

AWARD NUMBER: W81XWH-20-1-0488

TITLE: A Presurgical Window of Opportunity Trial of the Effect of Aspirin on Immunological Features of Ovarian Tumors

PRINCIPAL INVESTIGATOR: Shelley Tworoger, PhD

CONTRACTING ORGANIZATION: H. Lee Moffitt Cancer Center and Research Institute

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14. ABSTRACT The objective of this project is to conduct a window-of-opportunity, pre-surgical, randomized-controlled clinical trial to assess the efficacy and safety of standard-dose aspirin in improving prognosis-related tumor characteristics. The trial will enroll 100 newly diagnosed ovarian cancer patients who plan to be treated with neoadjuvant chemotherapy and interval debulking surgery into a randomized, controlled trial of daily 325mg enteric-coated aspirin vs. placebo. Currently, the trial is ready to begin at Moffitt Cancer Center pending receipt of the aspirin and placebo tablets in September 2021. Work is ongoing to initiate the trial at two external sites.					
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1. INTRODUCTION

The underlying premise of this research project is that blocking the downstream consequences of cyclooxygenase (COX)-facilitated prostaglandin production can reduce immune suppression, inflammation, and platelet production pathways that promote ovarian tumor progression as well as improve quality of life during chemotherapy. The objective of this project is to conduct a window-of-opportunity, pre-surgical, randomized-controlled clinical trial to assess the efficacy and safety of standard-dose aspirin, which inactivates COX enzymes, in improving prognosis-related tumor characteristics. The trial will enroll 100 newly diagnosed ovarian cancer patients who plan to be treated with neoadjuvant chemotherapy and interval debulking surgery into a randomized, controlled trial of daily 325mg enteric-coated aspirin vs. placebo. Our primary outcome will be change in density of immunosuppressive cell types (i.e., T-regulatory cells [Treg] and M2-type tumor-associated macrophages [TAM]) from diagnostic biopsy to debulking surgery. Secondary outcomes include: change in tumor burden, COX1/COX2 tumor expression, and levels of circulating markers of inflammation and platelet activation (IL-6 and p-selectin). We also will explore the impact of aspirin on physical and emotional symptoms during treatment and monitor safety of aspirin use via physician evaluations and self-reported symptoms of aspirin-related toxicities.

2. KEYWORDS

Aspirin; Inflammation; Ovarian cancer; Patient-reported outcomes; Randomized trial; Tumor immune microenvironment

3. ACCOMPLISHMENTS

What were the major goals of the project?

Major goals in SOW	Target dates for completion	Actual completion dates or percentage of completion *
Major Task 1: Finalize protocol for clinical trial of aspirin vs. placebo in the neoadjuvant setting of ovarian cancer therapy		
Subtask 1: Finalize regulatory documents and research protocol	Months 1-5	MCC: Completed month 11 AHO: 75% complete PMH: 25% complete
Major Task 2: Coordinate Trial initiation activities across Sites		
Subtask 1: Hire, train, and monitor study staff	Months 1-30	MCC: 75% complete AHO: 50% complete PMH: 50% complete
Major Task 3: Participant Recruitment, Treatment, and Participant Evaluation; Data Management and Outcome Evaluation		
Subtask 1: Create tracking systems and questionnaires	Months 1-3	MCC: Completed month 12 AHO: Completed month 12 PMH: Completed month 12
Subtask 2: Conduct trial of aspirin vs. placebo in the neoadjuvant chemotherapy setting in ovarian cancer patients	Months 6-34	0% complete

Subtask 3: Conduct appropriate assays on biospecimens and RECIST criteria evaluations collected on study in two batches; conduct necessary data cleaning	Months 7-35	0% complete
* AHO, AdventHealth-Orlando; MCC, Moffitt Cancer Center; PMH, Princess Margaret Hospital.		

What was accomplished under these goals?

Major Task 1: Finalize protocol for clinical trial of aspirin vs. placebo in the neoadjuvant setting of ovarian cancer therapy

- We completed all subtasks for Moffitt Cancer Center (MCC), including 1) submitting an IND application to the U.S. Food and Drug Administration (FDA); the FDA determined the trial to be exempt from IND regulations (IND 145302); 2) finalizing the research protocol and consent form and receiving approval of these items by the MCC Scientific Review Committee and Advarra IRB (approved 2 Mar 2021); and 3) receiving DoD HRPO approval (submitted application 24 Mar 2021; approved 14 July 2021).
- We completed some of the subtasks for AdventHealth-Orlando (AHO), including the items completed for MCC that are also relevant to AHO. Tasks that are remaining to complete for this site include applying to Advarra IRB and the DoD HRPO to include AHO as a study site and finalizing the research/financial agreement with AHO.
- We completed some of the subtasks for Princess Margaret Hospital (PMH), including the items completed for MCC that are also relevant to PMH. Tasks that are remaining to complete for this site include: submitting a Clinical Trial Application to HealthCanada; finalizing the research/financial/material transfer agreement with PMH; finalizing the research protocol and consent form for submission to the University Health Network Research Ethics Board (UHN REB); and applying to the UHN REB and the DoD HRPO to include PMH as a study site.

Major Task 2: Coordinate Trial initiation activities across Sites

- We completed the majority of the subtasks for MCC including identifying in-house staff within the Clinical Trial Office who will oversee and manage the study and completing the Site Initiation Visit (20 Aug 2021). The remaining task, assessing compliance and adherence to the study protocol, will be ongoing throughout the life of the trial.
- For AHO, we identified in-house staff that will oversee and manage the study. Tasks that remain include training of the trial staff and assessing compliance and adherence to the study protocol, which will be ongoing throughout the life of the trial.
- For PMH, we identified in-house staff that will oversee and manage the study. Tasks that remain include training of the trial staff and assessing compliance and adherence to the study protocol, which will be ongoing throughout the life of the trial.

Major Task 3: Participant Recruitment, Treatment, and Participant Evaluation; Data Management and Outcome Evaluation

- We completed Subtask 1 (Create tracking systems and questionnaires) for all sites. This included creating a study calendar in our study tracking system (OnCore) and finalizing the questionnaires. The MCC Participant Research, Interventions, & Measurements (PRISM) Core finished creating RedCap forms for all questionnaires and designing a system for email/text questionnaire reminders.

- Subtasks 2 and 3 have not started; these tasks include initiating participant recruitment, which is pending receipt of the study drug (aspirin and placebo tablets) at MCC in September 2021, conducting assays on biospecimens and RECIST criteria evaluations, and cleaning data. Delays in manufacture of the placebo tablet contributed to the delay in the trial start date (discussed below in Section 5).

What opportunities for training and professional development has the project provided?

Dr. Chern, the Early-Stage Investigator, is the protocol PI for the clinical trial. In this role, she is receiving guidance from the Moffitt Clinical Trial Office and study PI (Dr. Tworoger) as well as general guidance from other Gynecologic Oncologists at Moffitt. Through preparing the study to begin, Dr. Chern is learning about the contracting process with external sites and vendors as well as the training process for the Clinical Trials staff. In addition, given the delay in starting the trial, Dr. Chern is personally reaching out to contacts at other hospitals with the goal of finding potential other sites to join the trial and contribute to patient accrual.

How were the results disseminated to communities of interest?

We sent our proposed questionnaires to the trial patient advocate, Ms. Peg Ford, for review. We revised the questionnaires based on her feedback (e.g., chose shorter measures for some items and removed some items). We are sad to report that the other patient advocate we intended to include, Ms. Seana Roubinek, died on August 26, 2020.

What do you plan to do during the next reporting period to accomplish the goals?

We anticipate receiving the first batch of aspirin and placebo in appropriately labeled bottles for the United States sites by mid-to-late September of 2021. Due to the expiry date of the aspirin and some excipients in the placebo pill, we will have to repeat this process in the summer of 2022. At Moffitt, we will initiate the trial as soon as we get drug and evaluate if any changes are needed to the protocol after enrolling the first few patients.

For AHO, to accomplish the remaining subtasks during the next reporting period, the MCC PI and Clinical Trial Office are initiating weekly meetings with relevant staff at AHO to ensure that bottlenecks are addressed promptly so that the application to the central IRB and DoD HRPO and signing the site agreement can proceed with minimal delay.

For PMH, we are finalizing the contract with a Contract Research Organization (CRO) that has expertise in Canadian regulatory requirements to provide input and guidance on the application to HealthCanada for approval to use aspirin and placebo in the trial as well as coordinate in-person monitoring visits. The CRO will also provide input on the shipment of biologic specimens across international borders. In the next year, we plan to submit the Clinical Trial Application to HealthCanada; finalize the research/financial/material transfer agreement with PMH; submit the research protocol and consent form to the University Health Network Research Ethics Board (UHN REB); and apply to the DoD HRPO to include PMH as a study site.

4. IMPACT

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report.

What was the impact on other disciplines?

Nothing to Report.

What was the impact on technology transfer?

Nothing to Report.

What was the impact on society beyond science and technology?

Nothing to Report.

5. CHANGES/PROBLEMS**Changes in approach and reasons for change**

Nothing to Report.

Actual or anticipated problems or delays and actions or plans to resolve them

Due to COVID-19, research activities were halted or slowed down significantly at MCC, AHO, and PMH at various points during the past year. Further, due to COVID-19, PMH could not confirm that they would continue to participate in the trial until June 2021, delaying the Canadian regulatory submissions. Currently, research activities have re-started at all sites, allowing us to move forward with our research plan. In addition, we are contracting a CRO with expertise in Canadian regulatory requirements to assist the associated paperwork for PMH (which is in Toronto, Canada). Given the delay in starting the trial, we are also contacting other sites that might be able to join the study and thus help increase the rate of accrual.

In our SOW, we underestimated the time needed to obtain HRPO approval. This delay meant that Moffitt could not begin contracting activities with external sites (due to an internal Moffitt policy). Since the HRPO approval was received, work to draft an agreement for AHO has begun and is ongoing.

There was a delay in manufacture of the placebo tablet due to waiting for a batch of Povidone (one of excipients) with an acceptable expiration date to become available. If we used an earlier expiration date, the placebo would have expired less than a year after the study began. Although we still will need to create a second batch of placebo and buy another batch of aspirin to replace the current batch when it expires in December 2022, Sharp Clinical Services is in regular contact with the various manufacturers so that we can promptly purchase the necessary supplies when the expiration dates are acceptable.

Changes that had a significant impact on expenditures

Originally, we had planned to obtain the placebo and aspirin from Bayer, which provides these at cost. However, between the time the grant was submitted and funded, Bayer stopped providing aspirin and placebo for oncology-related clinical trials. Thus, we contracted with another vendor, Sharp Clinical Services, which is significantly more than the original budget. Moffitt Cancer Center has agreed to pay for the additional cost. Further, the individual at Moffitt with Canadian Regulatory Expertise left the institution and therefore, we plan to contract with a CRO to assist with this and the on-site monitoring, which will increase costs. However, because of COVID-related delays and delays in receiving the full IRB/HRPO approval, we only expended salary coverage for Drs. Tworoger, Chern, and Townsend and Ms. Hathaway, who worked on the study start-up and IRB activities, leading to substantial savings. Further, we did not accrue patients in Year 1, further saving funds, which will be used to accrue patients going forward. Study start-up costs as well as accrual and full

personnel costs will be in Year 2, including the possibility of finding a fourth site to increase the rate of accrual.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

- **Significant changes in use or care of human subjects**

Nothing to Report.

- **Significant changes in use or care of vertebrate animals**

Not Applicable.

- **Significant changes in use of biohazards and/or select agents**

Nothing to Report.

6. PRODUCTS

Publications, conference papers, and presentations

- **Journal publications**

Nothing to Report.

- **Books or other non-periodical, one-time publications**

Nothing to Report.

- **Other publications, conference papers, and presentations**

Nothing to Report.

- **Website(s) or other Internet site(s)**

Nothing to Report.

- **Technologies or techniques**

Nothing to Report.

- **Inventions, patent applications, and/or licenses**

Nothing to Report.

- **Other Products**

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Shelley Tworoger
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-6986-7046
Nearest person month worked:	1
Contribution to Project:	Dr. Tworoger has worked on managing the establishment of necessary contracts, finalizing the protocol, coordinating trial initiation across sites, finalizing tracking systems and questionnaires, and overseeing placebo manufacture and packaging/labeling of study drug.
Funding Support:	
Name:	Jing-Yi Chern
Project Role:	Co-Investigator (Early Career Investigator)
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Dr. Chern has worked on finalizing the protocol, coordinating trial initiation across sites, finalizing participant tracking systems, and contacting other potential external sites.
Funding Support:	
Name:	Mary Townsend
Project Role:	Applied Research Scientist
Researcher Identifier (e.g. ORCID ID):	0000-0003-2452-4477
Nearest person month worked:	1
Contribution to Project:	Dr. Townsend has worked on managing the establishment of necessary contracts, finalizing the protocol, coordinating trial initiation across sites, finalizing tracking systems and questionnaires, and overseeing placebo manufacture and packaging/labeling of study drug.
Funding Support:	

Name:	Cassandra Hathaway
Project Role:	Research Project Specialist
Researcher Identifier (e.g. ORCID ID):	0000-0002-2919-0499
Nearest person month worked:	2
Contribution to Project:	Ms. Hathaway has worked on coordinating trial initiation across sites, finalizing tracking systems and questionnaires, and overseeing placebo manufacture and packaging/labeling of study drug.
Funding Support:	

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

- Changes to Other Support are annotated on the Other Support documents that follow.

What other organizations were involved as partners?

Organization Name: Advent Health Orlando

Location of Organization: Orlando, Florida

Partner's contribution to the project

- **Collaboration** (Advent Health is an external site for the randomized trial)

Organization Name: Princess Margaret Hospital

Location of Organization: Canada

Partner's contribution to the project

- **Collaboration** (Princess Margaret Hospital is an external site for the randomized trial)

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: Not Applicable.

QUAD CHART: Not Applicable.

9. OTHER SUPPORT – CHANGES TO OTHER SUPPORT

9.1 TWOROGER, SHELLEY

Positions & Scientific Appointments

- 2017- Associate Center Director of Population Sciences and Senior Member, Moffitt
Cancer Center and Research Institute, Tampa, FL
- 2017- Courtesy Professor of Oncologic Sciences, University of South Florida, Tampa, FL

Additional Support From Foreign Or Domestic Entities

None

ACTIVE

Early Life Exposures and Risk of Developing Ovarian Cancer

Effort: 1.8 calendar

James and Esther King Biomedical Research Program - 9JK02

Grants Official: Bonnie Gaughan-Bailey, Bonnie.Gaughan-Bailey@flhealth.gov

2019/08/15 – 2022/08/31

Funding: \$504,838 total direct costs

Tworoger, Shelley (PI)

Project Goals: The major goal of this project is to use a unique life course approach to improve identification of women at high risk of ovarian cancer. Project goals: 1. Evaluate the influence of early life exposure to cigarette smoking on risk of ovarian cancer. We hypothesize that having a mother who smoked during pregnancy or a parent that smoked inside the home during childhood and younger age at starting smoking are associated with increased risk, particularly for mucinous tumors. 2. Evaluate the influence of early life psychosocial stress on risk of ovarian cancer. We hypothesize that social adversity and abuse during childhood and adolescence are associated with increased risk. 3. Evaluate the influence of early life physical activity on risk of ovarian cancer. We hypothesize that inactivity and moderate physical activity during middle and high school, or ages 18-22, are associated with increased risk while vigorous physical activity is associated with decreased risk.

Overlap: None

Making the Case: Chemopreventive Use of Aspirin for Ovarian Cancer - Integrating Epidemiological Data to Evaluate Population Subgroups and Tumor Expression

Effort: 0.72 calendar

DOD – Geneva Foundation W81XWH1910346 – Trabert (PI)

Grants Official: Andrea Masterson, amasterson@genevausa.org

2019/09/15 – 2022/09/30

Funding: \$348,135 subaward total direct costs

Role: Site PI

Project goals: Epidemiologic data highlight the potential for daily aspirin use to prevent ovarian cancer. Our central objectives are to understand the potential biological mechanisms, which will lend additional support for a causal association, and to identify the specific populations who could most benefit from daily aspirin use to fully inform prevention guidelines, which will be

accomplished by expanding the resources of the OC3 and OCAC consortia. Using these resources, we will evaluate the following Project goals: 1. Evaluate the relationship of updated daily aspirin use, including updated information on dose, duration, and frequency, and ovarian cancer risk using data from 14 cohorts. 2. Identify specific populations of women who could most benefit from aspirin chemoprevention in a well-powered investigation combining harmonized case-control (OCAC) and cohort (OC3) data. 3. Explore the potential mechanisms by which aspirin reduces ovarian cancer risk by utilizing ovarian tumor tissue from 8 cohort studies. Overlap: None

Moffitt Cancer Center (MCC) Support Grant

Effort: 2.4 calendar

National Cancer Institute - P30 CA076292 Cleveland, John (PI)

Grants Official: Joy Kearse, kearsej@nih.gov

1998/02/18 – 2022/01/31

Funding: \$14,954,830 total costs

Role: Associate Center Director of Population Science

Project goals: The grant provides support for key personnel involved in the cancer center's research mission.

The 142 MCC members span the basic, clinical, and population sciences. They are organized into five highly collaborative, multidisciplinary programs with exceptional levels of intra- (35%) and inter-programmatic (18%) publications. Under the leadership of Dr. John Cleveland, the fourth MCC Director, a Research Strategic Plan (RSP) was developed and implemented for "Moffitt 3.0." Four of six Associate Center Directors are new; and new leaders have been appointed in every program, with bold goals and specific aims. Two of the 13 shared resources have been significantly restructured (Chemical Biology, Molecular Genomics), and one new resource created (Collaborative Data Services) to better meet the changing needs of MCC scientists. Implementation of the strategic plan has been bolstered by substantial institutional investment, especially in basic science, immunotherapy, and clinical research infrastructure, including the recruitment of 45 new faculty members, of whom 32 are CCSG members. MCC is a leader in immunotherapy, and more than 40% of overall clinical trial accrual is to investigator-initiated studies. MCC population scientists initiated significant new efforts in cancer prevention and outcomes that include vaccines, tobacco cessation, and health disparities. This is particularly true in the unique Cancer problems in the catchment area – notably lung Cancer, melanoma, and HPV- prevention. MCC's Total Cancer Care protocol, the ground-breaking research strategy to realize the promise of personalized medicine, has continued to thrive, resulting in dramatic utilization of the Tissue Core and the formation of the oncology Research Information Exchange Network (ORIEN) that now includes eleven cancer centers across the nation, with several more poised to join the consortium this year. MCC requests funding for: five scientific programs, 13 shared resources, two clinical research components, planning and evaluation, administration, leadership, four staff investigators, and developmental funds. CCSG funds are leveraged more than 10-fold with institutional resources to maximize impact on Cancer prevention, treatment, and cure in the catchment area, the state of Florida and beyond.

Overlap: None

A Pre-surgical Window of Opportunity Trial of the Effect of Aspirin on Immunological Features of Ovarian Tumors

Effort: 0.6 calendar

DOD - OC190330

Grants Official: Karen Wylie, karen.m.wylie.civ@mail.mil

2020/09/01 – 2023/08/31

Funding: \$1,120,216 total costs

Role: Tworoger, Shelley (PI)

Project goals: 1) To evaluate the efficacy of aspirin for improving immunological characteristics of the tumor at interval debulking surgery among women diagnosed with ovarian cancer. We hypothesize that, compared with women assigned to a daily placebo pill, those assigned to daily 325mg aspirin will have: Primary: A greater decrease in density of tumor-associated macrophages (TAMs) and T-regulatory cells (Tregs) in the tumor and b. Secondary: (i) A greater percent improvement in response evaluation criteria in solid tumors (RECIST) standardized to the number of chemotherapy cycles completed; (ii) greater decrease in tumor COX1 and COX2 expression; (iii) greater decrease in platelet aggregation function; and (iv) greater decrease in plasma IL-6 levels. 2) To evaluate the efficacy of daily 325mg aspirin versus placebo pill for improving tolerance of neoadjuvant chemotherapy and quality of life. We hypothesize that, compared with women assigned to a daily placebo pill, those assigned to daily 325mg aspirin will have a. Secondary: Fewer physical symptoms, including fatigue, nausea, peripheral neuropathy, and sleep symptoms and b. Secondary: Fewer emotional symptoms, including depression and anxiety symptoms, and higher subjective cognitive function.

Overlap: None

NEW

Understanding racial/ethnic differences in ovarian cancer risk

Effort: 0.24 calendar months

NIH/NCI - 5U01CA164973-09 (Administrative Supplement) - LeMarchand, Loic (PI)

Grants Official: Somdat Mahabir, 240-276-6941, mahabir@mail.nih.gov

2022/01 – 2025/12

Funding: \$45,227 subaward total costs

Role: Site PI

The Multiethnic Cohort (MEC) Study began in 1993-1996 and includes more than 215,000 male and female residents of Hawaii and Southern California representing a diverse population of five major racial/ethnic groups. These participants have been followed over time for incidence of cancer and other health outcomes. Using this valuable resource, we have identified differences in ovarian cancer age-adjusted incidence rates by racial/ethnic group including high incidence in Native Hawaiians, moderate incidence in Latinas and low incidence in Asian and African American women as compared with White women. We propose to use this Administrative Supplement is to extend our studies of racial/ethnic differences in ovarian cancer risk in the MEC Study to evaluate risk associations by race/ethnicity using the Ovarian Cancer Consortium (OC3) dataset, which includes data from additional prospective cohort studies. Our goal for the Administrative Supplement is to build resources to understand racial/ethnic differences in ovarian cancer risk by providing funding for two cohort studies (MEC and the Southern Community Cohort Study) to contribute new data from a substantial number of non-White participants to the OC3 central database. These combined data will support our approved OC3 project and will also increase the racial/ethnic diversity represented in the OC3 that will be available to support future research projects. Study Aims are: 1) To build infrastructure in the OC3 by increasing the participant diversity to evaluate risk associations by race/ethnicity, and, 2) To explore differential ovarian cancer risk factors by race/ethnicity with a focus on hormone-related factors.

Overlap: None

NEW

Inflammatory and Immune Mechanisms Relating PTSD and Depression to Ovarian Cancer Risk

Effort: .39 calendar months

DOD - W81XWH2110326 - Kubzansky, Laura (PI)

Grants Official: Abigail Strock, 301-619-2342, abigail.l.strock.civ@mail.mil

2021/05/01 – 2024/04/30

Funding: \$138,127 subaward total costs

Role: Site PI

Project goals: This application is a critical extension of a current award that found that women with post-traumatic stress disorder (PTSD) have a two-fold higher risk of developing ovarian cancer. This in conjunction with prior work showing an increased risk among women with depression that appears to act through sympathetic nervous system activation of the beta-2-adrenergic receptor pathway, strongly supports continued evaluation of the epidemiology of these relationships as well as underlying biologic mechanisms. Findings from this expansion will provide deeper insight into the potential synergistic role of distress with inflammation and immunity in ovarian carcinogenesis that could lead to novel immunoprevention approaches. The specific aims are to: 1. Assess the timing of PTSD and depression onset and remission in relation to ovarian cancer risk and B-cell distributions and activity (e.g., antibody production) within the tumor microenvironment. 2. Assess a possible synergistic and/or mediating role of high inflammation in the relationship between PTSD or depression and ovarian cancer development. 3. Evaluate the relationship of PTSD and depression with markers of humoral and humoral immunity in circulation, measured using EWAS-based deconvolution of immune cell types.

Overlap: None

NEW

Changing contraceptive patterns and ovarian cancer risk

Effort: 0.84 calendar

NCI - 1R01CA258679-01 Terry (PI)

Grants Official: Angela Walters, angela.walters@nih.gov

2021/04/01 – 2026/03/31

Funding: \$773,879 subaward total costs

Role: Site PI

Project goals: 1) We will evaluate the association between IUD use and ovarian cancer risk in 15 case control studies (18,873 cases, 24,439 controls) and 6 cohort studies with prospectively collected data. 2) For the studies with detailed information, we will evaluate how type, duration, and timing of use influence ovarian cancer risk. 3) We will evaluate whether tumors that develop in women with a history of IUD use are more likely to develop high-grade serous ovarian cancer expressing immune markers compared to women who have not, and 4) Compare circulating inflammatory (CRP) and hormonal levels (E/P) biomarkers in women with and without IUD in the A2A cohort.

Overlap: None

NEW

Aspirin and NSAIDs use and ovarian cancer prognosis: a molecular epidemiological study

Effort: 0.6 calendar

DOD Ovarian Cancer Research Program - W81XWH-21-1-0914 - Merritt, Melissa (PI)

Grants Official: Jennifer Fox, Jennifer.l.fox1.civ@mail.mil

09/15/2021 – 09/14/2025

Funding: \$333,242 subaward total costs

Goals: The overall goal proposed project is to evaluate the association between aspirin and non-aspirin non-steroidal anti-inflammatory drug (NSAID) use (pre-diagnosis and post-diagnosis) with risk of ovarian cancer mortality using epidemiologic data from the ovarian cancer cohort consortium (OC3) accounting for the timing, frequency, quantity, dose and duration of use as well as examining potential molecular pathways of action.

Role: Mentor

Overlap: There is scientific overlap between the above proposed project (OC200236) and the application under consideration at the NIH/NCI (R01 CA270159) evaluating the role of aspirin use in survival of patients with ovarian cancer. If both projects are funded, the budgets will be adjusted appropriately in conjunction with agency staff.

FORMERLY UNREPORTED – no measurable effort

Elucidating Inflammatory and Metabolic pathways in Obstructive Sleep Apnea Development

Effort: 0 calendar

NIH/NHLBI - K01HL143034 Huang

Grants Official: Marishka Brown, marishka.brown@nih.gov

2018/07/01 – 2023/06/30

Funding: in kind

Role: Mentor

Project goals: The goal of this application is to understand the role of inflammatory and metabolic pathways using a diverse set of cohorts including men and women and individuals across racial/ethnic groups to understand predictors of obstructive sleep apnea. The project will consider Mendelian randomization techniques as well as measured biomarkers in the blood.

Overlap: None

PENDING

ALL NEW

Using Intratumoral and Dynamic Circulating Biologic Age to Predict Effectiveness of Ovarian Cancer Treatment

Effort: 0.6 calendar

DOD – US Army, Wang (PI)

02/2022 – 01/2026

Funding: \$1,194,075 proposed total costs

Role: Mentor

Project Goal: We propose to leverage unique data and serial specimens from a prospective clinical study and apply cutting-edge epigenetic technology that has excellent reproducibility and reliability to assess three aims. Aim 1. Evaluate intratumoral and circulating biologic age in relation to response to neoadjuvant chemotherapy. Aim 2. Assess modifiable lifestyle factors related to survival that are associated with biologic age. Aim 3. Explore how race/ethnicity is associated with pre-treatment biologic age and aging acceleration during neoadjuvant chemotherapy and debulking surgery.

Methylomic basis of ovarian cancer survival disparities among African-American and European-American women

Effort: 1.2 Calendar months

NIH/NCI - R01CA258375 – Peres (PI)

4/2022 – 03/2027

Funding: \$3,863,381 proposed total costs

Project Goal: To compare genome-wide profiles of DNA methylation in tumors from African ancestry (AA) and European ancestry (EA) women with ovarian cancer in association with prognosis, we posit that AA women will have a different composition of methylation patterns (i.e., a unique tumor DNA methylation signature) associated with poorer survival compared to EA women.

Role: Co-investigator

Overlap: None

Assessment of the Immune Landscape and Ovarian Cancer Survival Using Novel Spatial and Bayesian Statistical Methods

Effort: .6 calendar

NIH/NCI - R01 CA262421-01 - Fridley/Peres (MPI)

10/01/2022 - 09/30/2027

Funding: \$3,700,523 proposed total costs

Role: Co-Investigator

Project Goals: Aim 1: To develop spatial statistical approaches and software for the analysis of IF data that characterizes the spatial architecture of the tumor immune microenvironment (TIME). Moving beyond simple abundance measurements of immune cells, we will adapt commonly used ecological spatial statistical measures to evaluate the relationships and co-localization between immune cells, including measures of spatial clustering or segregation of immune cells in tumor vs stroma. Aim 2: To develop Bayesian models and software for the analysis of IF data and determination of immune subtypes while accounting for the zero-inflated nature of the immune count data. IF data often contain many samples in which no cells are positive for a given immune marker (i.e., many zero counts). Here, we will develop a Bayesian zero-inflated beta-binomial model and an integrated Bayesian clustering approach to determine immune subtypes that leverage both the abundance of immune cells and the spatial contexture while also incorporating the relationship between markers and multiple measurements from a single tumor sample. Aim 3: To characterize the immune landscape of ovarian tumors and develop an immunoscore predictive of survival. We will leverage existing IF data from >1,000 diverse EOC patients enrolled in established epidemiological studies to investigate key features of the TIME, including both the abundance and spatial context of immune cells within the tumor and stroma, in relation to the ovarian cancer-specific survival.

Overlap: There is scientific overlap between the above proposed project (R01 CA262421-01) and the below application under consideration at the Department of Defense (W81XWH-21-OCRP-IIRA) developing methods to characterize the spatial heterogeneity of the tumor immune microenvironment in ovarian cancer. If both projects are funded, the budgets will be adjusted appropriately in conjunction with agency staff.

Assessment of the tumor immune spatial landscape and ovarian cancer survival

Effort: 0.36 calendar months

DOD - W81XWH-21-OCRP-IIRA - Fridley/Peres (Co-PI)

10/2022 – 09/2025

Funding: \$1,225,246 total costs

Goals: To develop novel statistical methods and software for the downstream analysis of mIF data. A second goal is to apply these methods to the study of epithelial ovarian cancer (EOC), the deadliest gynecologic malignancy in the US, to develop an immunoscore predictive of survival among EOC patients.

Role: Co-Investigator

Overlap: There is scientific overlap between the proposed project (W81XWH-21-OCRP-IIRA) and the application under consideration at the NIH (R01 CA262421-01) developing methods to characterize the spatial heterogeneity of the tumor immune microenvironment in ovarian cancer. If both projects are funded, the budgets will be adjusted appropriately in conjunction with agency staff.

Sphingomyelins, statin use and ovarian cancer

Effort: 1.8 calendar months

NCI - Zeleznik, Oana (PI)

04/01/2022 – 06/30/2026

Funding: \$1,035,808 proposed subaward total costs

Role: Site PI

Project Goals: Aim 1: We hypothesize that statin use is associated with lower circulating levels of individual SMs (N=2157 NHS/NHSII samples). In exploratory analyses we will test the hypothesis that initiation of statin use lowers subsequent circulating SM levels. Aim 2: We hypothesize that women who use statins, especially for longer durations, have a lower future risk of ovarian cancer (overall and by histotype) and that this association is mediated by SMs (N=577 NHS/NHSII ovarian cancer cases). Aim 3: We hypothesize that higher genetically predicted levels of SMs, developed among 4944 NHS/NHSII women, represent causal factors in ovarian carcinogenesis and are associated with higher risk of ovarian cancer in OCAC (N=25,509 ovarian cancer cases). In exploratory analyses, we will test the hypothesis that lower genetically predicted response to statin therapy is associated with higher risk of ovarian cancer. Aim 4: We hypothesize that pre-diagnostic statin use and high circulating SM levels are key determinants of the multi-omics tumor space and will activate a series of biological pathways captured by gene expression (176 NHS/NHSII samples) and methylation patterns (161 NHS/NHSII/PLCO samples).

Overlap: None

Impact of pre-diagnosis and post-diagnosis analgesic use and tumor inflammation biomarkers on ovarian cancer survival

Effort: 2.4 calendar

NIH/NCI - R01CA 270159 – Merritt/Twooroger, MPI

04/2022 – 03/2027

Fund: \$1,259,747 Proposed total costs

Goals: The aims of this study leverage compelling epidemiological and experimental data that inflammation plays a role in ovarian cancer progression. Our study will impact ovarian cancer patients by generating key data that are needed to design efficient clinical trials to test the use of aspirin/NSAIDs in combination with standard treatment to improve patient survival. In the long term, this research will improve treatment strategies for women with ovarian cancer.

Role: Site PI

Overlap: There is scientific overlap between the above proposed project (R01 CA270159) and the application under consideration at the Department of Defense (OC200236) evaluating the role of aspirin use in survival of patients with ovarian cancer. If both projects are funded, the budgets will be adjusted appropriately in conjunction with agency staff.

Moffitt Cancer Center (MCC) Support Grant

Effort: 2.4 calendar

NCI - P30 CA076292 - Cleveland, John (PI)

2022/02/01 – 2027/01/31

Funding: \$25,313,785 total costs

Role: Associate Center Director of Population Science

Project goals: The grant provides support for key personnel involved in the cancer center's research mission.

The 142 MCC members span the basic, clinical, and population sciences. They are organized into five highly collaborative, multidisciplinary programs with exceptional levels of intra- (35%) and inter-programmatic (18%) publications. Under the leadership of Dr. John Cleveland, the fourth MCC Director, a Research Strategic Plan (RSP) was developed and implemented for "Moffitt 3.0." Four of six Associate Center Directors are new; and new leaders have been appointed in every program, with bold goals and specific aims. Two of the 13 shared resources have been significantly restructured (Chemical Biology, Molecular Genomics), and one new resource created (Collaborative Data Services) to better meet the changing needs of MCC scientists. Implementation of the strategic plan has been bolstered by substantial institutional investment, especially in basic science, immunotherapy, and clinical research infrastructure, including the recruitment of 45 new faculty members, of whom 32 are CCSG members. MCC is a leader in immunotherapy, and more than 40% of overall clinical trial accrual is to investigator-initiated studies. MCC population scientists initiated significant new efforts in cancer prevention and outcomes that include vaccines, tobacco cessation, and health disparities. This is particularly true in the unique Cancer problems in the catchment area – notably lung Cancer, melanoma, and HPV- prevention. MCC's Total Cancer Care protocol, the ground-breaking research strategy to realize the promise of personalized medicine, has continued to thrive, resulting in dramatic utilization of the Tissue Core and the formation of the oncology Research Information Exchange Network (ORIEN) that now includes eleven cancer centers across the nation, with several more poised to join the consortium this year. MCC requests funding for: five scientific programs, 13 shared resources, two clinical research components, planning and evaluation, administration, leadership, four staff investigators, and developmental funds. CCSG funds are leveraged more than 10-fold with institutional resources to maximize impact on Cancer prevention, treatment, and cure in the catchment area, the state of Florida and beyond.

Overlap: None

The Cancer Prevention and Wellness Research Facility: a biopsychosocial and metabolic research core

Effort: 1.2 calendar months (paid by Moffitt Cancer Center)

NCI - C06 OD032055- Tworoger (PI)

10/01/2021 – 09/30/2024

Funding: \$7,077,955 proposed total Costs

Project goals: Moffitt Cancer Center proposes to create a Cancer Prevention and Wellness Research Facility (CPWRF) that will consolidate and modernize existing human laboratory rooms for smoking and physiological/ behavioral monitoring studies and participant assessment collection rooms for functional/physical testing and biospecimen collections, with co-located specimen intake and processing space.

Overlap: None

Type II diabetes, related biomarkers and medications, and ovarian cancer

Effort: no measurable effort

NCI – R03 – Harris (PI), Role: Consultant

12/2021 – 11/2023

Project Goals: Aim 1 is to assess if the association between T2D and ovarian cancer risk differs by tumor characteristics and is modified by medication use to treat T2D using the Ovarian Cancer Cohort Consortium data. Aim 2 is to evaluate if metformin use abrogates the effect of T2D on worse survival among women with ovarian cancer, particularly among those with tumor associated macrophages.

Using biomarkers to elucidate the breastfeeding and ovarian cancer risk association

Effort: no measurable effort

Project Number: Pending

NIH/NCI, Sasamoto, PI, Role: Consultant

Primary Place of Performance: Brigham and Women's Hospital

Project/Proposal Start and End Date: 12/2021 – 11/2023

Goals: Aim 1 is to identify factors that mediate the association between breastfeeding and ovarian cancer risk and investigate subgroup-specific associations in 13 case-control and 10 prospective cohort studies, Aim 2 is to characterize the impact of breastfeeding on circulating inflammatory and metabolic markers in NHS/NHSII, and Aim 3 is to examine the association between breastfeeding and tumor immunity in NHS/NHSII and NEC.

COMPLETED

NEWLY INACTIVE

Dietary and Hormonal Determinants of Cancer, Project 3: Ovarian Cancer

Effort: 1.92 calendar

P01 CA087969, NCI - Eliassen, Heather (PI)

Grants Official: Gabriel Y. Lai, laigy@mail.nih.gov

2015/07/01 – 2021/06/30 NCE

Funding: \$47,002 subaward total direct costs

Role: Project Leader

Project goals: The major focus of the current proposal is on modifiable or treatable factors within two key, yet underexplored, pathways in Ovarian Cancer etiology: lipids and Inflammation. For the lipid pathway, we will examine plasma total cholesterol, HDL, and LDL as these markers can be altered by medication or lifestyle changes, as well as several other promising lipid classes, Lysophosphatidylcholines and Sphingomyelins, which have been suggested as early detection markers and also be important etiologically. These will be measured on a validated, semi-targeted metabolomics platform; this also will allow us to conduct a comprehensive discovery- based

analysis of other small molecule metabolites that may be important in ovarian carcinogenesis. The inflammation aims will build on work from the current P01 and cross-project collaboration with Project 2 (colorectal Cancer), taking an innovative approach that considers multiple facets of the Inflammatory milieu, including lifestyle factors (pro-inflammatory Diet, sedentary behavior, strength training), analgesic related factors (premenopausal NSAID use, urinary Prostaglandins), and chlamydia infection status. Importantly, we will explore potential underlying biologic mechanisms of action by evaluating risk factor associations by tumor aggressiveness, the amount of tumor-associated macrophage Infiltration, and global tumor gene expression to identify transcriptional alterations in tumors of patients with varying Inflammatory exposures. We propose to provide the first detailed evaluation of modifiable factors after diagnosis, including physical activity, Smoking, NSAIDs, and a pro-inflammatory Diet, and survival in stage I/II patients; no evidence-based recommendations currently are available.
Overlap: None

NEWLY INACTIVE

PREDICT: The Prospective Early Detection Consortium for Ovarian Cancer

Effort: 0.24 calendar

DOD - W81XWH1910307 Kaaks, Rudolf (PI)

Grants Official: Chris Baker, 301 619-2332, christopher.l.baker132.civ@mail.mil
2019/09/01 – 2021/08/31

Funding: \$32,590 subaward total direct costs

Role: Site PI

Project goals: 1. Establish an international consortium of large-scale prospective cohort studies and biobanks with blood samples collected prior to diagnostic surgery—“PREDICT”, the Prospective Early Detection Consortium for Ovarian Cancer—for the application of state-of-the-art “omics” technologies for biomarker discovery and validation; 2. Leverage existing data in individual cohorts to provide preliminary data for future studies; and 3. Initiate a “proof of concept” study validating a set of candidate tumor associated autoantibodies (TAABs) identified in an immuno-proteomics scan for antibodies against 768 candidate proteins.

Overlap: None

NEWLY INACTIVE

Understanding Ethnic Differences in Cancer: The Multiethnic Cohort Study - OC3 Supplement

Effort: 0.24 calendar months

NIH/NCI - 5U01CA164973-09 – Le Marchand, Loic (PI) OC3 Supplement Merritt, Melissa (PI)

Grants Official: Somdat Mahabir, mahabir@mail.nih.gov
2020/09/01 – 2021/08/31

Funding: \$27,460 total direct costs

Role: Site PI

Project goals: The Multiethnic Cohort (MEC) Study began in 1993-1996 and includes more than 215,000 male and female residents of Hawaii and Southern California representing a diverse population of five major racial/ethnic groups. These participants have been followed over time for incidence of cancer and other health outcomes. Using this valuable resource, we have identified differences in ovarian cancer age-adjusted incidence rates by racial/ethnic group including high incidence in Native Hawaiians, moderate incidence in Latinas and low incidence

in Asian and African American women as compared with White women. We also observed notable differences in ovarian risk factor associations across racial/ethnic groups for selected hormone-related factors that require validation. We propose to use this Administrative Supplement to extend our studies of racial/ethnic differences in ovarian cancer risk in the MEC Study to evaluate risk associations by race/ethnicity using the Ovarian Cancer Consortium (OC3) dataset, which includes data from additional prospective cohort studies. Our goal for the Administrative Supplement is to build resources to understand racial/ethnic differences in ovarian cancer risk by providing funding for two cohort studies (MEC and the Southern Community Cohort Study) to contribute new data from a substantial number of non-White participants to the OC3 central database. These combined data will support our approved OC3 project and will also increase the racial/ethnic diversity represented in the OC3 that will be available to support future research projects.

Overlap: None

NEWLY INACTIVE

Redefining Normal: Personalized CA125 Cutpoints for Ovarian Cancer Screening

Effort: 0.96 calendar

R01 CA193965, National Cancer Institute (NCI)

Terry, Kathryn (PI)

Grants Official: Christos F. Patriotis, patriotisc@mail.nih.gov

2016/06/01 – 2020/05/31

Funding: \$46,501 subaward total direct costs

Role: Co-Investigator

Project goals: Then, we will create personalized CA125 cutpoints based on each woman's individual characteristics that will determine what the "normal" CA125 threshold should be for that woman. We will evaluate the ability of personalized CA125 cutpoints versus a single cutpoint (35 U/mL) to distinguish cases from controls and ultimately determine whether addition of personalized CA125 to established risk prediction models improves their performance. We hypothesize that by reducing the background noise introduced by exposures that elevate or lower CA125, these personalized cutpoints will improve CA125 as an ovarian cancer screening biomarker for population based ovarian cancer screening.

Overlap: None

NEWLY INACTIVE

Pharma Observational/RWE Study Among I/O Patients - Feasibility Query and Pilot Review of Pathology Reports in EMR

Effort: 0 calendar

OT123-407 Bristol Meyers Squibb (Agreement)

Grants Official: Ilknur Acarlar, PhD, MBA, Ilknur.Acarlar@bms.com

01/02/2020 – 06/02/2021

Funding: \$98,696 agreement total costs

Role: PI

Project goals: Feasibility Analysis to determine Project Scope: 1. Feasibility Query Leveraging Moffitt Data Warehouse; 2. Pilot Review of Pathology Reports in EMR; 3. I/O Treatment Prediction Model development

Overlap: None

NEWLY INACTIVE

Posttraumatic Stress Disorder and Ovarian Cancer Risk

Effort: 0.3 calendar

W81XWH-17-1-0153 DOD - Kubzansky, Laura (PI)

Grants Official: Karen Wylie, PhD, karen.m.wylie.ctr@mail.mil

2017/09/30 – 2020/09/29

Funding: \$41,988 subaward total direct costs

Role: Co-I

Project goals: The project's specific aims are: (1) to determine if PTSD is longitudinally associated with increased risk of developing ovarian cancer and decreased survival after diagnosis; (2) to identify if PTSD influences biological and behavior-related processes also linked to increased ovarian cancer risk and decreased survival; and (3) to evaluate using formal statistical models if behavior-related pathways account for some of the association between PTSD and risk of developing ovarian cancer.

Overlap: None

Moffitt Imaging Biomarker Validation Center (MIBVAC)

Effort: .12 calendar

U01CA200464, NIH / NCI Heine/Gillies/Schabath (MPIs)

Grants Official: Richard V. Mazurchuk, mazurchukrv@mail.nih.gov

07/01/2016 – 03/31/2021

Funding: \$416,868

Role: Co – I

Project goals: This multi-PI grant award brings the Moffitt Cancer Center into the Early Detection Research Network (EDRN) of NCI. This study has three projects: For Aim 1, we will establish a breast image and data repository for the EDRN by providing two existing datasets (i.e., matched case-control datasets with images and relevant patient data from two full field digital mammography technologies) and develop a new case-control dataset with images from digital breast tomosynthesis (DBT). This new dataset will include 320 matched case-control pairs with DBT images and relevant demographical / clinical data. We will also evaluate and validate biomarkers from breast images. In Aim 2, we will evaluate and validate image biomarkers for the early detection of lung cancer using low dose CT and create an image/data pipeline resource for the EDRN. In Aim 3, we will conduct validation studies using image derived biomarkers for the EDRN. The PIs on this project will also form collaborative studies with complementary EDRN partners external to the Moffitt Cancer Center.

Overlap: None

National Spirituality and Health Consortium

Effort: 1.2 calendar

ID# 59607 Templeton Foundation

Shields (PI)

Grants Official: Nancy Thomas, nthomas5@partners.org

2017/06/01 – 2019/05/31

Role: Site PI

Project goals: The goal of this application is to create the National Consortium on Spirituality and Health, comprised of six national cohorts who will contribute standardized questions on religiosity and spirituality (R/S), demographic, clinical, and DNA for ~ 1,200 of their participants

to create the first prospective R/S research database. We will then evaluate the relationship of R/S measures with DNA methylation in five stress-related and serotonergic genes and telomere shortening as well as risk of hypertension, cardiovascular disease, and mortality.

Overlap: None

Biobank for Microbiome Research in Massachusetts: BIOM-Mass

No Number Massachusetts Life Science Center

Tworoger (PI)*

Grants Official:

2016/07/01 – 2019/06/30

Funding: \$4,912,307

Role: *relinquished PI to Dr. Eric Rimm as of 6/1/2017

Project goals: This Capital Grant is to develop necessary infrastructure to expand microbiome research. BIOM-Mass will create a state-of-the-art facility and integrated platform to collect, use, and analyze microbiome-targeted biospecimens in human populations. BIOM-Mass will: (a) collect microbiome specimens from prospective cohorts, including 25,000 individuals from the Nurses' Health Study II cohort; (b) leverage laboratory automation to collect and store biospecimens; and c) deploy a novel analysis and bioinformatics data portal.

Overlap: None

Characterizing Treatable Causes of Small Fiber Polyneuropathy in Gulf War Veterans

*Effort of 0.36 calendar, ended 2017/05/31

W81XWH-14-1-04999, U.S. Army Medical Research Acquisition Activity

Oaklander (PI)

Grant Official: Not Available

2014/09/30 – 2017/09/29

Funding: \$196,664

Role: Co-I

Project goals: This grant supports global development of a case definition for small-fiber polyneuropathy using the Delphi method among a cohort of experts, and then test the hypothesis that small-fiber polyneuropathy underlies a significant proportion of cases of Gulf War Illness.

Overlap: None

Psychological stress, associated biologic mediators, and ovarian cancer risk

Effort: 3.96 calendar

R01CA163451-03, NCI

Grants Official: Paige A. Green, mcdonaldp@mail.nih.gov

2012/09/13 - 2017/07/31

Funding: \$304,802

Role: PI

Project goals: This application will translate experimental research into prospective human studies and could improve our understanding of ovarian carcinogenesis and our ability to prevent this fatal disease. It will focus on the relationship of self-reported measures of stress (e.g., phobic anxiety, depression, job strain, care-giving stress, and social support) as well as biomarkers of stress (e.g., prolactin, telomere length). We also will evaluate the role of beta-blocker medications as animal models suggest that stress acts through the β 2-adrenergic receptor.

Overlap: None

Assessing the role of androgens in breast cancer risk

Effort: 2.16 calendar

R01CA166666, NIH

Hankinson (PI)

2012/09/01 – 2017/06/30

Grants Official: Crystal Wolfrey, wolfreyc@mail.nih.gov, Phone: 301-496-8634

Role: Co-I

Project goals: In this study, we propose to investigate the role of androgens in the etiology of breast cancer to help elucidate whether androgen acts directly or indirectly in breast tumor tissue. We aim to better define the role of androgens by evaluating circulating androgen levels, risk factors that may operate, at least in part, through an androgen pathway, and expression of androgen receptor as well as a novel androgen signaling signature in breast tumor tissue. Further, we will examine the associations between physical activity, energy balance, and circulating androgen levels.

Overlap: None

Psychosocial Stress and Ovarian Cancer Risk: Metabolomics and Perceived Stress

W81XWH-13-1-0493 DOD - Poole (PI)

2013/09/30 – 2017/04/30

Funding: \$750,000

Grants Official: Karen Wylie, PhD, karen.m.wylie.ctr@mail.mil

Role: Co-Investigator/Mentor

Project goals: The overall goal of this study is to develop a metabolomic profile of chronic stress using blood collected from women with post-traumatic stress disorder (PTSD) compared to those with a trauma but no PTSD and those with no trauma. Then this profile will be applied to a prospective study of ovarian cancer cases and controls to determine if a metabolomic profile of chronic stress is associated with increased risk of ovarian cancer.

Overlap: None

Development of the Ovarian Cancer Cohort Consortium: Risk factor associations by heterogeneity of disease

W81XWH-12-1-0561, Department of Defense Ovarian Cancer Research Program

Grants Official: Karen Wylie, PhD, karen.m.wylie.ctr@mail.mil

2012/09/30 - 2016/09/29

Funding: \$500,000

Role: PI

Project goals: The overall goal of this project is to pool data from at least 20 cohort studies from around the world to evaluate whether risk factor associations for ovarian cancer differ by various metrics of tumor heterogeneity. We will focus on known and putative ovarian cancer risk factors, such as parity, oral contraceptive use, tubal ligation, postmenopausal hormone use, etc. and will evaluate associations by histology, tumor dominance (as a surrogate for cell of origin), and tumor aggressiveness (defined by women who died within three years of diagnosis versus not). We will then use this information to develop an improved risk prediction model.

Overlap: None

Biochemical Markers in the Nurses' Health Study Cohort

U01CA049449, NIH/NCI

Hankinson (PI)

Grants Official: Tram K. Lam, lamt@mail.nih.gov, Phone: (240) 276-6967

2012/05/01 – 2016/08/31

Role: Co-Investigator

Project goals: We propose to continue our work identifying and validating biomarkers – particularly hormonal markers – that predict risk of invasive breast cancer in postmenopausal women. Using a prospective nested case-control design, we plan to analyze blood samples collected from the 32,826 participants in the Nurses' Health Study (NHS) who provided a blood sample in 1989-90 and, for 18,743 of these women, a second sample in 1999-2000. We propose to evaluate markers from several inter-related pathways to determine their role in cancer risk; a number of these aims are entirely new, while others extend our work in the most promising areas from the current grant cycle.

Overlap: None

Sleep quality in relation to metabolomics profiles and canonical stress hormones

TREC No number available, NIH

2015/06/01 – 2016/05/31

Funding: \$24,845

Grants Official: Crystal Wolfrey, wolfreyc@mail.nih.gov, Phone: 301-496-8634

Role: PI

Project goals: In this application, we propose to examine the relationship of self-reported sleep quality (using the Pittsburgh Sleep Quality Index, PSQI) and circadian factors (chronotype and shiftwork) with metabolic and stress hormone biomarkers. We will use data from the Mind-Body Study (MBS), a sub-study from the Nurses' Health Study II (NHSII), in which 226 women provided fasting blood samples to conduct metabolomic profiling, first morning urine samples to assess catecholamines, and five timed saliva samples over a day to measure diurnal cortisol rhythms. At biospecimen collection, women completed the PSQI, information on other stressors (e.g., discrimination, depression, social isolation, mindfulness, etc.), and weight, with corresponding detailed behavioral and co-morbidity data from the NHSII questionnaires.

Overlap: None

Growth Hormones and Breast Cancer Risk

R01CA138580-04, NCI

Grants Official: Tram K. Lam, lamt@mail.nih.gov

2010/07/01 - 2016/04/30

Funding: \$1,045,249

Role: PI

Project goals: We will examine whether prolactin is more strongly associated with risk of estrogen receptor positive tumors, as well as tumors staining positive for prolactin, prolactin receptor, cyclin D1, and phosphorylated STAT3 and STAT5. This study will provide the first prospective assessment of breast cancer risk with a prolactin bioactivity assay, and evaluate the addition of prolactin to a comprehensive risk prediction model for breast cancer.

Overlap: None

9.2 CHERN, JING-YI

Positions & Scientific Appointments

8/2020- Present Assistant Fellowship Program Director, H. Lee Moffitt Cancer Center/University of South Florida, Tampa, FL
8/2017- Present Assistant Member H. Lee Moffitt Cancer Center, Tampa, FL
8/2017- Present Assistant Professor, Department of Oncologic Sciences, University of South Florida, Tampa, FL

Additional Support from Foreign or Domestic Entities

None

ACTIVE

NEW

THIS AWARD

W81XWH-20-1-0488 - OC190330 (Tworoger) 09/01/2020 to 08/31/2023
0.6 CM

DOD/US Army \$340,580 Annual

DC/\$1,120,216 Total

Sponsor Contact Info: Karen Wylie, CDMRP, Scientific Officer, karen.m.wylie.civ@mail.mil
A Presurgical Window of Opportunity Trial of the Effect of Aspirin on Immunological Features of Ovarian Tumors

Goals: The main goals of our clinical trial are to assess the efficacy and safety of standard-dose aspirin in improving prognosis-related tumor characteristics at surgery and tolerance of neoadjuvant chemotherapy in women recently diagnosed with ovarian cancer.

Specific Aims: 1) To evaluate the efficacy of aspirin for improving immunological characteristics of the tumor at interval debulking surgery among women diagnosed with ovarian cancer. We hypothesize that, compared with women assigned to a daily placebo pill, those assigned to daily 325mg aspirin will have: a. Primary: A greater decrease in density of tumor-associated macrophages (TAMs) and T-regulatory cells (Tregs) in the tumor and b. Secondary: (i) A greater percent improvement in response evaluation criteria in solid tumors (RECIST) standardized to the number of chemotherapy cycles completed; (ii) greater decrease in tumor COX1 and COX2 expression; (iii) greater decrease in platelet aggregation function; and (iv) greater decrease in plasma IL-6 levels. 2) To evaluate the efficacy of daily 325mg aspirin versus placebo pill for improving tolerance of neoadjuvant chemotherapy and quality of life. We hypothesize that, compared with women assigned to a daily placebo pill, those assigned to daily 325mg aspirin will have: a. Secondary: Fewer physical symptoms, including fatigue, nausea, peripheral neuropathy, and sleep symptoms and b. Secondary: Fewer emotional symptoms, including depression and anxiety symptoms, and higher subjective cognitive function.

PENDING

None

IN-KIND

No domestic or foreign in-kind support.

ENDED

INACTIVE

(Peres/Chern)
0.24 CM

06/01/2019 to 5/31/2020

Moffitt Team Science Funding Opportunity

\$74,967

Sponsor Info: Maureen Ahearn, Moffitt Cancer Center, 813-734-8824;
intramuralprograms@moffitt.org

The impact of obesity and comorbidities on treatment efficacy and outcomes in ovarian cancer by race/ethnicity

This application proposes to characterize how obesity and other related comorbid conditions influence chemotherapy treatment selection and dosing modalities and whether these decisions impact treatment efficacy, toxicities, and outcomes in ovarian cancer patients. As racial/ethnic minorities have a greater burden of obesity and other related comorbidities, we will test our hypothesis that the negative consequences of these conditions on treatment and outcomes will disproportionately affect non-white patient populations.

Specific Aims: 1. Characterize chemotherapy treatment selection and dosing modalities among ovarian cancer patients by body mass index (BMI) and other obesity-related comorbidities (e.g., hypertension, diabetes mellitus, cardiovascular disease, renal disease); 2. Evaluate the impact of obesity and other related comorbidities on treatment efficacy, toxicities, and outcomes in these patients; and, 3. Explore whether the consequences of obesity and other related comorbidities on treatment and outcomes differ by race/ethnicity.

9.3 CONEJO-GARCIA, JOSE R.

POSITIONS & SCIENTIFIC APPOINTMENTS

2016-present Chair and Senior Member, Department of Immunology, Moffitt Cancer Center, Tampa, FL

2016-present Program Leader, Immuno-Oncology Program, Moffitt Cancer Center, Tampa, FL

2016-present Professor, Oncological Sciences, University of South Florida, Tampa, FL

ADDITIONAL SUPPORT FROM FOREIGN OR DOMESTIC ENTITIES

None

ACTIVE

Title: *B cell-dependent anti-tumor immunity in ovarian cancer*

Aim 1: Define the role of SATB1-dependent ICOS expression during TFH differentiation

Aim 2: Determine the role of SATB1 in TGF-beta-driven, Treg-dependent TFH differentiation

Aim 3: Recapitulate the mechanisms leading to the assembly and protective activity of TLS in ovarian cancer.

Grant Contact: Angela Walters

Email: angela.walters@nih.gov

Status of Support: Active

Project Number:

U01CA232758

Name of PD/PI: Conejo-Garcia (PI)

Source of Support: NIH/NCI (Moonshot)

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 09/2018 - 08/2023

Total Award Amount (including Indirect Costs): \$3,895,698

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2018	3.0 Calendar
2. 2019	3.0 Calendar
3. 2020	2.70 Calendar
4. 2021	2.70 Calendar
5. 2022	2.70 Calendar

NEW

Title: *Rapid Exoproteome Antigen Profiling of antibodies produced in the ovarian cancer microenvironment*

Aim 1: Define the role of SATB1-dependent ICOS expression during TFH differentiation

Aim 2: Determine the role of SATB1 in TGF- β -driven, Treg-dependent TFH differentiation

Aim 3: Recapitulate the mechanisms leading to the formation and protective activity of TLS in vivo in ovarian cancer.

Grant Contact: Angela Walters

Email: angela.walters@nih.gov

Status of Support: Active

Project Number: U01CA232758

Name of PD/PI: Conejo-Garcia (PI)

Source of Support: NIH/NCI (Collaborative Supplement)

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 12/2020 - 12/2021

Total Award Amount (including Indirect Costs): \$200,895

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2020	No Effort Assigned

Title: *Regulatory Dendritic Cells in Cancer*

Major Goals: The major aims of this project are: 1: Determine the anti-tumor effectiveness of targeting human BTN3A1 in vivo in tumor-bearing hosts; 2: Elucidate the molecular mechanism of T cell inhibition mediated by BTN3A1, based on the identification of a multimeric complex that co-IPs with BTN3A1 and 3: Define the mechanism of BTN3A1 deregulation at tumor beds.

Grant Contact: Joy Kearse

Email: kearsej@mail.nih.gov

Status of Support: Active

Project Number: R01CA124515

Name of PD/PI: Conejo-Garcia (PI)

Source of Support: NIH/NCI

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 07/2007 - 02/2023

Total Award Amount (including Indirect Costs): \$1,827,220

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2018	1.8 Calendar
2. 2019	1.8 Calendar
3. 2020	1.35 Calendar
4. 2021	1.35 Calendar
5. 2022	1.35 Calendar

Title: *Moffitt Cancer Center Support Grant*

Major Goals: The major goal of this project is to support infrastructure for transdisciplinary cancer-relevant research and to foster studies that would not occur without the climate, facilities, and research resources that a cancer center can uniquely provide.

Grant Contact: Joy Kears

Email: kearsej@nih.gov

Status of Support: Active

Project Number:

P30CA076292

Name of PD/PI: Cleveland (PI); Role: Chair of the Department of Immunology

Source of Support: NIH/NCI

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 02/1998 - 01/2022

Total Award Amount (including Indirect Costs): \$11,963,864

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2017	0.9 Calendar
2. 2018	0.9 Calendar
3. 2019	0.9 Calendar
4. 2020	0.9 Calendar
5. 2021	0.9 Calendar

Title: *Development of CAR-T/CER-T Therapies for Ovarian Cancer*

Major Goals: The major goals of this project are to perform the preclinical development of novel chimeric receptors expressing the FSH hormone as a targeting domain, to re-direct autologous T cells towards FSHR+ ovarian cancer cells.

Grant Contact: Latanya Scott

Email: latanya.scott@moffitt.org

Status of Support: Active

Project Number: 170713 SRA

Name of PD/PI: Conejo-Garcia (PI)

Source of Support: Certainty Therapeutics

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 11/2017 - 11/2021

Total Award Amount (including Indirect Costs): \$1,423,159

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2017	0.36 Calendar
2. 2018	0.36 Calendar
3. 2019	0.36 Calendar
4. 2020	0.36 Calendar

Title: *Targetable epigenetic mechanism driving Cutaneous T cell Lymphoma*

Aim 1: Elucidate the role of SATB1 silencing in the pathogenesis of CTCL

Aim 2: Define the complementary mechanisms leading to epigenetic silencing of SATB1 in Sezary Syndrome

Aim 3: Identify the combination of epigenetic drugs that more effectively restore SATB1 expression in Sezary cells.

Grant Contact: Joy Kearse

Email: kearsej@mail.nih.gov

Status of Support: Active

Project Number: R01CA240434

Name of PD/PI: Conejo-Garcia/Pinilla/Sokol (MPI)

Source of Support: NIH/NCI

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 07/2019 - 06/2024

Total Award Amount (including Indirect Costs): \$2,742,645

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2019	1.8 Calendar
2. 2020	1.35 Calendar
3. 2021	1.35 Calendar
4. 2022	1.35 Calendar
5. 2023	1.35 Calendar

Title: *Functional reprogramming of tumor-MDSC through antibody-based therapies targeting Notch ligands*

Aim 1: Determine the role of cancer cell-Jagged1-2 in the immunosuppressive activity induced by MDSC in tumor-bearing hosts

Aim 2: Elucidate the mechanisms leading to the upregulation of Jagged ligands in tumor-MDSC and understand the endogenous effects of MDSC-related Jagged1 in tumor-induced tolerance

Aim 3: Test the prediction that joint inhibition of Jagged in cancer cells and MDSC overcomes tumor-induced T cell suppression and enhances the efficacy of various forms of immunotherapy.

Grant Contact: Lillian S. Kuo

Email: kuols@mail.nih.gov

Status of Support: Active

Project Number: R01CA233512

Name of PD/PI: Rodriguez (PI), Role: Co-Investigator

Source of Support: NIH/NCI

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 06/2019 - 05/2024

Total Award Amount (including Indirect Costs): \$1,967,250

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2019	0.45 Calendar
2. 2020	0.45 Calendar
3. 2021	0.45 Calendar
4. 2022	0.45 Calendar
5. 2023	0.45 Calendar

NEW

Title: *Early Life Exposures and Risk of Developing Ovarian Cancer*

Major Goals: The major goal of this project is to evaluate several early life exposures (cigarettesmoking, social adversity and abuse, and physical activity) and risk of ovarian cancer in later life. Better understanding of the role of early life factors in ovarian cancer risk may help inform development of targeted prevention strategies.

Grant Contact: James Aldrich

Email: James.Aldrich@flhealth.gov

Status of Support: Active

Project Number: 9JK02

Name of PD/PI: Tworoger (PI), Role: Co-Investigator

Source of Support: Florida Biomedical Research Program James & Esther King

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 08/2020 - 02/2023

Total Award Amount (including Indirect Costs): \$504,838

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2020	0.36 Calendar
2. 2021	0.36 Calendar
3. 2022	0.36 Calendar

NEW

Title: *Notch signaling boosts T cell-based immunotherapy*

Major Goals: The major aims of this project are: 1: Define how the modulation of notch signaling significantly improves the therapeutic potential of adoptively-transferred T cells in models of melanoma, lung and ovarian cancer; 2: Elucidate the mechanisms whereby Notch active T cells become refractory to myeloid cell-driven immunosuppression in tumors and 3: Define concurrent genetic interventions that synergize with ectopic Notch activity in transferredT cells.

Grant Contact: James Aldrich

Email: James.Aldrich@flhealth.gov

Status of Support: Active

Project Number: 20B04

Name of PD/PI: Rodriguez/Luca (MPI), Role: Co-Investigator

Source of Support: Florida Biomedical Research Program Bankhead Coley

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 06/2020 - 05/2023

Total Award Amount (including Indirect Costs): \$636,610

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2020	0.18 Calendar
2. 2021	0.18 Calendar
3. 2022	0.18 Calendar

Title: *Finding Synergy with Radiation Therapy and Immunotherapy for Patients with Lung Cancer*
Major Goals: The major goal of this project is to test the hypothesis that combining systemic immunotherapy with radiation therapy will allow for vigorous T cell specific immune activation and improved local and distant tumor control among patients with lung cancer.
Grant Contact: John O. Ojeifo
Email: ojeifojo@mail.nih.gov
Status of Support: Active
Project Number: K08CA231454
Name of PD/PI: Perez (PI), Role: Mentor
Source of Support: NIH/NCI
Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL
Project/Proposal Start and End Date: 08/2019 - 07/2024
Total Award Amount (including Indirect Costs): \$1,193,760
Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2019	No Effort Assigned
2. 2020	No Effort Assigned
3. 2021	No Effort Assigned
4. 2022	No Effort Assigned
5. 2023	No Effort Assigned

NEW

Title: *CARM1-mediated regulation of YAP1 as a therapeutic target in lung cancer*
Major Goals: The major aims of this project are: 1: To understand the regulation of YAP1 by TBK1 in K-Ras mutant lung cancer and 2: To assess how CARM1-mediated regulation of YAP1 affects lung cancer metastasis.
Grant Contact: Joanna Watson
Email: watsonjo@mail.nih.gov
Status of Support: Active
Project Number: R01CA250276
Name of PD/PI: Chellappan (PI), Role: Co-Investigator
Source of Support: NIH/NCI
Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL
Project/Proposal Start and End Date: 08/2020 - 04/2025
Total Award Amount (including Indirect Costs): \$2,187,215
Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2020	0.3 Calendar
2. 2021	0.3 Calendar
3. 2022	0.3 Calendar
4. 2023	0.3 Calendar
5. 2024	0.3 Calendar

NEW

Title: *A Presurgical Window of Opportunity Trial of the Effect of Aspirin on Immunological Features of Ovarian Tumors*
Aim 1: To evaluate the efficacy of aspirin for improving immunological characteristics of the tumor at interval debulking surgery among women diagnosed with ovarian cancer
Aim 2: To evaluate the efficacy of daily 325mg aspirin versus placebo pill for improving tolerance of neoadjuvant chemotherapy and quality of life.

Grant Contact: Susan Dodd
 Email: susan.l.dodd4.civ@mail.mil
 Status of Support: Active
 Project Number: W81XWH-20-1-0488
 Name of PD/PI: Tworoger (PI), Role: Co-Investigator
 Source of Support: NIH/NCI
 Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL
 Project/Proposal Start and End Date: 09/2020 - 08/2023
 Total Award Amount (including Indirect Costs): \$1,120,216
 Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2020	0.24 Calendar
2. 2021	0.24 Calendar
3. 2022	0.24 Calendar

NEW

Title: *Actionable cell stress mechanisms governing $\alpha\beta$ and $\gamma\delta$ T cell responses against ovarian cancer*
 Major Goals: This grant is for pilot funds to support preliminary data for a P01 application. Grant
 Contact: Maureen Ahearn
 Email: IntramuralPrograms@moffitt.org
 Status of Support: Active
 Project Number: N/A
 Name of PD/PI: Conejo-Garcia / Rodriguez / Tworoger (MPI)
 Source of Support: H. Lee Moffitt Cancer Center & Research Institute, Miles for Moffitt
 Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL
 Project/Proposal Start and End Date: 01/2021 - 12/2021
 Total Award Amount (including Indirect Costs): \$150,000
 Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.12 Calendar

NEW

Title: *Role of Butyrophilins in Regulating T-Cell Activity*
 Major Goals: The major goal of this project is to generate preliminary results on the potential of neutralizing immunosuppressive butyrophilins in lung cancer patients resistant to PD-1 inhibitors to support a future Spore project.
 Grant Contact: Maureen Ahearn
 Email: IntramuralPrograms@moffitt.org
 Status of Support: Active
 Project Number: N/A
 Name of PD/PI: Conejo-Garcia (PI)
 Source of Support: H. Lee Moffitt Cancer Center & Research Institute, Lung Cancer Center of Excellence
 Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL
 Project/Proposal Start and End Date: 01/2021 – 12/2021
 Total Award Amount (including Indirect Costs): \$100,000
 Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.12 Calendar

NEW

Title: *Induction of Innate and Adaptive Anti-Tumor Immunity Against*

Aim 1: Predict neo-antigens and measure tumor-specific T-cell response and T-cell receptor repertoire in virus-injected AND companion (non-injected) CRLM tumors

Aim 2: Employ novel organotypic tumor cultures derived from CRLM tumors to query the tumor immune microenvironment and test the effectiveness of combining DNX-2401 and immune checkpoint inhibitors.

Grant Contact: Maureen Ahearn

Email: IntramuralPrograms@moffitt.org

Status of Support: Active

Project Number: N/A

Name of PD/PI: Anaya-Saenz / Conejo-Garcia / Fleming (MPI)

Source of Support: H. Lee Moffitt Cancer Center & Research Institute, Team Science Award

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 01/2021 - 12/2021

Total Award Amount (including Indirect Costs): \$150,000

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.12 Calendar

NEW

Title: *Investigating the prognostic role of intrinsic immune evasion mechanisms in HNSCC* Major

Goals: The major aims of this project are: 1: To generate HNSCC-specific immune signatures by integrating single-cell and bulk-tumor transcriptomic data using novel computational methods; 2: To discover immune-related lncRNA biomarkers and prioritize therapeutic targets by recalling existing transcriptome data and applying a resampling-based genome-wide method and 3: To combine baseline germline variants with tumor immune signatures and further examine its prognostic value in patients treated by immune checkpoint blockade.

Grants Management Specialist: Susan Medve

Email: medves@mail.nih.gov

Status of Support: Active

Project Number: R01DE030493

Name of PD/PI: Wang (PI), Role: Co-Investigator

Source of Support: NIH/NIDCR

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 04/2021 - 03/2024

Total Award Amount (including Indirect Costs): \$1,156,152

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.36 Calendar
2. 2022	0.36 Calendar
3. 2023	0.36 Calendar

NEW

Title: *Changing contraceptive patterns and ovarian cancer risk*

Major Goals: For the tissue related aims, tissue microarray slides will be sent from Brigham and Women's Hospital as well as Huntsman Cancer Institute to Moffitt Cancer Center for multiplex immunofluorescence staining. Dr. Conejo-Garcia will advise on the selection of markers and interpretation of the data.

Grant Contact: Angela Walters

Email: angela.walters@nih.gov

Status of Support: Active
 Project Number: R01CA258679
 Name of PD/PI: Tworoger (PI), Role: Co-Investigator
 Source of Support: NIH/NCI, PTE: Brigham & Women's Hospital
 Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL(Conejo-Garcia), Brigham & Women's Hospital (Boston, MA)
 Project/Proposal Start and End Date: 04/2021 - 03/2026
 Total Award Amount (including Indirect Costs): \$790,349
 Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.36 Calendar
2. 2022	0.36 Calendar
3. 2023	0.36 Calendar
4. 2024	0.36 Calendar
5. 2025	0.36 Calendar

NEW

Title: *Nitric oxide immune dependent resistance mechanisms to anti-PD-1 therapy*
 Major Goals: This project will investigate the nitric oxide dependent resistance mechanisms to anti-PD-1 therapy as a potential avenue for therapeutic development and intervention given that only 40% of melanoma patients have objective responses to anti-PD-1 therapy, allowing these patients to be treated with other potentially more effective therapies.
 Grant Contact: John O. Ojeifo
 Email: ojeifojo@mail.nih.gov
 Status of Support: Active
 Project Number: K08CA252164
 Name of PD/PI: Markowitz (PI), Role: Mentor
 Source of Support: NIH/NCI
 Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL
 Project/Proposal Start and End Date: 09/2021 - 08/2024
 Total Award Amount (including Indirect Costs): \$746,439
 Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.12 Calendar
2. 2022	0.12 Calendar
3. 2023	0.12 Calendar
4. 2024	0.12 Calendar

PENDING (ALL NEW)

Title: *Bile acids restrict functional reprogramming of myeloid-derived suppressor cells in tumor beds*
 Major Goals: The major aims of this project are: 1: Determine the restrictive action of the accumulated BAs in the functional transformation of PERK-null MDSC into myeloid cells that prime sustained protective anti-tumor T cell immunity, 2: Elucidate the mechanisms whereby BAs restrict PERK KO MDSC transformation in tumors and 3: Test the prediction that combined inhibition of PERK and IRE1 completely overcomes MDSC-associated immunosuppression and enhances the effectiveness of cancer immunotherapy.
 Grant Contact: Not available yet
 Status of Support: Pending

Project Number: R01CA262121

Name of PD/PI: Rodriguez (PI), Role: Co-Investigator

Source of Support: NIH/NCI/NIAID

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 07/2021 - 06/2026

Total Award Amount (including Indirect Costs): \$2,058,750

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.6 Calendar
2. 2022	0.6 Calendar
3. 2023	0.6 Calendar
4. 2024	0.6 Calendar
5. 2025	0.6 Calendar

Title: *Impact of pre-diagnosis and post-diagnosis analgesic use and tumor inflammation biomarkers on ovarian cancer survival*

Major Goals: The aims of this study leverage compelling epidemiological and experimental data that inflammation plays a role in ovarian cancer progression. Our study will impact ovarian cancer patients by generating key data that are needed to design efficient clinical trials to test the use of aspirin/NSAIDs in combination with standard treatment to improve patient survival. In the long term, this research will improve treatment strategies for women with ovarian cancer.

Status of Support: Pending

Project Number: R01CA270159

Name of PD/PI: Merritt (PI), Role: Co-Investigator

Source of Support: NIH/NCI (PTE: University of Hawaii)

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL (Tworoger and Conejo-Garcia), University of Hawaii (PTE)

Project/Proposal Start and End Date: 04/2022 - 03/2027

Total Award Amount (including Indirect Costs): \$1,259,747

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.24 Calendar
2. 2023	0.24 Calendar
3. 2024	0.24 Calendar
4. 2025	0.24 Calendar
5. 2026	0.24 Calendar
3. 2027	0.24 Calendar

Title: *Dietary and Hormonal Determinants of Cancer in Women*

Project 4 aims:

Aim 1: We consider that methylation clocks likely reflect the impacts of multiple biological mechanisms related to aging and seek to further understand the mechanisms underlying the relation between methylation and cancer and the relationship between cancer risk factors and methylation; Aim 2: We will extend the fatal cancer model we developed in the previous cycle of this grant, to consider the possibility that associations of both pre- and post-diagnosis risk factors may vary over time since diagnosis, as well as the possibility that some patients with cancer may be cured and their death rate will resemble that of the general population; Aim 3: We propose methods of analysis to study the associations between the presence and spatial clustering of immune markers in tumor cells and cancer survival.

Grant Contact: Not available yet

Status of Support: Pending

Project Number: P01

Name of PD/PI: Tworoger (Moffitt PI), Co-Investigator on Project 4

Source of Support: NIH/NCI, PTE: Brigham & Women's Hospital

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL (Tworoger and Conejo-Garcia), University of Hawaii (PTE)

Project/Proposal Start and End Date: 09/2021 - 08/2026

Total Award Amount (including Indirect Costs): \$1,285,043

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.36 Calendar
2. 2022	0.36 Calendar
3. 2023	0.36 Calendar
4. 2024	0.36 Calendar
5. 2025	0.36 Calendar

Title: *Spontaneous humoral responses open opportunities for novel immunotherapies against human cancer*

Aim 1: Determine the role of PD-1-specific antibodies spontaneously produced in human ovarian cancer; Aim 2: Define the feasibility of targeting intracellular tumor antigens with IgA.

Status of Support: Pending

Project Number: K99CA266947

Name of PD/PI: Biswas (PI), Role: Mentor

Grant Contact: Not available yet

Source of Support: NIH/NCI

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 12/2021 - 12/2026

Total Award Amount (including Indirect Costs): \$964,375

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.12 Calendar
2. 2022	0.12 Calendar
3. 2023	0.12 Calendar
4. 2024	0.12 Calendar
5. 2025	0.12 Calendar

Title: *Moffitt Cancer Center Support Grant*

Major Goals: The goal of this project is to support infrastructure for transdisciplinary cancer-relevant research and to foster studies that would not occur without the climate, facilities, and research resources that a cancer center can uniquely provide.

Grant Contact: Not available yet

Status of Support: Pending

Project Number: P30CA076292

Name of PD/PI: Cleveland (PI), Role: Chair of the Department of Immunology

Source of Support: NIH/NCI

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 02/2022 - 01/2027

Total Award Amount (including Indirect Costs): \$25,313,785

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.9 Calendar
2. 2022	0.9 Calendar
3. 2023	0.9 Calendar
4. 2024	0.9 Calendar
5. 2025	0.9 Calendar

Title: *Notch Signaling Renders T Cell Immunotherapy Effective Against Ovarian Carcinoma* Aim 1: Define how the modulation of Notch signaling during the generation of FSH-CER T cells significantly improves their therapeutic potential against FSHR+ ovarian carcinoma; Aim 2: Elucidate the mechanisms whereby Notch-active FSH-CER T cells become refractory to myeloid cell-driven immunosuppression in tumors; Aim 3: Modulate N1IC signaling in tumor-reactive T cells in vivo to maximize TRM cell differentiation.

Status of Support: Pending

Project Number: N/A

Name of PD/PI: Conejo-Garcia, J., Rodriguez, P. (MPI), Role: Initiating PI

Grant Contact: Not available yet

Source of Support: Dept. of the Army - Ovarian Cancer Research Program Investigator-Initiated Research Award (Partnering PI Option)

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 01/2022 - 12/2025

Total Award Amount (including Indirect Costs): \$658,800

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.6 Calendar
2. 2023	0.6 Calendar
3. 2024	0.6 Calendar
4. 2025	0.6 Calendar

Title: *Aberrant mRNA splicing as a mechanism of resistance to CD19-directed CAR T-cell therapy and radiation in relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL)* Major Goals: The goal of this study is to pave the way for eliminating CAR T and radiation resistance in R/R DLBCL.

Grant Contact: Not available yet

Status of Support: Pending

Project Number: N/A

Name of PD/PI: Robinson (PI), Role: Co-Investigator

Source of Support: American Cancer Society (ACS) Research Scholar Grant

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 01/2022 - 12/2025

Total Award Amount (including Indirect Costs): \$786,056

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.24 Calendar
2. 2023	0.24 Calendar
3. 2024	0.24 Calendar
4. 2025	0.24 Calendar

Title: *FMRG: Cyber: Bio: Agile Massively Distributed Point-of-Care Biomanufacturing of Therapeutic Peptides*

Major Goals: The goal of this study is to develop a rapid, and personalized approach for awakening the immune system to help fight cancer by building an A-Z system for discovering, optimizing and manufacturing personalized peptide-based cancer vaccines, with state-of-the-art patient information in the form of biomarker profiles unique to their tumors as the underlying training set for development.

Grant Contact: Not available yet

Status of Support: Pending

Project Number: N/A

Name of PD/PI: Gianneschi (Contact PI), Role: Co-PI

Source of Support: National Science Foundation (NSF), PTE: Northwestern University

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 12/2021 - 11/2025

Total Award Amount (including Indirect Costs): \$800,000

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	1.2 Calendar
2. 2023	1.2 Calendar
3. 2024	1.2 Calendar
4. 2025	1.2 Calendar

Title: *Aberrant mRNA splicing as a mechanism of resistance to CD19-directed CAR T-cell therapy and radiation in relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL)*

Major Goals: In this application, we propose the first comprehensive characterization of changes in mRNA splicing in R/R DLBCL with respect to resistance to CAR T-cell and radiation therapy. Grant

Contact: Not available yet

Status of Support: Pending

Project Number: R01

Name of PD/PI: Robinson/Locke (MPI), Role: Co-Investigator

Source of Support: NIH/NCI

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 04/2022 – 03/2027

Total Award Amount (including Indirect Costs): \$786,056

Person Months (Calendar/Academic/Summer) per budget period

Year	Person Months
1. 2022	0.36 Calendar
2. 2023	0.36 Calendar
3. 2024	0.36 Calendar
4. 2025	0.36 Calendar
5. 2026	0.36 Calendar
6. 2027	0.36 Calendar

Title: *The role of $\gamma\delta$ T cells in acute myeloid leukemia control*

Major Goals: We anticipate that this prospective longitudinal study findings can point to V γ 9V δ 2T cells to enhance the graft-versus-leukemia (GVL) activity and prevent AML relapse after HCT.

Grant Contact: Not available yet

Status of Support: Pending

Project Number: R01

Name of PD/PI: Bejanyan (PI), Role: Co-Investigator

Source of Support: NIH/NCI

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 02/2022 – 01/2027

Total Award Amount (including Indirect Costs): \$3,798,149
 Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	1.2 Calendar
2. 2023	1.2 Calendar
3. 2024	1.2 Calendar
4. 2025	1.2 Calendar
5. 2026	1.2 Calendar
6. 2027	1.2 Calendar

Title: *Assessment of the immune landscape and ovarian cancer survival using novel spatial and Bayesian statistical methods*

Major Goals: In this research, we will develop and test novel methods and approaches to analyze IF data that incorporates the spatial heterogeneity of the TIME in addition to abundance measures of immune cells, producing freely available software

Grant Contact: Not available yet

Status of Support: Pending

Project Number: R01CA262421

Name of PD/PI: Fridley (PI), Role: Co-Investigator

Source of Support: NIH/NCI

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 04/2022 – 03/2027

Total Award Amount (including Indirect Costs): \$3,699,808

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.36 Calendar
2. 2023	0.36 Calendar
3. 2024	0.36 Calendar
4. 2025	0.36 Calendar
5. 2026	0.36 Calendar
6. 2027	0.36 Calendar

Title: *Aspirin and NSAID use and ovarian cancer prognosis: a molecular epidemiological study*

Aim 1: is the OC3 epidemiologic analysis on aspirin and ovarian cancer survival; Aim 2: is immune profiling on the clinical trial tumor samples (current plans are to use imaging mass cytometry method in Akil Merchant's lab; no multiplex IF)

Grant Contact: Not available yet

Status of Support: Pending

Project Number: N/A

Name of PD/PI: Tworoger (PI), Role: Co-Investigator

Source of Support: CDMRP-OCA OVCA-ECIA, PTE: University of Hawaii

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 04/2022 – 03/2026

Total Award Amount (including Indirect Costs): \$333,242

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.12 Calendar
2. 2023	0.12 Calendar
3. 2024	0.12 Calendar
4. 2025	0.12 Calendar

5. 2026	0.12 Calendar
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Title: *Assessment of the tumor immune spatial landscape and ovarian cancer survival*

Major Goals: The first goal of this research is to develop novel statistical methods and software for the downstream analysis of mIF data. The second goal of this research is to apply these methods to the study of EOC, the deadliest gynecologic malignancy in the U.S., resulting in an immunoscore predictive of survival among EOC patients.

Grant Contact: Not available yet

Status of Support: Pending

Project Number: N/A

Name of PD/PI: Peres (PI), Role: Co-Investigator

Source of Support: CDMRP OCRP IIRA

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 10/2022 – 09/2025

Total Award Amount (including Indirect Costs): \$547,760

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.36 Calendar
2. 2023	0.36 Calendar
3. 2024	0.36 Calendar
4. 2025	0.36 Calendar

Title: *Developing an ESRI Neoantigen Response for Treatment of Metastatic Hormone Receptor Breast Cancer*

Major Goals: The goal of this study is to (1) Reduce overall mortality in breast cancer and (2) Revolutionize treatment regimens by replacing them with ones that are more effective, less toxic and impact survival.

Grant Contact: Not available yet

Status of Support: Pending

Project Number: N/A

Name of PD/PI: Conejo-Garcia (Partnering PI)

Source of Support: CDMRP-BCRP-BTA3

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 01/2022 - 12/2025

Total Award Amount (including Indirect Costs): \$2,141,000

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	1.8 Calendar
2. 2023	1.8 Calendar
3. 2024	1.8 Calendar
4. 2025	1.8 Calendar

Title: *Initiation and evolution of the ovarian cancer microenvironment*

Major Goals: The long-term goal of these studies is to understand and target spontaneous immune responses against ovarian cancer; an immunogenic disease with poor responses against PD-1 blockade.

Grant Contact: Not available yet

Status of Support: Pending

Project Number: R01CA157664

Name of PD/PI: Conejo-Garcia (PI)

Source of Support: NIH/NCI

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 04/2022 – 03/2027

Total Award Amount (including Indirect Costs): \$2,303,085

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	1.8 Calendar
2. 2023	1.8 Calendar
3. 2024	1.8 Calendar
4. 2025	1.8 Calendar
5. 2026	1.8 Calendar
6. 2027	1.8 Calendar

Title: *Notch signaling renders t cell immunotherapy effective against ovarian carcinoma*

Major Goals: The goal of this study is to pave the way to improve the effectiveness of checkpoint blockers or other immunotherapies that show limited success in aggressive tumors such as ovarian carcinoma.

Grant Contact: Not available yet

Status of Support: Pending

Project Number: N/A

Name of PD/PI: Conejo-Garcia (Initiating PI)

Source of Support: CDMRP-OCRP-IIRA

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 01/2022 – 12/2025

Total Award Amount (including Indirect Costs): \$670,000

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.6 Calendar
2. 2023	0.6 Calendar
3. 2024	0.6 Calendar
4. 2025	0.6 Calendar

Title: *Targeting Mitochondrial Stress Response Mediator LONP1 in Tumor Infiltrating Myeloid Cells*

Major Goals: The goal of this study is to address the *unmet and promising* therapeutic avenue of targeting suppressive myeloid cells towards developing an encompassing treatment regimen to produce lasting antitumor immunity.

Grant Contact: Not available yet

Status of Support: Pending

Project Number: F32

Name of PD/PI: Jimenez (PI), Role: Sponsor

Source of Support: NIH/NCI

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 04/2022 - 03/2025

Total Award Amount (including Indirect Costs): \$200,946

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.12 Calendar
2. 2023	0.12 Calendar
3. 2024	0.12 Calendar
4. 2025	0.12 Calendar

Title: *Dynamics of 4-1BB-dependent T and B cell responses induced by different doses of radiation*

Major Goals: The goal of these studies is to elucidate the dynamics of coordinated T and B cell responses induced by different doses of focalized radiation therapy in vivo in tumor-bearing hosts, with an emphasis on defining the role of humoral immunity and opportunities for synergy with 4-1BB agonists in future clinical trials

Grant Contact: Not available yet

Status of Support: Pending

Project Number: U01CA232758

Name of PD/PI: Conejo-Garcia (PI)

Source of Support: NIH/NCI (Collaborative Supplement)

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 09/2021 – 08/2021

Total Award Amount (including Indirect Costs): \$200,875

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	No Effort Assigned

Title: *Heterogeneity of metastatic small cell lung cancer; implications for the design of effective immunotherapies*

Major Goals: Aim 1: Define the immunogenic intra-and inter-tumor heterogeneity of human small cell lung cancer; Aim 2: Elucidate the trajectory of differentiation of tumor-reactive T cells in small cell lung cancer; Aim 3: Design cellular therapies that target heterogeneous metastatic disease

Grant Contact: Not available yet

Status of Support: Pending

Project Number: N/A

Name of PD/PI: Conejo-Garcia (Contact PI), Bradford Perez (Co-PI)

Source of Support: Florida Biomedical Research Program, Bankhead Coley Clinical Research

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 04/2022 – 09/2026

Total Award Amount (including Indirect Costs): \$1,499,999

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.6
2. 2023	0.6
3. 2024	0.6
4. 2025	0.6
5. 2026	0.6

COMPLETED

NEWLY INACTIVE

Title: *Initiation and evolution of the ovarian cancer microenvironment*

Major Goals: Aim 1: Determine the role of retrovirally-driven chimeric antigens in immune protection against ovarian cancer; Aim 2: Define the role of re-activated endogenous retroviruses in the evolution of anti-tumor immunity; Aim 3: Elucidate the mechanisms leading to the re-activation of ERVs in human ovarian cancer.

Status of Support: Completed

Project Number: R01CA157664

Name of PD/PI: Conejo-Garcia (PI)

Source of Support: NIH/NCI

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 04/2011 – 08/2021

NEWLY INACTIVE

Title: *Global Control of Ovarian Cancer Immunity by Aberrant ER Stress Responses*

Major Goals: The goal of Dr. Cubillos-Ruiz's proposal is to elucidate and target the role of ER stress in the abrogation of protective immune responses in ovarian cancer.

Status of Support: Completed

Number: W81XWH-16-1-0438

Name of PD/PI: Cubillos-Ruiz (PI), Role: Designated Mentor

Source of Support: CDMRP Ovarian Cancer Academy – Early Career Investigator Award (PTE: Cornell University)

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 11/2016-07/2021

NEWLY INACTIVE

Title: *Discovery, Optimization & Functional Characterization of Antibodies targeting CD277 and Human Galectin-1*

Major Goals: The goals of this project are to characterize human antibodies blocking BTN3A1, PD-L1 and galectins to boost protective immunity against established tumors, using models optimized in the lab.

Status of Support: Completed

Project Number: 60192495_14

Name of PD/PI: Conejo-Garcia (PI)

Source of Support: Compass Therapeutics Collaborative Agreement

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 0/2019-04/2021

NEWLY INACTIVE

Title: *CD277/Butyrophilin 3A1 is a Targetable Immune Regulator in Breast Cancer*

Aim 1: To determine the anti-tumor effectiveness of neutralizing human BTN3A1 in vivo
Aim 2: To elucidate the mechanism of alpha/beta T cell inhibition mediated by

BTN3A1

Aim 3: To define the effectiveness of activating gamma/delta T cells through antibody-bound
BTN3A1

Status of Support: Completed

Project Number: PF-18-04-01-LIB

Name of PD/PI: Payne (PI), Role: Mentor

Source of Support: American Cancer Society

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 07/2018-06/2020

NEWLY INACTIVE

Title: *Developing a Human in Mouse Cancer Model with a Completely Humanized Stroma*

Major Goals: The goal of this proposal is to generate a completely humanized model of cancer. We will then perform proof of principle experiments in ovarian cancer, a disease with clear clinical need, a biologically relevant stroma and good access to tissue

Status of Support: Completed

Project Number: R01CA211913

Name of PD/PI: Buckanovich (PI), Role: Co-Investigator

Source of Support: NIH/NCI (PTE: Magee Women's Research Institute)
Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL
Project/Proposal Start and End Date: 08/2017-06/2020

NEWLY INACTIVE

Title: *ER stress blunts development of Tissue-Resident Memory T cells and restricts efficacy of T cell immunotherapy in ovarian carcinoma*

Major Goals: The goal of this study is to target ER stress in adoptively-transferred T-cells re-directed against FSHR+ ovarian cancer through novel chimeric receptors to overcome the inhibitory effect of the tumor milieu and empower them to control established tumors.

Status of Support: Completed

Project Number: N/A

Name of PD/PI: Conejo-Garcia, Rodriguez (MPI)

Source of Support: V Foundation for Cancer Research - The Kay Yow Cancer Fund

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 02/2019-02/2020

Title: *Discovery of potential immune-preventative targets for ovarian cancer*

Major Goals: Aim 1: Define the specificities of IgG antibodies produced within the ovarian endometriosis microenvironment compared with those produced within ovarian cancer; Aim 2: Clone immortalized ovarian endometriosis-derived B cells and assess their therapeutic potential.

Status of Support: Completed

Project Number: U54CA163068

Name of PD/PI: Wright (PI), Role: PI of DRP

Source of Support: NIH/NCI (PHSU-MCC Partnership)

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 01/2019-12/2019

Title: *Functional reprogramming of tumor MDSCs through antibody-based therapies targeting NOTCH ligands*

Major Goals: This is a bridge funding mechanism to support the resubmission of NIH proposals that were scored at percentiles better than 20.

Status of Support: Completed

Project Number: 9BC06

Name of PD/PI: Rodriguez (PI), Role: Co-Investigator

Source of Support: Florida Biomedical Research Program

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 04/2019-09/2019

Title: *Determining the Role of Intratumoral Dendritic Cells in Anti-Tumor Immunity*

Major Goals: Aim 1: Determine how TIM-3 blockade alters the activation/function state of; Aim 2: Determine the functional relevance of cDC1s during TIM-3 blockade

Status of Support: Completed

Project Number: F31CA224963

Name of PD/PI: Gardner (PI), Role: Mentor

Source of Support: NIH/NCI

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 12/2018-09/2019

Title: *Role of Intestinal Microbiota in Lung Cancer Therapy*

Major Goals: The goal of this study is to define the effect of different immunotherapeutic

interventions on the microbiome of NSCLC patients, and to determine how these changes impact therapeutic effectiveness.

Status of Support: Completed

Project Number: N/A

Name of PD/PI: Pierce (PI), Role: Co-Investigator

Source of Support: Florida Academic Cancer Center Alliance (FACCA)

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 06/2018-05/2019

Title: *Rational Design of Effective Multi-modal Ovarian Cancer Immunotherapy*

Major Goals: In collaboration with Drs Curiel (UT San Antonio) and Dr. Powell (UPenn), these collaborative studies will test combining novel chimeric receptors targeting FSHR+ tumor cells expressed in autologous T cells with: 1) Treg depleting interventions and IL-2 signals; and 2) kinase inhibitors that prevent MDSC mobilization without impairing T cell effector activity; all in ovarian cancer models.

Status of Support: Completed

Project Number: N/A

Name of PD/PI: Curiel (PI), Role: Project 2 Leader

Source of Support: Ovarian Cancer Research Fund Alliance - Collaborative Research Development Grant

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 01/2017-12/2018

Title: *Effects of common polymorphisms in immune sensors in tumor immunosurveillance*

Major Goals: Aim 1: Determine how T cells influence tumor progression in wild-type vs. TLR5-deficient individuals. These results will dissect the suppressive mechanisms whereby T cells generated in the presence of TLR5 signaling promote tumor growth, while their counterpart in TLR5-deficient hosts delay malignant development; Aim 2: Elucidate why T cells acquire a different phenotype in TLR5-deficient tumor-bearing hosts. Because the ligand of TLR5 is a bacterial product, these results will elucidate how microbiota (carriers of the only endogenous ligand) drives the differentiation of T cells that determine immunosurveillance responses; Aim 3: Define differences in anti-tumor immunity between human TLR5-deficient and wild-type cancer patients, using our bank of viable ovarian and breast cancer dissociated specimens

Status of Support: Completed

Project Number: R01CA178687

Name of PD/PI: Conejo-Garcia (PI)

Source of Support: NIH/NCI

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 09/2013-06/2018

Title: *Chromatin Regulatory Mechanisms in Ovarian Cancer*

Major Goals: Program Project Developmental Funds

Status of Support: Completed

Project Number: N/A

Name of PD/PI: Marmorstein (PI), Role: Co-Investigator

Source of Support: Univ of Penn / Ovarian Cancer Research Fund

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 01/2014-12/2017

Title: *Rational design of effective multi-modal ovarian cancer immunotherapy*

Goals: Program Project Developmental Funds

Status of Support: Completed

Project Number: N/A

Name of PD/PI: Curiel (PI), Role: Co-Investigator

Source of Support: UTHSC / Ovarian Cancer Research Fund

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 01/2014-12/2017

Title: *Vascular Leukocytes influence the tumor microenvironment*

Major Goals: Aim 1: Define how Satb1 is the primary driver of the immunosuppressive properties of ovariancancer- associated VLCs; Aim 2: Define the role of Satb1 in the accumulation of regulatory DCs/VLCs within ovarian cancer; Aim 3: Establish the molecular factors modulating the overexpression of Satb1 in regulatoryDCs/VLCs in ovarian cancer

Status of Support: Completed

Project Number: R01CA124515

Name of PD/PI: Conejo-Garcia, PI)

Source of Support: NIH/NCI

Primary Place of Performance: H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

Project/Proposal Start and End Date: 09/2012-07/2017

9.4 JIM, HEATHER

POSITIONS & SCIENTIFIC APPOINTMENTS

2021 - Professor, Department of Oncologic Sciences, University of South Florida, ,
2020 - Tampa, FL
2019 - Senior Member, Moffitt Cancer Center, Health Outcomes and Behavior Program,
Tampa, FL
Co-Leader, Moffitt Cancer Center, Health Outcomes and Behavior Program,
Tampa, FL

ADDITIONAL SUPPORT FROM FOREIGN OR DOMESTIC ENTITIES

None

POSITIONS & SCIENTIFIC APPOINTMENTS

2021 - Professor, Department of Oncologic Sciences, University of South Florida, ,
2020 - Tampa, FL
2019 - Senior Member, Moffitt Cancer Center, Health Outcomes and Behavior Program,
Tampa, FL
Co-Leader, Moffitt Cancer Center, Health Outcomes and Behavior Program,
Tampa, FL

ADDITIONAL SUPPORT FROM FOREIGN OR DOMESTIC ENTITIES

None

ACTIVE

Moffitt Cancer Center Support Grant

Time Commitment: 0.9 calendar months

NIH/NCI

P30 CA076292

Program Officer: Joy Kearse, kearsej@nih.gov

Performance Period: 02/18/1998 – 01/31/2022

Level of Funding: \$14,954,830 Total costs

Project Goals: This grant provides support for key personnel involved in the cancer center's research mission.

Role: Program Co-Leader

Overlap: None

Integrating Health Informatics in a Scalable Stepped Care Self-Management Program for Survivors After Hematopoietic Cell Transplantation

Time Commitment: no measurable effort

NIH/NCI

R01CA215134

Program Officer: Nonniekaye Shelburne, nonniekaye.shelburne@nih.gov

Performance Period: 05/2018 – 04/2022

Level of Funding: \$3,563,362 Federal total costs

Specific Aims: 1) Among HCT survivors with poor health care adherence to cardiometabolic or new cancer surveillance and/or elevated cancer-related distress, determine the impact of a patient-centered, self-management stepped care program compared to an active control group provided access to HCT survivorship best practices; 2) Determine characteristics of intervention participants who require telehealth stepped care at 1-month; and 3) Determine resources that would be needed to sustain the intervention as a national HCT survivorship program if implemented through the CIBMTR/NMDP (i.e., costs, level of expertise, and use of intervention components relative to costs)

Role: Site PI

Overlap: None

Randomized Placebo Controlled Trial of Bupropion for Cancer Related Fatigue

Time Commitment: 2.4 calendar months

NIH/NCI

R01 CA214647

Program Officer: Marge Good, goodmj@mail.nih.gov

Performance Period: 06/12/2018 – 05/31/2023

Level of Funding: \$2,979,141 Total costs

Project Goals: The major goal of this project is to examine whether bupropion reduces cancer-related fatigue by suppressing inflammation. Results will provide significant new knowledge about management of cancer-related fatigue as well as the biological pathways by which fatigue occurs.

Role: PI

Overlap: None

Improving Prediction of Chemotherapy-Induced Nausea: Integrating Genes, Behavior, and the Microbiome

Time Commitment: 2.4 calendar months

R01 CA219389

NIH/NCI

Program Officer: Michelle Mollica, michelle.mollica@nih.gov

Performance Period: 07/01/2018 – 06/30/2023

Level of Funding: \$3,524,184 Total costs

Aims: 1) To conduct a genome-wide association study of nausea in cancer patients receiving moderately- or highly-emetogenic chemotherapy; 2) To identify biological pathways enriched by genetic variants associated with nausea; 3) To develop and validate a new algorithm to predict clinical risk of nausea based on host genetic, demographic, clinical, and patient-reported risk factors; 4) To explore associations of the pre-chemotherapy gut microbiome with nausea

Role: PI

Overlap: None

Novel Biomarkers for Cancer-Related Fatigue: Integrating Metabolomics, Genomics and Behaviors

Time Commitment: 1.44 calendar months

NIH/NCI

R01NR018762

Program Officer: Martha Matocha, matocham@mail.nih.gov

Performance Period: 05/01/2020 – 04/30/2025

Level of Funding: \$1,372,817 Sub award total costs

Aims: 1) Examine metabolomic gene variants as predisposing factors for cancer-related fatigue. 2) Examine the metabolome and metabolic pathways as precipitating factors for fatigue and 3) Evaluate diet, physical activity, sleep, and their relationships to the metabolome as perpetuating factors for fatigue.

Role: MPI

Overlap: None

EXTENDED

Survivorship in Lymphoma Patients Treated with Axicabtagene Ciloleucel: Neurocognitive and Patient-Reported Outcomes

Time Commitment: *0.6 calendar months*

Kite Pharma

18013103

Scientific Officer: Julia Snider, jsnider2@kitepharma.com; Liliosa Nyamutswa, lnyamutswa@kitepharma.com

Performance Period: 09/13/2019 - **09/13/2022**

Level of Funding: \$229,912 Total costs

Aims: 1) Evaluate longitudinal changes in neurocognition following axi-cel therapy, and 2) describe longitudinal changes in patient-reported outcomes for patients receiving axi-cel cell therapy.

Role: PI

Overlap: None

EXTENDED

Post-Hurricane Cancer Care: Patient Needs after Hurricane Maria

Time Commitment: 0.12 calendar months

NIH/NIMHD

R21MD013674, R21MD013674-02S1, R21MD013674-02S2

Program Officer: Jennifer Alvidrez, alvidrezjl@mail.nih.gov

Performance Period: 09/12/2018 – **05/31/2022 NCE**

Level of Funding: \$57,657 subaward total costs

Project Goals: The current study will describe unmet medical and psychological needs as well as barriers and facilitators to care in cancer patients in Puerto Rico. In addition, the study will assess the impact of extreme physical and mental stress on hypothalamic-pituitary-adrenal (HPA) axis functioning which is known to affect cancer biology.

Role: MPI

Overlap: None

Biopsychosocial Predictors of Tumor-Associated Inflammation and Progression

Time Commitment: 0.45 calendar months

NIH/NIMHD

Parent Grant: PHSU Specialized Center in Health Disparities - NIH-Assist Application ID 407903

Program Officer: Sandra San Miguel-Majors, sandra.sanmiguel-majors@nih.gov

Performance Period: 08/01/2019 – 07/31/2024

Level of Funding: \$217,608 Subaward total direct costs

Project Goals: The central hypothesis of this study is that exposure to social-environmental adversity exacerbate the biopsychosocial response to current social stressors [cancer experience] leading to depression symptoms and inflammation driven cancer progression.

Role: Co-Investigator

Overlap: None

Identifying and Reducing Disparities in Symptom Burden Among African American Prostate Cancer Survivors

Time Commitment: 0.12 calendar months

W81XWH2010126

DOD

Grants Management Specialist: Nrusingha Mishra, nrusingha.mishra.civ@mail.mil

Performance Period: 04/01/2020 – 03/31/2023

Level of Funding: \$902,615 Total costs

Project Goals: To identify disparities in pain, sleep disturbance, and depression among African American prostate cancer survivors and risk factors for these disparities.

Role: Co-Investigator

Overlap: None

Identifying and Reducing Disparities in Patient-Reported Outcomes Among African American Prostate Cancer Survivors

Time Commitment: 0.12 calendar months

NIH/NCI

R01CA242742

Program Officer: Lisa Gallicchio, lisa.gallicchio@nih.gov

Performance Period: 04/01/2020 – 3/031/2025

Level of Funding: \$1,891,425 Total costs

Project Goals: To identify disparities in patient-reported outcomes among African American

prostate cancer survivors and risk factors for these disparities.

Role: Co-Investigator

Overlap: None

Measuring Patient-Reported Outcomes Related to Radiopharmaceuticals for Prostate Cancer

Time Commitment: 0.12 calendar months

DOD

W81XWH2010351

Program Officer: Melanie Neagley, melanie.a.neagley.ctr@mail.mil

Performance Period: 09/09/2020 – 08/31/2023

Level of Funding: \$955,517 total direct costs

Project Goals: To develop and test a new patient-reported outcomes measure for prostate cancer patients receiving targeted radionuclide therapy.

Role: Co-Investigator

Overlap: None

NEW – THIS AWARD

A Pre-Surgical Window of Opportunity Trial of the Effect of Aspirin on Immunological Features of Ovarian Tumors

Time Commitment: 0.24 calendar months (as of 10/1/2021)

W81XWH2010488

DOD/US Army – Log# OC190330

Program Officer: Karen Wylie, karen.m.wylie.civ@mail.mil

Performance Period: 10/01/2020 – 09/30/2023

Level of Funding: \$800,000 total direct costs

Aims: 1) To evaluate the efficacy of aspirin for improving immunological characteristics of the tumor at interval debulking surgery among women diagnosed with ovarian cancer; and 2) To evaluate the efficacy of daily 325mg aspirin versus placebo pill for improving tolerance of neoadjuvant chemotherapy and quality of life.

Role: Co-Investigator

Overlap: None

NEW

Efficacy of a Mindfulness-Based Stress Management Program for Allogeneic HCT Care

Time Commitment: 0.6 calendar months

NIH/NCI

R01CA255265

Program Officer: Michelle Mollica, michelle.mollica@nih.gov

Performance Period: 04/01/2021 – 03/31/2026

Level of Support: \$2,880,495 Total costs

Role: Co-Investigator

Goals: This project will test a mindfulness-based intervention on caregiver burden, patient distress, and patient healthcare utilization, when compared to healthy living (active comparison) and usual care groups.

Role: Co-Investigator

Overlap: None

EXTENDED

Older Breast Cancer Patients: Risk for Cognitive Decline

Time Commitment: no measurable effort

NIH/NCI

R01CA129769

Program Officer: Todd Horowitz, todd.horowitz@nih.gov

Performance Period: 09/01/2015 – **11/30/2021 - NCE**

Level of Funding: \$80,777 subaward annual direct costs

Aims: 1) Ascertain trajectories of longitudinal cognitive function and test for differences in treatment exposure-control groups; 2) identify risk factors for cognitive decline in the 48 months post-enrollment and determine how effects are moderated by treatment exposure (chemotherapy>hormonal>control); and 3) assess how inflammatory products (CRP, IL6, and sTNFRII) co-vary with trajectories of cognition; and test if inflammation mediates effects of physical activity and multi-morbidity on cognitive decline.

Role: Site PI

Overlap: None

PENDING

ALL NEW

Pilot Study to Develop an eHealth Supportive Intervention for Patients with Metastatic Breast Cancer

Time Commitment: 0.24 calendar months

ECOG-ACRIN

Period of Performance: 08/01/2021 – 07/31/2022

Total Award Amount: \$99,994 total cost

Study Aims: 1) Adapt CBSM-MBC, 2) Test the feasibility and acceptability of eHealth CBSM-MBC, and 3) explore proof-of-concept in a single-arm pilot trial.

Role: Co-Investigator

Overlap: None

Gut Microbiome and Metabolome as a Biomarker of Chemoradiation Induced Oral Mucositis in Head and Neck Cancer Patients: Pilot Study

Time Commitment: 0.12 calendar months

ECOG-ACRIN

Period of Performance: 08/16/2021 – 08/15/2022

Total Award Amount: \$99,999

Goals: We propose a pilot study to evaluate longitudinal changes in gut microbiome (assessed with gut metagenomics) and metabolome (assessed with global unbiased metabolomics) and its association with patient and clinician reported measure of oral mucositis in HNSCC patients undergoing CRT.

Role: Co-Investigator

Overlap: None

Cancer-Related Cognitive Impairment: Real-time Evaluation and Assessment of Long-term Impact of Treatment on Young Adult Survivors (CRCI REALITY)

Time Commitment: no measurable effort

NIH/NCI

K99CA270294

Program Officer: Corinne Boulanger-Espeut, boulangc@mail.nih.gov

Performance Period: 4/1/2022 – 3/31/2027

Total Award Amount (Including Indirect Costs): \$966,980

Major Goals: The proposed training and research plan will facilitate the candidate's transition to independence as one of the few experts in cancer-related cognitive impairment among adolescent and young adult cancer survivors. The project will be a novel application of a validated ecological momentary assessment of objective cognitive function. An iterative mixed-methods approach will adapt the assessment to include within-person risk factors relevant to young adult survivors of adolescent cancer, pilot the revised assessment, and then conduct a large case-controlled cross-sectional test of the assessment.

Role: Primary Mentor

Overlap: None

Evaluating Remote Nutrition Monitoring after Pancreatectomy for Cancer Patients

Time Commitment: 1.2 calendar months

NIH/NCI

Project Number: GRANT13380840

Program Officer: Brandy Heckman-Stoddard, heckmanbm@mail.nih.gov

Project Period: 04/01/2022 – 03/31/2027

Total Award Amount \$4,068,422

Major Goals: To develop an evidence-based intervention to address malnutrition could improve care delivery for surgical patients and be expanded to other cancer patients at risk for malnutrition.

Role: Co-Investigator

Overlap: None

The Role of Biological Age in Cancer-related Cognitive Decline: Lessons for Alzheimer's Disease and Related Dementia (ADRD)

Time Commitment: 1.2 calendar months

NIH/NIA

R01AG075787

Program Officer: Suneja, Sanoj, sunejas@mail.nih.gov

Performance period: 09/01/2021 – 08/31/2026

Total Award Amount: \$500,623 Proposed sub award total costs

Major Goals: 1) Examine whether breast cancer survivors have greater biological aging over time compared to controls and determine whether variation in aging is related to treatment type; 2)

Test whether biological aging relates to cognitive and physical function in cases and controls and

3) Explore modifiable factors as they relate to biological aging, cognitive and physical health

Role: Site PI

Overlap: None

Developing an eHealth Quality of Life and Symptom Management Intervention for Metastatic Breast Cancer

Time Commitment: 0.6 calendar months

NIH/NCI

R21NR020251-01

Program Officer: Lynn Adams adamsls@mail.nih.gov

Performance Dates: 09/2021 – 08/2023

Total Award: \$452,925 Total costs

Major Goals: Supportive interventions designed to address disease- and treatment-related HRQOL and symptoms are critical to promoting patient-centered care and optimal health outcomes. To our knowledge, this will be the first study to adapt an evidence-based group intervention for the growing population of MBC meta-vivors receiving cutting-edge treatment. Results will inform our design of a fully powered RCT to test the efficacy of eHealth CBSM-MBC for mitigating deteriorations in HRQOL and reducing symptoms (future R01). This program of work will result in disseminable supportive care for the growing population of MBC meta-vivors

Role: Co-Investigator

Overlap: None

BMT-CARE: Multimodal Psychosocial Intervention for Caregivers of Patients Undergoing Hematopoietic Stem Cell Transplantation

Time Commitment: 1.2 calendar

NIH/NCI

Grant Number: Pending

Grant Official: TBA

Performance Date: 04/01/2022 – 03/31/2027

Award: \$893,951 Proposed Sub award total costs

Goals: The goal of this project is to 1) test the efficacy of BMT-CARE for improving caregiver quality of life, caregiving burden, depression and anxiety symptoms, coping, and self-efficacy; 2) examine the impact of BMT-CARE on patient-reported outcomes and health care utilization; and 3) identify critical facilitators and barriers for BMT-CARE implementation and adoption using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) QuEST (Qualitative Evaluation for Systematic Translation) mixed-methods framework.

Role: Site PI, Co-Investigator

The Multilevel Impact of COVID-19 & Earthquakes Exposure on Cancer Health Outcomes

Time commitment: 0.6 calendar

NIH/NCI

Grant Number: Pending

Program Officer: TBA

Performance Dates: 04/01/2022 – 03/31/2027

Total Award: \$875,605 Proposed sub award total costs

Major Goals: The proposed project will shift current research paradigms in health outcomes following natural disasters by exploring the effects of extreme stressors on biological processes known to affect cancer progression and comorbid conditions, including inflammation and stress hormones. This innovative study will provide valuable new knowledge to better understand the interactions among multilevel determinants of health. These data are critical, not only for communities affected by disasters, but those affected by health disparities in general.

Role: Site PI

Overlap: None

The feasibility, preliminary clinical efficacy and quality of life impact of a response based adaptive clinical trial using immunotherapy combination with VEGFR-TKI in patients with untreated advanced renal cell carcinoma

Time Commitment: .24 calendar

FBRP/Bankhead-Coley Cancer Research Program

Project Number: N/A

Project Officer:

Performance Dates: 04/2022 – 09/2026

Total Award: \$1,500,000

Major Goals: The goal of the proposal is to assess the non-inferior clinical efficacy of a response based adaptive administration of Pembro-Axi to patients with mcrRCC, as well as to assess the impact on patient reported quality of life and cost savings of a response based adaptive administration of Pembro-Axi to patients with mcrRCC and to assess the role of specific tumor related immune and molecular makers in predicting the clinical efficacy of a response based adaptive administration of Pembro-Axi to patients with mcrRCC. The goal of the proposal is to assess the non-inferior clinical efficacy of a response based adaptive administration of Pembro-Axi to patients with mcrRCC, as well as to assess the impact on patient reported quality of life and cost savings of a response based adaptive administration of Pembro-Axi to patients with mcrRCC and to assess the role of specific tumor related immune and molecular makers in predicting the clinical efficacy of a response based adaptive administration of Pembro-Axi to patients with mcrRCC.

Role: Co-Investigator

Overlap: None

Neurocognitive and Patient-Reported Outcomes after Chimeric Antigen Receptor T-Cell Therapy: A Controlled Comparison

Time Commitment: 2.4 calendar months

NIH/NCI

R01CA244328

Program Officer: Todd Horowitz, todd.horowitz@nih.gov

Performance Period: 04/01/2022 – 03/31/2027

Level of Funding: \$3,975,857 total direct costs

Project Goal: The goal of the current study is to better understand longitudinal change and biobehavioral mechanisms of patient-reported outcomes and neurocognition in 204 adult CAR T-cell therapy recipients compared to non-cancer controls.

Role: MPI

Overlap: None

Development and Validation of a Patient-Reported Measure Assessing Chimeric Antigen Receptor (CAR) T-Cell Therapy-Related Side Effects

Time Commitment: 2.4 calendar months

NIH/NCI

R03CA259489

Program Officer: Roxanne Jensen, roxanne.jensen@nih.gov

Performance Period: 04/01/2022 – 03/31/2024

Level of Funding: Total Costs \$164,700

Goals: To develop and validate a measure assessing acute and chronic patient-reported side effects associated with CAR T-cell therapy, in collaboration with the developers of the Functional Assessment for Chronic Illness Therapy (FACIT) measures, commonly used in cancer patients.

Role: Co-Investigator

Overlap: None

Effects of Aerobic or Resistance Exercise on Treatment-Related Outcomes in Metastatic Breast Cancer Survivors (Meta-vivors)

Time Commitment: 2.4 calendar months

NIH/NCI

U01CA271290

Program Officer: Frank Perna, pernafm@mail.nih.gov

Performance Period: 04/01/2022 – 03/31/2027

Level of Funding: \$2,727,599 Sub Award Total Costs

Goals: The overall objective of this study will focus on evaluating evidence-based exercise training and resistance training interventions in a novel population of breast cancer metastatic survivors treated with targeted therapy

Role: MPI

Overlap: None

Data Science to Improve Treatment Planning for Advanced Prostate Cancer Patients Treated with Radiotherapy

Time Commitment: 2.4 calendar

US Army

Grant Number: Pending

Program Officer: TBA

Performance Dates: 01/01/2022 – 12/31/2024

Total Award: \$1,531,547

Goals: 1) To develop deep learning models incorporating dosimetrics and radiomics for actuarial multi-endpoint prediction of clinician-rated toxicities among prostate cancer patients treated with radiation; 2) To develop deep learning models incorporating dosimetrics and radiomics for actual multi-endpoint prediction of PROs among prostate cancer patients treated with radiation; and 3) To validate deep learning models for actuarial multi-endpoint prediction of clinician-rated toxicities and PROs among prostate cancer patients treated with radiation in the VA.

Role: MPI

Overlap: None

Moffitt Cancer Center Support Grant

Time Commitment: 0.9 calendar months

NIH/NCI

P30CA076292

Program Officer: Joy Kearse, Email: kearsej@mail.nih.gov

Performance Period: 02/01/2022 – 01/31/2027

Total Award Amount \$25,313,785

Major Goals: The grant provides support for key personnel involved in the cancer center's research mission.

Role: Program Co-Leader

Overlap: None

Building Research Infrastructure and Data Generation Engine to enable Automated AI on Standardized Ontology and Big Data Repositories (BRIDGE2AI-SOAR)

Time Commitment: 1.2 calendar (2/1/2023)

NIH/NCI

Grant Number: Pending

Program Officer: TBA

Performance Dates: 02/02/2022 – 01/31/2026

Total Award: \$222,988

Goals: Bridge 2AI grant: transformative meant to fund data generation! fund the building blocks required to get to the point where we actually have good data on which to use AI for decision support and rapid improvement in clinical care. There are 6 required modules: teaming, tooling, standardization, data, education, and ethics. We are putting together an application for the data-rich radiation oncology specialty, with several of our specialty societies (ASTRO, AAPM), IHE-RO, and several institutions involved in each module. We've already been working society-wide on standardizing nomenclature (linked to medical oncology and MITRE/MCODE/CODEX) and are building a monster team for the other modules, catalyzing work already in progress.

Role: Site PI

Overlap: None

IN KIND

Understanding Cellular Mechanisms Associated with Chemotherapy-Induced Myotoxicity in Ovarian Cancer Patients

Status of Support: NA

Primary Place of Performance: Moffitt Cancer Center/Advent Health

Project/Proposal Start and End Date 03/2021 – 09/2021

Person Months (Calendar/Academic/Summer) per budget period: No measurable effort

Estimated Dollar Value of In-Kind Information: (~1% \$2,000)

The COACH Study: A Framework for individualized Coaching in Young Addult Cancer Survivors to Encourage Healthy Behaviors

Time Commitment: No measurable effort

NIH/NCI

R03CA270475

Program Officer: Tanya Agurs-Collins collinsta@mail.nih.gov

Performance Dates: 04/01/2022 – 03/31/2024

Total Award Amount (including Indirect Costs): Total Costs \$163,709

Aims: 1) Quantitatively assess diet and physical activity (PA) behaviors, awareness and adherence of American Cancer Society (ACS) guidelines, risk factors for non-adherence, preferences, and quality of life (QOL) in YA cancer survivors; and 2) Qualitatively examine factors related to diet and PA (e.g. sociocultural, environmental, individual), barriers and facilitators, and intervention format preferences in YA cancer survivors.

Role: Other Significant Contributor

Overlap: None

Completed Support (within the last three years)

Sickness Behaviors in Gynecologic Cancer Patients Treated with Chemotherapy

NIH/NCI

R01CA164109

Grants Management Officer: Diane St. Germain

Performance Period: 09/01/2012 – 06/30/2019

Specific Aims: 1) To identify the magnitude and features of changes in sickness behaviors (i.e., fatigue, depression, and disruptions in sleep and activity) and pro-inflammatory cytokines in gynecologic cancer patients treated with chemotherapy compared to women without cancer; 2) To examine changes in pro-inflammatory cytokines as a mechanism of changes in sickness behaviors related to receipt of platinum- and taxane-based chemotherapy; 3) To examine the effects of experimental induction of relaxed mood on pro-inflammatory cytokine levels and sickness behaviors in women treated for gynecologic cancer who report clinically significant fatigue or depression.

Role: PI

9.5 QIANXING (QUINCY) MO

Positions & Scientific Appointments

2018 - Associate Member, H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

2018 - Associate Professor, Morsani College of Medicine, University of South Florida, Tampa, FL

Additional Support from Foreign or Domestic Entities

None

OTHER SUPPORT – PROJECT/PROPOSAL

ACTIVE:

Title: *Mechanisms of Radioresistance and Strategies for Radiosensitization in OCCC*

Major Goals: The goal of this research is to determine the mechanisms underlying radioresistance in ARID1A-deficient cancer cells and to test strategy for overcoming radioresistance in ARID1A-deficient OCCC.

Status of Support: Active

Project Number: 5R01 CA181663-06

Name of PD/PI: Mo, Q.

Role: Principal Investigator, Subcontract

Source of Support: NIH/NCI (Sub/University of Texas)

Program Officer: Amanda Ferguson

Address: ACFerguson@mdanderson.org

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 08/01/2018 - 07/31/2022

Total Award Amount (including Indirect Costs): \$59,367

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2018	0.24 CM
2. 2019	0.24 CM
3. 2020	0.84 CM
4. 2021	0.57 CM

Title: *H. Lee Moffitt Cancer Center and Research Institute Support Grant*

Major Goals: To support infrastructure for transdisciplinary cancer-relevant research and to foster studies that would not occur without the climate, facilities, and research resources that a cancer center can uniquely provide.

Status of Support: Active

Project Number: 5P30 CA076292-23

Name of PD/PI: Cleveland, J.

Role: Co-Investigator

Source of Support: NIH/NCI

Program Officer: Joy Kearse, Grants Management Specialist

Address: kearsej@mail.nih.gov, (301) 631-3002 | Fax: (301) 451-5391

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 02/01/2017 - 01/31/2022

Total Award Amount (including Indirect Costs): \$14,954,830

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2017	1.20 CM
2. 2018	1.20 CM
3. 2019	1.20 CM
4. 2020	1.20 CM
5. 2021	1.20 CM

Title: *Cytokine-dependent Genetic Selection in Chronic Myelomonocytic Leukemia*

Major Goals: The overall goal of these experiments is to determine if inhibition of cytokines can keep CMML patients in a clinically asymptomatic state therefore switching CMML from a lethal leukemia to a chronic disease.

Specific Aims: (1) Determine if cytokine changes precede clonal evolution and disease progression in CMML. (2) Determine the role of cytokine receptors on disease progression in CMML. (3) Determine the impact of cytokines on CMML clonogenicity and mutational heterogeneity.

Status of Support: Active

Project Number: RSG-19-215-01-LIB

Name of PD/PI: Padron, E.

Role: Co-Investigator

Source of Support: American Cancer Society

Program Officer: Janet Meadows Harris

Address: (404) 329-7543 | janet.meadowsharris@cancer.org

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 01/01/2020 - 12/31/2023

Total Award Amount (including Indirect Costs): \$792,000

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2020	0.60 CM
2. 2021	0.60 CM

Year	Person Months
3. 2022	0.60 CM

NEW AWARDED GRANTS SINCE LAST SUBMISSION:

Title: *Predictive medicine in breast cancer: Using response to therapy to classify genetic variants of uncertain significance*

Major Goals: Accurately identifying women at risk and offering promising avenues of treatment will be critical to change the status quo and will directly benefit the ethnically diverse population in our catchment area. We need to reassess all Variants of Uncertain Significance (VUS). By leveraging the Syapse network (192,891 BC cases) we plan to address these unmet clinical needs.

Specific Aims: (1) To determine the extent to which patient outcomes can serve as a line of evidence to classify VUS in BRCA1/2. (2) To determine whether carriers of BRCA1/2 missense variants respond differently than carriers of truncating variants. (3) To comprehensively reassess all VUS in BRCA1/2 in the Syapse network BC cases.

Status of Support: Active

Project Number:

Name of PD/PI: Monteiro, A.

Role: Co-Investigator

Source of Support: MCC/MAC

Program Officer: Maureen Ahearn, Sponsored Research Administrator, Intramural Programs

Address: 12902 Magnolia Drive, Tampa, FL 33612 | (813) 745-8824 | maureen.ahearn@moffitt.org

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 07/14/2021 - 04/30/2022 (Effort Began on 09/01/2021)

Total Award Amount (including Indirect Costs): \$50,000

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.96 CM

Title: *Combination therapy using CDK9 and BRD4 inhibitors to combat lung adenocarcinoma*

Major Goals: We hypothesize that inhibiting both CDK9 and c-Myc would be an effective strategy to combat lung adenocarcinoma. We will test this hypothesis by conducting in vitro studies on lung adenocarcinoma cells harboring K-Ras and EGFR mutations and lung organoids derived from 4 different patients. In addition to the routine biological and biochemical studies, we will conduct a RNA-Seq analysis to determine the gene expression changes in response to CDK9 and BRD4 inhibitor treatment in the lung adenocarcinoma cells.

Specific Aims: (1) Elucidate the molecular mechanisms by which CDK9 and BRD4 regulate lung adenocarcinoma. (2) Determine the efficacy of CDK9 and BRD4 inhibitors in inhibiting tumor growth and metastasis in vivo.

Status of Support: Active

Project Number: W81XWH2110627

Name of PD/PI: Padmanabhan, J.

Role: Co-Investigator

Source of Support: US Army/CDMRP/LCRP

Program Officer: Darrell Beaver, Grants Specialist

Address: (301) 619-4019 | Darrell.L.Beaver4.civ@mail.mil

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 07/01/2021 - 06/30/2022

Total Award Amount (including Indirect Costs): \$164,700

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.36 CM

Title: *A Presurgical Window of Opportunity Trial of the Effect of Aspirin on Immunological Features of Ovarian Tumors*

Major Goals: The main goals of our clinical trial are to assess the efficacy and safety of standard-dose aspirin in improving prognosis-related tumor characteristics at surgery and tolerance of neoadjuvant chemotherapy in women recently diagnosed with ovarian cancer.

Specific Aims: (1) To evaluate the efficacy of aspirin for improving immunological characteristics of the tumor at interval debulking surgery among women diagnosed with ovarian cancer. (2) To evaluate the efficacy of daily 325mg aspirin versus placebo pill for improving tolerance of neoadjuvant chemotherapy and quality of life.

Status of Support: Active

Project Number: W81XWH-20-1-0488

Name of PD/PI: Tworoger, S.

Role: Co-Investigator

Source of Support: US Army/CDMRP/OCRP

Program Officer: Jennifer Fox, Grants Specialist

Address: jennifer.l.fox1.civ@mail.mil, (301) 619-2784

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 09/01/2020 - 08/31/2023 (Effort Began on 09/01/2021)

Total Award Amount (including Indirect Costs): \$1,120,216

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
2. 2021	0.60 CM
3. 2022	0.60 CM

Title: *Tumor and Metastatic Collagen Microenvironments: Divergent Targeting Approaches*

Major Goals: We will investigate the downstream regulator mechanisms of collagen receptor signaling in both the primary tumor and metastatic sites, and to exploit these regulatory processes as a revolutionizing approach to target metastases.

Status of Support: Active

Project Number: 2R01 CA175397-06A1

Name of PD/PI: Mo, Q.

Role: Principal Investigator, Subaward

Source of Support: NIH/NCI (Sub w/Cedars-Sinai Medical Center)

Program Officer: Elizabeth G. Snyderwine

Address: Elizabeth_snyderwine@nih.gov

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 05/15/2020 - 04/30/2025

Total Award Amount (including Indirect Costs): \$60,725

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2020	0.60 CM
2. 2021	0.48 CM
3. 2022	0.48 CM
4. 2023	0.48 CM

Year	Person Months
5. 2024	0.48 CM

Title: *Novel Biomarkers for Cancer-Related Fatigue: Integrating Metabolomics, Genomics and Behaviors*

Major Goals: This innovative study takes a rigorous, team science approach to unraveling the biological and behavioral mechanisms underlying cancer-related fatigue. The project leverages extensive collaborations and preliminary data from the ColoCare study. Results will be highly impactful, providing new avenues for risk prediction, prevention, and treatment of cancer-related fatigue.

Specific Aims: (1) To examine metabolomic gene variants as predisposing factors for cancer-related fatigue. (2) To examine the metabolome and metabolic pathways as precipitating factors for fatigue. (3) To evaluate diet, physical activity, sleep, and their relationships to the metabolome as perpetuating factors for fatigue

Status of Support: Active

Project Number: 5R01 NR018762-02

Name of PD/PI: Jim, H.

Role: Co-Investigator

Source of Support: NIH/NINR (Sub/Cedars-Sinai Medical Center)

Program Officer: Michelle R. Hamlet

Address: hamletm@mail.nih.gov

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 05/28/2020 - 03/31/2025

Total Award Amount (including Indirect Costs): \$1,372,817

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2020	0.72 CM
2. 2021	0.84 CM
3. 2022	0.84 CM
4. 2023	0.84 CM
5. 2024	0.84 CM

Title: *Overcoming Resistance in HER2 Breast Cancer through a Novel Immunotherapy Approach*

Major Goals: In this project we propose a novel immunotherapy to cause direct killing of HER2 MBC through immune mechanisms as well as induce tumor senescence, apoptosis and pyroptosis of both HER2 sensitive and resistant cells that can synergize with HER2 targeted agents.

Specific Aims: We will specifically test whether administration of DC1 and SEMA4D can (1) cause regression of metastatic HER2 breast cancer (2) generate anti-HER2 CD4 Th1 cells for adoptive Th1 cell transfer and (3) whether this novel therapy can result in tumor regression and prolonged survival. We will assess (2) the immune response and how long these adoptive CD4 Th1 responses survive in the peripheral blood; and (3) determine the mechanism by which the anti-HER2 CD4 Th1 mediate regression of HER2 breast cancer in preclinical models.

Status of Support: Active

Project Number: 21B02

Name of PD/PI: Czerniecki, B.

Role: Co-Investigator

Source of Support: FBRP/Bankhead-Coley Cancer Research Program

Program Officer: N/A

Address: N/A

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 05/20/2021 - 04/30/2026 (Effort Began on 07/01/2021)

Total Award Amount (including Indirect Costs): \$1,327,221

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.60 CM
2. 2022	0.60 CM
3. 2023	0.60 CM
4. 2024	0.60 CM
5. 2025	0.60 CM

Title: *Study to develop a predictive model of immune-related adverse events in patients treated with axicabtagene ciloleucel*

Major Goals: This is a prospective sample study to validate biomarkers including cytokines and catecholamines to predict the development of immune-related adverse events (CRS & NT) in patients treated with axicabtagene ciloleucel. The rationale for our protocol is that the rapid identification of patients at high risk for immune-related CAR T cell toxicities will allow us to stratify patients for outpatient management vs. inpatient infusion and early intervention with cytokine blocking agents. Specific Aims: (Primary Aim 1) Develop a predictive model to identify which patients are at highest risk of developing severe toxicities and stratify which patients can be treated safely in the outpatient setting. (Secondary Aim 1) Determine if proposed cytokine levels predict severe CRS and/or NT (Secondary Aim 2) Determine if catecholamines predict for severe CRS and/or NT. (Secondary Aim 3) Determine the effects of apheresis product on the development of severe CRS and/or NT. (Secondary Aim 4) Determine the correlation between post infusion peak CAR T expansion levels and severe toxicity

Status of Support: Active

Project Number: 2020-KMO-TM1

Name of PD/PI: Davila, M./Faramand, R.

Role: Co-Investigator

Source of Support: Kite Pharma

Program Officer: Adrian Bot, VP Translational Medicine

Address: abot@kitepharma.com, 1800 Stewart Street, Santa Monica, CA 90404

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 10/27/2020 - 10/26/2023

Total Award Amount (including Indirect Costs): \$2,636,615

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2020	0.60 CM
2. 2021	0.60 CM
3. 2022	0.60 CM

NEW PENDING SINCE LAST SUBMISSION:

Title: *A vicious cycle of pyroptotic cancer cells and fibroblasts fuels chemoresistance*

Major Goals: The ultimate goal is to develop an algorithm that can predict patient response after the first treatment cycle, such that innovative personalized treatments can be used to improve overall therapeutic response in subsequent treatment cycles. Such concepts likely extrapolate to other cancer types, and will provide conceptual understanding to patient response toward other anti-cancer therapies.

Status of Support: Pending

Project Number: 3R01CA175397-07S1

Name of PD/PI: Mo, Q.

Role: Principal Investigator, Subaward

Source of Support: NIH/NCI (Sub w/Cedars-Sinai Medical Center)

Primary Place of Performance: Moffitt Cancer Center
 Project/Proposal Start and End Date: 05/01/2021 – 04/30/2024
 Total Award Amount (including Indirect Costs): \$102,201
 Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	1.20 CM
2. 2022	1.20 CM
3. 2023	1.20 CM

Title: *Targeting Tumor Repopulation and the Immune Microenvironment to Overcome Chemoresistance*

Major Goals: The success of this study will identify drug targets that augment chemotherapy response. Moreover, these findings will establish a better biological understanding of how chemotherapy programs the immune microenvironment to impact therapeutic response.

Specific Aims: (1) Decipher a novel and unconventional mechanism leading to the release of extracellular (i.e., outside the cell) factors with pleiotropic function in modulating tumor repopulation and immune response. (2) Evaluate how these extracellular factors and their receptor pairs drive the repopulation of dormant cancer stem cells; and finally. (3) Investigate the immune-modulatory roles of these extracellular factors and determine how the inhibition of their release impacts chemotherapy response.

Status of Support: Pending

Project Number: 1 R01 CA255609-01A1

Name of PD/PI: Mo, Q.

Role: Principal Investigator

Source of Support: NIH/NCI Sub w/Cedars-Sinai Medical Center

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 08/01/2021 - 07/31/2026

Total Award Amount (including Indirect Costs): \$70,720

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.60 CM
2. 2022	0.60 CM
3. 2023	0.60 CM
4. 2024	0.60 CM
5. 2025	0.60 CM

Title: *Immunogenicity of a Third Dose of mRNA 1273 Vaccine (Moderna) Among Cancer Patients*

Major Goals: The goal of this study is to evaluate the immunogenicity of a third mRNA-1273 vaccine dose in HM and solid tumor cancer patients, as assessed one-month post-vaccination dose 3, and duration of antibody 6-month post-vaccination dose 3.

Specific Aims: (1) To evaluate immunogenicity among cancer patients to a third dose of 100 µg mRNA-1273 28 days and 6 months post-vaccination. (2) To evaluate neutralizing antibody responses among cancer patients to a third dose of 100 µg mRNA-1273 28 days and 6 months post-vaccination.

Status of Support: Pending

Project Number:

Name of PD/PI: Giuliano, A./Lancet, J.

Role: Co-Investigator

Source of Support: Moderna

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 09/08/2021 - 09/30/2024

Total Award Amount (including Indirect Costs): \$1,372,322

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.60 CM
2. 2022	0.60 CM
3. 2023	0.60 CM

Title: *Unraveling Early-Onset Colorectal Cancer Biology, Prognosis, and Survivorship*

Major Goals: Hypothesis 1: Early-onset CRC displays distinct molecular profiles associated with oxidative stress compared to tumors occurring at later ages. Categorization of early-onset disease by biological age, sex and race/ethnicity explains some of the observed heterogeneity of the disease characteristics. Hypothesis 2: Patients with early-onset CRC will experience greater treatment-related toxicity, report more symptoms and poorer quality of life, and higher risk of recurrence/death, compared to older CRC patients.

Specific Aims: (1) To conduct a multi-omics analysis by characterizing the tumor and adjacent normal mucosa microbiome, transcriptome, plasma metabolome, plasma proteome, and serum inflammatory biomarker profiles to identify a unique biologic fingerprint associated with early-onset CRC (n=500). (2) To determine the relationship between age at diagnosis (chronological and biological) and risk of (a) treatment-related adverse events, including dose-reduction; (b) patient-reported outcomes, oncofertility, and quality of life (QOL); and (c) clinical outcomes (recurrence, disease-free, overall survival, and progression-free survival)

Status of Support: Pending

Project Number: R01

Name of PD/PI: Siegel, E.

Role: Co-Investigator

Source of Support: NIH/NCI

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 12/01/2021 - 11/30/2026

Total Award Amount (including Indirect Costs): \$861,521

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.60 CM
2. 2022	0.60 CM
3. 2023	0.60 CM
4. 2024	0.60 CM
5. 2025	0.60 CM

Title: *Elucidating the immunological determinants of lung cancer health disparity in African American patients*

Major Goals: We hypothesize that the immune landscape of NSCLC in AA patients is skewed towards immunosuppressive signature the targeting of which would enhance anti-tumor immune response and reduce incidence of disease mortality, facilitating improved disease outcome. In order to test this hypothesis, we will perform comprehensive immunogenomic profiling of fresh tumor specimens as well as functional and drug efficacy studies.

Specific Aims: (1) To elucidate the cellular, molecular, and functional profile of tumor-associated immune cells in AA NSCLC patients. (2) To determine the therapeutic potential of combined PD-1 and TIGIT blockade as a treatment modality to support enhanced anti-tumor immunity in AA NSCLC disease setting.

Status of Support: Pending

Project Number:

Name of PD/PI: Adeegbe, D.

Role: Co-Investigator

Source of Support: Lung Cancer Research Foundation
 Primary Place of Performance: Moffitt Cancer Center
 Project/Proposal Start and End Date: 12/01/2021 - 11/30/2023
 Total Award Amount (including Indirect Costs): \$149,826
 Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.12 CM
2. 2022	0.60 CM

Title: *Lactate metabolism as a biological determinant and contributory factor to racial health disparity in NSCLC*

Major Goals: This project seeks to investigate whether the metabolic landscape of non-small cell lung cancer (NSCLC), the most common form of lung cancer is different in African American patients in a manner that fosters enhanced tumor growth and progression. Our main focus is on lactate metabolism, a metabolite that cancer cells co-opt to fuel their energy requirements.

Specific Aims: (1) We will conduct global metabolic profiling in African American NSCLC clinical specimens to glean metabolic signatures that may be unique to this patient population and determine whether the pattern of expression informs propensity for increased tumor cell growth and survival. (2) We will investigate the expression pattern of key lactate transporters MCT1 and MCT4 in patient tumor tissues and correlate this data with clinicopathological disease parameters. (3) Will interrogate the dependency of African American NSCLC cells on exogenous lactate utilization as a mechanism to support tumor cell survival and aggressive cell proliferation.

Status of Support: Pending

Project Number: 1 R01 CA269299-01

Name of PD/PI: Adeegbe, D.

Role: Co-Investigator

Source of Support: NIH/NCI

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 12/01/2021 - 11/30/2026

Total Award Amount (including Indirect Costs): \$2,469,329

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2021	0.60 CM
2. 2022	0.60 CM
3. 2023	0.60 CM
4. 2024	0.60 CM
5. 2025	0.60 CM

Title: *Developing an ESR1 Neoantigen Response for Treatment of Metastatic Hormone Receptor Breast Cancer*

Major Goals: We will test this hypothesis ex vivo and in preclinical models and translate these findings into two early phase safety studies to determine whether we can induce anti-ESR1 CD4 Th1 against wt and mutated ESR1 in patients with locally recurrent and MBC and these responses are safe and can impact disease. We also will attempt to isolate B cells, and antibodies against ESR1 mutations from patients with recurrence or MBC prior to and following vaccinations.

Specific Aims: (1) Assess the CD4 Th1 response against native and ESR1 mutations both human and murine models in vitro and in vivo in the presence and absence of SERDs and assess the expansion of these cells for adoptive therapy. (2) Identify anti-ESR1 specific B cells and antibody responses against ESR1 mutations in breast cancer patients and murine models.

(3) Perform pilot clinical trials to determine safety and feasibility of vaccinating patients against native and ESR1 mutations and determine whether anti-ESR1 CD4 Th1 can be safely administered to subjects with locally recurrent HRpos breast cancer (BC) and subjects with HRpos MBC.

Status of Support: Pending

Project Number: W81XWH-21-BCRP-BTA3

Name of PD/PI: IPI: Czerniecki, B./PPI: Conejo-Garcia, J.

Role: Co-Investigator

Source of Support: US Army/DOD/BRCP

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 01/01/2022 - 12/31/2025

Total Award Amount (including Indirect Costs): \$5,912,685

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.60 CM
2. 2023	0.60 CM
3. 2024	0.60 CM

Title: *The Immune Landscape of Appendiceal Cancers*

Major Goals: The overarching goal of this proposal is to develop ex-vivo stromal-inclusive models for future co-clinical trials.

Specific Aims: (1) To determine the immune profile in a large retrospective cohort of appendiceal cancer (AC) patients (low-grade mucinous, high-grade mucinous and goblet cell histologies). (2) To develop a novel ex vivo spheroid model with autologous stromal/immune cells for AC.

Status of Support: Pending

Project Number:

Name of PD/PI: Imanirad, I./Avram, D./Dineen, S.

Role: Co-Investigator

Source of Support: FBRP/James and Esther King Biomedical Research Program

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 04/01/2022 - 03/31/2025

Total Award Amount (including Indirect Costs): \$300,000

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.36 CM
2. 2023	0.36 CM
3. 2024	0.36 CM

Title: *Oct4-YAP1 interaction as a therapeutic target in lung cancer*

Major Goals: We propose to optimize the PPxY mimetics to enhance their drug-like properties as well as their overall potency.

Specific Aims: (1) To enhance the efficacy and optimize the drug-like properties of PPxY (2) To assess the molecular mechanisms by which the PPxY mimetics eliminates lung cancer cell lines and organoids. (3) To evaluate the in vivo efficacy of PPxY mimetics in immunodeficient and immunocompetent mouse models of lung cancer

Status of Support: Pending

Project Number: 1 R01 CA269888-01

Name of PD/PI: Chellappan, S./Lawrence, N.

Role: Co-Investigator

Source of Support: NIH/NCI

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 04/01/2022 - 03/31/2027
Total Award Amount (including Indirect Costs): \$3,788,100
Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.60 CM
2. 2023	0.60 CM
3. 2024	0.60 CM
4. 2025	0.60 CM
5. 2026	0.60 CM

Title: *Elucidating CDK9-mediated regulation of c-Myc and p53 as a therapeutic target in GBM*

Major Goals: The overall objective is to elucidate the molecular mechanisms underlying CDK9-mediated transcriptional, post- translational, or epigenetic regulation of p53 and c-Myc by conducting in vitro studies on patient derived primary GBM cells and organoids, and in vivo studies on GBM mouse models implanted orthotopically with GBM GSCs (21-23).

Specific Aims: (1) To understand the molecular mechanisms by which CDK9 regulates p53 and c-Myc, at transcriptional and post-translational level. (2) To assess the metabolic changes in AZD4573 treated and CDK9-knockout GBM cells. (3) To determine the efficacy and potential toxicity of the CDK9 inhibitor AZD4573 in vivo, using orthotopic implantation of patient derived GSCs.

Status of Support: Pending

Project Number: R01

Name of PD/PI: Chellappan, S./Padmanabhan, J.

Role: Co-Investigator

Source of Support: NIH/NCI

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 04/01/2022 - 03/31/2027

Total Award Amount (including Indirect Costs): \$2,459,693

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.60 CM
2. 2023	0.60 CM
3. 2024	0.60 CM
4. 2025	0.60 CM
5. 2026	0.60 CM

Title: *Defining the MYC-TFEB epigenetic circuit as a novel therapeutic vulnerability in myeloid malignancies*

Major Goals: This application represents comprehensive effort to mechanistically dissect the roles of MYC-TFEB axis in epigenetic and metabolic reprogramming and their impacts on myeloid cell fate. Further, the proposed studies will validate MYC-TFEB-KDM6B circuit as a novel therapeutic target in myeloid malignancies.

Specific Aims: (1) Assess the role of the MYC-TFEB circuit in KDM6B-dependent epigenetic reprogram in AML and MPN. (2) Define the role of TFEB-directed activation of glycolysis and TCA in AML and MPN cell fate. (3) Characterize the novel somatic mutations in TFEB and define their roles in AML.

Status of Support: Pending

Project Number:

Name of PD/PI: Yun, S.

Role: Co-Investigator

Source of Support: FBRP/Bankhead-Coley Cancer Research Program

Primary Place of Performance: Moffitt Cancer Center
 Project/Proposal Start and End Date: 04/01/2022 - 03/31/2025
 Total Award Amount (including Indirect Costs): \$600,000
 Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.60 CM
2. 2023	0.60 CM
3. 2024	0.60 CM

Title: *Discovery of Molecular Constituents from Plasma Exosomes as Biomarkers for Colorectal Cancer Early Detection and Outcome Prediction*

Major Goals: The objective of the project is to optimize plasma exosome isolations for CRC and to comprehensively evaluate multi-omic profiles (transcriptome, proteome, metabolome and lipidome) of exosomes in plasma from CRC patients (N=80), patients with preneoplastic polyps (N=40) and healthy controls (polyp free, N=40).

Specific Aims: (1) Determine the best approach for plasma exosome isolation and subsequent multi-omics analysis that discriminates CRC patients (N=10) from healthy controls (N=10).

(2) Identify molecular components from plasma exosomes that differentiate patients with CRC (N=80) and preneoplastic polyps (N=40) from healthy controls (polyp free, N=40) through multi-omic profiling analysis. (3) Explore if molecular constituents from plasma exosomes that differentiate colorectal cancer patients by stage and outcomes through multi-omic quantification analysis

Status of Support: Pending

Project Number:

Name of PD/PI: Siegel, E./Wang, L.

Role: Co-Investigator

Source of Support: FBRP/Bankhead-Coley Cancer Research Program

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 04/01/2022 - 03/31/2025

Total Award Amount (including Indirect Costs): \$599,975

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.36 CM
2. 2023	0.36 CM
3. 2024	0.36 CM

Title: *Investigating the prognostic value and therapeutic potential of CCR5+KLRG1+ effector T cells in Non-small cell lung cancer*

Major Goals: We seek to further characterize this new double positive effector T cell subset in a series of basic and translational studies.

Specific Aims: (1) To assess correlation between KLRG1/CCR5 positivity and disease clinicopathological parameters in NSCLC patients. (2) To elucidate the transcriptional program that governs CCR5+KLRG1+ effector CD4+ and CD8+ T cell function. (3) To determine the therapeutic potential of CCR5+KLRG1+ tumor-associated T cells for adoptive cellular therapy in NSCLC.

Status of Support: Pending

Project Number: LC210358

Name of PD/PI: Adeegbe, D.

Role: Co-Investigator

Source of Support: US Army/CDMRP/LCRP

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 05/01/2022 – 04/30/2024

Total Award Amount (including Indirect Costs): \$576,450
 Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.48 CM
2. 2023	0.48 CM

Title: *Mitotic kinases as therapeutic targets in E2F dysregulated breast cancers*

Major Goals: The team proposes to investigate breast cancer samples from NHB, NHW, C-H/L and H/L to generate genomic expression signatures correlate the expression of mitotic kinases with proliferation, EMT markers, EMT transcription factors and survival outcomes. Combinatorial inactivation of TTK, Nek2 and TBK1 in cell lines, PDX and orthotopic mouse models will address how they suppress invasion, survival and metastasis of TNBC.

Specific Aims: (1) Investigating if mitotic kinases drive poor prognosis of breast cancer in NHB, C-H/L and H/L women. (2) To determine if EMT triggered by mitotic kinases is due to their ability to trigger CA or EMT transcription factors. (3) To address how combined inhibition of mitotic kinases suppresses metastasis.

Status of Support: Pending

Project Number:

Name of PD/PI: Chellappan, S.

Role: Co-Investigator

Source of Support: NIH/NCI (Sub w/Ponce School of Medicine)

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 07/01/2022 - 06/30/2027

Total Award Amount (including Indirect Costs): \$1,127,600

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.60 CM
2. 2023	0.60 CM
3. 2024	0.60 CM
4. 2025	0.60 CM
5. 2026	0.60 CM

Title: *Combination Immunotherapy to De-Escalate Chemotherapy in Operable Her-2neu Overexpressing Breast Cancer*

Major Goals: We have designed a clinical trial that will attempt to improve pCR with preoperative combination immunotherapy with DC1 vaccination.

Specific Aims: (1) Evaluate in a clinical trial whether anti-Her2 and anti-Her3 boosting CD4 Th1 intratumoral DC1 in combination with trastuzumab and systemic blockade of Sema4D will eliminate HER2+HR+ IBC. (2) Determine whether the peripheral blood anti-HER2 and anti-HER3 CD4Th1 response to combination intratumoral DC1 plus immunotherapy can predict response to therapy. (3) Determine the mechanism by which Th1 cytokines and the immune response regulate disseminated cancer cells (DCC) formation in early breast cancer and control DCC survival in human models.

Status of Support: Pending

Project Number: R01

Name of PD/PI: Lee, M./Czerniecki, B.

Role: Co-Investigator

Source of Support: NIH/NCI

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 07/01/2022 - 06/30/2027

Total Award Amount (including Indirect Costs): \$3,961,150

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	0.60 CM
2. 2023	0.60 CM
3. 2024	0.60 CM
4. 2025	0.60 CM
5. 2026	0.60 CM

Overlap - NONE

COMPLETED:

Title: *Targeting Breast Cancer Micrometastases: To Eliminate the Seeds of Evil*

Major Goals: The major goal of this proposal is to establish a series of pre-clinical models that recapitulate the cellular nature of micrometastases, mimic their habitat and allow expedited testing of their drug responses.

Status of Support: Completed

Project Number: W81XWH-16-1-007

Name of PD/PI: Zhang

Role: Co-Investigator/ Biostatistician

Source of Support: DAMD

Program Officer: N/A

Address: N/A

Primary Place of Performance: Baylor College of Medicine

Project/Proposal Start and End Date: 03/01/2016 - 02/29/2021 (Effort Ended on 07/06/2018)

Total Award Amount (including Indirect Costs): \$500,000

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2016	1.20 CM
2. 2017	1.20 CM

Title: *Cancer-Associated Fibroblast in the Regulation of Bladder Cancer Stem Cells*

Major Goals: The long-term goal is to uncover druggable targets within this pathway for early bladder cancer intervention.

Status of Support: Completed

Project Number: 4R01 CA175397-04

Name of PD/PI: Chan

Role: Co-Investigator/Biostatistician

Source of Support: NIH/NCI

Program Officer: N/A

Address: N/A

Primary Place of Performance: Baylor College of Medicine

Project/Proposal Start and End Date: 09/30/2013 - 08/31/2018 (Effort Ended on 07/06/2018)

Total Award Amount (including Indirect Costs): \$207,500

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2013	1.20 CM
2. 2014	1.20 CM
3. 2015	1.20 CM
4. 2016	1.20 CM

Year	Person Months
5. 2017	1.20 CM

Title: *Molecular Analysis of Uterine Receptivity*

Major Goals: The goal of this proposal is to investigate how the hormone progesterone, acting through its receptor regulates the ability of the uterus to support embryo implantation and control processes that prevent diseases, such as endometriosis and endometrial cancer.

Status of Support: Completed

Project Number: 5R01 HD042311-13

Name of PD/PI: Lydon

Role: Co-Investigator/Biostatistician

Source of Support: NIH/NICHD

Program Officer: N/A

Address: N/A

Primary Place of Performance: Baylor College of Medicine

Project/Proposal Start and End Date: 07/01/2014 - 04/30/2019 (Effort Ended on 07/06/2018)

Total Award Amount (including Indirect Costs): \$207,500

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2014	0.60 CM
2. 2015	0.60 CM
3. 2016	0.60 CM
4. 2017	0.60 CM
5. 2018	0.60 CM

Title: *A Novel MIR-198 Replacement Therapy for Pancreatic Cancer*

Specific Aims: (1) Demonstrate the significant role of miR-198 and the tumorigenic factor interactome in human PC clinical prognosis in a large cohort of PC patient samples. (2) Design and characterize MSLN-specific targeted miR-198 nanoparticles for specifically delivering miR-198 to PC cells. (3) Demonstrate the therapeutic efficacy of MSLN-targeted miR-198 replacement in PC patient-derived xenograft (PDX) mouse models.

Status of Support: Completed

Project Number: 5 R01 CA183984-03

Name of PD/PI: Yao

Role: Co-Investigator

Source of Support: NIH/NCI

Program Officer: N/A

Address: N/A

Primary Place of Performance: Baylor College of Medicine

Project/Proposal Start and End Date: 02/03/2015 - 01/31/2021 (Effort Ended on 07/06/2018)

Total Award Amount (including Indirect Costs): \$249,000

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2015	0.60 CM
2. 2016	0.60 CM
3. 2017	0.60 CM
4. 2018	0.60 CM

Title: *Drug Discovery and Mechanistic Studies of Protein Methylation Targeting Leukemia*

Major Goals: The overall goals are to develop potent and selective inhibitors of LSD1 as potential drug candidates for leukemia treatment and to perform mechanistic studies to find LSD1's role in RUNX1-ETO leukemia.

Status of Support: Completed

Project Number: RP150129

Name of PD/PI: Song

Role: Co-Investigator/Biostatistician

Source of Support: CRIPT

Program Officer: N/A

Address: N/A

Primary Place of Performance: Baylor College of Medicine

Project/Proposal Start and End Date: 03/01/2015 - 02/28/2019 (Effort Ended on 07/06/2018)

Total Award Amount (including Indirect Costs): \$399,587

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2015	1.20 CM
2. 2016	1.20 CM
3. 2017	1.20 CM
4. 2018	1.20 CM

Title: *Developing New Combinatory Therapies for Pediatric High-Grade Glioma*

Major Goals: In this proposal, we will team up with the CPRIT-funded Texas Screening Alliance for Cancer Therapeutics to develop novel "anchor-probe" combinations for critical genetic mutations, confirm their therapeutic efficacy in our 16 PDOX models, the first and the largest panel in the world, and understand the mechanisms of cell killing and drug resistance in these tumors. Our goal is to establish strong preclinical rationale for these new combinatory therapies so that clinical trials can be initiated within 1-3 years.

Status of Support: Completed

Project Number: RP150032

Name of PD/PI: Li

Role: Co-Investigator/Biostatistician

Source of Support: CPRIT

Program Officer: N/A

Address: N/A

Primary Place of Performance: Baylor College of Medicine

Project/Proposal Start and End Date: 03/01/2015 - 02/28/2019 (Effort Ended on 07/06/2018)

Total Award Amount (including Indirect Costs): \$473,522

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2015	0.60 CM
2. 2016	0.60 CM
3. 2017	0.60 CM
4. 2018	0.60 CM

Title: *Mechanisms and Targeting Strategies for SWI/SNF Mutations in Cancer*

Major Goals: The goal of our study is to unravel the mechanisms by which SWI/SNF mutations contributes to cancer development and develop therapeutics targeting SWI/SNF-mutant tumors.

Status of Support: Completed

Project Number: RP160242

Name of PD/PI: Shen

Role: Biostatistician/Sub-Contract PI
 Source of Support: CPRIT (Sub w/MD Anderson Cancer Center)
 Program Officer: N/A
 Address: N/A
 Primary Place of Performance: Baylor College of Medicine
 Project/Proposal Start and End Date: 03/01/2016 - 02/28/2019 (Effort Ended on 07/06/2018)
 Total Award Amount (including Indirect Costs): \$6,710
 Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2016	0.60 CM
2. 2017	0.60 CM
3. 2018	0.60 CM

Title: *CPRIT Rising Star Award*
 Major Goals: The overall goal of the CPRIT award is to use proteogenomics and multi-omics data to better understand cancer biology and to improve cancer care.
 Status of Support: Completed
 Project Number: RR160027
 Name of PD/PI: Zhang
 Role: Biostatistician/Co-Investigator
 Source of Support: CPRIT
 Program Officer: N/A
 Address: N/A
 Primary Place of Performance: Baylor College of Medicine
 Project/Proposal Start and End Date: 08/31/2016 - 08/30/2021 (Effort Period: 09/01/2017 - 07/06/2018)
 Total Award Amount (including Indirect Costs): \$4,000,000
 Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2017	1.20 CM

Title: *Development of nuclear receptors and co-regulators as diagnostic and therapeutic targets of breast and lung cancers*
 Major Goals: N/A
 Status of Support: Completed
 Project Number: RP120732-P5
 Name of PD/PI: Xu
 Role: Biostatistician/Co-Investigator
 Source of Support: CPRIT Multi-Investigator Award
 Program Officer: N/A
 Address: N/A
 Primary Place of Performance: Baylor College of Medicine
 Project/Proposal Start and End Date: 8/31/2012 - 8/30/2018 (Effort Period: 07/01/2017 - 07/06/2018)
 Total Award Amount (including Indirect Costs): \$8,215,964
 Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2017	0.96 CM

Title: *Characterizing Supraclavicular Brown Adipose Tissue During Development and in Obesity*

Specific Aims: (1) Identify the developmental lineage giving rise to supraclavicular BAT; (2) Determine the physiological role and molecular signatures of supraclavicular BAT; (3) Investigate the effect of high-fat diet-induced obesity on supraclavicular brown adipocyte function.

Status of Support: Completed

Project Number: 16-GRNT3072000

Name of PD/PI: Chen

Role: Biostatistician/Co-Investigator

Source of Support: American Heart Association

Program Officer: N/A

Address: N/A

Primary Place of Performance: Baylor College of Medicine

Project/Proposal Start and End Date: 07/01/2016 - 06/30/2018

Total Award Amount (including Indirect Costs): \$70,000

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2016	0.60 CM
2. 2017	0.60 CM

Title: *A Phase III Randomized Trial Investigating Bortezomib (NSC# 681239; IND# 58443) on a Modified Augmented BFM (ABFM) Backbone on Newly Diagnosed T- Lymphoblastic Leukemia (T-ALL) and T- Lymphoblastic Leukemia L (T-LLY)-Correlative Studies*

Major Goals: N/A

Status of Support: Completed

Project Number: AALL1231

Name of PD/PI: Horton

Role: Biostatistician/Co-Investigator

Source of Support: Millennium Pharmaceuticals

Program Officer: N/A

Address: N/A

Primary Place of Performance: Baylor College of Medicine

Project/Proposal Start and End Date: 08/01/2015 - 07/31/2020 (Effort Ended on 07/06/2018)

Total Award Amount (including Indirect Costs): \$433,415

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2015	0.24 CM
2. 2016	0.24 CM
3. 2017	0.24 CM

Title: *The Cell of Origin of Breast Cancer Metastasis*

Major Goals: N/A

Status of Support: Completed

Project Number: R21CA202227

Name of PD/PI: Li

Role: Biostatistician/Co-Investigator

Source of Support: NIH/NCI

Program Officer: N/A

Address: N/A

Primary Place of Performance: Baylor College of Medicine

Project/Proposal Start and End Date: 12/01/2015-11/30/2017

Total Award Amount (including Indirect Costs): \$117,450

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2015	0.60 CM
2. 2016	0.60 CM

COMPLETED SINCE LAST SUBMISSION:

Title: *A Statistical Method for Integrative Pathway Analysis of Multiomics Data*

Major Goals: The goal is to develop a statistical method for integrative pathway analysis of multiomics data and to apply the method in cancer genomics study.

Status of Support: Completed

Project Number:

Name of PD/PI: Mo, Q.

Role: Co-Investigator

Source of Support: Bios2 Department Internal Funding

Program Officer: Brooke Fridley, Chair, Professor & Senior Member, Dept Biostatistics & Bioinformatics | Scientific Director, Biostatistics and Bioinformatics Shared Resource

Address: 12902 Magnolia Drive, Tampa, FL 33612 | (813) 745-1461 | Brooke.Fridley@Moffitt.org

Primary Place of Performance: Moffitt Cancer Center

Project/Proposal Start and End Date: 07/01/2020 - 06/30/2021

Total Award Amount (including Indirect Costs): \$25,000

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2020	0.60 CM

IN-KIND

None

9.6 WENHAM, ROBERT

Positions & Scientific Appointments

2016-present	Chair, Department of Gynecologic Oncology
2017-present	Senior Member, Programs of Gynecologic Oncology and Clinical Sciences, H. Lee Moffitt Cancer Center, Tampa, Florida
2018-present	Professor, Department of Oncologic Sciences, University of South Florida, Tampa, FL

Additional Support from Foreign or Domestic Entities

None

ACTIVE

NEW – THIS AWARD

W81XWH2010488	(Tworoger)	09/01/2020 to 08/31/2023
0.24 CM		
DOD/US Army - Log# OC190330		\$340,580 Annual
DC/\$1,120,216 Total		
Sponsor Contact Info: Grants Specialist: Jennifer Fox; Phone: 301-619-2784;		
Email: jennifer.l.fox1.civ@mail.mil		

A Presurgical Window of Opportunity Trial of the Effect of Aspirin on Immunological Features of Ovarian Tumors

Goals: The main goals of our clinical trial are to assess the efficacy and safety of standard-dose aspirin in improving prognosis-related tumor characteristics at surgery and tolerance of neoadjuvant chemotherapy in women recently diagnosed with ovarian cancer.

Specific Aims: 1) To evaluate the efficacy of aspirin for improving immunological characteristics of the tumor at interval debulking surgery among women diagnosed with ovarian cancer. We hypothesize that, compared with women assigned to a daily placebo pill, those assigned to daily 325mg aspirin will have: a. Primary: A greater decrease in density of tumor-associated macrophages (TAMs) and T-regulatory cells (Tregs) in the tumor and b. Secondary: (i) A greater percent improvement in response evaluation criteria in solid tumors (RECIST) standardized to the number of chemotherapy cycles completed; (ii) greater decrease in tumor COX1 and COX2 expression; (iii) greater decrease in platelet aggregation function; and (iv) greater decrease in plasma IL-6 levels. 2) To evaluate the efficacy of daily 325mg aspirin versus placebo pill for improving tolerance of neoadjuvant chemotherapy and quality of life. We hypothesize that, compared with women assigned to a daily placebo pill, those assigned to daily 325mg aspirin will have: a. Secondary: Fewer physical symptoms, including fatigue, nausea, peripheral neuropathy, and sleep symptoms and b. Secondary: Fewer emotional symptoms, including depression and anxiety symptoms, and higher subjective cognitive function.

COMPLETED

	(Vadaparampil/Wenham)	06/01/2018 to 05/31/2020
0.12 CM		
Miles For Moffitt		\$100,000
Sponsor Info: Maureen Ahearn, Moffitt Cancer Center, 813-734-8824;		
maureen.ahearn@moffitt.org		

Ovarian Cancer: Developing and Implementing Referral and Expanding Cascade Testing Systems (OC DIRECTS)

Goals: We aim to identify barriers to implementing referral of index patients and promoting cascade testing among at-risk relatives at Moffitt. We propose to use our findings to develop a functional prototype of a multilevel health information technology intervention to increase use of genetic counseling for ovarian cancer patients and promote cascade testing.