

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 2020

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## **Introduction**

On December 20, 2019, 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 through 2027. 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 and bronchus cancer, among women. According to the Annual Report to the Nation 2020, it was estimated that there would be approximately 276,480 new cases of breast cancer among women in the United States in 2020, and 42,170 women would die from the disease this year.<sup>1</sup>

Since 1998, increased support for breast cancer research has come from funding through the 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 2019, extending the sales period through December 31, 2027.

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 \$63.2 million – to eligible research. Of this amount, NCI obligated nearly \$56 million by the close of fiscal year 2020 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 the NCI research programs in detail. The studies currently funded include awards supported through the Molecular and Cellular Characterization of Screen-Detected Lesions Consortium and two randomized trial studies that include only female study subjects, the Breast Cancer Weight Loss (BWEL) Study and the Tomosynthesis Mammographic Imaging Screening Trial (TMIST).

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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)

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         |
| 2019                                                | \$1,449,512.98         |
| 2020                                                | \$1,059,632.56         |
| <b>Total</b>                                        | <b>\$63,225,028.38</b> |

## **Projects Currently Funded by Stamp Act Proceeds**

### ***Molecular and Cellular Characterization of Screen-Detected Lesions Consortium***

During fiscal year 2015, NCI began funding meritorious breast cancer applications 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 one project in fiscal year 2020.

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.

***University of California-San Francisco (CA196406)*** – 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 develop evidence to avoid the inadvertent labeling of indolent lesions as cancers. The project intends to develop better biologic discriminators among indolent, ultralow, low, and interval cancers (i.e., cancers missed by screening tests) 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 across the five University of California (UC) Medical Centers and the Sanford Health system in the rural Midwest. 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 specific subtypes of breast cancer, with the ultimate goal of adjusting screening and prevention activities to mitigate overdiagnosis and overtreatment for both in situ (i.e., tumors that have not migrated) and invasive lesions. Further, the project plans to address the specific features of interval cancers that may generate a better approach to screening and prevention than the current imaging-based screening paradigm. The overall approach seeks 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. Thus far, researchers have identified 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. Investigators also validated the 70-gene MammaPrint (MP) signature, showing that an ultra-low MP threshold identifies women with extremely low risk of progression to metastasis after surgery alone.

This grant award, affiliation, and funding information are in Appendix 5.

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

Through this randomized trial, researchers are 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 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 14 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 plus 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 Stamp Fund has been providing partial support for this study.

In April 2021, the BWEL trial successfully accomplished the enrollment of 3181 women and is now closed to accrual. More than 2800 patients have completed all baseline data collection and have been randomized to the weight loss intervention or health education control group, representing approximately 88% of the target enrollment. Participants have been enrolled from 49 states (at 1127 US sites) and 19 Canadian provinces, with approximately 50% of participants enrolling through community-based practice sites. Twenty-seven percent of study participants represent racial and/or ethnic minority groups. The study intervention is offered in both English and Spanish; community-based outreach and additional Spanish recruitment materials were used to increase the enrollment of Hispanic participants. The COVID-19 pandemic caused unanticipated delays in subject recruitment, but adjustments were made to continue recruitment and maintain operations to continue delivery of the BWEL interventions. For example, coaches were able to deliver the interventions remotely through HIPAA compliant systems developed for BWEL, and COVID-specific educational materials were developed for participants as part of the health education program.

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, the 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 (i.e., the identification of cancers at earlier stages) through timelier 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 Stamp Fund, specifically, supports the repository of these specimens that are stored at the ECOG-ACRIN Central Biorepository and Pathology Facility, MD Anderson Cancer Center.

As of January 28, 2020, 22,000 women have been randomized in the trial. There are 92 participating practices that have enrolled women, with an additional 30 practices in the credentialing phase. It is anticipated that 150 sites will participate during the next fiscal year. International sites include practices in Canada and South America, and others are being vetted or awaiting State Department clearance. Consenting and collection of biospecimens (buccal or blood) can be performed at any time during the duration of the screening component of the trial. As of December 2019, 25,969 women have consented to submitting specimens, and 9,675 specimens have been collected. The majority of the sites have opted to collect specimens at time point T1 vs. T0 (baseline), which lessens the burden on the staff during the recruitment entry point. Sites have communication interventions to facilitate collection of specimens at subsequent screening rounds. The study team has partnered with other stakeholders, including the Centers for Disease Control and Komen Foundation to enhance accrual.

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 increase the public's 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. The continued funding of studies – including those that are 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 the impacts of disease in breast cancer patients. These investigations, supported 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 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>Planned Future Projects</b> | <b>Stamp Funds Balance</b> |
|------------------------------|----------------------------------------------------------------------------------------------------|---------------------|--------------------------------|----------------------------|
| 2000-2002                    | Insight Awards                                                                                     | \$9,423,386         |                                |                            |
| 2003-2008                    | Exceptional Opportunities in Breast Cancer Research                                                | \$12,506,657        |                                |                            |
| 2006                         | TAILORx Trial                                                                                      | \$4,501,604         |                                |                            |
| 2006-2014                    | Breast Pre-Malignancy Program funding both intramural and extramural research projects             | \$14,156,657        |                                |                            |
| 2015-2020                    | Molecular and Cellular Characterization of Screen-Detected Lesions                                 | \$8,740,549         |                                |                            |
| 2018-2021                    | Breast cancer Weight Loss (BWEL)                                                                   | \$3,000,000         | \$1,000,000                    |                            |
| 2018-2024                    | Tomosynthesis Mammographic Imaging Screening Trial (TMIST)- Processing and Storage of Biospecimens | \$3,625,438         | \$1,818,000                    |                            |
| <b>Total</b>                 |                                                                                                    | <b>\$55,954,292</b> | <b>\$2,818,000</b>             | <b>\$11,099,649</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: Approved projects with estimated future out-year costs.

\*\* Stamp Funds Balance: NIH conducted an audit of the BCS resources and found approximately \$6.6 million of available resources that were not properly allocated to the BCS program. These additional resources relate to recoveries of previous obligations that occurred in the early 2000s and were returned to NCI.

## **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 86 Insight Awards totaling nearly \$9.4 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 high-quality and peer-reviewed breast cancer grant applications that were outside the funding ability for NCI in that fiscal year. Through this initiative, NCI provided grant support for a maximum of four years to 36 Exceptional Opportunities Awards, totaling \$12.4 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.

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

### ***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; 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>.

### ***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 campuses in Bethesda and Frederick, Maryland, and extramural research programs, which support investigations underway in universities, medical schools, hospitals, and research institutions across the country. 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, an NCI Breast Cancer Surveillance Consortium site. Funded by NCI through Breast Cancer Research Stamp funds and intramural funding between 2006 and 2009, 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 through 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 supported through Breast Cancer Research Stamp funds 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 the 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. 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):*** Androgen receptors, a certain type of cell receptor, have 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.

***Molecular and Cellular Characterization of Screen-Detected Lesions Consortium (2015-2019)***

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 in the extramural community 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. The use of enabling approaches and technologies was encouraged to determine 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 2020, 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 (i.e., tumors missed by annual screening) 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 disease progression. Identifying aggressive and indolent (i.e., slow growing) tumor microenvironment signatures will promote the development of more conservative treatment strategies for the subset of women with favorable prognoses and suggest novel targets for therapeutic intervention in cases with less favorable prognoses. Researchers have constructed large-scale tissue microarrays containing symptom and interval detected tumor/stroma samples and are using advanced imaging and computational methods to characterize distinct stromal cell populations and distinguish invasive tumor and benign stroma. Recently, investigators found that the novel non-coding RNA, Mitotically Associated lncRNA (MANCR), affects genome stability and is upregulated in aggressive breast cancers and associated with poor overall patient survival.

***Baylor College of Medicine (CA196386)*** – This grant supports the Baylor College of Medicine as the Coordinating and Data Management Group (CDMG) for the Molecular Characterization Labs (MCLs). NCI has used the Breast Cancer 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. The CDMG has recently described 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, NCI has used the Breast Cancer Research Stamp funds to partially support 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 consortium at large.

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

**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 | 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                                   | RUSO, 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<br>UNIVERSITY | BENNETT, JAMES A         | \$116,250 |
| 2001 | BAYLOR COLLEGE OF MEDICINE                    | ROSEN, JEFFREY           | \$109,322 |
| 2001 | BETH ISRAEL DEACONESS MEDICAL<br>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<br>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.          | \$119,639 |
| 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<br>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<br>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<br>NEW YORK UNIVERSITY                | KRETZSCHMAR, MARCUS<br>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          | \$121,499 |
| 2001 | STANFORD UNIVERSITY                                                     | CONTAG, CHRISTOPHER H        | \$119,597 |
| 2001 | UTAH UNIVERSITY                                                         | GRISSOM, CHARLES B           | \$112,500 |
| 2001 | UNIVERSITY OF VERMONT AND STATE<br>AGRICLTURAL COLLEGE                  | KRAG, DAVID N                | \$112,302 |
| 2001 | WAKE FOREST UNIVERSITY                                                  | SHELNESS, GREGORY S          | \$108,375 |
| 2001 | WAYNE STATE UNIVERSITY                                                  | FERNANDEZ-MADRID,<br>FELIX R | \$111,750 |
| 2001 | WHITEHEAD INSTITUTE FOR BIOMEDICAL<br>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               | \$108,032 |

|              |                                                  |                              |                    |
|--------------|--------------------------------------------------|------------------------------|--------------------|
| 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<br>FOUNDATION        | CHANCE, BRITTON              | \$103,350          |
| 2002         | MINNESOTA UNIVERSITY, TWIN CITIES                | SHEAFF, ROBERT J             | \$111,375          |
| 2002         | WAYNE STATE UNIVERSITY                           | FERNANDEZ-MADRID,<br>FELIX R | \$111,750          |
| 2002         | WHITEHEAD INSTITUTE FOR BIOMEDICAL<br>RESEARCH   | WEINBERG, ROBERT A           | \$116,238          |
| <b>Total</b> | <b>Insight Awards to Stamp-Out Breast Cancer</b> |                              | <b>\$9,423,386</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 INSTITUTE     | PRICE, JOHN T                 | \$108,000    |
| 2003               | TEXAS UNIVERSITY GALVESTON | 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 INSTITUTE     | PRICE, JOHN T                 | \$108,000    |
| 2004               | TEXAS UNIVERSITY GALVESTON | 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 GALVESTON              | 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 GALVESTON              | 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      | \$188,458           |
| 2008         | MASSACHUSETTS GENERAL HOSPITAL          | MOORE, ANNA         | \$616,625           |
| <b>Total</b> | <b>Exceptional Opportunities Awards</b> |                     | <b>\$12,506,657</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<br/>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                       | \$483,938    |
| 2008                   | UNIVERSITY OF CALIFORNIA SAN<br>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                       | \$491,050    |
| 2009                   | UNIVERSITY OF CALIFORNIA SAN<br>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<br>FDN, INC | COMIS, ROBERT L               | \$200,000    |
| 2010                   | NSABP FOUNDATION, INC.                     | WOLMARK, NORMAN               | \$97,000     |
| 2010                   | UNIVERSITY OF CALIFORNIA SAN<br>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<br>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            | \$160,898           |
| 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    | \$318,655           |
| 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    | \$327,572           |
| 2014         | STANFORD UNIVERSITY                 | CLARKE, MICHAEL    | \$455,316           |
| 2014         | NCI INTRAMURAL PROGRAM              | VARIOUS            | \$299,746           |
| <b>Total</b> | <b>Breast Pre-Malignancy Awards</b> |                    | <b>\$14,156,657</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          |
| 2019               | University of Vermont and State Agricultural College | Stein, Janet L.               | \$705,072          |
| 2019               | Baylor College of Medicine                           | Amos, Christopher I.          | \$111,054          |
| 2019               | University of California San Francisco               | Esserman, Laura J.            | \$701,540          |
| 2020               | University of California San Francisco               | Esserman, Laura J.            | \$654,899          |
| <b>Total</b>       | <b>Screen-Detected Lesions Awards</b>                |                               | <b>\$8,740,549</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<br/>Year</b> | <b>Institution</b>           | <b>Principal Investigator</b> | <b>Total</b>       |
|------------------------|------------------------------|-------------------------------|--------------------|
| 2018                   | Brigham and Women's Hospital | Mooney, Margaret M.           | \$1,000,000        |
| 2019                   | Brigham and Women's Hospital | Mooney, Margaret M.           | \$1,000,000        |
| 2020                   | Brigham and Women's Hospital | Mooney, Margaret M.           | \$1,000,000        |
| <b>Total</b>           | <b>BWEL Awards</b>           |                               | <b>\$3,000,000</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        |
| 2020               | ECOG-ACRIN Cancer Research Group | Lee, Cecilia H.               | \$915,752          |
| <b>Total</b>       | <b>TMIST Awards</b>              |                               | <b>\$3,625,438</b> |