

H. Lee Moffitt Cancer Center & Research Institute State Funding

NCI Cancer Center Program

Total Funding: \$25,374,656 Service Period: July 1, 2017 – June 30, 2018

General Use of Funds and Research Funded

Since being first designated as an NCI Cancer Center in 1998, the H. Lee Moffitt Cancer Center & Research Institute (Moffitt Cancer Center) has experienced a rapid trajectory of scientific and clinical growth. As reported last year, Moffitt's competitive renewal of its National Cancer Institute (NCI) Cancer Center Support Grant (CCSG), which conveys Comprehensive Cancer Center status, was successful. Only 49 cancer research institutions in the United States have received the prestigious designation. Obtaining and then maintaining this designation is the key goal of the NCI Cancer Center Program. Comprehensive Cancer Center status recognizes robust, collaborative clinical, basic and population science research; team science; scientific leadership; education programs; and research focused on benefitting the community. Moffitt is currently the only Comprehensive Cancer Center headquartered in the state of Florida, which has the second highest burden of cancer incidence and death in the United States. Designation is a testament to Moffitt's strong focus on translating research discoveries into new therapies. A patient treated at an NCI-designated Comprehensive Cancer Center receives today the most advanced treatments that will be the standard of care tomorrow. Thus, the benefits are not only for our patients, but also those across all of Florida and beyond. Moffitt's research achievements have been marked by transformational ideas, committed and nimble leadership, and significant institutional support and investment. This success would not have been possible without the recruitment, retention and support of clinical and lab based research faculty members. Continued success, including maintaining Comprehensive status, is dependent on the ongoing investment to support the rapid pace of discovery and the improved cancer treatments.

The NCI Cancer Centers Program is an integral part of the nation's cancer research effort and has contributed substantially to the increase in the number of cancer survivors throughout the state as well as to the quality of their lives. Discovery often begins in the laboratory, but keen observations at the bedside frequently spur laboratory experimentation. The laboratory based infrastructure enhances scientific productivity and innovation for cancer research, which attracts grant funding and private support to the state of Florida, which in turn creates jobs and fuels new discoveries. Laboratory science support is critical to ensuring scientists have the resources and supportive environment necessary to remain competitive in seeking grants that fund new discoveries. These technologies and skilled faculty and staff are critical for recruiting the best faculty nationally to Florida. The discoveries that come out of this support also enhance our understanding of cancer and leads to new preventive and therapeutic interventions. Our scientists rely on these specialized resources to conduct experiments that cannot be accomplished in their own lab.

The demand for Moffitt Cancer Center care reflects the numerous opportunities to participate in clinical trials and the documented superior outcomes. Moffitt Cancer Center primarily serves Floridians but is



also a magnet for out-of-state cancer patients. 96% of its patients live in Florida, with 58% coming from the surrounding four counties. In 2018, Moffitt continued to grow with 9,095 admissions, 23,199 new patients, and 406,117 outpatient visits.

With a goal of this program to develop two more NCI-designated Cancer Centers headquartered in Florida and focused first on Floridians, Moffitt Cancer Center continues to actively work with the University of Florida Cancer Center and the University of Miami Sylvester Cancer Center to help those centers achieve NCI status. The three centers have collaborated on pilot research projects, the leaders hold regular joint meetings, and each take turns hosting collaborative research retreats. Last year, the three Centers expanded their collaborations by holding small "think tank" retreats focused on specific research topics such -- the microbiome and health disparities. These produced larger research projects funded by the three centers.

Research and Clinical Faculty

Quality recruitment continues to be the most essential ingredient to ensuring quality science and ultimately the best cancer care. In addition, providing a strong academic environment of team science and collaboration helps with retention of existing faculty.

The state's investment has enabled Moffitt to recruit faculty at all levels (primarily from out of state), competing successfully for top-tier scientists against larger, more established institutions (including this year from MD Anderson, Dana Farber, and NCI among others). Investment in new faculty includes attractive start-up funding for them to jump start and supplement their research as a necessary and foundational step towards competing for extramural funding, especially from the National Cancer Institute. These funds allow faculty to develop preliminary data and generate ideas necessary to obtain grant funding, to develop clinical trials, and to apply new knowledge to provide outstanding patient care.

Moffitt continues to be a highly interactive, collaborative culture of team science drives research at the Cancer Center and serves as a magnet for talent. Bringing together laboratory scientists, applied scientists, and clinicians from a wide range of expertise to focus on the complexity of cancer translates into better outcomes and improved care. Having the clinical and research enterprises united offers an advantage in meeting our singular mission to prevent and cure cancer.

Expenditures for July 1, 2017 – June 30, 2018

Research Recruitment and Start-up Funds (3 faculty)	\$ 802,147
Clinical Faculty Recruitment (37 faculty)	4,511,027
Research Faculty Salaries (119 faculty)	15,575,600
Research and Clinical Support Expenses	<u>10,961,388</u>
Total	\$ 31,850,162

Laboratory, Shared Resource, and Equipment Support

Faculty conducting research requires support by an array of highly-trained staff and services. In addition to staff in the lab, faculty make use of "shared resources", which are centralized services with cutting



edge equipment and highly trained staff, so that each faculty member can make use of centralized services more efficiently. Faculty are provided access to cutting-edge equipment, skilled scientific staff and highly specialized analysis in a cost effective structure that allows Moffitt Cancer Center to quickly adopt cutting-edge technology, enable new discoveries and meet the needs of faculty. Services include but are not limited to shared resources in Biostatistics, Cancer Informatics, Chemical Biology, Analytic Microscopy, Flow Cytometry, Molecular Genomics, Proteomics and Cellular Therapies. A new Gene Targeting Core has expanded support for animal models including the innovative CRISPR technology. An effective infrastructure attracts scientists to Moffitt, improves success in obtaining grants, and more rapidly translates discoveries into the clinic.

Infrastructure support costs also include resources and expertise needed to develop and manage clinical trials for our clinical research faculty. Grant funding is typically not available for new clinical trials designed by our clinical research faculty until later in the development stage. While some industry funding is available, full costs are not always recoverable. Also, many studies are so novel that industry sponsors are hesitant to fund the ideas. Therefore the centralized support of clinical trials requires maintaining a workforce of highly trained research nurses, clinical trial coordinators and data managers. Clinical Trials provide one of the last crucial steps in transferring discoveries from the laboratory into novel treatments and cures. Studies initiated by the Cancer Center also draw patients to Moffitt from outside Florida. Moffitt placed over a 1,100 patients last year onto treatment trials, with 40% the accrual into trials designed by our faculty.

Clinical trials are heavily regulated and resource intensive to ensure the safety of patients and have over the last few years grown in complexity as they have grown in effectiveness. New immunotherapy and genetic studies promise to better personalize the clinical trial experience but also include higher costs to ensure their safety and efficacy. The Cancer Center's clinical and translational infrastructure enables the safe testing of novel therapies and ensuring data integrity that are essential to properly evaluate whether new therapies are superior to existing ones. These activities are all done in a way that protects patient privacy rights. To the patients of our state this also means greater access to clinical trials and to the most innovative cancer treatments.

Expenditures for July 1, 2017 – June 30, 2018

Research and Clinical Faculty (previously noted above)	\$ 31,850,162
Laboratory Supplies and Staffing (19 positions)	3,791,158
Biostatistical (analysis) Support (10 positions)	1,268,464
Clinical Trial Operations/Translational Support (57 positions)	3,932,931
Total NCI Cancer Program Expenditures	\$40,842,715

Additional Funding Generated

State of Florida Funding has helped Moffitt expand its annual research grant base of \$61,980,192 (FY17) and increasing it by \$8,141,066 to \$70,121,258 in (FY18). Since the creation of the Cancer Center



Funding program, Moffitt has increased its annual funding base by \$23.1M, demonstrating the value and return on investment from State support. The increase in funding included many new NCI funded grants (two U01s, one R00, one R37 and five R01s) and a continued increase in clinical trial revenue. Partnerships with industry also continued to increase and over the last five years have brought in commitments of \$61 Million. These partnerships aim to speed up the drug development pipeline, thereby benefitting Florida's cancer patients and state economic development.

Moffitt is a leader in immunotherapy including research and clinical trials involving monoclonal antibodies, immune checkpoint inhibitors, cancer vaccines, and nonspecific immunotherapy. Our expertise in cellular immunotherapy includes innovative research and clinical care involving CAR T-cell therapy, which has been shown to be effective in treating including diffuse large B-cell lymphoma, mantle cell lymphoma, acute lymphoblastic leukemia, transformed follicular lymphoma and follicular lymphoma; TCR gene transfers that can be used to treat several types of malignancies, including lung cancer, sarcomas and multiple myeloma; and TIL therapy, which has been effective in treating malignant melanoma, head and neck squamous cell carcinoma, genitourinary carcinoma and lung cancer.

Endowed Research Chair for Medical Director of Personalized Medical Institute

Total Funding: \$3,333,333 Service Period: July 1, 2013 – June 30, 2020

Endowed Chair

Dr. Howard L. McLeod

Responsibilities

Genetics Counseling (10%) Medical Director, DeBartolo Family Personalized Medicine Institute (PMI) (35%) Senior Member of Department of Cancer Epidemiology (55%)

Research Progress & Progress Toward Achieving Goals of Bankhead/Coley Program

As mentioned in previous years, the State of Florida Endowed Chair in cancer research was an important factor in Dr. McLeod's choice to accept the opportunity to join Moffitt Cancer Center as a senior faculty member in the Division of Population Sciences and founding Medical Director of the DeBartolo Family Personalized Medicine Institute (DFPMI). The DFPMI was established in 2012 to revolutionize the discovery, delivery and effectiveness of cancer care on an international scale. Providing oversight for Moffitt Cancer Center's Total Cancer Care[®] Study, the Institute seeks to create and share targeted treatments that will improve outcomes, cure disease, extend survivorship and improve quality of life for patients regardless of where they live. The personalized medicine efforts are also addressing the side effects of therapies, quality of life issues, symptom control and patient preferences. This pioneering work is putting the concepts of personalized medicine and precision cancer care into practice for the benefit of cancer patients in Florida, the nation and the world.



Dr. McLeod is a renowned expert on the role of genetics on the individual's response to cancer therapies. He has given over 1,000 invited lectures in 42 countries. He continues to be active as a reviewer for both grants and journals. For example, he currently serves as a member of the NHGRI Genomic Medicine Working Group and serves on the editorial board of *JCO Precision Oncology* (Founding Associate Editor), *Pharmacogenetics and genomics*, and *Pharmacogenomics*. Since his recruitment in 2013, Dr. McLeod has published over 550 articles, 18 of them in 2018, including high impact articles in *Nature, JAMA Neurology*, and *Scientific Reports*. He is a Co-investigator on two grants, including an R01, and last year he also obtained a grant as PI from Celgene. The project is a biomarker discovery study focused on pancreatic cancer. Dr. McLeod is also a founder of a Moffitt Cancer Center startup, Interpares Biomedicine, which is an early-stage immuno-oncology company.

As Chair of the Individualized Cancer Management (ICM) Department, Dr. McLeod oversees five high impact and clinically oriented clinical programs: Adolescent & Young Adult, Gene Home, Genetic Risk Assessment Service, Personalized Cancer Medicine and the Senior Adult Oncology. The Personalized Cancer Medicine program is comprised of the Personalized Medicine Clinical Service (PMCS) and Clinical Genomics Action Committee (CGAC). PMCS and CGAC were developed as pathways for direct clinical translation of results from genomic testing. PMCS provides consultation and interpretation of the tumor genetic sequencing results for Moffitt patients and serves as a resource to Moffitt physicians for input and advice regarding personalized medicine. CGAC serves as Moffitt's unique molecular tumor board and includes a diverse team with expertise from various disciplines.

Expenditures for July 1, 2017 – June 30, 2018

Lab Support and Other Expenditures	\$ 448,118
Endowment Fund Activity	
Funds Received in 2018	\$ 0
Fund Balance as of June 30, 2018	\$ 906,784



Cigarette Tax Proceeds

Total Funding: \$15,524,000 4.04% Service Period: July 1, 2017 – June 30, 2018

General Use of Funds and Research Funded

Cigarette Tax funds continue to be used for the purposes of constructing, furnishing, equipping, financing, operating and maintaining cancer research and clinical and related facilities and other properties owned or leased by the Cancer Center, as well as for the repayment of the debt incurred for the Cancer Center's Series 2012A bonds with additional bonds issued for the Series 2016A.

State Appropriations

Total Funding: \$10,576,890 Service Period: July 1, 2017 – June 30, 2018

General Use of Funds and Research Funded

Medical Residents, Graduate and Training Programs

Moffitt is the leading education facility of oncology in the State, part of the State University System and a Statutory Teaching Hospital. Over 2,614 Medical and Research students either rotate or work full time at Moffitt. These students include:

- Medical residents and fellows
- Undergraduate and advanced practice nursing students
- Radiologists
- Nutrition therapists
- Medical and physician assistants
- Pharmacy students
- Cancer biology graduate students
- Pre-doctoral level students assigned to research labs
- Research post doctorate and research scientist trainees
- Innovative internships in Cell Therapies manufacturing techniques
- Integrated Mathematical Oncology training for high school students

In addition, the State Appropriations also funds a portion of the infrastructure necessary for the diverse set of training programs to succeed. These activities include protected time for faculty to train and mentor students and other trainees and maintenance of a wide array of scientific literature and periodicals, which continues to increase as Moffitt expands into new areas of research.

Expenditures for July 1, 2017 – June 30, 2018

Medical Residents, Fellows and Other Training Positions \$ 8,664,680



Research Graduate Training and Other Research Education	3,666,445
Other Organizational Training and Education	<u>3,382,286</u>
Total	\$ 15,713,411

Junior Faculty (Assistant Members)

A shortfall of cancer physicians and researchers is projected nationally in the coming decades due to many challenges facing trainees and faculty first starting out. For researchers, the limited extramural funding and competition nationally against more senior faculty make it difficult for junior faculty just beginning their careers to be successful. Moffitt emphasizes recruitment and training of early career faculty members to provide a nurturing and robust scientific environment that encourages junior faculty to succeed.

<u>Expenditures for July 1, 2017 – June 30, 2018</u>	
Salary Support and Benefits	<u>\$ 3,025,637</u>
Total State Appropriation Expenditures	\$ 18,739,048

Additional Funding Generated

Moffitt actively seeks training grants and fellowships to provide support for training activities. At the graduate level, Dr. Kenneth Wright (Immunology) has directed an accredited PhD Program since 2001 in Cancer Biology, funded by Moffitt Cancer Center in collaboration with the University of South Florida. Taught exclusively by Moffitt faculty members, it has produced more than 45 graduates and currently have 25 active students. The training program expanded its Cancer Biology degree to include three new majors this year: 1) Integrated Mathematical Oncology; 2) Chemical Biology; and 3)Cancer Immunology Immunotherapy. With four majors, the program now contributes to the training of a more diverse group of tomorrow's scientists.

At the postdoctoral level, Moffitt Cancer Center has an NCI funded T32 in Tumor Immunology (CA115308) and a T32 in Cancer Epidemiology (CA147832). Other training grants include an R25 in Behavioral Oncology (CA090314), an R25 to improve communication skills in oncofertility (CA142519) and an R25 to assess risk of breast cancer in Latinos (CA217723-01). Additional T32 training grants are in preparation in the areas of pharmacology, and molecular oncology. Moffitt also leads numerous individuals training grants to support postdocs and junior faculty. For example, Dr. Fred Locke is PI of a K23 investigating multiple myeloma, Dr. Inna Smalley was awarded a K99 in the area melanoma, and Dr. Dennis Adeegbe was awarded a K22 in the area of Non-Small Cell Lung Cancer. In total, these training grants brought in over \$2.3M in funding to the Moffitt.



The growth of Moffitt's research training activities led to the decision to create a Director of Research Education position to lead the research education mission of the Cancer Center. Currently under recruitment, the position will focus primarily on the training and mentoring of graduate students, postdoctoral fellows and research faculty, as well as supervision of the Moffitt Office of Postdoctoral Affairs. Additionally, the Director will be responsible for coordinating all education activities across the Cancer Center, including continuing education, patient education and community education. The position will report to the Center Director and work closely with the institution's Chief Academic Officer.