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Brooke Fridley, PhD

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: Brooke Fridley

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

POSITION TITLE: Chair and Senior Member

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 within the CCSG is as Scientific Director for the Biostatistics and Bioinformatics Shared Resource (BBSR), which resulted from the merger of the Biostatistics Shared Resource and the Cancer Informatics Shared Resource. I joined the Moffitt Cancer Center in January 2017 as the Chair of the Department of Biostatistics and Bioinformatics. Prior to joining Moffitt Cancer Center, I was at the University of Kansas Medical Center and the Mayo Clinic. While at the University of Kansas Medical Center, I was Director of the Biostatistics and Informatics Shared Resource for the NCI designated University of Kansas Cancer Center and Site Director for the Kansas-INBRE Bioinformatics Core. My research focus is in the areas of statistical genomics, molecular epidemiology of cancer, cancer genomics, and pharmacogenomics. I have extensive experience as a collaborating statistician, particularly in the design and analysis of molecular studies involving multiple types of 'omic data. These collaborations have resulted in over 220 publications and 3 NIH grants for which I was PI. The BBSR provides exceptional, comprehensive, multidisciplinary and collaborative data science expertise to Moffitt Cancer Center researchers, with a focus on reproducible research.

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
2012-2016 Associate Professor of Biostatistics, University of Kansas Medical Center
2012-2016 Director, Biostatistics and Informatics Share Resource, University of Kansas Cancer Center
2012-2016 Site Director, K-INBRE Bioinformatics Core, University of Kansas Medical Center
2016 Awarded Tenure, University of Kansas Medical Center
2017-Present Chair and Senior Member, Department of Biostatistics and Bioinformatics, Moffitt Cancer Center

2018-Present Scientific Director, Biostatistics and Bioinformatics Shared Resource (BBSR), Moffitt Cancer Center

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
2017 Moffitt Cancer Center Distinguished Scholar

C. Contributions 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.

   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. 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. 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. 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). PMCID: PMC4873330

1. **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. **Fridley BL**, Dai J, Raghavan R, Li Q, Winham SJ, Hou X, Weroha SJ, Wang C, Kalli KR, Cunningham JM, Lawrenson K, Gayther SA, Goode EL. Transcriptomic Characterization of Endometrioid, Clear Cell, and High Grade Serous Epithelial Ovarian Carcinoma. *Cancer Epidemiol Biomarkers Prev*. 2018 Sept;27(9):1101-1109.
   c. 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. PMCID: PMC4984456.
   d. Earp, MA, Raghavan, R, Li Q, Dai, J, Winham, SJ, Cunningham, JM, Natanzon, N, Kalli, KR, Hou, X, Weroha, SJ, Haluska, P, Lawrenson, K, Gayther, SA, Wang, C, Goode, EL, **Fridley, BL.**

Characterization of Fusion Genes in Common and Rare Epithelial Ovarian Cancer Histologic Subtypes. (2017). *Oncotarget*, Jul 18;8(29). PMCID: PMC5564530.

2. **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 liver samples 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. 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. PMCID: PMC2562356
    b. 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. PMCID: PMC2963812
    c. **Fridley BL**, Ghosh TM, Wang A, Raghavan R, Dai J, Goode EL, Lamba JK. Genome-Wide Study of Response to Platinum, Taxane, and Combination Therapy in Ovarian Cancer: In vitro Phenotypes, Inherited Variation, and Disease Recurrence. *Front Genet*. 2016;7:37. PMCID: PMC4801852
    d. Meier R, Bi C, Gaedigk R, Heruth DP, Ye SQ, Leeder JS, **Fridley BL**. Ontogeny-related pharmacogene changes in the pediatric liver transcriptome. Pharmacogenet Genomics. 2018;28(3):86-94. PMCID: PMC5805126.

3. **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. 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. 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. PMCID: PMC3167019
    d. Raghavan R, Hyter S, Pathak HB, Godwin AK, Konecny G, Wang C, Goode EL, **Fridley BL**. Drug discovery using clinical outcome-based Connectivity Mapping: application to ovarian cancer. *BMC Genomics*. 2016;17(1):811. PMCID: PMC5069875.

4. **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. Li Q, Noel-MacDonnell JR, Koestler DC, Goode EL, **Fridley BL**. Subject level clustering using a negative binomial model for small transcriptomic studies. *BMC Bioinformatics*. 2018;19(1):474. doi: 10.1186/s12859-018-2556-9. PMCID: PMC6292049.

b. Noel-MacDonnell JR, Usset J, Goode EL, **Fridley BL**. Assessment of data transformations for model-based clustering of RNA-Seq data. *PLoS One*. 2018;13(2):e0191758. doi: 10.1371/journal.pone.0191758. PMCID: PMC5828440.
c. Chalise P, **Fridley BL**. Integrative clustering of multi-level 'omic data based on non-negative matrix factorization algorithm. *PLoS One*. 2017;12(5):e0176278. doi: 10.1371/journal.pone.0176278. PMCID: PMC5411077.
d. Raghavan R, Hyter S, Pathak HB, Godwin AK, Konecny G, Wang C, Goode EL, **Fridley BL.** Drug discovery using clinical outcome-based Connectivity Mapping: application to ovarian cancer. *BMC Genomics*. 2016;17(1):811. doi: 10.1186/s12864-016-3149-5. PMCID: PMC5069875.

Complete List of Published Work: https://www.ncbi.nlm.nih.gov/myncbi/collections/bibliography/41285880/

D. Additional Information: Research Support and/or Scholastic Performance
Ongoing Research Support

2P30 CA076292 (Sellers, T) 02/01/2017-01/31/2022
Moffitt Cancer Center Support Grant
The major goal is to provide leadership for the cancer center, which includes cell biology, immunology, clinical investigations and cancer control.
Role: Co-Investigator

U54 HD090258 (Leeder, S) 02/17/2017-01/31/2022
NIH/NICHD
Genomic- and Ontogeny-Linked Dose Individualization and cLinical Optimization for Kids (GOLDILOKs)
Goal: To increase the body of knowledge related to drug response in children by engaging a broad base of a multi-disciplinary clinical and translational scientists.
Roles: Director, Biostatistics Resource; Lead, Pilot Project

Reed (PI) 07/01/2016–06/30/2021
Pediatric Cancer Foundation
The Sunshine Project
The major goal of this research is to implement a novel collaborative approach that will accelerate the development of new drugs and therapies leading to the prevention and cure of pediatric cancers.
Role: Co-Investigator

U54 CA193489 (MPIs Gatenby, Gillies, Anderson) 09/23/2015-08/31/2020
NIH/NCI
Cancer as a Complex Adaptive System
Goals: The goal for Project 1 is identification of novel therapeutic strategies that can exploit evolutionary dynamics and molecular mechanism to improve clinical therapy. The goal for Project 2 includes development of methods to extract maximum amounts of information from clinically available data and development of computational models to optimize clinical therapy using often sparse dynamic data. Both projects will interact extensively with a core focused on developing computational models and applying sophisticated analytic methods to extract maximum knowledge from available molecular, pathological, and radiological clinical data.
Role: Co-Investigator

Miles for Moffitt (Vadaparampil) 06/01/2018-06/01/2019
Moffitt Cancer Center
Ovarian Cancer: Developing and Implementing Referral and Expanding Cascade Testing Systems (OC DIRECTS)
The goal of this study is to 1) Identify multilevel implementation barriers to GC/GT for ovarian cancer patients and cascade testing for at-risk relatives, 2) To assess concordance between provider self-reported and medical record verified referral and uptake of GC/GT for ovarian cancer patients, 3) Use data from Aims 1 and 2 to develop a functional prototype of a multilevel health information technology intervention to increase use of GC/GT for ovarian cancer patients and promote cascade testing.

Completed Research Support

1 P30 CA168524-01 (Jensen, R) 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, DE) 05/01/2012-04/30/2014
NIH/NIGMS 05/15/2014-04/30/2019
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

<NONE> (Hagan,C) 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

RSG-14-067-01-TBE (Chien, JR) 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

U19/U01 GM61388 (Weinshilboum, R) 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, BL) 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, JR) 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

Frederick Locke, MD

BIOGRAPHICAL SKETCH
DO NOT EXCEED FIVE PAGES.

NAME: Frederick L. Locke, M.D.

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

POSITION TITLE: Associate Member and Vice Chair, Department of Blood & Marrow Transplant and Cellular Immunotherapy, and Co-Leader, Immunology Program Moffitt Cancer Center

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Michigan State University, East Lansing	BS	05/1998	Physiology
Wayne State University, Detroit MI	MD	06/2002	Medicine
Detroit Medical Center/Wayne State University	ABIM	06/2005	Internal Medicine
University of Chicago	ABIM/Onc	06/2009	Hematology/Oncology
University of Chicago	Postdoctoral	07/2010	Immunology

A. Personal Statement

As a member of the Moffitt Cancer Center Department of Blood and Marrow Transplant and Cellular Immunotherapy (BMT CI), my focus is on the development of strategies to promote T cell responses against tumor associated antigens (TAA) for patients with multiple myeloma or lymphoma. I have significant experience as a principal investigator (PI) running cellular immunotherapy clinical trials. I am the Worldwide Co-Lead PI for the ZUMA-1 trial, the first multicenter trial evaluating CD19 CAR T cell therapy for adult aggressive lymphomas. I am also a national lead investigator for several other multi-center phase I/II studies treating aggressive lymphoma patients with anti-CD19 CAR T-cells.

My translational efforts are supported by an NCI K23 award aimed at evaluating T cell responses against TAAs in myeloma patients. I reported that a full length survivin vaccine is able to induce survivin specific T cell IFN-γ responses in vitro in myeloma patients, even when the survivin specific T cell precursor frequency is very low. These efforts justified a trial treating myeloma patients using a novel schedule for this survivin vaccine in conjunction with autologous transplant which recently completed the first stage of accrual. Ongoing laboratory efforts are aimed at categorizing neoantigen specific T cell responses in myeloma, while newer aims are investigating correlatives of response and toxicity in CAR T cell patients' samples.

My leadership roles within Moffitt are aligned to my effort of translational investigations of cellular immunotherapies. I am the Vice Chair of the BMT CI Department, Chair of the Moffitt Cellular Therapy Advisory Committee and the Chair of the Moffitt Immunotherapy Working Group. I was recently named the Co-Leader of the Moffitt Cancer Center Immunology Program, a key program which is part of the NCI Comprehensive Cancer Center Support Grant. As the Research Director and Clinical Director for Moffitt's Immune Cell Therapy (ICE-T) program, I lead a cross departmental effort providing specialized care of high risk immunotherapy and cellular therapy patients, regardless of tumor type. The ICE-T program utilizes the resources of the BMT-CI Department to deliver these therapies and the program was recognized when I received an NCI Cancer Clinical Investigator Team Leadership Award.

Locke FL, Anasetti C. Transplanters drive CARs to the clinic by brewing ICE-T: the Moffitt roadmap. *J Immunotherapy Cancer*. 2017 Jul 18;5:59.doi: 10.1186/s40425-017-0265-y. eCollection 2017 PMID: 28725432. PMCID: MC5514522

B. Positions and Honors

Positions

2009-2010 Clinical Associate, The University of Chicago Medical Center, Chicago, IL

2010-2017 Assistant Member, Department of Blood and Marrow Transplantation, Moffitt Cancer Center, Tampa, FL
2010-2017 Assistant Professor of Oncologic Sciences, University of South Florida, Tampa, FL
6/2017-present Vice Chair, Department of Blood & Marrow Transplant and Cellular Immunotherapy, Moffitt Cancer Center, Tampa, FL
7/2017-present Associate Member, Department of Blood & Marrow Transplant and Cellular Immunotherapy, Moffitt Cancer Center, Tampa, FL
7/2017-present Associate Professor of Oncologic Sciences, University of South Florida, Tampa, FL
2/2018-present Co-Leader, Immunology Program, Moffitt Cancer Center, Tampa, FL

Selected Honors & Awards

05/1998 Michigan State University Academic Athlete gold medal award winner
1997 Phi Kappa Phi National Honor Society & Golden Key National Honor Society
04/2004 First Place Original Research, Wayne State, 11th Annual Resident and Fellow Research Day
08/2008 National Institute of Health, T32 Ruth L. Kirschstein National Research Service Award Trainee
04/2009 Cancer Education Consortium Award for Molecular and Translational Research
06/2010 American Society of Clinical Oncology Foundation – Young Investigator Award
07/2011 American Society of Hematology, Clinical Research Training Institute
04/2012 American Cancer Society – Internal Research Grant Award
05/2015 Miles for Moffitt Scientist Award
09/2015 National Cancer Institute, K23 Mentored Patient-Oriented Research Career Development Award
03/2016 National Cancer Institute, Cancer Clinical Investigator Team Leadership Award
05/2017 Back to Back, Clinical Trial Plenary Oral Abstracts. AACR Annual Meeting, Washington DC
01/2018 ZUMA-1 trial abstract (first author) cited in ASCO report: Clinical Cancer Advance of 2018
02/2018 Moffitt Cancer Center, Distinguished Scholar
03/2018 Pinellas County Partners, Doctor Award
05/2018 Molecular Therapy, Best Manuscripts of 2017 selection (first author)
05/2018 Oncology Times, 2018 Excellence in Oncology Award
06/2018 ASCO 2018 Annual Meeting, Best of ASCO Abstract selection (first author)

C. Contributions to Science

1.Relapsed and refractory acute myeloid leukemia and myelodysplatic syndrome patients have poor outcomes. Because of the cumulative effects of chemotherapy and poor predicted outcomes, these patients are often not considered for allogeneic hematopoietic stem cell transplant (allo-HCT), which is the only potentially curative therapy. I demonstrated by retrospective review that chemotherapy with clofarabine immediately followed by initiation of reduced toxicity conditioning and allo-HCT at the cell nadir was feasible and could lead to prolonged disease free survival. This data prompted support for an investigator initiated clinical trial that again demonstrated this approach leads to acceptable OS for this extremely high risk population that would not otherwise be eligible for allo-HCT. For high risk patients this strategy continues to be used and studied at various transplant centers around the world. More recently, I analyzed stored samples from a trial that randomized allo-HCT patients to anti-CD25 monoclonal antibody or placebo as prophylaxis for acute GVHD. We showed that anti-CD25 decreased Tregs, and decreased relapse in MDS/AML patients, after transplant. This strategy warrants further study.

a. **Locke FL**, Artz A, Rich E, Zhang Y, van Besien K, Stock W. Feasibility of clofarabine cytoreduction before allogeneic transplant conditioning for refractory AML. *Bone Marrow Transplant*. 2010;45(12):1692-8. Epub 2010/03/09. doi: 10.1038/bmt.2010.32. PubMed PMID: 20208570.

b. **Locke F**, Agarwal R, Kunnavakkam R, van Besien K, Larson RA, Odenike O, et al. A novel clofarabine bridge strategy facilitates allogeneic transplantation in patients with relapsed/refractory leukemia and high-risk myelodysplastic syndromes. *Bone Marrow Transplant*. 2013;48(11):1437-43. PMCID: PMC4279870.

c. **Locke FL***, Pidala J*, Storer B, Martin PJ, Pulsipher MA, Chauncey TR, Jacobsen N, Kroger N, Walker I, Light S, Shaw BE, Beato F, Laport GG, Nademanee A, Keating A, Socie G, Anasetti C. CD25 Blockade Delays Regulatory T Cell Reconstitution and Does Not Prevent Graft-versus-Host Disease

After Allogeneic Hematopoietic Cell Transplantation. *Biol Blood Marrow Transplant.* 2017;23(3):405-11. Epub 2016/12/23. doi: 10.1016/j.bbmt.2016.12.624. PMID: 28007665. ***These Authors contributed equally.**

2. During my fellowship and post-doctoral study under Dr. Thomas Gajewski at the University of Chicago, my primary project was to delineate the importance of PTEN in peripheral T cells. PTEN is a phosphatase that plays a key role in the regulation of cellular survival and proliferation via negative regulation of the PI3K/Akt axis. The PI3 pathway is critical for cell growth, survival, and motility signaling in numerous cell types. PTEN is a negative regulator of TCR activation, making PTEN inhibition an attractive target for anti-cancer T cell-based immunotherapy. However, PTEN loss during thymic development can lead to lymphomagenesis. To determine the effects of PTEN absence on post-thymic, peripheral T cells, I utilized a novel method for deletion of genes directly in murine peripheral T cells. I showed that PTEN-deleted T cells exhibited enhanced IL-2 production, proliferation, and Akt phosphorylation upon TCR/CD28 engagement and that PTEN deleted CD8+ T cells exhibit increased anti-tumor cytotoxicity.

a. Driessens G, Zheng Y, **Locke F**, Cannon JL, Gounari F, Gajewski TF. Beta-catenin inhibits T cell activation by selective interference with linker for activation of T cells-phospholipase C-gamma1 phosphorylation. *J Immunol*. 2011;186(2):784-90. Epub 2010/12/15. doi: 10.4049/jimmunol.1001562. PubMed PMC4888792.

b. Zheng Y, Zha Y, Driessens G, **Locke F**, Gajewski TF. Transcriptional regulator early growth response gene 2 (Egr2) is required for T cell anergy in vitro and in vivo. *J Exp Med*. 2012;209(12):2157-63. PMCID: PMC3501351.

c. **Locke FL**, Zha YY, Zheng Y, Driessens G, Gajewski TF. Conditional deletion of PTEN in peripheral T cells augments TCR-mediated activation but does not abrogate CD28 dependency or prevent anergy induction. *J Immunol*. 2013;191(4):1677-85. PMCID: PMC3759681.

d. Evaristo C, Spranger S, Barnes SE, Miller ML, Molinero LL, **Locke FL**, Gajewski TF, Alegre ML. Cutting Edge: Engineering Active IKKbeta in T Cells Drives Tumor Rejection. *J Immunol*. 2016. PMCID: PMC4799771.

3. Despite the advent of novel therapies that prolong survival for patients with multiple myeloma, this disease remains incurable. These drugs work in part by modulating the immune system and I am working to develop cellular immunotherapeutic strategies against myeloma. Translational laboratory work I conducted at Moffitt revealed that there are fewer CD4 cells reactive against survivin in myeloma patients compared to healthy donors. Patients with lower survivin CD4 precursor frequency have higher survivin expression in their myeloma cells. A Moffitt created, full length survivin vaccine is able to induce survivin specific T cell IFN-gamma responses in vitro in myeloma patients, even when the survivin specific T cell precursor frequency is very low. I obtained an FDA IND to test this survivin vaccine in myeloma patients, and the survivin vaccine trial is ongoing (NCT02851056) using a novel vaccine schedule in conjunction with autologous transplant that I previously showed induces robust humoral and antibody responses against a pneumococcal vaccine.

a. **Locke FL**, Nishihori T, Alsina M, Kharfan-Dabaja MA. Immunotherapy strategies for multiple myeloma: the present and the future. *Immunotherapy*. 2013;5(9):1005-20. PMCID: PMC4905571.

b. **Locke FL**, Menges M, Veerapathran A, Coppola D, Gabrilovich D, Anasetti C. Survivin-specific CD4+ T cells are decreased in patients with survivin-positive myeloma. *Journal for Immunotherapy of Cancer*. 2015;3:20. PMCID: PMC4437443.

c. **Locke FL**, Menges M, Nishihori T, Nwoga N, Alsina M, Anasetti C. Boosting humoral and cellular immunity to pneumococcus by vaccination before and just after autologous transplant for myeloma. *Bone Marrow Transplant*. 2016; 51:291-294 PMID: 26457911

d. Gatenbee C, Folguera-Blasco N, Daneils C, Gallaher J, Rockne R, Adams C, Nicholson M, Maniati E, Kennedy J, Luddy K, **Locke FL**, Robertson-Tessi M. Exploiting Homeostatic Repopulation to Increase DC Vaccine Efficacy in Multiple Myeloma. Epub 2016/04/22. bioRxiv doi: 10.1101/049072.

4. Chimeric Antigen Receptor (CAR) T cell therapy directed at CD19 on the surface of B cell malignancies was developed over several decades at multiple institutions and subsequently licensed for clinical development. Through close collaboration with Kite Pharma, I was the first investigator to initiate, enroll, and treat a patient onto each of their first 3 clinical trials testing axicabtagene ciloleucel (axi-cel, formerly KTE-C19) against aggressive lymphomas. I am a Co-Lead investigator on the pivotal ZUMA-1 trial testing KTE-C19 in chemo-refractory Diffuse Large B cell Lymphoma. At the American Association for Cancer Research (AACR) annual meeting in 2017 I presented, for the first time, the pivotal phase II primary analysis results and the biomarker correlatives as back to back oral abstract presentations during the clinical trials plenary session, data which was critical to the FDA approval in October of 2017. These results have since been published in the New England Journal of Medicine, as a Co-First author, with longer follow-up published in The Lancet Oncology as first author. After FDA approval, our CAR T program, under my leadership, was the first in the world to treat a patient with commercial axicabtagene ciloleucel (Yescarta). More recently I spearheaded the creation of a 17 center consortium that is investigating real world outcomes of CAR T cells for lymphoma. We reported at the 2018 ASH annual meeting that outcomes with standard of care axi-cel are similar to those on the ZUMA-1 trial.

a. **Locke FL,*** Neelapu SS*, Bartlett NL, Siddiqi T, Chavez JC, Hosing CM, Ghobadi A, Budde LE, Bot A, Rossi JM, Jiang Y, Xue AX, Elias M, Aycock J, Wiezorek J, Go WY. Phase 1 Results of ZUMA-1: A Multicenter Study of KTE-C19 Anti-CD19 CAR T Cell Therapy in Refractory Aggressive Lymphoma. *Molecular Therapy*. 2017;25(1):285-95 PMCID: PMC5363293. ***These Authors contributed equally.**

b. Neelapu SS*, **Locke FL***, Bartlett NL, Lekakis LJ, Miklos DB, Jacobson CA, Braunschweig I, Oluwole OO, Siddiqi T, Lin Y, Timmerman JM, Stiff PJ, Friedberg JW, Flinn IW, Goy A, Hill BT, Smith MR, Deol A, Farooq U, McSweeney P, Munoz J, Avivi I, Castro JE, Westin JR, Chavez JC, Ghobadi A, Komanduri KV, Levy R, Jacobsen ED, Witzig TE, Reagan P, Bot A, Rossi J, Navale L, Jiang Y, Aycock J, Elias M, Chang D, Wiezorek J, Go WY. *N Engl J Med*. 2017 Dec 10. doi: 10.1056/NEJMoa1707447. [Epub ahead of print] PMID: 29226797 ***These Authors contributed equally.**

c. **Locke FL**, Ghobadi A, Jacobson CA, Miklos DB, Lekakis LJ, Oluwole OO, Lin Y, Braunschweig I, Hill BT,Timmerman JM, Deol A, Reagan PM, Stiff P, Flinn IW, Farooq U, Goy A, McSweeney PA, Munoz J, Siddiqi T, Chavez JC, Herrera AF, Bartlett NL, Wiezorek JS, Navale L, Xue A, Jiang Y, Bot A, Rossi JM, Kim JJ, Go WY, Neelapu SS. Long-term safety and activity of axicabtagene ciloleucel in refractory large B-cell lymphoma (ZUMA-1): a single-arm, multicentre, phase 1-2 trial. *Lancet Oncol*. 2018 Nov 30. pii: S1470-2045(18)30864-7. doi: 10.1016/S1470-2045(18)30864-7. [Epub ahead of print] PMID: 30518502

d. Nastoupil LJ, Jain, Spiegel JY, Ghobadi A, Lin Y, Dahiya S, Lunning MA, Lekakis LJ, Reagan PM, Oluwole OO, McGuirk JP, Deol A, Sehgal AR, Goy A, Hill BT, Andreadis C, Munoz J, Westin JR, Chavez JC, Cashen AF, Bennani NN, Rapoport AP, Vose JM, Miklos DB*, Neelapu SS*, **Locke FL***. (2018). Axicabtagene Ciloleucel (Axi-cel) CD19 Chimeric Antigen Receptor (CAR) T-Cell Therapy for Relapsed/Refractory Large B-Cell Lymphoma: Real World Experience. Blood, 132(Suppl 1), Oral Abstract 91. 2018 ASH Annual Meeting, San Diego, CA.https://doi.org/10.1182/blood-2018-99-114152. *Equal Contribution

5. CAR T cell therapy and other immune effector cell therapies may cause Cytokine Release Syndrome (CRS) and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), unique toxicities that require significant expertise for recognition and treatment. During the pivotal ZUMA-1 trial we recognized that earlier intervention with the anti-IL-6R blocking antibody tocilizumab and corticosteroids led to lower rates of severe CRS and ICANS and importantly did not prevent complete and durable responses. This led us to conduct a multi-center prophylactic tocilizumab safety expansion arm of ZUMA-1. I have participated in the creation of multi-center expert guidelines for the management of CRS and ICANS, including Co-chairing the NCCN practice guidelines for the management of CAR T cell Related Toxicities. Initially several different CRS and ICANS grading criteria existed and different pivotal CD19 CAR T cell trials utilized different criteria. In order to harmonize grading across trials I participated in patient level re-grading of CRS and ICANS for the pivotal trial of tisagenlecleucel in adult lymphoma, the JULIET trial. Most recently I served on the American Society for Blood and Marrow Transplant expert panel that aligned all toxicity grading.

a. **Locke FL**, Neelapu SS, Bartlett NL, Lekakis LJ, Jacobson CA, Braunschweig I, Oluwole OO, Siddiqi T, Lin Y, Timmerman JM, Reagan PM, Bot A, Rossi JM, Sherman M, Navale L, Jiang Y, Aycock JS, Elias

M, Wiezorek JS, Go WY, Miklos DB. Preliminary results of prophylactic tocilizumab after axicabtageneciloleucel (axi-cel; KTE-C19) treatment for patients with refractory, aggressive non-hodgkin lymphoma (NHL). American Society of Hematology 2017: 2017/12/09 Abstract 1547

b. NCCN Guidelines Version 1.2019: Management of Immunotherapy – Related Toxicities; CAR T cell Related Toxicites.; Chair: **Frederick Locke**, Co-Chair: Phillipe Armand. https://www.nccn.org/professionals/physician_gls/pdf/immunotherapy.pdf

c. Maziarz RT, Schuster SJ, Romanov VV, Rusch ES, Signorovitch J, Ericson SG, Maloney DG, **Locke FL**. Grading of Neurotoxicity in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (r/r DLBCL) Receiving Tisagenlecleucel Treatment in the JULIET Study. 60th ASH Annual Meeting Abstract Presentation. Abstract 4183 , 2018 ASH Annual Meeting. San Diego, CA.

d. Lee DW, Santomasso BD, **Locke FL**, Ghobadi A, Turtle CJ, Brudno JN, Maus MV, Park JH, Mead E, Pavletic S, Go WY, Eldjerou L, Gardner RA, Frey N, Curran KJ, Peggs K, Pasquini M, DiPersio JF, van den Brink MRM, Komanduri KV, Grupp SA, Neelapu SS. ASBMT Consensus Grading for Cytokine Release Syndrome and Neurological Toxicity Associated with Immune Effector Cells. Biol Blood Marrow Transplant. 2018 Dec 25. S1083-8791(18)31691-4. doi: 10.1016/j.bbmt.2018.12.758. [Epub ahead of print] Review. PMID: 30592986

Complete List of Published Work in MyBibliography (57 peer reviewed articles):

http://www.ncbi.nlm.nih.gov/sites/myncbi/1j5HMD4yxeg5t/bibliograpahy/48398907/public/?sort=date&direction=ascending

D. Research Support and/or Scholastic Performance

Ongoing

NIH/NCI K23-CA201594 (Locke) 09/01/2015 to 08/31/2020
Mentor: Jose Conejo-Garcia, Claudio Anasetti
Breaking immune tolerance to surviving in Multiple Myeloma
Specific Aims: 1) Determine whether survivin specific immune responses are induced in MM patients by a novel dendritic cell-based survivin vaccine; and, 2) Optimize methods for expansion of MM patients' TAA specific T cells suitable for adoptive transfer, with a focus on ex vivo application of inhibitors of phosphatase and tensin homolog (PTEN) protein to promote T cell anti-tumor immunity.

NIH/NCI 1U54CA193489-01A1 (Gatenby) 09/23/2015 – 08/31/2020
Co-Investigator: Frederick Locke, % effort: 1%
Title: Cancer as a Complex Adaptive System

Completed within last 3 years

P30 CA076292-18S4 (Sellers) 02/18/1998 - 01/31/2018
NIH/NCI Moffitt Cancer Center Support
CCSG Supplement (Locke-Supp PI) 03/01/2016 to 02/28/2018 (Support returned)
NIH/NCI/CCITLA
Designing, implementing, and leading an Immune and Cell Therapy (ICE-T) Program
The primary goal is to centralize and facilitate clinical care, trial coordination, data support, and regulatory processes for cellular therapy trials at Moffitt Cancer Center.

Brian D. Gonzalez, PhD

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: Brian D. Gonzalez

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

POSITION TITLE: Assistant Member

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 Miami, Coral Gables, FL	B.A.	12/2005	Psychology
University of South Florida, Tampa, FL	M.A.	05/2010	Clinical Psychology
University of South Florida, Tampa, FL	Ph.D.	08/2013	Clinical Psychology
Moffitt Cancer Center, Tampa, FL	Postdoctoral Fellow	05/2015	Behavioral Oncology

A. Personal Statement

I am Assistant Member, tenure-track, at Moffitt Cancer Center, where my research focuses on improving the quality of life of cancer survivors. I study quality of life issues, focusing on identifying risk factors for worse patient-reported outcomes and developing interventions for these outcomes among cancer survivors. As a licensed clinical psychologist with extensive experience examining and intervening upon patient-reported outcomes among cancer survivors, I am highly qualified to serve as PI for the proposed project. I have worked on several federally-funded projects, including several projects examining risk factors for patient-reported outcomes among prostate cancer survivors and minority cancer survivors. I have also worked on several projects to develop behavioral interventions cancer populations. For example, I am PI of an NCI-funded K01 project to identify risk factors for sleep disturbance in African American breast cancer survivors. This mixed-methods project culminates in the development and testing, via a randomized controlled trial, of a personalized mHealth intervention to reduce sleep disturbance in this minority population. I have also collaborated on other randomized controlled trials, such as a behavioral intervention to reduce stress among Latina cancer survivors. I am also PI of a project to develop an mHealth behavioral intervention targeted to hematopoietic stem cell transplant survivors. From various NCI-funded projects, I have a great deal of experience recruiting diverse cancer survivors to participate in studies and in implementing collection of patient-reported outcome data. I have personally led the analysis and interpretation of data from numerous such studies, resulting in several prostate cancer-related publications in high-impact journals:

a. **Gonzalez, BD**, Jim, HS, Booth-Jones, M, Small, BJ, Sutton, SK, Lin, HY, Park, JY, Spiess, PE, Fishman, MN, & Jacobsen, PB. Course and predictors of cognitive function in patients with prostate cancer receiving androgen-deprivation therapy: A controlled comparison. *Journal of Clinical Oncology*. 2015; 33(18):2021-2027. PMID: 25964245. PMCID: PMC4461804

b. **Gonzalez, BD**, Small, BJ, Cases, MG, Williams, N, Fishman, MN, Jacobsen, PB, & Jim, HSL. Sleep Disturbance in Men Receiving Androgen Deprivation Therapy for Prostate Cancer: The Role of Hot Flashes and Nocturia. *Cancer*. 2018; 124(3):499-506. PMID: 29072790. PMCID: PMC5780192

c. **Gonzalez, BD**, Jim, HS, Small, BJ, Sutton, SK, Fishman, MN, Zachariah, B, Heysek, RV, & Jacobsen, PB. Changes in physical functioning and muscle strength in men receiving androgen deprivation therapy for prostate cancer: A controlled comparison. *Supportive Care in Cancer*. 2015; 24(5):2201-2207. PMID: 26563183. PMCID: PMC4805468

d. Hoogland AI, Lechner SC, **Gonzalez BD**, Small BJ, Tyson DM, Asvat Y, Barata A, Gomez MF, Rodriguez Y, Jim HSL, Antoni MH, Jacobsen PB, Meade CD. Efficacy of a Spanish-Language Self-Administered Stress Management Training intervention for Latinas undergoing chemotherapy. *Psychooncology*. 2018; 27(4): 1305-1311. PMID: 29462503. PMCID: PMC5895519

B. Positions and Honors

Employment

2013 - 2015 R25T-funded Postdoctoral Fellow, Moffitt Cancer Center, Health Outcomes and Behavior Program, Tampa, FL

2015 - 2016 Assistant Professor of Medicine (tenure-track), Rutgers Cancer Institute of New Jersey, Population Science, New Brunswick, NJ

2016 - Assistant Member (tenure-track), Moffitt Cancer Center, Health Outcomes and Behavior Program, Tampa, FL

Honors

2007 - 2013 University of South Florida Student Government Conference Travel Award
2007 - 2013 University of South Florida Clinical Psychology Conference Travel Award
2014 Minority Initiative Travel Scholarship, American Psychosomatic Society
2014 Merit-Based Travel Award, Sleep Research Society
2015 Scholar, Young Investigator Colloquium, American Psychosomatic Society
2015 Scholar, Young Investigators Research Forum, American Academy of Sleep Medicine
2017 Scholar, Behavioral Sleep Medicine PRIDE Program (NHLBI-funded), Awarded by NYU Center for Healthful Behavior Change
2018 Scholar, American Association for Cancer Research Integrative Molecular Epidemiology Workshop

Professional Societies

2008 - Member, Society of Behavioral Medicine
2011 - 2012 Chair, Student Special Interest Group, Society of Behavioral Medicine
2013 - Member, American Psychosomatic Society
2013 - Member, Sleep Research Society
2013 - 2014 Program Committee Member, Society of Behavioral Medicine
2016 - Member, Trainee Education Advisory Committee, Sleep Research Society
2016 - 2018 Chair, Sleep Special Interest Group, Society of Behavioral Medicine
2018 - Chair, Special Interest Group Council, Society of Behavioral Medicine
2018 - Member, Board of Directors, Society of Behavioral Medicine

Professional Activities

2012 - Peer reviewer, *Journal of Clinical Oncology*, *Psychosomatic Medicine*, *Supportive Care in Cancer*, *Psycho-Oncology*, *BJU International*, *Journal of Cancer Survivorship*, *Annals of Depression and Anxiety*, *OncoTargets and Therapy*, *JAMA Oncology*,
2014 - 2017 *Ad hoc* grant application reviewer, *Agency for Healthcare Research and Quality*

C. Contributions to Science

1. I have focused on developing new theoretical models to better understand **risk of worse patient-reported outcomes among prostate cancer survivors**.

   a. **Gonzalez, BD**, Small, BJ, Cases, MG, Williams, N, Fishman, MN, Jacobsen, PB, & Jim, HSL. Sleep Disturbance in Men Receiving Androgen Deprivation Therapy for Prostate Cancer: The Role of Hot Flashes and Nocturia. *Cancer*. 2018; 124(3):499-506. PMID: 29072790. PMCID: PMC5780192

   b. **Gonzalez, BD**, Jim, HS, Booth-Jones, M, Small, BJ, Sutton, SK, Lin, HY, Park, JY, Spiess, PE, Fishman, MN, & Jacobsen, PB. Course and predictors of cognitive function in patients with prostate cancer receiving androgen-deprivation therapy: A controlled comparison. *Journal of Clinical Oncology*. 2015; 33(18):2021-2027. PMID: 25964245. PMCID: PMC4461804

   c. **Gonzalez, BD**, Jim, HS, Small, BJ, Sutton, SK, Fishman, MN, Zachariah, B, Heysek, RV, & Jacobsen, PB. Changes in physical functioning and muscle strength in men receiving androgen deprivation therapy for prostate cancer: A controlled comparison. *Supportive Care in Cancer*. 2015; 24(5):2201-2207. PMID: 26563183. PMCID: PMC4805468

d. **Gonzalez, BD**, Jim, HS, Donovan, KA, Small, BJ, Sutton, SK, Park, J, Lin, HY, Spiess, PE, Fishman, MN, Jacobsen, PB. Course and moderators of hot flash interference during androgen deprivation therapy for prostate cancer: A matched comparison. Journal of Urology. 2015; 194(3):690-695. PMID: 25791402. PMCID: PMC4546512

2. I have also focused on examining **risk factors for sleep disturbance in diverse cancer survivor populations**.

   a. **Gonzalez BD**, Small BJ, Cases MG, Williams NL, Fishman MN, Jacobsen PB, Jim HSL. Sleep disturbance in men receiving androgen deprivation therapy for prostate cancer: The role of hot flashes and nocturia. *Cancer*. 2018; 124(3):499-506. PMID: 29072790. PMCID: PMC5780192

   b. **Gonzalez BD**, Lu Q. Sleep disturbance among Chinese breast cancer survivors living in the USA. Support Care Cancer. 2018; 26(6):1695-1698. PMID: 29484499. PMCID: PMC5924438

   c. Garland SN, Zhou ES, **Gonzalez BD**, Rodriguez N. The quest for mindful sleep: A critical synthesis of the impact of mindfulness-based interventions for insomnia. *Current Sleep Medicine Reports*. 2016; 2(3):142-151. PMCID: PMC5300077

   d. Jim HS, Evans B, Jeong JM, **Gonzalez BD**, Johnston L, Nelson AM, Kesler S, Phillips KM, Barata A, Pidala J, Palesh O. Sleep disruption in hematopoietic cell transplantation recipients: prevalence, severity, and clinical management. *Biology of Blood and Marrow Transplantation*. 2014; 20(10):1465-84. PMCID: PMC4163090

3. I have also conducted extensive research on **predicting depression, pain, cognitive function, and other quality of life issues** among numerous cancer survivor populations.

   a. Donovan, KA, **Gonzalez, BD**, Small, BJ, Andrykowski, MA, Jacobsen, PB. Depressive symptom trajectories during and after adjuvant treatment for breast cancer. *Annals of Behavioral Medicine*. 2014; 47(3):292-302. PMID: 24158626. PMCID: PMC4313122

   b. **Gonzalez, BD**, Jacobsen, PB. Depression in lung cancer patients: The role of perceived stigma. *Psycho-Oncology*. 2012; 21(3):239-246. PMID: 25753772. PMID: 22383265

   c. **Gonzalez, BD**, Jim, HS, Cessna, JM, Small, BJ, Sutton, SK, Jacobsen PB. Concealment of lung cancer diagnosis: Prevalence and correlates. *Psycho-Oncology*. 2015; 24(12):1774-1783. PMCID: PMC4564357

   d. Philips, KM, McGinty, HL, **Gonzalez, BD**, Jim, HS, Small, BJ, Minton, S, Andrykowski, MA, & Jacobsen, PB. Factors associated with breast cancer worry 3 years after completion of adjuvant treatment. *Psycho-Oncology*. 2013; 22(4): 936-939. PMCID: PMC3392435

4. I have also used **sophisticated statistical analyses to examine biomarkers as predictors of the impact of cancer and treatment for cancer on quality of life issues**. This work has demonstrated the impact that treatment for cancer can have on cognitive function, hot flashes, pain, physical functioning, and quality of life as well as the significant moderating effects that biomarkers can have.

   a. **Gonzalez, BD**, Jim, HS, Booth-Jones, M, Small, BJ, Sutton, SK, Lin, HY, Park, JY, Spiess, PE, Fishman, MN, & Jacobsen, PB. Course and predictors of cognitive function in patients with prostate cancer receiving androgen-deprivation therapy: A controlled comparison. *Journal of Clinical Oncology*. 2015; 33(18):2021-2027. PMCID: PMC4461804

   b. **Gonzalez, BD**, Jim, HS, Donovan, KA, Small, BJ, Sutton, SK, Park, J, Lin, HY, Spiess, PE, Fishman, MN, Jacobsen, PB. Course and moderators of hot flash interference during androgen deprivation therapy for prostate cancer: A matched comparison. *Journal of Urology*. 2015; 194(3):690-695. PMCID: PMC4546512

   c. Rausch, SM, **Gonzalez, BD**, Clark, MM, Patten, C, Felten, S, Liu, H, Li, Y, Sloan, J, Yang, P. SNPs in PTGS2 and LTA predict pain and quality of life in long term lung cancer survivors. *Lung Cancer*. 2012; 77(1):217-230. PMCID: PMC4314090

   d. **Gonzalez, B.D.**, Jim, H.S.L., Small, B.J., Sutton, S.K., Fishman, M.N., Zachariah, B., Heysek, R.V., & Jacobsen, P.B. (2016). Physical Functioning and Muscle Strength in Men Receiving Androgen Deprivation Therapy for Prostate Cancer: A Controlled Comparison. *Supportive Care in Cancer*.

24:2201-2207. PMCID: PMC4805468

Complete List of Published Work in My Bibliography: https://bit.ly/2D532A3

D. Research Support

Ongoing Research Support

K01CA211789, National Cancer Institute Gonzalez (PI) 09/15/2016 – 08/31/2021
Developing a Culturally Targeted mHealth Intervention for Cancer-Related Sleep Disturbance in African American Breast Cancer Survivors
Project Goals: To 1) identify predictors of cancer-related sleep disturbance, 2) opportunities for culturally targeting an intervention for sleep disturbance, 3) develop an optimized, culturally targeted, and tailored mHealth intervention for cancer-related sleep disturbance, and 4) evaluate this intervention for acceptability, feasibility, and preliminary efficacy among African American breast cancer survivors.

G-17-900, Gateway Foundation for Cancer Research Kim (PI) 12/01/2017 – 11/30/2021
Impact of Cytoreductive Radical Prostatectomy on Oncologic and Quality of Life Outcomes in Men with Newly Diagnosed Metastatic Prostate Cancer
Project Goals: To test the efficacy of cytoreductive radical prostatectomy for improving cancer outcomes and improving quality of life in men with newly-diagnosed metastatic prostate cancer.
Role: Co-Investigator

IRG-14-189-19, ACS-IRG Gonzalez (PI) 12/01/2017 – 11/30/2018
Testing an mHealth Stepped-Care Intervention for Sleep Disturbance in HCT Survivors
Project Goals: To test the acceptability, feasibility, and preliminary efficacy of an mHealth stepped care intervention to reduce sleep disturbance in survivors of hematopoietic stem cell transplant.

Department of Health Outcomes and Behavior Gonzalez (PI) 08/24/2018 – 06/30/2019
Developing and Testing Virtual Reality for Relaxation Training in HCT Survivors
Project Goals: To develop and test a virtual reality mHealth intervention to enhance relaxation training in survivors of hematopoietic stem cell transplant.

Completed Research Support (past three years only)

Department of Health Outcomes and Behavior Gonzalez (PI) 10/01/2017 – 06/30/2018
Developing an mHealth Stepped-Care Intervention for Sleep Disturbance in HCT Survivors
Project Goals: To develop an mHealth stepped-care behavioral intervention to reduce sleep disturbance in survivors of hematopoietic stem cell transplant.

R01CA18562-S1, National Cancer Institute Bandera (PI) 09/01/2015 – 09/14/2016
Obesity, Related Comorbidities, and Breast Cancer Outcomes in African Americans
Project Goals: To evaluate the impact of obesity and its markers on breast cancer treatment and outcomes
Role: Co-Investigator (Funded via competitive NCI research supplement)

Jhanelle Gray, MD

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: JHANELLE GRAY, MD

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

POSITION TITLE: Associate Member, H. Lee Moffitt Cancer Center; Associate Professor, University of South Florida

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 Florida	BS	06/1997	Chemistry
Cornell University Medical College	MD	05/2001	Medicine

A. PERSONAL STATEMENT:

For the past 11 years, I have served as the Principal Investigator (PI) of 8 investigator-initiated, lung cancer treatment trials (IITs) focused on novel agents and PI for several early phase/lung cancer clinical trials including targeted therapy, immunotherapy and chemotherapy. Currently I have 5 active IITs which have all been formulated from a team science approach and 3 additional IIT in development. By partnering with basic scientist at Moffitt and providing data and observationally driven clinical input, I have been able to successfully open and publish these. The incorporation of serial tumor biopsies and blood collections to assess the predictive value of novel biomarkers identified in our preclinical work has been an integral aspect of these works. I have secured peer-reviewed grant funding derived from these trials including a DOD grant and Florida Department of Health Grant (> $2.5 M in funding) where I serve as PI. In addition, I serve as the Faculty Leader for Thoracic Clinical Research in the Department of Thoracic Oncology at Moffitt for which I not only lead the weekly thoracic clinical research meetings, monitor trial accruals, and lead the restructuring and development of our clinical trial portfolio and assignments (currently includes 25 clinical trials with active patients and 15 planned clinical trials undergoing regulatory and contract review) but also collaborate with the Clinical Trials Office to monitor data collection, maintenance, and integrity. Since my involvement in this role, Moffitt's Department of Thoracic Oncology clinical trials accrual has tripled to >140 patients/year. I served on our therapeutic Scientific Review Committee for 9 years, of which I was chair for 5 years. As a seasoned clinical investigator in thoracic oncology who has proficiently applied team science collaborations to formulate, design and execute scientifically driven, rationale trial design with novel therapeutics, I have the level of expertise needed to serve as co-Leader of the Chemical Biology Molecular Medicine Program.

B. POSITIONS AND HONORS:

Postgraduate Training and Fellowship Appointments:

2001-2004	Medicine Internship & Residency, The New York Presbyterian Hospital-Cornell, New York, NY
2004-2007	Oncology Fellowship, Moffitt Cancer Center and Research Institute, Tampa, FL
2004-2007	Hematology Fellowship, Moffitt Cancer Center and Research Institute, Tampa, FL
2007-2013	Assistant Professor, Department of Oncologic Sciences, University of South Florida, Tampa, FL
2008-2013	Assistant Member, Moffitt Medical Group, Moffitt Cancer Center and Research Institute, Tampa, FL
2013-Present	Associate Professor, Department of Oncologic Sciences, University of South Florida, Tampa, FL
2013- Present	Associate Member, Moffitt Medical Group, Moffitt Cancer Center and Research Institute, Tampa, FL
2018-Present	Co-Leader, Chemical Biology & Molecular Medicine Program, MCC-CCSG grant.

Professional Membership

2004-Present	Member, American Society of Clinical Oncology.
2008-2009	Member, Florida Medical Association
2008-Present	Member, Southwest Oncology Group
2009-Present	Member, International Association for the Study of Lung Cancer
2013-Present	Member, American Association for Cancer Research
2016-Present	Member, Florida American Society of Clinical Oncology

C. CONTRIBUTIONS TO SCIENCE

1. My early publications directly addressed the fact that lung cancer prevention could not be readily applied to patients at high risk for lung cancer. These investigations hold key clinical relevance, as by preventing the development of lung cancer, we can thus reduce the high mortality rates. The trial with enzastaurin was the first chemoprevention trial conducted with a novel small molecule target agent and set the framework for future trials in this setting at as MCC. To highlight this was one of the quickest lung cancer chemoprevention trials published to meet accrual goals, and helps to demonstrate the work accomplished to establish our current infrastructure for lung cancer screening and prevention. Overall, publications in this area document the barriers to completing prevention trials and document the safety in administering such novel therapeutics in a high-risk but otherwise healthy population. By reviewing the evidence, this body of work serves as a reference for chemoprevention trials in the future. I served as the primary investigator or co-investigator in all of these studies.
   a. **Gray J**, Mao JT, Szabo E, Kelley M, Kurie J, and Bepler G. Lung cancer chemoprevention: ACCP evidence-based clinical practice guideline (2nd Edition). *Chest*. 2007 Sep;132(3suppl): 56S-68S. PMID: 17873160.
   b. Alexandrow MG, Song LJ, Altiok S, **Gray J**, Haura EB, and Kumar NB. Curcumin: a novel Stat3 pathway inhibitor for chemoprevention of lung cancer. *Eur J Cancer Prev.* 2012 Sep;21(5):407-12. PMCID: PMC3319490.
   c. **Gray JE**, Altiok S, Alexandrow MG, Walsh FW, Chen J, Schell MJ, Tai DF, Bepler G. Phase 2 randomized study of enzastaurin (LY317615) for lung cancer prevention in former smokers. *Cancer*. 2013 Mar 1;119(5):1023-32. PMCID: PMC3578040.
   d. Kumar NB, Quinn, GP, Alexandrow, M, **Gray J**, Schell M, Sutton S, Haura EB. Chemoprevention trial feasibility using botanicals in exceptionally high risk populations for lung cancer. *Journal of Clinical Trials*. 2014. 4(4):1-6. PMCID: PMC4474484

2 Building upon this foundation of clinical trials and biomarker assessment, I have formulated, designed and executed trials focused initially upon HDAC inhibitors in the treatment of lung cancer. This body of work has now expanded to the evaluation of novel therapeutics via early phase clinical trials. These trials interrogated key pathways and biomarkers via serial biopsies and blood collection and served to establish the safety and efficacy of single agent and combination strategies among cancer patients particularly those afflicted with lung cancer. I have served as PI/co-PI on these projects.
   e. **Gray JE,** Haura E, Chiappori A, Tanvetyanon T, Williams C, Pinder-Schenck M, Kish J, Kreahling J, Lush R, Neuger A, Tetteh L, Akar A, Schell M, Zhao X, Bepler G, Altiok S. A phase I, pharmacokinetic and pharmacodynamic study of panobinostat, an HDAC inhibitor, in combination with erlotinib in patients with advanced aerodigestive tract tumors. *Clin Canc Res.*2014 Mar 15; 20(6):1644-55. PMID: 24429877
   f. **Gray JE**, Heist RS, Starodub AN, Camidge DR, Kio E, Masters G, Purcell WT, Guarino MJ, Misleh J, Schneider CJ, Schneider BJ, Ocean AJ, Johnson T, Gandhi L, Kalinsky K, Scheff RJ, Messersmith WA, Govindan SV, Maliakal P, Mudenda B, Wegener WA, Sharkey RM, and Goldenberg DM. Therapy of Small-cell Lung Cancer (SCLC) With a Topoisomerase-I-inhibiting Antibody-Drug Conjugate (ADC) Targeting Trop-2, Sacituzumab Govitecan. *CCR*. 2017 Jul 5. pii: clincanres.0933.2017. doi: 10.11558/1078-0432.CCR-17-0933. [Epub ahead of print] PMID: 28679770 Link: http://clincancerres.aacrjournals.org/content/23/19/5711.full-text.pdf

   g. Soria JC, Ohe Y, Vansteenkiste J, Reungwetwattana T, Chewaskulyong B, Lee KH, Dechaphunkul A, Imamura F, Nogami N, Kurata T, Okamoto I, Zhou C, Cho BC, Cheng Y, Cho EK, Voon PJ, Planchard D, Su WC, **Gray JE**, Lee SM, Hodge R, Marotti M, Rukazenkov Y, Ramalingam SS, for the FLAURA

Investigators*. Osimertinib versus gefitinib or erlotinib in patients with treatment naïve EGFR mutation-positive advanced NSCLC. *N Engl J Med* 2017 Nov 18. doi: 1056/NEJMoa 1713137. [E pub ahead of print] PMID: 29151359.

h. Le X*, Puri S*, Negrao MV*, Nilsson M, Robichaux J, Boyle T, J. Hicks K, Lovinger K, Roarty E, Rinsurongkawong W, Tang M, Elamin Y, Landry LC, Lewis J, Roth JA, Swisher SG, J Lee JJ, . William WN, Glisson BS, Zhang J, Papadimitrakopoulou VA, **Gray JE^,** Heymach J^. Landscape of EGFR -dependent and -independent resistance mechanisms to osimertinib and continuation therapy post-progression in EGFR-mutant NSCLC. Clin Cancer Res. 2018 Dec 15;24(24):6195-6203 PMCID: PMC6295279 [Available on 2019-12-15]

3. Immunotherapy has been proven to reduce the risk of cancer. Now immunotherapy, via generation of immune memory can lead to long term improvements in patients with lung cancer. Still not all patients will respond and additional strategies are needed. One area that my research has focused upon for many years now, are combination immunotherapy strategies including vaccines. Below are works that highlight my contribution to date to this field.

   i. **Gray JE**, Chiappori A, Williams CC, Tanvetyanon T, Haura EB, Creelan BC, Kim J, Boyle TA, Pinder-Schenck M, Khalil F, Altiok S, Devane R, Noyes D, Mediavilla-Varela M, Smilee R, Hopewell EL, Kelley L,, Antonia SJ. A phase I/randomized phase II study of GM.CD40L vaccine in combination with CCL21 in patients with advanced lung adenocarcinoma.. Cancer Immunol Immunother. 2018 Sep 12 PMCID: PMC6244998

   j. Garassino MC, Cho BC, Kim JH, Mazières J, Vansteenkiste J, Lena H, Jaime JC, **Gray JE**, Powderly J, Chouaid C, Bidoli P, Wheatley-Price P, Park K, Soo R, Huang Y, Wadsworth C, Dennis PA, Rizvi N. Durvalumab as third-line or later treatment for advanced non-small-cell lung cancer (ATLANTIC): an open-label, Phase 2 study. *Lancet Oncology*, 2018 Apr;19(4):521-536.; (Published online March 12, 2018).

   k. Antonia SJ, Villegas A, Daniel D, Vicente D, Murakami S[1], Hui R[1], Yokoi T[1], Chiappori A, Lee KH, de Wit M, Cho BC, Bourhaba M, Quantin X, Tokito T, Mekhail T, Planchard D, Kim YC, Karapetis CS, Hiret S, Ostoros G, Kubota K, **Gray JE**, Paz-Ares L, de Castro Carpeño J, Wadsworth C, Melillo G, Jiang H, Huang Y, Dennis PA, Özgüroğlu M; PACIFIC Investigators. Durvalumab after Chemoradiotherapy in Stage III Non-Small-Cell Lung Cancer. *The New England journal of medicine.* 2017. Sep 8. doi: 10.1056/NEJMoa1709937. Link: http://www.nejm.org/doi/full/10.1056/NEJMoa1709937.

   l. Gandhi L, Rodríguez Abreu D, Gadgeel S, Esteban E, Felip E, De Angelis F, Domine M, Clingan P, Hochmair MJ, Powell SF, Yee-Shan Cheng S, Bischoff HG, Peled N, Grossi F, Jennens RR, Reck M, Hui R, Garon EB, M.D., Boyer M, Rubio-Viqueira B, Novello S, Kurata T, **Gray JE**, Vida J, Wei Z, Yang J, Raftopoulos H, Pietanza MC, Garassino MC, for the KEYNOTE-189 Investigators*. Pembrolizumab-Pemetrexed-Platinum for Metastatic Non–Small-Cell Lung Cancer. *NEJM*, 2018 *N Engl J Med.* 2018

4. Quality in cancer care is of upmost importance as this can directly impact patient outcomes. Through a collaborative effort I have helped to lead the initiative to evaluate the quality variables in cancer care in the state of Florida. This body of work summarizes our finds that via feedback, improvement can be made at both academic and community oncology sites.

   m. **Gray JE**, Laronga C, Seigel EM, Lee JH, Fulp WJ, Fletcher M, Schreiber F, Brown R, Levine R, Cartwright T, Abesada-Terk G Jr, Kim G, Alemany C, Faig D, Sharp P, Markham MJ, Shibata D, Malafa M, Jacobsen PB. Degree of Variability in Performance on Breast Cancer Quality Indicators: Findings From the Florida Initiative for Quality Cancer Care. *J Oncol Pract.* 2011 Jul; 7(4):247-251. PMCID: PMC3140448.

   n. Jacobsen PB, Well KJ, Meade CD, Quinn GP, Lee JH, Fulp WJ, **Gray JE**, Baz RC, Springett GM, Levine RM, Markham MJ, Schreiber FJ, Cartwright TH, Burke JM, Siegel RD, Malafa MP, Sullivan D. Effects of a brief multimedia psychoeducational intervention on cancer patients' attitudes and interest regarding clinical trial participation: a multicenter randomized controlled trial. *J Clin Oncol.* 2012 Jul 10; 30(20)2516-21. PMCID: PMC4577714.

   o. Laronga C, **Gray JE**, Seigel EM, Lee JH, Fulp WJ, Fletcher M, Schreiber F, Brown R, Levine R, Cartwright T, Abesada-Terk G Jr, Kim G, Alemany C, Faig D, Sharp P, Markham MJ, Shibata D, Malafa M, Jacobsen PB. Florida Initiative for Quality Cancer Care: Improvements in Breast Cancer Quality Indicators During a 3-year Interval. *J Am Coll Surg. 2014.* 219(4):638-645. PMCID: PMC4505727

   p. Quinn GP, Pentz RD, Muñoz-Antonia T, Boyle TA Schabath MB, Pratt CL, Shaffer A, Duarte LF, Bowman-Curci M, Antonia S, Chiappori AA, Creelan BC, Gray JE, Williams CC, Haura EB. Patient,

caregiver and physician perspectives on participating in a thoracic rapid tissue donation program. Patient Education and Counseling. 2017 Nov 28. Epub ahead of print]. 2018 Apr;101(4):703-710. PMID: 29195718

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

D. RESEARCH SUPPORT
ONGOING

LC170340P1 W81XWH-17-LCRP-TRPA (Gray/Beg) 08/01/2018 to 07/31/2021
DOD Partnering PI Option with Dr. Beg
Defining Impact of HDAC Inhibitors on Tumor Immunogenicity, T cell functionality and PD-1 Blockade Response in NSCLC Patients
The overarching goal of these studies is to define combination strategies with PD-1 blockade which can modulate the tumor microenvironment in a manner that enhances the response rate.
Specific Aims: 1) Studies of tumor biopsies and blood specimens; and 2) NanoString gene expression studies of tumor biopsies, and response association with mutational load and STK11 mutations.
Funding approved; waiting on completion of regulatory compliance

7JK04 (Gray) 03/25/2017 to 02/28/2022
James & Esther King – State of Florida DOH
Targeting Immunosuppressive Cancer Associated Fibroblasts and Immune Checkpoints in NSCLC
Specific Aims: 1) To establish the safety and early efficacy of nivolumab plus/minus nintedanib in both immunotherapy-naïve and pre-treated patients with advanced NSCLC; 2) To correlate biomarkers of interest (including CAF number, TILs, IDO, PD-L1, GEP, mutation load, and other markers) obtained from tumor biopsies and blood with clinical response; and, 3) To evaluate resistance mechanisms (GEP, AQUA and other markers) in NSCLC tumor and blood specimens and correlate with clinical resistance.

8JK03 (Kumar) 05/03/2018 to 03/31/2023
State of Florida – James & Esther King
Chemoprevention of Lung cancer in Former Smokers
Specific Aims: 1) We will administer standardized agents in combination - Meriva-SF® (sustained release) Curcumin + Lovaza® (ω-3 -Acid Ethyl Esters) or placebo for 6 months to asymptomatic former smokers with lung nodules detected during LDCT screening (Lung-RADS 3) and compare change of size of CT-detected lung nodules. In addition, we will observe trends in the number of nodules≥4 mm, and lung nodule density of partially solid and non-solid Lung-RADS 3 nodules between the treatment and placebo arms; 2) Evaluate (a) adherence and compliance to study agents; (b) bioavailability of Meriva-SF® and ω-3 -Acid Ethyl Esters in plasma and urinary metabolites; (c) safety, as indicated by incidence of adverse events and toxicities, monitored using Common Toxicity Criteria, CBC, and CMP; and, 3) Evaluate treatment-related change in intermediate endpoint biomarkers in sputum cytology, inflammation- associated chemokines and cytokines; pro-resolving lipid mediators; and targeted pathways NF-κB / IKB-αphosphorylation and the correlation of these findings with modulation of size of lung nodules.
Notice receive; approved for funding.

1 U01 CA143062 (Gillies/Schabath) 03/09/2010 to 07/31/2021
NIH/NCI
Radiomics of NSCLC
The major goal of this project is to determine if quantitative analysis of clinical images can be prognostic and predictive of response to specific therapies
Co-Investigator

COMPLETED WITHIN LAST 3 YEARS

(Schabath) 11/03/2016 to 11/02/2018
Patients Like Me / M2GEN

Symptoms toxicity prevalence and quality of life benefit of targeted therapies and immunotherapies in lung cancer patients: An observational prospective cohort study within the Total Cancer Care population.
Exploratory aim: Identify potential differences in overall survival (OS) across treatment patterns, and to the extent possible, progression-free survival (PFS) across treatment patterns.
Specific Aims: 1) To track the toxicities/side-effects of FDA approved molecular targeted agents, immunotherapies, and combinations of treatments for NSCLC in a clinical setting for six months; 2) To assess the impact of these treatment regimens on patient toxicities, symptoms, function, and quality of life, after adjustment for clinical factors and patient characteristics during the 6 month follow-up period.
Role: Co-Investigator

(Gray) 07/01/2015 to 06/30/2018
Debartolo PMI / PRAPM
Circulating free DNA (cf-DNA) to identify and monitor mutations in patients with NSCLC
The goals are to evaluate circulating free DNA as a clinically feasible surrogate that provides a mechanism for predictive biomarker characterization of lung cancer
Role: PI

4KB17 (Antonia) 06/30/2014 to 12/31/2017
Florida Department of Health – J&E King
Expansion of enduring infrastructure to support lung cancer screening research
The purpose of this application is to expand and improve existing infrastructure to support lung cancer screening research at the Moffitt Cancer Center. The Specific Aims are to: i) address barriers to lung cancer screening, ii) establish lung cancer screening registry, iii) collect and process advanced digital features from CT scans, and iv) develop a smoking cessation program specifically for screening participants
Role: Co-Investigator; role ended

(Gray) 07/14/2016 to 07/13/2017
Genoptix, Inc.
Clinical Validation of Prediction of Immunotherapy Therapy Response Using PD1/PDL1 Interaction Measured by Quantitative Multiplex FIHC AQUA Test
Specific Aims: 1) To demonstrate the utility of the PD-1/PD-L1 multiplexed test in predicting response to anti-PD-1/Anti-PD-L1 in advanced melanoma patients; 2) To evaluate additional exploratory predictive markers, including those related to antigen presentation and immune infiltration; 3) To assess the performance of the assay in other pre-treatment samples from patients with non-melanoma cancers, including NSCLC, bladder, and renal cancers; 4) To investigate the performance of the assay and explore other biomarkers in patients treated with other immune checkpoint inhibitors.

CE-12-11-4351 (KM Islam / Gray) 07/01/2015 to 05/14/2016
University of Nebraska/PCORI
Patient-Defined Treatment Success & Preferences in Stage IV Lung Cancer Patients
Goal: To compare treatment preferences among different patient groups when available drugs offer the same survival but different side effects and then communicate patients' preferences to physicians to assess changes in clinical practice.

Conor Lynch, PhD

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: LYNCH, CONOR

eRA COMMONS USER NAME (agency login): LYNCHC1

POSITION TITLE: ASSOCIATE MEMBER

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
Dublin City University, Dublin, Ireland	BS	09/1997	Biotechnology
Dublin City University, Dublin, Ireland	PhD	09/2001	Molecular Biology
Vanderbilt University, Nashville, TN, USA		05/2006	Cancer Cell Biology

A. Personal Statement

I am currently an NCI funded Assoc. Member/Professor with tenure in the Tumor Biology Department at the Moffitt Cancer Center and serve as the Scientific Co-Director of the Moffitt Tissue Core. My primary research interest focuses on understanding the molecular and cellular factors that govern the growth of metastatic prostate cancer in the bone microenvironment. Despite medical advances, the American Cancer Society predicts that approximately 30,000 men will succumb to prostate cancer each year in the United States alone. The majority of these men will die from metastatic burden. Bone metastasis is a common event in prostate cancer progression with the resultant lesions severely impacting the patient's quality of life. In collaboration with the clinicians and physician scientists in Genitourinary Oncology at the Moffitt Cancer Center, we are focused on identifying the molecular mechanisms underlying prostate cancer metastasis and prostate cancer induced changes in the bone microenvironment. To this end, we incorporate a number of pre-clinical animal models that recapitulate the pathophysiology of human prostate to bone metastasis. We are also interested in testing a number of small molecule inhibitors in these models. My group has extensisive experience in prostate cancer progression, bone imaging and in bone histology/histomorphometry. In addition to prostate cancer, my team also focuses on multiple myeloma, osteosarcoma and bone metastatic breast cancer. We are 100% dedicated to identifying new therapies and treatment strategies that will effectively treat patients diagnosed and suffereing with skeletal malignancies.

Publications relating directly to this application:

a. **Lynch CC**, Hikosaka, A, Acuff HB, Martin MD, Kawai, N, Singh, RK, Vargo-Gogola, T, Begtrup, JL, Peterson, TE, Fingleton, B, Shirai, T, Matrisian LM and Futakuchi, M. (2005) Matrix Metalloproteinase-7 [MMP-7] promotes prostate cancer induced osteolysis via the solubilization of receptor activator of nuclear-κB ligand [RANKL]. Cancer Cell. 7: 485-496. **(356 citations to date)**
b. Thiolloy S, Halpern JL, Holt GE, Schwartz HE, Mundy GR, Matrisian LM and **Lynch CC**. (2009). Host derived MMP-7, but not MMP-9 impacts mammary tumor induced osteolysis. Cancer Res. August 15, 69:6747-55. PMCID: PMC2745595 **(59 citations to date)**
c. Araujo A, Cook LM, **Lynch CC*** and Basanta D (2014). An integrated computational model of the metastatic prostate cancer-bone microenvironment. Cancer Res. 1;74 (9) 2391-401. PMCID: PMC4023121 * Indicates Co-Senior Author. **(34 citations to date).**
d. Cook LM, Araujo A, Budzevich M, Pow-Sang JM, Basanta D and **Lynch CC**. (2015). Predictive computational modeling to define effective treatement for bone metastatic prostate cancer. *Nature Sci Rep. 2016 Jul 14;6:29384* **(15 citations to date).**

B. Positions

Positions and Employment

1997 - 2001 Graduate Student-Dr. Susan McDonnell, Dublin City University, Dublin, Ireland
2001 - 2006 Research Fellow-Dr. Lynn Matrisian, Vanderbilt University, Nashville, TN, USA
2006 - 2010 Research Assistant Professor, Vanderbilt University, Nashville, TN, USA

2009 - 2010	Co-Director of Orthopaedics and Rehabilitation Research Division, Vanderbilt University, Nashville, TN, USA.
2011 - 2016	Assistant Professor, Tumor Biology Department, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL, USA
2011 - Present	Associate Professor, Tumor Biology Department, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL, USA
2019 - Present	Scientific Co-Director of the Moffitt Cancer Center Tissue Core

Other Experience and Professional Memberships

2002 - Present	Member, American Association for Cancer Research
2002 - Present	Member, Metastasis Research Society
2011 - Present	Member, International Bone and Mineral Society
2011 - Present	Editorial Board, Clinical and Experimental Metastasis.
2011 - Present	Editorial Board, Cancer Research.
2012 - Present	Editorial Board, Cancer Control
2011 - Present	Member, Society for Basic Urology Research
2011 - Present	Ad hoc Reviewer, Yorkshire Cancer Research
2014 - Present	Editorial Board, American Journal of Clinical and Experimental Urology
2012 - Present	Elected Board Director, Metastasis Research Society
2013 – 2015	Ad hoc reviewer, DOD PCRP, Pathobiology (Dec 2013, Nov 2014)
2013 - Present	Editorial Board, American Journal of Clinical and Experimental Urology
2014 - Present	Elected Treasurer, Metastasis Research Society
2014 - Present	Ad hoc reviewer, Italian Ministry of Health
2014 - Present	Ad hoc reviewer, NCI RO3/R21/RO2 Omnibus Study Section
2016 - Present	Ad hoc reviewer, Susan G. Komen Breast Cancer Foundation
2018 - Present	Member of the Florida Biomedical Research Advisory Committee
2016 - Present	Board Director, Governance Chair, Vice Chair of the Florida Breast Cancer Foundation
2019 - Present	Chair of the Florida Breast Cancer Foundation
2019 - Present	Board Member of the Cancer And Bone Society

Honors

1999	Asher Korner Travelling Fellowship, University of Sussex, UK
2000	Travel Award, International Union of Biochemistry and Molecular Biology
2000	Young scientist award, Irish Association of Cancer Research (IACR)
2001	Best pre-doctoral presentation, Irish Biochemical Society
2001	Travel Award. MMP Gordon Conference
2004	Young Investigator Award, ICCBMT
2012	Miles For Moffitt Milestone Award, Moffitt
2013	Anna Valentine Foundation Award, Moffitt-USF
2015	Moffitt Team Science award
2016	Moffitt Junior Faculty Researcher of the year
2016	Moffitt Research Educator of the year.

C. Contribution to Science (selected from 52 total publications, >2,700 Citations)

1. **Understanding of Cancer Induced Bone Disease.** The major focus of my work to date has been on understanding the molecular mechanisms that drive the establishment and growth of bone metastatic cancer with a specific emphasis on prostate cancer. Early in my career I identified that MMPs were highly expressed at the tumor-bone interface namely, MMP-2, -3, -7, -9 and -13. MMPs have long been associated with cancer invasion and metastasis but clinical trials with broad-spectrum inhibitors in the 1990s performed poorly due to systemic effects and dose limiting toxicity. Subsequently, it has become apparent that MMPs have wide ranging effects including tumor suppressor functions and so I have been defining, in the context of bone metastasis, which individual MMPs contribute specifically to cancer progression. To this end we have made a number of important discoveries that demonstrate contributory roles for MMP-2 and MMP-7 in the progression of bone metastatic cancer. Based on these

findings, a major focus in the lab has been the development of bone seeking (tissue specific) bisphosphonate based MMP inhibitors.

a. Thiolloy S, Halpern JL, Holt GE, Schwartz HE, Mundy GR, Matrisian LM and **Lynch CC**. (2009). Host derived MMP-7, but not MMP-9 impacts mammary tumor induced osteolysis. Cancer Res. August 15, 69:6747-55. PMCID: PMC2745595 **(56 citations to date)**
b. Bruni-Cardoso A, Johnson LC, Peterson TE, Vessella RL and **Lynch CC**. (2010). Osteoclast MMP-9 directly affects angiogenesis in the prostate tumor-bone microenvironment. Mol. Cancer Res. 8(4): 459-70. PMCID: PMC2946627 **(40 citations to date)**
c. Thiolloy S, Edwards JR, Fingleton B, Rifkin DB, Matrisian LM, **Lynch CC**. (2012). An osteoblast-derived proteinase controls tumor cell survival via TGF-beta activation in the bone microenvironment. PLoS One. 2012;7(1):e29862. Epub 2012 Jan 4. PMCID: PMC3251607 **(36 citations to date)**
d. Tauro M, Shay G, Sansil SS, Laghezza A, Tortorella P, Neuger AM, Soliman H, **Lynch CC**. (2017). Bone seeking matrix metalloproteinase-2 inhibitors prevent bone metastatic breast cancer growth. Mol Cancer Ther. 2017 Mar;16(3):494-505 **(10 citations to date)**

2. **MMP substrate identification.** My under graduate rotation project in 1997 focused on correlating MMP-2 and MMP-9 activity with Dukes Stage in samples of colon cancer. Since my first zymogram, I have been fascinated by MMP biology and have dedicated much of my career to understanding the causal roles MMPs play in cancer progression. While MMPs can degrade the extracellular matrix, they also can process a number of non-matrix factors to soluble forms. During my career, that began in the laboratory of Prof. Lynn Matrisian at Vanderbilt University in Nashville, TN., I have found that MMPs can promote the solubilization of receptor activator of nuclear kappa B ligand (RANKL) to an active soluble form that promotes bone resorption via osteoclast activation, enhance the bioavailability of heparin bound growth factor (HB-EGF) to promote mammary gland carcinogenesis and control the release of transforming growth factor beta (TGFβ) from latent TGFβ binding protein (LTBP-3) and vascular endothelial growth factor-A (VEGF-A) in the bone microenvironment. Emerging studies are currently focused on Fas ligand solubilization in driving the evolution of apoptosis resistant prostate cancer cells in addition to the processing of parathyroid hormone related peptide (PTHrP) and how the resultant products promote osteoblast differentiation.

a. **Lynch CC** and Matrisian LM. Matrix metalloproteinases in tumor-host cell communication. Differentiation. 2002 Dec;70(9-10):561-73. PMID: 12492497 **(427 citations to date)**
b. **Lynch CC**, Hikosaka, A, Acuff HB, Martin MD, Kawai, N, Singh, RK, Vargo-Gogola, T, Begtrup, JL, Peterson, TE, Fingleton, B, Shirai, T, Matrisian LM and Futakuchi, M. (2005) Matrix Metalloproteinase-7 [MMP-7] promotes prostate cancer induced osteolysis via the solubilization of receptor activator of nuclear-κB ligand [RANKL]. Cancer Cell. 7: 485-496. PMID: 15894268 **(356 citations to date)**
c. **Lynch CC**, Vargo-Gogola T, Martin MD, Lynggi B, Fingleton B, Crawford HC, Carpenter G, and Matrisian LM. (2007) MMP-7 expression induces mammary tumorigenesis through the ErbB-4 receptor. Cancer Res. 2007 Jul 15;67(14):6760-7. PMCID: PMC2789265 **(67 citations to date)**
d. Tauro M, McGuire J, **Lynch CC**. New approaches to selectively target cancer associated matrix metalloproteinase activity. Cancer & Metastasis Reviews, Dec;33(4):1043-57. 2014 PMID: 25325988 **(46 citations to date)**

3. **Skeletal Biology.** I have also been very interested in skeletal development and structure. Understanding the cellular and molecular mechanisms of skeletal development can provide important insights into how cancers can develop or, how metastatic cancers can hijack bone specific processes. To this end we have made a number of important scientific contributions that have not only examined how individual MMPs can influence the structural integrity of the mineralized bone matrix but also have used our knowledge of bone biology to generate ectopic bone bioreactors via bone morphogenetic protein-2 (BMP-2) loading of a corraline scaffold that can be used as a model of bone metastasis. Further studies from my group have also defined how mesenchymal stem cells (MSCs), the cells that give rise to bone building osteoblasts, can be recruited by metastatic cancer cells in a chemokine dependent manner.

a. Halpern J, **Lynch CC**, Hamming D, Fleming J, Schwartz H, Matrisian LM, and Holt GE. The development of a novel murine bone bioreactor to study the effects of bone metastasis. Clin. Exp. Met**.** 23(7-8):345-56, 2006. **(33 citations to date)**

b. Bi X, Patil CA, **Lynch CC**, Pharr GM, Mahadevan-Jansen A and Nyman JS. Raman and mechanical properties correlate at whole bone- and tissue-levels in a genetic mouse model. J Biomech. 44(2): 297-303, 2010. **(58 citations to date)**
c. Nyman JS, **Lynch CC**, Thiolloy S, O'Quinn EC, Perrien DS, Patil CA, Bi Xiaohong, Pharr GM, Mahadevan-Jansen A and Mundy GR. Differential effects between the loss of MMP-2 and MMP-9 on structural and tissue level properties of bone JBMR. 26(6): 1252-60, 2011. **(80 citations to date)**
d. Halpern J, Kilbarger A, **Lynch CC**. Mesenchymal stem cells promote mammary cancer cell migration in vitro via the CXCR2 receptor. Cancer Lett. 308(1): 91-9, 2011. (**67 citations to date)**

4. **Breast cancer.** While many of my primary contributions have been in the field of bone metastatic prostate cancer, I have also made a number of contributions to our understanding of breast cancer progression and metastasis. I was the first to describe a role for the EGF receptor, ErbB4 in promoting mammary gland carcinogenesis. Previously, ErbB4 had been shown to be prognostic of better overall survival for women diagnosed with breast cancer. However, we showed that MMP-7 was capable of processing HB-EGF to a soluble form that could bind to ErbB4 and stimulate the cleavage of the receptor on the ectodomain by ADAM-17 and the endo-domain by gamma-secretase. The resultant internal cytoplasmic domain (ICD) could translocate to the nucleus and drive cell growth. In fact analysis of tissues for nuclear ErbB4 ICD correlated with a poorer overall survival for breast cancer patients. Additionally, we have looked breast cancer metastasis to lung and bone
   a. **Lynch CC**, Vargo-Gogola T, Martin MD, Lynggi B, Fingleton B, Crawford HC, Carpenter G, and Matrisian LM. (2007) MMP-7 expression induces mammary tumorigenesis through the ErbB-4 receptor. Cancer Res. 2007 Jul 15;67(14):6760-7. PMCID: PMC2789265 **(67 citations to date)**
   b. Martin MD, Carter KJ, Jean-Philippe SR, Chang M, Mobashery S, Thiolloy S, **Lynch CC**, Matrisian LM and Fingleton B. Effect of ablation or inhibition of stromal matrix metalloproteinase-9 on lung metastasis in a breast cancer model is dependent on genetic background. Cancer Res. August 1, 68(15) 6251-9, 2008. **(118 citations to date)**
   c. **Lynch CC**, Vargo-Gogola T, Matrisian LM and Fingleton B. MMP-7 processing of E-cadherin contributes to mammary gland epithelial cell growth *in vitro* and *in vivo*. Journal of Oncology, 2010:530745, 2010. **(41 citations to date)**
   d. Tauro M, Shay G, Sansil SS, Laghezza A, Tortorella P, Neuger AM, Soliman H, **Lynch CC**. (2017). Bone seeking matrix metalloproteinase-2 inhibitors prevent bone metastatic breast cancer growth. Mol Cancer Ther. 2017 Mar;16(3):494-505 **(10 citations to date)**

5. **Computational Modeling/Team Science.** Moffitt Cancer Center has one of the world's most unique resources in the Integrated Mathematical Oncology (IMO) Department. The IMO is dedicated to using modeling approaches to predict cancer behavior. Working in close collaboration with Dr. David Basanta of the IMO we have generated a computational model of the metastatic cancer bone microenvironment that allows us to explore the dynamic interactions between heterogeneous prostate cancer cells, osteoblasts and osteoclasts. The model faithfully recapitulates prostate cancer induced osteogenesis and has allowed us to predict the efficacy of standard of care treatments such as bisphosphonates and targeted therapies such as TGFβ. We are currently exploring the role of genetic drivers in heterogeneous primary prostate cancer progression. These projects have been true team science projects where every team member brings a unique set of skills that allows us to synergize and generate novel ideas and findings.
   a. Araujo A, Cook LM, **Lynch CC*** and Basanta D (2014). An integrated computational model of the metastatic prostate cancer-bone microenvironment. Cancer Res. 1;74 (9) 2391-401. PMCID: PMC4023121 * Indicates Co-Senior Author. **(34 citations to date).**
   b. Frieling, JS. Basanta, D and **Lynch CC**. (2015). Current and Emerging Opportunities to Eradicate Bone Metastatic Castration-Resistant Prostate Cancer (mCRPC). Cancer Control, Jan;22(1):109-20. 2015. **(16 citations to date)**
   c. Gallaher J, Cook LM, Gupta S, Araujo A, Dhillon D, Park JY, Scott, J, Basanta, D and **Lynch CC**. Improving Treatment Strategies for Patients with Metastatic Castrate Resistan Prostate Cancer through Personalized Computational Modeling. Clin Exp Metastasis. Dec;31(8):991-9. 2014 **(13 citations to date)**

d. Cook LM, Araujo A, Budzevich M, Pow-Sang JM, Basanta D and **Lynch CC**. (2015). Predictive computational modeling to define effective treatement for bone metastatic prostate cancer. *Nature Sci Rep. 2016 Jul 14;6:29384* **(15 citations to date)**

http://www.ncbi.nlm.nih.gov/sites/myncbi/conor.lynch.1/bibliography/41715826/public/?sort=date&direction=ascending

D. Research Support
Ongoing Research Support

1U01CA202958-01(PI: Basanta, D) 06/01/2016-05/31/2021 2.40 calendar months
NIH/NCI/NIAMS/NIBMB/NIEHS/NIA $2, 500,000
Multi-scale modeling of bone environment responses to metastatic prostate cancer.
A computational model will be developed that integrates key stromal and immune components. The impact of prostate cancer cells on the response of the stroma and the immune system will be examined in a temporal and multiscale manner.
Role: co-PI

Miles for Moffitt (PI: Lynch, C/Schonbrunn,E) 07/01/2018 - 05/31/2019 0.60 calendar
Moffitt Cancer Center $75,000
Dual BET Domain/Kinase Inhibitors for The Treatment of Multiple Myeloma
The goals of this project are to determine the efficacy of novel dual kinase inhibitors on the progression of multiple myeloma and to dissect the potential mechanisms of action of these reagents
Role: PI

W81XWH1810523 (PI: Lynch) 08/15/2018 - 08/14/2021 1.2 calendar
DOD $200,000
Mesenchymal Stem Cell Control of Metastatic Prostate Cancer Cell Evolution and Therapy Resistance in the Bone Microenvironment
The goal of this DOD application is to understand how mesenchymal stem cells contribute to the generation of apoptosis resistant prostate cancer cells via an IL-28 mechanism.
Role: PI

W81XWH1610673 (PI: Rai/Burnstein) 08/15/2018 - 08/14/2019 0.6 calendar
DOD $49,311
Redox stress-mediated inappropriate androgen receptor elevation as a novel treatment paradigm for castration-resistant prostate cancer
The goal of this DOD application is to understand how redox stress responses in bone metastatic cancer cells can be targeted to enhance the efficacy of hormone ablation therapy and delay the development of resistant disease.
Role: Sub-contract PI

Ken Tsai, MD, PhD

CURRICULUM VITAE

Kenneth Y. Tsai, M.D., Ph.D.

PRESENT TITLE AND AFFILIATION

Primary Appointment

Associate Member, Dermatopathology, Department of Anatomic Pathology, Moffitt Cancer Center, Tampa, FL

Co-Director, Donald A. Adam Center of Excellence in Melanoma and Skin Cancer

Dual/Joint/Adjunct Appointment

Associate Member, Department of Tumor Biology, Moffitt Cancer Center, Tampa, FL

Associate Professor, Departments of Dermatology & Cutaneous Surgery and Oncological Sciences, University of South Florida, Tampa, FL

CITIZENSHIP

United States

OFFICE ADDRESS

The H. Lee Moffitt Cancer Center & Research Institute
12902 Magnolia Dr
SRB-3
Tampa, FL 33612
Phone: 813-745-4864
Email: kenneth.tsai@moffitt.org

EDUCATION

Degree-Granting Education

Yale College, New Haven, CT, BS, 1993, Applied Physics

Massachusetts Institute of Technology, Cambridge, MA, PHD, 2001, Biology

Harvard Medical School, Boston, MA, MD, 2003, Medicine

Postgraduate Training

Clinical Internship, Internal Medicine, Massachusetts General Hospital, Boston, MA, 7/2003-6/2004

Clinical Residency, Dermatology, Harvard Medical School - Massachusetts General Hospital, Boston, MA, 7/2004-6/2007

Clinical Fellowship, Dermatopathology, Harvard Medical School - Beth Israel Deaconess Hospital, Boston, MA, 7/2007-6/2008

CREDENTIALS

Board Certification

American Board of Dermatology - Dermatology, 8/2007-12/2027

American Boards of Dermatology & Pathology - Dermatopathology, 9/2008-12/2028

Licensures

Active

Physician – Full, FL, ME129099, 1/2020

Inactive

Physician - Full, TX, M9706, 4/2008

Physician - Full, MA, 234517, 12/2007

EXPERIENCE/SERVICE

Academic Appointments

Associate Professor, Department of Dermatology, Division of Internal Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX, 9/2015-8/2016

Associate Professor, Department of Translational Molecular Pathology, Division of Pathology/Lab Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX, 9/2015-8/2016

Assistant Professor, Department of Translational Molecular Pathology, Division of Pathology/Lab Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX, 9/2014-8/2015

Assistant Professor, Department of Immunology, The University of Texas MD Anderson Cancer Center, Houston, TX, 7/2008-8/2014

Assistant Professor, Department of Dermatology, Division of Internal Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX, 7/2008-8/2015

Regular Faculty Member, University of Texas Graduate School of Biomedical Sciences, Houston, TX, 4/2009-8/2016

Institutional Committee Activities

Moffitt Cancer Center:

Senior Leadership Committee 1/2017 – present

Clinical Women Faculty Mentoring Program Mentor 3/2018 – present

Clinical Competency Committee (USF Dermatopathology Fellowship) 6/2018 – present

MD Anderson Cancer Center:

Division of Internal Medicine Faculty Research Committee, Committee Member, 9/2011-8/2016

Immunology Program Steering Committee, Member, 4/2012-9/2015

Odyssey Program Advisory Committee, Member, 9/2012-8/2015

Faculty Senate, Senator, 9/2012-8/2016

Institutional Animal Care and Use Committee, Member, 9/2015-8/2016

HONORS AND AWARDS

Medical Scientist Training Program, National Institutes of Health, 1994-2003

David Koch Foundation Graduate Fellowship, Massachusetts Institute of Technology, 2000

Chief Resident, Dermatology, Harvard Medical School - Massachusetts General Hospital, 2006-2007

Cyrus Research Scholar Award, Cyrus Family Foundation, 2012-2014

AACR Landon Foundation INNOVATOR Award, American Association for Cancer Research, 2013-2015

RESEARCH

Grants and Contracts

Funded Active

Co-Investigator (My Mahoney, PI), 5%, Effects of Extracellular Vesicles on miRNA Activity in Skin, 1R01-CAAR074314, NIH/NCI, 08/01/2018 – 05/31/2023, $50,000/year

Co-Investigator (Ravi Sahu, PI), 2%, Impact of platelet-activating factor in targeted therapy responses in melanoma, Elsa Pardee Foundation, 03/01/2018 – 02/20/2019, $50,000

Principal Investigator, 2%, HDACi for the Chemoprevention and Treatment of High-Risk Squamous Cell Carcinoma, FORMA Therapeutics, 10/1/2017-9/30/2018, $100,000

Co-Investigator (Julia Oh, PI), 5%, Skin Microbiome Interactions in Cutaneous Squamous Cell Carcinoma, RSG 16-255-01-MPC, American Cancer Society, 07/01/2017-06/30/2021, $50,000 ($12,500/year)

Co-Investigator (Elsa Flores, PI), 5%, Identification of Non-Coding RNAs to Therapeutically Target Undruggable Pathways in Metastatic Lung Adenocarcinoma and Squamous Cell Carcinoma, 7R35CA197452, NIH/NCI, 9/1/2016-3/31/2023, $62,500 ($12,500/year)

Principal Investigator, 15%, (PQA4) Molecularly Targeted Chemoprevention for Preneoplastic Squamous Epithelia, 1R01CA194617, NIH/NCI, 4/1/2015-3/30/2019, $1,400,000 ($350,000/year)

Principal Investigator, 15%, MicroRNA Targets for Chemoprevention of Squamous Cell Carcinoma, 1R01CA194062, NIH/NCI, 12/1/2015-11/30/2020, $1,025,000 ($200,000/year)

Completed

Principal Investigator, 3 months, A Modular Model for Studies of Immunosurveillance in Skin Cancer, ACS-IRG-08-061-01, American Cancer Society (ACS), 9/14/2009-9/14/2010, $30,000 ($30,000/year)

Principal Investigator, Genetic and Cellular Determinants of Immunosurveillance and Evasion in Skin Cancer, Research Scholar Award, American Skin Association, 1/1/2010-12/31/2010, $60,000 ($60,000/year)

Principal Investigator-MDACC, Modular Model for Studies of Immunosurveillance in Skin Cancer, 1R03AR059246, NIH/NIAMS, 7/1/2010-6/30/2014, $150,000 ($50,000/year)

Principal Investigator, Mechanisms of Apoptosis Resistance in BRAFi-treated Keratincytes, MD Anderson Cancer Center IRG, 7/15/2011-7/14/2012, $50,000 ($50,000/year)

Principal Investigator-MDACC, Integrative Genomic Analysis of Actinic Keratoses: Using Inter-lesional and Cross Species Analysis to Predict Progression to Cutaneous Squamous Cell Carcinoma, Duncan Family Institute, 8/15/2011-2/28/2014, $77,000 ($38,500/year)

Principal Investigator-MDACC, Pharmacologic BRAF Inhibition : The Impact of Stress Activated Protein Kinase Signaling, American Skin Association, 1/1/2012-12/31/2012, $60,000 ($60,000/year)

Principal Investigator-MDACC, Understanding Off-Target Effects of BRAF Inhibitors in Melanoma and Epithelial Cells, Elsa U. Pardee Foundation, 1/1/2012-3/31/2013, $157,000 ($157,000/year)

Co-Investigator, Mechanisms of Oncogene Dependence in Melanoma, P50 CA093459, NIH/NCI, 12/15/2012-12/14/2013, $25,000 ($25,000/year)

Principal Investigator-MDACC, Integrated Genomic Analysis of Cutaneous Squamous Cell Carcinoma Progression, MD Anderson Cancer Center IRG, 6/15/2013-6/14/2014, $50,000 ($50,000/year)

Collaborator, UT Center for Clinical and Translational Sciences (CCTS), TL1TR000369, National Center for Advancing Translational Science, PI - David McPherson, 6/1/2012-6/1/2015, $87,000 ($29,000/year)

Co-Investigator, 2%, Using UV induced epidermal mosaicism to predict skin cancer risk, Duncan Family Institute, PI - Paul Scheet, PhD, 8/1/2013-7/31/2015, $99,770 ($49,885/year)

Principal Investigator, 2%, Genomic Analysis of Cutaneous Squamous Cell Carcinoma Progression, Landon Foundation Innovator Award, American Association for Cancer Research (AACR), 10/1/2013-9/30/2015, $100,000 ($50,000/year)

Collaborator, Training Program in Cancer Immunobiology, 5T32CA009598, NIH/NCI, PI - James Allison, 4/1/2014-6/1/2015, $126,000 ($42,000/year)

Co-Principal Investigator, 5%, Realizing Personalized and Precision Medicine for Melanoma: A Rapid Assay for Measuring ERK Activity, Cancer Prevention & Research Institute of Texas (CPRIT), 9/1/2014-8/30/2016, $95,000 ($47,500/year)

Co-Principal Investigator, 10%, New Therapeutic Strategies for Metastatic Melanoma, Cancer Prevention & Research Institute of Texas (CPRIT), 9/1/2014-8/30/2017, $427,500 ($142,500/year)

Co-Investigator, 5%, Targeting p53 in cancer through manipulation of p63 and p73, RP140271, Cancer Prevention & Research Institute of Texas (CPRIT), 9/1/2014-8/30/2017, $30,000 ($10,000/year)

Collaborator, Role of JNK Signaling Pathway in BRAF Inhibitor Resistance in Human Melanoma, P50 CA093459, NIH/NCI, 2/1/2015-1/31/2016, $25,000 ($25,000/year)

Co-Principal Investigator, 5%, Assessing the risk of UV-induced skin cancer via non-invasive epidermal sampling, 1R21-CA191133, NIH/NCI, 2/1/2015-1/31/2018, $235,000 ($75,000/year)

Co-Investigator, Developmental Research Grant, Investigating the Therapeutic use of Pramlintide in cutaneous squamous cell carcinoma, 4P50CA168536 (PI-Vernon Sondak), NIH/NCI, PI – Elsa Flores, 1/1/2017-12/31/2017, $100,000

Patents and Technology Licenses

Patents

UCSB, Samir Mitragotri, Byeong Hee Hwang, Nishit Doshi, Kenneth Tsai, Russell M. Lebovitz. Compositions for Solubilizing Cells and/or Tissue, United States, 13/432,978, 3/28/2012, Filed

Grant Reviewer/Service on Study Sections

Study Section Review Committee for Basic Research Projects - Institutional Research Grants Program, MD Anderson Cancer Center, Member, 2011-2013

Study Section Review Committee for Basic Research Projects - Institutional Research Grants Program, MD Anderson Cancer Center, Vice Chair, 2013-2014

Study Section Review Committee for Basic Research Projects - Institutional Research Grants Program, MD Anderson Cancer Center, Chair, 2014-2016

Moffitt Cancer Center Grant Review Committee Ad-Hoc (4/2018)

NIH Study Sections:

2014: NCI Transition to Independence

2016: 2016/01 ZCA1 SRB-C (J1) S, 2016/01 ZRG1 OTC-K (04) M, 2016/05 ZCA1 SRB-C (M1) S

2017: ZCA1 SRB-8 (J1), ZRG1 OBT-Z (02) M, ACTS 2017/05, ZCA1 SRB-C (M1) S, TME 2017/10

2017: Deutsche Forschungsgemeinschaft – Research Grants Programme, DoD Epidermolysis Bullosa

2017-8: CDMRP – Epidermolysis Bullosa, Reviewer and Chair

2018: ZCA1 RPRB-L M1 P, NCI SPORE V; 2018/05 ACTS; 2019/1 ACTS; 2019/1 TME, PO1

PUBLICATIONS

Peer-Reviewed Original Research Articles

1. Tsai KY, Carnevale NT, Claiborne BJ, Brown TH. Efficient mapping from neuroanatomical to electrotonic space. Network 5(1):21-46, 2/1994.
2. Tsai KY, Carnevale NT, Brown TH. Hebbian learning is jointly controlled by electrotonic and input structure. Network 5(1):1-19, 2/1994.
3. Hoffman RE, Buchsbaum MS, Jensen RV, Guich SM, Tsai KY, Neuchterlein KH. Dimensional complexity of EEG waveforms in neuroleptic-free schizophrenics and normal controls. J Neuropsych Clin Neurosci 8:436-441, 1996.

4. Carnevale NT, Tsai KY, Claiborne BJ, Brown TH. Comparative electrotonic analysis of three classes of rat hippocampal neurons. J Neurophysiol 78(2):703-20, 8/1997. PMID: 9307106.
5. Lee KM, Tsai KY, Wang N, Ingber DE. Extracellular matrix and pulmonary hypertension: control of vascular smooth muscle cell contractility. Am J Physiol 274(1 Pt 2):H76-82, 1/1998. PMID: 9458854.
6. Tsai KY, Hu Y, Macleod KF, Crowley D, Yamasaki L, Jacks T. Mutation of E2f-1 suppresses apoptosis and inappropriate S phase entry and extends survival of Rb-deficient mouse embryos. Mol Cell 2(3):293-304, 9/1998. PMID: 9774968.
7. Alenghat FJ, Fabry B, Tsai KY, Goldmann WH, Ingber DE. Analysis of cell mechanics in single vinculin-deficient cells using a magnetic tweezer. Biochem Biophys Res Commun 277(1):93-9, 10/2000. PMID: 11027646.
8. Irwin M, Marin MC, Phillips AC, Seelan RS, Smith DI, Liu W, Flores ER, Tsai KY, Jacks T, Vousden KH, Kaelin WG. Role for the p53 homologue p73 in E2F-1-induced apoptosis. Nature 407(6804):645-8, 10/2000. PMID: 11034215.
9. Boyd SD, Tsai KY, Jacks T. An intact HDM2 RING-finger domain is required for nuclear exclusion of p53. Nat Cell Biol 2(9):563-8, 9/2000. PMID: 10980695.
10. Geng Y, Yu Q, Whoriskey W, Dick F, Tsai KY, Ford HL, Biswas DK, Pardee AB, Amati B, Jacks T, Richardson A, Dyson N, Sicinski P. Expression of cyclins E1 and E2 during mouse development and in neoplasia. Proc Natl Acad Sci U S A 98(23):13138-43, 11/2001. PMID: 11687642.
11. Tsai KY, MacPherson D, Rubinson DA, Crowley D, Jacks T. ARF is not required for apoptosis in Rb mutant mouse embryos. Curr Biol 12(2):159-63, 1/2002. PMID: 11818069.
12. Flores ER, Tsai KY, Crowley D, Sengupta S, Yang A, McKeon F, Jacks T. p63 and p73 are required for p53-dependent apoptosis in response to DNA damage. Nature 416(6880):560-4, 4/2002. PMID: 11932750.
13. Tsai KY, MacPherson D, Rubinson DA, Nikitin AY, Bronson R, Mercer KL, Crowley D, Jacks T. ARF mutation accelerates pituitary tumor development in Rb+/- mice. Proc Natl Acad Sci U S A 99(26):16865-70, 12/2002. PMID: 12486224.
14. Tsai KY, Tsao H. The genetics of skin cancer. Am J Med Genet C Semin Med Genet 131C(1):82-92, 11/2004. PMID: 15468170.
15. Tsai KY. Evidence-based medicine: do we use guidelines or mindlines? Commentary on: Evidence-based guidelines or collectively constructed "mindlines?" ethnographic study of knowledge management in primary care. Gabbay J, le May G BMJ. 2004;329:1013. Arch Dermatol 141(6):773-4, 6/2005. PMID: 15967926.
16. Niendorf KB, Goggins W, Yang G, Tsai KY, Shennan M, Bell DW, Sober AJ, Hogg D, Tsao H. MELPREDICT: a logistic regression model to estimate CDKN2A carrier probability. J Med Genet 43(6):501-6, 6/2006. PMID: 16169933.
17. Tsai KY, Tsao H. Primer on the human genome. J Am Acad Dermatol 56(5):719-35, 5/2007. PMID: 17437886.
18. Tsai KY. Systemic adjuvant therapy for patients with high-risk melanoma. Arch Dermatol 143(6):779-82, 6/2007. PMID: 17576946.
19. Tsai KY, Brenn T, Werchniak AE. Nodular presentation of secondary syphilis. J Am Acad Dermatol 57(2 Suppl):S57-8, 8/2007. PMID: 17637381.
20. Davis TL, Mandal RV, Bevona C, Tsai KY, Moschella SL, Staszewski R, Zembowicz A. Collagenous vasculopathy: a report of three cases. J Cutan Pathol 35(10):967-70, 6/2008. PMID: 18537865.
21. Tucker JD, Shah S, Jarell AD, Tsai KY, Zembowicz A, Kroshinsky D. Lues Maligna in Early HIV Infection Case Report and Review of the Literature. Sex Transm Dis. e-Pub 5/2009. PMID: 19455078.
22. Bergman H, Tsai KY, Seo SJ, Kvedar JC, Watson AJ. Remote assessment of acne: the use of acne grading tools to evaluate digital skin images. Telemed J E Health 15(5):426-30, 6/2009. PMID: 19548822.
23. Su X, Paris M, Gi YJ, Tsai KY, Cho MS, Lin YL, Biernaskie JA, Sinha S, Prives C, Pevny LH, Miller FD, Flores ER. TAp63 prevents premature aging by promoting adult stem cell maintenance. Cell Stem Cell 5(1):64-75, 7/2009. PMID: 19570515.

24. Yang G, Thieu K, Tsai KY, Piris A, Udayakumar D, Njauw C-NJ, Ramoni M, Tsao H. Dynamic Gene Expression Analysis Links Melanocyte Growth Arrest with Nevogenesis. Cancer Res 69(23):9029-37, 12/2009. e-Pub 11/2009. PMID: 19903842.
25. Silapunt S, Jordon RE, Piao Y, Tsai KY. Kaposi sarcoma presenting as a cutaneous horn. J Am Acad Dermatol 64(2):447-8, 2/2011. PMID: 21238839.
26. Matthias N, Lockworth CR, Zhang F, Lee MH, Yeung SC, Tsai KY, Hamir AN. Multiple cystic sweat gland tumors in transgenic mice. Comp Med 62(1):27-30, 2/2012. PMCID: PMC3276389.
27. Rangwala S, Tsai KY. Roles of the immune system in skin cancer. Br J Dermatol 165(5):953-65, 11/2011. PMCID: PMC3197980.
28. Su X, Gi YJ, Chakravarti D, Chan IL, Zhang A, Xia X, Tsai KY, Flores ER. TAp63 Is a Master Transcriptional Regulator of Lipid and Glucose Metabolism. Cell Metab 16(4):511-25, 10/2012. PMCID: PMC3483083.
29. Paliwal S, Hwang BH, Tsai KY, Mitragotri S. Diagnostic opportunities based on skin biomarkers. Eur J Pharm Sci 50(5):546-56, 12/2013. e-Pub 11/2012. PMID: 23159445.
30. Hwang BH, Doshi N, Tsai KY, Mitragotri S. A Reagent to Facilitate Protein Recovery from Cells and Tissues. Drug Deliv Transl Res 2(5):297, 10/2012.
31. Hwang BH, Tsai KY, Mitragotri S. Optimized lysis buffer reagents for solubilization and preservation of proteins from cells and tissues. Drug Deliv and Transl Res 3(5):428, 1/2013.
32. Tsai KY, Nowroozi S, Kim KB. Drug safety evaluation of vemurafenib in the treatment of melanoma. Expert Opin Drug Saf 12(5):767-75, 9/2013. e-Pub 6/2013. PMID: 23800008.
33. Curry JL, Torres-Cabala CA, Kim KB, Tetzlaff MT, Duvic M, Tsai KY, Hong DS, Prieto VG. Dermatologic toxicities to targeted cancer therapy: shared clinical and histologic adverse skin reactions. Int J Dermatol 53(3):376-84, 3/2014. e-Pub 7/2013. PMID: 23879247.
34. Vin H, Ching G, Ojeda SS, Adelmann CH, Chitsazzadeh V, Dwyer DW, Ma H, Ehrenreiter K, Baccarini M, Ruggieri R, Curry JL, Ciurea AM, Duvic M, Busaidy NL, Tannir NM, Tsai KY. Sorafenib suppresses JNK-dependent apoptosis through inhibition of ZAK. Mol Cancer Ther 13(1):221-229, 1/2014. e-Pub 10/2013. PMID: 24170769.
35. Vin H, Ojeda SS, Ching G, Leung ML, Chitsazzadeh V, Dwyer DW, Adelmann CH, Restrepo M, Richards KN, Stewart LR, Du L, Ferguson SB, Chakravarti D, Ehrenreiter K, Baccarini M, Ruggieri R, Curry JL, Kim KB, Ciurea AM, Duvic M, Prieto VG, Ullrich SE, Dalby KN, Flores ER, Tsai KY. BRAF inhibitors suppress apoptosis through off-target inhibition of JNK signaling. Elife 2(0):e00969, 2013. e-Pub 11/2013. PMCID: PMC3814616.
36. Pattanaprichakul P, Tetzlaff MT, Lapolla WJ, Torres-Cabala CA, Duvic M, Prieto VG, Tsai KY, Curry JL. Sweet syndrome following vemurafenib therapy for recurrent cholangiocarcinoma. J Cutan Pathol 41(3):326-8, 3/2014. e-Pub 12/2013. PMID: 24372055.
37. Chakravarti D, Su X, Cho MS, Bui NH, Coarfa C, Venkatanarayan A, Benham AL, Flores González RE, Alana J, Xiao W, Leung ML, Vin H, Chan IL, Aquino A, Müller N, Wang H, Cooney AJ, Parker-Thornburg J, Tsai KY, Gunaratne PH, Flores ER. Induced multipotency in adult keratinocytes through down-regulation of ?Np63 or DGCR8. Proc Natl Acad Sci U S A 111(5):E572-81, 2/2014. e-Pub 1/2014. PMCID: PMC3918754.
38. Ma Q, Li D, Carreño R, Patenia R, Tsai KY, Xydes-Smith M, Alousi AM, Champlin RE, Sale GE, Afshar-Kharghan V. Complement component C3 mediates Th1/Th17 polarization in human T-cell activation and cutaneous GVHD. Bone Marrow Transplant 49(7):972-6, 7/2014. e-Pub 4/2014. PMID: 24777193.
39. Curry JL, Tetzlaff MT, Nicholson K, Duvic M, Kim KB, Tsai KY, Hwu WJ, Hong DS, Prieto VG, Torres-Cabala CA. Histological features associated with vemurafenib-induced skin toxicities: examination of 141 cutaneous lesions biopsied during therapy. Am J Dermatopathol 36(7):557-61, 7/2014. PMID: 24950418.
40. Watson IR, Li L, Cabeceiras PK, Mahdavi M, Gutschner T, Genovese G, Wang G, Fang Z, Tepper JM, Stemke-Hale K, Tsai KY, Davies MA, Mills GB, Chin L. The RAC1 P29S Hotspot Mutation in Melanoma Confers Resistance to Pharmacological Inhibition of RAF. Cancer Res 74(17):4845-52, 9/2014. e-Pub 7/2014. PMCID: PMC4167745.
41. Pickering CR, Zhou JH, Lee JJ, Drummond JA, Peng SA, Saade RE, Tsai KY, Curry JL, Tetzlaff MT, Lai SY, Yu J, Muzny DM, Doddapaneni H, Shinbrot E, Covington KR, Zhang J, Seth S, Caulin C, Clayman GL, El-Naggar AK, Gibbs RA, Weber RS, Myers JN, Wheeler DA,

Frederick MJ. Mutational landscape of aggressive cutaneous squamous cell carcinoma. Clin Cancer Res 20(24):6582-92, 12/2014. e-Pub 10/2014. PMID: 25303977.
42. Venkatanarayan A, Raulji P, Norton W, Chakravarti D, Coarfa C, Su X, Sandur SK, Ramirez MS, Lee J, Kingsley CV, Sananikone EF, Rajapakshe K, Naff K, Parker-Thornburg J, Bankson JA, Tsai KY, Gunaratne PH, Flores ER. IAPP-driven metabolic reprogramming induces regression of p53-deficient tumours in vivo. Nature 517(7536):626-30, 1/2015. e-Pub 11/2014. PMCID: PMC4312210.
43. Fowler NH, Davis RE, Rawal S, Nastoupil L, Hagemeister FB, McLaughlin P, Kwak LW, Romaguera JE, Fanale MA, Fayad LE, Westin JR, Shah J, Orlowski RZ, Wang M, Turturro F, Oki Y, Claret LC, Feng L, Baladandayuthapani V, Muzzafar T, Tsai KY, Samaniego F, Neelapu SS. Safety and activity of lenalidomide and rituximab in untreated indolent lymphoma: an open-label, phase 2 trial. Lancet Oncol 15(12):1311-8, 11/2014. e-Pub 10/2014. PMID: 25439689.
44. Warthaka M, Adelmann CH, Kaoud TS, Edupuganti R, Yan C, Johnson WH, Ferguson S, Tavares CD, Pence LJ, Anslyn EV, Ren P, Tsai KY, Dalby KN. Quantification of a Pharmacodynamic ERK End Point in Melanoma Cell Lysates: Toward Personalized Precision Medicine. ACS Med Chem Lett 6(1):47-52, 1/2015. e-Pub 10/2014. PMCID: PMC4291693.
45. Cancer Genome Atlas Network. Genomic Classification of Cutaneous Melanoma. Cell 161(7):1681-96, 6/2015. PMID: 26091043.
46. Amaravadi RK, Hamilton KE, Ma X, Piao S, Portillo AD, Nathanson KL, Carlino MS, Long GV, Puzanov I, Xu X, Morrissette JJ, Tsai KY, Flaherty KT, Sosman JA, Goodman GR, McArthur GA, Rustgi AK, Metz DC, Schuchter LM, Chapman PB, Sepulveda AR. Multiple gastrointestinal polyps in patients treated with BRAF inhibitors. Clin Cancer Res 21(23):5215-21, 12/2015. e-Pub 7/2015. PMCID: PMC4668213.
47. Maresso KC, Tsai KY, Brown PH, Szabo E, Lippman S, Hawk ET. Molecular cancer prevention: Current status and future directions. CA Cancer J Clin 65(5):345-83, Sep-Oct, 9/2015. e-Pub 8/2015. PMID: 26284997.
48. Feldmeyer L, Ching G, Vin H, Ma W, Bansal V, Chitsazzadeh V, Jahan-Tigh R, Chu EY, Fuller P, Maiti S, Davis RE, Cooper LJ, Tsai KY. Differential T-cell subset representation in cutaneous squamous cell carcinoma arising in immunosuppressed versus immunocompetent individuals. Exp Dermatol 25(3):245-7, 3/2016. e-Pub 11/2015. PMID: 26475987.
49. Adelmann CH, Ching G, Du L, Saporito RC, Bansal V, Pence LJ, Liang R, Lee W, Tsai KY. Comparative profiles of BRAF inhibitors: the paradox index as a predictor of clinical toxicity. *Oncotarget* 2016 May 24;7(21):30453-60
50. Napoli M, Venkatanarayan A, Raujli P, Norton W, Mangala LS, Sood AK, Rodriguez-Aguayo C, Lopez-Berestein G, Tetzlaff M, Curry JL, Duvic M, Rook AH, Tsai KY, Coarfa C, Gunaratne PH, Flores ER. ΔNp63/DGCR8-dependent microRNAs mediate therapeutic efficacy of HDAC inhibitors in cancer. *Cancer Cell* 2016 Jun 13;29(6):874-88.
51. Adelmann CH, Truong KA, Liang RJ, Bansal V, Gandee L, Saporito RC, Lee W, Du L, Nicholas C, Napoli M, Mino B, South AP, Proby CM, Leigh IM, Coarfa C, Flores ER, Tsai KY. MEK Is a Therapeutic and Chemopreventative Target in Squamous Cell Carcinoma. *J Invest Dermatol.* 2016 Sep;136(9):1920-4
52. Chitsazzadeh V, Coarfa C, Drummond JA, Nguyen T, Joseph A, Chilukuri S, Charpiot E, Adelmann CH, Ching G, Nguyen TN, Nicholas C, Thomas VD, Migden M, MacFarlane D, Thompson E, Shen J, Takata Y, McNiece K, Polansky MA, Abbas HA, Rajapakshe K, Gower A, Spira A, Covington KR, Xiao W, Gunaratne P, Pickering C, Frederick M, Myers JN, Shen L, Yao H, Su X, Rapini RP, Wheeler DA, Hawk ET, Flores ER, Tsai KY. Cross-species identification of genomic drivers of squamous cell carcinoma development across preneoplastic intermediates. *Nat Commun*. 2016 Aug 30;7:12601.
53. Pant V, Xiong S, Chau G, Tsai K, Shetty G, Lozano G. Distinct downstream targets manifest p53-dependent pathologies in mice. *Oncogene*. 2016 Nov 3;35(44):5713-5721. doi: 10.1038/onc.2016.111.
54. Fiziev P, Akdemir KC, Miller JP, Keung EZ, Samant NS, Sharma S, Natale CA, Terranova CJ, Maitituoheti M, Amin SB, Martinez-Ledesma E, Dhamdhere M, Axelrad JB, Shah A, Cheng CS, Mahadeshwar H, Seth S, Barton MC, Protopopov A, **Tsai KY**, Davies MA, Garcia BA, Amit I, Chin L, Ernst J, Rai K. Systematic Epigenomic Analysis Reveals Chromatin

States Associated with Melanoma Progression. Cell Rep. 2017 Apr 25;19(4):875-889. doi: 0.1016/j.celrep.2017.03.078.

55. Ku AT, Shaver TM, Rao AS, Howard JM, Rodriguez CN, Miao Q, Garcia G, Le D, Yang D, Borowiak M, Cohen DN, Chitsazzadeh V, Diwan AH, **Tsai KY**, Nguyen H. TCF7L1 promotes skin tumorigenesis independently of β-catenin through induction of LCN2. Elife. 2017 May 3;6. pii: e23242. doi: 10.7554/eLife.23242.
56. Abbas H, Bao Bui NH, Rajapakshe K, Wong J, Gunaratne P, **Tsai KY**, Coarfa C, Flores ER. Distinct TP63 isoform-driven transcriptional signatures predict tumor progression and clinical outcomes. Cancer Res. 2017 Nov 27. pii: canres.1803.2017. doi: 10.1158/0008-5472.CAN-17-1803. PMID: 29180475
57. Campbell JD, … **Tsai KY**, … Cancer Genome Atlas Research Network, Stuart JM, Laird PW, Hoadley KA, Weinstein JN, Peto M, Pickering CR, Chen Z, Van Waes C. Genomic, Pathway Network, and Immunologic Features Distinguishing Squamous Carcinomas. Cell Rep. 2018 Apr 3;23(1):194-212.e6. doi: 10.1016/j.celrep.2018.03.063. PMID: 29617660
58. Cho RJ, Alexandrov LB…., **Tsai KY**, South AP. APOBEC mutation drives early-onset squamous cell carcinomas in recessive dystrophic epidermolysis bullosa. Sci Transl Med. 2018 Aug 22;10(455). pii: eaas9668. doi:10.1126/scitranslmed.aas9668. PubMed PMID: 30135250.

Invited Articles

1. Tsai KY. Assessing the treatment of nonmelanoma skin cancers. Arch Dermatol 147(5):605-6, 5/2011. PMID: 21576581.
2. Tsai KY. Introduction. Precision Medicine. Semin Cutan Med Surg 33(2):59, 6/2014. PMID: 25085662.
3. Tsai KY, Hawk ET. When "Effective" Prevention Agents Fail to Elicit Anticipated Effects: Challenges in Trial Design. Cancer Prev Res (Phila) 9(2):125-7, 2/2016. e-Pub 12/2015. PMID: 26714773.

Abstracts

1. Tsai KY, Carnevale NT, Claiborne BJ, Brown TH. Morphoelectrotonic transforms in three classes of rat hippocampal neurons. Society for Neuroscience Abstracts 19:1522, 1993.
2. Carnevale NT, Tsai KY, Gonzales R, Claiborne BJ, Brown TH. Biophysical accessibility of mossy fiber synapses in rat hippocampus. Society for Neuroscience Abstracts 20:715, 1994.
3. Carnevale NT, Tsai KY, Brown TH. Prediction of Hebbian learning in cells with biologically realistic electrotonic architecture. Society for Neuroscience Abstracts 21:604, 1995.
4. Carnevale NT, Tsai KY, Hines ML. The Electrotonic Workbench. Society for Neuroscience Abstracts 22:1741, 1996.
5. Dwyer DW, Leung ML, Thompson, TB, Tsai KY. Identification of mediators of immune evasion in a modular mouse model of squamous cell carcinoma. Journal of Investigative Dermatology 131(S1):S23, 4/2011.
6. Tsai KY, Vin H, Leung M, Chitsazzadeh V, Ojeda S, Dwyer D, Richards K, Stewart L, Curry J, Kim KB, Ciurea A, Duvic M, Prieto V, Ullrich S, Flores E. BRAF inhibitors suppress apoptosis through off-target inhibition of JNK signaling. J Clin Oncol 30(suppl; abstr 8537), 6/2012.
7. Vin H, Leung M, Ojeda S, Chitsazzadeh V, Dwyer D, Adelmann C, Ching G, Richards K, Stewart L, Ehrenreiter K, Baccarini M, Curry J, Kim K, Ciurea A, Duvic M, Prieto V, Ullrich S, Flores E, Tsai KY. BRAF inhibitors suppress apoptosis through off-target inhibition of JNK signaling. Journal of Investigative Dermatology 132(S1):S86, 6/2012.
8. Vin H, Leung M, Ojeda S, Chitsazzadeh V, Dwyer D, Adelmann C, Ching G, Richards K, Stewart L, Ehrenreiter K, Baccarini M, Curry J, Kim K, Ciurea A, Duvic M, Prieto V, Ullrich S, Flores E, Tsai KY. BRAF inhibitors suppress apoptosis through off-target inhibition of JNK signaling. Pigment Cell & Melanoma Research 26(5):895, 11/2012.
9. Chitsazzadeh V, Nguyen T, Joseph A, Gunaratne P, Coarfa C, Su X, Flores ER, Tsai KY. Identification and functional analysis of key genetic drivers of cutaneous squamous cell carcinoma. Journal of Investigative Dermatology 134(S1):S34, 5/2014.

10. Du L, Adelmann CH, Ching G, Chitsazzadeh V, Ojeda SS, Vin H, Kaoud T, Ferguson SB, Dalby KN, Tsai KY. Off-target effects of BRAF inhibitors: Roles in SCC induction and the relationship to paradoxical ERK signaling. Journal of Investigative Dermatolology 134(S1):S91, 5/2014.
11. Adelmann CH, Pence LJ, Warthaka M, Kaoud TS, Dalby KN, Tsai KY. Personalizing MAPK inhibitor therapy with a real-time ERK activity assay. AACR Precision Medicine Series Drug Sensitivity and Resistance: Improving Cancer Therapy 2014, 6/2014.

Book Chapters

1. Carnevale NT, Tsai KY, Claiborne BJ, Brown TH. Qualitative electrotonic comparison of three classes of hippocampal neurons in the rat. In: The Neurobiology of Computation. Ed(s) J Bower. Kluwer Academic Publishers: Norwell, MA, 1995.
2. Carnevale NT, Tsai KY, Claiborne BJ, Brown TH. The electrotonic transformation: a tool for relating neuronal form to function. In: Advances in Neural Information Processing Systems 7. Ed(s) G Tesauro, DS Touretzky, TK Leen. MIT Press: Cambridge, MA, 69-76, 1995.
3. Tsai KY, Hoang MP. Collision tumor of malignant melanoma and monocytic sarcoma. In: Cases in Dermatopathology - Pitfalls in Dermatopathology. Ed(s) Hoang MP, Duncan LM, Mihm Jr. MC, Murphy GM, Tahan SR. Knowledge Books & Software: Brisbane, QLD, Australia, 119-128, 2008.
4. Tsai KY. Lymphatic Tumours. In: Rook's Textbook of Dermatology, 9. Ed(s) T Bleiker, H Tsao. In Press.

Letters to the Editor

1. Tsai KY. A potential pathogenic role for aberrant DNA rearrangements in bridging dyscrasias of undetermined significance and lymphoma? Arch Dermatol 141(11):1468-9, 11/2005. PMID: 16301403.

EDITORIAL AND REVIEW ACTIVITIES

Editor/Service on Editorial Board(s)

Associate Editor, Journal Watch Dermatology, New England Journal of Medicine, Associate editor of basic science. Responsible for surveillance of literature and writing summaries. 2010-2016

Member of Editorial Review Board

Member, Editorial Board, Cancer Research, 2016-present

Member, Editorial Board, Journal of the American Academy of Dermatology, 2013-present

Journal Reviewer

Reviewer, British Journal of Dermatology, 2005-present

Reviewer, Archives of Dermatology, 2007-present

Reviewer, Journal of the American Academy of Dermatology, Elsevier, 2008-present

Reviewer, Cancer Research, 2011-present

Reviewer, Journal of Investigative Dermatology, 2011-present

Reviewer, Cancer Prevention Research, 2012-present

Reviewer, Journal of Clinical Oncology Precision Oncology, 2017-present

Reviewer, Journal of Controlled Release, 2012-present

Reviewer, Journal of Clinical Investigation, 2013-present

Reviewer, Molecular Cancer Research, 2013-present

Reviewer, The Oncologist, 2014-present

Reviewer, Oncotarget, 2015-present

Reviewer, Proceedings of the National Academy of Sciences, USA, 2015-present

Reviewer, Science Signaling, 2015-present

Other Editorial and Review Activities

Guest Editor, Seminars in Cutaneous Biology and Surgery, Guest Editor for Issue on Precision Medicine and Precision Therapeutics, 2013-2014

TEACHING

Teaching Within Current Institution – H. Lee Moffitt Cancer Center

Formal Teaching

Courses Taught

Lecturer, Cancer Biology I
Fall, 9/2017, 9/2018

Supervisory Teaching

Committees

Supervisory Committees

Genes & Development (Moffitt / MD Anderson), Andrew J. Davis

Examining Committees

USF Cancer Biology 10/2018 (Maclean Hall, Sae Bom Lee, Neel Jasani)

Direct Supervision

Graduate Students

Thesis Advisor, GSBS, Tran N. Nguyen, PhD, 3/2014-9/2018

Clinical Residents and Fellows

Attending Physician, Moffitt Cancer Center, Maria Deschaines, MD, 9/2016-6/2017

Attending Physician, Moffitt Cancer Center, Julie Gibbs, MD, 9/2017-6/2018

Attending Physician, Moffitt Cancer Center, Sophia Ma, MD, 9/2018-6/2019

Teaching at The University of Texas MD Anderson Cancer Center

Formal Teaching

Courses Taught

Lecturer, Fundamentals Mechanisms of Cancer Development, Course Number: GS04 0223, Course Hours: 4
Fall, 9/2011-9/2014

Lecturer, Molecular Biology of Eukaryotic Cells, Course Number: GS040123, Course Hours: 2
1/2012-5/2014

Lecturer, Cancer Biology, Course Hours: 2
2/2015-present

Supervisory Teaching

Committees

Supervisory Committees

Genes & Development, GSBS, Minsoon Cho

Immunology, Radhika Thokala, PhD

MD/PhD Program, Ramon Flores, MD/PhD

Immunology, Stephanie Dorta-Estremera, PhD

Genes & Development, Marco Leung, PhD

Cancer Biology, Simin Kiany, PhD

Genes & Development, Avinashnarayan Venkatanarayan

MD/PhD Program, Adam Wolfe

Human & Molecular Genetics, Uyen Le

Genes & Development, Andrew J. Davis

MD/PhD Program, Sarah Wu

MD/PhD, Pushan Dasgupta

Committee Member, GSBS, Hui-Ju Hsieh

Committee Member, Human & Molecular Genetics, Ruoji Zhou

Examining Committees

Thesis Defense, Immunology, Jahan Khalili

David Savage, MD/PhD Program

GSBS, Iman Doostan

Direct Supervision

Undergraduate and Allied Health Students

Research Mentor, Rice University Century Scholars Program, Harina Vin, 9/2009-6/2011

Research Mentor, Molecular Genetic Technology Program, Ibtesama Baig, BS, 9/2011-2/2012

Research Mentor, Rice University Century Scholars Program, Charles Adelmann, 10/2011-8/2015

Research Mentor, Lindy Pence, CPRIT / CURE, 6/2013-8/2013

Medical Students

Research Mentor, Baylor College of Medicine, Larissa Stewart, MD, 1/2011-6/2011

Graduate Students

Thesis Advisor, Vida Chitsazzadeh, PhD, 11/2011-7/2014

Research Rotation Mentor, Grant Fischer, MD, PhD, 6/2013-8/2013

Thesis Mentor, GSBS, Tran N. Nguyen, PhD, 3/2014-present

Postdoctoral Research Fellows

Research Mentor, Sandra Ojeda, PhD, 10/2011-9/2012

Research Mentor, Lili Du, PhD, 7/2013-8/2016

Research Mentor, Courtney Nicholas, PhD, 4/2014-6/2015

Clinical Residents and Fellows

Attending Physician, UT Dermatopathology Fellowship Program, University of Texas Health Sciences Center - Houston, Valencia D. Thomas, MD, 7/2008-6/2009

Attending Physician, Dermatology Residency Program, The University of Texas MD Anderson Cancer Center and Houston Health Sciences Center, Dermatology Residents, 7/2008-present

UT Dermatopathology Fellowship Program, Kim Whisenant, MD, 7/2009-6/2010

Attending Physician, UT Dermatopathology Fellowship, University of Texas Health Sciences Center - Houston, Scott D. Bangert, MD, 7/2010-6/2011

Attending Physician, UT Dermatopathology Fellowship, University of Texas Health Sciences Center - Houston, Sarah Galfione, MD, 7/2011-6/2012

Attending Physician, UT Dermatopathology Fellowship, University of Texas Health Sciences Center - Houston, Daryl Sulit, MD, 7/2012-6/2013

Attending Physician, UT Dermatopathology Fellowship, University of Texas Health Sciences Center - Houston, Julia Kauffman, MD, 7/2012-6/2013

Attending Physician, UT Dermatopathology Fellowship, Meghan Abuzeid, MD, 7/2013-6/2014

Attending Physician, UT Dermatopathology Fellowship, Richard Jahan-Tigh, MD, 7/2013-6/2014

Research Mentor, Swiss Cancer League, Laurence Feldmeyer, MD, 6/2014-6/2015

Attending Physician, UT Dermatopathology Fellowship, Andrea Haws, MD, 7/2014-6/2015

Attending Physician, UT Dermatopathology Fellowship, Kevin Krauland, MD, 7/2015-6/2016

Teaching Outside Current Institution

Formal Teaching

Courses Taught

Teaching Assistant, Introductory Biology, Massachusetts Institute of Technology, Course Number: 7.014
Spring, 2/1997-5/1997

Teaching Assistant, General Immunology, Massachusetts Institute of Technology, Course Number: 7.23
Fall, 9/1997-12/1997

Training Programs

Lecturer, Dermatology Residency Program, University of Texas Health Sciences Center / Baylor
7/2008-8/2016

Supervisory Teaching

Committees

Direct Supervision

Undergraduate and Allied Health Students

Non-Resident Tutor in Physics, Dunster House, Harvard College, Undergraduates, Harvard College, 9/1996-6/1997

Resident Tutor in Physics, Dunster House, Harvard College, Undergraduates, Harvard College, 9/1997-6/2001

CONFERENCES AND SYMPOSIA

Organization of Conferences/Symposia (Include chairing session)

Texas Dermatological Society, Texas Dermatological Society, Houston, TX, Chair, 5/2011

Presentations at National or International Conferences

Invited

Tsai KY. Molecular Classification of Melanoma, American Academy of Dermatology Annual Meeting, San Francisco, CA, 3/10/2009

Tsai, KY. Molecular Classification of Melanoma, American Academy of Dermatology Annual Meeting, Miami, FL, 3/6/2010

Molecular Classification of Melanoma, American Academy of Dermatology Annual Meeting, New Orleans, LA, 2/8/2011

Pathology Babble: What does my DERMATOPATHOLOGIST Mean?, American Society of Dermatologic Surgery, Washington, DC, 11/3/2011

Journal Watching : Genetics and Genomics in Dermatology, American Academy of Dermatology Annual Meeting, San Diego, CA, 3/17/2012

Tsai KY. BRAF inhibitors suppress apoptosis through off-target inhibition of JNK signaling, Research in Cutaneous Surgery Minisymposium, Society of Investigative Dermatology, Raleigh, NC, 5/10/2012

Journal Watching, American Academy of Dermatology Annual Meeting, Miami, FL, 3/3/2013

Journal Watching, American Academy of Dermatology Annual Meeting, Denver, CO, 3/24/2014

New and Emerging Therapeutics, American Academy of Dermatology Annual Meeting, Denver, CO, 3/24/2014

Genomics of Squamous Cell Carcinoma Development, International Transplant Skin Cancer Collaborative, Essex, MA, 10/18/2014

Journal Watching, American Academy of Dermatology Annual Meeting, San Francisco, CA, 3/20/2015

Skin & Systemic Malignancy, American Academy of Dermatology Annual Meeting, San Francisco, CA, 3/21/2015

Journal Watching, American Academy of Dermatology Annual Meeting, Washington, DC, 3/5/2016

Novel Therapies for Squamous Cell Carcinoma, American Academy of Dermatology Annual Meeting, Washington, DC, 3/5/2016

Skin and Systemic Disease, American Academy of Dermatology Annual Meeting, Washington, DC, 3/6/2016

Genomics of High-Risk SCC, American Academy of Dermatology Annual Meeting, Washington, DC, 3/7/2016

MOC-D Skin Cancer, American Academy of Dermatology, Washington, DC, 3/6/2016

Genomics and the Microenvironment of Skin Cancers, Clinical Research Scholars Session, Society for Investigative Dermatology Annual Meeting, Phoenix, AZ, 5/14/2016

The Microenvironment of Skin Cancers, Kansas Society of Dermatology & Dermatologic Surgery Annual Meeting, Kansas, KS, 8/27/2016

Genomics of Cutaneous Squamous Cell Carcinoma: Implications Cancer Development for Therapy, Kansas Society of Dermatology & Dermatologic Surgery Annual Meeting, Kansas, KS, 8/27/2016

STAMP: Surfactant-mediated Tissue Acquisition for Molecular Profiling (STAMP): Applications in Skin and Skin Cancer, Integrated Molecular Analysis Technologies (IMAT) NCI PI Meeting, 12/2/2016

Genomic analysis reveals drivers of high-risk subsets of cutaneous squamous cell carcinoma, Society for Investigative Dermatology Annual Meeting, Portland, OR, 4/27-28/2017

A cohort of miRNAs can be used as an early predictive biomarker of UV-driven cutaneous squamous cell carcinoma, Society for Investigative Dermatology Annual Meeting, Portland, OR, 4/29/2017

UV-Induced Somatic Mosaicism as a Marker of Skin Cancer Risk, Barrier Function of Mammalian Skin, Gordon Conference 2017, 8/14/2017

STAMP: Surfactant-mediated Tissue Acquisition for Molecular Profiling (STAMP): Applications in Skin and Skin Cancer, Integrated Molecular Analysis Technologies (IMAT) NCI PI Meeting, 12/7/2017

The Applied –Omics of Cutaneous Squamous Cell Carcinoma, 13th International Skin Carcinogenesis Conference, Austin, TX, 10/30/2018

Other, Including Scientific Exhibitions

ARF is not required for apoptosis in Rb-deficient embryos., Gordon Research Conferences, RI, 1999

Loss of p19ARF fails to suppress apoptosis in Rb mutant embryos but cooperates with loss of Rb in pituitary tumorigenesis., Cancer Genetics & Tumor Suppressor Genes Meeting, Cold Spring Harbor Laboratories, Cold Spring Harbor, NY, 2000

Leung, ML. Vemurafenib / PLX4720 suppresses apotposis by inhibition of JNK signaling, Oregon Health & Science University, Montagna Symposium on the Biology of the Skin, Portland, OR, 10/14/2011

BRAF inhibitors suppress apoptosis through off-target inhibition of JNK signaling, American Society of Clinical Oncology Annual Meeting, Chicago, IL, 6/3/2012

Functional Genomic Characterization of Cutaneous Squamous Cell Carcinoma Progression, Society of Investigative Dermatology Annual Meeting, Albuquerque, NM, 5/8/2014

MEK is a therapeutic and chemopreventative target in squamous cell carcinoma, Society for Investigative Dermatology Annual Meeting, Phoenix, AZ, 5/13/2016

Genomics of Cutaneous Squamous Cell Carcinoma Development: Implications for Prevention, KeraCon-IDEA Joint Conference, Denver, CO, 9/29/2016

Seminar Invitations from Other Institutions

Immunosurveillance in Skin Cancer, University of Pennsylvania School of Medicine, Dermatology, Philadelphia, PA, 2/22/2011

Pharmacologic BRAF Inhibition by PLX4720 / Vemurafenib: Novel Off-Target Effects and Mechanisms of Resistance, Indiana University, Dermatology, Indianapolis, IN, 8/17/2011

Genomics of Cutaneous Squamous Cell Carcinoma Progression, University of Massachusetts Medical Center, Dermatology, Worcester, MA, 4/20/2012

BRAF Inhibitors: Novel Off-target Effects & Mechanisms of Adverse Effects, Wistar Institute, Philadelphia, PA, 1/8/2013

BRAF Inhibitors: Novel Off-target Effects & Mechanisms of Adverse Effects, University of Pennsylvania, Dermatology, Philadelphia, PA, 1/8/2013

Cutaneous Squamous Cell Carcinoma: Lessons from BRAF Inhibitors and Insights from Genomics, Thomas Jefferson University, Dermatology, Philadelphia, PA, 12/18/2013

Cutaneous Squamous Cell Carcinoma: Lessons from BRAF Inhibitors and Insights from Genomics, Massachusetts General Hospital, Pathology, Boston, MA, 4/4/2014

Towards a New Paradigm of Chemoprevention: The Genomics of Cutaneous Squamous Cell Carcinoma Development, University of Arizona Cancer Center, Cancer Prevention and Control Program, Tucson, AZ, 4/9/2014

Cutaneous Squamous Cell Carcinoma: Lessons from BRAF Inhibitors and Insights from Genomics, Boston University, Dermatology, Boston, MA, 5/23/2014

Cutaneous Squamous Cell Carcinoma: Lessons from BRAF Inhibitors and Insights from Genomics, Massachusetts Institute of Technology, Koch Institute for Integrative Cancer Research, Cambridge, MA, 8/1/2014

Cutaneous Squamous Cell Carcinoma: Lessons from BRAF Inhibitors and Insights from Genomics, Moffitt Cancer Center, Tampa, FL, 7/13/2015

Genomics of Cutaneous Squamous Cell Carcinoma Development: Implications for Prevention and Therapy, Dept of Dermatology University of California San Francisco, CA, 10/12/2016

The Applied Genomics of Cutaneous Squamous Cell Carcinoma, Department of Dermatology / Gates Center for Regenerative Medicine, University of Colorado, CO, 4/24/2018

Dissection of Kinase Drivers in Skin Cancer, Division of Chemical Biology & Medicinal Chemistry, University of Texas, Austin, TX, 11/01/2018

Other Presentations at State and Local Conferences

Tsai KY. Immunology of Skin Cancer, Grand Rounds, Internal Medicine and Cancer Survivorship, M.D. Anderson Cancer Center, Internal Medicine, Houston, TX, 1/16/2009

Tsai KY. Immunology of Skin Cancer, Immunology of Skin Cancer, Internal Medicine and Cancer Survivorship, M.D. Anderson Cancer Center, Houston, TX, 5/28/2010

Mechanisms of Keratinocytic Tumor Growth in Mutant BRAF- Inhibitor Treated Patients, Melanoma and Skin Cancer Research Seminar, MD Anderson Cancer Center, Houston, TX, 4/18/2011

Pharmacologic BRAF Inhibition by PLX4720 / Vemurafenib: Novel Off-Target Effects and Mechanisms of Resistance, Internal Medicine and Cancer Survivorship, MD Anderson Cancer Center, Houston, TX, 6/10/2011

Pharmacologic BRAF Inhibition by PLX4720 / Vemurafenib: Novel Off-Target Effects and Mechanisms of Resistance, Center for Cancer Immunology Research, MD Anderson Cancer Center, Houston, TX, 11/7/2011

The Dermatopathology of Melanoma: Everything You Always Wanted To Know But Were Afraid To Ask, Melanoma Medical Oncology Grand Rounds, MD Anderson Cancer Center, Melanoma Medical Oncology, Houston, TX, 11/28/2011

Non-melanoma Skin Cancer Research Retreat: New Targets, Head & Neck Surgery Retreat, MD Anderson Cancer Center, Head & Neck Surgery, Houston, TX, 12/2/2011

Integrated Genomic Analysis of Cutaneous Squamous Cell Carcinoma Progression, Cancer Prevention Grand Rounds, MD Anderson Cancer Center, Houston, TX, 2/7/2013

Integrated Genomic Analysis of Cutaneous Squamous Cell Carcinoma Progression, Internal Medicine and Cancer Survivorship, MD Anderson Cancer Center, Houston, TX, 3/15/2013

Genomic Analysis of Cutaneous Squamous Cell Carcinoma Progression, Cancer Prevention and Control Workshop, Global Academic Programs, MD Anderson Cancer Center, Houston, TX, 4/5/2013

Cutaneous Squamous Cell Carcinoma: Lessons from BRAF Inhibitors and Insights from Genomics, Thoracic, Head & Neck Oncology Research Seminar, MD Anderson Cancer Center, Houston, TX, 8/19/2014

Genomics of Cutaneous Squamous Cell Carcinoma Development: Implications for Prevention and Therapy, Tumor Biology Departmental Retreat, Moffitt Cancer Center, Tampa, FL, 12/7/2016

Public Service Presentations and Fundraising Activities

Morning Blend (ABC 28) - National Skin Cancer Detection and Prevention Month, Tampa, FL, 5/9/2017

Moffitt Cancer Center Sarasota Luncheon, Sarasota, FL, 11/1/2017

FOX 13 – Melanoma Monday, Tampa, FL, 5/7/2018

PROFESSIONAL MEMBERSHIPS/ACTIVITIES

Professional Society Activities, with Offices Held

National and International

American Academy of Dermatology, Schaumberg, IL
Basic Science Curriculum Committee, 12/2007

American Academy of Dermatology, Schaumberg, IL
Fellow, 7/2008-present

Society for Investigative Dermatology, Cleveland, OH
Member, 7/2009-present

American Academy of Dermatology - Academic Dermatology Leadership Program, Schaumberg, IL
Member, 12/2010-8/2011

American Society of Clinical Oncology, Alexandria, VA
Member, 10/2011-present

American Joint Committee on Cancer (AJCC) - Non-Melanoma Skin Expert Panel
Member, 2/2014-2/2015

American Society of Dermatopathology, Deerfield, IL
Fellow, 7/2014-present

American Academy of Dermatology - Melanoma Advisory Task Force, Schaumberg, IL
Member, 3/2015-7/2016

American Academy of Dermatology Task Force on Skin Cancer Screening
Member, 10/2015-7/2016

American Board of Dermatology Science & Research Content Development Committee
Member, 3/2017-present

Society for Investigative Dermatology Scientific Programs Committee
Member, 5/2018-5/2023

International Transplant Skin Cancer Collective, Research Committee Chair, 3/2018-present

Dermatology Foundation
Medical and Scientific Review Committee, 2/2019-2/2021

DATE OF LAST CV UPDATE: 11/28/2018

Susan Vadaparampil, PhD

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: Susan Thomas Vadaparampil, PhD

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

POSITION TITLE: Senior Member/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 Florida, Gainesville, FL	B.S.	05/1995	Health Science Education
University of Florida, Gainesville, FL	M.H.S.E.	12/1996	Public Health Education
Indiana University, Bloomington, IN	Ph.D.	05/2000	Health Behavior
John Hopkins University, Baltimore, MD	M.P.H.	05/2001	Epidemiology
National Cancer Institute (NCI), Bethesda, MC	Post-Doctor	08/2003	Cancer Prevention

A. Personal Statement

The focus of my research has been to accelerate the adoption of cancer prevention and control interventions into the clinic and community. My research program applies behavioral science, epidemiology, health services, and clinical perspectives to genetic counseling and testing for hereditary cancer, human papillomavirus vaccination, and reproductive health. Each line of research has been consistently supported with extramural funding, influenced by transdisciplinary collaboration, and generated contributions to the scientific literature and clinical practice. I have led R01 and R01-equivalent grants from federal, foundation, and state agencies. I have published 200 peer reviewed manuscripts and served as a standing member of multiple national peer review committees focused on cancer prevention and control. I have worked with diverse populations with regard to age, gender, race/ethnicity, health literacy, and socioeconomic status. Throughout my career, I have infused community collaboration and health equity as key areas of emphasis in my work. I also have leveraged my research expertise and community partnerships to accelerate adoption of evidence based guidelines among community based providers and educators.

As Associate Center Director, I have primary responsibility for overseeing the CCSG Community Outreach and Engagement (COE) Office. I work closely with community partners and Program Leaders in the Divisions of Population and Basic Science to develop shared COE vision, goals, and metrics to measure impact of Moffitt research within our catchment area. The COE office continually monitors and prioritizes catchment area needs, oversees tracking practices and data collection of COE activities, enhances and extends community partnerships that facilitate research, and fosters community engaged research to address the needs of the catchment area.

B. Positions and Honors

Positions

2003-2008 Assistant Member, Moffitt Cancer Center, Tampa, FL
2003-2008 Assistant Professor, Department of Oncologic Sciences, College of Medicine, University of South Florida, Tampa, FL
2005-2008 Assistant Professor (joint appointment), Department of Family and Community Health, College of Public Health, University of South Florida, Tampa, FL
2009-2014 Associate Professor, Department of Oncologic Science, College of Medicine, University of

South Florida, Tampa, FL

2009-2014 Associate Professor (joint appointment), Department of Family and Community Health, College of Public Health, University of South Florida, Tampa, FL

2009-2014 Associate Member, Moffitt Cancer Center, Tampa, FL

2014- Professor, Department of Oncologic Science, College of Medicine, University of South Florida, Tampa, FL

2014- Professor (joint appointment), Department of Family and Community Health, College of Public Health, University of South Florida, Tampa, FL

2014- Senior Member, Moffitt Cancer Center, Tampa, FL

2016-2018 Vice Chair, Health Outcomes and Behavior Program, Moffitt Cancer Center, Tampa, FL

2018- Associate Center Director, Community Outreach & Engagement, Moffitt Cancer Center, Tampa, FL

Honors

Membership in Peer Review Committees

2014-2017 Charter Member and Chair, Cancer Control and Prevention: Psychosocial and Behavioral Research Peer Review Committee, American Cancer Society

2011-2015 Charter Member, CLHP Study Section Review Group, National Institutes of Health

Membership on Editorial Boards

2015-2018 Member, Journal of Clinical Oncology Editorial Board

2008- Member, PDQ Cancer Genetics Editorial Board, National Cancer Institute

Other Honors

2008 Hiroomi Kawano New Investigator Award, International Psycho-Oncology Society

2009 Outstanding Young Alumnus Award, University of Florida, Gainesville, FL

2010 National Institutes of Health Merit Award (Group), for service on NCI PDQ in Cancer Genetics

2009-2013 National Institutes of Health Clinical Loan Repayment Program, NCI

2013 Research Mentor of the Year, Moffitt Cancer Center, Tampa, FL

C. Contributions to Science

1. **Reducing Disparities in Genetic Counseling and Testing in Minority Communities**. Over the past decade, I have worked on multiple projects to understand key barriers and facilitators to uptake of genetic counseling in Hispanic and Black communities This body of work has been critical towards informing the intervention targets proposed in the current study related to awareness, language, and access. Of particular note, my work has examined the important role of sub-ethnicity, language, and culture to better identify and tailor interventions to address the unique needs of minority communities.
    a. Gonzalez BD, Hoogland AI, Kasting ML, Cragun D, Kim J, Ashing K, Holt CL, Hughes Halbert C, Pal T, **Vadaparampil ST**. (2018). Psychosocial Impact of BRCA Testing in Young Black Breast Cancer Survivors. Pyshco Oncology, Sep 12 [Epub ahead of print]. PMID: 30207419.
    b. **Vadaparampil ST**, Malo T, Nam K, Nelson A, de la Cruz C, Quinn GP. (2014). From Observation to Intervention: Development of a Psychoeducational Intervention to Increase Uptake of BRCA Genetic Counseling among High-Risk Breast Cancer Survivors. Journal of Cancer Education, 29(4):709-19. PMID:24706196. PMCID:PMC4532283.
    c. Mai PL, **Vadaparampil ST**, Breen N, McNeel TS, Wideroff L, Graubard BI. (2014). Awareness of Cancer Susceptibility Genetic Testing: the 2000, 2005, 2010 National Health Interview Surveys. American Journal of Preventive Medicine, 46(5):440-8. PMID: 24745633. PMCID:PMC4042677.
    d. Quinn GP, McIntyre J, **Vadaparampil ST**. (2011). Preferences for Hereditary Breast and Ovarian Cancer Information among Mexican, Cuban and Puerto Rican Women at Risk. Public Health Genomics, 14(4-5): 248-58. PMID: 20150724. PMCID: PMC3136388.

2. **Improving Uptake of HPV Vaccination**. I was among the first researchers to document, on a national and state level, the low and stagnant physician recommendation of HPV vaccination rates in the first five years post-FDA licensure and ACIP guidelines. Prior to this work, the vast majority of studies focused on hypothetical scenarios of recommendation before clinical availability of the vaccine. Notably, response rates range from 50% to 68%, among the highest for physician surveys, lending the generalizability of study findings. In addition to scientific publications, this work has garnered national attention and been featured in major news outlets including the Wall Street Journal and U.S. News and World Report and cited in the President's Cancer Panel Advisory Report on HPV vaccination.

a. Kasting ML, Christy SM, Sutton S, Lake P, Malo TL, Roetzheim RG, Schechtman T, Zimet GD, Walkosz BJ, Salmon DA, Kahn JA, Giuliano AR, **Vadaparampil ST**. (2018). Florida Physicians' Reported use of AFIX-Based Strategies for Human Papillomavirus Vaccination, accepted, American Journal of Preventive Medicine.* pii: S0091-7435(18)30282-2. doi: 10.1016/j.ypmed.2018.09.004. [Epub ahead of print]. PMID: 30219689.
b. **Vadaparampil ST**, Malo TM, Sutton SK, Ali KN, Kahn J, Casler A, Salmon D, Walkosz B, Roetzheim G, Zimet G, Giuliano AR. (2016). Missing the Target for Routine Human Papillomavirus Vaccination: Consistent and Strong Physician Recommendations are Lacking for 11-12 Year Old Males. Cancer Epidemiology Biomarkers and Prevention. Oct 25(10):1435-1446. PMID: 27486020. PMCID: PMC505012.
c. **Vadaparampil ST**, Malo TL, Kahn JA, Salmon D, Lee JH, Quinn GP, Roetzheim R, Bruder KL, Proveaux T, Halsey N, Giuliano AR. Physicians' HPV Vaccine Recommendations at Three and Five Years Post-Licensure. (2014). American Journal of Preventive Medicine, 46(1):80-4. PMID: 24355675. PMCID: PMC3895928.
d. **Vadaparampil ST**, Staras SAS, Malo TL, Eddleton KZ, Christie J, Rodriguez M, Giuliano AR, Shenkman EA. (2013). Provider Factors Associated with Disparities in Human Papillomavirus Vaccination among Low-Income 9- to 17-Year-Old Girls. Cancer, 119(3):621-8. PMID: 23341308. PMCID: PMC3800018.

3. **Outreach and Education in the Minority Communities**. An integral component of my research program has been engagement in minority communities to address cancer prevention needs through research, outreach and education. I have used a variety of approaches including community advisory panels for specific studies, community advisory boards to guide larger research initiatives, and innovative strategies for engagement and community education.
   a. Scherr CL, Bomboka L, Nelson A, Pal T, **Vadaparampil ST**. (2017). Tracking the dissemination of a culturally targeted brochure to promote awareness of hereditary breast and ovarian cancer among Black women. Patient Education and Counseling. 100(5):805-811. PMID: 27866793. PMCID: PMC5400706.
   b. **Vadaparampil ST**, Simmons VN, Lee J-H, Malo T, Klasko L, Rodriguez M, Waddell R, Gwede CK, Meade CD. (2014). Journal Clubs: An Educational Approach to Advance Understanding among Community Partners and Academic Researchers about CBPR and Cancer Health Disparities. Journal of Cancer Education. Mar; 29(1):122-8. PMID: 24078328. PMCID: PMC4201936.
   c. Gwede CK, Castro E, Brandon TH, McIntyre J, Meade CD, Munoz-Antonia T, Simmons VN, **Vadaparampil ST**, Jimenez J, Quinn GP. (2012). Developing Strategies for Reducing Cancer Disparities via Cross-Institutional Collaboration: Outreach Efforts for the Partnership between the Ponce School of Medicine and the Moffitt Cancer Center. Health Promotion Practice. 13(6):807-15. PMID: 22167362. PMCID: PMC3708698.
   d. Simmons VN, Jimenez JC, Castro E, Litvin EB, Gwede CK, **Vadaparampil ST**, McIntyre J, Meade CD, Brandon TH, & Quinn, G .P. (2011). Initial Efforts in Community Engagement with Health Care Providers: Perceptions of Barriers to Care for Cancer Patients in Puerto Rico. Puerto Rico Health Sciences Journal. 30(1):28-34. PMID: 21449495. PMCID: PMC3685431.

4. **Development of Training Curricula in Cancer Prevention and Control.** Our team has developed and delivered numerous innovative training programs focused on various aspects of cancer prevention and control for researchers, health care providers, and public health professinals. We have contributed to the literature by sharing findings and also disseminating our training using technology and collaborative approaches that extend beyond our cancer center and local catchment area.
   a. Kasting ML, Scherr CL, Ali KN, Lake P, Malo TL, Johns T, Roetzheim RG, Quinn GP, **Vadaparampil ST.** (2017) HPV Vaccination Training Experience Among Family Medicine Residents and Faculty. Fam Med. 2017 Oct; 49: (9) 714-722 PMID: 29045989. PMCID:PMC5801740.
   b. Rivera YM, Moreno L, Briant KJ, Vélez H, Jiménez JC, Torres J, **Vadaparampil ST**, Muñoz-Antonia T, Quinn GP. (2016). Developing Sustainable Cancer Education Programs: Training Public Health Students to Deliver Cancer 101 in Puerto Rico. J Cancer Educ. 31(4):776-783. PMID: 27424481. PMCID:PMC5243927.
   c. **Vadaparampil ST**, Gwede CK, Meade C, Kelvin J, Reich RR, Reinecke J, Bowman M, Sehovic I, Quinn GP. (2016) ENRICH: A Promising Oncology Nurse Training Program to Implement ASCO Clinical Practice Guidelines on Fertility for AYA Cancer Patients. Patient Educ Couns 2016

Nov;99(11):1907-1910. pii: S0738-3991(16)30211-7. PMID: 27241831. PMCID:PMC5069115. IF: 2.199.

Full list of published works:
https://www.ncbi.nlm.nih.gov/labs/bibliography/susan.vadaparampil.1/bibliography/public/

D. Research Support

1R25CA217723 Graves-Georgetown/Vadaparampil-MCC, MPI's 08/01/2017–07/31/2022
*Programa de ARBOLES Familiares: **A**ssessing **R**isk of **B**reast Cancer through **O**utreach to **L**atinas with **E**ducation and **S**upport*
The major goal of this study is to 1) Refine and finalize a cancer genetic HBOC education curriculum for bilingual (Spanish-English) community outreach and education professionals (CORE-P). 2) Implement the ARBOLES Familiares training among 250 bilingual Spanish-English CORE-P using an in-person workshop followed by online and telephone supported learning. 3) Identify the impact of the ARBOLES Familiares on participants' knowledge, self-efficacy, skills and community impact among high-risk Latinas.

#17110601 Vadaparampil, Site PI 07/01/2017 – 06/30/2022
1R01 CA204819 Subaward from Vanderbilt University/NIH Prime (Pal, PI)
Breast Cancer In Blacks: Impact of Genomics, Healthcare Use and Lifestyle on Outcomes (BRIGHT)
Goals: The goals of this proposal are 1) assess the contribution of biologic and non-biologic factors on high mortality rates observed among young Black women with BC and generate a risk score, to help identify those at risk for poorer outcomes, and 2) investigate molecular features of the subgroup with TNBC.
Role in the study: Co-Investigator/Site PI

2U54 CA163068 Wright/Sullivan, MPI's 09/25/2017-08/31/2022
NIH/NCI
Ponce School of Medicine - Moffitt Cancer Center Partnership (2/2)
The goal of the PHSU-MCC Partnership is to further grow and engage faculty and students in cancer precision medicine research that directly impacts the Hispanic/Latino populations in Florida and Southwest Puerto Rico.
Role: Co-Leader, Outreach Core; Co-Investigator, Full Research Project 1; Co-Investigator, Research Education Core

2R25 CA142519 Vadaparampil/Quinn MPIs 09/01/2016–08/31/2021
NIH/NCI
***E**nriching **C**ommunication Skills for **H**ealth Professionals in **O**ncofertility (ECHO)*
The goals of this training program are to develop a national group of trained oncology allied health care professionals (AHPs) who are able to address the unique reproductive health issues faced by Adolescent and Young Adult (AYA) oncology patients through improved knowledge and communication skills.

R25CA090314 Brandon, PI 09/01/2014 –08/31/2019
Behavioral Oncology Education and Career Development
The goal of this program is to train post-doctoral fellows to become successful independent investigators in behavioral oncology.
Role: Associate Director

RSG 14-162-01-CPHPS Kanetsky PI 01/01/2015–12/31/2019
American Cancer Society
Using MC1R Genotype to Impact Melanoma Risk Behavior
This project seeks to evaluate the impact of receipt of MC1R genotype on 1) personal sun protection behaviors and 2) skin awareness and examination. Results will help inform whether targeted genetic screening to a subgroup of the general population without traditional clinical risk factors for melanoma can positively influence risk behaviors associated with melanoma.
Role: Co-Investigator

1R21 CA201827 O'Neill, PI 07/01/2016–06/30/2019
Georgetown University/NIH
A Question Prompt List to Promote Communication in Genomic Medicine

The goals of this study are to examine intervention feasibility. Feasibility will be examined in 4 areas: 1) patient and oncologist acceptability, 2) subject recruitment and retention, 3) intervention fidelity, and 4) program logistics. Assess intervention effects on oncologist-patient communication quality and involvement around the RS and treatment selection. Evaluate intervention effects on comprehension, satisfaction, and treatment preferences and selection.
Role: Moffitt Site PI/Co-I

MRSG 13-234-01-PCSM Reblin, PI 07/01/2013-06/30/2019
American Cancer Society (ACS)
Caregiver Relationship Quality & Communication in Advanced Cancer Care
The goal of this mentored research project is to use a multidisciplinary, multilevel approach to define how communication differs by relationship quality and how both these features impact advanced cancer caregivers' psychological health and stress responses. We will explore how relationship quality impacts 1) psychological stress in spouse/partner caregivers of home hospice cancer patients using self-report data and 2) communication and physical stress response in spouse/partner caregivers of advanced cancer patients using ambulatory data collection methods within a naturalistic setting.
Role: Mentor

Completed Research Support (Selected)
R03 CA194643 Scherr, PI 02/15/2016–01/31/2019
Northwestern University/Prime: NIH
***C**ommunicate and **LE**arn **A**bout you**R** **V**ariant of **U**ncertain **S**ignificance (CLEAR VUS)*
The educational booklet developed in this grant proposal will increase patient understanding, improve judgment and decision making, and facilitate communication about variant of uncertain significance results from multigene panel testing for hereditary breast and ovarian cancer.
Role: Site PI & Mentor

RSG-11-268-01-CPPB Vadaparampil PI 07/01/2011 – 06/30/2017
American Cancer Soviet
***B**ehavioral and **E**motio**N**al **I**mpact of BRCA **T**esting in **A**frican Americans (BENITA)*
We have proposed the current study to use the resources of our existing study to carefully evaluate the impact of BRCA testing on AA women's cancer risk management behaviors, the psychological impact of testing, and the impact of testing on the family.

5-R25CA1425-19-05 Quinn, Vadaparampil MPIs 08/02/2011-07/31/2017
NIH R25
Fertility **R**eproduction **a**nd **C**ancer **T**raining **I**nstitute for **O**ncology **N**ursing. (FRACTION)
The overall goal of this project is to improve the quality of life for cancer survivors. The goal of this will be to provide a distance learning based educational program for nurses in the oncology care setting. It will include a web-based 10 module training curricula (PACT); an on-going web based interactive applied learning component including internet interactions and discussions among participants; and an opportunity for assessment of institutional readiness and train the trainer consultation. The aim is to train a total of 250 nurses working with cancer patients during the five-years of the grant.

1 R21 HG006415-01 Vadaparampil, PI 09/13/2011 – 6/30/2016
National Human Genome Research Institute/NIH R21
Genetic Education to Promote Counseling Attendance after Surgical Treatment (GET PAST)
The goal of this study is to develop and pilot test a psycoeducational intervention to increase uptake of genetic counseling among high risk breast cancer patients.

R01 AI076440-01 Vadaparampil, PI 07/01/2008–12/31/2014
National Institute of Allergy and Infectious Disease
Recommendation of HPV Vaccination among U.S. Physicians
The major goal of this project is to assess factors at the physician, practice, and policy level that impact recommendation of HPV vaccination in a national sample of primary care physicians.

Ken Wright, PhD

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: Wright, Kenneth L.

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

POSITION TITLE: Senior Member, Moffitt Cancer Center; Professor, University of South Florida

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 Florida, Gainesville, FL	BS	05/1984	Chemistry
University of Massachusetts, Worcester, MA	PhD	10/1990	Cell Biology
University of North Carolina, Chapel Hill, NC	Post-doc	11/1996	Molecular Immunology

A. Personal Statement

I am a Senior Member of the Immunology Department and Director of Cancer Research Career Development and Education at the Moffitt Cancer Center. I have been successful and productive in guiding my own NIH funded research laboratory for the past 18 years. I have made important discoveries leading to an understanding of the transcriptional reprogramming driven by the PRDM1 transcription repressor protein in B lymphocytes, myeloma cells and Natural Killer cells. These studies have allowed us to discover that key factors impacting the functional response of Mantle Cell Lymphoma to novel therapeutic drugs. The expanding focus of my research has been to establish rational approaches for the use of novel anti-lymphoma and anti-leukemic agents which can effectively kill tumor cells while maintaining or enhancing the anti-tumor function of Natural Killer cells. Specific emphasis is at the level of characterizing select epigenetic regulators and identifying highly selective inhibitors of these enzymes.

As a principal investigator at the Moffitt Cancer Center I have an established track record and demonstrated commitment to education and training. In 2001, I was part of a group that established the Cancer Biology PhD Program at the Moffitt Cancer Center and University of South Florida. I assumed directorship in 2002 and have led this program to a highly competitive national position with approximately 33 students currently enrolled and 60 graduates. I led our PhD program to become a founding member of the national Cancer Biology Training Consortium, which 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” and I served on its Executive Board for 3 years.

I am also the contact PI for the NCI funded PACHE U54 Ponce Health Sciences University-Moffitt Cancer Center (PHSU-MCC) Partnership, and have served as the Co-leader of the Training and Career Development Core during the U56 and first U54 funding period. In addition to my current role as contact PI, I also serve as the Co-leader of the Research and Education Core (REC). The objective of the U54 REC is to increase the numbers and success of basic science investigators and clinical research scientists focused on enhancing cancer research for the Puerto Rican Hispanic/Latino (H/L) population. This training program accomplishes these goals through enhancement of the academic, research, and professional competence of both the underrepresented minority students and those serving these populations (Appleyard et al. 2014. *Reviews on Recent Clinical Trials*. 9:254-62. PMCID: PMC4378863). I continue to lead the administrative and educational efforts of the Partnership to meet the short and long term objectives, and support the focus toward precision medicine.

In addition, at the Moffitt Cancer Center I served for 4 years as faculty director for our undergraduate summer research program. I also serve(d) on multiple educational and institutional committees including the LINK-ET program to introduce underserved students to the emerging technologies, and the General Medical

Education committee for our clinical fellows. In my own laboratory I have mentored 9 PhD students, 19 undergraduates, and 3 undergraduate international exchange students. My leadership skills have been further developed through serving as interim Immunology Program Leader for the Moffitt Cancer Center NCI P30 grant for 3 years in addition to currently serving as vice-chair of the department.

B. Positions and Honors

Positions and Employment

1996 – 1997	Research Assistant Professor, Lineberger Comprehensive Cancer Center, University of North Carolina-Chapel Hill, Chapel Hill, NC
1997 – 2000	Assistant Professor, Department of Biochemistry and Molecular Biology, College of Arts and Sciences, University of South Florida, Tampa, FL
1997 – 2006	Assistant Member, Immunology Program, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL
2000 – 2006	Assistant Professor, Department of Interdisciplinary Oncology, College of Medicine, University of South Florida, FL
2002 – Present	Director, Cancer Biology PhD Program, University of South Florida, Tampa, FL
2006 – 2015	Associate Professor, Department of Oncological Sciences, College of Medicine, University of South Florida, Tampa, FL
2006 – 2015	Associate Member, Immunology Program, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL
2013 – 2016	Interim Chair, Department of Immunology, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL
2013 – 2016	Interim Co-Program Leader of Immunology, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL
2013 – 2017	Executive Committee Member, Cancer Biology Training Consortium (CABTRAC)
2015 – Present	Professor, Department of Oncological Sciences, College of Medicine, University of South Florida, Tampa, FL
2015 – Present	Senior Member, Immunology Program, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL
11/2016 – 01/2019	Vice-Chair, Department of Immunology, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL
01/2019 – Present	Director, Cancer Research Career Development and Education, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL

Honors and Awards

1987 – 1989	Samuel Roberts Noble Foundation Pre-doctoral Fellowship
1990 – 1992	Lineberger Comprehensive Cancer Center Postdoctoral Fellowship - NIH Training Grant
1992 – 1995	Arthritis Foundation Postdoctoral Fellowship
2001	The Robert Grasso Award for Teaching Excellence, College of Medicine, USF
2004	Outstanding Faculty Research Achievement Award, University of South Florida
2013	Educator of the Year, Moffitt Cancer Center

C. Contribution to Science

1. Major histocompatibility complex (MHC) class II molecules play a fundamental role in presenting exogenous antigenic peptides to CD4 helper T lymphocytes. Constitutive expression of MHC class II molecules is restricted to professional antigen-presenting cells and can be induced by interferon-g (IFN-g) in macrophages, endothelial cells, and fibroblasts. The MHC-II family of genes is coordinately regulated at the level of transcription through a co-activator, CIITA, which is the key regulatory molecule of MHC-II. Our studies led to an understanding of the regulatory control of CIITA promoter activity in B-lymphocytes and myeloma. In addition to identifying the activation elements we contributed key findings revealing transcriptional repression of CIITA by PRDM1 (BLIMP1) in multiple myeloma cells and dissected the domains of PRDM1 required for suppression. Knowledge of these control factors has provided mechanisms to manipulate antigen presentation and enhance tumor immunity. In addition these early characterizations of PRDM1 led to a large effort to understand its role in multiple cell types and its potential to act as a tumor suppressor.

a. Ghosh N, Piskurich JF, Wright G, Hassani K, Ting JP, **Wright KL**. A novel element and a TEF-2-like element activate the Major histocompatibility complex class II transactivator in B-lymphocytes. J Biol Chem. 1999 Nov 5;274(45):32342-50. PMID: 10542275.
b. Ghosh N, Gyory I, Wright G, Wood J, **Wright KL**. Positive regulatory domain I binding factor 1 silences class II transactivator expression in multiple myeloma cells. J Biol Chem. 2001 May 4;276(18):15264-8. PMID: 11279146.
c. Wong AW, Ghosh N, McKinnon KP, Reed W, Piskurich JF, **Wright KL**, Ting JP. Regulation and specificity of MHC2TA promoter usage in human primary T lymphocytes and cell line. J Immunol. 2002 Sep 15;169(6):3112-9. PMID: 12218128.
d. Piskurich JF, Gilbert CA, Ashley BD, Zhao M, Chen H, Wu J, Bolick SC, **Wright KL**. Expression of the MHC class II transactivator (CIITA) type IV promoter in B lymphocytes and regulation by IFN-gamma. Mol Immunol. 2006 Feb;43(6):519-28. PMCID:PMC1482792.

2. Given the significance of PRDM1 in suppressing CIITA and the growing appreciation that it played a critical role in B cell terminal differentiation, we undertook a study to define the mechanism of PRDM1 function. PRDM1 is a DNA binding protein that silences expression of specific genes and drives a global gene expression reprogramming during differentiation in immune cells. Using multiple in vivo and in vitro approaches we demonstrated that full-length PRDM1 is required for silencing MHC class II presentation in plasma cells but that a novel truncated isoform was expressed in multiple myeloma. This isoform, with diminished repressive activity, deletes a unique domain with homology to histone methyltransferases. This was the second PRDM family member shown to have truncation of this region associated with tumorgenesis, a property that now defines the entire family. In a seminal finding, we mechanistically defined PRDM1 mediated silencing mediated through recruitment of the histone methyltransferase, G9a. This was the first clearly defined mechanism of targeting G9a in eukaryotic cells.
    a. Gyory I, Fejer G, Ghosh N, Seto E, **Wright KL**. Identification of a functionally impaired positive regulatory domain I binding factor 1 transcription repressor in myeloma cells lines. J Immunol. 2003 Mar 15;170(6):3125-33. PMID: 12626569.
    b. Gyory I, Wu J, Fejer G, Seto E, **Wright KL**. PRDI-BF1 recruits the histone H3 methyltransferase G9a in transcriptional silencing. Nat Immunol. 2004 Mar;5(3):299-308. PMID: 14985713.

3. We have also made key contributions to defining the role of PRDM1 in B cell function and in B cell lymphoma. Our studies in Mantle Cell Lymphoma (MCL) have allowed us to discover that PRDM1 plays a key functional role in the response of MCL to therapeutic drugs. Specifically, Bortezomib activity on MCL depends on PRDM1 induction and subsequent down-regulation of PRDM1 target genes for full activity. Working with our collaborative team focused on MCL we have defined epigenetic control via histone deacetylase inhibition which both inhibit tumor viability and increase immune cell response to the MCL tumors. We have also revealed mechanisms of PRDM1 transcription induction and used global gene expression profiling to broaden our understanding of PRDM1's role in B cells. These studies included revealing the direct suppression of multiple germinal center genes and their contribution to lymphoma sub-types including Diffuse Large B cell lymphoma. Together with our collaborators, we have also established micro-RNA regulation of PRDM1 contributing to Follicular lymphoma. More recently, in conjunction with two other laboratories, we have revealed a role for PRDM1 in maintaining the latent stage of EBV infection, revealing a therapeutic target to induce the lytic life cycle and expose EBV tumors to immune surveillance and destruction. Together these studies have elucidated key control points in B cell differentiation and lymphomagenesis and have provided new insights into potential therapeutic targets.
    a. Desai S, Bolick SC, Maurin M, **Wright KL**. PU.1 regulates positive regulatory domain I-binding factor 1/Blimp-1 transcription in lymphoma cells. J Immunol. 2009 Nov 1;183(9):5778-87. PMCID: PMC3164282.
    b. Cubedo E, Maurin M, Jiang X, Lossos IS, **Wright KL**. PRDM1/Blimp1 Down-regulates Expression of Germinal Center Genes LMO2 and HGAL. FEBS J. 2011 Sep;278(17):3065-75. PMCID: PMC3158840.
    c. Lin J, Lwin T, Zhao JJ, Tam W, ChoiYS, Moscinsky LC, Dalton WS, Sotomayor EM, **Wright KL**, Tao J. Follicular dendritic cell-induced microRNA-mediated upregulation of PRDM1 and downregulation of BCL-6 in non-Hodgkin's B-cell lymphomas. Leukemia. 2011 Jan;25(1):145-52. PMCID: PMC3083119.

d. Desai S, Maurin M, Smith MA, Bolick SC, Dessureault S, Tao J, Sotomayor E, **Wright KL**. PRDM1 is required for mantle cell lymphoma response to bortezomib. Mol Cancer Res. 2010 Jun;8(6):907-18. PMCID: PMC2891394.

4. Our research has greatly expanded the role of PRDM1 by showing that it has unexpected and critical roles in both human dendritic cells (DC) and human natural killer (NK) cells. In DCs, PRDM1 controls antigen presentation through direct suppression of all three CIITA promoters, thus silencing new MHC-II synthesis and allowing highly efficient presentation of captured antigens. We established that PRDM1 and IRF8 counter regulate gene expression in DCs revealed that PRDM1 binding led to a discharge of transcription factors at the target promoters followed by recruitment of epigenetic enzymes and accumulation of suppressive histone marks. Subsequently, we were the first to identify that PRDM1 regulates NK cell function. PRDM1 did not alter the initial cytotoxicity but rather limited cytokine production in primary human NK cells. This suggested that PRDM1 prevents NK over-activity and exhaustion. Global gene expression profiling identified multiple key targets of PRDM1 in NK cells leading to ongoing studies addressing the activity of NK cells in MCL patients and the significance of altered PRDM1 and histone deacetylase activity in response to therapy.
    a. Smith MA, Maurin M, Cho H, Becknell B, Freud AG, Yu J, Wei S, Djeu J, Celis E, Caligiuri M, **Wright KL**. PRDM1/Blimp-1 controls effector cytokine production in human NK cells. J Immunol. 2010 Nov 15;185(10):6058-67. PMCID: PMC3864810.
    b. Smith MA, Wright G, Wu J, Tailor P, Ozato K, Chen X, Wei S, Piskurich JF, Ting JP, **Wright KL**. Positive regulatory domain I (PRDM1) and IRF8/PU.1 counter-regulate MHC class II transactivator (CIITA) expression during dendritic cell maturation. J Biol Chem. 2011 Mar 11;286(10):7893-904. PMCID: PMC3048676.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/kenneth.wright.2/bibliograpahy/44815397/public/?sort=date&direction=descending

D. Research Support

Ongoing Research Support

U54 CA163068 Muñoz-Antonia/Sullivan (MPIs) 09/24/2012 – 09/23/2022
NIH/NCI
2/2 Ponce Health Sciences University-Moffitt Cancer Center Partnership
The goal of this grant is to further grow and engage faculty and students in cancer precision medicine research that directly impacts the H/L populations in Florida and Puerto Rico.
Role: Co-Investigator, Administrative Core; Co-Leader, Research Education Core

R01 CA164641 Wright 06/18/2013 – 04/30/2019
NIH/NCI (NCE)
Natural killer cell regulation by PRDM1 and IFR4/8
The goal of this research is to define the novel role of PRDM1 transcription factor in controlling NK cell function and impact on NK cells in patients with Mantle Cell Lymphoma.
Role: Principal Investigator

16-M69 Wright (MCC-PI) 07/03/2014 - 06/30/2019
George Washington University
R01 CA187040 (Seto)
NIH/NCI
Targeting SIRT1 in Mantle Cell Lymphoma
Goal: The goal of this research is to define the novel role of PRDM1 transcription factor in controlling NK cell function and impact on NK cells in patients with Mantle Cell Lymphoma.
Role: Co-Investigator

P20 CA202920 Meade/Cress (MPIs) 09/21/2017 – 08/31/2021
National Institute of Health – CRCHD
Southeast Partnership for Improving Research and Training in Cancer Health Disparities (SPIRIT-CHD)
SPIRIT-CHD links Moffitt and the Louisiana State University Health Sciences Center. The effort seeks to reduce cancer health disparities by conducting precision medicine/biospecimen research in underserved patient populations, and developing a joint cancer research education program.
Role: Internal Advisor

N/A Wright 06/01/2018 – 05/30/2019
Miles for Moffitt
HDAC11 a novel therapeutic target for myeloproliferative neoplasms (MPN) through metabolic alterations
The goal of this research is to mechanistically define the role and impact of HDCA11 in MPN.
Role: Principal Investigator

Completed Research Support

T32 CA115308 Wright 07/01/2005 – 08/31/2018
NCI/NIH
Tumor Immunology Training Program
This training program seeks to rapidly advance the careers of post-doctoral fellows and PhD students in the area of tumor immunology.

P30 CA076292 Sellers 02/01/2012 – 01/31/2017
NIH/NCI
H. Lee Moffitt Cancer Center Support Grant
The Cancer Center Support grant funds the scientific infrastructure of the cancer center, including scientific leadership and administration; research resources that give ready access to the state-of-the art technologies; and flexible funds that help the center pursue its planned objectives and take immediate advantage of new research opportunities.
Role: Interim Immunology Program Leader, role ended 11/2016

U54 CA163068 Muñoz-Antonia/Sullivan (MPIs) 09/24/2012 – 09/23/2017
NIH/NCI
Ponce School of Medicine-Moffitt Cancer Center Partnership
The goal of this grant is to support the development of an academic partnership between the H. Lee Moffitt Cancer Center and the Ponce School of Medicine in Puerto Rico.
Role: Co-Leader, Training/Career Development Core

N/A Wright 09/15/2014 – 11/30/2016
Forma Therapeutics, Inc.
Project F2-Identification and Characterization of Non-Histone Targets for HDAC 6, 8 and 11 in Melanoma and Mantle Cell Lymphoma
The goal of this research is to characterize highly selective HDAC inhibitors to define the non-histone protein targets in MCL and melanoma.
Role: Principal Investigator

N/A Wright 11/01/2016 – 06/30/2018
Forma Therapeutics, Inc.
Defining the Role of HDAC8 in Natural Killer Cell Function
The goal of this research is to characterize the role of HDAC8 inhibition on the function of primary human NK cells from normal and MCL patients.
Role: Principal Investigator

N/A Wright 12/20/2017 – 06/30/2018
Forma Therapeutics, Inc.
Identification and Characterization of Non-Histone HDAC Substrates
The goal of this research is to define and functionally characterize select targets of HDAC11.
Role: Principal Investigator