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TITLE: Genetic Factors in Breast Cancer: Center for Interdisciplinary Biobehavioral Research

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14. ABSTRACT
The Behavioral Center has three primary Objectives: 1) To support an integrated, interdisciplinary Program of Research consisting of three synergistic Research Projects each of which addresses an important issue in breast cancer genetic research with African American women that entails critical psychological or behavioral issues. Thus, our first purpose is to do outstanding research, with implications for our understanding of the etiology of breast cancer, as well as for our understanding of behavior per se. 2) To encourage the development of truly interdisciplinary thinking among the faculty involved in the Program of Research that can serve as a model for other institutions. Thus, our second purpose is to show by example, not only the utility of an interdisciplinary approach (synergy with Objective 1), but one approach that may facilitate its achievement - working together on an integrated project that addresses important issues of interest to all members of the research team. We propose to bridge the gap between biobehavioral research and epidemiologic approaches. 3) To facilitate the development of truly interdisciplinary perspectives among new investigators in breast cancer research. Thus, our third purpose is to provide both interdisciplinary training through both didactic and Ahands-on@ (synergy with Objective 1) research, as well as informal seminars (synergy with Objective 2) to outstanding young investigators likely to represent the future of the field.

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REPORT OVERVIEW

Annual Award Number DAMD17-01-1-0334

Center Grant Overall Report

  Project 1 Report
  Project 2 Report
  Project 3 Report
  Core A Report
  Core B Report
  Core C Report
  Code D Report
CENTER GRANT

Genetic Factors in Breast Cancer:
Center for Interdisciplinary Biobehavioral Research
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INTRODUCTION:

The central goal of the Breast Cancer Behavioral Center of Excellence in the Department of Oncological Sciences of the Mount Sinai School of Medicine is to explore the reciprocal interactions between genetic aspects of breast cancer and biopsychosocial factors in African-American women. While African American women are less likely to develop breast cancer than Caucasian women overall, they are more likely to develop early-onset breast cancer. Overall, they are also more likely to die of the disease. The causes of these health disparities are not yet known, but are likely to involve a complex interplay between genetic factors and biopsychosocial factors at cellular, personal and societal levels.

The Behavioral Center has three primary Objectives: 1) To support an integrated, interdisciplinary Program of Research consisting of three synergistic Research Projects each of which addresses an important issue in breast cancer genetic research with African American women that entails critical psychological or behavioral issues. Thus, our first purpose is to do outstanding research, with implications for our understanding of the etiology of breast cancer, as well as for our understanding of behavior per se. 2) To encourage the development of truly interdisciplinary thinking among the faculty involved in the Program of Research that can serve as a model for other institutions. Thus, our second purpose is to show by example, not only the utility of an interdisciplinary approach (synergy with Objective 1), but one approach that may facilitate its achievement - working together on an integrated project that addresses important issues of interest to all members of the research team. We propose to bridge the gap between biobehavioral research and epidemiologic approaches. 3) To facilitate the development of truly interdisciplinary perspectives among new investigators in breast cancer research. Thus, our third purpose is to provide both interdisciplinary training through both didactic and “hands-on” (synergy with Objective 1) research, as well as informal seminars (synergy with Objective 2) to outstanding young investigators likely to represent the future of the field.

The Behavioral Center’s interdisciplinary research efforts to explore this complex topic are grounded in the biobehavioral model of health and disease. According to this theoretical perspective, what people think and feel affects the state of their health in at least two basic ways: 1) by affecting their behavioral choices (e.g., including those for primary prevention (e.g., alcohol consumption), secondary prevention (e.g., following cancer screening guidelines) and tertiary prevention (e.g., following treatment schedules)), and 2) by affecting their biological processes (e.g., increased cortisol levels with stress), each of which is controlled by the central nervous system. A better understanding of the role of biobehavioral factors on the genetic aspects of breast cancer.
in African American women may have profound implications for cancer prevention and control, as it may suggest novel strategies to reduce the threat posed by this disease to this underserved population.

The Program of Research consists of three synergistic Projects (and four supporting Cores), each of which are reported upon separately below.

The three Projects in the MSSM Center apply the biobehavioral perspective to three distinct loci where such factors are likely to impact genetic issues in breast cancer:

- **Project 1**, “Behavior, estrogen metabolism, and breast cancer risk: A molecular epidemiologic study” (Ambrosone, PI)--Psychological and behavioral factors are investigated as potential etiological agents in the development of breast cancer, operating through interactions with underlying genetic factors.

- **Project 2**, “Impact of culturally tailored counseling on psychobehavioral outcomes and BRCA decision making among women with breast cancer” (Valdimarsdottir, PI)--Cultural, psychological and behavioral factors are investigated for their potential impact on patients’ decisions regarding genetic testing for breast cancer susceptibility.

- **Project 3**, “Immune surveillance, stress, and inherited susceptibility to breast cancer: A psychobiological analysis of the healthy daughters of breast cancer patients” (Bovbjerg, PI)--Psychological and behavioral factors are investigated as sources of variability in phenotypic expression of possible biological pathways involved in familial risk of breast cancer, such as immune surveillance mechanisms.

All three Projects are synergistic with one another both theoretically and practically (e.g., Project 1 serves as entry point for participants for Projects 2 & 3) and each Project uses all of the Cores, which are dedicated to:

- Core A, Recruitment, Tracking, and Interviewing;
- Core B, Molecular Diagnostic and Research;
- Core C, Biostatistics and Data Management;
- Core D, Training.

In addition to supporting the three original projects, the Center has also served as a catalyst for the development of several related research studies, now funded by independent DOD Idea awards, that interact both intellectually (shared measures) and practically (shared participants) with the projects in the Center. The Center has also played an instrumental role in the development of another DOD funded Center at Columbia University Medical College, providing intellectual input (Bovbjerg and
Ambroson are co-investigators) and critical practical support. The Behavioral Center will be the primary referral source of recently diagnosed African-American breast cancer patients that are the focus of the new cohort study, and will provide previously collected data (e.g., family history information) for the proposed analyses.

**BODY:**
In April 2004 we received official notification of approval of the HSRRB of the USAMRAA for all of the proposed three Projects. Thus we were able to begin recruiting for all three projects. However, because of the delay in receiving the initial approval, as well as more recent delays in receiving approvals for modifications to the protocol, some of which were designed to enhance recruitment efforts, we remain substantially behind our anticipated timeline for completion of the tasks listed in the Statements of Work for each of the Projects and Cores (as detailed for each Project and Core in separate sections below). In June, 2005, we submitted a Request for Supplemental Funding in order to: 1) bring to fruition the three integrated projects originally supported by the Center; 2) enable the full multiplier effect of the Center on three related, independently funded DOD studies (Idea Awards); and 3) ensure the success of a newly funded DOD Center of Excellence at Columbia University Medical Center examining racial disparities in the initiation and intensity of adjuvant therapy for breast cancer. We were granted a two-year extension (Amendment # P00004).

**KEY RESEARCH ACOMPLISHMENTS:**
At this point in the research, while data collection is ongoing, results are not yet available. See detailed responses for each Project and Core below.

**REPORTABLE OUTCOMES:**

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<th>Project ID</th>
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<th>End Date</th>
<th>Funding</th>
</tr>
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<td>BC009027</td>
<td>03/1/05</td>
<td>02/28/10</td>
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<tr>
<td>DOD (Bovbjerg, Site-PI)</td>
<td>Direct Costs (MSSM): Current Yr: $135,783/ Total: $781,643</td>
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</table>

Project Title: "Causes of Racial Disparities in the Optimal Receipt and Compliance with Adjuvant Systemic Therapy for Breast Cancer"

**CONCLUSIONS:**
The results of this research will provide further understanding of the role of biobehavioral factors on the genetics of breast cancer in African-American women. They may thus have profound implications for cancer prevention and control, as they may suggest novel strategies to reduce the threat posed by this disease to this important underserved population. See detailed responses for each Project and Core below.

**REFERENCES:**
None

**APPENDICES:**
None
PROJECT 1

Behavior, estrogen metabolism, and breast cancer risk:
A molecular epidemiologic study
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**Project 1**

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Project 1:  
Behavior, estrogen metabolism, and breast cancer risk:  
A molecular epidemiologic study

Principal Investigator: Dr. Christine Ambrosone

INTRODUCTION: 
African-American women are more likely to experience menarche at an earlier age and to have higher estrogen levels than Caucasian women. They are also more often diagnosed with breast cancer at an early age and have a more aggressive disease. We hypothesize that earlier, more aggressive breast cancer is related to earlier menarche and to lifetime hormonal exposures. Both breast cancer and early menarche are likely to be related to behavioral and reproductive factors, and to individual differences in hormone production and metabolism.

In a case control study, we plan to identify 800 African-American women with incident breast cancer at hospitals in NYC with the largest referral patterns for African Americans and 800 controls using random digit dialing. In-person interviews will be conducted and a blood specimen drawn. Statistical analyses will be performed to address each of the following research topics. We will explore relationships between risk of breast cancer and a number of risk factors that will affect hormonal levels in women. We will also study how those factors may affect age at menarche. Because there is evidence that stressful events in early childhood result in early menarche, we will also evaluate the impact of childhood events on onset of menses. In addition, we will look at whether earlier menarche and factors related to greater lifetime exposure to estrogens will be associated with earlier age at breast cancer diagnosis and markers of more aggressive disease. Therefore, we will evaluate relationships between breast cancer risk and lifetime physical activity patterns, alcohol consumption, smoking, diet, weight and weight change throughout the life, early life events, and hormonal and reproductive factors, with data collected through an in-person interview. We will also evaluate genetic differences in hormone metabolism. The same factors, childhood body size, physical activity and early stressful events will also be evaluated in relation to age at menarche.

There are few data to explain the earlier incidence of breast cancer and more aggressive disease among African Americans, and results from this study will elucidate the probable link between breast cancer risk, early age at menarche and hormonal milieu, and the factors that predict them. This molecular epidemiologic study will take into account the role of behavioral factors and early childhood lifetime events in breast cancer etiology, which has not been explored to date.

BODY:  
Statement of Work

Task 1. Start-up and organizational tasks:
   a. Develop study protocols for ascertainment of cases at each site
   b. Identify, hire, and train interviewers
c. Pilot test study questionnaire and refine accordingly  
d. Develop other study-related instruments and data collection forms  
e. Design database for subject tracking and data entry of questionnaire and other  
data collection forms, incorporate logic and validity checks

Task 1 has been completed.

Task 2. Identify and recruit study subjects:  
a. Identify ~1,400 incident breast cancer cases at participating hospitals through daily or weekly contact with institutions or private doctor’s offices  
b. Verify case eligibility and obtain physician consent to contact cases  
c. Identify ~1,200 controls through the use of random digit dialing for those 20 to 64 years of age and Health Care Finance Administration roosters for those 65 to 74 years of age  
d. Assign unique identification number to each potential participant to be used on all study materials (to ensure confidentiality, personal identifiers will be kept separate from all other data)  
e. Mail introductory letter  
f. Telephone contact of potential subjects  
   1) Introduce study  
   2) Schedule in-person interview at a time and place that is convenient for participant

Task 3. Conduct in-person interview:  
a. Obtain informed consent and signed medical release form  
b. Interviewer administers:  
   1) Main questionnaire  
   2) Block food frequency questionnaire  
c. Measure height, weight, waist and hip circumference  
d. Collect blood specimens

Since receiving HSRRB approval on April 16th, 2004, we have been working to put the approved protocol through the IRBs of collaborating hospitals. Final HSRRB approval of these documents at many sites is still pending. At approved sites, we continue to recruit patients through physician referrals. These potential participants have been contacted via letter and phone call from the study staff, and interviews have been conducted.

We have initiated identifying potential controls through random digit dialing. Those who agree to be contacted are sent a letter and brochure and a call is made subsequently to provide further information regarding the study and to schedule an appointment. The interview process is conducted in the same manner as that outlined for cases.

In order to explore the mechanisms of black/white differences, we recently sought and obtained funding from the NCI to build upon the infrastructure of this award and to enroll Caucasian women in NYC and New Jersey and additional African-American women, for
a total of 1200 cases and 1200 controls of each race. The protocol and study questionnaire for these awards are the same.

In year 5, we added another site for recruitment, Columbia University Medical Center, with co-investigators Dr. Alfred Neugut and Dr. Dawn Hershman.

Because of the continued work involved in revising the protocols and consents to increase the numbers of African Americans and to include Caucasians, we have not enrolled as many cases and controls as we had anticipated. This year, we have collected data on 239 participants. However, pending approval of the additional hospitals and expansion of our study catchment area, we expect that our numbers will greatly increase.

Task 4. Interviewer quality control:
   a. Review the first batch of interviews (n~10) by each interviewer and provide feedback to each interviewer
   b. Review all interview-related materials for completeness and internal consistency
   c. Provide feedback to interviewers on a regular basis
   d. Call back a ten percent sample of both cases and controls to validate questionnaire administration and key information collected

Task 5. Abstract pathology and breast cancer treatment information:
   a. Abstract tumor specific characteristics such as tumor size, stage, grade, nodal involvement, and hormone receptor from pathology reports
   b. Abstract breast cancer related treatment including surgery and prescribed adjuvant therapies from medical records and physicians' patient files

Task 6. Data entry:
   a. Information obtained throughout the study (participant contact information, main questionnaire, pathology and treatment abstract form, body size measurements) will be entered as collected
   b. All data will be double key entered to ensure accuracy

Task 7. Food frequency questionnaire data processing:
   a. Food frequency questionnaires are sent for scanning and nutrient analysis
   b. Data files containing raw data and nutrient information are returned to Mount Sinai on a disk

We have continued to review questionnaires with interviewers and to abstract medical record information for enrolled patients. Data are entered under the direction of Core C (see separate report, below), after questionnaires are reviewed and coded by two RAs.

Task 8. Perform genotyping (Core B):

Blood samples are being collected and DNA extracted. DNA will be banked until the completion of data collection at which time genotyping will be performed.

Task 9. Data cleaning, statistical analysis, and manuscript preparation:
a. Write logic checks to determine out-of-range variable values and inconsistencies
b. Comprehensive analyses of data
c. Drafts of manuscripts
d. Manuscripts submitted

Data collected are being ‘cleaned’ by investigation of outliers, etc., and programming performed for appropriate transformation of variables from questionnaire data by Core C (see report, below). As yet, we have no results from our study, since data collection is ongoing.

KEY RESEARCH ACCOMPLISHMENTS:
Refined infrastructure for molecular epidemiologic study (questionnaire, protocols and equipment for blood processing and specimen banking, interviewing, hiring, and training interviewers, databases for participant tracking). Identified new sites for recruitment, identify eligible patients and controls; conduct interviews, process and bank specimens; continue DNA extractions; code questionnaires and enter data.

REPORTABLE OUTCOMES:
We have no reportable outcomes at this time.

CONCLUSIONS:
Currently, we are continuing to enroll participants into the study at the approved hospitals and await approval for requested changes from HSRRB to recruit at other additional hospitals. No analyses have been performed. Thus, no findings can be reported at this time.

REFERENCES:
None

APPENDICES:
None
PROJECT 2

Impact of culturally tailored counseling on psychobehavioral outcomes and BRCA decision making among women with breast cancer
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Project 2:
Impact of culturally tailored counseling on psychobehavioral outcomes and BRCA decision making among women with breast cancer

Principal Investigator: Dr. Heiddis Valdimarsdottir

INTRODUCTION:
Between 5-10% of all breast cancer cases are inherited and demonstrate clear patterns of dominant transmission. These syndromes of breast cancer susceptibility have been linked to mutations in at least two genes, BRCA1 and BRCA2. Individuals with mutations in BRCA1/2 have a 40% to 85% cumulative risk of developing breast cancer and a 5% to 60% cumulative risk of developing ovarian cancer. The decision to undergo genetic testing for breast cancer susceptibility is complex, as women have to evaluate the many potential benefits (e.g., increased surveillance if a woman is found to be a mutation carrier) and risks (e.g., increased distress if a woman is found to be a mutation carrier) associated with genetic testing. An important goal of genetic counseling is to improve knowledge and comprehension about these benefits and risks that are involved in genetic testing.

Research in genetic counseling has shown that many counselees have difficulty comprehending probability information, although some studies of genetic counseling have demonstrated gains in knowledge. However, in that research, as many as one-half of the counselees were no better informed after their counseling. Lerman et al. demonstrated increased knowledge of BRCA1/2 testing following genetic counseling; but the average knowledge scores were only 65% at the one-month follow-up assessment, with African-American women having the smallest increases in knowledge. These results may not be surprising as African-American women have been found to have less prior knowledge and information about genetic testing than other women. Lerman et al. reported that education and counseling increased the probability that African-American women banked a blood sample for BRCA testing, but this was not the case for Caucasian women. Our research indicates that although African-American women may be willing to provide blood samples for genetic testing, 20% of them may decline to receive their test results once they are available. This is significantly higher than the 2% refusal rate that we have observed for Caucasian women.

These findings raise the possibility that African-American women may experience decisional conflict with regard to testing even after they have undergone standard genetic counseling. One explanation for these findings may be that standard genetic counseling does not specifically address the unique concerns and attitudes that African-American women have about genetic testing. As reviewed in detail in the body of the grant, there is evidence that culture-specific variables play an important role in BRCA-decision making. For example, Hughes et al. reported that compared to Caucasian women, a greater proportion of African-American women endorsed the following items as risks of BRCA testing: a) death from cancer is inevitable, b) modern medicine is not trustworthy, c) testing would be too difficult to handle emotionally, and d) testing might have a significant effect on family members. Another potential barrier to genetic testing among
African Americans may be mistrust of the medical community, as African-American women have reported that suspicion influences their medical decisions in general. Genetic counseling that addresses these unique concerns may be more effective in reducing distress associated with testing which, in turn, may increase the likelihood that the counseling will be effective in increasing knowledge about genetics. Increasing knowledge about genetics may not only increase the probability that women make an informed decision with regard to testing, but it may also affect their attitudes toward surveillance and preventive options as well as increase the likelihood that they will talk to their family members about their breast cancer risk.

The goal of the proposed research is therefore to develop and evaluate the impact of culturally tailored genetic counseling on patient decision making regarding BRCA testing and subsequent cognitive, emotional, and behavioral outcomes. African-American women whose family histories of cancer are suggestive of a hereditary breast/ovarian cancer syndrome will be randomized to receive either Standard Genetic Counseling (SGC) or Culturally Tailored Genetic Counseling (CT-GC). As the CT-GC addresses culture specific benefits and barriers to breast cancer susceptibility testing, we hypothesize that women in the CT-GC group will: 1) be more likely to elect the option that is most consistent with their personal preference; 2) report greater decisional satisfaction and less decisional conflict; 3) report less distress which, in turn, will enhance retention of knowledge and information provided in the counseling session; 4) report stronger intentions to adhere to screening guidelines and to participate in prevention options; and 5) be more likely to disseminate information provided in the counseling to their first-degree relatives.

BODY:
During the course of the study, it was related to us that some participants were tired and hungry following their genetic counseling sessions. To remedy this situation, we offered water and snacks to all participants.

At this time, we have begun to analyze the data we have collected through baseline interviews. Two abstracts have been accepted for poster presentation and platform presentation at the National Society of Genetic Counseling Annual Education Conference in Nashville, TN in November, 2006. The poster focuses on differences that we have seen between African American women as compared to African Caribbean women seeking genetic counseling. The platform presentation examines differences in levels of distress at baseline in African American women as compared to Caucasian women.

KEY RESEARCH ACCOMPLISHMENTS:
In this past project year, we have collected data on 44 women.

REPORTABLE OUTCOMES:
We have no reportable outcomes at this time.

CONCLUSIONS:
To date, the culturally tailored counseling protocol has been developed and we have data on 44 women in this grant year. A total of 78 women have been enrolled since the study began.

REFERENCES:
None

APPENDIX:
None
PROJECT 3

Immune surveillance, stress and inherited susceptibility to breast cancer: A psychobiological analysis of the healthy daughters of breast cancer patients
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## Project 3

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Project 3:
Immune surveillance, stress, and inherited susceptibility to breast cancer:
A psychobiological analysis of the healthy daughters of breast cancer patients

Principal Investigator: Dr. Dana H. Bovbjerg

INTRODUCTION:
Among first degree relatives of breast cancer patients, mutations in the autosomal dominant breast cancer susceptibility genes (BRCA1/BRCA2), account for less than half the attributable increased risk of breast cancer. This study uses a longitudinal study design comparing the daughters of Cases (N=150) to the daughters of Controls (N=150) in Project 1 to examine the possibility that inherited deficits in immune surveillance mechanisms (e.g., natural killer cell activity, cytokine production) may account for the residual familial risk that cannot be attributed to mutations. The study also explores the contribution of stress-induced immune modulation and inheritance of polymorphisms in the genes coding for two key cytokines, interferon gamma and tumor necrosis factor alpha, to the low surveillance phenotype.

Each participating daughter is assessed (Core A) on two separate occasions approximately 3 months apart at the same time of day. At each assessment standardized self-report measures are completed and, following at least 20 minutes of quiet rest, a blood sample collected. Blood samples are assayed for immune function and cytokine genotypes (Core C). Routine statistical analyses (Core B) will test study hypotheses after anticipated sample sizes are achieved.

The study could have profound implications for the eradication of breast cancer if the results of the proposed research are consistent with the hypothesis that deficits in immune surveillance contribute to familial risk above and beyond effects of stress. Such results would raise the possibility that appropriate interventions to increase the activity of immune surveillance mechanisms in daughters at familial risk, including reduced stress-induced immune suppression, might delay the onset or even prevent the development of breast cancer.

The specific aims for this study are: 1) To examine the possibility that variability in the strength of immune defenses may be associated with familial risk of breast cancer; 2) To determine the immunomodulatory effects of concurrently assessed stress responses and behavioral variables; 3) To investigate the possibility that the reductions in NK cell activity associated with familial risk of breast cancer may reflect a broader pattern of inherited alterations in key cytokine pathways; and 4) To conduct an exploratory analysis of the possibility that Case-daughters’ levels of stress may be affected by their mothers’ participation in genetic counseling.

BODY:
We received approval HSRRB approval from the Department of Defense for this study in November, 2004. We received approval to extend recruitment to include daughters of women who may not have participated in Project 1 ("Behavior, estrogen metabolism and
breast cancer risk: A molecular epidemiologic study"), but who would have been eligible for the study. To reduce the possibility of selection bias in the study sample, we also modified the exclusion criteria. The protocol was amended to exclude the collection of blood pressure and heart rate data; instead, cortisol levels in self collected saliva samples will be used to provide an independent assessment of stress. In addition, saliva/buccal cell collection is offered as a less invasive alternative to participants who are unable to provide a blood specimen. These amendments were made in an effort to reduce participant burden. Anthropometric measures were added to the protocol in the form of body composition analysis using a Tanita scale and waist and hip measurements.

Statement of Work:

Task 1: Successful application for HSRRB approval through the USAMRAA office
Task 2: Setting up of Project 3 procedures
Task 3: Screening and recruitment of study participants
Task 4: Inclusion of study subjects
Task 5: Second assessment of study subjects
Task 6: Data processing
Task 7: Statistical analysis

With HSRRB approval in place, in the past two year we have completed tasks -1 and 2, getting HSRRB approval and setting up study procedures. With the help of Core A, we have begun tasks 3-5, screening, recruiting and interviewing study subjects. In consultation with Core C, we have begun task 6, setting up systems for data entry and cleaning.

KEY RESEARCH ACOMPLISHMENTS:
In this grant year, we have collected data for Project 3 from 27 women.

REPORTABLE OUTCOMES:
We have no reportable outcomes at this time.

CONCLUSIONS:
The study could have profound implications for the eradication of breast cancer, if the results of the proposed research are consistent with the hypothesis that deficits in immune surveillance contribute to familial risk above and beyond effects of stress. Such results would raise the possibility that appropriate interventions to increase the activity of immune surveillance mechanisms in daughters at familial risk, including reductions in stress-induced immune suppression, might delay the onset or even prevent the development of breast cancer. At this point in the research, no results are yet available.

REFERENCES:
None

APPENDICES:
None
CORE A

Recruitment, Tracking and Interviewing Core
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CORE A:
Recruitment, Tracking and Interviewing Core

Principal Investigador: Lina Jandorf, M.A.

INTRODUCTION:
This Core has the responsibility of contacting the identified cases, controls, and healthy adult daughters of the cases and controls, for participation in Projects 2 and 3 during the extension period of the grant. Training for the interviewers includes information on how to conduct each assessment/interview, to collect blood specimens, contact and conduct the telephone assessments for the Cases in Project 2 and the healthy adult daughters of both cases and controls for Project 3 and track their involvement across and within the project. With the additional funding of related Department of Defense projects (‘Increasing Breast Cancer Surveillance Among African American Breast Cancer Survivors’ [DAMD 17-03-1-0454; SIS] and ‘Immune Surveillance, Cytokines, and Breast Cancer Risk: Genetic and Psychological Influences in African American Women’ [DAMD 17-02-1-0501; Cytokine Study]) the staff of the core has assisted in contacting Project 1 cases for SIS and Project 1 controls for the Cytokine Study. They have also been trained to conduct the interviews for the Cytokine Study.

BODY:
Since the completion of the initial funding, all tasks noted in the Statement of Work have been completed.

KEY RESEARCH ACCOMPLISHMENTS:
The following numbers are for this past grant year. For Project 2, data has been collected on 75 women. For Project 3, we have collected data from 27 women. For the SIS study, 55 potential participants have been identified from Project 1 and contacting to schedule interviews. For the Cytokine Study, we have interviewed 50 participants and have 21 in process. On an ongoing basis, we continue to receive referrals from Project 1 and complete Project 2, 3 and cytokine interviews.

REPORTABLE OUTCOMES:
There are no results available at this time.

CONCLUSIONS:
The Core is fully operational. All tools (Interviewer manuals, assessment batteries, tracking database,) are in place and we are actively recruiting and interviewing women.

REFERENCES:
None

APPENDICES:
None
CORE B

Molecular, Diagnostics and Research Core
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Core B:  
Molecular, Diagnostics and Research Core

Principal Investigator: Dr. Margaret McGovern

INTRODUCTION:
The Molecular Diagnostic and Research Core of the Center for Interdisciplinary Biobehavioral Research provides expert molecular studies to identify: 1) molecular changes in two genes associated with breast cancer, BRCA 1 and BRCA2 (Project 2); and 2) molecular differences in DNA that are associated with variability in the level of production of certain proteins that are normally found in the body that also may effect cancer risk (Projects 1 & 3).

The Molecular Diagnostic and Research Core investigators work with the individual project directors to identify relevant genetic risk factors, establish laboratory analyses to detect their presence in study subjects, and carry out all molecular analyses as per the individual study protocols. These analyses allow the investigators of the Center to assess the impact of these genetic factors on cancer risks, and on the psychobiology of the interaction of generic factors with family history, stress and ethnicity. The Core directors are working closely with the center investigators in developing cost efficient protocols for the molecular testing.

BODY:

Statement of Work:

Task 1. To establish the methodology for the determination of the genotype of estrogen receptor genes and polymorphisms.

Allele specific oligonucleotide hybridization technology has been established in the core laboratory for genotyping for polymorphisms. This capability is routinely available and can be scaled up to handle large volumes of samples if required.

Task 2. Sequencing of BRCA 1 and 2 genes using DNA from subjects recruited from Project 2.

The core laboratory has received 44 specimens which have been sequenced through an agreement with Myriad Laboratories.

Task 3. Determination of genotypes for estrogen receptor polymorphisms.

DNA has been isolated and banked from each of the participants included in Project 1. Specimens have not yet been processed for determination of genotypes, as batch processing at the end of the study is more efficient and effective.

Task 4. Determination of the genotype for polymorphisms in TNFa.
DNA has been isolated and banked from each of the participants included in Project 1. Specimens have not yet been processed for determination of genotypes, as batch processing at the end of the study is more efficient and effective.

Task 5. Integration of Core laboratory into activities of training core.

The Core Laboratory professional staff provides educational sessions to trainees and investigators. The Core Laboratory Principal Investigator offered a course each year, open to trainees and investigators. This course, entitled “Molecular for the Clinical Investigator” includes a series of lectures on the application of molecular techniques in clinical investigation.

KEY RESEARCH ACCOMPLISHMENTS:
None.

REPORTABLE OUTCOMES:
The Core Laboratory has established a system for the storage and retrieval of study specimens that will safeguard confidentiality and ensure accurate retrieval. Blood samples have been processed following established procedures for the isolation and storage of DNA from all consenting participants in the Projects. The laboratory has worked with the project PIs in the establishment of a system for the storage of specimens in a liquid nitrogen straw system.

CONCLUSIONS:
At this point in the research, no results are yet available.

REFERENCES:
None

APPENDICES:
None
CORE C

Biostatistics and Data Management Core
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INTRODUCTION:
The objective of the Biostatistics and Data Management Core is to provide databases for entry, storage, and retrieval of data collected in the three projects of this Center. The quality of the data will be monitored at each step in the process. The Core will also provide statistical analyses of the data using appropriate models to address the specific aims/objectives of each project.

The three projects in this Center project each collect multiple sets of interrelated data to address their study hypotheses. It is extremely important that the data that are collected be managed in a careful way and that the analyses that are performed on the data use statistics that lead to valid conclusions.

Without good management of data, cleaning of data to provide a valid dataset, and appropriate statistical analyses of the collected data, the work in three projects would be of little value. The members of this Core will work closely with the investigators of the three projects and members of the other Cores to coordinate the data activities so that this work is done in a timely manner.

BODY/ KEY RESEARCH ACHIEVEMENTS:

During the past year members of the Biostatistics and Data Management Core have worked on creating a database in ACCESS for the questionnaire in Project 2. Work has been completed on the database itself and on the creation of labels and formats for the variables in the database. Work is in progress on bringing these labels and formats into a codebook in SAS.

Data from Project 1 Questionnaires have been double entered for 797 subjects (457 controls and 340 cases). For the women with double-entry, the two versions of entered data have been compared and the resulting discrepancies have been investigated and resolved. Data entry (1st and 2nd entry) is in progress for the questionnaires collected in Project 2. For data that have been entered, the 1st and 2nd entries have been compared, and any discrepancies have been investigated.

SAS datasets have been created by merging data from the Project 1 and Project 2 questionnaires, at the request of the investigators. This merging has been done on two separate times during the past year.

Flowcharts are generated bi-weekly to aid investigators in monitoring the progress of subject recruitment. The flowcharts are for the Center as a whole, as well as for each Project.
SAS programs have been written and data have been analyzed from Project 1. These analyses have been conducted to estimate the odds ratios for established risk factors for breast cancer from this data set.

Members of the Biostatistics Core have set up data-entry, tracking, and batching system databases for Project 3, and have trained research assistants from Project 3 to use the systems. Members have also created a paraffin block and pathology tracking database for personnel in Project 1 to be able to track eligible cases who consent to have paraffin blocks analyzed upon completion of Project 1. In addition, the Biostatistics Core has set up numerous queries in ACCESS for Project 1 personnel to determine eligibility status and current study status for all enrolled cases and controls.

Members of this Core have downloaded Food Frequency Questionnaire (FFQ) reports and data files from Fred Hutchinson Cancer Research Center (FHCRC) and updated the tracking database to account for all FFQ’s from our study that have been scanned at FHCRC. Members also maintain the tracking databases, set up security for new interviewers, and make the necessary changes to registry settings to use WORD 2003 mail merges from ACCESS.

**REPORTABLE OUTCOMES:**
None

**CONCLUSIONS:**
None

**REFERENCES:**
None

**APPENDICES:**
None
CORE D

Training Core
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**Core D**

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**INTRODUCTION:**
Breast cancer continues to be a preeminent cause of morbidity and mortality among American women, despite the recent encouraging news that cancer incidence and mortality rates have inched downward in the past decade. The risk of early mortality is a particularly a concern for African-American women. African-American women are more frequently diagnosed with advanced, aggressive tumors, and those under age 50 have nearly twice the breast cancer risk of white women. The research literature suggests that it is the interaction of behavioral and genetic factors, which may account for clinical findings among African-American women. However, few researchers today are equipped with the skills necessary to investigate the interactions among behavioral factors, genetics, and culture. The goal of the Training Core in Biobehavioral Breast Cancer Research is to foster the development of interdisciplinary researchers focused on epidemiological and biobehavioral aspects of breast cancer that are particularly relevant to African Americans through a broadly based, multidisciplinary postdoctoral training program involving a required curriculum of formal lectures, participation in specialized seminar series, "hands-on" research experience with the guidance of a nationally-recognized research mentor, and formal, as well as hands-on, training in the preparation of research papers and grants. This training will act as a bridge between behavioral and epidemiological approaches to breast cancer research.

**BODY:**
Because of delays waiting for HSRRB approval for Projects 1, 2, and 3, which were intended to provide direct research experience for trainees, we had to modify the timeline in our initial Statement of Work. However with the recent HSRRB approval for the Projects, we have been able to complete Tasks 1 and 2.

Tasks 1(months 1-24) and 3 (months 24-48):
- a) Recruit applications;
- b) Evaluate potential trainees;
- c) Develop and schedule Foundations Curriculum;
- d) Coordinate training with ongoing Cancer Center Training Programs;
- e) Schedule seminar series;
- f) Run Foundations and Seminar Series;
- g) Establish hands-on research experience for each Trainee;
- h) Schedule and run Luncheon Lecture Series;
- i) Guide development of independent research project for each Trainee;
- j) Provide oversight for each Trainee’s independent project;
- k) Conduct formal evaluations of Trainees and Program;
- l) Facilitate preparation of research reports and grant applications;

Tasks 2 and 4: Prepare and submit required reports for BCRP
Because of delays imposed by the HSRRB review process, Task 1, subsections g and i-l were accomplished with related research approved by the Mt Sinai Institutional Review Board for protection of human subjects, and funded by other sources. Task 2 is completed with this report. In this past year of the grant, we have accomplished Task 3, recruiting and evaluating of a second class of postdoctoral trainees. Two new trainees began the program in the fall of 2005 and have undertook the full training program outlined in subsections c-l, with the ability to participate in the Center research projects now approved by HSSRB.

**KEY RESEARCH ACOMPLISHMENTS:**
The following is a sample of the training curriculum provided in the past year:

**Core Courses (subsections c,d,f):**

*Introduction to Cancer Biology*

10/20/2005 Introduction to Cell and Molecular Biology, Dr. James Manfredi, Associate Professor, Oncological Sciences and Molecular, Cell And Developmental Biology

10/27/2005 DNA and RNA, Dr. James Manfredi, Associate Professor, Oncological Sciences and Molecular, Cell and Developmental Biology

11/3/2005 DNA and RNA (Journal Club), Dr. James Manfredi, Associate Professor, Oncological Sciences & Molecular, Cell and Developmental Biology

11/10/2005 Proteins and Enzymes, Dr. Avrom Caplan, Associate Professor, Pharmacology and Biological Chemistry

11/17/2005 Proteins and Enzymes (Journal Club), Dr. James Manfredi, Associate Professor, Oncological Sciences and Molecular, Cell and Developmental Biology

12/1/2005 Metabolism, Dr. Christine Ambrosone, Associate Clinical Professor, Oncological Sciences

12/8 2005 Metabolism (Journal Club), Dr. Lois Resnick-Silverman, Assistant Professor, Oncological Sciences,

12/15/2005 Carcinogenesis, Dr. Edward Johnson, Professor, Oncological Sciences and Professor, Medicine

1/5/2006 Cancer Genetics, Dr. Stuart Aaronson, Professor & Chair, Oncological Sciences and Professor, Medicine

1/12/2006 Cancer Genetics (Journal Club), Dr. Stuart Aaronson, Professor & Chair, Oncological Sciences and Professor, Medicine

1/19/2006 Metastasis, Dr. Liliana Ossowski, Professor, Medicine / Hematology and Medical Oncology, Professor, Center For Anatomy and Functional Morphology, Professor, Oncological Sciences

1/26/2006 Metastasis (Journal Club), Dr. Liliana Ossowski, Professor, Medicine / Hematology and Medical Oncology, Professor, Center For Anatomy and Functional Morphology, Professor, Oncological Sciences

2/2/2006 Tumor Suppressors, Dr. James Manfredi, Associate Professor, Oncological Sciences and Molecular, Cell and Developmental Biology
2/9/2006  Tumor Suppressors (Journal Club), Dr. James Manfredi, Associate Professor, Oncological Sciences & Molecular, Cell and Developmental Biology
2/16/2006  Oncogenes, Dr. Andrew Chan, Associate Professor, Oncological Sciences
2/23/2006  Oncogenes (Journal Club), Dr. Andrew Chan, Associate Professor, Oncological Sciences
3/9/2006  Inherited Predisposition, Dr. Jia Chen, Associate Professor, Community And Preventive Medicine, Associate Professor, Pediatrics, Associate Professor, Oncological Sciences

Behavioral Medicine Course
1/4/2006  Introduction, History & Model, Dr. William Redd, Professor, Oncological Sciences & Dr. Michael Diefenbach, Assistant Professor, Urology, and Assistant Professor, Oncological Sciences
1/11/2006  Social Influences on Health & Behavior, Dr. Christine Rini, Assistant Professor, Oncological Sciences
1/18/2006  Stress, Dr. Heiddis Valdimarsdottir, Assistant Professor, Oncological Sciences
1/25/2006  Behavioral Intervention, Dr. Katherine DuHamel, Assistant Clinical Professor, Oncological Sciences
2/1/2006  Palliative Care, Dr. Son Mun, Assistant Clinical Professor, Geriatrics and Adult Development, Assistant Clinical Professor, Medicine / General Medicine
2/15/2006  Complimentary Medicine, Dr. Guy Montgomery, Associate Professor, Oncological Sciences
2/22/2006  The Biopsychosocial Model & Cancer, Dr. Dana Bovbjerg, Associate Professor, Oncological Sciences
3/1/2006  Obesity, Dr. Maida Galvez, Assistant Professor, Community and Preventive Medicine, Assistant Professor, Pediatrics / General Pediatrics
3/8/2006  Addiction, Dr. Joel Erblich, Assistant Professor, Oncological Sciences
3/15/2006  Race in health care and health outcomes, Dr. Haley Thompson, Assistant Professor

An Introduction to Statistical Analysis of Mediators and Moderators
6/8/2006  Mediator Models in Biobehavioral Research - Background and Current Recommendations, Dr. Gary Winkel, Professor, City University of New York
6/22/2006  Statistical Issues in Mediation Analyses - Examples in Biobehavioral Research, Dr. Gary Winkel, Professor, City University of New York
6/29/2006  Moderator Models in Biobehavioral Research - Background and Statistical Analyses, Dr. Gary Winkel, Professor, City University of New York
7/6/2006  Moderator Models Involving Categorical Variables, Categorical and Continuous Variables, and Continuous Variables. Dr. Gary Winkel, Professor, City University of New York
7/20/2006  An Epidemiological Critique of the Mediation-Moderation Model, Dr. Jim Godbold, Research Professor, Community and Preventative Medicine, MSSM

**Work-in-Progress presentations (subsections i,l):**

10/19/2005  Breast Cancer Surgery and Recovery: Analysis of a Brief Hypnosis Intervention, Dr. Guy Montgomery, Associate Professor, Oncological Sciences

12/14/2005  Patient Navigation for CRC Screening with Low Income Minorities. Dr. William Redd, Professor, Oncological Sciences

12/16/2005  The Functions of Affect in Treatment Decisions of Rising PSA Patients. Dr. Michael Diefenbach, Assistant Professor, Urology, Assistant Professor, Oncological Sciences

1/3/2006  Predictors of Outcomes in Black and White Breast Cancer Cases, Dr. Kandace Amend, Assistant Professor, Oncological Sciences

3/10/2006  Grant proposal review, Dr. Anna Rusiewicz, Postdoctoral Fellow

6/14/2006  An Exploratory Grant for Behavioral Research in Cancer Control, Dr. Christine Rini, Assistant Professor, Oncological Sciences

6/27/06  Training Patients and Partners for HSCT: A Novel Coping Skills Intervention, Dr. Catalina Lawsin, Postdoctoral Fellow

**Seminar/Lecture Series (subsections e,f,h):**

9/16/2005  "Consort: What is it & Does it Help Behavioral Medicine?" Dr. Karina Davidson, Director of Intervention Research, Behavioral Cardiovascular Health & Hypertension Program, Columbia University

9/23/2005  "Psychological and neurobiological mechanisms of placebo analgesia," Dr. Donald D. Price, Professor, Departments of Oral Surgery and Neuroscience University of Florida

10/21/2005  "But I can't find my way home...Perspectives on Cancer-Related Cognitive Difficulties" Dr. Pamela J. Shapiro, Postdoctoral Fellow, Department of Psychiatry, Cancer Control and Outcomes Program, University of Pennsylvania

11/4/2005  “Cognitive Behavioral Interventions – Challenges to Findings,” Dr. Barbara A. Given, Dr. Charles W. Given, University Distinguished Professor: Associate Chair, Research, College of Nursing; Department of Family Practice, Michigan State University

11/4/2005  "Using Computer Kiosks for Breast Cancer Education Among African American Women in Five Community Settings" Dr. Matthew W. Kreuter, Professor and Director, Health Communication Research Laboratory, School of Public Health, Saint Louis University

11/11/2005  "Can a Vegan Diet Help Breast and Prostate Cancer Patients?" Dr. Lilli B. Link, Associate Research Scientist, Mailman School of Public Health, Cancer Epidemiology, Columbia University

11/18/2005  "Yoga for Underserved Breast Cancer Patients: A Randomized-Controlled Trial," Dr. Alyson Moadel, Assistant Professor, Department of Epidemiology & Population Health; Division of Health, Behavior and
Nutrition, Director of Psychosocial Oncology Program, Albert Einstein College of Medicine

12/2/2005  “Psychobiology of Resilience to Stress,” Dr. Dennis Charney, Dean of Research Mount Sinai School Medicine

12/9/2005  "Protein Modulation of Nausea," Dr. Robert Stern, Distinguished Professor of Psychology, Pennsylvania State University

12/12/2005  “Effects of spiritual healing on cancer cells in vitro,” Dr. Bobby Zachariae, Professor, Aarhus University Hospital, Denmark

12/16/2005  "A cognitive-social approach to understanding aspects of breast cancer,” Dr. Kerry Sherman, Professor of Health Psychology and Behavioral Medicine, Department of Psychology, Macquarie University, Australia

1/6/2006  "Determinants of refugee mental health: A global meta-analysis," Dr. Matthew Porter, Psychologist, New York Presbyterian Medical Center

1/27/2006  “Psychosocial functioning and supportive care needs post-radiation treatment for intracranial meningiomas,” Dr. Maria Kangas, Lecturer in Psychology/Clinical and Counseling Psychologist, Macquarie University, Australia

2/3/2006  “Suggestion, attention and conflict reduction in the brain,” Dr. Amir Raz, Assistant Professor of Clinical Neuroscience, Department of PsychiatryColumbia University & New York State Psychiatric Institute

3/10/2006  "NYU Center of Excellence: Response, Resistance and Metastisis of Locally Advanced Breast Cancer in a Multiethnic Cohort," Dr. Silvia Formenti, Professor and Chair, Department of Radiation Oncology, New York University

3/31/2006  "Cancer Targeting in the 21st Century," Dr. Stuart Aaronson, Professor and Chair, Department of Oncological Sciences, Mount Sinai School of Medicine

4/7/2006  "Personalized Tobacco - Related Risk Counseling in Dental Clinic Smokers: Preliminary Results," Dr. Jamie Ostroff, Chief Behavioral Sciences Service Associate, Attending Psychologist Psychiatry and Behavioral Sciences Memorial Sloan-Kettering Cancer Center

4/20/2006  "It's all in your head: The use of MRI in Psychobiological Research," Dr. Stefan Gold, Department of Neurology and Cousins Center for Psychoneuroimmunology, Geffen School of Medicine at UCLA

4/21/2006  "Lung Cancer Epidemiology: Defining a High Risk Group", Dr. Michele Cote, Assistant Professor, Wayne State University and Karmanos Cancer Center

6/27/2006  "Health Effects of Relational Trauma," Dr. Rachel Goldsmith, Annette Urso Rickel Foundation

6/28/2006  "Neuropattern - A clinical translational tool for diagnostic assessment of stress-related disorders," Dr. Dirk Hellhammer, Professor for Clinical and Theoretical Psychobiology, Department of Psychobiology, University of Trier, Germany

7/7/2006  "Potlucks as a Place of Resistance: Black Breast Cancer Survivors," LaShaune Johnson, Department of Sociology, University of California, Santa Barbara
7/13/2006  "Surviving Breast Cancer: Exploring the Significance and Meaning for African American Women," Dr. Tiffany Edwards, Postdoctoral Fellow, Department of Psychiatry and Behavioral Sciences, Emory School of Medicine

7/14/2006  "Determinants of the Placebo Response: Initial Severity and Individual Differences," Dr. Irving Kirsch, Professor for School of Applied Psychosocial Studies, University of Plymouth

7/18/2006  "The Effects of Advertising on Attitudes toward Tobacco Use and Decisions about Smoking among Virginia Adolescents," Dr. John Rosser Matthews, Department of Epidemiology & Community Health, School of Medicine, Virginia Commonwealth University

7/21/2006  “Who Benefits from Emotional Disclosure: An Examination of Personality Differences among Cancer Patients,” Dr. Sandra Zakowski, Associate Professor, Rosalind Franklin University of Medicine and Science

8/2/2006  “Parsing the Clinical Heterogeneity of Schizophrenia: Differential Effects of Individual Susceptibility Loci,” Pamela DeRosse, Senior Research Coordinator, Department of Psychiatric Research, Zucker Hillside Hospital

8/3/2006  “Effects of Cocaine and Cocaine Abstinence on Sleep, Cognition, Affect and Dreams,” Dr. Pia Wigren, Department of Neurology, New York Sleep Institute, NYU School of Medicine

9/15/2006  “An Introduction to the Design and Analysis of Field Studies of Stress Effects,” Dr. Gary James, Professor Department of Anthropology and Institute for Primary and Preventative Health Care, Binghamton University; Decker School of Nursing

REPORTABLE OUTCOMES:
Two postdoctoral fellows have participated in the training program during the past year, Dr. Keren Shakhar and Dr. Caroline Wright. Listed below are the posters, lectures and papers they produced between 9/15/05 and 9/14/06.

DR. KEREN SHAKHAR  received a PhD in Psychology from Tel Aviv University in Israel. Her research focuses on immunological factors in breast cancer risk.


DR. CAROLINE WRIGHT  received a PhD in Health Psychology from University College London in England. Her research centers on familial cancer risk and biological reactivity.
Wright CE, Valdimarsdottir HB, Erblich J, Bovbjerg DH. Poor Sleep the Night before an Experimental Stress Task is Associated with Reduced Cortisol Reactivity in Healthy Women. *Biological Psychology*, In press.


In addition, Dr. Wright submitted an application for a Department of Defense Breast Cancer Research Program Multidisciplinary Postdoctoral Award entitled, “Poor sleep prior to surgery, emotional distress, & perioperative cortisol responses in breast cancer patients: Impact on side-effects & postoperative recovery.” Dr. Wright submitted a second application to the Susan G. Komen Breast Cancer Association entitled, “Sleep, surgery, and daily cortisol rhythms in breast cancer patients: Implications for survival.”

**Graduates of the Training Program:**

**DR. NAA OYO A. KWATE:** Dr. Kwate received a Ph.D. in Clinical Psychology from St. John’s University in New York. Her research focused on health disparities in cancer prevention and control. Dr. Kwate is now an Associate Research Scientist at the Mailman School of Public Health, Columbia University.


**DR. ANNE FATONE:** Dr. Fatone received a Ph.D. in Clinical & Health Psychology from Yeshiva University in New York, NY. Her research has focused on the effects of psychosocial factors in participation of medical minority populations in cancer prevention efforts. Dr. Fatone is now an Instructor at the Mount Sinai School of Medicine.


**CONCLUSIONS:**
We have conducted a broad-based postdoctoral training program to prepare Four Trainees for interdisciplinary research in biobehavioral approaches to breast cancer. The first class of trainees, Dr. Kwate and Fatone, have gone on to pursue independent research careers investigating biobehavioral processes involved in cancer and their interactions with minority culture. As we continue the training program with our newest recruits Dr. Shakhar and Wright, we anticipate that they will add even more to the literature on addressing some of the more critical minority issues in biobehavioral aspects of cancer with potential clinical implications for prevention, screening, diagnosis, treatment, and survival in this underserved population.
REFERENCES:
None

APPENDICES:
None