

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute

Report to Congress:

Use of Funds Received for Semipostal Stamp for Breast Cancer Research

Fiscal Year 2018

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## **Introduction**

On December 11, 2015, Congress reauthorized the Stamp Out Breast Cancer Act, which extended the authority of the U.S. Postal Service to issue a semipostal stamp to raise funds for breast cancer research. A provision of this law requires that the National Institutes of Health (NIH) and the Department of Defense each submit an annual report concerning the use of any amounts received from the sale of the stamps, including a description of any significant advances or accomplishments, to Congress and the Government Accountability Office (GAO) (39 U.S.C. 414). To fulfill this requirement, the following report has been prepared by the National Cancer Institute (NCI), NIH, Department of Health and Human Services.

This report highlights the research currently funded by proceeds from the semipostal stamp for breast cancer research. Additional information related to the Breast Cancer Research Stamp is available electronically on the NCI website at <http://www.cancer.gov/aboutnci/overview/contributing>.

## **Background**

In the United States, breast cancer is the most common non-skin cancer and the second leading cause of cancer death, after lung cancer, among women. According to the Annual Report to the Nation on the Status of Cancer 2019, it is estimated that there will be approximately 268,600 new cases of breast cancer among women in the United States in 2019, and 41,760 women will die from the disease this year.<sup>1</sup>

Since 1998, increased support for breast cancer research has come from funding through the highly successful Stamp Out Breast Cancer Act. The breast cancer research stamp is offered through the United States Postal Service as an alternative to a first class postage stamp. The Stamp Out Breast Cancer Act (The Stamp Act), which Congress initially enacted in 1997, stipulates that 70 percent of the proceeds from the stamp surcharge be directed to NIH for breast cancer research and 30 percent to the Department of Defense for the same purpose. Congress reauthorized the Stamp Act in 2015, extending the sales period through December 31, 2019.

In November 1998, NCI began receiving Breast Cancer Research Stamp proceeds from the United States Postal Service. Since then, NCI has allocated the proceeds – totaling \$60.7 million – to eligible research. Of this amount, NCI obligated \$50.9 million by the close of fiscal year 2018 through multiple extramural grant programs, as well as some NCI intramural research programs. NCI senior leadership considers a program's potential to make significant progress against breast cancer when selecting programs for funding.

The sections of this report that follow discuss NCI research programs in detail. The studies currently funded are two randomized trial studies that include only female study subjects, the Breast Cancer Weight Loss (BWEL) Study and the Tomosynthesis Mammographic

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<sup>1</sup> [https://seer.cancer.gov/report\\_to\\_nation/statistics.html](https://seer.cancer.gov/report_to_nation/statistics.html)

Imaging Screening Trial (TMIST).

NCI receives the Breast Cancer Research Stamp funds in May and November of each fiscal year. The table below lists the annual amounts received during each fiscal year since the inception of the program.

<b>Breast Cancer Research Stamp Act Collections</b>	
<b>FY</b>	<b>Total</b>
1999	\$4,150,210.00
2000	\$3,101,033.00
2001	\$5,556,224.67
2002	\$3,594,619.80
2003	\$5,175,938.00
2004	\$4,813,994.00
2005	\$4,372,191.62
2006	\$4,467,540.23
2007	\$3,006,105.81
2008	\$4,855,539.01
2009	\$3,403,204.50
2010	\$2,344,610.59
2011	\$2,048,555.12
2012	\$1,622,774.59
2013	\$1,403,656.57
2014	\$1,160,055.41
2015	\$1,251,477.38
2016	\$1,707,408.51
2017	\$1,387,066.59
2018	\$1,293,677.44
<b>Total</b>	<b>\$60,715,882.84</b>

## Projects Currently Funded by Stamp Act Proceeds

During fiscal year 2015, NCI began funding meritorious breast cancer applications, with consideration also given to funding priorities and public health significance, among other factors, submitted in response to the RFAs entitled, "Molecular and Cellular Characterization of Screen-Detected Lesions" (RFA-CA-14-010 and RFA-CA-14-011), with Stamp Act proceeds. NCI continued to fund these projects in fiscal year 2018.

***Molecular and Cellular Characterization of Screen-Detected Lesions Consortium*** (an extramural component that began in FY 2015)

This NCI initiative addresses one of the most challenging problems in oncology: predicting more precisely whether lesions that are detected by sensitive screening tests are indolent (hence, not requiring extensive treatment) or progressive and potentially life-threatening. The overarching goal of this initiative is to identify cellular and molecular characteristics that distinguish progressive from non-progressive lesions.

NCI published two Funding Opportunity Announcements (RFA-CA-14-010 and RFA-CA-14-011) soliciting applications from multi-disciplinary teams to undertake a comprehensive molecular characterization of tumor tissue, cell, and microenvironment components of screen-detected early lesions, as well as interval, and symptom-detected cancers in one or more of the following tumor sites: breast, prostate, lung, melanoma, and pancreas. Use of enabling approaches and technologies were encouraged to determine both the cellular and molecular phenotypes of early lesions, to assess the degree to which the behavior of these lesions is predictable or not, and to allow better predictions of the fate of such lesions.

From fiscal years 2015 through 2018, NCI used the Breast Cancer Research Stamp Fund to support the following three meritorious applications received in response to these solicitations that are specifically focused on breast cancer:

***University of Vermont and State Agricultural College*** (CA196383): The goal of this project is to identify tumor microenvironment signatures that predict the aggressiveness of early stage, screen-detected breast cancers by minimally invasive methods. The researchers will leverage and refine state-of-the-art technologies to characterize aggressive signatures based on the cellular composition and gene expression of specific cell populations within the tumor microenvironment of interval- and symptom-detected invasive breast cancers. The researchers will then determine whether the presence of these aggressive tumor microenvironment signatures in early stage, screen-detected breast cancer is associated with progression. Identifying aggressive and indolent tumor microenvironment signatures will promote the development of more conservative treatment strategies for the subset of women with favorable prognosis and suggest novel targets for therapeutic intervention in cases with unfavorable prognosis. The project has constructed large-scale tissue microarrays containing symptom and interval detected tumor/stroma samples and is using advanced imaging and computational methods to characterize distinct stromal cell populations and distinguish invasive tumor and benign

stroma. In addition, gene expression differences between patient and normal stromal cells show differences depending on their position relative to the tumor mass and reveal cytokine/chemokine signaling that mediate tumor host interactions.

***University of California-San Francisco*** (CA196406): The study is Elucidating the Molecular and Contextual Basis for IDLE (Indolent Lesions of Epithelial origin) Ultralow Risk Lesions and the Tumor Immune Microenvironment of High Risk in situ and invasive Breast Cancers. The goal of this project is to identify better ways to screen for and treat the most aggressive cancers and avoid overdiagnosis and overtreatment, as well as the inadvertent labeling of indolent lesions as cancers. The project intends to develop better biologic discriminators among IDLE, ultralow, low, and interval cancers (usually highly proliferative hormone receptor (HR)-negative and/or HER2-positive tumors) by harnessing a network of research collaborators and unique data sets. Assays developed through this research can be tested in samples from a unique, prospectively randomized trial of annual vs. personalized screening via the ATHENA Breast Health Network. This Network is a collaboration of the breast cancer and primary care communities across the five University of California (UC) Medical Centers and has been expanded recently to include the Sanford Health system in the rural Midwest. ATHENA was established to address the big issues in breast cancer screening and care that require a population-based approach. Germline profiling will be available on all women in the personalized arm and expression profiling will be available for all tumors diagnosed. The project also aims to find out who is at risk for what subtype of cancer so that the approach to screening and prevention can be adjusted and overdiagnosis and overtreatment for both in situ and invasive lesions can be mitigated. Further, the project plans to address the specific features of interval cancers (cancers missed by screening tests) that may generate a better approach to screening and prevention than the current imaging-based screening paradigm. The overall approach is to retrospectively optimize and prospectively validate new and emerging molecular, morphometric, and tumor immune microenvironment assays, and to prospectively add the context of germline predisposition. The ability to accurately distinguish ultralow risk from IDLE lesions and to understand the biologic basis of interval cancers will help refocus screening efforts and treatment at diagnosis. A key finding of the project that may help future clinical evaluation was the identification of five distinct immune subtypes in breast cancer involving either elevated or reduced levels of inflammatory cells or cytokines with significant outcome differences, including response to immune checkpoint inhibitor-based therapies. Lastly, two multiplex immune biomarker panels that detect different immune cell populations and proliferation markers are being applied to the analysis of a retrospective cohort of 120 DCIS cases to test for DCIS stratification into indolent/ultralow, moderate and high-risk breast lesions.

***Baylor College of Medicine*** (CA196386): This grant funds the Baylor College of Medicine to serve as the Coordinating and Data Management Group (CDMG) for the Molecular Characterization Labs (MCLs).<sup>[1]</sup> The NCI has used the Breast Cancer

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<sup>[1]</sup> Because the principal investigator on this award, Christopher Amos, changed institutions in 2017, the award

Research Stamp funds to partly support the CDMG for breast cancer-related efforts including statistical support and computational analysis of MCL breast cancer site-generated data. Recent developments emerging from the CDMG describe two testing methods (Marcenko-Pastur Distribution and Tracy-Widom Tests) that may support a more accurate prediction of biologically relevant outcomes from observable genomic variables, including breast cancer-associated variables. Furthermore, the NCI has used the Breast Cancer Research Stamp funds to partially fund the CDMG in protocol development for collaborative breast cancer projects aimed at the validation of molecular signatures distinguishing indolent from aggressive, screen-detected and interval/symptom-detected lesions and for the prospective collection of biospecimens by the individual breast cancer MCL sites. CDMG-related efforts led to the recent development of an integrated data sharing platform to facilitate the acquisition, processing and distribution of data sets between MCL breast cancer partner sites and the Early Detection Research Network at large.

The list of grant awards, affiliations, and funding information are in Appendix 5.

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for the CDMG has moved to Baylor College of Medicine from Dartmouth College. The award's history is available at [https://projectreporter.nih.gov/project\\_info\\_history.cfm?aid=9334552&icde=0](https://projectreporter.nih.gov/project_info_history.cfm?aid=9334552&icde=0).

## **New Programs funded in Fiscal Years 2017-2018**

### ***Breast cancer Weight Loss (BWEL)***

A randomized trial evaluating the impact of a supervised weight loss intervention plus health education materials versus health education materials alone upon invasive disease-free survival in overweight and obese women with stage II-III breast cancer. BWEL is a rigorously designed trial conducted by the Alliance National Clinical Trials Network (NCTN) Group. The study will enroll 3,136 women with stage II-III hormone receptor positive or triple negative breast cancer diagnosed within the previous 12 months who have a BMI  $\geq 27$  kg/m<sup>2</sup>. Women will enroll in BWEL after completing surgery, chemotherapy, and radiation (if indicated) and be randomized to either a 2-year intervention of a supervised weight loss program + health education materials or health education materials alone. The primary endpoint is disease-free survival with secondary endpoints that include the impact of the weight loss intervention on overall survival, development of other medical problems, quality of life, and correlative science objectives that evaluate specific translational mechanisms linking obesity with breast cancer. The NCI has used the Breast Cancer Research Stamp funds to provide partial support for this study.

In the past year, BWEL has met its target enrollment goals. Some of the earliest patients recruited into the study have successfully completed the two year intervention. A formal Correlative Science Committee was established and work has begun to develop planned correlative work with biospecimens (blood, tumor tissue and benign tissue) collected from BWEL study participants.

BWEL recruitment has enrolled 1770 patients and are on track to complete enrollment in the summer of 2020. BWEL was able to stand up the Spanish language version of the intervention this year; and have initiated the enrollment of Spanish speaking patients this year and continues work to build the Latina cohort.

The list of grant awards, affiliations, and funding information are in Appendix 6.

### ***Tomosynthesis Mammographic Imaging Screening Trial (TMIST)-- Processing and Storage of Biospecimens***

During fiscal year 2017, NCI began supporting the Tomosynthesis Mammographic Imaging Screening Trial (TMIST); a large nationwide randomized trial of the two most commonly used mammography screening technologies: Tomosynthesis (TM) and Digital Mammography (DM). The purpose of the trial is to evaluate whether the newer technology (TM) produces a stage shift through earlier detection of the most aggressive tumors or merely detection of additional cancers that may not be dangerous to the woman. Through long-term follow-up, this study should also provide information on the relative impact of the new technology on breast cancer mortality. TMIST will also provide measurements of the diagnostic accuracy of the currently available technologies in women undergoing current state-of-the-art treatments.

In addition, through the analysis and correlation of the genetic features of all breast lesions



undergoing biopsy in the TMIST participants during the trial, this study should substantially increase the understanding of the biology of breast cancers detected through screening and how those factors vary by method of detection. These specimens will provide a rich biorepository for future hypothesis generation and testing in this domain. The NCI will use the Breast Cancer Research Stamp funds to support the repository of these specimens that are stored at the Eastern Cooperative Oncology Group (ECOG)- American College of Radiology Imaging Network (ACRIN) Central Biorepository and Pathology Facility, MD Anderson Cancer Center.

Currently, 8,310 new and 3,078 Canadian roll-in participants are enrolled to TMIST. New participants represent 68 sites, with 38 percent of accrual from NCI Community Oncology Research Programs (NCORP) sites, 51 percent from non-NCORP sites, and 11 percent from Canada. To date, 1,896 buccal samples and 1,787 blood samples have been shipped to the MD Anderson ECOG-ACRIN biorepository. Efforts for recruiting new sites, completing credentialing, and recruiting new participants are ongoing.

The list of grant awards, affiliations, and funding information are in Appendix 7.

### **Conclusion**

Breast cancer research has benefited from the innovative funding source that Congress established in the Stamp Out Breast Cancer Act. The additional funding has allowed cancer researchers to enhance their knowledge of genetics and molecular biology in ways that may support the development of more effective and less toxic treatments for breast cancer. Moreover, through the Molecular and Cellular Characterization of Screen-Detected Lesions Consortium funded by Stamp Act proceeds, NCI supports investigations to distinguish screen-detected lesions that are life threatening from those that are indolent. These investigations and others funded with Stamp Act proceeds have the potential to contribute to the prevention, detection, and treatment of breast cancer malignancies, while also appropriately protecting women from unnecessary aggressive treatments. The continued funding of studies – evaluating screening techniques, before symptoms appear, and preventing the risk of recurrence of breast cancer in women who are overweight – will provide important insights into potential strategies to reduce cancer incidence. The Stamp Act proceeds affords NCI the ability to support the most innovative laboratory research and clinical trials to transform today’s data into tomorrow’s most groundbreaking clinical discoveries.

The summary below lists all the programs that NCI has supported or currently supports with Breast Cancer Research Stamp collections:

<b>Fiscal Year(s) Funded</b>	<b>NCI Program Title</b>	<b>Obligated</b>	<b>Projected Funding for Future Years</b>	<b>Stamp Funds Balance</b>
2000-2002	Insight Awards	\$9,487,803		
2003-2008	Exceptional Opportunities in Breast Cancer Research	\$12,506,659		
2006	TAILORx Trial	\$4,501,604		
2006-2014	Breast Pre-Malignancy Program funding both intramural and extramural research projects	\$14,092,240		
2015-2019	Molecular and Cellular Characterization of Screen-Detected Lesions	\$6,567,984	\$1,639,548	
2018-2024	Tomosynthesis Mammographic Imaging Screening Trial (TMIST)- Processing and Storage of Biospecimens	\$2,709,686	\$4,702,000	
2018-2021	Breast cancer Weight Loss (BWEL)	\$1,000,000	\$3,000,000	
<b>Total</b>		<b>\$50,865,966.19</b>	<b>\$9,341,548</b>	<b>\$508,369</b>

Note: Some amounts displayed in this table may be different than amounts displayed in reports from prior years. The primary reason for such differences relates to funding balances that were not fully expended on project activities and were reclaimed through the grant accounting process.

\*Planned Future Projects: Future projects are pending anticipated collections.

## **Appendix 1. Summaries for Completed Programs Funded with Proceeds from the Breast Cancer Research Stamp**

### ***Insight Awards to Stamp Out Breast Cancer (2000-2002)***

The Insight Awards to Stamp Out Breast Cancer program was designed to support research grants considered high risk, with the potential for high reward. One of the central aims of this initiative was to challenge existing paradigms and to develop new methodologies and technologies in breast cancer research. Using funds from the proceeds made available via Breast Cancer Research Stamp Act, NCI awarded 87 Insight Awards totaling nearly \$9.5 million to extramural research investigators located at universities and medical schools across the country.

The list of grant awards, affiliations, and funding information are in Appendix 2.

### ***Exceptional Opportunities in Breast Cancer Research (2003-2008)***

Under the Exceptional Opportunities in Breast Cancer Research program, NCI used the Breast Cancer Research Stamp proceeds to support additional high-quality and peer-reviewed breast cancer grant applications in that fiscal year. Through this initiative, NCI provided grant support for a maximum of four years to 35 Exceptional Opportunities Awards, totaling \$12.5 million. Breast cancer research benefited from the Institute's ability to expand its research portfolio and focus on the many critical areas of breast cancer by supporting these additional grants.

### ***Trial Assigning Individualized Options for Treatment (TAILORx) (2006)***

In 2006, NCI used Breast Cancer Research Stamp proceeds to support the Trial Assigning Individualized Options for Treatment (TAILORx). The goal of TAILORx is examining whether genes that are frequently associated with risk of recurrence for women with early-stage breast cancer can be used to assign patients to the most appropriate and effective treatment. The trial completed accrual in October 2010 and is ongoing. In June 2018, results were reported from an analysis of women in the intermediate risk-group. Findings showed that adjuvant hormone therapy alone worked as well as hormone therapy and chemotherapy together. After 9 years of follow-up, the rates of invasive disease-free survival were 83.3% for hormone therapy alone and 84.3% for hormone therapy and chemotherapy, and for overall survival, the rates were 93.9% and 93.8%, respectively. Additionally, in September 2015, results were reported from an analysis of the women in the lowest- risk group. The findings showed that at 5 years, rates of distant relapse-free survival were 99.3 percent, of invasive disease-free survival were 93.8 percent, and of overall survival were 98.0 percent. These results provide prospective evidence that the gene expression test identifies women with a low risk of recurrence who can be spared chemotherapy. More information can be found at: <http://www.cancer.gov/types/breast/research/tailorx>.

The list of awards, affiliations, and funding information are in Appendix 3.

### ***Breast Pre-Malignancy Program (2006-2014)***

The Trans-NCI Breast Pre-Malignancy Program represented a comprehensive program in breast cancer pre-malignancy research that includes the areas of prevention, etiology, biology, diagnosis, and molecular epidemiology. The program consisted of both NCI researchers located on the NIH campus in Bethesda and Frederick, Maryland, and extramural research programs, which support research underway in universities, medical schools, hospitals, and research institutions across the country. This provided an opportunity to create a collaborative and integrated scientific program across NCI divisions and centers, and to synergistically reach new discoveries and interventions. The Trans-NCI Breast Pre-Malignancy Program consists of six research components supporting research on pre-malignant lesions, cancer prevention techniques, and methods for detecting breast cancer or pre-cancers earlier. The program involved work on characterization and imaging of breast cancer stem cells, the biology of breast pre-malignancy, molecular epidemiology of mammographic density, strategies to improve accuracy of mammography interpretation, the evaluation of decision-making approaches used by women recruited for chemoprevention trials, molecular target identification (biomarkers), imaging, and translational research.

#### Previously Funded Intramural Research:

- *Development and Characterization of Affibody®-Based Biconjugates for Molecular Imaging and Targeted Therapy of HER2-Positive Breast Cancers*
- *Isolation, Propagation, Characterization, and Imaging of Breast Cancer Stem Cells to Improve Early Diagnosis and Therapy in Breast Cancer*
- *Image Guided Therapy with Targeted SPIO Carbon-Nanostructure*
- *Preclinical Consortium for Brain Metastases of Breast Cancer*
- *Personalized Medicine Approach to Triple-Negative Breast Cancers*
- *Analysis of Gene Expression Patterns Downstream of Multiple Metastasis Suppressor Genes Identifies New Potential Therapeutic Targets for Breast Cancer*
- *Maternal Pregnancy Factors and Breast Cancer Risk*

#### Previously Funded Extramural Research:

- *Multi-parameter Monitoring of Breast Cancer Progression and Therapeutic Response (CA135650)*
- *Characterizing the Evolution of Pre-malignant Tissues at High Risk for Malignancy (CA135626)*
- *A Study to Evaluate Different Decision-Making Approaches Used by Women Known to be at High Risk for Breast Cancer (Grant Supplement) (CA37377)*
- *PARP Inhibition in BRCA Mutation Carriers – A Pilot Study (CA037403)*
- *Assessing and Improving Mammography (AIM) Study*

### ***Breast Radiology Evaluation and Study of Tissues (BREAST) Stamp Project (Intramural) (2010-2014)***

The NCI Breast Radiology Evaluation and Study of Tissues (BREAST) Stamp Project is a molecular epidemiologic study of mammographic density (MD), one of the strongest breast cancer risk factors, undertaken by NCI researchers in partnership with the University of Vermont (UVM), an NCI Breast Cancer Surveillance Consortium (BCSC) site. Funded by NCI through Breast Cancer Research Stamp funds between 2006 and 2009 along with

intramural funding, 465 women who were referred for diagnostic image-guided breast biopsy were enrolled from 2007 to 2010. Participants consented to 10 years of passive follow-up, and analyses are ongoing. Participants provided risk factor data and donated blood, oral rinses and breast tissues. As the data from this study have become available, researchers continue to conduct analyses for an increasing number of projects utilizing this rich resource.

A novel component of the BREAST Stamp Project has been the incorporation of cutting-edge methods to measure MD as a volume, in addition to its traditional measure as a two-dimensional area. Researchers found that area and volumetric MD measures exhibit some overlap in risk factor associations, but divergence as well, particularly for body mass index, suggesting that breast cancer risk assessments may vary depending on the MD measurement technique used (Cancer Epidemiol Biomarkers Prev. 2014;23:2338-48). Circulating markers that influence or reflect increased cellular proliferation may also relate to elevated MD and breast cancer risk. Researchers observed that women with diagnoses of cellular proliferation had longer leukocyte telomeres (protective ends of chromosomes). If replicated, this finding may suggest that leukocyte telomere length is a marker of risk for proliferative breast disease among women referred for biopsy based on breast imaging (BMC Cancer. 2015;15:823). Investigators also utilized a highly reproducible assay to measure serum estrogens and estrogen metabolites and evaluate their relationship with MD. Their findings suggest that elevated serum estrogen profiles are associated with higher MD (Horm Cancer. 2015;6:107-19). The biopsy tissues collected from study participants have also offered remarkable opportunities to better understand the determinants of elevated MD at the tissue level. Their findings suggest that associations of MD with breast cancer may partly reflect amounts of at-risk epithelium (Cancer Prev Res [Phila]. 2016;9:149-58 and Breast Cancer Res. 2016;18:24).

The list of grant awards, affiliations, and funding information are in Appendix 4.

#### ***The Breast Cancer Metabolomics Project (Intramural) (2010-2014)***

The primary aim of NCI's Breast Cancer Metabolomics Project, which NCI supported with Breast Cancer Research Stamp funding between 2010 and 2014, was to identify metabolic profiles that precede the development of breast cancer. The research team used the most advanced metabolic profiling technology to simultaneously characterize levels of more than 500 circulating metabolites, including lipids, proteins, and sex hormones in prediagnostic blood samples through two different studies. The first study included 360 breast cancer cases and 360 women without breast cancer from a large, well-characterized cohort of women residing in Shanghai, China. The second study included 500 breast cancer cases and 500 women without breast cancer from a large, well-characterized cohort of women residing in the United States.

The project was designed to proceed in three stages. In 2010-2011, the research team completed the first stage, which involved evaluating four leading metabolic profiling labs using six different metabolic profiling technologies, and selecting a lab to perform the work for future stages. In 2011-2012, the team completed the second stage of the study, which entailed identifying metabolic profiles for two breast cancer-related exposures, excess body weight and physical activity. By analyzing samples from nearly 1,000 study participants

from the U.S. and Shanghai, the research team identified 40 body weight-related metabolites, many with no previously known link to body weight. They also identified three novel metabolites correlated with physical activity levels, as measured by wearable physical activity monitors. Two manuscripts have been published describing results from this second stage. The third stage of the study – metabolomics analysis of the breast cancer cases and controls – was initiated in August 2012 and completed in 2014.

The preliminary data from this project has been highly informative and formed the basis for two recent successful grant applications by the research team to expand their analyses into a breast cancer replication study and a pancreatic cancer study. The research team published papers supported by this grant on metabolomics and epidemiology (*Cancer Epidemiol Biomarkers Prev* April 2013 22; 6312013), on metabolic correlates of body mass index (*Metabolomics* [2014] 10:259–269), and on plasma metabolic profiles of type 2 diabetes risk (*Metabolomics* [2016] 12:3).

***Maternal Pregnancy Factors and Breast Cancer Risk Study (Intramural) (2010-2014)***

The goal of this study, which NCI used Breast Cancer Research Stamp funds to support from 2010 to 2014, was to identify possible links between pregnancy factors and breast cancer risk. Investigators at NCI, in collaboration with researchers at the Fred Hutchinson Cancer Research Center in Seattle, Washington, compared pregnancy-related information from women who delivered babies prior to a breast cancer diagnosis to the information from women without breast cancer who had deliveries during the same period. The study results suggest that delivery of a large (4,000 grams or more) infant and bleeding in the first trimester and later in the pregnancy may be associated with an increased risk of breast cancer. In addition, having a pregnancy complicated by preeclampsia or carrying a twin or multiple gestation may be associated with a decreased risk of breast cancer. These results were published in *Cancer Epidemiology, Biomarkers and Prevention* (2013;22:835-47).

Using data from the study, researchers are conducting a second record linkage to the participant's offspring birth records to improve their ability to examine associations for factors related to a participant's own pregnancy. Moreover, including information from all case/control offspring birth and fetal death records allows researchers to consider not only factors associated with a woman's most recent pregnancy, but also to evaluate summary factors across all pregnancies (for example, the number of pregnancies affected by preeclampsia or other conditions) using data collected at the time of the pregnancy compared to information based on what a subject may recall. Researchers are currently developing this data set for analysis. NCI researchers have also conducted a population-based nested case control study of breast cancer among female members of Washington State birth cohorts and are drafting a paper on how in utero and early life exposures may impact subsequent cancer risk of offspring.

***The Biology of Estrogen Receptor-Negative Breast Cancer in Various Racial and Ethnic Groups (2010-2014)***

The objectives and goals of this component of a trans-NCI program were to identify the differences between estrogen receptor positive (ER +) and estrogen receptor negative (ER -)

human breast cancers; identify the subtypes or heterogeneity within ER - breast cancers using human samples (normal and malignant); and determine possible differences in the biology of ER - breast cancers among various racial and ethnic groups. Through this Request for Applications (RFA), NCI awarded three grants in September 2010, each for five years. The NCI used Breast Cancer Research Stamp funding to support these grants until fiscal year 2014.

***Stanford University (CA154209):*** The team analyzed the genome of individual cancer cells to resolve seemingly contradictory findings regarding normal stem cells in the mammary glands. One research group has identified normal human mammary stem cells as being negative or low in key markers known as CD49f and EPCAM, while another claimed that these cells positively express both markers. The results from this work have demonstrated that mouse repopulating units (MRU) with the same phenotypes have similar mammary gland regeneration capacity. Since each population can give rise to the other, their data shows these are likely two different physiological stem cell states.

***Ohio State University (CA154200):*** A cell receptor known as androgen receptor has been associated with the development of triple negative breast cancer, but its role in the different subtypes has not been clearly defined. The investigators studied the expression of androgen receptors in 678 breast cancers, including 396 triple negative cancers (TNBC). They found that androgen receptor expression was associated with a better prognosis in a subtype of TNBC known as non-basal TNBC. These findings confirm the use of androgen receptor expression as an important prognostic tool in non-basal triple negative breast cancers, and also suggest targeting of new androgen receptor-related molecular pathways in patients with these cancers.

***University of Michigan (CA154224):*** The investigators have focused on understanding the molecular factors in the development of the highly aggressive triple negative breast cancer (TNBC) and identifying clinically useful markers of this disease. They have identified a protein known as EZH2 as a novel regulator of stem cells in breast tissue. In TNBC, high EZH2 results in increasing the breast cancer stem cell population, which is associated with more aggressive disease. The investigators developed a large database of breast cancer samples obtained from Ghanaian patients and are examining the biological significance of high EZH2 levels in Caucasian, African American and Ghanaian women with TNBC.

The list of grant awards, affiliations, and funding information are in Appendix 4.

**Appendix 2. Insight Awards to Stamp Out Breast Cancer Funded with Proceeds from the Breast Cancer Research Stamp**

<b>Fiscal Year</b>	<b>Institution</b>	<b>Principal Investigator</b>	<b>Total</b>
2000	ALBANY MEDICAL COLLEGE OF UNION UNIVERSITY	BENNETT, JAMES A	\$116,250
2000	BAYLOR COLLEGE OF MEDICINE	ROSEN, JEFFREY	\$78,488
2000	BETH ISRAEL DEACONESS MEDICAL CENTER	JUNGHANS, RICHARD P	\$130,500
2000	CALIFORNIA UNIVERSITY, IRVINE	BLUMBERG, BRUCE	\$105,946
2000	CALIFORNIA UNIVERSITY, SAN FRANCISCO	COLLINS, COLIN C	\$110,625
2000	CENTER FOR MOLECULAR MEDICINE AND IMMUNOLOGY/GARDEN STATE CANCER CENTER	BLUMENTHA, ROSALYN D	\$142,500
2000	CLEMSON UNIVERSITY	CHEN, WEN Y	\$105,000
2000	COLUMBIA UNIVERSITY HEALTH SCIENCES	SWERGOLD, GARY D	\$127,875
2000	DANA-FARBER CANCER INSTITUTE	KUFE, DONALD W.	\$126,138
2000	FOX CHASE CANCER CENTER	RUSSO, JOSE	\$126,866
2000	GEORGETOWN UNIVERSITY	WONG, LEE-JUN C	\$116,950
2000	HADASSAH UNIVERSITY HOSPITAL	VLODAVSKY, ISRAEL	\$61,000
2000	HAWAII UNIVERSITY	GOTAY, CAROLYN C	\$99,411
2000	ILLINOIS UNIVERSITY	WESTBROOK, CAROL A	\$115,959
2000	INSTITUTE FOR CANCER RESEARCH	YEUNG, ANTHONY T	\$126,866
2000	HENRY M. JACKSON FOUNDATION	LECHLEIDER, ROBERT J	\$74,000
2000	JEFFERSON THOMAS UNIVERSITY	SAUTER, EDWARD R	\$117,851
2000	LONG ISLAND JEWISH MEDICAL CENTER	SHI, Y ERIC	\$116,616
2000	VIRGINIA MASON RESEARCH CENTER	NELSON, BRAD H	\$47,250
2000	MASSACHUSETTS GENERAL HOSPITAL	HABER, DANIEL A.	\$129,500
2000	MASSACHUSETTS UNIVERSITY, AMHERST	JERRY, D JOSEPH	\$115,125
2000	MELBOURNE UNIVERSITY	THOMPSON, ERIK W	\$75,000
2000	MOUNT SINAI SCHOOL OF MEDICINE	KRETZSCHMAR, MARCUS D	\$125,387
2000	NEW YORK STATE UNIVERSITY	MUTI, PAOLA C	\$68,950



2000	PENNSYLVANIA UNIVERSITY	LEMMON, MARK A.	\$118,875
2000	PENNSYLVANIA UNIVERSITY	RADICE, GLENN L	\$118,875
2000	PITTSBURGH UNIVERSITY	NICHOLS, MARK D	\$112,500
2000	SCHEPENS EYE RESEARCH INSTITUTE	D'AMORE, PATRICIA A	\$121,500
2000	UTAH UNIVERSITY	GRISSOM, CHARLES B	\$112,125
2000	VERMONT UNIVERSITY	KRAG, DAVID N	\$113,250
2000	WAKE FOREST UNIVERSITY	SHELNESS, GREGORY S	\$108,750
2000	YALE UNIVERSITY	ZHANG, HUI	\$122,625
2001	ALBANY MEDICAL COLLEGE OF UNION UNIVERSITY	BENNETT, JAMES A	\$116,250
2001	BAYLOR COLLEGE OF MEDICINE	ROSEN, JEFFREY	\$109,322
2001	BETH ISRAEL DEACONESS MEDICAL CENTER	JUNGHANS, RICHARD P	\$128,509
2001	CALIFORNIA UNIVERSITY, IRVINE	BLUMBERG, BRUCE	\$112,800
2001	CALIFORNIA UNIVERSITY, SAN FRANCISCO	COLLINS, COLIN C	\$110,625
2001	CALIFORNIA UNIVERSITY, IRVINE	RADANY, ERIC H	\$112,800
2001	GARDEN STATE CANCER CENTER	BLUMENTHAL, ROSALYN D	\$142,500
2001	CLEMSON UNIVERSITY	CHEN, WEN Y	\$105,000
2001	COLUMBIA UNIVERSITY HEALTH SCIENCES	FISHER, PAUL B	\$127,875
2001	COLUMBIA UNIVERSITY HEALTH SCIENCES	SWERGOLD, GARY D	\$127,875
2001	DANA-FARBER CANCER INSTITUTE	GARBER, JUDY E	\$128,750
2001	DANA-FARBER CANCER INSTITUTE	KUFE, DONALD W.	\$125,862
2001	FOX CHASE CANCER CENTER	RUSSO, JOSE	\$126,133
2001	GEORGETOWN UNIVERSITY	BYERS, STEPHEN W	\$116,550
2001	GEORGETOWN UNIVERSITY	DICKSON, ROBERT B.	\$116,600
2001	GEORGETOWN UNIVERSITY	WONG, LEE-JUN C	\$116,400
2001	HADASSAH UNIVERSITY HOSPITAL	VLODAVSKY, ISRAEL	\$61,000
2001	HAWAII UNIVERSITY, MANOA	GOTAY, CAROLYN C	\$101,000
2001	JOHNS HOPKINS UNIVERSITY	FEDARKO, NEAL S	\$122,750
2001	ILLINOIS UNIVERSITY	WESTBROOK, CAROL A	\$116,475

2001	INSTITUTE FOR CANCER RESEARCH	YEUNG, ANTHONY T	\$126,133
2001	HENRY M. JACKSON FOUNDATION FOR THE ADVANCEMENT OF MILITARY MEDICINE	LECHLEIDER, ROBERT J	\$74,000
2001	JEFFERSON THOMAS UNIVERSITY	SAUTER, EDWARD R	\$82,386
2001	LONG ISLAND JEWISH MEDICAL CENTER	SHI, Y ERIC	\$103,844
2001	VIRGINIA MASON RESEARCH CENTER	NELSON, BRAD H	\$47,250
2001	MASSACHUSETTS GENERAL HOSPITAL	HABER, DANIEL A.	\$127,500
2001	MASSACHUSETTS UNIVERSITY, AMHERST	JERRY, D JOSEPH	\$112,323
2001	MEDICAL DIAGNOSTIC RESEARCH FOUNDATION	CHANCE, BRITTON	\$92,500
2001	MELBOURNE UNIVERSITY	THOMPSON, ERIK W	\$75,000
2001	MINNESOTA UNIVERSITY, TWIN CITIES	SHEAFF, ROBERT J	\$111,375
2001	MOUNT SINAI SCHOOL OF MEDICINE OF NEW YORK UNIVERSITY	KRETZSCHMAR , MARCUS D	\$127,125
2001	NORTHWESTERN UNIVERSITY	JORDAN, VIRGIL C	\$110,250
2001	PENNSYLVANIA UNIVERSITY	LEMMON, MARK A.	\$118,875
2001	PENNSYLVANIA UNIVERSITY	RADICE, GLENN L	\$118,875
2001	PITTSBURGH UNIVERSITY	NICHOLS, MARK D	\$112,500
2001	SCHEPENS EYE RESEARCH INSTITUTE	D'AMORE, PATRICIA A	\$121,500
2001	STANFORD UNIVERSITY	CONTAG, CHRISTOPHER H	\$119,597
2001	UTAH UNIVERSITY	GRISSOM, CHARLES B	\$112,500
2001	UNIVERSITY OF VERMONT AND STATE AGRICLTURAL COLLEGE	KRAG, DAVID N	\$112,302
2001	WAKE FOREST UNIVERSITY	SHELNESS, GREGORY S	\$108,375
2001	WAYNE STATE UNIVERSITY	FERNANDEZ-MADRID, FELIX R	\$111,750
2001	WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH	WEINBERG, ROBERT A	\$116,250
2001	YALE UNIVERSITY	ZHANG, HUI	\$122,625
2002	CALIFORNIA UNIVERSITY, IRVINE	RADANY, ERIC H	\$112,800
2002	COLUMBIA UNIVERSITY HEALTH SCIENCES	FISHER, PAUL B	\$127,875
2002	DANA-FARBER CANCER INSTITUTE	GARBER, JUDY E	\$101,810

2002	FOX CHASE CANCER CENTER	RUSSO, JOSE	\$4,300
2002	GEORGETOWN UNIVERSITY	BYERS, STEPHEN W	\$116,400
2002	GEORGETOWN UNIVERSITY	DICKSON, ROBERT B.	\$116,400
2002	JOHNS HOPKINS UNIVERSITY	FEDARKO, NEAL S	\$122,625
2002	MEDICAL DIAGNOSTIC RESEARCH FOUNDATION	CHANCE, BRITTON	\$103,350
2002	MINNESOTA UNIVERSITY, TWIN CITIES	SHEAFF, ROBERT J	\$111,375
2002	WAYNE STATE UNIVERSITY	FERNANDEZ-MADRID, FELIX R	\$111,750
2002	WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH	WEINBERG, ROBERT A	\$116,238
<b>Total</b>	<b>Insight Awards to Stamp-Out Breast Cancer</b>		<b>\$9,487,803</b>

\*Some amounts displayed in this table may be different than amounts displayed in reports from prior years. The primary reason for such differences relates to funding balances that were not fully expended on project activities and were reclaimed through the grant accounting process.

### Appendix 3. Exceptional Opportunities in Breast Cancer Research Funded with Proceeds from the Breast Cancer Research Stamp

<b>Fiscal Year</b>	<b>Institution</b>	<b>Principal Investigator</b>	<b>Total</b>
2003	CALIFORNIA UNIVERSITY	NEUHAUSEN, SUSAN L.	\$545,271
2003	COLUMBIA UNIVERSITY	HARLAP, SUSAN	\$616,010
2003	HOPKINS JOHNS UNIVERSITY	OUWERKERK, RONALD	\$154,852
2003	MISSOURI UNIVERSITY	SAUTER, EDWARD R	\$33,055
2003	NORTHWESTERN UNIVERSITY	HUANG, SUI	\$389,482
2003	PENNSYLVANIA UNIVERSITY	LEE, WILLIAM M	\$198,759
2003	PITTSBURGH UNIVERSITY	WIENER, ERIK C	\$405,009
2003	ST VINCENT'S INST	PRICE, JOHN T	\$108,000
2003	TEXAS UNIVERSITY GALVESTO	LU, LEE-JANE W	\$532,409
2003	TORONTO UNIVERSITY	VOGEL, WOLFGANG F	\$81,000
2003	WISCONSIN UNIVERSITY	SCHULER, LINDA A.	\$285,725
2004	CALIFORNIA UNIVERSITY	NEUHAUSEN, SUSAN L.	\$545,576
2004	COLUMBIA UNIVERSITY	HARLAP, SUSAN	\$599,223
2004	HOPKINS JOHNS UNIVERSITY	OUWERKERK, RONALD	\$148,832
2004	NORTHWESTERN UNIVERSITY	HUANG, SUI	\$389,522
2004	PENNSYLVANIA UNIVERSITY	LEE, WILLIAM M	\$198,759
2004	PITTSBURGH UNIVERSITY	WIENER, ERIK C	\$410,511
2004	ST VINCENT'S INST	PRICE, JOHN T	\$108,000
2004	TEXAS UNIVERSITY GALVESTO	LU, LEE-JANE W	\$566,037
2004	TORONTO UNIVERSITY	VOGEL, WOLFGANG F	\$81,000
2004	WISCONSIN UNIVERSITY	SCHULER, LINDA A.	\$237,691
2005	CALIFORNIA UNIVERSITY	NEUHAUSEN, SUSAN L.	\$561,474
2005	COLUMBIA UNIVERSITY	HARLAP, SUSAN	\$600,585
2005	NORTHWESTERN UNIVERSITY	HUANG, SUI	\$400,140
2005	PENNSYLVANIA UNIVERSITY	LEE, WILLIAM M	\$198,759
2005	PITTSBURGH UNIVERSITY	WIENER, ERIK C	\$423,007
2005	TEXAS UNIVERSITY GALVESTO	LU, LEE-JANE W	\$550,147
2005	WISCONSIN UNIVERSITY	SCHULER, LINDA A.	\$254,625
2006	CALIFORNIA UNIVERSITY	NEUHAUSEN, SUSAN L.	\$561,838
2006	PENNSYLVANIA UNIVERSITY	LEE, WILLIAM M	\$194,088
2006	PITTSBURGH UNIVERSITY	WIENER, ERIK C	\$404,520
2006	TEXAS UNIVERSITY GALVESTO	LU, LEE-JANE W	\$24,291
2007	CALIFORNIA UNIVERSITY	NEUHAUSEN, SUSAN L.	\$424,870
2007	TEXAS UNIVERSITY GALVESTON	LU, LEE-JANE W	\$468,507
2007	PENNSYLVANIA UNIVERSITY	LEE, WILLIAM M	\$188,460
2008	MASSACHUSETTS GENERAL HOSPITAL	MOORE, ANNA	\$616,625
<b>Total</b>	<b>Exceptional Opportunities</b>		<b>\$12,506,659</b>

\*Some amounts displayed in this table may be different than amounts displayed in reports from prior years. The primary reason for such differences relates to funding balances that were not fully expended on project activities and were reclaimed through the grant accounting process.

**Appendix 4. Breast Cancer Pre-Malignancy Program Funded with Proceeds from  
the Breast Cancer Research Stamp**

<b>Fiscal Year</b>	<b>Institution</b>	<b>Principal Investigator</b>	<b>Total</b>
2006	BAYLOR COLLEGE OF MEDICINE	OSBORNE, C KENT	\$249,838
2006	DARTMOUTH COLLEGE	CARNEY, PATRICIA A	\$101,546
2006	GROUP HEALTH COOPERATIVE	BUIST, DIANA SM	\$114,226
2006	GROUP HEALTH COOPERATIVE	MIGLIORETTI, DIANA L	\$217,296
2006	NCI INTRAMURAL PROGRAM	VARIOUS	\$369,794
2006	NORTH CAROLINA UNIVERSITY	YANKASKAS, BONNIE C	\$90,514
2007	UNIVERSITY OF VERMONT	GELLER, BERTA	\$115,047
2007	NCI INTRAMURAL PROGRAM	VARIOUS	\$419,818
2008	UNIVERSITY OF CALIFORNIA SAN FRANCISCO	TLSTY, THEA	\$666,024
2008	NSABP FOUNDATION, INC.	WOLMARK, NORMAN	\$119,226
2008	UNIVERSITY OF VERMONT	GELLER, BERTA	\$230,312
2008	NCI INTRAMURAL PROGRAM	VARIOUS	\$490,754
2009	UNIVERSITY OF CALIFORNIA SAN FRANCISCO	TLSTY, THEA	\$640,750
2009	MASSACHUSETTS GENERAL HOSPITAL	MOORE, ANNE	\$598,918
2009	NSABP FOUNDATION	WOLMARK, NORMAN	\$123,992
2009	NCI INTRAMURAL PROGRAM	VARIOUS	\$508,939
2010	FRONTIER SCI & TECHNOLOGY RSCH FDN, INC	COMIS, ROBERT L	\$200,000
2010	NSABP FOUNDATION, INC.	WOLMARK, NORMAN	\$97,000
2010	UNIVERSITY OF CALIFORNIA SAN FRANCISCO	TLSTY, THEA D	\$634,250
2010	MASSACHUSETTS GENERAL HOSPITAL	MOORE, ANNA	\$94,933
2010	OHIO STATE UNIVERSITY	HUEBNER, KAY	\$548,311
2010	STANFORD UNIVERSITY	CLARKE, MICHAEL	\$553,639
2010	UNIVERSITY OF MICHIGAN AT ANN ARBOR	KLEER, CELINA G	\$353,718
2010	NCI INTRAMURAL PROGRAM	VARIOUS	\$108,313
2011	MASSACHUSETTS GENERAL HOSPITAL	MOORE, ANNA	\$488,276
2011	OHIO STATE UNIVERSITY	HUEBNER, KAY	\$465,130
2011	UNIVERSITY OF MICHIGAN AT ANN ARBOR	KLEER, CELINA G	\$341,695
2011	STANFORD UNIVERSITY	CLARKE, MICHAEL	\$520,754
2011	NCI INTRAMURAL PROGRAM	VARIOUS	\$160,895
2012	OHIO STATE UNIVERSITY	SHAPIRO, CHARLES L	\$443,720
2012	STANFORD UNIVERSITY	CLARKE, MICHAEL	\$505,636
2012	UNIVERSITY OF MICHIGAN AT ANN ARBOR	KLEER, CELINA G	\$340,325
2012	NCI INTRAMURAL PROGRAM	VARIOUS	\$364,718
2013	OHIO STATE UNIVERSITY	SHAPIRO, CHARLES L	\$411,074

2013	STANFORD UNIVERSITY	CLARKE, MICHAEL	\$449,650
2013	UNIVERSITY OF MICHIGAN AT ANN ARBOR	KLEER, CELINA G	\$318,654
2013	NCI INTRAMURAL PROGRAM	VARIOUS	\$157,408
2014	OHIO STATE UNIVERSITY	HUEBNER, KAY	\$394,509
2014	UNIVERSITY OF MICHIGAN AT ANN ARBOR	KLEER, CELINA G	\$327,573
2014	STANFORD UNIVERSITY	CLARKE, MICHAEL	\$455,316
2014	NCI INTRAMURAL PROGRAM	VARIOUS	\$299,749
<b>Total</b>	<b>Breast Pre-Malignancy Awards</b>		<b>\$14,092,240</b>

\*Some amounts displayed in this table may be different than amounts displayed in reports from prior years. The primary reason for such differences relates to funding balances that were not fully expended on project activities and were reclaimed through the grant accounting process.

**Appendix 5. Molecular and Cellular Characterization of Screen-Detected Lesions Consortium Funded with Proceeds from the Breast Cancer Research Stamp**

<b>Fiscal Year</b>	<b>Institution</b>	<b>Principal Investigator</b>	<b>Total</b>
2015	Dartmouth College	Amos, Christopher I.	\$120,910
2015	University of California San Francisco	Esserman, Laura J.	\$796,788
2015	University of Vermont and State Agricultural College	Stein, Janet L.	\$717,240
2016	Dartmouth College	Amos, Christopher I.	\$118,438
2016	University of California San Francisco	Esserman, Laura J.	\$786,457
2016	University of Vermont and State Agricultural College	Stein, Janet L.	\$749,256
2017	Baylor College of Medicine	Amos, Christopher I.	\$99,440
2017	Dartmouth College	Amos, Christopher I.	\$16,345
2017	University of California San Francisco	Esserman, Laura J.	\$782,497
2017	University of Vermont and State Agricultural College	Stein, Janet L.	\$741,335
2018	University of Vermont and State Agricultural College	Stein, Janet L.	\$741,429
2018	Baylor College of Medicine	Amos, Christopher I.	\$113,545
2018	University of California San Francisco	Esserman, Laura J.	\$784,304
<b>Total</b>	<b>Screen-Detected Lesions Awards</b>		<b>\$6,567,984</b>

\*Because the principal investigator on this award, Christopher Amos, changed institutions in 2017, the award for the CDMG has moved to Baylor College of Medicine from Dartmouth College. The award's history is available at [https://projectreporter.nih.gov/project\\_info\\_history.cfm?aid=9334552&icde=0](https://projectreporter.nih.gov/project_info_history.cfm?aid=9334552&icde=0).

**Appendix 6. Breast cancer Weight Loss (BWEL) Trial Funded with Proceeds  
from the Breast Cancer Research Stamp**

<b>Fiscal Year</b>	<b>Institution</b>	<b>Principal Investigator</b>	<b>Total</b>
2018	Brigham and Women's Hospital	Mooney, Margaret M.	\$1,000,000
<b>Total</b>	<b>BWEL Awards</b>		<b>\$1,000,000</b>



**Appendix 7. Tomosynthesis Mammographic Imaging Screening (TMIST) Trial  
Funded with Proceeds from the Breast Cancer Research Stamp**

<b>Fiscal Year</b>	<b>Institution</b>	<b>Principal Investigator</b>	<b>Total</b>
2018	ECOG-ACRIN Cancer Research Group	Lee, Cecilia H.	\$2,709,686
<b>Total</b>	<b>TMIST Awards</b>		<b>\$2,709,686</b>