814) and will ascertain if this will be able to be safely translated into a trial for cancer survivors with peripheral neuropathy from taxol and other agents. **Smith** (R01HD049615) is continuing to study the effects of hormonal deprivation on pain including vaginal and pelvic pain. **Future:** Based on pilot finding with DHA and cognition, a SWOG trial is planned with fMRI in selected institutions supported by a NCI Program announcement Leveraging Cognitive Neuroscience Research to Improve Assessment of Cancer Treatment Related Cognitive Impairment PAR-16-212 and 13.

Meeting Catchment Area Needs with CPS Research

Kansas ranks 9th in adult obesity and 13th in obesity amongst teens. Obesity is a factor in development and outcome after diagnosis of three of the four most common cancers (breast, colon and prostate) in the KUCC catchment area. Rural residents are often challenged in access to weight loss and survivorship services. A CDC grant, Kansas Survivor Care Quality Initiative (KSCQI), in partnership with the Kansas Department of Health and Environment, **Klemp**, (CDC 6 NY58P006113-01-01) addresses the quantity and quality of life among Kansas cancer survivors. The purpose of project is to increase both survivor and clinician knowledge of cancer follow-up care, screening and preventive lifestyle behaviors, and awareness/increased participation in chronic disease prevention and control programs (e.g., tobacco cessation, cancer screening, weight control). The Greater Plains Collaborative (GPC) (IRB#00003138) is a network (PCORNET) of health systems in 12 states committed to a shared vision of improving healthcare delivery through ongoing learning, adoption of evidence-based practices, active research dissemination and data sharing. The GPC is led by KUMC (**Waitman**, PI) and focuses on breast cancer and obesity. The GPC Breast Cancer Study, "Share Thoughts on Breast Cancer, (**Klemp** KUMC-PI; IRB#00002794) was undertaken to learn more about the experiences of breast cancer survivors and examine what information they are given, what influences their treatment choice, their experiences with care, and late effects of their cancer. Between June-July of 2015 ~1,987 questionnaires were mailed to breast cancer survivors in eight Midwestern states. 62% completed the survey and 69% signed consent for their medical records to be accessed and 52% were also willing to be contacted for future research. **Future:** Projects are being developed focused on access to and receipt of genetic testing, survivorship care and cancer screening, and the management of physical and psychosocial effects of cancer.

Value Added by CPS Program to KUCC

CPS fosters collaboration by promoting transdisciplinary participation in disease working groups, supports attendance at scientific meetings, and makes a great effort to involve Masters of Clinical Research, MD PHD, and pre- and post-doctoral students in prevention and research projects. We also mentor and support junior faculty with pilot funding, and promote their projects in the Cooperative group and translational Science arena (e.g., Cold Spring Harbor), all in an effort to grow the next generation of prevention and survivorship researchers. Concern about the dwindling supply of clinicians in prevention research prompted an ASCO sponsored survey of medical oncology fellows during their in-training exam. Fellows were interested in Prevention but were reluctant to embark on a research career due to a perceived lack of training, mentors, and opportunities underscoring the importance of early and continued mentoring. Along with KUCC and CPS pilot funds, ACS-IRG pilot grants for junior faculty (**Kimler** PI IRG-09-062) and BIRCWH (**Carlson** PI) have been

important sources of support and mentoring for our junior faculty (**Fabian**, *J Clin Oncol,* 2015). The majority of our full and associate members at one time or another have had pilot funds from one or more of these sources focusing on translational collaborations between basic and clinical scientists. Most of our members review applications for Frontiers/ CTSA, ACS-IRG, and KUCC pilot awards. In addition, beginning in 2013, the CPS leadership (including theme leaders) have made internal decisions for use of CPS development funds ($50,000 per year) which have primarily been allocated for pilot projects. Our latest example (2016) is Lisa **Harlan-Williams** who had noted in pre-clinical specimens that loss of BRCA1 triggered a change to glycolytic metabolism typical of cancer cells. In order to explore the feasibility of using this observation as a short-term prediction for breast cancer, **Harlan-Williams** is currently studying cells obtained by RPFNA from *BRCA1* mutation carriers (**Fabian**) and characterizing the extracellular acidification rate as an indicator of glycolysis and the oxygen consumption rate, an indicator of mitochondrial oxidative phosphorylation.

Value Added by KUCC to Programmatic Efforts

CPS and KUCC leadership have worked together to increase the capacity and productivity of the CPS program. Specifically, KUCC supported the faculty recruitment of **Dixon** to KUMC and **Maliski** as Associate Director for Health Equity. CPS has received $50,000 for travel awards and program-specific pilot awards (**Table 4**). In addition, CPS members were also the recipients of KUCC-directed pilot project awards. For example, **Behbod** received a KUCC pilot award in 2014 that resulted in an AACR grant award. Further details on pilot project awards and outcomes can be found in the Developmental Funds Other Attachments. CPS members have also made extensive use of KUCC shared resources as shown in Table 3 (Other Attachments).

Table 4. Program-Directed Pilot Awards

CPS Member	Research Focus
Bansal	MicroRNA in Barrett's Esophagus
Hamilton-Reeves	Energy balance for prostate cancer prevention and survivorship
Valdez	Hormonal regulation of IKK during DCIS transition to IDC
Gibson (new)	A televideo exercise and nutrition program for adult survivors of pediatric cancer
Harlan-Williams	Metabolic profiles of RPFNA samples from *BRCA1* mutation carriers

Future Plans

In the next five years CPS plans to continue the translational interaction between basic, behavioral and clinical scientists in primary prevention and survivorship trials. Specific objectives include the following:

- Increase metabolomics and energy balance basic science capabilities. A COBRE multi-PI grant has been submitted with metabolomics as a research core.
- Increase cross-disciplinary and disease site sharing of new biomarkers (such as miRNA and RNA binding proteins from GI into breast) and intervention strategies.
- Submit a PREVENT grant to facilitate moving gingerols (**Timmerman,** D3ET) into early colon and breast cancer prevention trials.
- Increase prevention clinical trials in sites in addition to breast with the recruitment of new faculty (John Taylor GU), Anwaar Saeed (GI Med Onc) and Lauren Nye (Breast Med Onc). Trials of omega-3 fatty acids in individuals with Lynch Syndrome and diet and exercise in African-American breast cancer survivors are planned for 2017.
- Increase nursing research with the addition of **Maliski**. An R01-sponsored trial of cognitive dysfunction following androgen deprivation therapy is being started. A trial of exercise following change in arm bio-impedence measurements in breast cancer survivors (**Wagner**, Korentager) is under discussion.
- Increase translation of CPS pilot studies into national studies (cognitive dysfunction, omega-3 fatty acids + arginine in cystectomy patients, pre-operative weight loss intervention in prostatectomy patients).
- Serve as a central lab for biomarkers for national trials (e.g., Neuregulin and SNPs for SWOG S1501: prevention of cardiac dysfunction by carvedilol).

Progress Report Publications

This component has no publications resulting from Cancer Center Support Grant funds.

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Resource Sharing Plan

The University of Kansas Cancer Center (KUCC) and its scientific community understands its responsibility to comply with the instructions for the Resource Sharing Plans provided within the SF 424 (R&R) Application General Instructions and Supplemental Grant Application Instructions. When resources are developed with NIH funds via this Cancer Center Support Grant P30 mechanism, KUCC will ensure findings are made readily available to the NIH and the scientific community in a timely manner.

Data Sharing Plan

KUCC will adhere to the Final NIH Statement on Sharing Research Data and refer to the National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research. KUCC encourages the free flow of information and ideas while recognizing the timeliness of data sharing, the rights and privacy of human subjects and issues related to proprietary data. KUCC encourages data documentation, using a data-sharing agreement and selecting an appropriate method for sharing; considering the sensitivity of the data, the size of the dataset and the volume of requests anticipated.

Additionally, KUCC encourages any user of a CCSG-supported shared resource to acknowledge the source of data upon which their manuscript is based either in the Acknowledgments section or with authorship on the paper. Furthermore, any research project that received direct cost support from the CCSG is encouraged to cite the P30 CA168524. In both cases, citing the P30 CA168524 grant number and then being compliant with the NIH Public Access Policy is required.

Sharing Model Organisms

In the event that a model organism is developed, KUCC will comply with the NIH Policy on Sharing of Model Organisms for Biomedical Research. KUCC will work with the NIH/NCI to share and disseminate the critical model organism in a timely manner.

Genome Wide Associate Studies

When applicable, KUCC will comply with the NIH Genomic Data Sharing Policy. KUCC supports the sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. All research studies funded through the CCSG involving genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data will be submitted in a timely manner.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 016060860

Legal Name*: University of Kansas Medical Center Research Institute, Inc,
Department:
Division:
Street1*: MSN 1039, 3901 Rainbow Blvd
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Deborah		Maloney	MSM

Position/Title: Director, Sponsored Programs Administration
Street1*: 3901 Rainbow Boulevard
Street2: Mail Stop 1039
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 66103-2937
Phone Number*: 913-588-1261 Fax Number: 913-588-3225 Email: spa@kumc.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): University Affiliated Nonprofit Organization

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Drug Discovery, Delivery, & Experimental Therapeutics Research Program

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2017	06/30/2022

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Kansas Medical Center
Duns Number:	016060860
Street1*:	MS 1018, 3901 Rainbow Boulevard
Street2:	
City*:	Kansas City
County:	Wyandotte
State*:	KS: Kansas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	66160-0000
Project/Performance Site Congressional District*:	KS-003

Project/Performance Site Location 1

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The Children's Mercy Hospital
DUNS Number:	073067480
Street1*:	2401 Gilham Road
Street2:	
City*:	Kansas City
County:	
State*:	MO: Missouri
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	64108-4619
Project/Performance Site Congressional District*:	MO-005

File Name

Additional Location(s)

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ❍ **Yes** ● **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ❍ No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	D3ET_ProjectSummary_final1019659703.pdf
8. Project Narrative*	
9. Bibliography & References Cited	D3ET_ReferencesCited_Final1019857923.pdf
10.Facilities & Other Resources	
11.Equipment	
12. Other Attachments	D3ET_Other_Attachments_Final21019857920.pdf

Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Drug Discovery, Delivery and Experimental Therapeutics – Project Summary

The Drug Discovery, Delivery and Experimental Therapeutics (D3ET) research program integrates a broad range of research areas that contribute to the discovery and delivery of new cancer therapeutic strategies, identification of companion biomarkers, translation of the most promising therapeutic strategies to the clinic and the evaluation of these strategies in experimental therapeutics trials. D3ET is organized around three, central highly-integrated scientific themes: 1) Discover and Deliver New Cancer Therapeutic Strategies; 2) Develop New Cancer Therapeutic Strategies; and 3) Evaluate New Cancer Therapeutic Strategies in Experimental Therapeutics Trials. D3ET has 60 members (33 PhD's and 27 MD's), including 39 full and 21 associate members. Membership reflects a range of senior and early-stage investigators with 20 Professors, 13 Associate Professors and 17 Assistant Professors. D3ET members are drawn from 25 departments across Children's Mercy, The University of Kansas in Lawrence and The University of Kansas Medical Center in Kansas City, providing a rich environment for discipline diversity and team science.

During the reporting period (CY15), 51% of the 39 full members serve as principal investigators on externally funded, peer-reviewed grants. From 2012-2015, the D3ET program achieved a strong and growing cancer-focused research portfolio. In 2015, D3ET members conducted research on 36 cancer-relevant, peer-reviewed projects representing $9.1M in extramural funding, including $3.1M in funding obtained directly from the National Cancer Institute (NCI). The 15 NCI funded grants represented 35% of total peer-reviewed funding. D3ET has grown clinical research primarily by members successfully obtaining grants from industry to support clinical trial activities. The D3ET program has made impressive progress in publishing its research, and increasing intra-programmatic and inter-programmatic collaborations. Between 2012 and 2015, D3ET members published 617 cancer-relevant publications, including 67 papers with a journal impact factor of ≥8. Twenty-nine percent of D3ET published research over this time period represented intra-programmatic collaborations and 23% involving inter-programmatic collaborations. Consistent with its research themes and objectives, 51% of D3ET publications included external industry, academia, government or disease philanthropy collaborators. Alan Gamis, MD (Children's Mercy) and Scott Weir, PharmD, PhD (KUMC), who bring complimentary scientific expertise in drug discovery, development and experimental therapeutics and strong track records of mentorship, jointly lead D3ET. Steve **Williamson**, MD, Medical Director for the Clinical Trials Office and D3ET member, completes the leadership team representing adult cancer experimental therapeutics.

Drug Discovery, Delivery and Experimental Therapeutics – Other Attachments

Table 1 – Externally Funded, Cancer-Related Research Projects
Table 2 – Program Members
Table 3 – Shared Resource Usage
Table 4 – Programmatic Activities
Table 5 – Publications
Table 6 – Clinical Research

Table 1. Externally Funded, Cancer-Related Research Projects as of 12/31/2015 – Drug Discovery, Delivery & Experimental Therapeutics

Table 1. Program Funding											
PI	**Specific Funding Source**	**Project Number**	**Project Start Date**	**Project End Date**	**Project Title**	**Annual Project Direct Costs**	**Annual Project Total Costs**	**Program Code**	**Percent**	**Annual Program Direct Costs**	**Annual Program Total Costs**
PEER-REVIEWED PROJECTS											
Anant S Weir SJ	NCI	5R01CA182872-02	1/1/2014	12/31/2018	NOVEL DUAL NOTCH/PXR TARGETING FOR COLON CANCER THERAPY			D3ET	100%	$208,107	$314,242
Blagg BSJ	NCI	5U01CA109265-09	7/1/2004	6/30/2019	HSP90 INHIBITORS	$151,915	$218,972	D3ET	100%	$151,915	$218,972
Blagg BSJ	NINDS	5R01NS075311-04	4/1/2012	3/30/2016	CHAPERONE THERAPEUTICS FOR THE TREATMENT OF DPN	$218,750	$317,274	D3ET	100%	$218,750	$317,274
Cancer Relevance (NS075311): *The investigator is synthesizing and optimizing novobiocin-based HSP90 inhibitors for the treatment of diabetic peripheral neuropathy. Chemotherapy-induced peripheral neuropathy and neuropathy associated with diabetes (induced oxidative stress) both upregulate matrix metalloprotease 13 (MMP-13), a collagenase that damages peripheral nerves. Pharmacologic inhibition of MMP-13 reverses paclitaxel-induced neuropathy in vitro. Reference: Lisse et al, PNAS 2016 113(15):E2189-98.*											
Blagg BSJ	NCI	2R01CA120458-10A1	5/19/2006	6/30/2019	DEVELOPMENT AND EVALUATION OF PURINE AND COUMARIN BASED HSP90 INHIBITORS	$277,849	$372,418	D3ET	100%	$277,849	$372,418
Blagg BSJ	NCI	5U01CA120458-09	5/19/2006	6/30/2019	DEVELOPMENT AND EVALUATION OF PURINE AND COUMARIN BASED HSP90 INHIBITORS	$248,460	$326,800	D3ET	100%	$248,460	$326,800
Blagg BSJ	NCI	5R01CA167079-04	4/6/2012	3/31/2017	DEVELOPMENT OF HSP90 INHIBITORS FOR THE TREATMENT OF CANCER	$263,376	$312,346	D3ET	100%	$263,376	$312,346
Chennathukuzhi V	NICHD	5R01HD076450-03	8/12/2013	4/30/2018	THE ROLE OF REST IN THE PATHOGENESIS OF UTERINE FIBROIDS	$227,306	$326,867	D3ET	100%	$227,306	$326,867
Cancer Relevance (HD076450): *Although uterine fibroids are not a precursor to malignant lesions, many studies have shown that leiomyomas serve as clonal growth models for malignancy. Growth factors such as EGF, PDGF, IGF, TGF, and VEGF along with signaling cascades Ras-Erk/MAPK and PI3K-AKT-mTor play important roles in cell proliferation and migration in uterine fibroids (leiomyoma) and leiomyosarcoma (Ciarmela et al, Human Repro Update 2011 17(6):772-90). Deranged Cripto mRNA expression has been observed in leiomyomas and leiomyosarcomas, and, when normal uterine myometrial tissues are treated with deranged Cripto mRNA, cell proliferation and migration rate is increased (Strizzi et al, J Pathol 2007 211:36-44).*											
Forrest ML	NCI	5R01CA173292-03	3/1/2013	2/28/2018	BIOMATERIALS FOR TREATMENT OF HEAD AND NECK CANCER	$195,937	$289,331	D3ET	100%	$195,937	$289,331
Godwin AK	NCI	5R01CA140323-05	4/1/2010	1/31/2016	EXPLOITING BIOLOGICAL NETWORKS TO IMPROVE CLINICAL TREATMENT OF OVARIAN CANCER	$206,260	$309,390	D3ET	100%	$206,260	$309,390
Godwin AK	NCI	3R01CA140323-05S1	4/1/2010	1/31/2016	EXPLOITING BIOLOGICAL NETWORKS TO IMPROVE CLINICAL TREATMENT OF OVARIAN CANCER	$56,093	$84,070	D3ET	100%	$56,093	$84,070
Godwin AK	NCI	3R01CA140323-05S2	4/1/2010	1/31/2016	EXPLOITING BIOLOGICAL NETWORKS TO IMPROVE CLINICAL TREATMENT OF OVARIAN CANCER	$71,222	$107,546	D3ET	100%	$71,222	$107,546
Godwin AK	NCI University of Texas Health Science Center	3U01CA086402	5/15/2000	6/30/2016	EDRN - SAN ANTONIO CENTER FOR BIOMARKERS OF RISK FOR PROSTATE CANCER [SABOR]	$82,533	$124,625	D3ET	100%	$82,533	$124,625
Godwin AK	NCI Fox Chase Cancer Center	3U01CA113916	3/31/2005	6/30/2016	FOX CHASE CLINICAL EPIDEMIOLOGY AND VALIDATION CENTER	$32,805	$49,536	D3ET	100%	$32,805	$49,536
Hanzlik R	NIGMS	5P30GM110761-02	7/1/2015	6/30/2016	PROTEIN STRUCTURE AND FUNCTION (PILOT PROJECTS PROGRAM)			D3ET	100%	$250,000	$375,000
Cancer Relevance (GM110761): *The Center of Biomedical Research Excellence (COBRE) in Protein Structure and Function provides cloning, expression and purification of prokaryotic and eukaryotic proteins, fragment screening for drug discovery, biomolecular NMR studies of biomolecules, and protein x-ray structure characterization support for KUCC drug discovery activities. Additionally, this COBRE has provided pilot awards to KUCC researchers in support research activities described above.*											
Karanicolas J	NIGMS	5R01GM099959-04	4/1/2012	3/31/2017	IDENTIFYING INHIBITORS OF PROTEIN INTERACTIONS USING POCKET OPTIMIZATION	$190,000	$277,075	D3ET	100%	$190,000	$277,075
Cancer Relevance (GM099959): *The pocket optimization approach to characterizing drug target structure supporting design and synthesis of protein-protein interaction inhibitors is relevant to cancer targets.*											

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Lamb AL	NSF	1403293	7/15/2014	6/30/2017	ENZYMES OF ORNITHINE-HYDROXAMATE SIDEROPHORES	$409,104	$606,000	D3ET	100%	$409,104	$606,000
Cancer Relevance (1403293): *The role of iron in tumor initiation, tumor growth, tumor microenvironment, and in metastasis was reviewed recently (Torti and Torti, Nature Rev 2013 13:342-355). Siderophores are molecules synthesized by bacteria to acquire and conserve iron. As a result, siderophore enzymes, their structure and function, have been a basis for drug discovery (He and Xie, Acta Pharmaceutica 2011 1(1):8-13). Iron chelators derived from Mycobacterium siderophores have been shown to induce apoptosis (Pahl et al, Breast Cancer Res Treat 2001 69:69-79), alter cell cycle regulatory proteins (Pahl et al, J Exp Ther Oncol 2007 6:193-200), and induce hypoxia inducible factors 1 and 2 (Chong et al, Cancer Res 2002 62:6924-6927) in cancer cell lines. This grant focuses on characterizing how bacteria synthesize siderophores.*										
Lamb AL	NIAID	5K02AI093675-04	3/1/2011	2/29/2016	STRUCTURE-FUNCTION ANALYSES OF SIDEROPHORE BIOSYNTHETIC ENZYMES	$99,000	$106,920	D3ET	100%	$99,000	$106,920
Cancer Relevance (AI093675): *This grant focuses on characterizing the structure and function of siderophore enzymes identified above as a foundation for drug discovery.*											
Leeder JS	NICHD University of Washington	1R01HD081299-01A1	4/1/2015	2/29/2020	PBPK PREDICTION OF ONTOGENY MEDIATED ALTERATION IN HEPATIC DRUG ELIMINATION	$240,739	$240,739	D3ET	100%	$240,739	$240,739
Cancer Relevance (HD081299): *This research project integrates age-dependent physiologic parameters with drug-specific parameters (e.g., drug metabolizing enzymes, drug transporters, protein binding) to develop pediatric physiologically based pharmacokinetic models. With validation, this model can be generalized for any drug and indication, including cancer. To create the model, Leeder and colleagues are characterizing the hepatic expression of drug metabolizing enzymes and transporters in children employing multiple reaction monitoring proteomics, and comparing expression to adults.*											
Li B	NCI	5R21CA175279-02	1/1/2014	12/31/2015	PROSTATE-TARGETED CRMP4 SARNA AS ANTI-METASTATIC THERAPY	$108,750	$164,213	D3ET	100%	$108,750	$164,213
Lunte SM Ackley BD	NIGMS	5P20GM103638-04	7/1/2015	6/30/2016	MOLECULAR ANALYSIS OF DISEASE PATHWAYS (IDENTIFYING MRNAS ASSOCIATED WITH A SYNAPTOGENIC CALCIUM-MEDIATED PATHWAY)			D3ET	100%	$120,308	$180,462
Cancer Relevance (GM103638): *The Center for Biomedical Research Excellence (COBRE) in Molecular Analysis of Disease Pathways provides genome sequencing support for the production and verification of genetically modified cells, synthesis and evaluation of novel fluorescent probes for investigation of biochemical pathways and drug delivery, and production of unique micro-fabricated devices for studying genetically modified organisms (e.g., zebra fish) and biological pathways. This COBRE has supported or is currently supporting several cancer relevant projects including microfluidic single cell analysis of cancer exosomes (Zeng), microlfuidic engineering of immunogenic exosomes for personalized cancer vaccine (He, Kansas State), functional analysis of Ewings sarcoma proteins EWS/FLI1 and EWS in zebrafish (Azuma), and multicellular evolution of reprogramming cell cycle regulation (Olson, Kansas State).*										
Lunte SM Johnson MA	NIGMS	5P20GM103638-04	7/1/2015	6/30/2016	MOLECULAR ANALYSIS OF DISEASE PATHWAYS (NEUROTRANSMITTER INTERACTIONSON SUB-SECOND TIMESCALES)			D3ET	100%	$122,138	$183,206
Cancer Relevance (GM103638): *The Center for Biomedical Research Excellence (COBRE) in Molecular Analysis of Disease Pathways provides genome sequencing support for the production and verification of genetically modified cells, synthesis and evaluation of novel fluorescent probes for investigation of biochemical pathways and drug delivery, and production of unique micro-fabricated devices for studying genetically modified organisms (e.g., zebra fish) and biological pathways. This COBRE has supported or is currently supporting several cancer relevant projects including microfluidic single cell analysis of cancer exosomes (Zeng), microlfuidic engineering of immunogenic exosomes for personalized cancer vaccine (He, Kansas State), functional analysis of Ewings sarcoma proteins EWS/FLI1 and EWS in zebrafish (Azuma), and multicellular evolution of reprogramming cell cycle regulation (Olson, Kansas State).*										
McGuirk JP	NHLBI University of Nebraska Medical Center	5U10HL069233-15	9/30/2001	6/30/2017	NEBRASKA/KANSAS BLOOD AND MARROW TRANSPLANT RESEARCH NETWORK	$125,999	$154,372	D3ET	100%	$125,999	$154,372
Prisinzano TE	NIGMS	5R24GM111385-02	8/1/2014	7/31/2017	LEGACY CONTINUATION OF THE KU CMLD MISSION	$344,634	$516,951	D3ET	100%	$344,634	$516,951
Richter M	NIMH PINNACLE TECHNOLOGY, INC	9R44MH107036-02	12/1/2011	2/28/2017	A TISSUE IMPLANTABLE MICROBIOSENSOR	$122,188	$177,284	D3ET	100%	$122,188	$177,284
Cancer Relevance (MH107036): *This Phase II SBIR award supports development of biosensor platform technology development that can be applied across disease areas including cancer. Nanoetching and electrophoretically manipulated enzyme immobilized nanoparticles are applied to implantable biosensors. Although the prototype biosensor measures glucose, similar implantable biosensors are being developed with NCI support to monitor cancer and inflammatory diseases.*											
Richter M	NIDA Pinnacle Technology Inc	5R44DA033701-03	9/30/2013	2/29/2016	DEVELOPMENT OF A NICOTINE BIOSENSOR	$306,456	$443,956	D3ET	100%	$306,456	$443,956

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Roy A	NIAID Kansas State University	1R21AI115187-01A1	7/15/2015	6/30/2016	HIGH-THROUGHPUT FLUORESCENCE SCREENING FOR INHIBITORS OF TONB-DEPENDENT IRON TRANSPORT	$50,000	$75,000	D3ET	100%	$50,000	$75,000
Cancer Relevance (AI115187): *TonB-dependent transporters located in the outer membrane of gram negative bacteria catalyze the uptake of iron complexes into bacterial cells. The ability of gram negative bacteria to take up iron complexes is correlated to the pathogenesis of many bacterial species. TonB active transport of iron is a process that undergoes conformational motion. The cancer relevance of this research project is that Roy successfully developed a fluorescence spectroscopic assay to identify compounds that inhibit conformational change in the transporter, and in doing so, reduce the virulence of gram negative bacteria in patients with compromised immune function. The assay strategy offers a different approach to identifying inhibitors of drug transporters activated in chemoresistance.*										
Scott EE	NIGMS	2R37GM076343-10	1/1/2006	2/29/2020	STRUCTURAL BASIS OF CYTOCHROME P450 ACTIVITY	$230,000	$341,187	D3ET	100%	$230,000	$341,187
Scott EE Aube J (UNC)	NIGMS	5R01GM102505-04	7/1/2012	3/31/2016	STRUCTURE AND FUNCTION OF CYTOCHROME P450 17A1	$190,000	$277,878	D3ET	100%	$95,000	$138,939
Siahaan TJ	NINDS	5R01NS075374-05	8/15/2011	6/30/2016	MODULATING THE BBB TO IMPROVE DRUG DELIVERY TO THE BRAIN	$222,710	$304,650	D3ET	100%	$222,710	$304,650
Tunge J	NSF	1465172	7/1/2015	6/30/2018	CATALYTIC SYNTHESIS VIA C-C CLEAVAGE	$308,751	$435,000	D3ET	100%	$308,751	$435,000
Cancer Relevance (1465172): *In synthetic and medicinal chemistry, researchers access reactive intermediates used in chemical synthesis through formation of stoichemetric organometallics under extreme basic conditions or through the use of high-energy reduced metals. Decarboxylative couplings developed by Tunge are more environmentally benign than the methods described in the previous sentence because the chemical reactions are performed under much milder conditions. This more environmentally friendly synthetic chemistry approach is relevant to synthesis of novel classes of compounds with cancer relevant activities.*											
Volkin D Forrest ML Middaugh CR *et al*	FDA	5U01FD005285-02	9/10/2014	3/31/2017	DEVELOPMENT OF AN INTEGRATED MATHEMATICAL MODEL FOR COMPARATIVE CHARACTERIZATION OF COMPLEX MOLECULE	$133,333	$200,000	D3ET	100%	$133,333	$200,000
Volkin D Karanicolas J	NIH Health Research Inc	272201400021C-2-0-1	9/30/2015	9/29/2016	B CELL EPITOPE DISCOVERY AND MECHANISMS OF ANTIBODY PROTECTION	$247,558	$371,337	D3ET	100%	$247,558	$371,337
Cancer Relevance (272201400021C): *This cancer relevant research project is developing, implementing and validating integrated mathematical algorithms to assess the similarity of multiple batches of two different complex biological molecules using analytical comparability data sets from biological, chemical, and physical characterization methods. This mathematical model is directly relevant to characterization, stabilization and formulation of biologics as cancer treatments.*											
Xu L	Susan G. Komen Foundation	PDF14301553	8/2/2014	8/1/2017	NOVEL ANTI-METASTAMIR THERAPY FOR METASTATIC BREAST CANCER	$180,000	$180,000	D3ET	100%	$180,000	$180,000
Xu L Aube J (UNC)	NCI	1R01CA191785-01A1	7/1/2015	5/31/2020	MOLECULAR CANCER THERAPY TARGETING HUR-ARE INTERACTION	$290,500	$432,001	D3ET	100%	$145,250	$216,001
Xu L Neufeld KL Aube J (UNC)	NCI	5R01CA178831-02	9/19/2014	8/31/2017	SMALL MOLECULES MODULATING RNA-BINDING PROTEIN MSI1	$291,662	$432,491	D3ET	100%	$97,221	$144,164
Zeng Y	NCI	5R21CA186846-02	8/1/2014	7/31/2017	INTEGRATED MICROFLUIDIC EXOSOME PROFILING FOR EARLY DETECTION OF CANCER	$162,276	$212,274	D3ET	100%	$112,276	$137,274
Cancer Relevance (T32ES007079): *Consistent with KUCC's vision to train the next generation of leaders in cancer research, clinical care, and advocacy, the Toxicology Training Program (TTP) at KUMC is recognized internationally as a Center of Excellence for training in toxicology. The TTP has trained over 300 students in toxicological sciences over the past 30 years. It continues today through modernized training, improved recruitment of students, updated courses, expansion of participating faculty, and increased exposure to outside leaders and opportunities in the field.*											
					Peer-Reviewed Research Subtotals:					**$6,502,028**	**$9,123,146**

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
NON-PEER-REVIEWED PROJECTS											
Abhyankar A	Therakos, Inc.		5/12/2010	12/31/2016	A STUDY OF EXTRACORPOREAL PHOTOPHEREIS WITH UVADEX IN THE SETTING OF A STANDARD MYELOABLATIVE CONDITIONING REGIMEN IN UNRELATED DONOR	$32,412	$32,412	D3ET	100%	$32,412	$32,412
Abhyankar S	GlaxoSmithKline (fka: Glaxo Wellcome)		2/1/2013	12/31/2020	A PHASE III, RANDOMISED, OBSERVER-BLIND, PLACEBO CONTROLLED, MULTICENTRE, CLINICAL TRIAL TO ASSESS THE PROPHYLACTIC EFFICACY, SAFETY, AND IMMUNOGENICITY OF GSK BIOLOGICALS HERPES ZOSTER GE/AS01B CANDIDATE VACCINE WHEN ADMINISTERED	$53,043	$70,548	D3ET	100%	$53,043	$70,548
Abhyankar S	University of Nebraska Medical Center	PROTOCOL #0901	2/14/2012	12/31/2020	A RANDOMIZED, MULTI-CENTER, PHASE III OF ALLOGENEIC STEM CELL TRANSPLANATION COMPARING REGIMEN INTENSITY IN PATIENTS WITH MYELODYSPLASTIC SYNDROME OR ACUTE MYELOID LEUKEMIA	$15,275	$20,316	D3ET	100%	$15,275	$20,316
Abhyankar S	Pfizer		2/1/2013	12/31/2020	AN OPEN LABEL, RANDOMIZED PHASE 3 STUDY OF INOTUZUMAB OZOGAMICIN COMPARED TO A DEFINED INVESTIGATOR'S CHOICE IN ADULT PATIENTS WITH RELAPSED OR REFRACTORY CD22- POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)	$18,933	$25,181	D3ET	100%	$18,933	$25,181
Berkland C	American Heart Assoc - Midwest Affiliate		7/1/2014	6/30/2016	NON-ABSORBED MICELLE SEQUESTRANT POLYMERS FOR THE TREATMENT OF WESTERN DIET-INDUCED OBESITY	$95,224	$95,224	D3ET	100%	$95,224	$95,224
Clough L	Ansun BioPharma, Inc.		4/29/2014	12/31/2021	A PHASE II, RANDOMIZED, DOUBLE BLIND, PLACEBO CONTROLLED STUDY TO EXAMINE THE EFFECTS OF DAS181 IN IMMUNOCOMPROMISED SUBJECT WITH LOWER RESPIRATORY TRACT PARAINFLUENZA INFECTION ON SUPPLEMENTAL OXYGEN	$40,112	$53,349	D3ET	100%	$40,112	$53,349
Clough L	Merck, Sharp and Dohme Corp.		7/9/2014	12/31/2021	A PHASE III RANDOMIZED, PLACEBO-CONTROLLED CLINICAL TRIAL TO EVALUATE THE SAFETY AND EFFICACY OF MK-8228 FOR THE PREVENTION OF CLINICALLY SIGNIFICANT HUMAN CYTOMEGALOVIRUS INFECTION IN ADULT, CMV-SEROPOSITIVE ALLOGENIC HEMATOPOIETIC STEM CELL TRANSPLANT	$28,032	$35,632	D3ET	100%	$28,032	$35,632

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Clough L	Optimer Pharmaceuticals Inc		8/20/2012	12/31/2020	DEFLECT1 A PHASE 3B, MULTI CENTER, DOUBLE BLIND, RANDOMIZED, PLACEBO CONTROLLED STUDY TO DEMONSTRATE THE SAFETY AND EFFICACY OF FIDAXOMICIN FOR PROPHYLAXIS AGAINST CLOSTRIDIUM DIFFICILE	$42,742	$56,846	D3ET	100%	$42,742	$56,846
Cancer Relevance: *Chemotherapy and bone marrow transplant are well recognized as independent factors in development of Clostridium Difficile in cancer patients.*											
Fabian CJ Khan QJ Sharma P	GlaxoSmithKline (fka: Glaxo Wellcome)		1/25/2011	12/31/2020	PHASE II TRIAL OF LAPATINIB AND RAD-001 FOR HER2 POSITIVE METASTATIC BREAST CANCER	$49,955	$66,440	D3ET	100%	$49,955	$66,440
Forrest ML	NanoPharm, LLC	IND0069745	11/1/2011	12/31/2015	TRANSLATIONAL DEVELOPMENT OF INTRALYMPHATIC CHEMOTHERAPIES	$188,690	$188,690	D3ET	100%	$188,690	$188,690
Forrest ML Schoeneich C	Inez Jay Fund	FND0074591	7/1/2015	6/30/2016	MECHANISTIC UNDERSTANDING OF OXIDATION OF THERAPEUTIC PROTEINS AFTER SUBCUTANEOUS ADMINISTRATION	$30,000	$30,000	D3ET	100%	$30,000	$30,000
Godwin AK	Inhibikase Therapeutics, Inc		12/7/2015	12/6/2016	EVALUATION OF RE-ENGINEERED PROTEIN KINASAE INHIBITORS IN A GIST ANIMAL MODEL	$25,918	$39,655	D3ET	100%	$25,918	$39,655
Godwin AK	Braden's Hope Foundation		9/1/2015	8/31/2016	THE ACHILLES' HEEL AND NOVEL TARGETED THERAPIES OF EWING SARCOMA	$100,000	$100,000	D3ET	100%	$100,000	$100,000
Holzbeierlein JM	Heat Biologics, Inc.		10/28/2014	12/30/2020	A PHASE 1/2, PLACEBO-CONTROLLED, RANDOMIZED STUDY TO EVALUATE THE SAFETY, IMMUNE RESPONSE AND CLINICAL ACTIVITY OF HS-410 IN PATIENTS WITH HIGH-RISK NON-MUSCLE INVASIVE BLADDER CANCER WHO HAVE UNDERGONE TRANSURETHRAL	$30,639	$40,750	D3ET	100%	$30,639	$40,750
Holzbeierlein JM	Argos Therapeutics, Inc.		5/13/2013	12/31/2020	AN INTERNATIONAL PHASE 3 RANDOMIZED TRIAL OF AUTOLOGOUS DENDRITIC CELL IMMUNOTHERAPY (AGS-003) PLUS STANDARD TREATMENT OF ADVANCED RENAL CELL CARCINOMA (ADAPT)	$31,258	$41,573	D3ET	100%	$31,258	$41,573
Huang CH Neupane PC	Celgene Corporation		10/31/2014	12/31/2020	A PHASE III, RANDOMIZED, OPEN-LABEL, CROSS-OVER, MULTI-CENTER, SAFETY AND EFFICACY STUDY TO EVALUATE NAB-PACLITAXEL (ABRAXANE) AS MAINTENANCE TREATMENT AFTER INDUCTION WITH NAB-PACLITAXEL PLUS CARBOPLATIN IN SUBJECTS WITH SQUAMOUS CELL	$18,086	$24,055	D3ET	100%	$9,043	$12,028
Johnson GA	NRG Oncology Foundation, Inc.		3/1/2014	12/31/2020	GOG STUDIES	$18,303	$24,343	D3ET	100%	$18,303	$24,343

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Kambhampati S	Celgene Corporation		10/29/2012	12/31/2021	A PHASE 2, MULTI-CENTER, RANDOMIZED, OPEN-LABEL, PARALLEL-GROUP STUDY OF A LENALIDOMIDE (REVLIMID) REGIMIN FOR A SEQUENTIAL AZACITICINE (VIDAZA) PLUS LENALIDOMIDE (REVLIMID) REGIMIN VERSUS AN AZACITICINE (VIDAZA) REGIMEN FOR THERAPY OF OLDER SUBJECTS	$77,575	$103,175	D3ET	100%	$77,575	$103,175
Karanicolas J	Inez Jay Fund		7/1/2014	6/30/2016	IDENTIFYING STABILIZERS OF P53 USING POCKET COMPLEMENTARITY	$28,000	$28,000	D3ET	100%	$28,000	$28,000
Khan QJ	Oncothyreon, Inc.		5/27/2014	12/31/2020	PHASE 1B, OPEN-LABEL STUDY TO ASSESS THE SAFETY AND TOLERABILITY OF ONT-380 COMBINED WITH ADO-TRASTUZUMAB EMTANSINE (T-DM1)	$86,276	$114,534	D3ET	100%	$86,276	$114,534
Lin TL	AbbVie, Inc.		1/27/2015	12/31/2020	A PHASE 1/2 STUDY OF ABT-199 IN COMBINATION WITH LOW-DOSE CYTARABINE IN TREATMENT-NAIVE SUBJECTS WITH ACUTE MYELOGENOUS LEUKEMIA WHO ARE >= 65 YEARS OF AGE AND WHO ARE NOT ELIGIBLE FOR STANDARD ANTHRACYCLINE-BASED INDUCTION THERAPY	$52,061	$69,176	D3ET	100%	$52,061	$69,176
Lin TL	Pfizer Inc		11/28/2012	12/31/2020	A PHASE 1B STUDY TO EVALUATE THE SAFETY AND PRELIMINARY EFFICACY OF PF-04449913, AN ORAL HEDGEHOG INHIBITOR, IN COMBINATION WITH INTENSIVE CHEMOTHERAPY, LOW DOSE ARA-C OR DECITABINE IN PATIENTS WITH ACUTE MYELOID LEUKEMIA OR HIGHRISK	$16,266	$21,634	D3ET	100%	$16,266	$21,634
Lin TL	Celator Pharmaceuticals Inc		10/6/2014	12/31/2020	AN OPEN LABEL PHASE II PHARMACOKINETIC AND PHARMACODYNAMIC ASSESSMENT OF THE POTENTIAL FOR QTC PROLONGATION FOLLOWING FIRST INDUCTION TREATMENT WITH CPX-351 (CYTARABINE: DAUNORUBICIN) LIPOSOME INJECTION IN ACUTE LEUKEMIAS AND MDS PATIENTS	$184,265	$245,007	D3ET	100%	$184,265	$245,007
Lin TL	Celator Pharmaceuticals Inc		3/8/2013	12/31/2020	PHASE III, MULTICENTER, RANDOMIZED, TRAIL OF CPX-351 (CYTARABINE:DAUNORUBICIN) LIPOSOME INJECTION VERSUS CYTARABINE AND DAUNORUBICIN IN PATIENTS 60-75 YEARS OF AGE WITH UNTREATED HIGH RISK (SECONDARY) AML	$25,503	$33,919	D3ET	100%	$25,503	$33,919

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
McGuirk JP	Astellas Pharma US, Inc.		10/31/2013	12/30/2020	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE 3 TRIAL TO EVALUATE THE PROTECTIVE EFFICACY AND SAFETY OF A THERAPEUTIC VACCINE, ASP0113, IN CYTOMEGALOVIRUS (CMV)-SEROPOSITIVE RECIPIENTS UNDERGOING ALLOGENEIC, HEMATOPOIETIC CELL TRANSPLANT (HCT)	$36,204	$48,151	D3ET	100%	$36,204	$48,151
McGuirk JP	Fresenius Biotech		2/6/2012	12/31/2020	A RANDOMIZED, PROSPECTIVE, DOUBLE BLIND, PLACEBOCONTROLLED, PHASE 3 STUDY OF US-ATG-F PROPHYLAXIS AS A SUPPLEMENT TO STANDARD OF CARE PROPHYLAXIS TO PREVENT MODERATE TO SEVERE CHRONIC GVHD IN ADULT ACUTE MYELOID LEUKEMIA, ACUTE LYMPHOID LEUKEMIA,	$43,777	$58,224	D3ET	100%	$43,777	$58,224
Neupane PC	Celgene Corporation		10/31/2014	12/31/2020	A PHASE III, RANDOMIZED, OPEN-LABEL, CROSS-OVER, MULTI-CENTER, SAFETY AND EFFICACY STUDY TO EVALUATE NAB-PACLITAXEL (ABRAXANE) AS MAINTENANCE TREATMENT AFTER INDUCTION WITH NAB-PACLITAXEL PLUS CARBOPLATIN IN SUBJECTS WITH SQUAMOUS CELL	$18,086	$24,055	D3ET	100%	$18,086	$24,055
Neupane PC	VentiRx Pharmaceuticals		2/11/2014	12/31/2020	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF CHEMOTHERAPY PLUS CETUXIMAB IN COMBINATION WITH VTX-2337 IN PATIENTS WITH RECURRENT OR METASTATIC SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK	$129,239	$171,887	D3ET	100%	$129,239	$171,887
Perez R	Millennium Pharmaceuticals Inc		9/13/2013	12/31/2020	A PHASE 1 PHARMACOKINETIC STUDY OF ORAL MLN9708 IN PATIENTS WITH ADVANCED SOLID TUMORS OR HEMATOLOGIC MALIGNANCIES WITH VARYING DEGREES OF LIVER DYSFUNCTION	$19,984	$26,579	D3ET	100%	$19,984	$26,579
Perez R	ImmunoGen, Inc		2/19/2014	12/31/2020	A PHASE 1, FIRST-IN-HUMAN STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS AND PHARMACODYNAMICS OF IMGN853 IN ADULTS WITH OVARIAN CANCER AND OTHER FOLR1-POSITIVE SOLID TUMORS	$131,534	$174,940	D3ET	100%	$131,534	$174,940

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Perez R	TetraLogic Pharmaceuticals Corporation		4/10/2014	12/31/2020	A PHASE 1B, OPEN-LABEL, NON-RANDOMIZED MULTICENTER STUDY OF BIRINAPANT IN COMBINATION WITH CONATUMUMAB IN SUBJECTS WITH RELAPSED EPITHELIAL OVARIAN CANCER, PRIMARY PERITONEAL CANCER OR FALLOPIAN TUBE CANCER	$106,076	$141,081	D3ET	100%	$106,076	$141,081
Perez R	Novartis Pharmaceuticals Corp		3/19/2014	3/19/2016	A PHASE IB, MULTI-CENTER, TWO PARALLEL GROUP, OPEN-LABEL, DRUG-DRUG INTERACTION STUDY TO ASSESS THE EFFECT OF LDE225 ON THE PHARMACOKINETICS OF BUPROPION AND WARFARIN IN PATIENTS WITH ADVANCED SOLID TUMORS	$111,347	$148,092	D3ET	100%	$111,347	$148,092
Perez R	Bristol-Myers Squibb Company		6/25/2012	12/31/2020	A PHASE IB, OPEN-LABEL, MULTICENTER STUDY OF BMS-936564 IN COMBINATION WITH LENALIDOMIDE (REVLIMID) PLUS LOW-DOSE DEXAMETHASONE, OR WITH BORTEZOMIB (VELCADE) PLUS DEXAMETHASONE IN SUBJECTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA	$52,690	$70,078	D3ET	100%	$52,690	$70,078
Perez R	Dompe s.p.a.		2/15/2013	12/31/2020	A SINGLE ARM, PREOPERATIVE, PILOT STUDY TO EVALUATE THE SAFETY AND BIOLOGICAL EFFECTS OF ORALLY ADMINISTERED REPARIXIN IN EARLY BREAST CANCER PATIENTS WHO ARE CANDIDATES FOR SURGERY	$50,843	$67,621	D3ET	100%	$50,843	$67,621
Perez R	Millennium Pharmaceuticals Inc		8/13/2013	12/31/2020	PHASE 1/1B PHARMACOKINETICS STUDY OF ORAL MLN9708 PLUS DEXAMETHASONE IN RELAPSED/REFRACTORY MULTIPLE MYELOMA PATIENTS WITH NORMAL RENAL FUNCTION OR SEVERE RENAL IMPAIRMENT	$30,178	$40,137	D3ET	100%	$30,178	$40,137
Perez R	Eli Lilly & Company		6/22/2012	12/31/2020	PHASE 2 STUDY TO EVALUATE THE PHARMACOKINETICS AND DRUG-DRUG INTERACTION OF CETUXIMAB AND CARBOPLATIN IN PATIENTS WITH RECURRENT OR METASTATIC CARCINOMA OF THE HEAD AND NECK	$89,372	$118,752	D3ET	100%	$89,372	$118,752
Perez R	Dompe s.p.a.		4/24/2013	12/31/2020	PHASE IB PILOT STUDY TO EVALUATE REPARIXIN IN COMBINATION WITH CHEMOTHERAPY WITH WEEKLY PACLITAXEL IN PATIENTS WITH HER-2 NEGATIVE METASTATIC BREAST CANCER (MBC)	$49,184	$65,415	D3ET	100%	$49,184	$65,415

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Raja V	Bristol-Myers Squibb Company		4/2/2014	12/31/2020	A PHASE IIIB-IV SAFETY TRIAL OF NIVOLUMAB (BMS-936558) IN SUBJECTS WITH ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER WHO HAVE PROGRESSED DURING OR AFTER RECEIVING AT LEAST ONE PRIOR SYSTEMIC REGIMEN	$121,510	$159,883	D3ET	100%	$121,510	$159,883
Rajewski R	Ligand Pharmaceuticals, Inc.		8/1/2012	3/31/2016	EVALUATING THE USEFULNESS OF CAPTISOL AS A CONSUMER PRODUCT ADDITIVE	$221,928	$221,928	D3ET	100%	$221,928	$221,928
Cancer Relevance: *Captisol is an excipient used to formulate liquid drug products containing active pharmaceutical ingredient with poor water solubility.*											
Schoeneich C	Genentech, Inc.		4/8/2014	3/31/2016	ANALYSIS OF LIGHT-INDUCED ANTIBODY AGGREGATES	$19,292	$30,000	D3ET	100%	$19,292	$30,000
Cancer Relevance: *This industry-sponsored research project is relevant to the characterization, stabilization and formulation of antibody-based biologics, including anticancer agents.*											
Schoeneich C	Genentech, Inc.		4/8/2014	7/31/2016	DETECTION AND MECHANISM OF D-AMINO ACID FORMATION	$165,611	$258,000	D3ET	100%	$165,611	$258,000
Cancer Relevance: *This industry sponsored research project characterizes the mechanism of D-amino acid formation and detection of these amino acids in biologic drug substance and product, and is directly relevant to biologics-based anticancer agents.*											
Schoeneich C	Genentech, Inc.		4/8/2014	7/31/2016	OXIDATIVE DEGRADATION OF POLYSORBATE	$154,093	$240,000	D3ET	100%	$154,093	$240,000
Cancer Relevance: *This industry-sponsored research project characterizes the mechanism of polysorbate oxidative degradation. Polysorborbate is a co-solvent commonly used in the formulation of small molecule and biologic drug products, including anticancer agents.*											
Sharma P	Conquer Cancer Foundation of ASCO		7/1/2015	6/30/2018	EVALUATION OF BRCANESS PHENOTYPE AS PROGNOSTIC MARKER IN TRIPLE-NEGATIVE BREAST CANCER UTILIZING SPECIMENS FROM SWOG 9313	$140,187	$150,000	D3ET	100%	$140,187	$150,000
Sharma P	Novartis Pharmaceuticals Corp		2/12/2015	12/31/2020	PHASE I/II STUDY OF BYL719 AND NAB-PACLITAXEL (ABRAXANE) IN PATIENTS WITH LOCALLY RECURRENT OR METASTATIC HER-2 NEGATIVE BREAST CANCER	$28,418	$32,641	D3ET	100%	$28,418	$32,641
Sharma P	Celgene Corporation		6/29/2015	12/31/2020	ROMIDEPSIN IN LOCALLY RECURRENT OR METASTATIC TRIPLE NEGATIVE BREAST CANCER	$36,458	$47,664	D3ET	100%	$36,458	$47,664
Van Veldhuizen PJ	Agensys, Inc.		9/24/2013	12/31/2020	A PHASE 1 STUDY OF THE SAFETY AND PHARMACOKINETICS OF ESCALATING DOSES OF ASG-22CE GIVEN AS MONOTHERAPY IN SUBJECTS WITH METASTATIC UROTHELIAL CANCER THAT EXPRESS NECTIN-4	$44,093	$58,644	D3ET	100%	$44,093	$58,644
Van Veldhuizen PJ	Altor Bioscience Corporation		11/19/2012	12/31/2020	A PHASE IB/II TRIAL OF ALT-801 IN COMBINATION WITH CISPLATIN AND GEMCITABINE IN MUSCLE INVASIVE OR METASTATIC UROTHELIAL CANCER	$31,473	$41,859	D3ET	100%	$31,473	$41,859
Van Veldhuizen PJ	Prometheus Laboratories, Inc.		7/31/2012	12/31/2020	PROLEUKIN OBSERVATIONAL REGISTRY TO EVALUATE THE TREATMENT PATTERNS AND CLINICAL RESPONSE IN MALIGNANCY	$30,902	$41,099	D3ET	100%	$30,902	$41,099
Volkin D Middaugh CR	Janssen Research and Development, LLC		7/24/2015	7/23/2017	EVALUATE THE FEASIBILITY OF DEVELOPING ULTRA-HIGH CONCENTRATION FORMULATION	$128,200	$200,000	D3ET	100%	$128,200	$200,000
Cancer Relevance: *This industry-sponsored research project evaluates the feasibility of developing ultra high concentration biotechnology-based drug products, and is directly relevant to the formulation of biotechnology-based anticancer agents.*											

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Volkin D Middaugh CR	Medimmune, Inc.		6/1/2009	9/15/2016	STABILITY AND DYNAMICS OF IMMUNOGLOBULINS	$891,978	$1,307,746	D3ET	100%	$891,978	$1,307,746
Cancer Relevance: *This industry-sponsored research project characterizes the stability of immunoglobulins, and is directly relevant to biologics-based anticancer agents.*											
Williamson SK	Daiichi Sankyo Pharma Development		3/22/2013	12/31/2020	A PHASE 3, RANDOMIZED, DOUBLE-BLIND STUDY OF TIVANTINIB (ARQ 197) IN SUBJECTS WITH MET DIAGNOSTIC-HIGH INOPERABLE HEPATOCELLULAR CARCINOMA (HCC) TREATED WITH ONE PRIOR SYSTEM THERAPY	$20,557	$27,341	D3ET	100%	$20,557	$27,341
Yacoub A	Gilead Sciences, Inc.		2/9/2015	12/31/2020	A PHASE 3, RANDOMIZED STUDY TO EVALUATE THE EFFICACY OF MOMELOTINIB VERSUS BEST AVAILABLE THERAPY IN ANEMIC OR THROMBOCYTOPENIC SUBJECTS WITH PRIMARY MYELOFIBROSIS, POST-POLYCYTHEMIA VERA MYELOFIBROSIS, OR POST-ESSENTIAL	$55,296	$73,478	D3ET	100%	$55,296	$73,478
Yacoub A	Celgene Corporation		10/15/2014	12/31/2020	A PHASE 3B RANDOMIZED STUDY OF LENALIDOMIDE (CC-5013) PLUS RITUXIMAB MAINTENANCE THERAPY FOLLOWED BY LENALIDOMIDE SINGLE-AGENT MAINTENANCE VERSUS RITUXIMAB MAINTENANCE IN SUBJECTS WITH RELAPSED/REFRACTORY FOLLICULAR,	$21,185	$28,175	D3ET	100%	$21,185	$28,175
Yacoub A	MEI Pharma, Inc.		7/30/2014	12/31/2020	A PHASE II OPEN-LABEL, SINGLE-ARM, TWO-STAGE, MULTICENTER TRIAL OF PRACINOSTAT IN COMBINATION WITH AZACITIDINE IN ELDERLY (AGE MORE THAN 65 YEARS) PATIENTS WITH NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA (AML)	$27,835	$37,021	D3ET	100%	$27,835	$37,021
Yacoub A	Janssen Research and Development, L.L.C.		9/24/2014	12/31/2020	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE 3 STUDY OF THE BRUTON'S TYROSINE KINASE INHIBITOR, PCI-32765 (IBRUTINIB), IN COMBINATION WITH EITHER BENDAMUSTINE AND RITUXIMAB (BR) OR RITUXIMAB, CYCLOPHOSPHAMIDE,	$32,978	$43,795	D3ET	100%	$32,978	$43,795
Yacoub A	Seattle Genetics, Inc.		8/16/2013	12/31/2020	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE 3 STUDY OF BRENTUXIMAB VEDOTIN AND CHP (A+CHP) VERSUS CHOP IN THE FRONTLINE TREATMENT OF PATIENTS WITH CD30-POSITIVE MATURE T-CELL LYMPHOMAS	$29,028	$36,339	D3ET	100%	$29,028	$36,339
Yacoub A	Millennium Pharmaceuticals Inc		12/12/2013	12/31/2020	A RANDOMIZED, OPEN-LABEL, PHASE 3 TRIAL OF A+AVD VERSUS ABVD AS FRONTLINE THERAPY IN PATIENTS WITH ADVANCED CLASSICAL HODGKIN LYMPHOMA	$75,529	$100,454	D3ET	100%	$75,529	$100,454

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Yacoub A	Incyte Corporation		7/16/2013	12/31/2020	POLYCYTHEMIA VERA SYMPTOM STUDY EVALUATING RUXOLITINIB VERSUS HYDROXYUREA IN A RANDOMIZED, MULTICENTER, DOUBLE-BLIND, DOUBLE-DUMMY, PHASE 3 EFFICACY AND SAFETY STUDY OF PATIENT REPORTED OUTCOMES	$29,796	$39,628	D3ET	100%	$29,796	$39,628
Yacoub A	Myeloproliferative Disorders-Research Co		3/4/2015	12/31/2020	SINGLE ARM SALVAGE THERAPY WITH PEGYLATED INTERFERON ALFA-2A FOR PATIENTS WITH HIGH RISK POLYCYTHEMIA VERA OR HIGH RISK ESSENTIAL THROMBOCYTHEMIA WHO ARE EITHER HYDROXYUREA RESISTANT OR INTOLERANT OR HAVE HAD A ABDOMINAL VEIN THROMBOSIS	$16,917	$22,500	D3ET	100%	$16,917	$22,500
					Non-Peer-Reviewed Research Subtotals:					**$4,471,303**	**$5,901,639**
								D3ET Grand Totals		**$10,973,331**	**$15,024,785**

PEER-REVIEWED TRAINING PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Hagenbuch B	NIEHS	5T32ES007079-35	7/1/1979	6/30/2017	TRAINING PROGRAM IN ENVIRONMENTAL TOXICOLOGY	$310,062	$332,910	D3ET	100%	$310,062	$332,910
Cancer Relevance (ES007079): *Consistent with KUCC's vision to train the next generation of leaders in cancer research, clinical care, and advocacy, the Toxicology Training Program (TTP) at KUMC is recognized internationally as a Center of Excellence for training in toxicology. The TTP has trained over 300 students in toxicological sciences over the past 30 years. It continues today through modernized training, improved recruitment of students, updated courses, expansion of participating faculty, and increased exposure to outside leaders and opportunities in the field.*											
Pesseto Z Mentor: (Godwin AK) Barohn RJ	NCATS	5KL2TR000119-05	3/1/2014	2/28/2017	HEARTLAND INSTITUTE FOR CLINICAL AND TRANSLATIONAL RESEARCH (A MULTI-PRONGED DRUG REPURPOSING APPROACH TO DEVELOP INDIVIDUALIZED THERAPIES FOR EWING SARCOMA)	$73,989	$73,989	D3ET	100%	$73,989	$73,989
Prisinzano TE Lamb AL	NIGMS	2T32GM008545-22	7/1/1994	6/30/2020	TRAINING GRANT IN DYNAMIC ASPECTS OF CHEMICAL BIOLOGY	$347,360	$364,909	D3ET	100%	$347,360	$364,909
Cancer Relevance (GM008545): *Consistent with KUCC's vision to train the next generation of leaders in cancer research, clinical care, and advocacy, the doctoral training program in the Dynamic Aspects of Chemical Biology at KU aims to educate doctoral graduates across the chemistry biology interface. Trainees gain exposure to modern experimental techniques and theories in disciplines across the chemical biology interface and are fully prepared to embark on careers in contemporary chemical biology. Trainees are placed in team science environments to solve chemical biology problems across scientific disciplines. Student projects span a wide array of disease states and health issues, including cancer, diabetes, heart disease, pathogenic microbes and antimicrobials/antibiotics, Alzheimer's and Parkinson's disease, and addiction.*											
Siahaan TJ Volkin D	NIGMS	5T32GM008359-25	9/27/1989	6/30/2019	PHARMACEUTICAL ASPECTS OF BIOTECHNOLOGY	$324,643	$342,192	D3ET	100%	$324,643	$342,192
Cancer Relevance (GM008359): *Consistent with KUCC's vision to train the next generation of leaders in cancer research, clinical care, and advocacy, this program trains pharmaceutical scientists to develop products arising from biotechnology research, i.e., therapeutic drugs and vaccines. This program has been in existence for 26 years, training a new breed of pharmaceutical scientists who employ interdisciplinary approaches to solving difficult problems in characterizing, stabilizing and formulating biotechnology products. The major areas of emphasis for this training program include traditional pharmaceutics (formulation, analytical chemistry, and drug delivery), protein structure and bioinformatics, and vaccine stabilization and formulation. Students participating in this two-year program are required to complete a 3-6 month industrial internship.*											

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Lin TL	NCI	5K23CA158146-04	8/18/2012	7/31/2016	CHEMOTHERAPY RESISTANCE IN ALL: ROLE OF THE BONE MARROW MICROENVIRONMENT	$162,000	$174,960	D3ET	100%	$162,000	$174,960
Peterson B	ACS		8/1/2015	7/31/2016	MEDICINAL CHEMISTRY PREDOCTORAL FELLOWSHIP	$26,000	$26,000	D3ET	100%	$26,000	$26,000
Peterson B	NIGMS	5K12GM063651-14	7/1/2001	7/31/2017	UNIVERSITY OF KANSAS/HASKELL INDIAN NATIONS UNIVERSITY IRACDA PROJECT	$481,796	$518,455	D3ET	100%	$481,796	$518,455
Cancer Relevance (GM063651): *Consistent with KUCC's vision to train the next generation of leaders in cancer research, clinical care, and advocacy, the Institutional Research and Academic Career Development Award Project (IRACDA) introduces at the Haskell Indian Nations University, Lawrence, KS, to career opportunities in chemistry. Building upon the established partnership between KU and Haskell Indian Nations University, IRACDA combines mentored research training at KU with the opportunity to develop teaching skills in a neighboring tribal college. Three American Indians currently serve as role models and mentors for Haskell students in the sciences. Three American Indians, who have successfully completed the training program, currently serve as role models and mentors for Haskell students in the sciences. IRACDA combines mentored research training at KU with the opportunity to develop teaching skills in a neighboring tribal college. The award will support a total of fifteen postdoctoral IRACDA scholars.*										
					Peer-Reviewed Training Subtotals:	$1,725,850	$1,833,415			**$1,725,850**	**$1,833,415**

CHILDREN'S MERCY NON-PEER-REVIEWED PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Chastain K	Braden's Hope Foundation		8/30/2015	9/1/2016	IN VITRO AND IN VIVO TESTING OF THREE NOVEL COMPOUNDS IN PEDIATRIC RHABDOMYOSARCOMA	$193,000	$193,000	D3ET	100%	$193,000	$193,000
					Non-PeerReviewed Research Totals:	$193,000	$193,000			**$193,000**	**$193,000**

CHILDREN'S MERCY PEER-REVIEWED TRAINING PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Program Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Leeder JS	NICHD	2T32HD069038-06	5/1/2011	4/30/2017	CHILDREN'S MERCY HOSPITAL COLLABORATIVE FELLOWSHIP PROGRAM IN PEDIATRIC PHARMACOLOGY	$134,764	$108,186	D3ET	100%	$134,764	$108,186
					Peer-Reviewed Training Totals:	$134,764	$108,186			**$134,764**	**$108,186**

Table 2 – Program Members

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Abhyankar	Sunil	Internal Medicine - Clinical Oncology	University of Kansas Medical Center, Kansas City, KS	Professor	Associate
August	Keith	Pediatric Hematology/Oncology	Children's Mercy	Assistant Professor of Pediatrics; Director - Leukemia & Lymphoma Program	Full
Baltezor	Michael	Director, Lead Development and Optimization Shared Resource	University of Kansas, Lawrence, KS	Director	Full
Balusu	Ramesh	Internal Medicine	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Associate
Berkland	Cory	Chemical & Petroleum Engineering	University of Kansas, Lawrence, KS	Professor	Associate
Blagg	Brian	Medicinal Chemistry	University of Kansas, Lawrence, KS	Professor	Full
Chastain	Kate	Pediatric Hematology/Oncology	Children's Mercy Kansas City, Kansas City, MO	Assistant Professor	Associate
Chen	Qi	Pharmacology	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full
Chennathukuzhi	Vargheese	Molecular & Integrative Physiology	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Clough	Lisa	Infectious Diseases	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full
Dakhil	Shaker	Cancer Center	University of Kansas, Wichita, KS	Professor	Associate
Drisko	Jeanne	Integrative Medicine	University of Kansas Medical Center, Kansas City, KS	Riordan Endowed Professor of Orthomolecular Medicine	Associate
Flatt	Terrie	Pediatrics	Children's Mercy Kansas City, Kansas City, MO	Director; Assistant Professor of Pediatrics	Full
Forrest	Marcus	Pharmaceutical Chemistry	University of Kansas, Lawrence, KS	Assistant Professor	Full
Gamis	Alan	Pediatrics	Children's Mercy Kansas City, Kansas City, MO	Professor	Full
Godwin	Andrew	Pathology and Laboratory Medicine	University of Kansas Medical Center, Kansas City, KS	Professor and Director of Molecular Oncology	Full
Guest	Erin	Pediatrics	Children's Mercy Kansas City, Kansas City, MO	Assistant Professor	Full
Hagenbuch	Bruno	Pharmacology, Toxicology and Therapeutics	University of Kansas Medical Center, Kansas City, KS	Professor & Vice Chair	Full
Hanzlik	Robert	Medicinal Chemistry	University of Kansas, Lawrence, KS	Professor	Full

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Holzbeierlein	Jeffrey	Institute for Reproductive Health and Regenerative Medicine; Urology Surgery	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full
Kambhampati	Suman	Hematology/Oncology	University of Kansas Medical Center, Kansas City, KS	Clinical Associate Professor	Associate
Karanicolas	John	Molecular Biosciences, Center for Bioinformatics	University of Kansas, Lawrence, KS	Assistant Professor	Associate
Lamb	Audrey	Molecular Biosciences	University of Kansas, Lawrence, KS	Associate Professor	Associate
Leeder	Steven	Pharmacology, Toxicology & Therapeutics AND Children's Mercy	University of Kansas Medical Center, Kansas City, KS	Adjunct Professor	Full
Li	Benyi	Institute for Reproductive Health and Regenerative Medicine; Urology Surgery	University of Kansas Medical Center, Kansas City, KS	Associate Professor; Director of Basic Science Research	Full
Lin	Tara	Internal Medicine/Hematology & Hematology	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full
Madan	Rashna	Pathology and Laboratory Medicine	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Associate
Mammen	Joshua	Preventive Medicine and Public Health	University of Kansas Medical Center, Kansas City, KS	Assistant Professor & Associate Director of Functional MRI	Full

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
McGuirk	Joseph	Hematology/Oncology	University of Kansas Medical Center, Kansas City, KS	Professor and Interim Division Director	Full
Middaugh	Charles	Pharmaceutical Chemistry	University of Kansas, Lawrence, KS	Distinguished Professor	Full
Mirza	Moben	Urology Surgery	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full
Mitchell	Melissa	Radiation Oncology - School of Medicine	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Full
Myers	Gary	Pediatric Hematology/Oncology	Children's Mercy Kansas City, Kansas City, MO	Associate Professor	Full
Neupane	Prakash	Hematology/Oncology	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Associate
Pathak	Harsh	Pathology & Laboratory Medicine	University of Kansas Medical Center, Kansas City, KS	Research Assistant Professor	Associate
Perez	Raymond	Internal Medicine	University of Kansas Medical Center, Kansas City, KS	Professor	Full
Peterson	Blake	Medicinal Chemistry	University of Kansas, Lawrence, KS	Regents Distinguished Professor	Associate

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Prisinzano	Thomas	Medicinal Chemistry	University of Kansas, Lawrence, KS	Chairperson-Professor	Associate
Rajewski	Roger	Pharmaceutical Chemistry	University of Kansas, Lawrence, KS	Research Professor	Full
Rao Manepalli	Rekha	Cancer Center	University of Kansas Medical Center, Kansas City, KS	Research Assistant Professor	Full
Reed	Gregory	Pharmacology, Toxicology and Therapeutics	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Full
Richter	Mark	Molecular Biosciences	University of Kansas, Lawrence, KS	Chairperson-Professor	Associate
Roy	Anuradha	Biomedical Services Labs	University of Kansas, Lawrence, KS	Director	Full
Schoeneich	Christian	Pharmaceutical Chemistry	University of Kansas, Lawrence, KS	Distinguished Professor/Chair	Full
Schoenen	Frank	Structural Biology Center	University of Kansas, Lawrence, KS	Senior Investigator	Associate
Scott	Emily	Medicinal Chemistry	University of Kansas, Lawrence, KS	Professor	Full
Sharma	Priyanka	Hematology/Oncology	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Associate
Siahaan	Teruna	Pharmaceutical Chemistry	University of Kansas, Lawrence, KS	Professor	Associate

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Thrasher	James	Institute for Reproductive Health and Regenerative Medicine; Urology Surgery	University of Kansas Medical Center, Kansas City, KS	Professor; Professor and Chair	Full
Timmermann	Barbara	Medicinal Chemistry	University of Kansas, Lawrence, KS	Distinguished Professor	Associate
Tolbert	Thomas	Pharmaceutical Chemistry	University of Kansas, Lawrence, KS	Associate Professor	Full
Tunge	Jon	Chemistry	University of Kansas, Lawrence, KS	Professor	Associate
Volkin	David	Pharmaceutical Chemistry	University of Kansas, Lawrence, KS	Distinguished Professor	Full
Wang	Fen	Radiation Oncology - School of Medicine	University of Kansas Medical Center, Kansas City, KS	Associate Professor	Associate
Weir	Scott	Pharmacology	University of Kansas Medical Center, Kansas City, KS	Professor	Full
Wick	Jo	Biostatistics	University of Kansas Medical Center, Kansas City, KS	Assistant Professor	Associate
Williamson	Stephen	Hematology/Oncology	University of Kansas Medical Center, Kansas City, KS	Professor	Full
Xu	Liang	Molecular Biosciences	University of Kansas, Lawrence, KS	Associate Professor	Full

Last Name	First Name	Department	Institution	Academic Rank	Role in Program
Yacoub	Abdulraheem	Hematology/Oncology	University of Kansas Medical Center, Kansas City, KS	MD	Full
Zeng	Yong	Chemistry	University of Kansas, Lawrence, KS	Assistant Professor	Full

Table 3 – Shared Resource Usage

Shared Resource	Number of program members using the shared resource	Percentage of shared resource usage by program members
Biospecimen (BSR)	19	43%
Biostatistics & Informatics (BISR)	12	21%
Lead Development & Optimization (LDOSR)	23	55%
Transgenic & Gene-Targeting (TGTSR)	3	12%
Clinical Pharmacology (CPSR)	11	52%

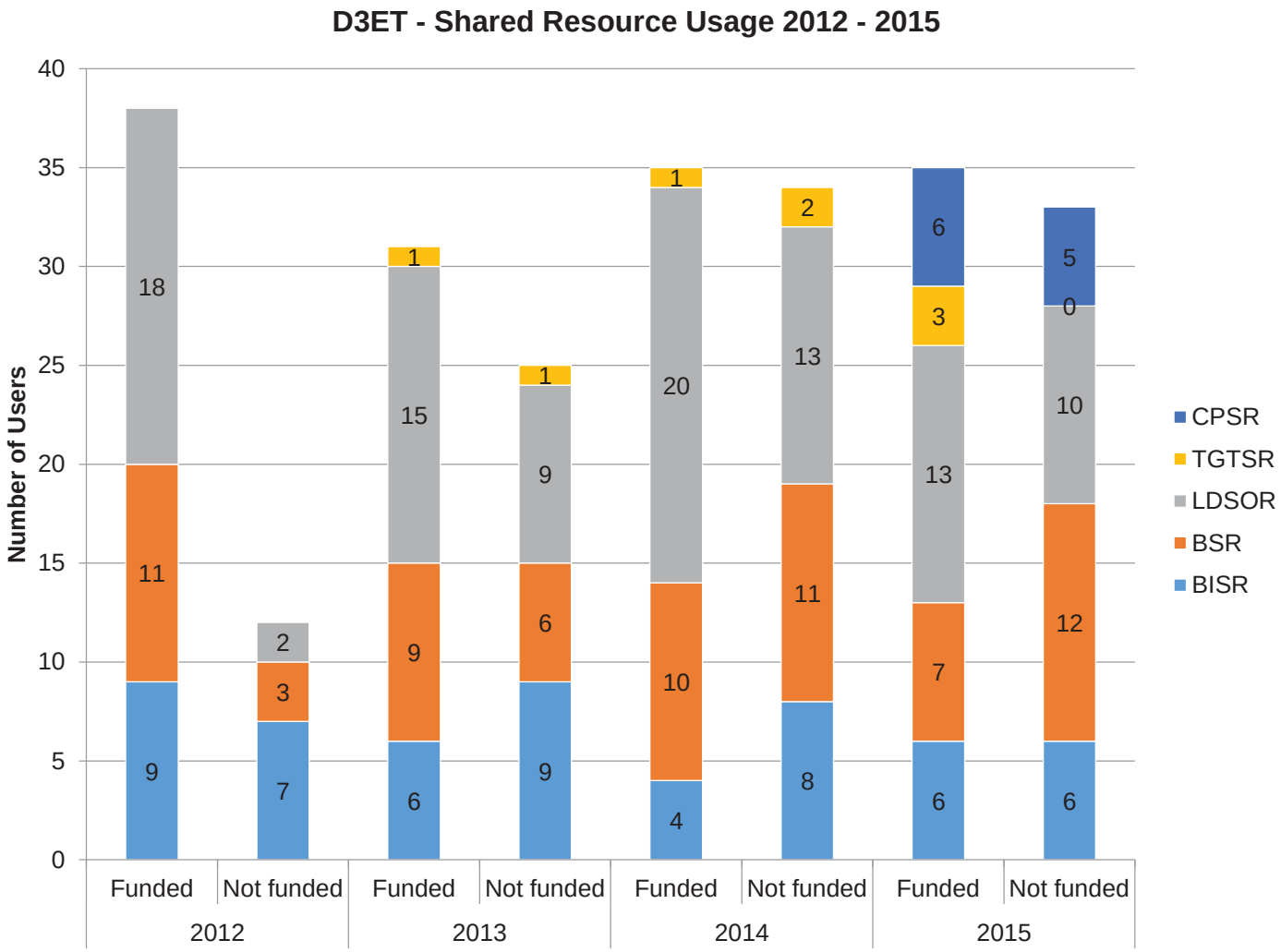

Table 4 – Programmatic Activities

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
2011				
Programmatic	12/16/11	KUCC	Scott Weir Kapil Bhalla Andrew Godwin	D3ET program and project presentation organization
Programmatic	2/11-12/11 Monthly	KUCC	Ray Perez Scott Weir	Integration of drug discovery and development with early phase clinical trials
Project	1/11-12/11 Monthly	Silvergate CM KUCC	Tyce Bruns Michael Beckloff Michael Baltezor	Public-private partnership to develop pediatric oral liquid formulation of 6MP
Project	1/11-12/11 Monthly	KSU KUCC MCA	Stephan Bossmann Tyce Bruns	Integration of cancer diagnostics platform developed at KSU with KUCC clinical programs
Project	1/11-12/11 Monthly	LLS NCATS KUCC	James Kasper Sitta Sittampalam Kevin Schorno Scott Weir	Monthly management of project activities across the three partner organizations comprising The Learning Collaborative as well as clinical trial activities at NHLBI and The Ohio State University Comprehensive Cancer Center
Project	1/11-12/11 Monthly	Scripps Institute KUCC	Dale Boger George Vielhauer Scott Weir Michael Baltezor Melinda Broward	Monthly management of drug discovery activities supporting selection of optimized lead candidates for advancement to in vivo proof of principle in validated mouse models of prostate cancer
Project	1/11-12/11 Monthly	KUMC KU Hospital KUCC	Ossama Tawfik Fang Fan Brian Potetz Scott Weir Robyn Wood	Monthly management of product development activities to create and advance TelePAPology medical device. Telepapology is a product that enables digital evaluation of cell block preparations of liquid-based and conventional Pap smears. Product development was supported by IAMI.
Project	1/11-10/11 Monthly	KUCC KU	Nikki Cheng Sarah Kieweg Terry Faddis Scott Weir Robyn Wood	Monthly management of product development activities to create and advance a microfluidics device to model cancer cell behavior. Product development was supported by IAMI.
Project	1/11-12/11 Monthly	KUCC KUMC KU	Lisa Harlan-Williams Roy Jensen Scott Weir Jeff Aube Frank Schoenen Michael Baltezor Melinda Broward	Monthly management of integrated drug discovery activities across campuses focused on discovering BRCA-1 activators. R03 award supported large scale HTS screen conducted at NCATS. Drug discovery activities were supported by IAMI.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Project	1/11-12/11 Monthly	KUCC	Barbara Timmermann Mark Cohen Abbas Samadi Betha Aswini Motiwala Hashim Robert Gollapudirao Hauaping Zhang Michael Baltezor Melinda Broward	Monthly management of integrated drug discovery activities across campuses focused on discovering withanolide natural product derived compounds with anticancer activities. Drug discovery activities were supported by IAMI.
Project	2011 Quarterly	SIMR KUCC	Sitta Sittampalam Anu Roy Linheng Li John Perry Scott Weir Melinda Broward	Quarterly management of integrated drug discovery activities across KUCC consortium members focused on discovering Wnt-PTEN dual pathway inhibitors to eliminate leukemic stem cells. Drug discovery activities were supported by a grant provided by the Kansas Bioscience Authority.
Project	2011 Quarterly	KUCC	Kurt Klassen Rathnam Chaguturu Anu Roy Peter MacDonald Scott Weir Sitta Sittampalam Melinda Broward	Quarterly management of integrated drug discovery activities across campuses focused on discovering NRF2 inhibitors as anticancer agents. Drug discovery activities were supported by a peer-reviewed grant.
Project	1/11, 6/11, 7/11	KUCC	James Calvet Anu Roy Michael Baltezor Melinda Broward Kevin Schorno	Management of integrated drug discovery activities across campuses focused on determining preclinical proof of principle of lonidamine analogs in validated animal models of PKD.
2012				
Programmatic	4/6/12	KUCC	Ross Stein	Program meeting introducing the Lab for Early Stage Translational Research and opportunities to access KUCC developmental funds enabling drug discovery projects.
Programmatic	11/8/12	KUCC	Ross Stein Jeff Aube Michael Baltezor Suman Kambhampati Scott Weir	Program meeting introducing drug discovery and delivery capabilities to program meetings. The Learning Collaborative, a partnership between KUCC, NCATS and LLS, was also introduced to program members.
Programmatic	2/12-12/12 Monthly		Ray Perez Scott Weir	Integration of drug discovery and development with early phase clinical trials
Programmatic	2/12-11/12 Monthly	KUCC UCCC	Laura Simon Tyce Bruns Scott Weir	Monthly review of progress in establishing and advancing collaborative cancer projects with the UCCC including their consortium members Denver Children's Hospital, and Colorado State University (CSU) Flint Animal Cancer Center.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Programmatic	2/12-11/12 Quarterly	KUCC CSU	Rod Page Doug Thamm Tyce Bruns Scott Weir	Quarterly implementation meetings to establish collaborative comparative oncology projects between CSU and KUCC in Diffuse Large B Cell Lymphoma and Osteosarcoma.
Project	1/12-12/12 Monthly	NCATS CM	Sitta Sittampalam Kathleen Neville Tyce Bruns Andrew Godwin Scott Weir	Monthly review of sarcoma research projects enabled and facilitated by The Sarcoma Learning Collaborative, a partnership between NCATS, Children's Mercy Kansas City, and KUCC.
Project	1/12-12/12 Monthly	KSU KUCC MCA	Stephan Bossmann Tyce Bruns	Integration of cancer diagnostics platform developed at KSU with KUCC clinical programs.
Project	1/12-12/12 Monthly	LLS NCATS KUCC	James Kasper Sitta Sittampalam Kevin Schorno Scott Weir	Monthly management of project activities across the three partner organizations comprising The Learning Collaborative as well as clinical trial activities at NHLBI and The Ohio State University Comprehensive Cancer Center.
Project	2012 Quarterly	KUCC CM PTN	Kathleen Neville Tyce Bruns Mike Baltezor Scott Weir	Quarterly management of collaborative project in which LDOSR developed an oral, pediatric liquid formulation of hydroxyurea for use in a multicenter clinical trial in Sickle Cell Anemia patients conducted by the Pediatric Trial Network (Duke University).
Project	1/12-12/12 Monthly	KUMC KUH KUCC	Ossama Tawfik Fang Fan Brian Potetz Scott Weir Robyn Wood	Monthly management of product development activities to create and advance TelePAPology medical device. Telepapology is a product that enables digital evaluation of cell block preparations of liquid-based and conventional Pap smears. Product development was supported by IAMI.
Project	6/12-12/12 Monthly	KUCC KU	Scott Weir Robyn Wood Shri Anant Greg Reed Jeff Holzbeierlein Michael Baltezor	Monthly management of project activities across campuses and contract research organizations supporting development of Ciclopirox Prodrug (CPX-POM) as an anticancer agent. Product development was supported by IAMI.
Project	8/12-10-12 Monthly	KUCC OCI	Aaron Schimmer Robyn Wood Michael Baltezor Scott Weir	Development and submission of a Therapeutics for Rare and Neglected Diseases (NCATS) grant submission, describing CPX-POM for the treatment of AML.
Project	2012 Quarterly	SIMR KUCC	Sitta Sittampalam Anu Roy Linheng Li John Perry Scott Weir Melinda Broward	Quarterly management of integrated drug discovery activities across KUCC consortium members focused on discovering Wnt-PTEN dual pathway inhibitors to eliminate leukemic stem cells. Drug discovery activities were supported by a grant provided by the Kansas Bioscience Authority.
Project	2012 Quarterly	KUCC KU KUMC	Bruno Hagenbuch Barbara Timmermann Melinda Broward	Quarterly management collaborative drug discovery project focused on identifying natural products that are substrates for the OATP family of transporters.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Project	9/5/12	KUCC KU KUMC	Dan Dixon Ray Perez Anu Roy Ross Stein Melinda Broward	Kickoff meeting to initiate inter-programmatic collaboration funded by KUCC Pilot award to develop, validate and conduct HTS in support of identifying compounds that are substrates for colorectal cancer prevention targets including COX2.
Project	1/12-12/12 Monthly	KUCC KUMC KU	Lisa Harlan-Williams Roy Jensen Scott Weir Jeff Aube Frank Schoenen Michael Baltezor Melinda Broward	Monthly management of integrated drug discovery activities across campuses focused on discovering BRCA-1 activators. R03 award supported large scale HTS screen conducted at NCATS. Drug discovery activities were supported by IAMI.
Project	11/12-12/12 Weekly	KUCC KU KUMC	Andrew Godwin Scott Weir Anu Roy Melinda Broward Ziyan Pessetto Tyce Bruns	Weekly management of HTS activities focused on evaluating the LDOSR compound libraries in novel Ewings sarcoma target identified by D3ET member Godwin.
Project	7/12-8/12 Weekly	KUCC KU KUMC	Barbara Timmermann Mark Cohen Abbas Samadi Betha Aswini Motiwala Hashim Robert Gollapudirao Hauaping Zhang Michael Baltezor Melinda Broward	Weekly project team meetings to select optimized lead candidate from family withanolide natural product analogs with anticancer activities. Drug discovery activities were supported by IAMI.
Programmatic	4/30/12	NCATS KUCC KU KUMC	Sitta Sittampalam Scott Weir	Program meeting hosting NCATS to introduce their capabilities and programs available to D3ET members. Presentation was entitled “Translational Sciences at the NIH: Therapeutics for Rare and Neglected Diseases (TRND) and Bridging the Gaps in Translational Research (BrIDGs) Programs”.
2013				
Programmatic	12/6/13	KUCC	Jeff Aube’	Program meeting scientific presentation by D3ET Co-Leader entitled “Probes of GTPases”.
Programmatic	11/7/13	KUCC	Jeff Aube’ Ray Perez	Program meeting to roll out D3ET Pilot Project program to members with emphasis on intra- and inter-programmatic collaboration.
Programmatic	1/13-12/13 Quarterly	CSU KUCC	Rod Page Doug Thamm Tyce Bruns Scott Weir	Quarterly implementation meetings to establish collaborative comparative oncology projects between CSU and KUCC in Diffuse Large B Cell Lymphoma and Osteosarcoma.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Project	1/13-12/13 Monthly	NCATS CM KUCC	Sitta Sittampalam Kathleen Neville Tyce Bruns Andrew Godwin Scott Weir	Monthly review of sarcoma research projects enabled and facilitated by The Sarcoma Learning Collaborative, a partnership between NCATS, Children's Mercy Kansas City, and KUCC.
Project	4/1-12/13 Monthly	CM CSU	Joy Fulbright Kathleen Neville Scott Weir Tomoo Iwakuma Doug Thamm Anu Roy Melinda Broward Tyce Bruns	Monthly management of Midwest Cancer Alliance funded comparative oncology project in osteosarcoma, focused on rediscovery and repurposing of FDA approved drugs in canine and human Osteosarcoma.
Programmatic	2/13	POETIC KUCC CM	Kathleen Neville Tyce Bruns Scott Weir	Presentation of KUCC Drug Discovery and Development capabilities to Pediatric Oncology Experimental Therapeutics Investigators Consortium national meeting hosted by CM.
Project	1/13-12/13 Monthly	KSU KUCC MCA	Stephan Bossmann Tyce Bruns	Integration of cancer diagnostics platform developed at KSU with KUCC clinical programs.
Project	1/13-12/13 Monthly	LLS NCATS KUCC	James Kasper Sitta Sittampalam Kevin Schorno Scott Weir	Monthly management of project activities across the three partner organizations comprising The Learning Collaborative as well as clinical trial activities at NHLBI and The Ohio State University Comprehensive Cancer Center.
Project	4/13-12/13 Monthly	KUCC KU KUMC CM University of Alberta NCATS Kevin Gray Foundation	Scott Weir Kathleen Neville Joy Fulbright Sitta Sittampalam Naren Narendran Anu Roy Melinda Broward Tyce Bruns	Monthly management of drug rediscovery and repurposing of FDA approved drugs for the treatment of Rhabdomyosarcoma. This project was and continues to be supported by the Kevin Gray Foundation, a Kansas City philanthropic organization supporting KUCC's efforts to identify and advance new treatments for this sarcoma.
Project	5/1/13	UNMC KUCC KU KUMC	Melanie Simpson Joseph Barycki Anu Roy Melinda Broward	Kickoff meeting to plan development of a HTS assay to support cancer research activities at the NCI Cancer Center at the University of Nebraska Medical Center. The screen focused on identifying compounds that modulate UGDH.
Project	1/13-12/13 Monthly	KUMC KU Hospital KUCC	Ossama Tawfik Fang Fan Brian Potetz Scott Weir Robyn Wood	Monthly management of product development activities to create and advance TelePAPology medical device. Telepapology is a product that enables digital evaluation of cell block preparations of liquid-based and conventional Pap smears. Product development was supported by IAMI.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Project	6/13-12/13 Monthly	KUCC KU	Scott Weir Robyn Wood Shri Anant Greg Reed Jeff Holzbeierlein Michael Baltezor	Monthly management of project activities across campuses and contract research organizations supporting development of Ciclopirox Prodrug (CPX-POM) as an anticancer agent. Product development was supported by IAMI.
Programmatic	6/13-12/13 Monthly	KUMC KUCC KU	Shri Anant Scott Weir Jeff Aube Frank Schoenen Dan Dixon Liang Xu Kristi Neufeld Shahid Umar Prahbu Ramamoorthy Melinda Broward Robyn Wood	Monthly management of collaborative cancer research and drug discovery activities focused on identifying compounds that inhibit binding of RNA proteins. Supported by KUCC developmental funds, this effort is focused on enabling and facilitating collaborations focused on RNA binding proteins to strengthen multi-PI R01 applications leading to the development of competitive SPORE applications. Associate Directors Anant (Cancer Prevention) and Weir (Translational Research) co-lead this effort.
Project	11/13-12/13 Weekly	KUCC UMKC Whiteboard to Boardroom Avon Foundation	Roy Jensen Scott Weir Robyn Wood James Baxendale Andrew Godwin Qamar Khan IAMI Advisory Board members Mike Webb and Mike Powell	Weekly management of grant development activities responding to the Avon Breast Cancer Challenge RFA. The collaborative grant application outlined product development activities necessary to develop and commercialize a breast cancer diagnostic test to predict responders to taxane therapy.
Project	7/13-10/13 Weekly	KUCC KUMC KU UCHSC	Scott Weir Shrikant Anant Michael Baltezor Robyn Wood John Taylor	Weekly management of the development of a NCATS TRND grant application seeking support to develop CPX-POM for the treatment of high risk non-muscle invasive bladder cancer. This application was developed in collaboration with John Taylor at University of Connecticut Health Sciences Center.
Project	6/13-7/13 Weekly	KUCC KUMC	Rekha Rao-Manepalli Shri Anant Robyn Wood Scott Weir	Weekly management of LLS Quest for Cures grant application seeking funding to support “Modeling the bone marrow microenvironment for Leukemia research”.
Programmatic	3/13, 8/13	KUCC IAMI	Dan Welch Scott Weir Shri Anant Andrew Godwin Roy Jensen	Biannual meeting organized by Associate Directors Welch (Basic Research) and Weir (Translational Research) to enable and facilitate chemistry/biology collaborations across Cancer Biology and D3ET programs.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Programmatic	1/13, 12/13	KUCC KU KUMC	Andrew Godwin Jeremy Chien Rhonda Johnson Kathy Roby Gary Johnson Harsh Pathak Scott Weir Brooke Fridley Melinda Broward	Biannual meeting co-led by Jeremy Chien and KUCC Deputy Director Andrew Godwin to enable and facilitate collaborative research projects focused on discovery and development of new treatments for ovarian cancer. Organized by Chien and Godwin, the Ovarian Cancer Learning Collaborative is supported by KUCC developmental funds.
Programmatic	8/13,11/13	SIMR CM KUCC KU KUMC	Ali Shilatifard Erin Guest Anu Roy Darren Wilson Scott Weir Melinda Broward Alan Gamis Keith August	Led by Associate Director Weir, KUCC developmental funds were used to support collaborations across consortium members leading to development and submission of multi-PI R01 applications focused on pediatric hematologic malignancies.
Programmatic	1/13-12/13 Monthly	KUCC KU KUMC	James Calvet Alan Yu Darren Wallace Michael Baltezor Scott Weir Anu Roy Melinda Broward	Monthly meetings to identify and advance collaborative research focused on drug discovery, delivery and development of new therapeutics for PKD. D3ET capabilities serve as Core 4 of the awarded P30 grant to establish the PKD Center.
Project	10/13-11/13 Bi-Monthly	KUCC KUMC Cardinal Health	James Calvet Alan Yu Mireilli El Ters Scott Weir Melinda Broward	Inter-programmatic collaboration to design and initiate experimental therapeutics trial evaluating Nicotinamide in PKD patients. Pilot data generated from this trial enabled R21 award for expanded experimental therapeutics trial.
Project	2013 Quarterly	SIMR KUCC	Sitta Sittampalam Anu Roy Linheng Li John Perry Scott Weir Melinda Broward Alan Gamis Erin Guest Keith August Tara Lin Ray Perez	Quarterly management of integrated drug discovery activities across KUCC consortium members focused on discovering Wnt-PTEN dual pathway inhibitors to eliminate leukemic stem cells. Results from the HTS assay identified that antracyclines, in low concentrations, act as dual pathway inhibitors. Pediatric and adult hematologists and oncologists were engaged to develop a translational research strategy to advance this treatment concept to pediatric and adult blood cancer patients.
Project	2013 Quarterly	KUCC KU KUMC	Dan Dixon Ray Perez Anu Roy Ross Stein Melinda Broward	Quarterly management meetings to discover lead candidates as substrates for colorectal cancer prevention targets including COX2.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Project	2/13, 5/13	KUCC KU KUMC	Barbara Timmermann Mark Cohen Abbas Samadi Betha Aswini Motiwala Hashim Robert Gollapudirao Hauaping Zhang Michael Baltezor Melinda Broward	Weekly project team meetings to select optimized lead candidate from family withanolide natural product analogs with anticancer activities. Drug discovery activities were supported by IAMI.
Project	1/13-12/13 Monthly	KUCC KUMC KU	Lisa Harlan-Williams Roy Jensen Scott Weir Jeff Aube Frank Schoenen Michael Baltezor Melinda Broward	Monthly management of integrated drug discovery activities across campuses focused on discovering BRCA-1 activators. R03 award supported large scale HTS screen conducted at NCATS. Drug discovery activities were supported by IAMI.
Project	4/13-5/13, Weekly	KUCC KU KUMC	Andrew Godwin Scott Weir Anu Roy Melinda Broward Ziyan Pessetto Tyce Bruns	Review results of HTS assays and develop strategies to discover novel, new agents to treat Ewings sarcoma.
Programmatic	8/2/13	KUCC KU KUMC	Scott Weir	D3ET presentation to PKD researchers attending the PKD Center Sullivan Conference “Drug Discovery and Development Overview”.
Programmatic	9/20/13	KUCC KU KUMC	David Wilson	D3ET presentation to PKD researchers attending the PKD Center Sullivan Conference “Target Identification and validation Early Assay Development”.
Programmatic	11/11/13	KUCC KU KUMC	Anu Roy	D3ET presentation to PKD researchers attending the PKD Center Sullivan Conference “Method Optimization Validation and Large Compound Screens Confirming HTS”.
Programmatic	11/22/13	KUCC KU KUMC	Michael Baltezor	D3ET presentation to PKD researchers attending the PKD Center Sullivan Conference “Pharmacokinetics/ eADME, in Vitro and in Vivo Formulations”.
2014				
Programmatic	2/7/14	KUCC, KUMC, KU, SIMR, CM	Ray Perez	D3ET seminar entitled “Rational Design of SPRY2-Cbi TKB Domain Inhibitors”.
Programmatic	3/7/14	KUCC, KUMC, KU, SIMR, CM	Qi Chen	D3ET seminar entitled “Losing and Finding ways at C: The role of Vitamin C in cancer treatment”.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Programmatic	4/4/14	KUCC, KUMC, KU, SIMR, CM	Teruna Siahaan	D3ET seminar entitled “Overcoming challenges of delivering molecules to the brain”.
Programmatic	5/2/14	KUCC, KUMC, KU, SIMR, CM	Andrew Godwin	D3ET seminar entitled “Circulating Ovarian Cancer Biomarkers and Early Detection”.
Programmatic	6/6/14	KUCC, KUMC, KU, SIMR, CM	Rehka Rao-Manepalli	D3ET seminar entitled “Fibrosis in Myeloproliferative Disorders”.
Programmatic	7/11/14	KUCC, KUMC, KU, SIMR, CM	Francisco Diaz	D3ET seminar entitled “Compound Ranking in High-Throughput Screening by Using the Data from Cell-Based Assays”.
Programmatic	9/5/14	KUCC, KUMC, KU, SIMR, CM	John Karanicolas	D3ET seminar entitled “New Computational Approaches for Designing Compounds that Target Non-Traditional Drug Targets”.
Programmatic	10/3/14	KUCC, KUMC, KU, SIMR, CM	Blake Peterson	D3ET seminar entitled “Synergistic Antibody Conjugates for Synthetic Lethal Targeting of Cancer”.
Programmatic	11/7/14	KUCC, KUMC, KU, SIMR, CM	Bhaskar Das	D3ET seminar entitled “Biology Oriented Boron Chemical Synthesis for Cancer Treatment”.
Programmatic	12/5/14	KUCC, KUMC, KU, SIMR, CM	Brooke Fridley	D3ET seminar entitled “Cancer Research and the Biostatistics and Informatics Shared Resource”.
Programmatic	1/14-12/14 Quarterly	CSU KUCC	Rod Page Doug Thamm Tyce Bruns Scott Weir	Quarterly implementation meetings to establish collaborative comparative oncology projects between CSU and KUCC in Diffuse Large B Cell Lymphoma and Osteosarcoma.
Project	1/14-12/14 Monthly	NCATS CM KUCC	Sitta Sittampalam Kathleen Neville Tyce Bruns Andrew Godwin Scott Weir	Monthly review of sarcoma research projects enabled and facilitated by The Sarcoma Learning Collaborative, a partnership between NCATS, Children’s Mercy Kansas City, and KUCC.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Programmatic	7/29/14-8/1/14	KU KUMC KUCC University of Nottingham	Sam Enna David Kendell Steve Alexander Barrie Killan Paul Terranova Nancy Muma Robert Simari Scott Weir Robyn Wood Bruno Hagenbuch	Hosted University of Nottingham Site at KUMC to explore collaborations across therapeutic areas including cancer.
Project	1/14-12/14 Monthly	KSU KUCC MCA	Stephan Bossmann Tyce Bruns	Integration of cancer diagnostics platform developed at KSU with KUCC clinical programs.
Project	2/14-4/14	Thrasos KUCC KUMC	Darren Wallace Scott Weir Melinda Broward Phillipe Bey Louisa Petropoulos	D3ET created the opportunity for collaboration with Thrasos Therapeutics to evaluate one of their development candidates in validated animal models of PKD at KUMC
Project	1/14-12/14 Monthly	LLS NCATS IAMI	James Kasper Sitta Sittampalam Kevin Schorno Scott Weir	Monthly management of project activities across the three partner organizations comprising The Learning Collaborative as well as clinical trial activities at NHLBI and The Ohio State University Comprehensive Cancer Center.
Project	1/14-12/14 Monthly	CM CSU KUCC KUMC KU	Joy Fulbright Kathleen Neville Scott Weir Tomoo Iwakuma Doug Thamm Anu Roy Melinda Broward Tyce Bruns	Monthly management of Midwest Cancer Alliance funded comparative oncology project in osteosarcoma, focused on rediscovery and repurposing of FDA approved drugs in canine and human Osteosarcoma.
Project	1/14-12/14 Monthly	KUCC CM Kevin Gray Foundation NCATS KUMC KU	Scott Weir Kathleen Neville Joy Fulbright Sitta Sittampalam Naren Narendran Anu Roy Melinda Broward Tyce Bruns	Monthly management of drug rediscovery and repurposing of FDA approved drugs for the treatment of Rhabdomyosarcoma. This project was and continues to be supported by the Kevin Gray Foundation, a Kansas City philanthropic organization supporting KUCC's efforts to identify and advance new treatments for this sarcoma.
Project	1/14-12/14 Monthly	NCATS KUCC CM KUMC KU	Scott Weir Kathleen Neville Sitta Sittampalam Anu Roy Tyce Bruns Shrikant Anant	Monthly management of drug rediscovery and repurposing of FDA approved drugs for the treatment of synovial sarcoma. This project was and continues to be supported philanthropically with the goal of identifying and advancing new treatments for synovial sarcoma.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Project	2014 Quarterly	KUMC KUH KUCC	Ossama Tawfik Fang Fan Brian Potetz Scott Weir Robyn Wood	Monthly management of product development activities to create and advance TelePAPology medical device. Telepapology is a product that enables digital evaluation of cell block preparations of liquid-based and conventional Pap smears. Product development was supported by IAMI.
Project	1/14-12/14 Monthly	KUCC KUMC KU UCHSC	Scott Weir Robyn Wood Shri Anant Greg Reed Jeff Holzbeierlein Michael Baltezor John Taylor	Monthly management of project activities across campuses and contract research organizations supporting development of Ciclopirox Prodrug (CPX-POM) as an anticancer agent. Product development was supported by IAMI.
Programmatic	1/14-12/14 Monthly	KUMC KUCC KU	Shri Anant Scott Weir Jeff Aube Frank Schoenen Dan Dixon Liang Xu Kristi Neufeld Shahid Umar Prahbu Ramamoorthy Melinda Broward Robyn Wood	Monthly management of collaborative cancer research and drug discovery activities focused on identifying compounds that inhibit binding of RNA proteins. Supported by KUCC developmental funds, this effort is focused on enabling and facilitating collaborations focused on RNA binding proteins to strengthen multi-PI R01 applications leading to the development of competitive SPORE applications. Associate Directors Anant (Cancer Prevention) and Weir (Translational Research) co-lead this effort.
Project	1/14-2/14 Weekly	KUCC UMKC Whiteboard to Boardroom Avon Foundation	Roy Jensen Scott Weir Robyn Wood James Baxendale Andrew Godwin Qamar Khan IAMI Advisory Board members Mike Webb and Mike Powell	Weekly management of grant development activities responding to the Avon Breast Cancer Challenge RFA. The collaborative grant application outlined product development activities necessary to develop and commercialize a breast cancer diagnostic test to predict responders to taxane therapy.
Project	12/14	KUCC KUMC KU	Shri Anant Scott Weir Robyn Wood Michael Baltezor	Kickoff of inter-programmatic drug discovery collaboration supported by NCI RO1 award focused on discovering and advancing novel dual pathway inhibitors of Notch and PXR, with a target treatment indication for colorectal cancer. Associate Directors Anant (Cancer Prevention) and Weir (Translational Research) are co-Principal Investigators conducting this research.
Project	1/14-3/14 Weekly	KUCC KUMC KU UCHSC	Scott Weir Shri Anant Robyn Wood John Taylor Michael Baltezor	Inter-institutional collaboration to seeking support from the Bladder Cancer Advocacy Network (BCAN) to expand research efforts in characterizing the activity of Ciclopirox Prodrug in non-muscle invasive bladder cancer.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Programmatic	4/14-12/14 Monthly	KUCC KUMC KU	Jeremy Chien Andrew Godwin Gary Johnson Kathy Roby Rhonda Johnson Harsh Pathak Scott Weir Brooke Fridley Melinda Broward	Biannual meeting co-led by Jeremy Chien and KUCC Deputy Director Andrew Godwin to enable and facilitate collaborative research projects focused on discovery and development of new treatments for ovarian cancer. Organized by Chien and Godwin, the Ovarian Cancer Learning Collaborative is supported by KUCC developmental funds.
Project	3/14-11/14 Monthly	KUCC KUMC KU	Gary Doolittle Danny Welch Anu Roy Scott Weir Melinda Broward Tyce Bruns	Monthly planning and execution of inter-programmatic collaboration to rediscover and repurpose FDA approved drugs for the treatment of melanoma across responsive and difficult to treat genetic mutations. This project is co-led by Midwest Cancer Alliance Director Gary Doolittle (CPS), Associate Director of Basic Research Danny Welch (CB), and Associate Director for Translational Research Scott Weir (D3ET) utilizing the LDOSR.
Project	2/14-12/14	SIMR KUCC	Sitta Sittampalam Anu Roy Linheng Li John Perry Scott Weir Melinda Broward Alan Gamis Erin Guest Keith August Tara Lin Ray Perez	Monthly management of integrated drug discovery activities across KUCC consortium members focused on discovering Wnt-PTEN dual pathway inhibitors to eliminate leukemic stem cells. Results from the HTS assay identified that antracyclines, in low concentrations, act as dual pathway inhibitors. Pediatric and adult hematologists and oncologists were engaged to develop a translational research strategy to advance this treatment concept to pediatric and adult blood cancer patients.
Programmatic	1/14-12/14 Monthly	KUCC KU KUMC	James Calvet Alan Yu Darren Wallace Michael Baltezor Scott Weir Anu Roy Melinda Broward	Monthly meetings to identify and advance collaborative research focused on drug discovery, delivery and development of new therapeutics for PKD. D3ET capabilities serve as Core 4 of the awarded P30 grant to establish the PKD Center.
Project	6/14, 8/14	KUCC CM KUMC KU	Seth Septer Shri Anant Anu Roy Scott Weir Melinda Broward	Collaborative project to support Children's Mercy research fellow Seth Septer to characterize the role FAP/APC in high-risk Lynch Syndrome patients. This research, being conducted by Septer in Shrikant Anant's laboratory was supported by a Midwest Cancer Alliance grant.
Project	6/14-10/14 Monthly	KUCC KUMC KU	Andrew Godwin Rebecca Burkhalter Anu Roy Scott Weir Melinda Broward Frank Shoenen	Intra-programmatic drug discovery project to identify novel treatments for ovarian cancer. Efforts in 2014 focused on developing and validating a HTS assay to identify inhibitors of Kif15/TPX2, with the goal of identifying probes that would aid in validating the proposed target in ovarian cancer, and if successful, would support a competitive NCI R01 application.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Project	2014 Quarterly	KUCC KUMC KU	Lisa Harlan-Williams Roy Jensen Scott Weir Jeff Aube Frank Schoenen Michael Baltezor Melinda Broward	Monthly management of integrated drug discovery activities across campuses focused on discovering BRCA-1 activators. R03 award supported large scale HTS screen conducted at NCATS. Drug discovery activities were supported by IAMI.
2015				
Programmatic	1/9/15	KUCC, KUMC, KU, SIMR, CM	Takefumi Komiya	D3ET seminar entitled “Targeting of CREB Sgnaling in Thoracic Oncology”
Programmatic	2/6/15	KUCC, KUMC, KU, SIMR, CM	Priscilla Goncalves	D3ET program meeting with guest speaker from NIH Clinical Research Center. Dr. Goncalves presented a seminar entitled “Lessons Learned in Adenoid Cystic Carcinoma from a Clinical Pbservation to the Development for a Phase 2 trial”
Programmatic	6/5/15	KUCC, KUMC, KU, SIMR, CM	Qamar Khan	D3ET seminar entitled “Liminal B Breast Cancer”
Programmatic	9/11/15	KUCC, KUMC, KU, SIMR, CM	Larry Sklar	D3ET seminar presented by Dr. Sklar from the University of New Mexico Comprehensive Cancer Center entitled “High Throughput Screening and Flow Cytometry”
Programmatic	10/2/15	KUCC, KUMC, KU, SIMR, CM	Shri Anant	D3ET seminar presented by CPS member Shrikant Anant entitled “Tumor in a Dish”
Programmatic	11/6/15	KUCC, KUMC, KU, SIMR, CM	Linheng Li	D3ET seminar presented by CB member Linheng Li entitled “Role of β-catenin in Cancer Stem Cell Renewal”
Programmatic	7/7/15	KUCC, KUMC, KU, SIMR, CM	Scott Weir Frank Schoenen Melinda Broward Andrew Godwin Joel McGuirk Kristi Neufeld Katherine Chastain Howard Rosenthal Kim Kimminau	D3ET program meeting showcasing basic, translational and clinical research topics including cancer biology of colorectal cancer, biomarker discovery, discovery of first-in-class p97 inhibitors, current treatment strategies in pediatric sarcomas, surgical oncology strategies in sarcomas, and engaging patients in research.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Project	7/16/15	KUCC, KUMC, KU, SIMR, CM	Scott Weir Robyn Wood Roy Jensen Jeff Reene Dan Welch Parvesh Kumar David Frankland Keith Illig Brian Leist Michael Marc	Introduction of Novation IQ technology for ablation of hepatic tumors
Programmatic	11/13/15	KUCC, KUMC, KU, SIMR, CM	Scott Weir Melinda Broward	D3ET program meeting at the annual KUCC Research Symposium, with presentation entitled “Improving our Cancer Drug Discovery Portfolio”
Programmatic	11/13/15	KUCC, KUMC, KU, SIMR, CM	John Taylor	D3ET program meeting at the annual KUCC Research Symposium with guest speaker John Taylor from University of Connecticut Health Sciences Center, presenting “Preclinical Modeling of Bladder Cancer; Potential Role of MIF Inhibition”
Programmatic	12/2/15	KUCC KUMC KU	Michael Baltezor Frank Schoenen Anu Roy Melinda Broward	D3ET seminar to visiting China delegation of student Physician Scientists entitled “Cancer Drug Discovery”
Programmatic	1/15-12/15 Quarterly	CSU KUCC	Rod Page Doug Thamm Tyce Bruns Scott Weir	Quarterly implementation meetings to establish collaborative comparative oncology projects between CSU and KUCC in Diffuse Large B Cell Lymphoma and Osteosarcoma.
Project	1/15-12/15 Monthly	NCATS CM KUCC	Sitta Sittampalam Kathleen Neville Tyce Bruns Andrew Godwin Scott Weir	Monthly review of sarcoma research projects enabled and facilitated by The Sarcoma Learning Collaborative, a partnership between NCATS, Children’s Mercy Kansas City, and KUCC.
Project	1/15-12/15 Monthly	KSU KUCC MCA	Stephan Bossmann Tyce Bruns	Integration of cancer diagnostics platform developed at KSU with KUCC clinical programs.
Project	1/15-12/15 Monthly	LLS NCATS IAMI	James Kasper Sitta Sittampalam Kevin Schorno Scott Weir	Monthly management of project activities across the three partner organizations comprising The Learning Collaborative as well as clinical trial activities at NHLBI and The Ohio State University Comprehensive Cancer Center.
Project	6/15, 12/15	KUCC KUMC KU Lombardi Comprehensive Cancer Center at Georgetown University	Scott Weir Robyn Wood Shri Anant Lee Byers Glasgow Albanese	Collaboration with Lombardi Cancer Center to evaluate their zebrafish cancer model in non-muscle invasive bladder cancer, testing with Ciclopirox Prodrug.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Project	2/17/15	Thrasos KUCC KUMC	Darren Wallace Scott Weir Melinda Broward Phillipe Bey Louisa Petropoulos	D3ET created the opportunity for collaboration with Thrasos Therapeutics to evaluate one of their development candidates in validated animal models of PKD at KUMC
Project	2/15-12/15 Monthly	KUCC KU KUMC Siteman Comprehensive Cancer Center at Washington University	Josh Rubin Scott Weir Anu Roy Melinda Broward	Collaboration between KUCC and UWSTL Cancer Center members (D3ET and LDOSR) to develop, validate, and screen compounds in male and femal primary tumor-derived cell lines entitled “Gender Specific FDA Repurposed Drug Screening Against Glioblastoma Brain Tumors Cells”.
Project	10/13/15	SIMR NCATS KUCC UCHSC	Linheng Li John Perry Scott Weir Sitta Sittampalam Michael Baltezor Tara Lin Greg Reed Kasi Lu Melinda Broward	Evaluation of novel, nanoparticle formulation developed at UConn and its applicability to delivering low-dose anthracyclines in eliminating leukemic stem cells.
Project	1/15-12/15 Monthly	KUCC CM Kevin Gray Foundation NCATS KUMC KU	Scott Weir Kathleen Neville Joy Fulbright Sitta Sittampalam Naren Narendran Anu Roy Melinda Broward Tyce Bruns	Monthly management of drug rediscovery and repurposing of FDA approved drugs for the treatment of Rhabdomyosarcoma. This project was and continues to be supported by the Kevin Gray Foundation, a Kansas City philanthropic organization supporting KUCC’s efforts to identify and advance new treatments for this sarcoma.
Project	1/15-12/15 Monthly	NCATS KUCC CM KUMC KU	Scott Weir Kathleen Neville Sitta Sittampalam Anu Roy Tyce Bruns Shrikant Anant	Monthly management of drug rediscovery and repurposing of FDA approved drugs for the treatment of synovial sarcoma. This project was and continues to be supported philanthropically with the goal of identifying and advancing new treatments for synovial sarcoma.
Project	1/15-12/15 Monthly	KUCC KUMC KU UCHSC	Scott Weir Robyn Wood Shri Anant Greg Reed Jeff Holzbeierlein Michael Baltezor John Taylor	Monthly management of project activities across campuses and contract research organizations supporting development of Ciclopirox Prodrug (CPX-POM) as an anticancer agent. Product development was supported by IAMI.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Programmatic	1/15-12/15 Monthly	KUMC KUCC KU	Shri Anant Scott Weir Jeff Aube Frank Schoenen Dan Dixon Liang Xu Kristi Neufeld Shahid Umar Prahbu Ramamoorthy Melinda Broward Robyn Wood	Monthly management of collaborative cancer research and drug discovery activities focused on identifying compounds that inhibit binding of RNA proteins. Supported by KUCC developmental funds, this effort is focused on enabling and facilitating collaborations focused on RNA binding proteins to strengthen multi-PI R01 applications leading to the development of competitive SPORE applications. Associate Directors Anant (Cancer Prevention) and Weir (Translational Research) co-lead this effort.
Project	1/15/-12/15 Monthly	KUCC KUMC KU	Shri Anant Scott Weir Robyn Wood Michael Baltezor	Monthly management of inter-programmatic drug discovery activities supported by NCI RO1 award focused on discovering and advancing novel dual pathway inhibitors of Notch and PXR, with a target treatment indication for colorectal cancer. Associate Directors Anant (Cancer Prevention) and Weir (Translational Research) are co-Principal Investigators conducting this research.
Project	3/15-12/15 Monthly	KUCC KUMC KU	Scott Weir Robyn Wood Shri Anant Eugene Lee Greg Reed Hobbs Appel Kevin Schorno	Monthly management of inter-programmatic collaboration between CB, CPS and D3ET to repurpose ethacrynic acid for chemotherapy-resistant (Mitomycin-C and cisplatin) non-muscle invasive bladder cancer resulting in an experimental therapeutics trial opening in 2016.
Project	4/15-5/15 Weekly	KUCC KUMC KU UCHSC	Scott Weir Shri Anant Eugene Lee John Taylor Robyn Wood	Multi-PI grant application development, seeking funding from the V Foundation to expand Ciclopirox Prodrug mechanism of action research in non-muscle invasive bladder cancer.
Project	1/15-12/15 Monthly	SIMR KUCC KUMC KU	Linheng Li Scott Weir Tara Lin Ray Perez Greg Reed Michael Baltezor John Perry Melinda Broward	Translation of basic cancer research conducted at the Stowers Institute to a clinical proof of concept trial in AML patients opening in 2016 to evaluate the activity of Low dose Daunorubicin in inhibiting AML patients.
Project	3/30/15	SIMR KUCC KUMC KU	Linheng Li Al Gamis Keith August Erin Guest Scott Weir Tara Lin Ray Perez Greg Reed Michael Baltezor John Perry Melinda Broward	Inter-programmatic meeting to explore the relevance of leukemic stem cell target in pediatric blood cancers resulting in collection of biospecimens from patients, evaluated at the Stowers Institute, establishing presence of the proposed drug target in approximately half of pediatric lymphocytic leukemia patients.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Programmatic	1/15-12/15 Monthly	KUCC KU KUMC	James Calvet Alan Yu Darren Wallace Michael Baltezor Scott Weir Anu Roy Melinda Broward	Monthly meetings to identify and advance collaborative research focused on drug discovery, delivery and development of new therapeutics for PKD. D3ET capabilities serve as Core 4 of the awarded P30 grant to establish the PKD Center.
Project	9/15/-10/15 Bi-Monthly	KUCC KUMC KU	Carol Fabian Bruce Kimler Scott Weir Barbara Timmermann Lisa Harlan-Williams Stacy Hebroff Roy Jensen Dan Dixon Michael Baltezor Frank Schoenen	Inter-programmatic (D3ET, CPS) collaboration to prepare NCI Prevent application describing discovery and development of chemoprevention agents for women at high risk of developing breast cancer.
Project	1/15-12/15 Monthly	KUCC KUMC KU	Gary Doolittle Danny Welch Anu Roy Scott Weir Melinda Broward Tyce Bruns	Monthly planning and execution of inter-programmatic collaboration to rediscover and repurpose FDA approved drugs for the treatment of melanoma across responsive and difficult to treat genetic mutations. This project is co-led by Midwest Cancer Alliance Director Gary Doolittle (CPS), Associate Director of Basic Research Danny Welch (CB), and Associate Director for Translational Research Scott Weir (D3ET) utilizing the LDOSR.
Project	6/16/15, 10/21/15	KUCC KUMC KU CM	Scott Weir Shri Anant Steve Leeder Aravind Sugumar Frank Schoenen Melinda Broward Anu Roy	Inter-programmatic (D3ET, CPS) collaboration to identify and validate bitter taste receptors (e.g., TAS2R38) as therapeutic targets for pancreatic cancer.
Project	1/15-12/15 Quarterly	KUCC CM KUMC KU	Seth Septer Shri Anant Anu Roy Scott Weir Melinda Broward	Collaborative project to support Children's Mercy research fellow Seth Septer to characterize the role FAP/APC in high-risk Lynch Syndrome patients. This research, being conducted by Septer in Shrikant Anant's laboratory was supported by a Midwest Cancer Alliance grant.
Project	1/15-12/15 Quarterly	KUCC KUMC KU	Andrew Godwin Rebecca Burkhalter Anu Roy Scott Weir Melinda Broward Frank Shoenen	Intra-programmatic drug discovery project to identify novel treatments for ovarian cancer. Efforts in 2014 focused on developing and validating a HTS assay to identify inhibitors of Kif15/TPX2, with the goal of identifying probes that would aid in validating the proposed target in ovarian cancer, and if successful, would support a competitive NCI R01 application.

Type	Date	Partner(s)	Presenter(s)	Title/Agenda
Project	2015 Quarterly	KUCC KUMC KU	Scott Weir Lisa Harlan-Williams Roy Jensen Qamar Khan Dan Li Anu Roy Melinda Broward	Inter-programmatic (D3ET, CPS) collaboration in drug rediscovery and repurposing of FDA-approved drugs to improve treatment outcomes in Luminal B breast cancer

Table 5 – Drug Discovery, Delivery and Experimental Therapeutics
The D3ET program had 617 publications from 2012-2015; 140 (23%) inter-programmatic, 180 (29%) intra-programmatic, 315 (51%) inter-institutional, and 67 (11%) of these publications were high impact (JIF ≥ 8).

Table 5. Program Publications

Inter	Intra	External	Publication
With PMCID			
		x	Abdel-Wahab O, Pardanani A, Bernard OA, Finazzi G, Crispino JD, Gisslinger H, Kralovics R, Odenike O, **Bhalla** K, Gupta V, Barosi G, Gotlib J, Guglielmelli P, Kiladjian JJ, Noel P, Cazzola M, Vannucchi AM, Hoffman R, Barbui T, Thiele J, Van Etten RA, Mughal T, Tefferi A. Unraveling the genetic underpinnings of myeloproliferative neoplasms and understanding their effect on disease course and response to therapy: proceedings from the 6th International Post-ASH Symposium. Am J Hematol. 2012;87(5):562-8. Epub 2012/03/31. doi: 10.1002/ajh.23169. PubMed PMID: 22460584; PMCID: PMC3491640.
			Aberger M, Wilson B, **Holzbeierlein** JM, Griebling TL, Nangia AK. Testicular self-examination and testicular cancer: a cost-utility analysis. Cancer medicine. 2014;3(6):1629-34. Epub 2014/08/12. doi: 10.1002/cam4.318. PubMed PMID: 25103095; PMCID: PMC4298389.
		x	**Abhyankar** S, Demner-Fushman D, McDonald CJ. Standardizing clinical laboratory data for secondary use. J Biomed Inform. 2012;45(4):642-50. Epub 2012/05/09. doi: 10.1016/j.jbi.2012.04.012. PubMed PMID: 22561944; PMCID: PMC3419308.
			Ackley BD. Wnt-signaling and planar cell polarity genes regulate axon guidance along the anteroposterior axis in C. elegans. Developmental neurobiology. 2014;74(8):781-96. Epub 2013/11/12. doi: 10.1002/dneu.22146. PubMed PMID: 24214205; PMCID: PMC4167394.
	x	x	Agola JO, Hong L, Surviladze Z, Ursu O, Waller A, Strouse JJ, Simpson DS, Schroeder CE, Oprea TI, **Golden** JE, **Aubé** J, Buranda T, Sklar LA, Wandinger-Ness A. A competitive nucleotide binding inhibitor: in vitro characterization of Rab7 GTPase inhibition. ACS Chem Biol. 2012 Jun 15;7(6):1095-108. Epub 2012 Apr 23. PubMed PMID: 22486388; PubMed Central PMCID: PMC3440014.
x		x	**Aires** DJ, Rockwell G, Wang T, Frontera J, **Wick** J, Wang W, Tonkovic-Capin M, Lu J, E L, Zhu H, Swerdlow RH. Potentiation of dietary restriction-induced lifespan extension by polyphenols. Biochim Biophys Acta. 2012;1822(4):522-6. Epub 2012/01/24. doi: 10.1016/j.bbadis.2012.01.005. PubMed PMID: 22265987; PMCID: PMC3643308.
		x	**Aldrich** JV, Senadheera SN, Ross NC, Ganno ML, Eans SO, McLaughlin JP. The macrocyclic peptide natural product CJ-15,208 is orally active and prevents reinstatement of extinguished cocaine-seeking behavior. J Nat Prod. 2013;76(3):433-8. Epub 2013/01/19. doi: 10.1021/np300697k. PubMed PMID: 23327691; PMCID: PMC3879116.
x	x		Alhafez A, **Aljitawi** OS, **Lin** TL, **Ganguly** S, **Abhyankar** S, **McGuirk** JP. Bendamustine associated with irreversible ascending paralysis. Case reports in hematology. 2013;2013:931519. doi: 10.1155/2013/931519. PubMed PMID: 23533850; PubMed Central PMCID: PMC3600208.
			Alhakamy NA, **Berkland** CJ. Polyarginine molecular weight determines transfection efficiency of calcium condensed complexes. Mol Pharm. 2013;10(5):1940-8. Epub 2013/03/29. doi: 10.1021/mp3007117. PubMed PMID: 23534410; PMCID: PMC4207646.
	x	x	Alhakamy NA, Ishiguro S, Uppalapati D, **Berkland** CJ, **Tamura** M. AT2R Gene Delivered by Condensed Polylysine Complexes Attenuates Lewis Lung Carcinoma after Intravenous Injection or Intratracheal Spray. Mol Cancer Ther. 2016;15(1):209-18. Epub 2015/12/08. doi: 10.1158/1535-7163.mct-15-0448. PubMed PMID: 26637367; PMCID: PMC4707093.
			Alhakamy NA, Kaviratna A, **Berkland** CJ, Dhar P. Dynamic measurements of membrane insertion potential of synthetic cell penetrating peptides. Langmuir. 2013;29(49):15336-49. Epub 2013/12/04. doi: 10.1021/la403370p. PubMed PMID: 24294979; PMCID: PMC3918496.

Inter	Intra	External	Publication
			Alhakamy NA, Nigatu AS, **Berkland** CJ, Ramsey JD. Noncovalently associated cell-penetrating peptides for gene delivery applications. Therapeutic delivery. 2013;4(6):741-57. Epub 2013/06/07. doi: 10.4155/tde.13.44. PubMed PMID: 23738670; PMCID: PMC4207642.
		x	Ali AM, Reis JM, Xia Y, Rashid AJ, Mercaldo V, Walters BJ, Brechun KE, Borisenko V, Josselyn SA, **Karanicolas** J, Woolley GA. Optogenetic Inhibitor of the Transcription Factor CREB. Chemistry & biology. 2015;22(11):1531-9. Epub 2015/11/23. doi: 10.1016/j.chembiol.2015.09.018. PubMed PMID: 26590638; PMCID: Pmc4656143.
x	x		**Aljitawi** OS, Li D, Xiao Y, Zhang D, Ramachandran K, Stehno-Bittel L, **Van Veldhuizen** P, Lin TL, **Kambhampati** S, **Garimella** R. A novel three-dimensional stromal-based model for in vitro chemotherapy sensitivity testing of leukemia cells. Leuk Lymphoma. 2014;55(2):378-91. Epub 2013/04/10. doi: 10.3109/10428194.2013.793323. PubMed PMID: 23566162; PMCID: PMC4090917.
x	x		**Aljitawi OS**, Li D, Xiao Y, Zhang D, Ramachandran K, Stehno-Bittel L, **Van Veldhuizen** P, **Lin** TL, **Kambhampati** S, Garimella R. A novel three-dimensional stromal-based model for in vitro chemotherapy sensitivity testing of leukemia cells. Leukemia & lymphoma. 2014;55(2):378-91. doi: 10.3109/10428194.2013.793323. PubMed PMID: 23566162; PubMed Central PMCID: PMC4090917.
x		x	**Aljitawi OS**, Xiao Y, Eskew JD, Parelkar NK, Swink M, Radel J, **Lin** TL, **Kimler** BF, **Mahnken** JD, **McGuirk** JP, Broxmeyer HE, Vielhauer G. Hyperbaric oxygen improves engraftment of ex-vivo expanded and gene transduced human CD34(+) cells in a murine model of umbilical cord blood transplantation. Blood cells, molecules & diseases. 2014;52(1):59-67. doi: 10.1016/j.bcmd.2013.07.013. PubMed PMID: 23953010; PubMed Central PMCID: PMC4075130.
	x		Alontaga AY, Li Y, Chen CH, Ma CT, Malany S, Key DE, Sergienko E, Sun Q, Whipple DA, Matharu DS, Li B, Vega R, Li YJ, **Schoenen** FJ, **Blagg** BS, Chung TD, Chen Y. Design of high-throughput screening assays and identification of a SUMO1-specific small molecule chemotype targeting the SUMO-interacting motif-binding surface. ACS combinatorial science. 2015;17(4):239-46. Epub 2015/02/27. doi: 10.1021/co500181b. PubMed PMID: 25719760; PMCID: Pmc4609574.
	x		Alsenaidy MA, Jain NK, Kim JH, **Middaugh** CR, **Volkin** DB. Protein comparability assessments and potential applicability of high throughput biophysical methods and data visualization tools to compare physical stability profiles. Frontiers in pharmacology. 2014;5:39. Epub 2014/03/25. doi: 10.3389/fphar.2014.00039. PubMed PMID: 24659968; PubMed Central PMCID: PMCPmc3950620.
	x		Alsenaidy MA, Kim JH, Majumdar R, Weis DD, Joshi SB, **Tolbert** TJ, **Middaugh** CR, **Volkin** DB. High-throughput biophysical analysis and data visualization of conformational stability of an IgG1 monoclonal antibody after deglycosylation. J Pharm Sci. 2013;102(11):3942-56. Epub 2013/10/12. doi: 10.1002/jps.23730. PubMed PMID: 24114789; PMCID: PMC3832129.
	x		Alsenaidy MA, Okbazghi SZ, Kim JH, Joshi SB, **Middaugh** CR, Tolbert TJ, **Volkin** DB. Physical stability comparisons of IgG1-Fc variants: effects of N-glycosylation site occupancy and Asp/Gln residues at site Asn 297. J Pharm Sci. 2014;103(6):1613-27. Epub 2014/04/18. doi: 10.1002/jps.23975. PubMed PMID: 24740840; PMCID: PMC4512762.
			Alturkmani HJ, Pessetto ZY, **Godwin** AK. Beyond standard therapy: drugs under investigation for the treatment of gastrointestinal stromal tumor. Expert Opin Investig Drugs. 2015;24(8):1045-58. Epub 2015/06/23. doi: 10.1517/13543784.2015.1046594. PubMed PMID: 26098203; PMCID: PMC4594857.

Inter	Intra	External	Publication
		x	Amin A, Dudek AZ, Logan TF, Lance RS, **Holzbeierlein** JM, Knox JJ, Master VA, Pal SK, Miller WH, Jr., Karsh LI, Tcherepanova IY, DeBenedette MA, Williams WL, Plessinger DC, Nicolette CA, Figlin RA. Survival with AGS-003, an autologous dendritic cell-based immunotherapy, in combination with sunitinib in unfavorable risk patients with advanced renal cell carcinoma (RCC): Phase 2 study results. J Immunother Cancer. 2015;3:14. Epub 2015/04/23. doi: 10.1186/s40425-015-0055-3. PubMed PMID: 25901286; PMCID: PMC4404644.
		x	Antoniou AC, Kuchenbaecker KB, Soucy P, Beesley J, Chen X, McGuffog L, Lee A, Barrowdale D, Healey S, Sinilnikova OM, Caligo MA, Loman N, Harbst K, Lindblom A, Arver B, Rosenquist R, Karlsson P, Nathanson K, Domchek S, Rebbeck T, Jakubowska A, Lubinski J, Jaworska K, Durda K, Zlowowcka-Perlowska E, Osorio A, Duran M, Andres R, Benitez J, Hamann U, Hogervorst FB, van Os TA, Verhoef S, Meijers-Heijboer HE, Wijnen J, Gomez Garcia EB, Ligtenberg MJ, Kriege M, Collee JM, Ausems MG, Oosterwijk JC, Peock S, Frost D, Ellis SD, Platte R, Fineberg E, Evans DG, Lalloo F, Jacobs C, Eeles R, Adlard J, Davidson R, Cole T, Cook J, Paterson J, Douglas F, Brewer C, Hodgson S, Morrison PJ, Walker L, Rogers MT, Donaldson A, Dorkins H, **Godwin** AK, Bove B, Stoppa-Lyonnet D, Houdayer C, Buecher B, de Pauw A, Mazoyer S, Calender A, Leone M, Bressac-de Paillerets B, Caron O, Sobol H, Frenay M, Prieur F, Ferrer SU, Mortemousque I, Buys S, Daly M, Miron A, Terry MU, Hopper JL, John EM, Southey M, Goldgar D, Singer CF, Fink-Retter A, Tea MK, Kaulich DU, Hansen TV, Nielsen FC, Barkardottir RB, Gaudet M, Kirchhoff T, Joseph V, Dutra-Clarke A, Offit K, Piedmonte M, Kirk J, Cohn D, Hurteau J, Byron J, Fiorica J, Toland AE, Montagna M, Oliani C, Imyanitov E, Isaacs C, Tihomirova L, Blanco I, Lazaro C, Teule A, Valle JD, Gayther SA, Odunsi K, Gross J, Karlan BY, Olah E, Teo SH, Ganz PA, Beattie MS, Dorfling CM, van Rensburg EU, Diez O, Kwong A, Schmutzler RK, Wappenschmidt B, Engel C, Meindl A, Ditsch N, Arnold N, Heidemann S, Niederacher D, Preisler-Adams S, Gadzicki D, Varon-Mateeva R, Deissler H, Gehrig A, Sutter C, Kast K, Fiebig B, Schafer D, Caldes T, de la Hoya M, Nevanlinna H, Muranen TA, Lesperance B, Spurdle AB, Neuhausen SL, Ding YC, Wang X, Fredericksen Z, Pankratz VS, Lindor NM, Peterlongo P, Manoukian S, Peissel B, Zaffaroni D, Bonanni B, Bernard L, Dolcetti R, Papi L, Ottini L, Radice P, Greene MH, Loud JT, Andrulis IL, Ozcelik H, Mulligan AU, Glendon G, Thomassen M, Gerdes AM, Jensen UB, Skytte AB, Kruse TA, Chenevix-Trench G, Couch FJ, Simard J, Easton DF, Cimba S-B, Hebon, Embrace, Study GC, kConFab I. Common variants at 12p11, 12q24, 9p21, 9q31.2 and in ZNF365 are associated with breast cancer risk for BRCA1 and/or BRCA2 mutation carriers. Breast Cancer Res. 2012;14(1):R33. Epub 2012/02/22. doi: 10.1186/bcr3121. PubMed PMID: 22348646; PMCID: PMC3496151.
	x		Arora J, Hickey JM, Majumdar R, Esfandiary R, Bishop SM, Samra HS, **Middaugh** CR, Weis DD, Volkin DB. Hydrogen exchange mass spectrometry reveals protein interfaces and distant dynamic coupling effects during the reversible self-association of an IgG1 monoclonal antibody. mAbs. 2015;7(3):525-39. Epub 2015/04/16. doi: 10.1080/19420862.2015.1029217. PubMed PMID: 25875351; PMCID: PMC4622866.
			Atay S, Banskota S, Crow J, Sethi G, Rink L, **Godwin** AK. Oncogenic KIT-containing exosomes increase gastrointestinal stromal tumor cell invasion. Proceedings of the National Academy of Sciences of the United States of America. 2014;111(2):711-6. Epub 2014/01/01. doi: 10.1073/pnas.1310501111. PubMed PMID: 24379393; PubMed Central PMCID: PMCPmc3896203.
x			Atay S, **Godwin** AK. Tumor-derived exosomes: A message delivery system for tumor progression. Communicative & integrative biology. 2014;7(1):e28231. Epub 2014/04/30. doi: 10.4161/cib.28231. PubMed PMID: 24778765; PubMed Central PMCID: PMCPmc3995727.
			Aube J. Synthetic probes for the study of biological function. Beilstein journal of organic chemistry. 2013;9:79-80. doi: 10.3762/bjoc.9.10. PubMed PMID: 23401731; PubMed Central PMCID: PMC3566862.
	x		Bagby TR, Duan S, Cai S, Yang Q, Thati S, **Berkland** C, Aires DJ, **Forrest** ML. Lymphatic trafficking kinetics and near-infrared imaging using star polymer architectures with controlled anionic character. Eur J Pharm Sci. 2012;47(1):287-94. Epub 2012/05/02. doi: 10.1016/j.ejps.2012.04.016. PubMed PMID: 22546180; PMCID: PMC4301975.

Inter	Intra	External	Publication
		x	Bao L, Cowan MJ, Dunham K, Horn B, **McGuirk J,** Gilman A, Lucas KG. Adoptive immunotherapy with CMV-specific cytotoxic T lymphocytes for stem cell transplant patients with refractory CMV infections. J Immunother. 2012;35(3):293-8. PMCID: 3306600.
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		x	Schilder RJ, Brady WE, Lankes HA, Fiorica JV, Shahin MS, Zhou XC, Mannel RS, Pathak HB, Hu W, Alpaugh RK, Sood AK, **Godwin** AK. Phase II evaluation of dasatinib in the treatment of recurrent or persistent epithelial ovarian or primary peritoneal carcinoma: A Gynecologic Oncology Group study. Gynecol Oncol. 2012. Epub 2012/06/20. doi: 10.1016/j.ygyno.2012.06.009. PubMed PMID: 22710075.
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	x		Wieliczka ML, **Ganguly** S, **Abhyankar** S, **Lin** T, **McGuirk** JP, **Aljitawi OS**. Rituximab as a treatment for factor VIII inhibitor in a patient with chronic GVHD. Bone marrow transplantation. 2014;49(4):588. doi: 10.1038/bmt.2013.229. PubMed PMID: 24442248
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Inter	Intra	External	Publication
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			Zhang HP, Hagan K, Patel O, Tong XQ, Day VW, **Timmermann** BN. 6 alpha,7 alpha-Epoxy-5 alpha-hydroxy-1-oxo-22R-witha-2,24-dienolide(withanolide B), 5 beta,6 beta-Epoxy-4 beta,20-dihydroxy-1-oxo-22R-witha-2,24-dienolide(withanolide D), and 4 beta,27-Dihydroxy-1-oxo-22R-witha-2,5,24-trienolide(5,6-deoxywithaferin A) in Roots of Withania somnifera: Isolation and Their Crystal Structures. J Chem Crystallogr. 2014;44(3):169-76. doi: 10.1007/s10870-014-0499-1. PubMed PMID: WOS:000331650500007.
			Zhao H, Michaelis ML, **Blagg** BS. Hsp90 modulation for the treatment of Alzheimer's disease. Adv Pharmacol. 2012;64:1-25. Epub 2012/07/31. doi: 10.1016/B978-0-12-394816-8.00001-5. PubMed PMID: 22840743.
x		x	Zhao M, Tang SN, Marsh JL, **Shankar** S, **Srivastava** RK. Ellagic acid inhibits human pancreatic cancer growth in Balb c nude mice. Cancer letters. 2013;337(2):210-7. doi: 10.1016/j.canlet.2013.05.009. PubMed PMID: 23684930.
		x	Zhou S, Mozziconacci O, Kerwin BA, **Schoneich** C. Fluorogenic tagging methodology applied to characterize oxidized tyrosine and phenylalanine in an immunoglobulin monoclonal antibody. Pharmaceutical research. 2013;30(5):1311-27. Epub 2013/02/16. doi: 10.1007/s11095-012-0970-7. PubMed PMID: 23412915.
		x	Zhou S, Mozziconacci O, Kerwin BA, **Schoneich** C. The photolysis of disulfide bonds in IgG1 and IgG2 leads to selective intramolecular hydrogen transfer reactions of cysteine Thiyl radicals, probed by covalent H/D exchange and RPLC-MS/MS analysis. Pharmaceutical research. 2013;30(5):1291-9. Epub 2013/01/12. doi: 10.1007/s11095-012-0968-1. PubMed PMID: 23307417.

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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BMT CTN	Multiple	NCT02081248	BMT CTN 1205	Abhyankar, S	D3ET	10/14/2014		N/A	Hsr	Easy to Read Informed consent (ETRIC) for Hematopoietic Cell Transplantion Clinical Trials	Y		20	6	7	0	0	
BMT CTN NHLBI	Multiple	NCT02208037	BMT CTN 1203	Abhyankar, S	D3ET	11/20/2014		II	Sup	A Multi-center Phase II Trial Randomizing Novel Approaches for Graft-versus-Host Disease Prevention Compared to Contemporary Controls	Y		10	10	11	0	0	
BMT CTN	Multiple	NCT01597778	BMT CTN 1101	Aljitawi, O	D3ET	10/9/2012		III	Tre	A Multi-Center, Phase III, Randomized Trial of Reduced Intensity (RIC) Conditioning and Transplantation of Double Unrelated Umbilical Cord Blood (dUCB) versus HLA-Haploidentical Related Bone Marrow (haplo-BM) for Patients with Hematologic Malignancies	Y		20	8	17	0	0	
Alliance for Clinical Trials in Oncology	Other Endocrine System	NCT01841736	A021202	Al-Kasspooles, M	D3ET	7/28/2014		II	Tre	Prospective Randomized Phase II Trial of Pazopanib (NSC # 737754, IND 75648) Versus Placebo in Patients With Progressive Carcinoid Tumors	Y		5	0	1	1	1	Meets definition of Rare Cancer and/or Molecular Target with low frequency
COG	Lymphoma	NCT01979536	ANHL12P1	August, K	D3ET	3/19/2014		II	Tre	A Randomized Phase II study of Brentuximab Vedotin (NSC# 749710) and Crizotinib (NSC# 749005) in Patients with Newly Diagnosed Anaplastic Large Cell Lymphoma (ALCL) IND #117117	Y		5	1	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Bone	NCT02470091	AOST1321	August, K	D3ET	12/28/2015		II	Tre	Denosumab in Treating Patients With Recurrent or Refractory Osteosarcoma	Y		5	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Bone	NCT02484443	AOST1421	August, K	D3ET	12/17/2015		II	Tre	Dinutuximab in Combination With Sargramostim in Treating Patients With Recurrent Osteosarcoma	Y		5	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
GOG	Multiple	NCT00719303	GOG 0225	Chapman, J	D3ET	1/10/2013		III	Tre	Can Diet and Physical Activity Modulate Ovarian, Fallopian Tube and Primary Peritoneal Cancer Progression-Free Survival?	Y		20	3	12	0	0	
GOG	Cervix	NCT01266460	GOG 0265	Chapman, J	D3ET	8/10/2015		II	Tre	A Phase II Evaluation of ADXS11-001 (NSC 752718, BB-IND #13,712) in the Treatment of Persistent or Recurrent Squamous or Non-Squamous Cell Carcinoma of the Cervix	Y		3	0	0	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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GOG	Cervix	NCT01414608	GOG 0274	Chapman, J	D3ET	8/30/2012	06/12/2015	III	Tre	A PHASE III TRIAL OF ADJUVANT CHEMOTHERAPY AS PRIMARY TREATMENT FOR LOCALLY ADVANCED CERVICAL CANCER COMPARED TO CHEMORADIATION ALONE: THE OUTBACK TRIAL	Y		5	1	5	0	0	
ECOG CTSU/SWOG	Multiple	NCT02115282	E2112	Doolittle, G	D3ET	6/18/2015		III	Tre	A Randomized Phase III Trial of Endocrine Therapy plus Entinostat/Placebo in Men and Postmenopausal Women with Hormone Receptor-Positive Advanced Breast Cancer	Y		10	0	0	2	2	Protocol open only at community and MCA sites.
ECOG CTSU/SWOG	Lung	NCT01107626	ECOG E5508	Doolittle, G	D3ET	10/15/2014	05/08/2015	III	Tre	Randomized Phase III Study of Maintenance Therapy with Bevacizumab, Pemetrexed, or a Combination of Bevacizumab and Pemetrexed Following Carboplatin, Paclitaxel and Bevacizumab for Advanced Non-Squamous NSCLC	Y		8	0	0	3	3	Protocol open only at MCA sites
SWOG	Melanoma, skin	NCT02196181	SWOG S1320	Doolittle, G	D3ET	8/17/2015		II	Tre	A Randomized, Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAFV600E/K Mutant Melanoma	Y		16	2	2	0	0	
BMT CTN	Multiple Myeloma	NCT02322320	BMT CTN 07LT	Ganguly, S	D3ET	4/24/2015		III	Tre	Continued, Long-Term Follow-Up and Lenalidomide Maintenance Therapy for Patients Who Have Enrolled on BMT CTN 0702	Y		14	3	3	0	0	
BMT CTN	Multiple Myeloma	NCT02440464	BMT CTN 1302	Ganguly, S	D3ET	9/1/2015		II	Tre	Multicenter Phase II, Double-blind Placebo Controlled Trial of Maintenance Ixazomib after Allogeneic Hematopoietic Stem Cell Transplantation for High Risk Multiple Myeloma	Y		24	0	0	0	0	
COG	Brain	NCT01217437	ACNS0821	Ginn, K	D3ET	4/21/2011		II	Tre	Temozolomide with Irinotecan versus Temozolomide, Irinotecan plus Bevacizumab (NSC# 704865, BB-IND# 7921) for Recurrent/Refractory Medulloblastoma/CNS PNET of Childhood, A COG Randomized Phase II Screening Trial	Y		8	1	5	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT01553149	ACNS1022	Ginn, K	D3ET	6/1/2011		II	Tre	Low-Dose or High-Dose Lenalidomide in Treating Younger Patients With Recurrent, Refractory, or Progressive Pilocytic Astrocytoma or Optic Pathway Glioma	Y		5	0	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

Interventional:

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ECOG CTSU/SWOG	Kidney	NCT01575548	ECOG E2810	Hashmi, M	D3ET	12/10/2013		III	Tre	Randomized, Double-Blind Phase III Study of Pazopanib vs. Placebo in Patients with Metastatic Renal Cell Carcinoma Who Have No Evidence of Disease Following Metastatectomy	Y		10	0	3	0	0	
SWOG	Urinary Bladder	NCT02177695	S1314	Hashmi, M	D3ET	6/19/2015		II	Tre	A RANDOMIZED PHASE II STUDY OF CO-EXPRESSION EXTRAPOLATION (COXEN) WITH NEOADJUVANT CHEMOTHERAPY FOR LOCALIZED, MUSCLE-INVASIVE BLADDER CANCER	Y		12	2	2	0	0	
SWOG	Prostate	NCT01809691	SWOG S1216	Hashmi, M	D3ET	9/11/2013		III	Tre	A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 With Androgen Deprivation Therapy + Bicalutamide in Patients With Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer	Y		30	2	8	3	12	
COG	Multiple	NCT01307579	ACCL0933	Hetherington, M	D3ET	8/18/2011		III	Sup	A Randomized Open-Label Trial of Caspofungin versus Fluconazole to Prevent Invasive Fungal Infections in Children Undergoing Chemotherapy for Acute Myeloid Leukemia (AML)	Y		5	0	7	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Leukemia	NCT01503632	ACCL1033	Hetherington, M	D3ET	8/2/2012		III	Sup	A Comprehensive Approach to Improve Medication Adherence in Pediatric ALL	Y		12	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT01817075	ACCL1034	Hetherington, M	D3ET	12/28/2013		III	Sup	To determine whether chlorhexidine gluconate cleansing decreases central line associated bloodstream infection in children with cancer or those receiving an allogeneic hematopoietic cell transplantation.	Y		10	0	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT01503515	ACCL1131	Hetherington, M	D3ET	6/27/2013		III	Sup	A Phase III Open-Label Trial of Caspofungin vs. Azole Prophylaxis for Patients at High-Risk for Invasive Fungal Infections (IFI) Following Allogeneic Hematopoietic Cell Transplantation (HCT)	Y		25	4	9	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Lymphoma, Leukemia	NCT01190930	AALL0932	Hetherington, M	D3ET	9/14/2010		III	Tre	Treatment of Patients with Newly Diagnosed Standard Risk B-Precursor Acute Lymphoblastic Leukemia (B-ALL) or Localized B-Lineage Lymphoblastic Lymphoma (B-Lly)	Y		110	14	60	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

Interventional:

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COG	Leukemia	NCT01406756	AALL1131	Hetherington, M	D3ET	12/15/2011		III	Tre	A Phase III Randomized Trial for Newly Diagnosed *High Risk B-precurso* r Acute Lymphoblastic Leukemia (ALL) Testing Clofarabine (IND# 73789, NSC# 606869) in the Very High Risk Stratum	Y		45	8	26	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Lymphoma, Leukemia	NCT02112916	AALL1231	Hetherington, M	D3ET	9/27/2014		III	Tre	A Phase III Randomized Trial Investigating Bortezomib (NSC# 681239; IND# 58443) on a Modified Augmented BFM (ABFM) Backbone in Newly Diagnosed T- Lymphoblastic Leukemia (T-ALL) and T-Lymphoblastic Lymphoma (T-LLy)	Y		10	1	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Leukemia	NCT02101853	AALL1331	Hetherington, M	D3ET	8/18/2015		III	Tre	Risk-Stratified Randomized Phase III Testing of Blinatumomab (IND#117467, NSC#765986) in First Relapse of Childhood B-Lymphoblastic Leukemia (B-ALL)	Y		5	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT01371981	AAML1031	Hetherington, M	D3ET	8/16/2011		III	Tre	A Phase III Randomized Trial for Patients with de novo AML using Bortezomib and Sorafenib for Patients with High Allelic Ratio FLT3/ITD	Y		15	1	9	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
NCI	Brain	NCT01381718	ACCL0922	Hetherington, M	D3ET	12/19/2012		II	Tre	Randomized Phase II placebo-controlled trial that will evaluate brain tumor survivors for neurocognitive deficit.	Y		20	1	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT00085735	ACNS0331	Hetherington, M	D3ET	11/15/2004	07/08/2015	III	Tre	A Study Evaluating Limited Target Volume Boost Irradiation and Reduced Dose Craniospinal Radiotherapy and Chemotherapy in Children with Newly Diagnosed Standard Risk Medulloblastoma	Y		15	0	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT00392327	ACNS0332	Hetherington, M	D3ET	6/20/2007		III	Tre	Efficacy of Carboplatin Administered Concomitantly With Radiation and Isotretinoin as a Pro-Apoptotic Agent in Other Than Average Risk Medulloblastoma/PNET Patients	Y		10	0	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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COG	Brain	NCT00336024	ACNS0334	Hetherington, M	D3ET	9/17/2007		III	Tre	A Phase III Randomized Trial for the Treatment of Newly Diagnosed Supratentorial PNET and High Risk Medulloblastoma in Children < 36 Months Old with Intensive Induction Chemotherapy with Methotrexate Followed by Consolidation with Stem Cell Rescue vs. the Same Therapy Without Methotrexate	Y		5	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT01096368	ACNS0831	Hetherington, M	D3ET	5/20/2010		III	Tre	Phase III Randomized Trial of Post-Radiation Chemotherapy in Patients with Newly Diagnosed Ependymoma	Y		8	0	3	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT01602666	ACNS1123	Hetherington, M	D3ET	7/25/2012		II	Tre	Phase II Trial of Response Based Radiation Therapy for Patients with Localized Central Nervous System Germ Cell Tumors	Y		12	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT02017964	ACNS1221	Hetherington, M	D3ET	1/24/2014		II	Tre	Study is to see if subjects with M0 Desmoplastic Medulloblastoma treated with usual chemotherapy without intraventricular methotrexate maintain good survival outcome.	Y		8	2	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT01231906	AEWS1031	Hetherington, M	D3ET	1/20/2011		III	Tre	Randomized Phase 3 trial will test the efficacy of adding vincristine-topotecan cyclophosphamide to the interval compressed 5 drug backbone.	Y		25	1	8	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT02306161	AEWS1221	Hetherington, M	D3ET	12/8/2015		II	Tre	Randomized Phase II Trial Evaluation the Addition of the IGF-1R Monoclonal Antibody Receptor Ganitumab to Multiagent Chemotherapy for Patients with Newly Diagnosed Metastatic Ewing Sarcoma	Y		6	1	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Liver	NCT00980460	AHEP0731	Hetherington, M	D3ET	11/19/2009		III	Tre	A Phase III Study . The purpose of this study is to get rid of the cancer and not have it come back in a greater number of children with hepatoblastoma.	Y		8	0	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Lymphoma	NCT02166463	AHOD1331	Hetherington, M	D3ET	6/22/2015		III	Tre	A Randomized Phase III Study of Brentuximab Vedotin (SGN-35, IND #117117) for Newly Diagnosed High Risk Classical Hodgkin Lymphoma (cHL) in Children and Adolescents	Y		20	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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COG	Multiple	NCT00567567	ANBL0032	Hetherington, M	D3ET	1/7/2002	07/31/2015	III	Tre	Phase III Randomized Study of Chimeric Antibody 14.18 (ch14.18) in High Risk Neuroblastoma Following Myeloblative Therapy and Autologous Stem Cell Transplant	Y		40	0	13	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT02176967	ANBL1232	Hetherington, M	D3ET	3/6/2015		III	Tre	Utilizing Response- and Biology-Based Risk Factors to Guide Therapy in Patients with Non-High Risk Neuroblastoma	Y		10	1	3	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Lymphoma, Leukemia	NCT01595048	ANHL1131	Hetherington, M	D3ET	5/1/2013		III	Tre	Study to find out what effects using rituximab in combination with the DA-EPOCH chemotherapy regimen will have on children with PMLBL	Y		2	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT02180867	ARST1321	Hetherington, M	D3ET	5/13/2015		II/III	Tre	Pazopanib Neoadjuvant Trial in Non-Rhabdomyosarcoma Soft Tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minues Pazopanib (NSC# 737754, IND #118613)	Y		5	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Leukemia	NCT01824693	ASCT1221	Hetherington, M	D3ET	4/13/2014		II	Tre	A randomized Phase II trial designed to identify which myeloablative hematopoietic cell transplant (HCT) preparative regimen has a lower relapse and treatment related mortality (TRM) rate in children with juvenile myelomonocytic leukemia (JMML).	Y		5	1	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
SWOG	Kidney	NCT01120249	SWOG S0931	Holzbeierlein, J	D3ET	12/15/2011		III	Tre	EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy, a Phase III Study	Y		25	4	17	6	7	
Alliance for Clinical Trials in Oncology	Lung	NCT02193282	A081105	Huang, C	D3ET	5/6/2015		III	Tre	Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients With Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-small Cell Lung Cancer (NSCLC)	Y		24	0	0	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency
ECOG CTSU/Alliance	Lung	NCT02201992	E4512	Huang, C	D3ET	5/6/2015		III	Tre	A Phase III Double-Blind Trial for Surgically Resected Early Stage Non-small Cell Lung Cancer: Crizotinib Versus Placebo for Patients With Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein	Y		8	0	0	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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SWOG	Lung	NCT00946712	SWOG S0819	Huang, C	D3ET	1/21/2010	05/01/2015	III	Tre	A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab With or Without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC)	Y		35	0	19	0	27	Protocol suspended to new enrollment in 2014 by sponsor and never re-opened at site.
SWOG	Lung	NCT02154490	SWOG S1400	Huang, C	D3ET	2/6/2015		II/III	Tre	A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer	Y		12	0	0	7	7	
ECOG CTSU/SWOG	Other Hematopoietic	NCT00843882	ECOG E2905	Kambhampati, S	D3ET	9/2/2010	10/31/2015	III	Tre	Randomized Phase III Trial Comparing the Frequency of Major Erythroid Response (MER) to Treatment with Lenalidomide (Revlimid®) Alone and in Combination with Epoetin Alfa (Procrit®) in Subjects with Low- or Intermediate-1 Risk MDS and Symptomatic Anemia	Y		0	0	0	0	1	Protocol was open at an NCTN component site.
NCCTG CTSU/RTOG	Brain and Nervous System	NCT01372774	NCCTG N107C / RTOG 1270	Kumar, P	D3ET	10/28/2013	12/18/2015	III	Tre	A Phase III Trial of Post-Surgical Stereotactic Radiosurgery (SRS) Compared With Whole Brain Radiotherapy (WBRT) for Resected Metastatic Brain Disease	Y		10	2	6	2	2	
NRG	Lung	NCT02186847	NRG-LU001	Kumar, P	D3ET	6/9/2015		II	Tre	Randomized Phase II Trial of Concurrent Chemoradiotherapy +/- Metformin HCL in Locally Advanced NSCLC	Y		20	0	0	3	3	
RTOG NSABP	Breast-Female	NCT01872975	NSABP B-51/RTOG 1304	Kumar, P	D3ET	12/16/2013		III	Tre	A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy	Y		10	1	1	3	4	
RTOG CTSU/EORTC	Brain and Nervous System	NCT00626990	RTOG 0834	Kumar, P	D3ET	7/2/2015	09/16/2015	III	Tre	Phase III Trial on Concurrent and Adjuvant Temozolomide Chemotherapy in non-1p/19q Deleted Anaplastic Glioma: The CATNON Intergroup Trial	Y		10	0	0	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency
RTOG	Prostate	NCT01368588	RTOG 0924	Kumar, P	D3ET	02/06/2012		III	Tre	Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial	Y		15	2	7	2	7	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

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RTOG	Head and Neck	NCT01953952	RTOG 1221	Kumar, P	D3ET	11/13/2014	02/16/2015	II	Tre	Randomized Phase II Trial of Transoral Endoscopic Head And Neck Surgery followed by Risk-Based IMRT and Weekly Cisplatin versus IMRT and Weekly Cisplatin for HPV Negative Oropharynx Cancer	Y		10	0	0	0	0	
ECOG CTSU/SWOG	Lymphoid Leukemia	NCT02003222	ECOG E1910	Lin, T	D3ET	10/6/2014		III	Tre	A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL-negative B lineage Acute Lymphoblastic Leukemia in Adults	Y		25	1	3	0	0	
SWOG	Myeloid and Monocytic Leukemia	NCT01802333	SWOG S1203	Lin, T	D3ET	10/21/2013	11/04/2015	III	Tre	A Randomized Phase III Study of Standard Cytarabine plus Daunorubicin (7+3) Therapy or Idarubicin with High Dose Cytarabine (IA) versus IA with Vorinostat (IA+V) in Younger Patients with Previously Untreated Acute Myeloid Leukemia (AML)	Y		30	10	26	0	0	
SWOG	Multiple Myeloma	NCT01668719	SWOG S1211	Lipe, B	D3ET	4/16/2013		I/II	Tre	A Randomized Phase I/II Study of Optimal Induction Therapy of Bortezomib, Dexamethasone and Lenalidomide with or without Elotuzumab (NSC-764479) for Newly Diagnosed High Risk Multiple Myeloma (HRMM)	Y		20	4	9	3	3	
RTOG	Head and Neck	NCT00956007	RTOG 0920	Lominska, C	D3ET	5/3/2010	12/22/2015	III	Tre	A Phase III Study of Postoperative Radiation Therapy (IMRT)+/- Cetuximab for Locally-Advanced Resected Head and Neck Cancer	Y		30	0	9	2	4	Biomarker-driven trial with high screen fail rate
RTOG	Head and Neck	NCT01810913	RTOG 1216	Lominska, C	D3ET	9/4/2013		II/III	Tre	Randomized Phase II/III Trial of Surgery and Postoperative Radiation Delivered with Concurrent Cisplatin Versus Docetaxel Versus Docetaxel and Cetuximab for High-Risk Squamous Cell Cancer of the Head and Neck	Y		10	1	2	1	3	
COG CTSU/NRG	Soft Tissue	NCT02180867	COG ARST1321	Mammen, J	D3ET	3/27/2015		II/III	Tre	Pazopanib Neoadjuvant Trial in Non-Rhabdomyosarcoma Soft Tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib	Y		12	1	1	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency
NRG	Head and Neck	NCT02254278	NRG-HN002	Mammen, J	D3ET	6/19/2015		II	Tre	A Randomized Phase II Trial for Patients with p16 Positive, Non-Smoking Associated, Locoregionally Advanced Oropharyngeal Cancer	Y		16	1	1	1	1	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

Interventional:

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RTOG	Esophagus	NCT01196390	RTOG 1010	Mammen, J	D3ET	8/23/2012	11/10/2015	III	Tre	A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma	Y		8	0	2	0	4	
RTOG	Multiple	NCT01672892	RTOG 1203	Mitchell, M	D3ET	8/15/2014	08/27/2015	III	Tre	A Randomized Phase III Study Of Standard Vs. IMRT Pelvic Radiation For Post-Operative Treatment Of Endometrial And Cervical Cancer (TIME-C)	Y		10	3	4	0	0	
Alliance for Clinical Trials in Oncology	Prostate	NCT01949337	A031201	Sharma, P	D3ET	2/20/2015		III	Tre	Phase III Trial of Enzalutamide (NSC # 766085) Versus Enzalutamide, Abiraterone and Prednisone for Castration Resistant Metastatic Prostate Cancer	Y		20	4	4	4	4	
NRG AstraZeneca	Multiple	NCT02032823	NSABP B-55 / D081CC00006	Sharma, P	D3ET	2/16/2015		III	Tre	A Randomised, Double-blind, Parallel Group, Placebo-controlled Multi-centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients With Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy	Y		20	1	1	0	0	
SWOG	Breast-Female	NCT01272037	SWOG S1007	Sharma, P	D3ET	4/19/2011	10/15/2015	III	Tre	A Phase III, Randomized Clinical Trial Of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less	Y		60	3	12	7	21	
SWOG	Multiple	NCT01674140	SWOG S1207	Sharma, P	D3ET	3/18/2014		III	Tre	Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk Hormone Receptor-Positive and HER2/NEU Negative Breast Cancer. e3 Breast Cancer Study-evaluating everolimus with endocrine therapy	Y		20	0	0	6	8	
ECOG CTSU/NRG	Head and Neck	NCT01898494	E3311	Shnayder, Y	D3ET	6/15/2015		II	Tre	Phase II randomized trial of Transoral Surgical Resection followed by low-dose or standard-dose IMRT in resectable p16+ Locally advanced oropharynx cancer.	Y		5	0	0	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

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BMT CTN	Myeloid and Monocytic Leukemia	NCT02345850	BMT CTN 1301	Shune, L	D3ET	11/25/2015		III	Sup	A Randomized, Multi-Center, Phase III Trial of Calcineurin Inhibitor-Free Interventions for Prevention of Graft-versus-Host Disease	Y		15	0	0	0	0	
Alliance for Clinical Trials in Oncology CTSU/CALGB	Non-Hodgkins Lymphoma	NCT01511562	CALGB 51101	Shune, L	D3ET	10/1/2015		II	Tre	A Randomized Phase II Trial of Myeloablative verses non-Myeloablative Consolidation Chemotherapy for Newly Dianosed Primary CNS B-cell Lymphoma	Y		6	0	0	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency
Alliance for Clinical Trials in Oncology	Breast-Female	NCT01901094	A011202	Wagner, J	D3ET	7/2/2014		III	Tre	A Randomized Phase III Trial Evaluating the Role of Axillary Lymph Node Dissection in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy	Y		10	7	9	0	0	This is a high screen fail trial.
Alliance for Clinical Trials in Oncology	Breast-Female	NCT01439711	CALGB 40903	Wagner, J	D3ET	4/22/2015	01/11/2016	II	Tre	Phase II Study of Neoadjuvant Letrozole for postmenopausal women with estrogen receptor positive ductal carcinoma in situ (DCIS)	Y		10	0	0	0	0	
CALGB CTSU/SWOG	Prostate	NCT01238172	CALGB 70807	Williamson, S	D3ET	2/14/2012	10/01/2015	N/A	Tre	The Mens Eating and Living (MEAL) Study: A Randomized Trial of Diet to Alter Disease Progression in Prostate Cancer Patients on Active Surveillance	Y		10	0	8	1	2	
CALGB CTSU/SWOG	Colon	NCT01150045	CALGB 80702	Williamson, S	D3ET	3/18/2011	11/20/2015	III	Tre	A Phase III Trial of 6 versus 12 Treatments of Adjuvant FOLFOX Plus Celecoxib or Placebo for Patients with Resected Stage II Colon Cancer	Y		50	3	7	7	31	
CALGB CTSU/SWOG	Prostate	NCT00430183	CALGB 90203	Williamson, S	D3ET	9/26/2007	03/04/2015	III	Tre	Randomized Phase III Study of Neo-Adjuvant Docetaxel and Androgen Deprivation Prior to Radical Prostatectomy Versus Immediate Radical Prostatectomy in Patients with High-Risk, Clinically Localized Prostate Cancer	Y		20	0	10	0	3	
ECOG CTSU/SWOG	Pancreas	NCT01824875	ECOG E2211	Williamson, S	D3ET	8/27/2014		II	Tre	A Randomized Phase II Study of Temozolomide or Temozolomide and Capecitabine in Patients with Advanced Pancreatic Neuroendocrine Tumors	Y		6	3	3	1	1	Meets definition of Rare Cancer and/or Molecular Target with low frequency

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

Interventional:

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SWOG	Multiple	NCT01498289	SWOG S1201	Williamson, S	D3ET	8/7/2012	04/01/2015	II	Tre	A Randomized Phase II Pilot Study Prospectively Evaluating Treatment for Patients Based on ERCC1 (Excision Repair Cross-Complementing 1)for Advanced/Metastatic Esophageal, Gastric or Gastroesophageal Junction (GEJ) Cancer	Y		10	0	0	1	4	
SWOG	Liver	NCT02042443	SWOG S1310	Williamson, S	D3ET	12/8/2014	05/15/2015	II	Tre	Randomized Phase II Trial of Single Agent MEK Inhibitor Trametinib (GSK1120212) vs 5-Fluorouracil or Capecitabine in Refractory Advanced Biliary Cancer	Y		10	2	2	0	0	
SWOG	Colorectal	NCT02164916	SWOG S1406	Williamson, S	D3ET	1/16/2015		II	Tre	Randomized Phase II Study of Irinotecan and Cetuximab with or without Vemurafenib in BRAF Mutant Metastatic Colorectal Cancer.	Y		15	2	2	0	0	
Alliance for Clinical Trials in Oncology	Lymphoid Leukemia	NCT01886872	A041202	Yacoub, A	D3ET	7/23/2014	12/28/2015	III	Tre	A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Brutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (> 65 years of age) with Chronic Lymphocytic Leukemia (CLL)	Y		10	1	1	4	5	
ECOG CTSU/SWOG	Multiple Myeloma	NCT01169337	ECOG E3A06	Yacoub, A	D3ET	11/15/2013		II/III	Tre	Randomized Phase III Trial of Lenalidomide Versus Observation Alone in Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma	Y		20	5	9	3	3	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

Interventional:

EXTERNALLY PEER-REVIEWED												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
Giselle Sholler	Brain	NCT02395666	NMTRC003B	August, K	D3ET	6/18/2014		II	Pre	Preventative Trial of Difluoromethylornithine (DFMO) in High Risk Patients With Neuroblastoma That is in Remission	Y		30	2	11	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Giselle Sholler	Multiple	NCT02162732	NMTRC009	August, K	D3ET	11/21/2014			Tre	Molecular-Guided Therapy for Childhood Cancer	Y		8	2	3	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Giselle Sholler	Multiple	NCT02139397	NMTRC010B	August, K	D3ET	6/18/2014		I/II	Tre	Study of DFMO in Combination With Bortezomib for Relapsed or Refractory Neuroblastoma	Y		10	0	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Giselle Sholler	Multiple	NCT00601003	V0706	August, K	D3ET	1/5/2011		II	Tre	Study of Nifurtimox to Treat Refractory or Relapsed Neuroblastoma or Medulloblastoma	Y		8	0	4	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Department of Defense (DOD) Sidney Kimmel Comprehensive Cancer Center	Prostate	NCT02286921	J14146	Holzbeierlein, J	D3ET	9/24/2015		II	Tre	A Randomized Phase II Study Comparing Bipolar Androgen Therapy vs. Enzalutamide in Asymptomatic Men with Castration Resistant Metastatic Prostate Cancer: The TRANSFORMER Trial	Y		10	1	1	0	0	
University of Texas Health Science Center	Multiple Sites	NCT01911208	RECRUIT	McGuirk, J	D3ET	5/20/2015		N/A	Hsr	A Randomized Recruitment Intervention Trial (RECRUIT)	Y		15	4	6	0	0	
Patient-Centered Outcomes Research Institute (PCORI)	Other Hematopoietic	NCT02200133	13-SCP	McGuirk, J	D3ET	6/2/2015		N/A	Sup	Randomized Study of Individualized Care Plans for Hematopoietic Cell Transplant Survivors	Y		100	42	42	0	0	
Myeloproliferative Disorders-Research Consortium	Other Hematopoietic	NCT01259817	MPD-RC-111	Yacoub, A	D3ET	3/27/2015	01/01/2016	II	Tre	Single Arm Salvage Therapy with Pegylated Interferon alfa-2a for Patients with High Risk Polycythemia Vera or High Risk Essential Thrombocythemia who are either Hydroxyurea Resistant or Intolerant or have had a Abdominal Vein Thrombosis	Y		20	14	14	0	0	
Myeloproliferative Disorders-Research Consortium	Myeloid and Monocytic Leukemia	NCT01259856	MPD-RC-112	Yacoub, A	D3ET	6/4/2015		III	Tre	Randomized Trial of Pegylated Interferon Alfa-2a versus hydroxyurea Therapy in the Treatment of high Risk Polycythemia Vera and high Risk Essential Thrombocythemia	Y		12	8	8	0	0	
Myeloproliferative Disorders-Research Consortium	Myelofibrosis	NCT01790295	MPD-RC-114	Yacoub, A	D3ET	6/17/2015		II	Tre	Exploring the potential of dual kinase JAK 1/2 Inhibitor Ruxolitinib (INC424) with Reduced Intensity Allogeneic Hematopoietic Cell Transplantation in Patients wtih Myelofibrosis	Y		4	1	1	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

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The SWOG/Hope Foundation Impact Award	Multiple	NCT02087657	Auto-HBO	Aljitawi, O	D3ET	3/13/2014	01/22/2015	Device	Tre	Pilot Study Exploring the Use of Hyperbaric Oxygen in Autologous PBSC Transplantation	N	20	20	0	23	0	0	Protocol suspended to new enrollment throughout 2015 while amendment was written
KU Endowment Association Frontiers	Multiple	NCT02099266	BMT-2011-08-01	Aljitawi, O	D3ET	6/4/2013	02/23/2015	Device	Tre	A Pilot Study to Determine the Safety and Efficacy of Using Hyperbaric Oxygen Therapy to Improve Umbilical Cord Blood Stem Cell Homing and Subsequent Engraftment	N	15	15	3	15	0	0	
Millennium Pharmaceuticals	Lymphoma, Leukemia	NCT02535806	MERCY01	August, K	D3ET	6/11/2015		II	Tre	MERCY01 - A Pilot Study of Mitoxantrone-Based Four Drug Reinduction in Combination with Bortezomib for Relapsed or Refractory Acute Lymphoblastic Leukemia or Lymphoblastic Lymphoma in Children and Young Adults	N	10	10	1	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Thomas Jefferson University	Multiple	NCT01833351	KUMC 12680	Drisko, J	D3ET	7/1/2011	09/11/2015	I	Tre	Pharmacokinetic Evaluation of Intravenous Ascorbic Acid	N	66	66	4	34	0	0	
Investigator	Prostate	NCT01777061	KUMC 13429	Dusing, R	D3ET	4/19/2013		N/A	Dia	Clinical Management Decisions Based on [11C]acetate Positron Emission Tomography Performed on Prostate Cancer Patients with Biochemical Recurrence	N	250	250	113	249	0	0	
Celgene University of Nebraska	Non-Hodgkins Lymphoma	NCT01035463	RV-LYM-PI-0328	Ganguly, S	D3ET	3/10/2015	07/14/2015	I/II	Tre	Phase I/II Study of Lenalidomide Maintenance Following BEAM (+/- Rituximab) for Chemo-Resistant or High Risk Non-Hodgkin's Lymphoma	Y		20	4	4	0	0	
Baylor University Medical Center	Liver	NCT02081755	HCCBAYLOR12	Gilroy, R	D3ET	12/18/2014		IV	Tre	A 36 month multi-center, open label, randomized, comparator study to evaluate the efficacy and safety of everolimus immunosuppression treatment in liver transplantation for hepatocellular carcinoma exceeding Milan criteria.	Y		35	11	11	0	0	
GlaxoSmithKline	Breast-Female	NCT01283789	2010-IIT-Novartis-RAD-001	Khan, Q	D3ET	2/22/2011		II	Tre	Phase II Trial of Lapatinib and RAD-001 for HER2 Positive Metastatic Breast Cancer	N	45	45	0	20	0	0	Protocol was temporarily suspended to enrollment most of 2015.
University of Kansas Cancer Center	Multiple	NCT02595320	2015-X7-7-LQT	Khan, Q	D3ET	10/1/2015		II	Tre	Randomized open-label trial of dose dense, fixed dose capecitabine compared to standard dose capecitabine in metastatic breast cancer and advanced/metastatic GI cancers.	Y	183	183	9	9	6	6	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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Department of Defense (DOD)	Prostate	NCT00669162	KUMC 12313	Kumar, P	D3ET	2/24/2011	07/30/2015	I/II	Tre	A Phase I/II Trial of Post-Prostatectomy Radiation Therapy, Hormonal Therapy and Concurrent Docetaxel for High Risk Pathologic T2-T3N0M0 Prostate Cancer	Y	25	25	0	21	0	6	Protocol was temporarily suspended to enrollment all of 2015.
Investigator	Multiple Myeloma		KUMC 13350	Lipe, B	D3ET	8/16/2012	05/30/2015	Feasibility/Pilot	Bas	Correlation Between Bone Metabolism and Risk Group of MGUS and Pilot trial of vitamin D supplementation	Y	55	55	3	56	0	6	
AngioDynamics University of Arkansas	Breast-Female	NCT01420380	104603	McGinness, M	D3ET	4/12/2011		N/A	Tre	ABLATE Trial: Radiofrequency Ablation After Breast Lumpectomy (eRFA) Added To Extend Intraoperative Margins in the Treatment of Breast Cancer	Y		40	8	34	0	0	
FRONTIERS	Prostate	NCT02198859	KUMC 13582	Mirza, M	D3ET	4/11/2014		I	Tre	Phase 1 Study of Evaluation of Lithium and its effect on clinically localized prostate cancer	N	18	18	3	9	0	0	
Investigator	Multiple		KUMC 13833	Mische Lawson, L	D3ET	8/29/2013	06/29/2015	N/A	Sup	Effectiveness of Music and Art in Reducing Symptoms Related to Blood and Marrow Transplantation: A Pilot Study	N	60	60	18	42	0	0	
University of Chicago	Head and Neck	NCT01111058	09-266-B	Neupane, P	D3ET	6/8/2012	04/01/2015	II	Tre	Randomized Double-Blind Phase II Trial of Everolimus versus Placebo as Adjuvant Therapy in Patients with Locally Advanced Squamous Cell Cancer of the Head and Neck (SCCHN)	Y		10	2	9	0	0	
Univ. of Kansas Cancer Center	Breast-Female	NCT02413320	2014-BRST-TNBC-LQT	Sharma, P	D3ET	7/9/2015		II	Tre	Randomized open label Phase II trial of neoadjuvant Carboplatin plus Docetaxel or Carboplatin plus Paclitaxel followed by Adriamycin plus Cyclophosphamide in stage I-III triple-negative breast cancer.	Y	100	100	6	6	6	6	
Novartis Pharmaceuticals	Breast-Female	NCT02379247	CBYL719XUS06T	Sharma, P	D3ET	3/3/2015		I/II	Tre	Phase I/II study of BYL719 and Nab-Paclitaxel (Abraxane) in patients with locally recurrent or metastatic HER-2 negative breast cancer	Y	54	34	9	9	0	0	
Celgene	Multiple	NCT02393794	RM-CL-PI-002783	Sharma, P	D3ET	7/17/2015		I/II	Tre	Phase I/II trial of Cisplatin + Romidepsin in locally recurrent or metastatic triple negative breast cancer or BRCA 1/BRCA 2 mutation associated locally recurrent or metastatic breast cancer	N	54	54	4	4	0	0	
Investigator	Head and Neck	NCT02338102	STUDY00000087	Shnayder, Y	D3ET	10/24/2013	06/11/2015	Feasibility/Pilot	Sup	Nasal Saline Irrigation after Radiation Therapy for Oropharyngeal Cancer: A Pilot Study	N	40	40	0	36	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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Brain Tumor Trials Collaborative (BTTC)	Brain and Nervous System	NCT01434602	BTTC09-01	Taylor, S	D3ET	4/17/2014		I/II	Tre	BTTC09-01: A Phase I-II trial Everolimus and Sorafenib in Patients with Recurrent High-Grade Gliomas	Y		10	0	2	0	0	Trial was suspended to new enrollment on 3/19/2015.
Weill Cornell Medical College	Prostate	NCT00859781	0810010067 (J591+Ketoconazole)	Williamson, S	D3ET	12/14/2012	04/28/2015	II	Tre	A Randomized Phase 2 Trial of 177Lu Radiolabeled Monoclonal Antibody HuJ591 (177Lu-J591) and Ketoconazole in Patients with High-Risk Castrate Biochemically Relapsed Prostate Cancer After Local Therapy	Y		10	1	3	0	0	
Albert Einstein College of Medicine of Yeshiva University	Myelodysplastic Syndrome	NCT01772420	2012-407	Yacoub, A	D3ET	7/31/2015		II	Tre	Phase II Study of Lenalidomide and Eltrombopag in Patients with Symptomatic Anemia in Low or Intermediate I Myelodysplastic Syndrome (MDS)	Y		15	5	5	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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Novartis Pharmaceuticals	Non-Hodgkins Lymphoma		CCTL019B2206	Abhyankar, S	D3ET	7/29/2015		II	Oth	A multicenter study of apheresis collection of peripheral blood mononuclear cells (PBMC)in patients with CD19 expressing malignancies who could be eligible for a CTL019 clinical research trial	Y		15	9	9	0	0	
GlaxoSmithKline	Multiple	NCT01610414	115523 (Zoster-002)	Abhyankar, S	D3ET	3/11/2013	03/13/2015	III	Sup	Observer-blind study to evaluate efficacy, safety, and immunogenicity of GSK Biologicals' Herpes Zoster vaccine GSK1437173A	Y		30	0	28	0	0	
Kyowa Pharmaceutical	Non-Hodgkins Lymphoma	NCT01728805	0761-010	Abhyankar, S	D3ET	4/30/2015	11/30/2015	III	Tre	Open-Label, Multi-Center, Randomized Study of Anti-CCR4 Monoclonal Antibody KW-0761 (mogamulizumab) Versus Vorinostat in Subjects with Previously Treated Cutaneous T-Cell Lymphoma	Y		5	2	2	0	0	
Hoffman-LaRoche Abbvie	Non-Hodgkins Lymphoma	NCT02187861	BO29337	Abhyankar, S	D3ET	5/14/2015	02/19/2016	II	Tre	A Phase II, Open-Label Study Evaluating the Safety and Efficacy of GDC-0199 (ABT-199) plus Bendamustine plus Rituximab (BR) in Comparison with BR Alone or GDC-0199 plus Rituximab (R) in Patients with Relapsed and Refractory Follicular Non-Hodgkin's Lymphoma	Y		5	3	3	0	0	
Incyte Corporation	Pancreas	NCT02119663	INCB 18424-363	Al-Rajabi, R	D3ET	5/28/2015	02/15/2016	III	Tre	A Randomized, Double-Blind, Phase 3 Study of the JAK 1/2 Inhibitor, Ruxolitinib or Placebo in Combination With Capecitabine in Subjects With Advanced or Metastatic Adenocarcinoma of the Pancreas Who Have Failed or Are Intolerant to First-Line Chemotherapy (The JANUS 2 Study)	Y		10	0	0	0	0	This is a high screen fail trial.
NewLink Genetics Corporation	Pancreas	NCT01836432	NLG-0505	Al-Rajabi, R	D3ET	5/19/2014	12/17/2015	III	Tre	A Phase III Study of Chemotherapy With or Without Algenpantucel-L (HyperAcute®-Pancreas) Immunotherapy in Subjects with Borderline Resectable or Locally Advanced Unresectable Pancreatic Cancer	Y		20	11	15	0	0	
Millennium Pharmaceuticals	Lymphoma	NCT01492088	C25002	August, K	D3ET	6/1/2013		I/II	Tre	Study of Brentuximab Vedotin (SGN-35) in Pediatric Patients With Relapsed or Refractory Systemic Anaplastic Large-Cell Lymphoma or Hodgkin Lymphoma	Y		5	0	3	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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Celgene, COG	Leukemia	NCT02538965	CC-5013-AML-002, AAML1522	August, K	D3ET	12/3/2015		II	Tre	A Study of Lenalidomide in Pediatric Subjects With Relapsed or Refractory Acute Myeloid Leukemia	Y		5	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Ansun Biopharma, Inc	Other Hematopoietic	NCT01644877	DAS181-2-05	Clough, L	D3ET	5/5/2014		II	Sup	A Phase II, Randomized, Double-Blind, Placebo-controlled study to examine the effects of DAS181 in immunocompromised subjects with Lower Respiratory Tract Parainfluenza Infection on Supplemental Oxygen	Y		6	2	3	0	0	
Ansun Biopharma, Inc	Other Hematopoietic	NCT01924793	DAS181-2-06	Clough, L	D3ET	2/18/2014		II	Sup	An Open Label study to examine the effects of DAS181 administered by Dry Powder Inhaler (DPI) or Nebulized formulation in Immunocompromised subjects with Parainfluenza (PIV) infection	Y		6	0	0	0	0	Open label extension protocol - on temporary suspension
Merck and Co.	Other Hematopoietic	NCT02137772	MK-8228-001	Clough, L	D3ET	7/18/2014		III	Sup	A Phase III Randomized, Placebo-controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-8228 (Letermovir) for the Prevention of Clinically Significant Human Cytomegalovirus (CMV) Infection in Adult, CMV-Seropositive Allogeneic Hematopoietic Stem Cell Transplant Recipients	Y		10	2	4	0	0	
Optimer Pharmaceuticals	Multiple	NCT01691248	OPT-80-302	Clough, L	D3ET	10/3/2012	01/08/2015	III	Sup	DEFLECT-1: A Phase 3b Multi-Center, Double-Blind, Randomized, Placebo Controlled Study to Demonstrate the Safety and Efficacy of Fidaxomicin for Prophylaxis against CLostridium difficilE-Associated Diarrhea in Adults Undergoing Hematopoietic Stem Cell Transplantation	Y		20	0	14	0	0	
Prometheus Laboratories	Melanoma, skin	NCT01856023	12PLK02	Doolittle, G	D3ET	9/30/2014	06/29/2015	IV	Tre	Open-Label, Randomized, Multi-Center Study Comparing the Sequence of High Dose Aldesleukin (Interleukin-2) and Ipilimumab (Yervoy®) in Patients with Metastatic Melanoma	Y		15	1	1	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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Novartis Pharmaceuticals	Breast-Female	NCT02278120	CLEE011E2301	Doolittle, G	D3ET	8/28/2015		III	Tre	A Phase III randomized, double-blind, placebo-controlled study of LEE001 or placebo in combination with tamoxifen and goserelin or a non-steroidal aromatase inhibitor (NSAI) and goserelin for the treatment of premenopausal women with hormone receptor positive, HER2-negative, advanced breast cancer	Y		18	0	0	0	0	
Hoffman-LaRoche	Melanoma, skin	NCT01667419	GO27826	Doolittle, G	D3ET	9/24/2013	09/16/2015	III	Tre	A PHASE III, RANDOMIZED, DOUBLE-BLIND,PLACEBO-CONTROLLED STUDY OF VEMURAFENIB RO5185426) ADJUVANT THERAPY IN PATIENTS WITH SURGICALLY RESECTED, CUTANEOUS BRAF-MUTANT MELANOMA AT HIGH RISK FOR RECURRENCE	Y		8	1	1	0	0	
NewLink Genetics Corporation	Melanoma, skin	NCT02054520	NLG0304	Doolittle, G	D3ET	12/9/2015		II	Tre	A Phase 2b Study of Immune Checkpoint Inhibition With or Without Dorgenmeltucel-L (HyperAcute Melanoma) Immunotherapy for Stage IV Melanoma Patients	Y		12	0	0	0	0	
Bayer Healthcare Pharmaceuticals US Oncology	Colorectal	NCT02425683	USOR 13050	Flanagan, J	D3ET	8/27/2015		II	Tre	A randomized, Phase II Study of High-Risk Colorectal Cancer Patients (Stage IIIC) treated with Either Regorafenib or Standard of Care (No Treatment) after Adjuvant FOLFOX	Y		5	0	0	0	0	Open only at community sites. Enrollment low due to US Oncology Research contract negotiations.
Pfizer	Non-Hodgkins Lymphoma	NCT02213263	B3281006 / USOR 14020	Flanagan, J	D3ET	2/3/2015		III	Tre	A Phase 3, Randomized, Double-Blind Study Of PF-05280586 Versus Rituximab For The First-Line Treatment Of Patients With CD20-Positive, Low Tumor Burden, Follicular Lymphoma	Y		4	0	0	0	0	Open only at community sites. Enrollment low due to US Oncology Research contract negotiations.
Momenta Pharmaceuticals, Inc.	Pancreas	NCT01621243	MOM-M402-103 / USOR 13131	Flanagan, J	D3ET	6/18/2015		I/II	Tre	A Phase I/II , Two-Part, Multicenter Study to Evaluate the Safety and Efficacy of M402 in combination with nabpaclitaxel and gemcitabine in patients with metastatic pancreatic cancer	Y		4	0	0	1	1	Open only at community sites. Enrollment low due to US Oncology Research contract negotiations.

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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Ambit Biosciences Corporation	Myeloid and Monocytic Leukemia	NCT02039726	AC220-007	Ganguly, S	D3ET	12/9/2014		III	Tre	A PHASE 3 OPEN-LABEL RANDOMIZED STUDY OF QUIZARTINIB (AC220) MONOTHERAPY VERSUS SALVAGE CHEMOTHERAPY IN SUBJECTS WITH FLT3-ITD POSITIVE ACUTE MYELOID LEUKEMIA (AML) REFRACTORY TO OR RELAPSED AFTER FIRST-LINE TREATMENT WITH OR WITHOUT HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT) CONSOLIDATION	Y		8	4	4	0	0	Biomarker-driven trial with high screen fail rate
Medimmune	Non-Hodgkins Lymphoma	NCT01453205	CD-ON-MEDI-551-1088	Ganguly, S	D3ET	1/6/2015	09/18/2015	II	Tre	A Phase 2 Randomized Open-label Study of MEDI-551 in Adults With Relapsed or Refractory DLBCL	Y		10	4	4	0	0	
Argos	Kidney	NCT01582672	AGS-003-007	Holzbeierlein, J	D3ET	8/15/2013	07/15/2015	III	Tre	An International Phase 3 Randomized Trial of Autologous Dendritic Cell Immunotherapy (AGS-003) Plus Standard Treatment of Advanced Renal Cell Carcinoma (ADAPT)	Y		10	1	3	0	0	
Heat Biologics	Urinary Bladder	NCT02010203	HS410-101	Holzbeierlein, J	D3ET	12/19/2014	02/16/2016	I/II	Tre	A Phase 1/2, Placebo-Controlled, Randomized Study to Evaluate the Safety, Immune Response and Clinical Activity of HS-410 in Patients with High-Risk Non-Muscle Invasive Bladder Cancer Who Have Undergone Transurethral Resection of Bladder Tumor (TURBT) and Received Prior Treatment with Induction Bacillus Calmette–Guérin (BCG)	Y		20	3	3	0	0	
NewLink Genetics Corporation	Lung	NCT01774578	NLG0301	Huang, C	D3ET	4/10/2014		II/III	Tre	An Open-label, Randomized Phase IIB/III Active Control Study of Second-line HyperAcute®-Lung (tergenpumatucel-L) Immunotherapy versus Docetaxel in Progressive or Relapsed Non-Small Cell Lung Cancer	Y		20	4	12	0	0	
Onconova Therapeutics, Inc.	Myelodysplastic Syndrome	NCT01928537	04-24 (Onconova)	Kambhampati, S	D3ET	3/31/2014	01/09/2015	III	Tre	Phase IIIB, Open-label, Multi-Center Study of the Efficacy and Safety of Rigosertib Administered as 72-hour Continuous Intravenous Infusions in Patients with Myelodysplastic Syndrome with Excess Blasts Progressing On or After Azacitidine or Decitabine	Y		5	0	1	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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Millenium Pharmaceuticals	Breast-Female	NCT02049957	C31001	Khan, Q	D3ET	5/29/2015	01/21/2016	I/II	Tre	A Phase 1b/2 Study of Safety and Efficacy of MLN0128 (Dual TORC1/2 Inhibitor) in Combination with Exemestane or Fulvestrant Therapy in Postmenopausal Women with ER+/HER2-Advanced or Metastatic Breast Cancer that has Progressed on Treatment with Everolimus in Combination with Exemestane or Fulvestrant	Y		6	1	1	0	0	
Oncothyreon, Inc	Multiple	NCT01983501	ONT-380-004	Khan, Q	D3ET	11/3/2014	07/21/2015	I	Tre	Phase 1b, Open-Label Study to Assess the Safety and Tolerability of ONT-380 Combined with Ado-Trastuzumab Emtansine (T-DMI)	Y		10	5	5	0	0	
Cerulean Pharma Inc	Kidney	NCT02187302	CRLX101-208	Komiya, T	D3ET	7/2/2015	10/19/2015	II	Tre	A Randomized, Phase 2 Study to Assess the Safety and Efficacy of CRLX101 in Combination with Bevacizumab in Patients with Metastatic Renal Cell Carcinoma (RCC) versus Standard of Care (SOC)(Investigator's Choice)	Y		12	1	1	0	0	
Incyte Corporation	Lung	NCT02119650	INCB 18424-266	Komiya, T	D3ET	9/17/2014		II	Tre	A Randomized, Double-Blind Phase 2 Study of Ruxolitinib or Placebo in Combination With Pemetrexed/Cisplatin and Pemetrexed Maintenance for Initial Treatment of Subjects With Nonsquamous Non–Small Cell Lung Cancer That Is Stage IIIB, Stage IV, or Recurrent	Y		10	0	0	3	3	Biomarker-driven trial with high screen fail rate
Merck and Co.	Lung	NCT02142738	MK-3475-024	Komiya, T	D3ET	8/6/2015	09/22/2015	III	Tre	A Randomized Open-Label Phase III Trial of MK-3475 Versus Platinum Based Chemotherapy in 1L Subjects With PD-L1 Strong Metastatic Non-Small Cell Lung Cancer	Y		12	0	0	0	0	Biomarker-driven trial with high screen fail rate
Pfizer	Multiple	NCT02312037	B1761026	Lin, T	D3ET	3/9/2015		IV	Oth	Gemtuzumab Ozogamicin (Mylotarg (Registered)) Expanded Access Protocol For Treatment Of Patients In The United States With Relapsed/Refractory Acute Myelogenous Leukemia Who May Benefit From Treatment And Have No Access To Other Comparable/Alternative Therap	Y		5	2	2	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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Astellas Pharma US	Myeloid and Monocytic Leukemia	NCT02236013	2215-CL-0103	Lin, T	D3ET	3/17/2015		I	Tre	A Phase 1 Study of ASP2215 in Combination with Induction and Consolidation Chemotherapy in Patients with Newly Diagnosed Acute Myeloid Leukemia	Y		8	0	0	0	0	Protocol was temporarily suspended to enrollment most of 2015.
Pfizer	Multiple	NCT01546038	B1371003	Lin, T	D3ET	8/27/2013	03/04/2015	II	Tre	A Phase 1b/2 Study to Evaluate the Safety and Efficacy of PF-04449913, an Oral Hedgehog Inhibitor, in Combination with Intensive Chemotherapy, Low Dose ARA-C or Decitabine in Patients with Acute Leukemia or High-Risk Myelodysplastic Syndrome	Y		10	0	4	0	0	
Novartis Pharmaceuticals	Myeloid and Monocytic Leukemia	NCT01744665	CAMN107A US37	Lin, T	D3ET	2/3/2014	01/13/2015	II	Tre	A phase II randomized, multicenter study of treatment-free remission in chronic myeloid leukemia in chronic phase (CML-CP) patients who achieve and sustain MR4.5 after switching to nilotinib	Y		10	0	1	0	1	Sponsor reported slow accrual study-wide.
Celator Pharmaceuticals Inc	Multiple	NCT02238925	CLTR0310-206	Lin, T	D3ET	10/7/2014	06/01/2015	II	Tre	An Open Label Phase II Pharmacokinetic and Pharmacodynamic Assessment of the Potential for QTC Prolongation Following First Induction Treatment with CPX-351 (CYTARABINE:DAUNORUBICIN Liposome Injection) in Acute Leukemias and MDS Patients	Y		12	12	18	0	0	
Karyopharm Therapeutics, Inc	Myeloid and Monocytic Leukemia	NCT02088541	KCP-330-008	Lin, T	D3ET	11/18/2015		II	Tre	A randomized, open label, phase 2 wstudy of the selectibe inhibitor of nuclear export 9SINE) selinexor 9KPT-330) versus specified physician's choice in patients > 60 years old with relapsed/refractory acute myeloid leukemia (AML) who are ineligile for intensive chemortherapy and/or transplantation	Y		5	0	0	0	0	
AbbVie	Myeloid and Monocytic Leukemia	NCT02287233	M14-387	Lin, T	D3ET	3/5/2015		I	Tre	A Phase 1/2 Study of ABT-199 in Combination with Low-Dose Cytarabine in Treatment-Naïve Subjects with Acute Myelogenous Leukemia Who Are ≥ 65 Years of Age and Who Are Not Eligible for Standard Anthracycline-Based Induction Therapy	Y		12	4	4	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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Janssen	Multiple Myeloma	NCT02136134	54767414MMY3004	Lipe, B	D3ET	5/11/2015	07/09/2015	III	Tre	Phase 3 STudy Comparing Daratumumab, Bortezomib and Dexamethasone (DVd) vs Bortezomib and Dexamethasone (Vd) in Subjects with Relapsed or Refractory Multiple Myeloma	Y		20	3	3	0	0	
Array BioPharma	Multiple Myeloma	NCT02092922	ARRAY-520-215	Lipe, B	D3ET	6/30/2015	06/30/2015	II	Tre	A Multicenter Phase 2 Study of Single-agent Filanesib (ARRY-520) in Patients with Advanced Multiple Myeloma	Y		15	0	0	0	0	On day of site activation, received sponsor letter closing the study to enrollment.
EMD Serono	Melanoma, skin	NCT01973608	EMR 062235-005	Lominska, C	D3ET	1/22/2015	02/11/2015	II	Tre	A Safety Study for MSB0010445 in Combination with Stereotactic Body Radiation in Advanced Melanoma Subjects Following Prior Treatment with Ipilimumab	Y		10	0	0	0	0	
Astellas Pharma US Abbott Laboratories	Multiple	NCT01877655	0113-CL-1004	McGuirk, J	D3ET	2/6/2014	05/12/2015	III	Pre	A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial to Evaluate the Protective Efficacy and Safety of a Therapeutic Vaccine, ASP0113, in Cytomegalovirus (CMV)-Seropositive Recipients Undergoing Allogeneic, Hematopoietic Cell Transplant (HCT)	Y		30	0	2	0	0	
Novartis Pharmaceuticals	Non-Hodgkins Lymphoma	NCT02445248	CCTL019C2201	McGuirk, J	D3ET	7/29/2015		II	Tre	A phase II, single arm, multicenter trial to determine the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL)	Y		15	9	9	0	0	
Polyphor Ltd	Multiple	NCT01413568	POL-4	McGuirk, J	D3ET	10/31/2014	07/24/2015	I/II	Tre	A Phase I/II Study Evaluating the Safety and Efficacy of Intravenous POL6326 for the Mobilization and Transplantation of HLA-Matched Sibling Donor Hematopoietic Stem Cells in Patients with Advanced Hematological Malignancies	Y		10	0	0	0	0	
Novartis	Lymphoma		CCTL019B2206	Myers, G	D3ET	10/16/2014		NA	Oth	A MULTICENTER STUDY OF APHERESIS COLLECTION OF PERIPHERAL BLOOD MONONUCLEAR CELLS (PBMC) IN PATIENTS WITH CD19 EXPRESSING MALIGNANCIES WHO COULD BE ELIGBLE FOR A CTL019 CLINICAL RESEARCH TRIAL	Y		6	3	3	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

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Novartis	Leukemia	NCT02445222	CCTL019A2205B	Myers, G	D3ET	10/28/2014		II	Tre	A PHASE II, SINGLE ARM, MULTICENTER TRIAL TO DETERMINE THE EFFICACY AND SAFETY OF CTL019 IN PEDIATRIC PATIENTS WITH RELAPSED AND REFRACTORY B-CELL ACUTE LYMPHOBLASTIC LEUKEMIA	Y		6	1	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Novartis	Leukemia	NCT02435849	CCTL019B2202	Myers, G	D3ET	6/4/2015		II	Tre	A PHASE II, SINGLE ARM, MULTICENTER TRIAL TO DETERMINE THE EFFICACY AND SAFETY OF CTL019 IN PEDIATRIC PATIENTS WITH RELAPSED AND REFRACTORY B-CELL ACUTE LYMPHOBLASTIC LEUKEMIA	Y		6	2	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
CytRx	Soft Tissue	NCT02049905	ALDOXORUBICIN-P3-STS-01	Myron, M	D3ET	4/23/2015	11/26/2015	III	Tre	A Multicenter, Randomized, Open-Label Phase 3 Study to Investigate the Efficacy and Safety of Aldoxorubicin Compared to Investigator's Choice in Subjects with Metastatic, Locally Advanced, or Unresectable Soft Tissue Sarcomas Who Either Relapsed or Were Refractory to Prior Non-Adjuvant Chemotherapy	Y		8	0	0	3	3	Protocol open only at community sites.
Janssen	Soft Tissue	NCT00210665	ET743-SAR-3002	Myron, M	D3ET	6/29/2012	10/30/2015	III	Tre	A Multicenter, Open-Label Single-Arm Study of YONDELIS (trabectedin)for Subjects With Locally Advanced or Metastatic Soft Tissue Sarcoma Excluding Leiomyosarcoma and Liposarcoma Who Have Relapsed or Are Refractory to Standard of Care Treatment	Y		20	0	0	8	17	Protocol open only at community sites.
Merck and Co.	Head and Neck	NCT02358031	3475-048	Neupane, P	D3ET	12/3/2015		III	Tre	A Phase 3 Clinical Trial of Pembrolizumab (MK-3475) in First Line Treatment of Recurrent/Metastic Head and Neck Squamous Cell Carcinoma	Y		10	0	0	0	0	
Celgene	Lung	NCT02027428	ABI-007-NSCL-003	Neupane, P	D3ET	1/23/2015		III	Tre	A PHASE III, RANDOMIZED, OPEN-LABEL, CROSSOVER, MULTI-CENTER, SAFETY AND EFFICACY STUDY TO EVALUATE NAB-PACLITAXEL (ABRAXANE®) AS MAINTENANCE TREATMENT AFTER INDUCTION WITH NAB-PACLITAXEL PLUS CARBOPLATIN IN SUBJECTS WITH SQUAMOUS CELL NON-SMALL CELL LUNG CANCER (NSCLC)	Y		6	2	2	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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Medimmune	Head and Neck	NCT02262741	D4190C00011	Neupane, P	D3ET	8/4/2015	12/10/2015	I	Tre	A Phase 1 Study to Evaluate the Safety, Tolerability, and Efficacy of MEDI4736 in Combination with Tremelimumab or Tremelimumab Alone in Subjects with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck	Y		7	0	0	0	0	
VentiRx Pharmaceuticals	Head and Neck	NCT01836029	VRXP-A202	Neupane, P	D3ET	5/9/2014	08/26/2015	II	Tre	A Randomized, Double-Blind, Placebo-Controlled Study of Chemotherapy Plus Cetuximab in Combination with VTX-2337 in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck	Y		10	8	10	0	0	
Onyx Pharmaceuticals	Multiple Myeloma	NCT01568866	2011-003	Pendergrass, K	D3ET	11/2/2012	09/03/2015	III	Tre	A Randomized, Open-label, Phase 3 Study of Carfilzomib Plus Dexamethasone vs. Bortezomib Plus Dexamethasone in Patients with Relapsed Multiple Myeloma	Y		5	0	0	0	2	Protocol open only at community sites.
BioMarin	Breast-Female	NCT01945775	673-301	Pendergrass, K	D3ET	2/20/2015		III	Tre	A Phase 3, Open-Label, Randomized, Parallel, 2-Arm, Multi-Center Study of BMN 673 versus Physician's Choice in Germline BRCA Mutation Subjects with Locally Advanced and/or Metastatic Breast Cancer, Who Have Received No More than 2 Prior Chemotherapy Regimens for Metastatic Disease	Y		10	0	0	0	0	Protocol open only at community sites.
Millenium Pharmaceuticals	Non-Hodgkins Lymphoma	NCT00931918	C05013	Pendergrass, K	D3ET	6/17/2011	04/28/2015	II	Tre	An Open-Label, Randomized, Phase 2 Study to Assess the Effectiveness of RCHOP With or Without VELCADE in Previously Untreated Patients with Non-Germinal Center B-Cell-like Diffuse Large B-Cell Lymphoma	Y		4	0	0	0	1	
Millenium Pharmaceuticals	Multiple Myeloma	NCT01850524	C16014	Pendergrass, K	D3ET	4/15/2014	01/29/2015	III	Tre	A Phase 3, Randomized, Double-Blind, Multicenter Study Comparing Oral MLN9708 Plus Lenalidomide and Dexamethasone Versus Placebo Plus Lenalidomide and Dexamethasone in Adult Patients With Newly Diagnosed Multiple Myeloma	Y		5	0	0	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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Eli Lilly	Head and Neck	NCT01063075	14E-MC-JXBB	Perez, R	D3ET	8/30/2012	04/02/2015	II	Tre	Phase 2 Study to Evaluate the Pharmacokinetic and Drug-Drug Interaction of Cetuximab and Carboplatin in Patients with Advanced Solid Tumors	Y		15	9	18	0	0	
Onyx Pharmaceuticals	Multiple Myeloma	NCT01832727	2012-001	Perez, R	D3ET	2/16/2015	06/22/2015	I/II	Tre	Phase 1b/2, Multicenter, Open-label Study of Oprozomib and Dexamethasone in Patients with Relapsed and/or Refractory Multiple Myeloma	Y		10	2	2	0	0	
Agensys, Inc.	Lymphoid Leukemia	NCT02175433	AGS67E-14-1	Perez, R	D3ET	9/26/2014		I	Tre	A Phase I Study Evaluating Safety, Tolerability and Pharmacokinetics of Escalating Doses of AGS67E Given as Monotherapy in Subjects with Refractory or Relapsed Lymphoid Malignancies	Y		10	5	5	0	0	
Agensys, Inc.	Urinary Bladder	NCT02091999	ASG-22CE-13-2	Perez, R	D3ET	5/19/2014		I	Tre	A Phase 1 Study of the Safety and Pharmacokinetics of Escalating Doses of ASG-22CE Given as Monotherapy in Subjects with Metastatic Urothelial Cancer and Other Malignant Solid Tumors that Express Nectin-4	Y		12	5	6	0	0	Biomarker-driven trial with high screen fail rate
Millenium Pharmaceuticals	Multiple	NCT01830816	C16015	Perez, R	D3ET	9/12/2013	02/19/2015	I	Tre	Phase 1/1b Pharmacokinetics Study of Oral MLN9708 in Patients with Relapsed/Refractory Multiple Myeloma and Advanced Solid Tumors with Normal Renal Function or Severe Renal Impairment	Y		10	0	6	0	0	
Millenium Pharmaceuticals	Multiple Sites	NCT01912222	C16018	Perez, R	D3ET	10/18/2013	03/03/2015	I	Tre	A Phase 1 Pharmacokinetic Study of Oral MLN9708 in Patients with Advanced Solid Tumors or Hematologic Malignancies with Varying Degrees of Liver Dysfunction	Y		10	0	3	0	0	
Altor Bioscience	Urinary Bladder	NCT01326871	CA-ALT-801-01-10	Perez, R	D3ET	1/4/2013	02/25/2015	I/II	Tre	A Phase 1b/II Trial of ALT-801 in Combination with Cisplatin and Gemcitabine in Muscle Invasive or Metastatic Urothelial Cancer	Y		16	0	7	0	0	
Novartis Pharmaceuticals	Multiple	NCT01769768	CLDE225A2112	Perez, R	D3ET	4/30/2014		I	Tre	A Phase Ib, Multi-Center, Two Parallel Group, Open-Label, Drug-Drug Interaction Study to Assess the Effect of LDE225 on the Pharmacokinetics of Bupropion and Warfarin in Patients with Advanced Solid Tumors	Y		10	8	13	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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Medimmune	Multiple	NCT02118337	D6020C00001	Perez, R	D3ET	8/10/2015		I	Tre	A Phase 1, Open-label Study to Evaluate the Safety and Tolerability of MEDI0680 (AMP-514) in Combination with MEDI4736 in Subjects with Advanced Malignancies	Y		36	0	0	0	0	Trial was suspended by the sponsor on the day of activation pending review of dose escalation data. Not open to new enrollment as of 7/1/2016.
ImmunoGen, Inc	Multiple	NCT01609556	IMGN853-0401	Perez, R	D3ET	7/25/2014		I	Tre	A Phase 1, First-in-Human Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of IMGN853 in Adults with Ovarian Cancer and other FOLR1-Positive Solid Tumors	Y		15	6	7	0	0	This is a high screen fail trial.
Incyte Corporation	Multiple	NCT02327078	INCB 24360-204	Perez, R	D3ET	6/23/2015		I/II	Tre	A Phase 1/2 Study of the Safety, Tolerability, and Efficacy of INCB24360 Administered in Combination With Nivolumab in Select Advanced Cancers	Y		18	3	3	0	0	
Medimmune	Multiple	NCT00983619	MI-CP204	Perez, R	D3ET	11/18/2014	09/23/2015	I	Tre	An Open-Label, Phase 1/2 Study of MEDI-551, a Humanized Monoclonal Antibody Directed Against CD19, in Adult Subjects with Relapsed or Refractory Advanced B-cell Malignancies	Y		10	1	1	0	0	
Dompe s.p.a.	Breast-Female	NCT01861054	REP0210	Perez, R	D3ET	4/26/2013	04/01/2015	II	Tre	A Single Arm, Preoperative, Pilot Study to Evaluate the Safety and Biological Effects of Orally Administered Reparixin in Early Breast Cancer Patients who are Candidates for Surgery	Y		12	0	4	0	0	
TetraLogic Pharmaceuticals	Multiple	NCT01940172	TL32711-POC-0090-PTL	Perez, R	D3ET	8/12/2014	05/22/2015	I	Tre	A Phase 1b, Open-Label, Non-Randomized Multicenter Study of Birinapant in Combination with Conatumumab in Subjects with Relapsed Epithelial Ovarian Cancer, Primary Peritoneal Cancer or Fallopian Tube Cancer	Y		10	5	6	0	0	
Bristol-Myers Squibb	Lung	NCT02066636	USON 13-179 / BMS CA209-153	Raja, V	D3ET	10/28/2014	03/30/2015	III	Tre	A Phase IIIb/IV Safety Trial of Nivolumab (BMS-936558) in Subjects with Advanced or Metastatic Non-Small Cell Lung Cancer Who Have Progressed During or After Receiving At Least One Prior Systemic Regimen (CA209153)	Y		5	0	0	12	15	
DFINE, Inc	Multiple	NCT02225223	DF-14-01	Sayed, D	D3ET	4/29/2015		Device	Tre	Evaluation of Targeted Radiofrequency Ablation and Vertebral Augmentation prior to or following Radiation Therapy to Treat Painful Metastatic Vertebral Body Tumor(s)	Y		20	2	2	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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Celgene	Breast-Female	NCT02374099	CC-486-BRSTM-001	Sharma, P	D3ET	11/17/2015		II	Tre	A phase 2, randomized, open-label, two-arm study to assess the efficacy and safety of the epigenetic modifying effects of CC-486 (Oral Azacitidine)in combination with Fulvestrant in postmenopausal women with ER+, HER2- metastatic breast cancer who have progressed on an aromatase inhibitor	Y		10	0	0	0	0	
Northwest Biotherapeuticis, Inc.	Brain and Nervous System	NCT00045968	020221 (DCVax®-L)	Taylor, S	D3ET	4/9/2013		III	Tre	A Phase III Clinical Trial Evaluating DCVax®-L, Autologous Dendritic Cells Pulsed with Tumor Lysate Antigen for the Treatment of Glioblastoma Multiforme	Y		20	2	13	0	0	This is a high screen fail trial.
Janssen Previously Aragon	Prostate	NCT01946204	ARN-509-003	VanVeldhuizen, P	D3ET	7/2/2014	07/30/2015	III	Tre	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men with Non-Metastatic (M0) Castration-Resistant Prostate Cancer	Y		10	0	0	0	0	
Acceleron	Liver	NCT02024087	A041-05	Williamson, S	D3ET	11/20/2014	02/15/2016	I/II	Tre	A Phase 1b, Open Label Study of Dalantercept plus Sorafenib in Patients with Advanced Hepatocellular Carcinoma	Y		10	3	3	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency
ArQule	Liver	NCT01755767	ARQ 197-A-U303	Williamson, S	D3ET	5/9/2013	01/15/2016	III	Tre	A Phase 3, Randomized, Double-Blind Study Of TIVANTINIB (ARQ 197) In Subjects With MET Diagnostic-High Inoperable Hepatocellular Carcinoma(HCC)Treated With One Prior Systemic Therapy	Y		10	1	4	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency
Bristol-Myers Squibb	Kidney	NCT02231749	CA209-214	Williamson, S	D3ET	6/17/2015	09/23/2015	III	Tre	A Phase 3, Randomized, Open-Label Study of Nivolumab Combined with Ipilimumab Versus Sunitinib Monotherapy in Subjects with Previously Untreated, Advanced or Metastatic Renal Cell Carcinoma (CheckMate 214, CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 214)	Y		10	1	1	0	0	
The Rogosin Institute	Colorectal	NCT02046174	RI-MB-203	Williamson, S	D3ET	5/27/2015		II	Tre	A Phase IIb, Nonrandomized, Open-Label Trial with Mouse Renal Adenocarcinoma (RENCA) Cell Containing Agarose-Agarose Macrobeads Compared with Best Supportive Care in Patients with Treatment-Resistant, Metastatic Colorectal Carcinoma	Y		25	6	6	2	2	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

Interventional:

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Sotio a.s.	Prostate	NCT02111577	SP005	Williamson, S	D3ET	8/5/2015		III	Tre	A Randomized, Double Blind, Multicenter, Parallel-Group, Phase III Study to Evaluate Efficacy and Safety of DCVAC/PCa Versus Placebo in Men with Metastatic Castration Resistant Prostate Cancer Eligible for 1st Line Chemotherapy	Y		10	2	2	0	0	
Millenium Pharmaceuticals	Hodgkins Lymphoma	NCT01712490	C25003	Yacoub, A	D3ET	3/31/2014	08/07/2015	III	Tre	A Randomized, Open-label, Phase 3 Trial of A+AVD Versus ABVD as Frontline Therapy in Patients With Advanced Classical Hodgkin Lymphoma	Y		10	3	5	2	2	
Celgene	Non-Hodgkins Lymphoma	NCT02285062	CC-5013-DLC-002	Yacoub, A	D3ET	12/18/2015		III	Tre	Phase 3 randomized, double-blind, placebo controlled, multicenter study to compare the efficacy and safety of lenalidomide (CC-5013) plus R-CHOP chemotherapy (R2-CHOP) versus placebo plus R-CHOP Chemotherapy in subjects with previously untreated activated B-Cell type Diffuse Large B-Cell Lymphoma	Y		14	0	0	0	0	
Celgene	Non-Hodgkins Lymphoma	NCT01996865	CC-5013-NHL-008	Yacoub, A	D3ET	1/5/2015		III	Tre	A phase 3 randomized study of lenalidomide (CC-5013) plus rituximab maintenance therapy followed by lenalidomide single-agent maintenance versus rituximab maintenance in subjects with relapsed/refractory follicular, marginal zone or mantle cell lymphoma	Y		20	5	5	2	2	
Novartis Pharmaceuticals	Myelodysplastic Syndrome	NCT02159040	CICL670AUS47	Yacoub, A	D3ET	2/24/2015	08/07/2015	II	Tre	A 2-year, multi-center, Phase II, open-label, fixed-dose, randomized comparative trial of azacitidine, with or without deferasirox in patients with higher risk myelodysplastic syndromes	Y		10	0	0	0	0	
Gilead Sciences	Multiple	NCT02101268	GS-US-352-1214	Yacoub, A	D3ET	1/28/2015	01/12/2016	III	Tre	A Phase 3, Randomized Study to Evaluate the Efficacy of Momelotinib versus Best Available Therapy in Anemic or Thrombocytopenic Subjects with Primary Myelofibrosis, Post-polycythemia Vera Myelofibrosis, or Post-Essential Thrombocythemia Myelofibrosis who were Treated with Ruxolitinib	Y		5	4	4	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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MEI Pharma	Myelodysplastic Syndrome	NCT01993641	MEI-005	Yacoub, A	D3ET	8/14/2014	01/08/2015	II	Tre	A Phase II Simon Two-Stage Study of the Addition of Pracinostat to a Hypomethylating Agent (HMA) in Patients with Myelodysplastic Syndrome (MDS) Who Have Failed to Respond or Maintain a Response to the HMA Alone	Y		7	0	1	0	0	
Janssen	Non-Hodgkins Lymphoma	NCT01974440	PCI-32765FLR3001	Yacoub, A	D3ET	11/17/2014	11/05/2015	III	Tre	A Randomized, Double-blind, Placebo-controlled Phase 3 Study of the Bruton's Tyrosine Kinase Inhibitor, PCI-32765 (Ibrutinib), in Combination with Either Bendamustine and Rituximab (BR) or Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (R-CHOP) in Subjects with Previously Treated Indolent Non-Hodgkin Lymphoma (iNHL)	Y		10	2	3	0	0	
Astex Pharmaceuticals	Myeloid and Monocytic Leukemia	NCT02348489	SGI-110-04	Yacoub, A	D3ET	8/18/2015		III	Tre	A Phase 3, Multicenter, Open-label, Randomized Study of SGI-110 versus Treatment Choice (TC) in Adults with Previously Untreated Acute myeloid Leukemia (AML) Who Are Not Considered Candidates for Intensive Remission Induction Chemotherapy	Y		8	3	3	0	0	
Seattle Genetics	Non-Hodgkins Lymphoma	NCT01777152	SGN35-014	Yacoub, A	D3ET	8/23/2013		III	Tre	A randomized, double-blind, placebo-controlled, phase 3 study of brentuximab vedotin and CHP (A+CHP) versus CHOP in the frontline treatment of patients with CD30-positive mature T-cell Lymphomas	Y		10	2	3	0	0	Meets definition of Rare Cancer and/or Molecular Target with low frequency

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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GOG	Other Female Genital	NCT01500512	GOG 0270	Chapman, J	D3ET	3/21/2013	02/25/2015	N/A	Oth	GROningen INternational Study on Sentinel Nodes in Vulvar Cancer (GROINSS-V)II: An Observational Study	Y		6	0	1	0	0	
COG	Multiple	NCT01117168	ACCRN07	Hetherington, M	D3ET	4/8/2008		NA	Oth	Protocol for the Enrollment on the Official COG Registry, The Childhood Cancer Research Network (CCRN)	Y		N/A	80	507	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital; Site target enrollment is 200 per year.
COG	Multiple	NCT00736749	ALTE05N1	Hetherington, M	D3ET	6/17/2010		NA	Oth	Umbrella Long-Term Follow-up Protocol	Y		100	0	6	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT00772200	ALTE07C1	Hetherington, M	D3ET	4/2/2009		NA	Oth	Neuropsychological, social, emotional & behavioral outcomes in children with cancer	Y		20	1	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
NMDP	Other Hematopoietic	NCT01351545	10-CBA	McGuirk, J	D3ET	9/6/2011		N/A	Oth	A multicenter access and distribution protocol for unlicensed cryopreserved cord blood units (CBUs) for transplantation in pediatric and adult patients with hematologic malignancies and other indications	Y		N/A	8	40	0	0	
BMT CTN NIH	Other Hematopoietic	NCT02016781	BMT CTN 1102	McGuirk, J	D3ET	2/10/2014		N/A	Oth	A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Aged 50-75 with Intermediate-2 and High Risk Myelodysplastic Syndrome	Y		20	6	12	0	0	
BMT CTN	Multiple	NCT01879072	BMT CTN 1202	McGuirk, J	D3ET	8/27/2014		N/A	Oth	Prospective Multi-Cohort for the Evaluation of Biomarkers Predicting Risk of Complications and Mortality Following Allogeneic HCT	Y		80	0	10	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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Frontiers: HICTR	Brain and Nervous System		KUMC 12996	Choi, I	D3ET	12/21/2011		N/A	Oth	Metabolic Biomarkers of Brain Lesion Activity in Living Human Brain	N	30	30	3	19	0	0	
Institutional	Multiple		TeleMed	Hall, N	D3ET	4/10/2015		NA	Oth	Outreach Medicine and the Role of Telemedicine in Pedatric Hematology Oncology	N	64	64	42	42	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital

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AO Spine North America	Non Cancer	NCT01825161	SPN-12-002	Arnold, P	D3ET	2/25/2014		N/A	Oth	The Epidemiology, Process and Outcomes of Spine Oncology (EPOSO)	Y		25	2	6	0	0	
Monteris Medical	Brain and Nervous System	NCT01651078	CPL00020-09	Chamoun, R	D3ET	12/17/2014	12/31/2015	N/A	Oth	LAASR: Laser Ablation After Stereotactic Radiosurgery	Y		5	2	2	0	0	
Prometheus Laboratories	Multiple	NCT01415167	10PLK13	Doolittle, G	D3ET	9/5/2012		N/A	Oth	Proleukin® Observational Registry to Evaluate the Treatment Patterns and Clinical Response in Malignancy	Y		60	12	52	0	0	
Novartis Pharmaceuticals	Non-Hodgkins Lymphoma	NCT02445222	CCTL019A2205B	McGuirk, J	D3ET	12/28/2015		N/A	Oth	Long Term Follow-Up of Patients Exposed to Lentiviral-Based CD19 directed CART Cell Therapy	Y		7	0	0	0	0	
DFINE, Inc	Ill-Defined Sites	NCT02419703	DF-15-03	Sayed, D	D3ET	10/29/2015		N/A	Oth	The STAR™ Tumor Ablation Registry	Y		50	2	2	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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COG	Lymphoma, Leukemia	NCT00897325	AALL05B1	Hetherington, M	D3ET	2/9/2007		NA	Oth	A Children's Oncology Group Protocol for Collecting and Banking Relapsed Acute Lymphoblastic Leukemia Research Specimens	Y		N/A	0	9	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Leukemia	NCT01142427	AALL08B1	Hetherington, M	D3ET	8/23/2010		N/A	Oth	Classification of Acute Lymphoblastic Leukemia	Y		115	32	126	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Leukemia	NCT00959283	AAML08B1	Hetherington, M	D3ET	8/10/2009		NA	Oth	Biology Study of Transient Myeloproliferative Disorder (TMD) in Children with Down Syndrome (DS)	Y		8	0	3	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT00898079	ABTR01B1	Hetherington, M	D3ET	3/9/2004		NA	Oth	A Children's Oncology Group Protocol for Collecting and Banking Pediatric Research Specimens Including Rare Pediatric Tumors	Y		100	6	26	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT00898755	ABTR04B1	Hetherington, M	D3ET	9/10/2007		NA	Oth	Establishing Continuous Cell Lines and Xenografts from Pediatric Cancers for Biological and Pre-Clinical Therapeutic Studies	Y		10	0	0	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT00919750	ACNS02B3	Hetherington, M	D3ET	7/21/2004		NA	Oth	A Children's Oncology Group Protocol for Collecting and Banking Pediatric Brain Tumor Research Specimens	Y		80	6	41	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Ewing Sarcoma	NCT00899990	AEWS07B1	Hetherington, M	D3ET	3/28/2008		NA	Oth	A Children's Oncology Group Protocol for Collecting and Banking Ewing Sarcoma Specimens	Y		40	1	13	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT00082745	ALTE03N1	Hetherington, M	D3ET	10/5/2004		NA	Oth	Key Adverse Events After Childhood Cancer	Y		50	1	16	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Lymphoma	NCT01793233	ALTE11C1	Hetherington, M	D3ET	8/15/2014		NA	Oth	Longitudinal Assessment of Ovarian Reserve in Adolescents with Lymphoma	Y		25	2	2	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Brain	NCT00904241	ANBL00B1	Hetherington, M	D3ET	9/1/2000		NA	Oth	Neuroblastoma Biology Studies	Y		250	7	76	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Lymphoma	NCT01000753	ANHL04B1	Hetherington, M	D3ET	10/20/2006		NA	Oth	Rare and Cutaneous Non-Hodgkin Lymphoma Registry	Y		5	0	1	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

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COG	Sarcoma	NCT00899275	AOST06B1	Hetherington, M	D3ET	4/4/2008		NA	Oth	A Children's Oncology Group Protocol for Collecting and Banking Osteosarcoma Specimens	Y		25	1	9	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Kidney	NCT00898365	AREN03B2	Hetherington, M	D3ET	6/14/2006		NA	Oth	Renal Tumors Classification, Biology and Banking Study	Y		100	1	39	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
COG	Multiple	NCT00919269	D9902	Hetherington, M	D3ET	8/18/2000		NA	Oth	A Group Wide Protocol for Collecting and Banking Pediatric Cancer Research Specimens. A Intergroup Rhabdomyosarcoma Study Group Protocol.	Y		100	1	49	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Alliance for Clinical Trials in Oncology	Lung	NCT02194738	A151216	Huang, C	D3ET	5/6/2015		N/A	Oth	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)	Y		16	0	0	4	4	
ECOG CTSU	Breast-Female	NCT00433511	EL112LAB / E5103	Sharma, P	D3ET	9/17/2013		N/A	Oth	EL112LAB: North American Breast Cancer Groups Biospecimen Bank for Determinants of Late Relapse in Operable Breast Cancer	Y		15	1	7	0	0	
ECOG CTSU/SWOG	Breast-Female	NCT00310180	EL112LAB / PACCT-1	Sharma, P	D3ET	9/17/2013		N/A	Oth	EL112LAB: North American Breast Cancer Groups Biospecimen Bank for Determinants of Late Relapse in Operable Breast Cancer	Y		15	0	3	0	4	

EXTERNALLY PEER-REVIEWED												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH	Head and Neck		13-413	Lominska, C	D3ET	3/31/2015		N/A	Oth	UNDERSTANDING THE MECHANISM OF RADIOTHERAPY-INDUCED DENTITION BREAKDOWN	Y		50	7	7	0	0	
Myeloproliferative Disorders-Research Consortium	Myeloid and Monocytic Leukemia	NCT00665067	MPD-RC-107	Yacoub, A	D3ET	3/27/2015		N/A	Bas	Correlative Biomarker Study for MPD-RC Treatment Studies in the Philadelphia Chromosome Negative Myeloproliferative neoplasms	Y		30	25	25	0	0	

Table 6 – Drug Discovery, Delivery and Experimental Therapeutics – Clinical Research
The University of Kansas Cancer Center
Reporting Period: 01/01/2015 - 12/31/2015
Data Table 4 - Clinical Research Protocols

P30CA168524

Ancillary/Correlative:

INSTITUTIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
The University of Kansas - Investigator	Unknown Sites	NCT01166776	KUMC 12129	Aljitawi, O	D3ET	6/25/2010		N/A	Bas	Decellurization of Umbilical Cord Whartons Jelly for Tissue Regenerative Applications Including Avascular Necrosis	N	65	65	9	57	0	0	
American Cancer Society	Leukemia		Ikaros	August, K	D3ET	11/21/2011		NA	Bas	Characterizing the expression pattern of the Ikaros family of transcription factors in T-ALL patients.	N	10	10	2	7	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Midwest Cancer Alliance	Multiple		SID	Chastain, K	D3ET	3/11/2015		NA	Bas	Development of a novel drug screening system for pediatric solid tumors through a 'Sarcoma in a Dish' in vitro model	N	60	60	5	5	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Thomas Jefferson University	Multiple Sites		KUMC 12845	Drisko, J	D3ET	11/7/2011	09/11/2015	N/A	Bas	Evaluation of Intravenous Ascorbic Acid: Imaging with MRI-Spectroscopy	N	10	10	4	10	0	0	
The Childrens Mercy Hospital	Leukemia		Guest Doxo	Guest, E	D3ET	3/5/2014		NA	Bas	Using doxorubicin as a target-therapeutic agent in pediatric acute leukemia	N	100	100	17	37	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital
Investigator	Multiple		Heme-2011-08-01	Kambhampati, S	D3ET	2/20/2012	02/09/2015	N/A	Bas	Down-regulation of complement regulatory protein expression as a new approach to increase efficacy of antibody therapy in low grade lymphoproliferative disorders.	N	60	60	0	71	0	0	Accrual goals were exceeded in Sept 2014. The PI was working on a protocol revision to include additional samples. Protocol never reopened to enrollment.
Midwest Cancer Alliance / Alex's Lemonade Stand	Multiple		Exosomes	Samuel , G	D3ET	3/15/2013		NA	Bas	Pediatric Sarcoma Exosomes (Protocol has been approved - information sharing only)	N	N/A	25	2	20	0	0	Protocol is open at a consortium site/The Childrens Mercy Hospital

INDUSTRIAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institutions(s)		Comments
Specific Funding Source	Anatomic Site	NCT Number	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
Imago BioSciences Inc	Myeloid and Monocytic Leukemia		IMG-CTP-001	Lin, T	D3ET	8/17/2015		N/A	Bas	A Study of Minimal Residual Disease (MRD) after Standard-of-Care Induction in Patients with Acute Myeloid Leukemia (AML)	Y		8	3	3	0	0	

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Scott Middle Name James Last Name*: Weir Suffix: PhD

Position/Title*: Professor
Organization Name*: University of Kansas Medical Center
Department: Pharmacology
Division: School of Medicine
Street1*: MS 1018, 3901 Rainbow Boulevard
Street2:
City*: Kansas City
County: Wyandotte
State*: KS: Kansas
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 66160-0000

Phone Number*: 913-588-4798 Fax Number: 913-588-4701

E-Mail*: sweir@kumc.edu

Credential, e.g., agency login: SJWEIR

Project Role*: Other (Specify) Other Project Role Category: Project Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Alan Middle Name Last Name*: Gamis Suffix:

Position/Title*: Chief, Professor
Organization Name*: The Children's Mercy Hospital
Department: Pediatric Oncology
Division: Hematology/Oncology/BMT
Street1*: 2401 Gilham Road
Street2:
City*: Kansas City
County:
State*: MO: Missouri
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 64108-4619

Phone Number*: 816-302-6808 Fax Number: 816-983-6314

E-Mail*: agamis@cmh.edu

Credential, e.g., agency login: AGAMIS1

Project Role*: Other (Specify) Other Project Role Category: Project Lead

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Gamis_Bio_CCSG1019913995.pdf

Attach Current & Pending Support: File Name:

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ❍ Yes ❍ No

*Agency-Defined Phase III Clinical Trial? ❍ Yes ❍ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ❍ Yes ❍ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

❍ Yes ❍ No

If "No" to AVMA guidelines, describe method and proved scientific justification

3. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

❍ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator / Change of Institution Section

❑ Change of Project Director / Principal Investigator

Name of former Project Director / Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12250478 Funding Opportunity Number: PAR-13-386 . Received Date: 2016-09-21T11:24:21.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction	
1. Introduction to Application (Resubmission and Revision)	
Research Plan Section	
2. Specific Aims	D3ET_SpecificAims_final1019659706.pdf
3. Research Strategy*	D3ET_ResearchStrategy_final1019857919.pdf
4. Progress Report Publication List	Progress_Report_Publications_Blank1019754759.pdf
Human Subjects Section	
5. Protection of Human Subjects	
6. Data Safety Monitoring Plan	
7. Inclusion of Women and Minorities	
8. Inclusion of Children	
Other Research Plan Section	
9. Vertebrate Animals	
10. Select Agent Research	
11. Multiple PD/PI Leadership Plan	
12. Consortium/Contractual Arrangements	
13. Letters of Support	
14. Resource Sharing Plan(s)	Resource_Sharing_Plan__Generic1019913996.pdf
15. Authentication of Key Biological and/or Chemical Resources	
Appendix	
16. Appendix	

Tracking Number: GRANT12250478
Funding Opportunity Number: PAR-13-386. Received Date: 2016-09-21T11:24:21.000-04:00

Drug Discovery, Delivery and Experimental Therapeutics – Specific Aims

The Drug Discovery, Delivery and Experimental Therapeutics (D3ET) research program integrates a broad range of research areas that contribute to the discovery of new cancer therapeutic strategies, development of the most promising therapeutic strategies to enable advancement to the clinic and the evaluation of these strategies in hypothesis-driven experimental therapeutics trials. D3ET members share the common goal of discovering and advancing paradigm-changing new cancer treatments to pediatric, adolescent, adult and elderly patients. Members have expertise in a wide range of disciplines, all of which are being applied to cancer-related research projects. D3ET members strive to achieve scientific excellence within their respective basic, applied and clinical science disciplines as well as strive to achieve excellence in translational science.

The work of D3ET is organized around three, central highly integrated scientific themes: 1) Discover and Deliver New Cancer Therapeutic Strategies; 2) Develop New Cancer Therapeutic Strategies; and 3) Evaluate New Cancer Therapeutic Strategies in Experimental Therapeutics Trials. These themes are pursued in the following ways:

Theme 1 – Discover and Deliver New Cancer Therapeutic Strategies

- Conduct medicinal chemistry initiatives to synthesize and optimize novel, new anticancer agents that engage with validated drug targets.
- Conduct pharmaceutical chemistry research to identify novel ways of effectively and safely delivering anticancer agents.
- Conduct *in vitro* and *in vivo* preclinical studies to identify opportunities to repurpose FDA-approved and abandoned drugs for the treatment of cancer.

Theme 2 – Develop New Cancer Therapeutic Strategies

- Through productive, intra-programmatic, inter-programmatic and external collaborations, conduct studies necessary to advance new cancer therapeutic strategies to patients.
- Develop a critical mass of translational scientists who possess competencies and capabilities necessary to test new cancer therapeutic hypotheses across the drug discovery and development continuum.

Theme 3 – Evaluate New Cancer Therapeutic Strategies in Experimental Therapeutics Trials

- Integrate genetic and epigenetic patterns of cancer, biomarker discovery and validation, pharmacogenomics, drug-exposure and drug-response data into precision medicine strategies.
- Conduct hypothesis-driven, rigorously designed, patient-driven, cancer experimental therapeutics trials in pediatric, adolescent, adult and elderly cancer patients to determine clinical proof of concept for new cancer therapeutic strategies.

Inspired by the KUCC vision statement, D3ET leverages unique regional scientific assets to build a nationally significant cancer research center that is a leading institution for transforming laboratory and bedside discoveries into new therapeutic approaches. The work of D3ET members contributes to promoting a cancer center culture whose highest priority is to foster discovery and advancement of paradigm-changing therapeutic advances resulting in improved survival and quality of life for our patients.

Drug Discovery, Delivery and Experimental Therapeutics – Research Strategy

Overview

The D3ET research program conducts research with the ultimate goal of reducing the burden of cancer by discovering, developing and evaluating new cancer therapeutic agents that will ultimately improve survival and quality of life for cancer patients. D3ET members perform *in vitro* and *in vivo* proof of principle studies in validated preclinical models of cancer and advance the most promising new therapeutic strategies to hypothesis-driven, rigorously-designed experimental therapeutic clinical trials. As clinical proof of concept is established, sources of variability in drug response and drug exposure are identified to build a foundation for precision therapeutics. **Table 1** provides an overview of many key features of the D3ET program. D3ET has 60 members, including 39 full and 21 associate. Membership reflects a range of senior and early-stage investigators with 20 Professors, 13 Associate Professors and 17 Assistant Professors. Members are drawn from Children's Mercy (CM), Kansas City and University of Kansas (KU) institutions, providing a rich environment for team science. In the previous funding period, 51% of the 39 full members served as PIs on externally funded, peer-reviewed grants. Members conducted research on 36 cancer-relevant, peer-reviewed projects representing $9.1M in extramural funding, including $3.1M from the NCI. The 15 NCI-funded grants represented 35% of total peer-reviewed funding for the program and 24% of total NCI funding for KUCC. The growth of the D3ET program results from active external recruitment, attracting promising faculty from KU, KUMC and CM, as well as active mentoring of trainees and young faculty. D3ET leadership worked closely with KUCC's External Advisory Board (EAB) to improve the program. A major focus has been to increase the program's experimental therapeutics research portfolio. D3ET worked to enhance the quality of hypothesis-driven investigator-initiated trials (IITs) to better position the clinical research for success in pursuing peer-reviewed funding. Consistent with this focus, D3ET members have doubled non-peer reviewed funding to $5.9M, the majority (>80%) of which, represents funding for industry-sponsored clinical trials. Over 2012-2015, D3ET members published 617 cancer-relevant publications, an average of 10 publications per member. Twenty-nine percent of these publications represented intra-programmatic collaborations, 23% represented inter-programmatic collaborations and 51% represented external collaborative publications (19% with other NCI designated cancer centers). Based on journal impact factors ≥ 8.0 (criteria defined by the KUCC EAB across the four KUCC programs), 67 publications (11%) qualified as high-impact.

Table 1. Program Metrics

Members (2015)		
Total	**Full**	**Associate**
60	39 (65%)	21 (35%)

Funding (2015)		
Type	**# of grants**	**$ (total costs)**
NCI	15	3,170,927
Other NIH	17	4,531,219
Other Peer Reviewed	4	1,421,000
Total Peer Reviewed	**36**	**9,123,146**
Other	59	5,901,639
Total Funding	**95**	**15,024,785**

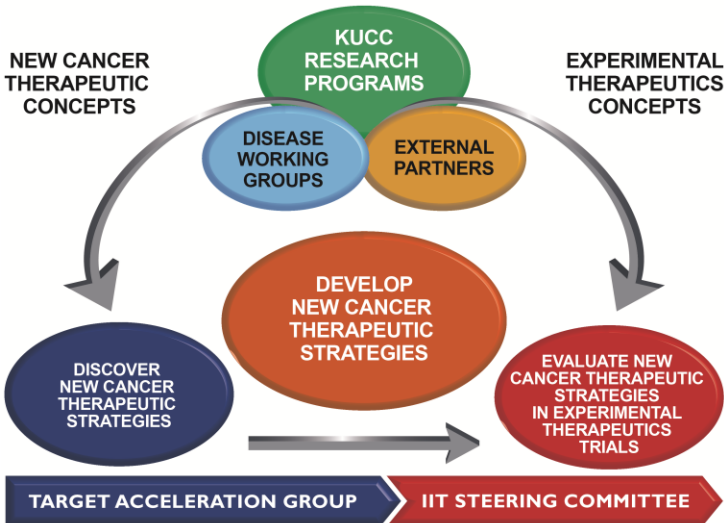
Publications (2012-2015)	
Total	**617**
High Impact	67 (11%)
Inter-programmatic	140 (23%)
Intra-programmatic	180 (29%)
External collaborative	315 (51%)

Trial Accrual (2015)		
Type of trial	**# of trial**	**# participants**
Diagnostic	1	113
Health Services Research	2	10
Prevention	2	2
Supportive Care	14	15
Treatment	182	491
Observational	14	158
Ancillary/Correlative: Basic Science	9	67
Ancillary/Correlative: Other	18	70

The foundation for scientific quality and cancer focus of the D3ET research program can be attributed to strengths in cancer biology, molecular genetics and epigenetics, genomics, medicinal chemistry, pharmaceutical chemistry, bioanalytical chemistry, drug metabolism, pharmacokinetics and pharmacodynamics, pharmacogenomics, experimental therapeutics, translational science and regulatory science. KUCC leadership identified the need to create and foster translational research. As illustrated in **Figure 1**, a culture has been established whereby concepts for new cancer therapeutic strategies, as well as concepts for hypothesis-driven experimental therapeutics trials, are conceived within the four research programs, within the 13 Disease Working Groups (DWGs; 10 disease-specific and three non-disease-specific) and through collaborative research with industry, academia, government and disease philanthropy partners.

Projects are enabled and facilitated at the chemistry/biology interface by the Target Acceleration Group (TAG). The Investigator-Initiated Trial Steering Committee (IITSC) enables and facilitates experimental therapeutics trial concepts conceived by basic, translational and clinical researchers from idea to patient enrollment. The TAG and IITSC have become translational research catalysts for KUCC.

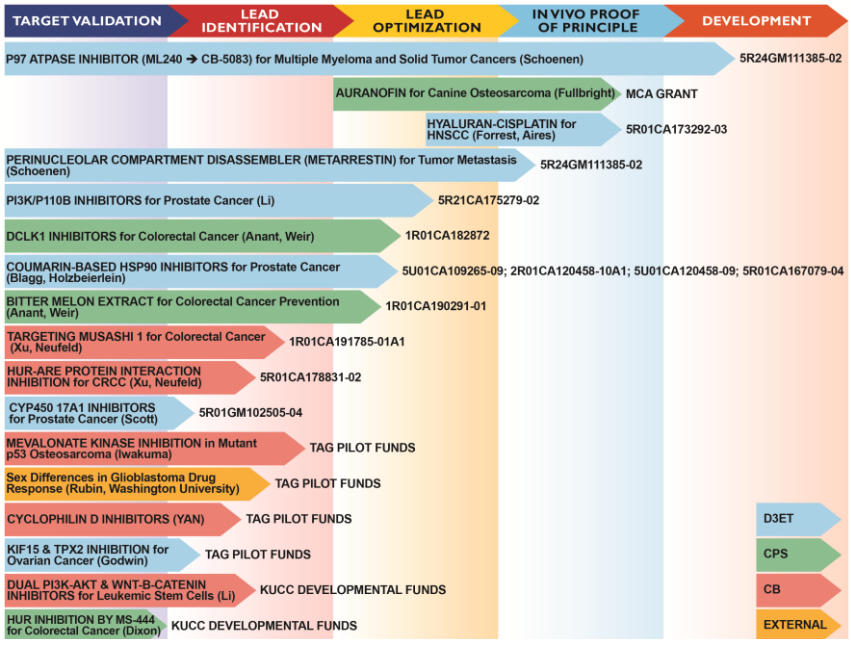
Figure 1. KUCC Translational Research



Target Acceleration Group - In order to build a sustainable portfolio of high-potential cancer drug discovery projects, D3ET and the Lead Development and Optimization Shared Resource (LDOSR) refined its approach to partnering with cancer biologists in 2014. The mission of TAG is to accelerate drug discovery projects from target identification through *in vivo* preclinical proof of principle. Through a multidisciplinary team of experts (team membership provided in the Lead Development and Optimization shared resource component of this grant application), TAG provides high throughput screening (HTS) assay development and validation, routine HTS screening of chemical libraries, medicinal chemistry, synthetic chemistry, pre-formulation, formulation development, preclinical safety and pharmacokinetics and project management expertise to translate innovative cancer biology discoveries into drug discovery projects.

Chaired by Associate Director for Translational Research and D3ET program co-leader, Scott **Weir**, TAG utilizes resources provided by a drug discovery-dedicated $1.5M philanthropic fund earmarked to enable and advance promising drug discovery projects. From 2014-2015, TAG supported 104 grant applications submitted by KUCC members from all four KUCC research programs and other NCI-designated cancer centers. To date, 20 applications were successful in securing externally peer-reviewed funding, as well as internal support through KUCC pilot awards and the Midwest Cancer Alliance (MCA). Additionally, TAG has directly invested pilot funds to enable18 drug discovery projects. Progress in creating new projects and advancing existing projects within the KUCC drug discovery project portfolio are highlighted in **Figure 2**.

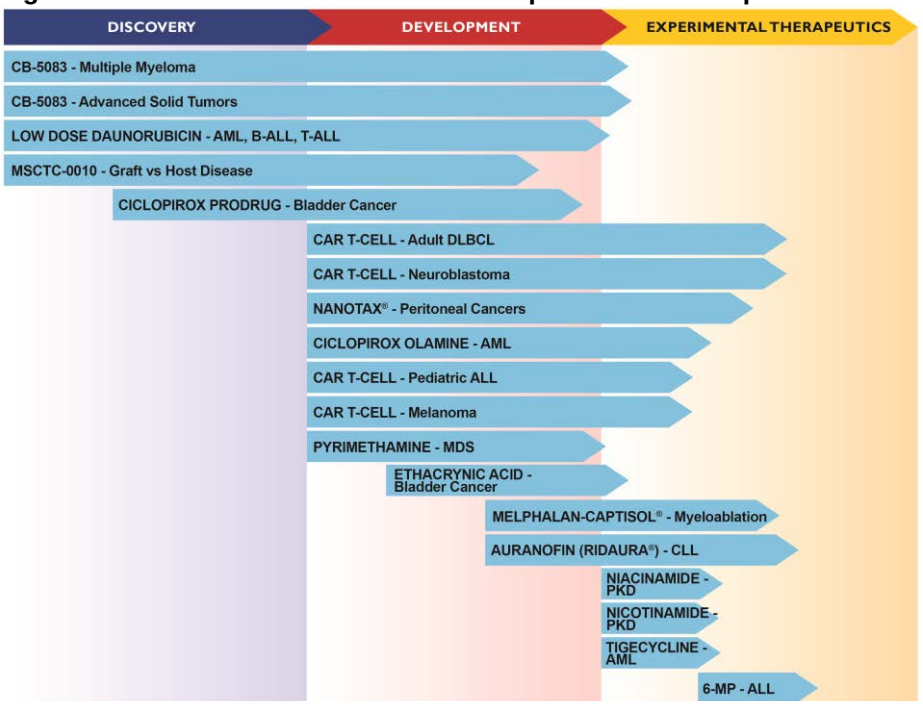
Figure 2. KUCC's Drug Discovery Research Portfolio. Sources of funding, stage of drug discovery and development and project of origin are indicated.



A current snapshot of D3ET's current portfolio of Theme 1 projects is illustrated in **Figure 3**. Since 2012, existing drug discovery projects have been advanced to measurable milestones and new drug discovery projects have been created in collaboration with cancer biologists across the KUCC research programs, other NCI Cancer Centers, as well as researchers at other academic centers. Ten of the projects illustrated in the schematic are NCI or NIH funded with the remainder supported, in part, through KUCC developmental funds, pilot funds, as well as grants provided by the MCA. Through productive intra-programmatic, inter-programmatic and external collaborations, KUCC develops and executes development plans to advance new cancer

therapeutic strategies from preclinical proof of principle to clinical proof of concept. Described later in section *'Value Added by KUCC to Programmatic Efforts',* this effort is led by the Institute for Advancing Medical Innovation (IAMI). Directed by **Weir**, IAMI employs a robust, proven product development-focused translational research process to advance cancer-relevant drug and diagnostic products to patients. IAMI forms multidisciplinary, multi-organizational project teams comprised of basic, translational and clinical researchers to develop new cancer therapeutic concepts. Project teams are co-led by the research Principal Investigator(s) and industry-experienced project managers residing in the LDOSR. **Baltezor**, **Gamis**, **Weir** and **Williamson** play active roles in forming and mentoring teams. Drug discovery and development guidelines, developed by KUCC, NCATS, the NCI SBIR Program and Cardinal Health serve as a roadmap for KUCC researchers engaged in translation (Hughes, *NCBI Bookshelf, National Library of Medicine, National Institutes of Health,* 2012). **Figure 3** summarizes D3ET progress in translating discoveries to experimental therapeutics trials. Over the current funding period, D3ET initiated 17 experimental therapeutics trials evaluating new agents arising from KUCC research. It is anticipated that two novel cancer therapeutics discovered at KUCC, MSCTC-0010 and Ciclopirox Prodrug (both highlighted below), will advance to patients in early 2017. D3ET members employ many different paths to advance new cancer therapeutic strategies to patients, including partnering with established biotechnology and pharmaceutical companies through traditional license agreements, pursuing opportunities to collaborate with NCI's Experimental Therapeutics (NExT) program and forming startup companies that pursue SBIR/STTR seed funding followed by capital fund raising campaigns. Unique to KUCC is the IAMI partnership with BioNovus Innovations LLC, described in *'Value Added by KUCC to Programmatic Efforts',* providing a preferred for-profit partnership path to advance KUCC new cancer therapeutic strategies to patients. Examples of D3ET research advancing to patients are described in the scientific highlights section.

Figure 3. D3ET Research Translated to Experimental Therapeutics Trials



The Investigator-Initiated Trial Steering Committee - In August 2014, KUCC announced an RFA for IIT proposals that would evaluate important and relevant therapeutic interventions in the cancer populations treated at KUCC and MCA sites. From the seven LOI submitted, four were selected for full proposals and three (**Sharma**, **Khan** (CPS) and **Ganguly**) were ultimately awarded KUCC support ($50,000/year for two years) in January 2015. The three studies have lead to 30, 45 and 14 patient accruals to date. Based on the interest of this funding mechanism, a second RFA was announced in January 2016. Of the nine LOI's submitted in response to the second RFA, most by first time trial PIs, four were selected for full proposals and KUCC funding. To support this growing interest and activity by our clinical scientists, a permanent review committee was formed by **Weir** and **Williamson**, in order to provide expertise to help develop and refine the growing number of clinical concepts. The goals of this joint committee (referred to as IIT Steering Committee - IITSC), co-chaired by **Weir** and **Williamson**, are to: 1) address unmet needs in the clinical care of our patients; 2) enable and advance hypothesis-driven IITs that could compete for external funding opportunities; 3) create a rich translational medicine culture for basic and clinical scientists, providing access to mentors and supporting faculty and staff career development; and 4) effectively and efficiently utilize KUCC shared resources to support IITs. Since forming the IITSC in 2016, 15 IIT concepts from 20 investigators have been presented and most are moving forward with full proposals. **Godwin** (Deputy Director) has been able to obtain $500,000 from

KUCC, as well as an additional $100,000 from Radiation Oncology (matching funds for two IITs by Rad Onc faculty members) to support the top prioritized scientific pilot IITs in CY16. Other IITs are being supported by pharma sponsors or departmental resources. IITSC membership is described in the *Clinical Protocol and Data Management* section of this grant application.

Contributions to Major NIH Programs - Historically, a significant portion of D3ET NCI and other NIH funding came from major NIH-funded medicinal and pharmaceutical chemistry research programs, contributing to KU's School of Pharmacy ranked in the top four among US pharmacy programs each the past 15 years. From 1972-2014, KU conducted pre-formulation and formulation research on promising anticancer agents identified by NCI's Experimental Therapeutics (NExT) program (Proj. No. 261200700011C, **Stella** and **Rajewski**). Approximately 50% of development candidates advancing through NExT were assigned to KU over the life of the contract. Taxol® (paclitaxel), Velcade® and pentostatin commercial parenteral formulations were developed at KU. The Center for Cancer Experimental Therapeutics was established in 2000 as a NIH Center of Biomedical Research Excellence (COBRE, 8P30GM103495, **Timmermann**). NIH funding continued through 2015, supporting 100 research projects at the chemistry/biology interface as well as supporting high throughput screening and synthetic chemistry cores. Now in its eleventh year, supported by a legacy continuation grant from NIH (5R24GM111385-02, Aubé and **Prisinzano**), the NIH funded Chemical Methodologies and Library Development Center (KU CMLD) has generated 209 publications and provided >7,000 compounds to the academic research community. The KU Specialized Chemistry Center (KU SCC) joined the Molecular Libraries Probe Production Centers Network (MLPCN) in 2008 (U54-HG005031) as one of two national centers of excellence in chemical lead and probe development. Over the past six years, the KU SCC produced 33 published probes and synthesized 7,953 new small molecules provided to 97 collaborators. However, despite discontinuation of these national programs by the NIH, the D3ET program achieved a strong and growing cancer-focused research portfolio, as described above.

Program Development and Response to the 2012 NCI Review

D3ET worked closely with the KUCC EAB to grow and further develop its cancer focus and enhance its collaborative synergies. Responses to criticisms are detailed in **Table 3**. Under the leadership of program co-leaders **Gamis** and **Weir**, the D3ET program has made considerable progress in the following areas consistent with its research themes:

- Established a sustainable pipeline or portfolio of high potential cancer small molecule drug discovery projects at the chemistry/biology interface.
- Increased the number and improved the quality of hypothesis-driven investigator initiated clinical trials that have the potential to secure peer-reviewed funding.
- Expanded KUCC's pipeline of novel cancer therapeutics projects to include cancer immunotherapy.

Table 3. D3ET Program Development in Response to 2012 CCSG Critique

2012 CCSG Critique	D3ET Response
Develop a critical mass of dedicated translational scientists as well as clinical investigators with expertise in early-stage clinical trials	As described above, KUCC's culture of translational research has been enhanced by the formation of TAG and IITSC.
Develop a dedicated clinical pharmacology shared resource that incorporates pharmacokinetics and pharmacodynamics, biomarkers and imaging	The Clinical Pharmacology Shared Resource, led by **Reed**, has advanced from a developing shared resource to an established shared resource described in the CCSG application. Additionally, the Biomarker Discovery Laboratory (BDL), led by **Godwin**, provides correlative science expertise and supports clinical trial research as it relates to predictive and prognostic biomarkers.
Articulate a coherent plan for integrating clinical disease team activities with drug discovery efforts	D3ET program members and members from both the TAG and IITSC participate in the Disease Working Group meetings (described in the CPDM section) in order to facilitate drug discovery efforts with clinicians.
Integrate personalized medicine throughout all stages of drug development	Deputy Director, **Godwin**, is the director of the Clinical Molecular Oncology Laboratory (CMOL) at KUMC and co-chairs the KU Health System's Personalized Medicine Steering Committee. The CMOL is a CLIA-certified, CAP-accredited molecular pathology laboratory. In FY16, the CMOL provided over 1,600 DNA/RNA-based diagnostic tests to support the care of our cancer patients. Between the expertise in the BDL and the CMOL,

	Godwin and staff are supporting correlative biomarker studies for >20 clinical trials at both the local and national levels.
Integrate the efforts of KUMC and community oncologists in the development of investigator-initiated, hypothesis-driven clinical trials	Community-based oncologists actively participate in the previously mentioned Disease Working Groups (DWG). IITs are conceptually developed within each DWG based on input from all members. Examples of IITs conducted in collaboration with community-based oncologists include the X7-7 trial led by **Khan** (CPS), including community sites through the MCA, and the triple negative breast cancer IIT led by **Sharma**. All IITs are considered for activation at all sites, if feasible, based on the type of protocol and sponsor.
A truly novel drug has yet to emerge from this program, but there is great potential for this to happen, should novel targets and combinations be identified	Four novel drugs, representing innovative therapeutic approaches to treating cancer, have emerged from D3ET over the last grant period: 1. CB-5083 is a first-in-class p97 ATPase inhibitor being evaluated in Phase I trials in multiple myeloma and solid tumor cancers. 2. Ciclopirox Prodrug is being developed as the first systemic treatment for non-muscle invasive bladder cancer. 3. MSCTC-0010, a suspension of mesenchymal stem cells isolated from the Wharton's Jelly fraction of human umbilical cords, is being developed for the treatment of *de novo* high-risk acute or steroid-refractory acute Graft Versus Host Disease. 4. Metarrestin is a first-in-class perinucleolar compartment disassembler synthesized at KUCC. KUCC, NCI, NCATS and Northwestern University are developing this drug collaboratively. A proposal seeking NExT support is currently under review by the NCI.

Qualifications and Contributions of the Program Leaders

Gamis and **Weir** were appointed D3ET co-leaders in 2015. The D3ET co-leaders bring exceptional research and leadership expertise and an ability to build intra-programmatic and inter-programmatic collaborations across all themes and disciplines. **Weir** has played a leadership role within the D3ET program since its inception in 2006. From 2006-2012, **Weir** co-led the D3ET program. In 2012, he assumed the role of Associate Director for Translational Research. In his translational research role, **Weir** continued to work closely with former D3ET co-leaders Jeffrey Aubé and Raymond **Perez**. With the departure of Aubé to the University of North Carolina in 2015, and KUCC priorities requiring **Perez** to focus on early phase cancer clinical trial accruals, **Weir** returned as co-leader in 2015. **Gamis** leads efforts to fully integrate CM capabilities (*e.g.,* genomic medicine, pediatric cancer clinical trials and pharmacogenomics) into D3ET and KUCC. **Gamis** and **Weir** work together to guide D3ET program growth through the use of pilot funds, monthly webinars, regular program meetings and other *ad hoc* meetings to present novel cancer therapeutic approaches or ideas. Each activity aims to create occasions for scientific interactions, multi-PI research initiatives and opportunities to collaborate on multidisciplinary, multi-organizational, translational research teams. Additionally, **Gamis** and **Weir** spend considerable time mentoring D3ET members as well as members of other programs.

Alan S. **Gamis**, MD, MPH is a nationally recognized leader in the field of pediatric cancer experimental therapeutics. **Gamis** has played a significant role in the Children's Oncology Group's Myeloid Disease Scientific Committee research agenda as the chair of two national trials, the member of numerous other national AML trials, a member of the Myeloid Disease Scientific Committee, was chair of this committee for the previous six years, and is chair emeritus now. **Gamis** was chair of the first COG trial for Downs Syndrome (DS) children with AML, COG A2971, which published seminal manuscripts on both Transient Myeloproliferative Disorder (**Gamis**, *Blood*, 2011) and on DS-associated AML (Sorrell, *Cancer*, 2012). Following this, he chaired the randomized Phase III trial, COG AAML0531, which showed a significant improvement in event-free survival through a reduction in relapse with the conjugated CD33 antibody, Gemtuzumab Ozogamicin (GO) (**Gamis**, *J Clin Oncol*, 2014; Pollard, *J Clin Oncol*, 2016; Tarlock, *Clin Cancer Res*, 2016). This clinical trial was designed to achieve numerous clinical and biologic objectives with ongoing research from the large database derived from this trial as well as the large Biorepository from the enrolled patients, including the ongoing NCI TARGET research project sequencing over 200 diagnostic, remission and relapse trios for disease evolution and potential targets (Farrar, *Cancer Res*, 2016; Meshinchi, *Cancer Res*, 2016). As the Myeloid Disease committee chair, **Gamis** oversaw the development of numerous Phase II (new agent, AAML-05P1, AAML-07P1, AAML0523) and III (DS, AAML0431), APL (AAML0631), and de novo AML trials in childhood AML including

the recent Phase III trial, COG AAML1031, examining the incorporation of bortezomib in the treatment of children with AML, and now is participating in the design of the next COG Phase III that will be studying the optimization of GO in childhood AML therapy and potential leukemic modifiers to enhance GO efficacy. Prior to his COG Myeloid Disease chairmanship, **Gamis** was the national chair of the Pediatric Blood and Marrow Transplant Consortium (NIH BAA-RM-04-23) and during that time competed successfully for the NHLBI RFA to be one of the 13 original principle investigators of the NHLBI's U01-supported Blood and Marrow Transplant Clinical Trials Network (BMT CTN) when it first formed (U01 HL69254-01). He currently serves on the NCI's PDQ Pediatric Treatment Editorial Board overseeing the Myeloid Diseases section as well as participating in its other hematopoietic malignancy sections.

Scott J. **Weir,** PharmD, PhD has over 30 years professional experience in drug discovery, development and experimental therapeutics. In addition to his role as co-leader of D3ET, **Weir** serves as Associate Director for Translational Research. In this capacity, **Weir** led efforts to establish two KUCC translational research catalysts. He chairs TAG and co-chairs the IITSC, both described previously in this program description. Much of **Weir's** program leadership activities involve working with D3ET members to leverage KUCC resources. **Weir** also leads a nationally recognized product development-focused translational research enterprise, IAMI, described in section "*Value Added by KUCC to Programmatic Efforts"*. **Weir** led the establishment of high-performance collaborations and partnerships with industry, academia, government and disease philanthropy organizations to bring new drug therapies to patients. Prior to joining KUCC in 2006, **Weir** spent 20 years in the pharmaceutical industry, where he led innovative approaches to lead development and optimization, early drug development and early phase clinical trials, including the successful development and registration of several drug products. In 2012, **Weir** was appointed to the National Center for Advancing Translational Sciences (NCATS) Advisory Council as well as to the Cures Acceleration Network Board at the NIH. In 2013-2014, **Weir** co-led the NCATS Working Group charged with defining strategic goals and objectives for the CTSA program that are in place today. In KUCC's partnership with CicloMed LLC, **Weir** continues to be actively involved in the development of Ciclopirox Prodrug for the treatment of non-muscle invasive bladder cancer. In collaboration with, **Anant** (CPS), **Weir** studies the Notch signaling pathway and its inhibition by natural products (Co-Investigator, 1R01CA190291) and small molecule inhibitors (Multi-PI, R01CA182872).

Scientific Quality and Cancer Focus

Over the current funding period, D3ET has concentrated its research efforts to establish a sustainable pipeline or portfolio of high potential, cancer relevant, small molecule drug discovery projects at the chemistry/biology interface, increase the number and improve the quality of hypothesis-driven IITs trials that have the potential to secure peer-reviewed funding and expand KUCC's pipeline of novel cancer therapeutics projects to include cancer immunotherapy. The following scientific highlights are representative of D3ET's research efforts organized around three scientific themes.

Theme 1 – Discover and Deliver New Cancer Therapeutic Strategies

Campaign to Identify Reversible Small Molecule Inhibitor of p97 (U54-HG005031). The AAA ATPase p97 participates in key steps in ubiquitin-dependent protein quality control, autophagy and fundamental cell functions (**Figure 4**, Chou, *PNAS*, 2011). P97 is overexpressed in some cancers, but its role in tumor development, at the time, was largely unknown. In collaboration with Ray Deshaies (MH 085687) at the California Institute of Technology and Tsui-Fen Chou at the UCLA Jonsson Comprehensive Cancer Center, **Schoenen** synthesized the first selective inhibitor of p97, DBeQ, which was used to validate p97 as a cancer drug target (Chou, *Probe Report from the NIH Molecular Libraries Program, National Center for Biotechnology Information*, 2013). **Schoenen** optimized DBeQ to provide ML240 and ML241, selective inhibitors of p97 to possess druggable properties as well as composition of matter

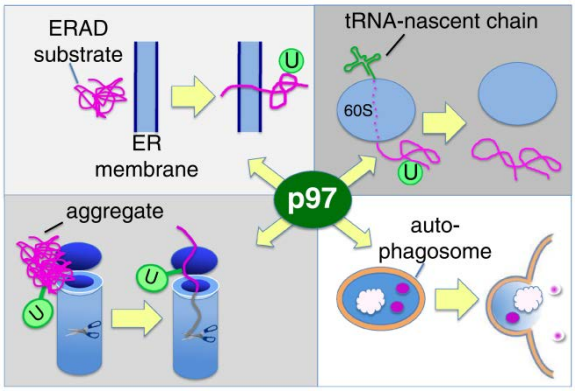


Figure 4. p97 is a Key Player in Protein Homeostatis. Upper left: p97 extracts unfolded or misassembled proteins from the ER. Upper right: p97 recognizes ribosomes that have stalled during translation and releases the nascent chain from the ribosome. Lower left: protein and protein-RNA aggregates require p97 for metabolism. Lower right: p97 is required for autophagosome maturation.

intellectual property (Chou, *J Mol Biol*, 2014; Fang, *Chem Med Chem*, 2015; Gui, *Chem Med Chem*, 2016; US Patent 8865708 B2, October 21, 2014). Following a license agreement with Cleave Biosciences Inc., CB-5083, a close derivative of ML240, was developed. CB-5083 is currently being evaluated in two phase I clinical trials, one in relapsed and refractory multiple myeloma (NCT02223598) and the other in solid tumors refractory to the standard-of-care (NCT02243917). KUCC participates in a Cleave Biosciences sponsored Phase I trial (CLC-104) evaluating the safety, pharmacokinetics and pharmacodynamics of CB-5083 alone and in combination with cytarabine in AML patients with D3ET member, **Lin**, as investigator.

Small Molecules Modulating RNA-Binding Protein Msi1 (Xu and Neufeld, R01CA178831). RNA-binding protein Musashi-1 (MSI1) is overexpressed in a number of cancers including glioblastoma, breast and colon cancers. Known mRNA targets of Msi1 include Numb, APC and p21WAF-1, key regulators of Notch, Wnt signaling and cell cycle progression. Msi1 negatively regulates translation by binding sequence elements within the 3'-UTRs of target mRNAs. **Xu** and **Neufeld** (CB) leveraged KUCC pilot funds to secure NCI funding to discover/validate a new class of small molecule inhibitors targeting Msi1 to its RNA binding site (**Xu**, *Mol Oncol*, 2015). Multiple small molecule compounds have been identified to disrupt Msi1-Numb RNA binding, previously considered a non-druggable target. Medicinal chemistry efforts are ongoing to improve upon nanomolar potency hits identified to date. **Karanicolas** developed a computational model as a basis for the structure-based design of novel inhibitors. The natural product (-)-Gossypol, identified as the first small molecule inhibitor of Msi1/RNA binding, was used to validate the drug target *in vitro* and *in vivo* (Lian, *Cell Death Differ*, 2011; Meng, *Mol Cancer Ther*, 2008; Lian, *Mol Cancer Ther*, 2012; Lian, *Autophagy*, 2010).

Biomaterials to Selectively Deliver Cytotoxics in Head and Neck Cancer (Forrest, CA173292). Forrest and **Aires** (CB) have developed novel biomaterials for the treatment of head and neck cancer (HNSCC). Cytotoxics currently used in the treatment of HNSCC have poor delivery into the lymphatics and provide only a marginal benefit to radiation and surgery alone. **Forrest** and **Aires** deliver cytotoxic agents to tumors and the draining lymph nodes by chemically linking cytotoxics, such as cisplatin, to novel polysaccharides (Zhang, *BAOJ Pharm Sci,* 2015; Zhang, *J Pharm Sci,* 2016). In an ongoing comparative oncology clinical trial, three out of seven canine HNSCC patients had a durable clinical response following treatment with hyaluronan-cisplatin (HP-100), with two patients having no recurrence over 18 months (**Figure 5**, Cai, *Am J Vet Res,* 2015). This is the first therapy for HNSCC to target delivery of cytotoxic agents directly to the lymphatic system. **Forrest** successfully leveraged KUCC pilot funds to secure a NCI-funded R01 (R01 CA173292), and now **Forrest** and **Aires** have also secured a NCI contract (HHSN261201500047C, PI Groer) to develop a hyaluronan-cytotoxic therapeutic that targets cancer stem cell subpopulations in breast cancer.

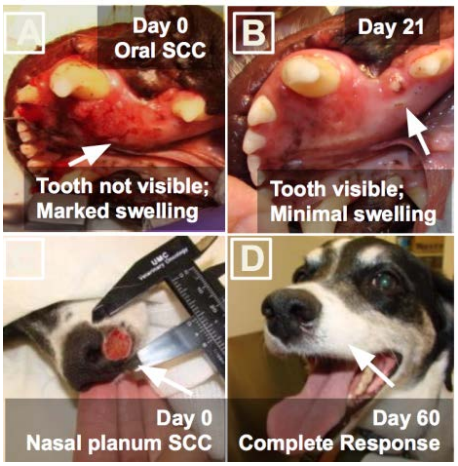


Figure 5. Complete Response in Canines with Squamous Cell Carcinoma (SCC) Receiving HP-100. Dog 1 (A) Oral SCC occludes tooth; (B) 21 days post HP-100 (30 mg/m^2), tumor receded; tooth visible. Dog received 3 additional doses every 21 days, and had complete remission at 2.5 years post-treatment. Dog 2 (C) Nasal SCC; (D) 60 days post HP-100 lesion is absent. Dog had complete remission at 6 months post-treatment.

Theme 2 – Develop New Cancer Therapeutic Strategies

Chimeric Antigen Receptor T-Cell Therapeutics (Doolittle, Fullbright, McGuirk, Myers, Yankee). Employing a novel, proprietary approach to fusing synthetic molecules that bind tumor antigens with endogenous signaling proteins, **Yankee** (CB) and **Myers** advanced this technology to patients evaluating donor-derived, viral-specific cytotoxic T-lymphocytes transducted with a first generation chimeric antigen receptor targeting GD2. Conducted in pediatric patients with neuroblastoma following a mismatched related donor hematopoietic stem cell transplant, this trial was the first to show expansion of first generation CAR-modified T-cells *in vivo*. In 2015, both KUMC and CM opened studies of CD19 specific CAR T-cells in adult patients with relapsed/refractory diffuse large B-cell lymphoma (NCT02445222) and pediatric patients with acute lymphoblastic leukemia (NCT02228096) at CM. Sponsored by Novartis Pharmaceuticals Inc., KUMC is

the leading enrollment site for the adult study led by **McGuirk**. **Myers** is the PI at CM and also serves on the pediatric trial study steering committee providing national oversight. Patients from as far away as Australia and Portugal have traveled to Kansas City to participate in NCT02445222 to date. Leveraging this expertise in CAR T-cell therapy, **Doolittle** (CCPH) and **Fulbright** have collaborated with **Myers** to open a study of autologous, vaccine-specific T-cell enriched GD2 CAR modified T-cells in patients with relapsed/refractory melanoma.

Ciclopirox Prodrug for the Treatment of High Risk NMIBC (Weir and Anant). Bladder cancer is the sixth most common cancer in US men and women with ~76,000 new cases diagnosed and ~16,000 bladder cancer-related deaths each year. Bladder cancer is two diseases, muscle invasive (MIBC) and non-muscle invasive bladder cancer (NMIBC), each with different treatment approaches and drastically different outcomes. About 75% of new cases are patients with NMIBC, a less aggressive cancer, but with the highest recurrence rate of any known cancer and risk of progressing to MIBC. Management of NMIBC is transurethral resection of tumors lining the bladder followed by topical administration of Bacillus Calmette-Guerin vaccine, Mitomycin C, or cisplatin. No new treatments for NMIBC have been introduced since 1998. **Weir** and **Anant** (CPS) discovered and developed *Ciclopirox Prodrug* (CPX-POM) as potentially the first systemic treatment of NMIBC (**Figure 6**). With composition of matter intellectual property, CPX-POM is being developed as a potential breakthrough treatment in the management of high-grade NMIBC. CPX, a FDA-approved topical antifungal agent, possesses anticancer activity against NMIBC *in vitro* and *in vivo* via novel mechanisms of action, including inhibition of the Notch signaling pathway via dissociation of the γ-secretase complex. In collaboration with John Taylor (University of Connecticut Health Sciences Center), **Weir** and **Anant** demonstrated that systemic administration of CPX-POM significantly decreases tumor size, results in migration to lower stage tumors and reduction in downstream Notch signaling pathway proteins *in vivo*, in a validated model of bladder cancer (issued US patent 8,609,637; issued certificate of Japanese patent No.5853028). The LDOSR provided drug synthesis, formulation development, preclinical safety and pharmacokinetic support. CPX-POM has been licensed to a local biotechnology firm, CicloMed, LLC. KUCC is partnering with CicloMed to advance CPX-POM to clinical proof of concept, with **Lee** (CB) evaluating the agent in patients beginning 2017. The CPSR will provide clinical pharmacology support for clinical proof of concept trials sponsored by CicloMed. CPX-POM will represent the first KU-invented anticancer agent advanced from the bench to the bedside at KUCC.

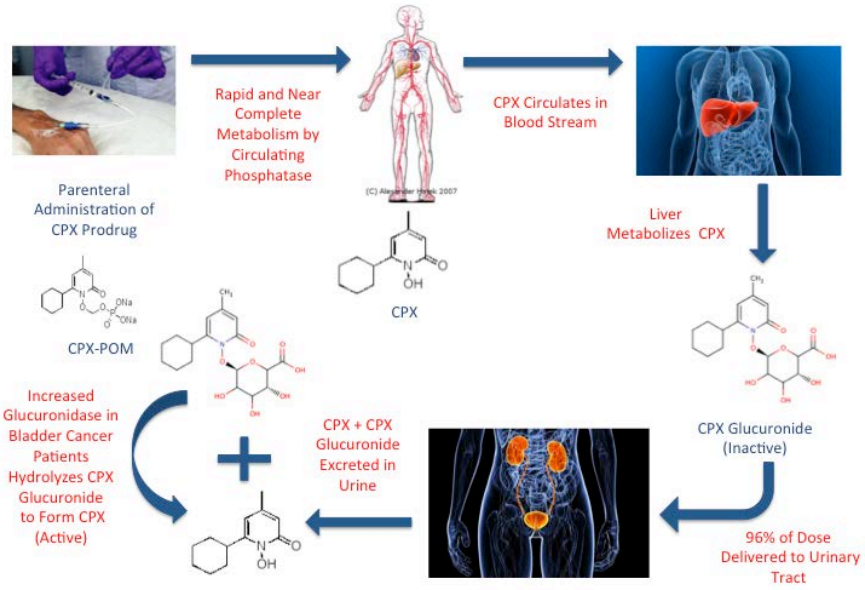


Figure 6. Selective Delivery of Ciclopirox following Systemic Administration of Ciclopirox Prodrug. Once introduced into systemic circulation, CPX-POM is rapidly and completely metabolized to form the active moiety, ciclopirox (CPX). Once in the systemic circulation, CPX is primarily metabolized to form an inactive glucuronide metabolite, followed by urinary excretion of CPX and metabolite. A portion of the inactive glucuronide metabolite is hydrolyzed in the urine of bladder cancer patients to reactivate CPX. CPX-POM administration results in urine concentrations of CPX that exceed *in vitro* IC_{50} values by 15-30 fold at well-tolerated doses in mice, rats and dogs.

Stem Cell Therapy for Graft Versus Host Disease (Abyankar and McGuirk). McGuirk and **Abynankar** are collaborating with the Midwest Stem Cell Therapy Center (MSCTC) at KUMC to develop MSCTC-0010 for the treatment of *de novo* high-risk acute or steroid refractory acute Graft Versus Host Disease (GVHD). MSCTC-0010 is an allogeneic, unmatched, tissue-derived suspension of human Wharton's Jelly mesenchymal stem cells (WJMSC) from umbilical cords. WJMSCs are obtained under Good Manufacturing Practice/Good Tissue Practice (GLP) conditions at the MSCTC. *In vitro* immunosuppression studies conducted at the MSCTC, as well as literature evidence established proof of principle. On February 4, 2016, KUCC and MSCTC participated

in Type B Pre-IND meeting with the Food and Drug Administration (FDA) to discuss chemistry, manufacturing, pre-clinical and clinical issues for a Phase I Investigational New Drug (IND) submission. As a result of the Pre-IND meeting with FDA, GLP preclinical safety studies are ongoing with an IND submission planned for 4Q2016 with first patient enrolled 1Q2017. Necessary support to advance MSCTC-0010 to clinical proof of concept has been provided by KUCC developmental funds, philanthropic and institutional funding.

Theme 3 – Evaluate New Cancer Therapeutic Strategies in Experimental Therapeutics Trials

Clinical and Biological Characteristics of Triple Negative Breast Cancer (Sharma, PSWOG-S9313C-SWOG-ICSC_R01PAPP01, CS1416_ R01CAPOH01). Sharma established a multisite prospective regional clinical and biospecimen registry (NCT # 02302742) through the Biospecimen Shared Resource (BSR). The molecular features of Triple Negative Breast Cancer (TNBC) patients comprising this registry (>760 TNBC patients) were examined to evaluate *BRCA*ness, including germline mutations in *BRCA1*, *BRCA2* and related genes, as a prognostic and predictive marker of therapeutic response. **Sharma** was the first to report the prevalence of germline *BRCA* mutations in unselected TNBC and also validate NCCN guidelines for germline testing in TNBC patients (**Sharma**, *Breast Cancer Res Treat*, 2014), as well as the first to report the significant efficacy of platinum-taxane chemotherapy combination in TNBC and the positive impact of neoadjuvant chemotherapy on axillary nodal involvement in patients with node negative disease (**Sharma**, *Clin Cancer Res*, 2016; **Sharma**, *J Cancer Ther Res*, 2014). **Sharma** translated these findings into two national intergroup projects (SWOG S9313c and S1416; **Figure 7**). **Sharma** also received the 2015 Conquer Cancer Foundation of ASCO Advanced Clinical Research Award in Breast Cancer as a result of her efforts. KUCC members participating in this interdisciplinary work include **Godwin** (as the director of the BSR and coordinator of the correlative studies), CPS members **Jensen**, **Klemp**, **Kimler**, **Khan; Reed** (CPSR); and **Fridley** (CCPH).

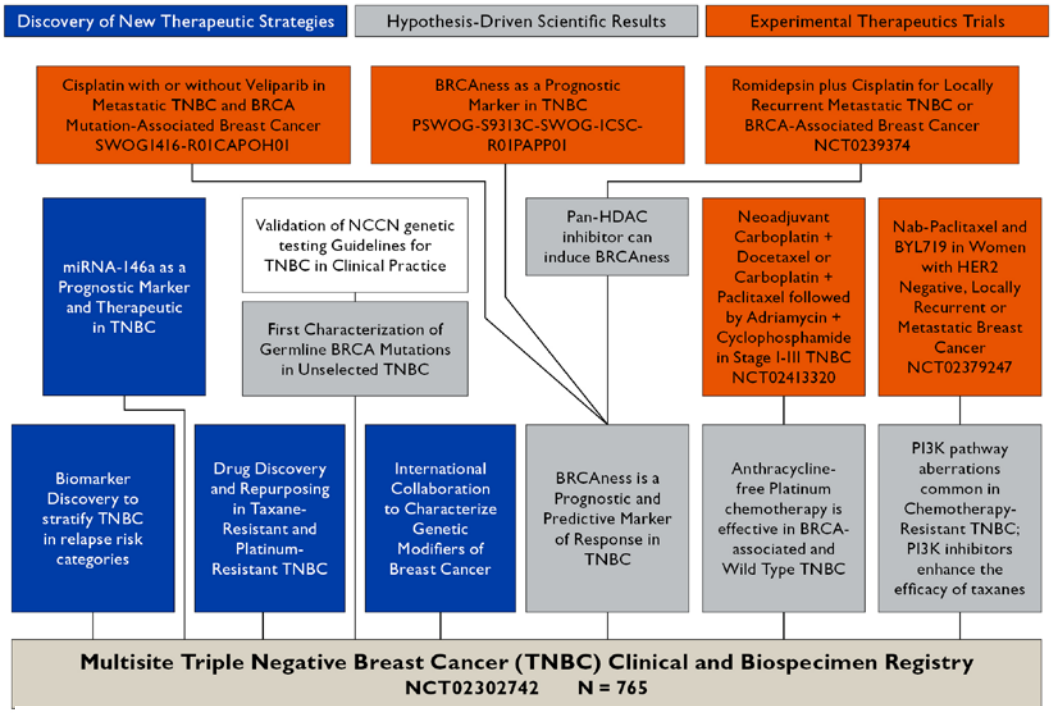


Figure 7. Triple Negative Breast Cancer (TNBC) Experimental Therapeutics Program. Data generated from an ongoing TNBC clinical and biospecimen registry have created a platform for validating NCCN Guidelines for genetic testing for TNBC, biomarker discovery, drug discovery and repurposing and hypothesis-driven experimental therapeutics trials.

Preventing Infections and Cachexia in Bladder Cancer Patients (Hamilton-Reeves, KL2 TR000119-04). Infections and muscle wasting (cachexia) are common after radical cystectomy in muscle invasive bladder cancer patients. Despite improved surgical techniques that reduce the length of stay after surgery, infections and cachexia continue to plague patients. Improving immune function through enhanced nutrition before and after surgery could be a low risk, high-impact means of protecting against infections and muscle wasting. **Hamilton-Reeves** (CPS), **Lee** (CB) and **Holzbeierlein** conducted a randomized pilot study in 29 men scheduled for radical cystectomy to evaluate nutrition regimens for reducing infections and muscle wasting, funded by KL2 TR000119-04. As illustrated in **Figure 8**, **Yankee** (CB) determined that myeloid-derived suppressor cells (MDSCs) were significantly lower in patients receiving Specialized Immunonutrition (SIM) compared to oral nutrition supplements (control group) (**Hamilton-Reeves**, *Eur Urol,* 2016). Expansion of

MDSCs post-operatively contributes to a lower resistance to infection and exacerbating muscle breakdown. Patients who received SIM before and after a radical cystectomy had a 39% decrease in infection rates after surgery compared to a control group who received an oral nutrition supplement. Patients who received SIM before and after a radical cystectomy did not lose as much skeletal muscle or bodyweight after surgery compared to a control group. **Holzbeierlein**, **Lee** (PI) and **Hamilton-Reeves** are testing the intervention to better identify malnourished radical cystectomy patients before surgery and assist with transitional care after surgery to further improve outcomes. **Hamilton-Reeves** and her team are working on a resubmission of R01CA207692 (Score 32, 19th percentile) to fund the body composition and translational outcomes for a SWOG multi-center trial.

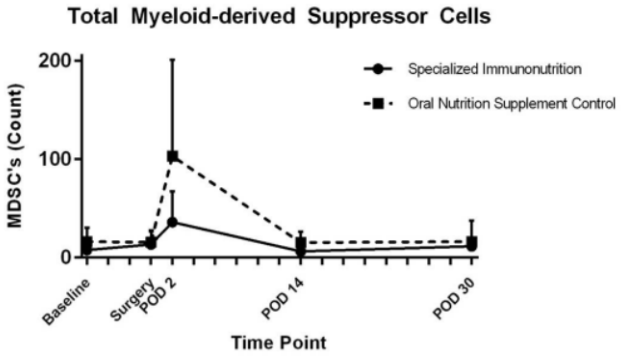


Figure 8. MDSC counts over time in radical cystectomy patients being treated for primary bladder cancer.

Tumor-derived exosomes: A message delivery system for tumor progression and disease monitoring. For the past several years **Godwin**, **Zeng** (KU-Lawrence) and most recently **Soper** (a newly appointed Foundation Distinguished Professor at KU), have been evaluating the role of extracellular vesicles (EVs), primarily focused on exosomal biology in cancer initiation, progression and drug resistance, as well as exploiting them as circulating biomarkers for early detection and monitoring disease state. **Godwin** (R01CA106588) and colleagues report the first evidence that gastrointestinal stromal tumor (GIST) cells invade the interstitial stroma directly through the release of oncogenic KIT-containing exosomes (**Figure 9**), which triggers the phenotypic conversion of stromal progenitor smooth muscle cells to tumor-promoting cells (Atay, *Proc Natl Acad Sci USA*, 2014; Atay, *Commun Integr Biol*, 2014). Their studies indicated that exosome release and subsequent MMP1 induction created a positive feedback-loop mechanism established between tumor and stromal cells which drives GIST development and offers new insights for potential therapeutic strategies to block GIST progression and metastatic spread. In parallel, the researchers sought to exploit exosomes as potential biomarkers to detect and monitor disease states. **Godwin** and **Zeng** fabricated the first microfluidic platform (lab-on-a-chip) to streamline and expedite the exosome analysis pipeline by integrating specific immune-isolation and targeted protein analysis of circulating exosomes (He, *Lab Chip*, 2014), leading to a collaborative NCI award (R21CA186846) and several pending grant applications. **Zeng** and colleagues subsequently developed 2nd generation microfluidic platforms based on a novel nanostructured graphene oxide/polydopamine (GO/PDA) interface (Zhang, *Lab Chip*, 2016; Zhao, *Lab Chip* 2016). **Soper** (P41EB020594: Center of BioModular Multiscale Systems for Precision Medicine), an expert in circulating tumor cells capture microfluidic devices, in collaboration with **Godwin,** have explored additional microfluidic devices for the analysis of EVs, especially “rare” disease-associated exosomes in liquid biopsies. To further support these efforts, **Godwin** has formed the Extracellular Microvesicle Laboratory at KUMC, which included studies by physician scientists Glenson Samuel, MD, FAAP (Pediatric Hematologist Oncologist at Children’s Mercy, funded by the Alex’s Lemonade Stand Foundation, and regional awards through the MCA and Noah’s Bandage Project) and Neil Dunavin, MD, MHS (Blood and Marrow Transplantation physician at KUCC who started in August, 2016).

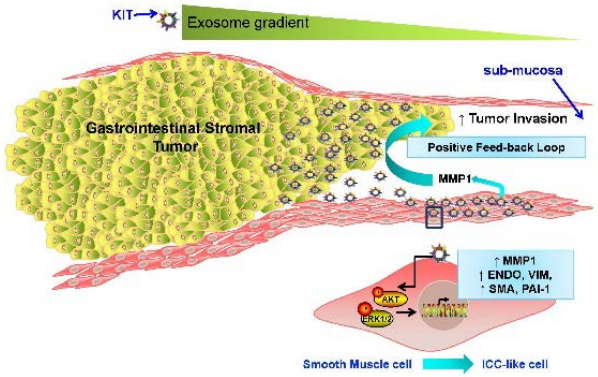


Figure 9. Proposed model of tumor-stromal positive feedback loop mediated by oncogenic KIT-bearing tumor exosomes in the regulation of tumor invasion.

Cancer Research Relevant to Our Catchment Area

KUCC patients have gained access to innovations directly resulting from D3ET research, including promising new cancer treatments not available elsewhere. Programmatic initiatives in drug repurposing have created

opportunities for our patients to gain access to promising new cancer trials not available elsewhere and to do so, in many cases, much more quickly than from drug discovery-based trials. In partnership with The Leukemia and Lymphoma Society (LLS) and the NCATS at the NIH (**Weir**, *Cancer Research,* 2012), the D3ET program advanced an *in vitro* discovery that Auranofin (Ridaura®) killed chronic lymphocytic leukemia (CLL) cells to enrolling a CLL patient on the Auranofin trial in just eleven months. Mechanistic studies conducted by D3ET provided the rationale for advancing this drug to patients, particularly in patients in our catchment area with difficult-to-treat 11q and 17p deletion CLL who participated in the trial (Fiskus, *Cancer Res*, 2014).

Transdisciplinary Research Collaboration

As described in the 'Overview', KUCC identified the need to create and foster a culture of translational research. TAG and IITSC function as catalysts for multidisciplinary, multi-organizational collaboration and have enabled **Weir** and **Gamis** to focus much of their D3ET leadership efforts on engaging program members in developmental therapeutic initiatives to enhance those members academic productivity.

Value Added by KUCC to Programmatic Efforts

In 2006, KUCC made a $300,000 investment to create the Office of Therapeutics, Drug Discovery and Development (OTDD). OTDD quickly established innovative drug discovery, development and translational research best practices and new cancer therapeutics projects within KUCC. Through innovative partnerships with industry, academia, government and disease philanthropy partners, KUCC was successful in advancing several new cancer treatments to patients over 2006-2008. Leveraging these successes, KUCC was awarded an $8.1M grant awarded by the Ewing Marion Kauffman Foundation in January 2009, along with an $8.0M matched investment made by KU Endowment Association to expand the OTDD, creating the Institute for Advancing Medical Innovation (IAMI). IAMI is a nationally recognized program that transforms laboratory and bedside discoveries into new drug therapies, diagnostics, and medical devices, and then translates those medical innovations to patients. IAMI invests sufficient resources into projects to advance them to the stage that they can be partnered with the private sector. To date, IAMI has invested >$8.1M in 48 drug, diagnostic, and medical device projects. Nine investments have resulted in royalty-bearing license agreements, and one drug product, Epaned™, has been FDA approved. IAMI has invested $2.8M in 15 cancer projects. In 2015, IAMI established a preferred partnership agreement with a group of Kansas City investors organized as BioNovus Innovations LLC. Through the partnership, IAMI has a for-profit partner with the resources and expertise to commercialize promising cancer drug, diagnostic and medical device projects. Ciclopirox Prodrug (CPX-POM), as previously described, is the first IAMI project licensed under this agreement. BioNovus is investing sufficient funds to advance CPX-POM through clinical proof of concept trials. Through IAMI and its partnership with BioNovus, KUCC has a clear path to commercialization for cancer relevant drug, diagnostic and medical device innovations arising from its research programs.

Consortium Partners

Biomarkers in Infant Acute Lymphocytic Leukemia. The Center for Pediatric Genomic Medicine (CPGM) at CM is the first genome center in the world inside a children's hospital. This center is also the first focused on genome sequencing and analysis of inherited children's diseases. Building upon the strengths of the CPGM, CM established the Center for Cancer Genomics Program (CCGP) in 2015 under the leadership of **Guest**. In collaboration with Johns Hopkins University, whole genome, whole exome, mRNA and whole genome bisulfite sequencing have been performed on 44 patients participating in COG AALL0631 (NCT00557193), including pediatric ALL patients within our catchment area. Supported in part by an MCA pilot grant, this was the first comprehensive study of genomic and epigenomic profiling in infant ALL. **Guest** and her collaborators established that increased transcription start site methylation is associated with decreased gene expression in ALL (**Figure 10**). Building upon the data generated, **Guest** is leading a national cooperative group (COG) trial evaluating azacitidine in

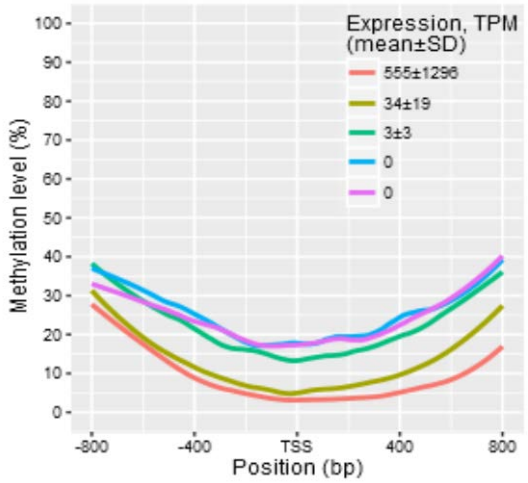


Figure 10. Percentage of Methylation Near the Transcription Start Sites for 5 Quintiles of Genes, ranked according to mean transcript expression. Data generated from an infant ALL case with *MLL*-R at the time of initial diagnosis. TPM, transcripts per million; SD, standard deviation.

combination with standard of care chemotherapy in newly diagnosed ALL with MLL gene rearrangement (COG AALL15P1, NCT02828358). This trial was approved by NCI CTEP in March and opened in August 2016. Targeted enrollments is 55 patients in this national COG trial.

Hypothesis-Driven Experimental Therapeutics Trial Evaluating Low-Dose Daunorubicin in Relapsed/Refractory Acute Leukemia (Li & Lin). A multidisciplinary, multi-organizational team of basic, translational and clinical scientists co-led by Stowers investigator Linheng **Li** (CB), **Lin** and Broward (LDOSR Project Director), have advanced a laboratory discovery made by **Li** to a clinical proof of concept trial in acute myeloid leukemia. Loss of the PTEN tumor suppressor activates the PI3K/AKT pathway. If Wnt signaling is abnormally activated at the same time, β-catenin is then phosphorylated by AKT at a c-terminal serine 552. **Li** (CB) demonstrated that serine 552 phosphorylation is critical to the successful interaction between AKT and β-catenin (Perry, *Genes Dev,* 2011). This successful interaction induces proliferation of leukemia stem cells. Through high throughput screening, **Roy** identified that anthracyclines inhibit cooperation between AKT and β-catenin *in vitro.* **Li** established *in vivo* proof of principle, demonstrating that anthracyclines administered at 1/40th the cytotoxic dose, depleted leukemia initiating stem cells (LSCs) in a validated mouse model (**Figure 11**). **Lin** and **Li** (CB) established that the target, *i.e.,* presence of phosphorylated serine 552, was in 6/10 AML patients, 5/10 B-ALL patients, and 7/10 T-ALL patients. As a result, **Lin**, **Perez** and **Reed** are conducting a hypothesis-driven IIT to evaluate low-dose daunorubicin as an inhibitor of β-catenin S552 phosphorylation in AML and ALL patients.

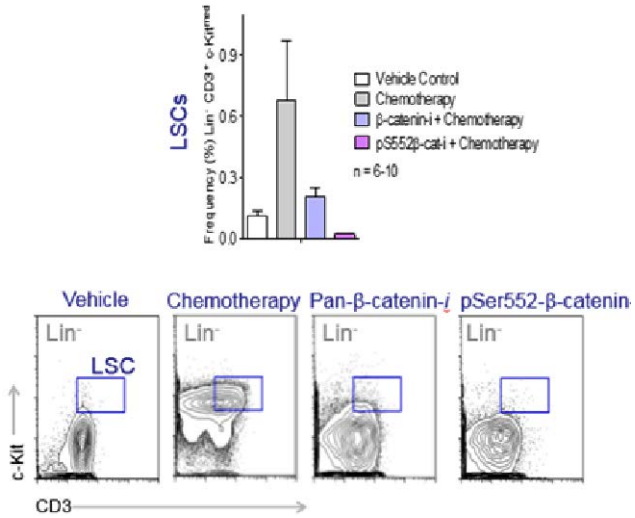


Figure 11. Low-dose Doxorubicin Depletes LSCs *In Vivo* in a PTEN/ β-catenin Double Mutant Mouse Model.

Future Plans

The D3ET program has a strong research and clinical base that includes investigators who are highly collaborative, conducting cancer-focused research that spans the breadth of drug discovery, development and experimental therapeutics. Future plans are to:

- Invest developmental funds to expand the scope and success of early stage clinical investigators;
- Partner with CPS to discover/develop small molecule and natural product chemoprevention agents;
- Leverage **Leeder's** newly funded U54 Center for Genomic and Ontogeny-Linked Dose Individualization and Clinical Optimization for Kids to develop age- and patient-appropriate dosing strategies for promising cancer treatment and prevention agents;
- Leverage **Soper's** expertise in molecular diagnostics and microfluidic technology to analyze a variety of circulating biomarkers for disease management. Soper, Director of the Center for BioModular Multiscale Systems for Precision Medicine (NIH; P41EB020594), will join KU and KUCC in August 2016;
- Translate KUCC-funded pilot IITs into R21- and R01-funded studies and continue to create opportunities for KUCC clinicians to lead national clinical trials and conduct correlative science studies to gain insight into molecular mechanisms;
- Integrate patients' perspectives into the research process at early phases through the PIVOT Project. The PIVOT Project expands on KUCC's mission to empower patients and advance quality cancer research by offering an engagement venue and framework for patients and researchers; and
- Establish collaborations with other NCI Cancer Centers including Kentucky, New Mexico, Iowa and Washington University, enabling peer-reviewed multi-PI research projects as well as providing access to KUCC drug discovery and development capabilities.

Progress Report Publications

This component has no publications resulting from Cancer Center Support Grant funds.

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Resource Sharing Plan

The University of Kansas Cancer Center (KUCC) and its scientific community understands its responsibility to comply with the instructions for the Resource Sharing Plans provided within the SF 424 (R&R) Application General Instructions and Supplemental Grant Application Instructions. When resources are developed with NIH funds via this Cancer Center Support Grant P30 mechanism, KUCC will ensure findings are made readily available to the NIH and the scientific community in a timely manner.

Data Sharing Plan

KUCC will adhere to the Final NIH Statement on Sharing Research Data and refer to the National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research. KUCC encourages the free flow of information and ideas while recognizing the timeliness of data sharing, the rights and privacy of human subjects and issues related to proprietary data. KUCC encourages data documentation, using a data-sharing agreement and selecting an appropriate method for sharing; considering the sensitivity of the data, the size of the dataset and the volume of requests anticipated.

Additionally, KUCC encourages any user of a CCSG-supported shared resource to acknowledge the source of data upon which their manuscript is based either in the Acknowledgments section or with authorship on the paper. Furthermore, any research project that received direct cost support from the CCSG is encouraged to cite the P30 CA168524. In both cases, citing the P30 CA168524 grant number and then being compliant with the NIH Public Access Policy is required.

Sharing Model Organisms

In the event that a model organism is developed, KUCC will comply with the NIH Policy on Sharing of Model Organisms for Biomedical Research. KUCC will work with the NIH/NCI to share and disseminate the critical model organism in a timely manner.

Genome Wide Associate Studies

When applicable, KUCC will comply with the NIH Genomic Data Sharing Policy. KUCC supports the sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. All research studies funded through the CCSG involving genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data will be submitted in a timely manner.