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

PRINCIPAL INVESTIGATOR: Dana H. Bovbjerg, Ph.D.
Doctor Christine Ambrosone
Doctor Heiddis Valdimarsdottir
Ms. Lina Jandorf
Doctor Margaret McGovern
Doctor Jim Godbold

CONTRACTING ORGANIZATION: Mount Sinai School of Medicine
New York, New York 10029-6574

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13. ABSTRACT (Maximum 200 Words) The central goal of the Breast Cancer Behavioral Center is to further our understanding of the impact of biobehavioral factors on genetic aspects of breast cancer in African American women. The Center has three aims: 1) To support an integrated, interdisciplinary, Program of Research consisting of three synergistic Research Projects (with 4 supporting Cores), each of which addresses an important cancer topic and includes psychological and/or behavioral issues. Thus, we propose research projects with implications for breast cancer etiology, behavioral issues, and their interaction; 2) To encourage the development of interdisciplinary thinking among the faculty involved in the Program of Research that can serve as a model for other institutions. Thus, we propose to demonstrate, by example, the utility of an interdisciplinary approach by 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, we propose to provide interdisciplinary training through both didactic and "hands-on" research, as well as informal seminars to outstanding young investigators who 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

Core D Report

CENTER GRANT

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

CENTER GRANT

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**Behavioral Center of Excellence Award:
Genetic Factors in Breast Cancer:
Center for Interdisciplinary Biobehavioral Research**

Principal Investigator: Dr. Dana H. Bovbjerg

INTRODUCTION:

The central goal of the Breast Cancer Behavioral Center of Excellence in the Ruttenberg Cancer Center of the Mount Sinai School of Medicine is to further our understanding of the impact of biobehavioral factors on genetic aspects of breast cancer in African American women. Several lines of research supported our choice of this theme, including: 1) Accumulating evidence indicates that what has been called the "biobehavioral model" or "biopsychosocial model" of health and disease may have considerable relevance for cancer generally, and for breast cancer in particular. Broadly stated, the premise of this model, now supported by substantial empirical evidence, is that what people think and feel affects the state of their health in at least two basic ways: by affecting their behavioral choices (e.g., alcohol consumption, screening decisions) and by affecting their biological processes (e.g., increased catecholamine levels with stress), each of which is controlled by the central nervous system. 2) Breast cancer in African American women is on average diagnosed at a younger age, with more advanced, aggressive tumors, and poorer prognosis. Although such findings raise the possibility of differences in the nature of the disease itself and attest to the importance of further study of underlying mechanisms responsible, particularly the role of hormonal factors, research is scant.

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

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

study. Ambrosone (PI) and colleagues will use a classic case-control design to examine the contribution of gene-environment interactions in breast cancer risk, specifically relations between early life stress, reproductive, hormonal and lifestyle factors and polymorphisms in enzymes involved in estrogen metabolism. In addition, this study will evaluate whether specific exposure, particularly early stage at menarche, as well as gene-environment interactions are related to earlier onset of breast cancer and more aggressive disease.

Project 2: Impact of culturally tailored counseling on psychobehavioral outcomes and BRCA decision making among women with breast cancer. Valdimarsdottir (PI) and colleagues will use a randomized clinical trial design to investigate the cognitive, emotional, and behavioral impact of providing culturally-tailored genetic counseling to those breast cancer patients (Cases) in Project 1 whose cancer is likely to have an inherited genetic basis. In addition, this study will examine if the benefits of the culturally tailored counseling will be greater for more traditional (less acculturated) African American women.

Project 3: Immune surveillance, stress, and inherited susceptibility to breast cancer: a psychobiological analysis of the healthy daughters of breast cancer patients. Bovbjerg (PI) and colleagues will use a longitudinal study design comparing the daughters of Cases in Project 1, to the daughters of Controls 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 among daughters of patients whose cancers cannot be attributed to mutations in BRCA1 or BRCA2 genes. In addition, the study will explore 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.

These Projects synergize with one another both theoretically and practically. Each also is supported by the four Cores, which are dedicated to: A) Recruitment, Tracking, and Interviewing; B) Molecular Diagnostic and Research; C) Biostatistics and Data Management; and, D) Training.

Further understanding of the role of biobehavioral factors on the genetics 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.

BODY:

We still have not received official notification of approval of the HSRRB of the USAMRAA for any of the proposed three Projects, although our Mount Sinai Institutional Review Board has approved all for the past two years. Indeed, for two of the three (Projects 2 & 3), the Army HSRRB is apparently still awaiting the results of preliminary administrative review by Dr. Maryann F. Pranulis (Human Subjects Protection Scientist). Due the extensive time required for this Army HSRRB review we have fallen 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). Briefly, Project 1 received conditional approval from the Army HSRRB in April 2003 pending revisions to the consent document and protocol. The revised documents were submitted on April 25, 2003 and acknowledgement of receipt was received on April 28, 2003 with a caveat that the revised consent document had to be reviewed by the Acting Chair of the HSRRB. We still are awaiting a formal response from this review. In the absence of formal approval, we have continued to collect pilot data to enhance our readiness to make up for lost time once approval is obtained (see Project 1, below). Project 2 has yet to be

reviewed by the HSRRB. Our most recent attempt to satisfy HSRRB requirements was the submission on 3/3/03 of extensive clarifications/revisions requested by Dr. Pranulis in January 2003. We have had no formal response in the past 6 months. During the past year, Project 2 has developed and pilot tested the culturally tailored genetic counseling intervention; prepared all questionnaires; and trained key research personnel to be ready to make up for lost time once Army HSRRB approval is obtained. Project 3 has also not been reviewed by the Army HSRRB. Our most recent attempt to satisfy HSRRB requirements was the submission in March 2003 of further extensive clarifications/revisions requested by Dr. Pranulis in January 2003. We have had no formal response to those materials since that time. Based on the time required for processing previous clarifications/revisions (5 months [and counting]), we can only be cautiously optimistic that we can complete the required review process prior to the third annual report of this 4 year grant. Although we have husbanded our resources and plan to request a no cost extension of the Center grant, until we receive HSRRB approval we cannot determine whether we will be able to complete all the tasks associated with the Statements of Work as approved by peer review of submitted grant. Modification of those tasks may thus have to be requested next year, depending upon the outcome of our attempts to satisfy the requirements detailed by Dr. Pranulis for the HSRRB of the USAMRAA. While awaiting HSRRB approval, our second goal for the next year is to pilot all procedures and complete all Tasks that can be completed without such approval. We thus propose to be ready ourselves for immediate, effective, implementation of the proposed research once approval has been obtained.

KEY RESEARCH ACOMPLISHMENTS:

At this point in the research, with no approval by the HSRRB of the USAMRAA, results are not yet available. See detailed responses for each Project and Core below.

REPORTABLE OUTCOMES:

See detailed responses for each Project and Core below.

CONCLUSIONS:

With no approval by the HSRRB of the USAMRAA as yet, results are not available. During the next year we hope to be allowed by the HSRRB to initiate the proposed research, which has been approved by our local IRB (Mt Sinai) for the past two years. The results of this research collected over the ensuing years will provide further understanding of the role of biobehavioral factors on the genetics of breast cancer in African American women. The proposed research may thus have profound implications for cancer prevention and control, as it 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.

PROJECT 1

"Behavior, estrogen metabolism and breast cancer risk: a molecular epidemiologic study"

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 often diagnosed with breast cancer at an early age and have more aggressive disease. They are also more likely to experience menarche at an earlier age and to have higher estrogen levels. We hypothesize that earlier, more aggressive disease 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 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 the 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. We also will study 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. In a case control study, we will identify African American women with incident breast cancer at hospitals in NYC with the largest referral patterns for African Americans and controls using random digit dialing. Both groups will be recruited (n=1600) by culturally sensitive breast cancer survivors. In-person interviews will be conducted and a blood specimen drawn. Statistical analyses will be performed to address each of the aims. 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, Months 1–6:**

- 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

In Year 2 of the grant we continue to refine supporting study materials and strengthen the infrastructure of the study as per our proposed statement of work while we wait for HSRRB approval to conduct the study. We have modified the protocol, informed consent documents and study-related instruments and forms to facilitate data collection and tracking based on recommendations from HSRRB and to be in compliance with HIPAA. We have modified the study protocols for case ascertainment at hospitals and private doctor's offices in Manhattan, Brooklyn, Queens, and the Bronx and are in the final stages of obtaining protocol approval from each institution. We also have identified and contacted physicians at additional hospitals that we would like to include as participating sites. The study questionnaire has been modified and bound. Materials for the training of interviewers and maintenance of data quality have been updated. The textual content for participant letters and a brochure introducing the study has been finalized and was submitted for IRB review. Four interviewers have been hired and trained. A database in ACCESS[®] has been designed and validated for subject tracking.

None of the seven subsequent tasks have been performed while we wait for HSRRB approval. We, therefore, propose to modify the timeline for subsequent tasks by adding 18 months to the proposed start time and 12 months to the proposed end date. We anticipate requesting a no cost extension to allow us to complete the research.

KEY RESEARCH ACCOMPLISHMENTS:

- Refine infrastructure for molecular epidemiologic study (questionnaire, protocols and equipment for blood processing and specimen banking, interviewing, hiring, and training interviewers, databases for participant tracking).

REPORTABLE OUTCOMES:

Source: DOD (Funded)
Grant Number: BC011079
Project Title: Immune Surveillance, Cytokines and Breast Cancer Risk: Genetic and Psychological Influences in African American Women
Project Period: 7/01/02-6/30/07 Total Direct Costs: \$624,946
P.I.: D. Bovbjerg

Source: K07/NIH (Funded)
Grant Number: CA93447-01A1
Project Title: Energy Balance & Breast Cancer in African Americans
Project Period: 9/30/02-9/29/07 Total Direct Costs: \$666,225
P.I.: J. Britton

Source: NCI (Pending)
Grant Number: N/A
Project Title: Race & Risk Factors for Early/Aggressive Breast Cancer
Project Period: 4/01/03-3/30/08 Total Direct Costs: 3,509,587
P.I.: C. Ambrosone

CONCLUSIONS:

At this time no participants have been recruited to this study because we have not received HSRRB approval. No data has been gathered and no analyses have been performed. Thus, no findings can be reported at this time.

REFERENCES:

None

APPENDICES:

Questionnaire

June 18, 2003

Study ID#: _____



WOMEN'S CIRCLE OF HEALTH

Interviewer ID _____

Date of interview ____/____/____
Month Day Year

Time interview began ____:____am/pm

Time interview ended ____:____am/pm

Breaks: _____

Length of interview: _____

Has reference date changed from diagnosis date?

☐ Yes ☐ No ☐ DK

Has participant previously been consented?

☐ Yes ☐ No ☐ DK

Was blood drawn prior to date of interview?

☐ Yes ☐ No ☐ DK

Does participant want study results?

☐ Yes ☐ No ☐ DK

Was a continuation booklet used?

☐ Yes ☐ No ☐ DK

Has participant agreed to be contacted for other studies?

☐ Yes ☐ No ☐ DK

Case ☐ 1

Control ☐ 2

	Date	Initials
Interviewer:		
Reviewed by:		
Coded 1:		
Coded 2:		

A. DEMOGRAPHICS SECTION

Interviewer, please enter the reference date
in the following format: **MMDDYYYY**, e.g. April 4,
1950 = '04041950'

____/____/____
Month Day Year

CASES ONLY:

When did a doctor first tell you that you had breast cancer?

____/____/____
Month Day Year

At what hospital were you 1st diagnosed with breast cancer? _____

What was the name of the doctor who 1st diagnosed your breast cancer? _____

If self-reported date is EARLIER than assigned RD then use as RD throughout interview

Since many people have never been in an interview exactly like this, let me start by explaining to you how it works. In this interview I am going to read you a set of questions exactly as they are worded, so that every person in the study is answering the same questions. If at any time during the interview you are not clear about what is wanted, be sure to ask me. Also, it is very important that your answers be accurate and complete. Please take as much time as you need. If there are any questions that you are uncomfortable with, please feel free to tell me and we will skip them. Throughout this interview we are interested in things you did before (RD). This is the date that you became eligible for this health study. I'll begin by asking you some questions about your background.

A1. What is your date of birth?

____/____/____
Month Day Year

99 ☐ DK/Refused

A2. What is your current age?

____ age

99 ☐ DK/Refused

A3. In what U.S. state or foreign country were you born?

(Name of state or country)

99 ☐ DK/Refused

If participant was born in foreign country ask A4, otherwise go to A5.

A4. How old were you when you moved to the U.S.?

____ age

99 ☐ DK/Refused

A5. Do you consider yourself to be of Latina or Hispanic origin?

- 1 ☐ Yes
 2 ☐ No
 9 ☐ DK/Refused

Show
Card

**A5a. Do you consider yourself to be any of the following?
(Check all that apply)**

- 01 ☐ Mexican/Mexican American/Chicano
 02 ☐ Puerto Rican
 03 ☐ Cuban
 04 ☐ Caribbean or West Indian
 05 ☐ Dominican
 06 ☐ Other (please specify): _____
 99 ☐ DK/Refused

A6. What is your race? (Check all that apply.)

- 01 ☐ White
 02 ☐ Black/African American
 03 ☐ Black/African
 04 ☐ Black-West Indian / Caribbean
 05 ☐ Black-Other
 06 ☐ American Indian or Alaska Native
 07 ☐ Asian Indian
 08 ☐ Chinese
 09 ☐ Filipino
 10 ☐ Korean
 11 ☐ Vietnamese
 12 ☐ Other Asian
 13 ☐ Native Hawaiian
 14 ☐ Guamanian or Chamorro
 15 ☐ Samoan
 16 ☐ Other Pacific Islander
 17 ☐ Some other race (specify): _____
 99 ☐ DK/Refused

Eligible for Project 2
If Case, give Project 2 (TACT) brochure
(see criteria for Project 2 consent)

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Card

A6a. Interviewer: If participant does not choose one category please mark your assessment of race.

- 01 ☐ White
 02 ☐ Black
 03 ☐ Asian/Pacific Islander
 04 ☐ Other: _____

A7. What was the highest grade of school that you completed?

- 1 ☐ Less than 8th grade
 2 ☐ 8th to 11th grade
 3 ☐ High school graduate or equivalent (GED)
 4 ☐ Technical or vocational school
 5 ☐ Some college
 6 ☐ College graduate
 7 ☐ Post-graduate degree
 9 ☐ DK/Refused

Show
Card

A8. Are you adopted?

- 1 ☐ Yes
 2 ☐ No
 9 ☐ DK/Refused

A9. Can you answer questions about your blood relatives?

- 1 ☐ Yes
 2 ☐ No (C1)

In the next set of questions I will ask you about your parents and grandparents.

A10. In what U.S. state or foreign country was your MOTHER born?

99 ☐ DK/Refused

(Name of state or country)

A11. Is your MOTHER of Latina or Hispanic origin?

- 1 ☐ Yes
 2 ☐ No
 9 ☐ DK/Refused

Show
Card

A11a. Does she consider herself to be any of the following?
 (Check all that apply)

- 01 ☐ Mexican/Mexican American/Chicano
 02 ☐ Puerto Rican
 03 ☐ Cuban
 04 ☐ Caribbean or West Indian
 05 ☐ Dominican
 06 ☐ Other (please specify): _____
 99 ☐ DK/Refused

A12. What is your MOTHER'S race? (Check all that apply)

- 01 ☐ White
 02 ☐ Black/African American
 03 ☐ Black/African
 04 ☐ Black-West Indian / Caribbean
 05 ☐ Black-Other
 06 ☐ American Indian or Alaska Native
 07 ☐ Asian Indian
 08 ☐ Chinese
 09 ☐ Filipino
 10 ☐ Korean
 11 ☐ Vietnamese
 12 ☐ Other Asian
 13 ☐ Native Hawaiian
 14 ☐ Guamanian or Chamorro
 15 ☐ Samoan
 16 ☐ Other Pacific Islander
 17 ☐ Some other race (specify): _____
 99 ☐ DK/Refused

Show
Card

A13. What was the highest grade of school your MOTHER completed?

- 1 ☐ Less than 8th grade
 2 ☐ 8th to 11th grade
 3 ☐ High school graduate or equivalent (GED)
 4 ☐ Technical or vocational school
 5 ☐ Some college
 6 ☐ College graduate
 7 ☐ Post-graduate degree
 9 ☐ DK/Refused

Show
Card

A14. In what country was your MOTHER'S MOTHER (maternal grandmother) born?

 (Name of country)
99 ☐ DK/Refused
A15. In what country was your MOTHER'S FATHER (maternal grandfather) born?

 (Name of country)
99 ☐ DK/Refused
A16. In what U.S. state or foreign country was your FATHER born?

 (Name of country)
99 ☐ DK/Refused
A17. Is your FATHER of Latino or Hispanic origin?

- 1 ☐ Yes
 2 ☐ No
 9 ☐ DK/Refused

A17a. Does he consider himself to be any of the following?
 (Check all that apply)

- 01 ☐ Mexican/Mexican American/Chicano
 02 ☐ Puerto Rican
 03 ☐ Cuban
 04 ☐ Caribbean or West Indian
 05 ☐ Dominican
 06 ☐ Other (please specify): _____
 99 ☐ DK/Refused

Show
Card

A18. What is your FATHER'S race? (Check all that apply)

- 01 ☐ White
 02 ☐ Black/African American
 03 ☐ Black/African
 04 ☐ Black-West Indian / Caribbean
 05 ☐ Black-Other
 06 ☐ American Indian or Alaska Native
 07 ☐ Asian Indian
 08 ☐ Chinese
 09 ☐ Filipino
 10 ☐ Korean
 11 ☐ Vietnamese
 12 ☐ Other Asian
 13 ☐ Native Hawaiian
 14 ☐ Guamanian or Chamorro
 15 ☐ Samoan
 16 ☐ Other Pacific Islander
 17 ☐ Some other race (specify): _____
 99 ☐ DK/Refused

Show
Card

A19. What was the highest grade of school that your FATHER completed?

- 1 ☐ Less than 8th grade
 2 ☐ 8th to 11th grade
 3 ☐ High school graduate or equivalent (GED)
 4 ☐ Technical or vocational school
 5 ☐ Some college
 6 ☐ College graduate
 7 ☐ Post-graduate degree
 9 ☐ DK/Refused

Show
Card

A20. In what country was your FATHER'S MOTHER (paternal grandmother) born?
 99 ☐ DK/Refused

 (Name of country)
A21. In what country was your FATHER'S FATHER (paternal grandfather) born?
 99 ☐ DK/Refused

 (Name of country)

B. FAMILY HEALTH HISTORY

In this section of the questionnaire I would like to ask you about the health history of your blood relatives. This would include your parents, siblings and children. I am interested in both living and deceased members of your family, but only full-blood relatives.

B1. Is your father still living?

- 1 ☐ Yes _____ → B1a. How old is he? _____ age
- 2 ☐ No _____ → B1b. How old was he or what year was it when he died?
- 9 ☐ DK/Refused _____ age OR _____ year

B2. (Has/was) your father ever (been) diagnosed with cancer?	B3. What type(s) of cancer did he have?	B4. How old was he when this cancer was first diagnosed?
1 <input type="checkbox"/> Yes _____ →	a. _____	a. _____ age
2 <input type="checkbox"/> No (B5)	b. _____	b. _____ age
9 <input type="checkbox"/> DK/Refused (B5)	c. _____	c. _____ age

B5. Is your mother still living?

- 1 ☐ Yes _____ → B5a. How old is she? _____ age
- 2 ☐ No _____ → B5b. How old was she or what year was it when she died?
- 9 ☐ DK/Refused _____ age OR _____ year

B6. (Has/was) your mother ever (been) diagnosed with cancer?	B7. What type(s) of cancer did she have?	B8. How old was she when this cancer was first diagnosed?
1 <input type="checkbox"/> Yes _____ →	a. _____	a. _____ age
2 <input type="checkbox"/> No (B9)	b. _____	b. _____ age
9 <input type="checkbox"/> DK/R (B9)	c. _____	c. _____ age

Now I would like to ask about your full brothers and sisters, that is, those with whom you share both birth mother and father. Please include brothers and sisters who are living or deceased, but do not include adopted, foster, half or step brothers or sisters.

B9. How many full brothers do you have? _____ number of brothers

B10. How many full sisters do you have? _____ number of sisters

Now let's start with the oldest among your sibling(s).

B11. What is the first name of your (oldest/next) sibling?	B12. Is (name) a male or female?	B13. Is (he/she) still living?	B14. How old [is (he/she)/was (he/she) when (he/she) died]?	B15. [Has/was] (he/she) ever (been) diagnosed with cancer?	B16. What type(s) of cancer did he/she have?	B17. How old was (he/she) when this cancer was first diagnosed?
a	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ 9 <input type="checkbox"/> DK/Refused (b)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
b	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ 9 <input type="checkbox"/> DK/Refused (c)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
c	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ 9 <input type="checkbox"/> DK/Refused (d)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
d	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ 9 <input type="checkbox"/> DK/Refused (e)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
e	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ 9 <input type="checkbox"/> DK/Refused (f)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age

B11. What is the first name of your (oldest/next) sibling?	B12. Is (name) a male or female?	B13. Is (he/she) still living?	B14. How old [is (he/she)/ was (he/she) when (he/she) died]?	B15. [Has/was] (he/she) ever (been) diagnosed with cancer?	B16. What type(s) of cancer did he/she have?	B17. How old was (he/she) when this cancer was first diagnosed?
f	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ 9 <input type="checkbox"/> DK/Refused (g)	a. _____ b. _____ c. _____	a. ____ age b. ____ age c. ____ age
g	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ 9 <input type="checkbox"/> DK/Refused (h)	a. _____ b. _____ c. _____	a. ____ age b. ____ age c. ____ age
h	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ 9 <input type="checkbox"/> DK/Refused (i)	a. _____ b. _____ c. _____	a. ____ age b. ____ age c. ____ age
i	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ 9 <input type="checkbox"/> DK/Refused (j)	a. _____ b. _____ c. _____	a. ____ age b. ____ age c. ____ age
j	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ 9 <input type="checkbox"/> DK/Refused (B18)	a. _____ b. _____ c. _____	a. ____ age b. ____ age c. ____ age

If more than 10 siblings check here ____ and add additional pages.

Now I would like to ask you about your children. Again, please include only your biological children, whether they are living or deceased, but not adopted, foster or step-children.

B18. How many biological children have you had?

[If no children, B26]

B19. What is the first name of your (oldest/next) child?	B20. Is (he/she) male or female?	B21. Is (he/she) still living?	B22. How old [is (he/she)/was (he/she) [when (he/she) died]? _____ age	B23. [Has/was] (he/she) ever (been) diagnosed with cancer?	B24. What type(s) of cancer did he/she have?	B25. How old was (he/she) when this cancer was first diagnosed?
a	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	_____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No (b) 9 <input type="checkbox"/> DK/Refused (b)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
b	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	_____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No (c) 9 <input type="checkbox"/> DK/Refused (c)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
c	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	_____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No (d) 9 <input type="checkbox"/> DK/Refused (d)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
d	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	_____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No (e) 9 <input type="checkbox"/> DK/Refused (e)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
e	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	_____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No (f) 9 <input type="checkbox"/> DK/Refused (f)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age

B19. What is the first name of your (oldest/next) child?	B20. Is (he/she) male or female?	B21. Is (he/she) still living?	B22. How old [is (he/she)/was (he/she)]when (he/she) died]?	B23. [Has/was] (he/she) ever (been) diagnosed with cancer?	B24. What type(s) of cancer did he/she have?	B25. How old was (he/she) when this cancer was first diagnosed?
f	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ 9 <input type="checkbox"/> DK/Refused (g)	a. _____ b. _____ c. _____	a. ____ age b. ____ age c. ____ age
g	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ 9 <input type="checkbox"/> DK/Refused (h)	a. _____ b. _____ c. _____	a. ____ age b. ____ age c. ____ age
h	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ 9 <input type="checkbox"/> DK/Refused (i)	a. _____ b. _____ c. _____	a. ____ age b. ____ age c. ____ age
i	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ 9 <input type="checkbox"/> DK/Refused (j)	a. _____ b. _____ c. _____	a. ____ age b. ____ age c. ____ age
j	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ 9 <input type="checkbox"/> DK/Refused	a. _____ b. _____ c. _____	a. ____ age b. ____ age c. ____ age

If any living daughters are > 18 years old then eligible for Project 3, complete contact form and check box on post-interview checklist!

B26. Have any of your other relatives, such as grandparents, aunts, uncles, cousins, or half-siblings, been diagnosed with breast or ovarian cancer?

- 1 ☐ Yes
 2 ☐ Yes, possibly
 3 ☐ No (C1)
 9 ☐ DK/Refused (C1)

B27. As far as you know, which relatives were diagnosed with breast cancer?
 (Check all that apply)

01 <input type="checkbox"/> None	
02 <input type="checkbox"/> Mother's mother	At what age was she diagnosed? _____ age
03 <input type="checkbox"/> Father's mother	At what age was he diagnosed? _____ age
04 <input type="checkbox"/> Mother's sister(s)	a. How many with breast cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age
05 <input type="checkbox"/> Father's sister(s)	b. How many with breast cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age
06 <input type="checkbox"/> My maternal half sister(s)	c. How many with breast cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age
07 <input type="checkbox"/> My paternal half sister(s)	d. How many with breast cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age
08 <input type="checkbox"/> Maternal male relatives	e. How many with breast cancer? _____ At what age(s) (was he/were they) diagnosed? _____ age _____ age _____ age _____ age
09 <input type="checkbox"/> Paternal male relatives	f. How many with breast cancer? _____ At what age(s) (was he/were they) diagnosed? _____ age _____ age _____ age _____ age
10 <input type="checkbox"/> Other relative(s)	g. Please specify who: _____ _____ At what age(s) (was she or he /were they) diagnosed? _____ age _____ age _____ age _____ age _____ age
99 <input type="checkbox"/> DK/Refused	

B28. As far as you know, which relatives were diagnosed with ovarian cancer?
(Check all that apply)

01 <input type="checkbox"/> None	
02 <input type="checkbox"/> Mother's mother	At what age was she diagnosed? _____ age
03 <input type="checkbox"/> Father's mother	At what age was she diagnosed? _____ age
04 <input type="checkbox"/> Mother's sister(s)	a. How many with ovarian cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age
05 <input type="checkbox"/> Father's sister(s)	b. How many with ovarian cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age
06 <input type="checkbox"/> My maternal half sister(s)	c. How many with ovarian cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age
07 <input type="checkbox"/> My paternal half sister(s)	d. How many with ovarian cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age
08 <input type="checkbox"/> Other relative(s)	e. Please specify who: _____ _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age
99 <input type="checkbox"/> DK/Refused	

C. PRENATAL EXPOSURES

Now I would like to ask you some information about when your mother was pregnant with you.

C1. Were you a twin or multiple birth?

- 1 ☐ Yes, twin (C2)
 2 ☐ Yes, multiple (C3)
 3 ☐ No (C5)
 9 ☐ DK/Refused (C5)

C2. Was your twin female?

- 1 ☐ Yes (C4)
 2 ☐ No (C5)
 9 ☐ DK/Refused (C5)

C3. Were any of your siblings in this multiple birth female?

- 1 ☐ Yes (C4)
 2 ☐ No (C5)
 9 ☐ DK/Refused (C5)

C4. Do you have an identical sibling?

- 1 ☐ Yes
 2 ☐ No
 9 ☐ DK/Refused

C5. Do you know how much you weighed when you were born?

- 1 ☐ Yes
 2 ☐ No
 9 ☐ DK/Refused

C5a. What was your weight?

_____ pounds _____ ounces

If birthweight is known, skip to question C8.

C6. Do you think you weighed less than 5 ½ pounds?

- 1 ☐ Yes (C8)
 2 ☐ No
 9 ☐ DK/Refused

C7. Do you think you weighed 9 pounds or more?

- 1 ☐ Yes
 2 ☐ No
 9 ☐ DK/Refused

C8. As far as you know, did your mother breastfeed you?

- 1 ☐ Yes _____ →
2 ☐ Yes probably/possibly
3 ☐ No
9 ☐ DK/Refused

C8a. How long did she breastfeed you?

____ months
99 ☐ DK/Refused

C9. As far as you know, did your mother smoke when she was pregnant with you?

- 1 ☐ Yes
2 ☐ Yes probably/possibly
3 ☐ No
9 ☐ DK/Refused

D. MENSTRUAL HISTORY

Now I would like to ask you some questions about your own reproductive and medical history.

D1. Approximately how old were you when you had your first menstrual period?

____ . ____ age 99 ☐ DK/Refused

D2. Did you have your period during the 12 months before (RD)?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK/Refused

D3. How would you characterize your menstrual status during the 12 months before (RD)?

- 01 ☐ Still having periods and not going through menopause or the change of life
02 ☐ Still having periods but possibly beginning menopause or the change of life
03 ☐ Still having periods and on hormone replacement therapy
04 ☐ Going through menopause or the change of life
05 ☐ Postmenopausal
06 ☐ Was pregnant
07 ☐ Other (specify): _____
99 ☐ DK/Refused

Show
Card

D4. During what month and year or at what age did you have your last period?

____ / ____ OR ____ age
Month Year

Check answer to question D2, if respondent answered Yes or DK/R, skip to question E1. If No, then ask:

D5. Please tell me all the reasons your menstrual periods stopped. (Check all that apply.)

- 01 ☐ They stopped naturally
02 ☐ I had a hysterectomy
03 ☐ I had both ovaries removed
04 ☐ I was having or had radiation treatment/chemotherapy
05 ☐ I was nursing
06 ☐ I was taking hormones
07 ☐ Other (specify): _____
08 ☐ I had one ovary removed
99 ☐ DK/Refused

Show
Card

D6. Around the time your periods stopped, how much did you weigh?

____ pounds OR ____ kilograms

999 ☐ DK/Refused

E. PREGNANCY HISTORY

Now I would like to ask you about your pregnancy history.

E1. During your lifetime, how many times have you been pregnant? Be sure to count this pregnancy if you are currently pregnant.

____ Pregnancies (Use 00 for never pregnant and skip to F1)

E2. Are you currently pregnant?

1 ☐ Yes _____ →

E2a. How many weeks or months?

_____ weeks or _____ months

2 ☐ No

If this is the participant's first and only pregnancy skip to E7

	E3. What was the outcome of your (first/next) pregnancy?	E4. How many weeks or months did this pregnancy last?	E5. In what month and year did this pregnancy end?	E6. Did you breast-feed this baby? If so, for how long?
a	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6a. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
b	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6b. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused

	E3. What was the outcome of your (first/next) pregnancy?	E4. How many weeks or months did this pregnancy last?	E5. In what month and year did this pregnancy end?	E6. Did you breast-feed this baby? If so, for how long?
c	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____/_____ Month Year	1 <input type="checkbox"/> Yes E6i. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____ _____ _____ _____	_____ Months Or _____ Weeks	_____/_____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
d	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____/_____ Month Year	1 <input type="checkbox"/> Yes E6j. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____ _____ _____ _____	_____ Months Or _____ Weeks	_____/_____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
e	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____/_____ Month Year	1 <input type="checkbox"/> Yes E6k. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____ _____ _____ _____	_____ Months Or _____ Weeks	_____/_____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused

	E3. What was the outcome of your (first/next) pregnancy?	E4. How many weeks or months did this pregnancy last?	E5. In what month and year did this pregnancy end?	E6. Did you breast-feed this baby? If so, for how long?
f	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6i. How long? ↓ _____ Months 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	
g	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6j. How long? ↓ _____ Months 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	
h	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6k. How long? ↓ _____ Months 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	

	E3. What was the outcome of your (first/next) pregnancy?	E4. How many weeks or months did this pregnancy last?	E5. In what month and year did this pregnancy end?	E6. Did you breast-feed this baby? If so, for how long?
i	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6i. How long? ↓ _____ Months 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	
j	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6j. How long? ↓ _____ Months 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	
k	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6k. How long? ↓ _____ Months 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	

	E3. What was the outcome of your (first/next) pregnancy?	E4. How many weeks or months did this pregnancy last?	E5. In what month and year did this pregnancy end?	E6. Did you breast-feed this baby? If so, for how long?
l	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____/_____ Month Year	1 <input type="checkbox"/> Yes E6l. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____ _____ _____ _____	_____ Months Or _____ Weeks	_____/_____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
m	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____/_____ Month Year	1 <input type="checkbox"/> Yes E6m. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____ _____ _____ _____	_____ Months Or _____ Weeks	_____/_____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
n	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____/_____ Month Year	1 <input type="checkbox"/> Yes E6n. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____ _____ _____ _____	_____ Months Or _____ Weeks	_____/_____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused

	E7. During any of your pregnancies did a doctor ever tell you that you had:	E8. Which pregnancies were they?
a	Hypertension or high blood pressure? 1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No (E7b) 9 <input type="checkbox"/> DK/Refused (E7b)	a. _____ (Pregnancy letter) b. _____ (Pregnancy letter) c. _____ (Pregnancy letter) d. _____ (Pregnancy letter)
b	Toxemia or pre-eclampsia? This is when you have high blood pressure, swelling and protein in your urine. 1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No (E7c) 9 <input type="checkbox"/> DK/Refused (E7c)	a. _____ (Pregnancy letter) b. _____ (Pregnancy letter) c. _____ (Pregnancy letter) d. _____ (Pregnancy letter)
c	Diabetes or high blood sugar? 1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No (F1) 9 <input type="checkbox"/> DK/Refused (F1)	a. _____ (Pregnancy letter) b. _____ (Pregnancy letter) c. _____ (Pregnancy letter) d. _____ (Pregnancy letter)

F. ORAL CONTRACEPTIVES AND HORMONE REPLACEMENT THERAPY

Now I'd like to ask you about your use of hormones for birth control, menopause or other reasons.

F1. Before (RD) had you ever used pills, shots, patches or hormone implants for birth control or to regulate periods?

- 1 ☐ Yes
2 ☐ No (F5)
9 ☐ DK/Refused (F5)

F2. How old were you when you first started using pills, shots, patches or hormone implants for birth control or to regulate periods?

___ age

F3. How old were you when you last used pills, shots, patches or hormone implants for birth control or to regulate periods?

___ age

00 ☐ Still Taking

F4. Considering that you may have started and stopped several times, for how many months or years altogether did you use pills, shots, patches or implants for birth control or to regulate periods?

___ months OR ___ years

Now I am going to ask you questions about hormones that you may have taken for other reasons than birth control or to regulate periods. If you have had breast cancer, please do not include hormones that were taken for treatment of your breast cancer.

F5. Before (RD), had you ever used estrogen, progestins, or other female hormones for hormone replacement therapy during or after the change of life? This includes for menopausal symptoms, osteoporosis or heart disease.

- 1 ☐ Yes
2 ☐ No (G1)
9 ☐ DK/Refused (G1)

	F6. Do you recall the name of the hormone that you (first/next) used? <div>Show Card</div>	F7. What type of hormones did you use? <div>Show Card</div>	F8. At what age or in what year did you start taking (hormone in F6)?	F9. At what age or in what year did you stop taking (hormone in F6)?	F10. For how many months or years altogether did you take hormone in F6?
a	1 <input type="checkbox"/> Yes (specify): _____ (F8) _____ 2 <input type="checkbox"/> No (F7)	1 <input type="checkbox"/> Estrogen only 2 <input type="checkbox"/> Progestin only 3 <input type="checkbox"/> Both Estrogen and Progestin 9 <input type="checkbox"/> DK/Refused	_____ year OR _____ age 00 <input type="checkbox"/> still taking	_____ year OR _____ age 00 <input type="checkbox"/> still taking	_____ months OR _____ years
b	1 <input type="checkbox"/> Yes (specify): _____ (F8) _____ 2 <input type="checkbox"/> No (F7)	1 <input type="checkbox"/> Estrogen only 2 <input type="checkbox"/> Progestin only 3 <input type="checkbox"/> Both Estrogen and Progestin 9 <input type="checkbox"/> DK/Refused	_____ year OR _____ age	_____ year OR _____ age 00 <input type="checkbox"/> still taking	_____ months OR _____ years
c	1 <input type="checkbox"/> Yes (specify): _____ (F8) _____ 2 <input type="checkbox"/> No (F7)	1 <input type="checkbox"/> Estrogen only 2 <input type="checkbox"/> Progestin only 3 <input type="checkbox"/> Both Estrogen and Progestin 9 <input type="checkbox"/> DK/Refused	_____ year OR _____ age	_____ year OR _____ age 00 <input type="checkbox"/> still taking	_____ months OR _____ years

	F6. Do you recall the name of the hormone that you (first/next) used? <div>Show Card</div>	F7. What type of hormones did you use? <div>Show Card</div>	F8. At what age or in what year did you start taking (hormone in F6)?	F9. At what age or in what year did you stop taking (hormone in F6)?	F10. For how many months or years altogether did you take hormone in F6?
d	1 <input type="checkbox"/> Yes (specify): _____ (F8) 2 <input type="checkbox"/> No (F7)	1 <input type="checkbox"/> Estrogen only 2 <input type="checkbox"/> Progestin only 3 <input type="checkbox"/> Both Estrogen and Progestin 9 <input type="checkbox"/> DK/Refused	_____ year OR _____ age 00 <input type="checkbox"/> still taking	_____ year OR _____ age 00 <input type="checkbox"/> still taking	_____ months OR _____ years
e	1 <input type="checkbox"/> Yes (specify): _____ (F8) 2 <input type="checkbox"/> No (F7)	1 <input type="checkbox"/> Estrogen only 2 <input type="checkbox"/> Progestin only 3 <input type="checkbox"/> Both Estrogen and Progestin 9 <input type="checkbox"/> DK/Refused	_____ year OR _____ age	_____ year OR _____ age 00 <input type="checkbox"/> still taking	_____ months OR _____ years
f	1 <input type="checkbox"/> Yes (specify): _____ (F8) 2 <input type="checkbox"/> No (F7)	1 <input type="checkbox"/> Estrogen only 2 <input type="checkbox"/> Progestin only 3 <input type="checkbox"/> Both Estrogen and Progestin 9 <input type="checkbox"/> DK/Refused	_____ year OR _____ age	_____ year OR _____ age 00 <input type="checkbox"/> still taking	_____ months OR _____ years

G. MAMMOGRAPHY SCREENING

A mammogram is an x-ray taken only of the breasts by a machine that presses the breast between two plastic plates. In the following questions, please tell me about your mammography history. For women with breast cancer: Please **EXCLUDE** any mammograms that were used to diagnose your recent breast cancer.

G1. Has a doctor ever recommended that you have a screening mammogram?

- 1 ☐ Yes
 2 ☐ No
 9 ☐ DK/Refused

G2. Before (RD), had you ever had a screening mammogram?

- 1 ☐ Yes
 2 ☐ No (G6)
 9 ☐ DK/Refused (G6)

G3. Before (RD) at what age or what year did you have your first screening mammogram?

____ OR ____
 Age Year

G4. How many screening mammograms had you had before (RD)?

____ number of mammograms (If participant only had 1 mammogram then skip to G6).

G5. Before (RD) at what age or what year was your last screening mammogram?

____ OR ____ / ____
 Age Month Year

G6. Before the (RD) did you examine your breasts for lumps?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK/Refused

Show
Card

G6a. How often did you perform breast self-exams?

- 01 ☐ Once a day
- 02 ☐ Once a week
- 03 ☐ Twice a month
- 04 ☐ Once a month
- 05 ☐ Once every other month (6 times/year)
- 06 ☐ Once every third month (4 times/year)
- 07 ☐ 2-3 times/year
- 08 ☐ Once a year
- 09 ☐ Less than once a year
- 99 ☐ DK/Refused

G7. Before the (RD) did your healthcare provider examine your breasts for lumps?

- 1 ☐ Yes
- 2 ☐ No (G8)
- 9 ☐ DK/Refused (G8)

Show
Card

G7a. Before your (RD) when was your last clinical breast exam?

- 1 ☐ Within the last year
- 2 ☐ Within the last year and a half
- 3 ☐ Within the last 2 years
- 4 ☐ Within the last 2-5 years
- 5 ☐ More than 5 years ago
- 9 ☐ DK/Refused

G8. Before (RD), has a doctor ever told you that you had benign breast disease, such as non-cancerous cyst or breast lump?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK/Refused

FOR WOMEN WITHOUT BREAST CANCER (CONTROLS) GO TO G10.

FOR WOMEN WITH BREAST CANCER (CASES) ONLY:

G9. How was your breast cancer first found?

- 01 ☐ Routine self-exam
- 02 ☐ Accidental self discovery
- 03 ☐ Accidental discovery by a partner
- 04 ☐ Routine physical exam by doctor
- 05 ☐ Routine mammogram
- 06 ☐ Some other way (specify) _____
- 99 ☐ DK/Refused

□□□□

FOR CONTROLS ONLY:

G10. If you were to discover a lump in your breast, what hospital would you go to for medical attention?

(specify name)

G11. In what borough or city and state is this hospital located?

(specify borough or city and state)

H. SMOKING HISTORY

Now, I would like to ask you some questions about cigarette smoking.

H1. Have you ever smoked at least one cigarette per day for one year?

- 1 ☐ Yes
 2 ☐ No (I1)
 9 ☐ DK/Refused (I1)

H2. How old were you when you first started smoking cigarettes on a regular basis?

_____ age started

H3. When you first started smoking regularly, how many cigarettes did you smoke per day? (One package contains 20 cigarettes.)

_____ number of cigarettes 99 ☐ DK/ Refused

H4. Were you a smoker on (RD)?

- 1 ☐ Yes (H6)
 2 ☐ No (H5)
 9 ☐ DK/ Refused (H5)

H5. At what age did you last stop smoking cigarettes?

_____ age stopped 99 ☐ DK/ Refused

H6. Thinking about when you first started smoking until you stopped, or the present, was there ever a period of one year or more in which you did not smoke cigarettes?

- 1 ☐ Yes
 2 ☐ No (H8)
 9 ☐ DK/ Refused (H8)

H7. For how many years from when you started until you stopped, or the present, did you not smoke cigarettes?

_____ years 99 ☐ DK/ Refused

H8. On average, during periods that you smoked, how many cigarettes (do/did) you usually smoke per day? (One package contains 20 cigarettes.)

_____ number of cigarettes 999 ☐ DK/ Refused

If participant had a FTP, ask H9. If not, go to I1.

H9. Did you smoke anytime before your first full-term pregnancy?

- 1 ☐ Yes
2 ☐ No (I1)
9 ☐ DK/ Refused (I1)

H10. Considering that you may have started and stopped several times, for how many months or years total did you smoke before your first full-term pregnancy?

____ months OR ____ years 99 ☐ DK/ Refused

H11. During this time before your first full-term pregnancy, on average how many cigarettes did you smoke per day?

____ number of cigarettes 999 ☐ DK/ Refused

I. HAIR PRODUCTS

The next set of questions ask about your use of different hair products including hair dye, relaxers and cholesterol-containing conditioning hair creams. For these questions, we are only interested in products that you used consistently for at least one year.

11. Have you ever regularly dyed your hair for at least one year with permanent hair dye? By regularly we mean more than TWO times per year.

- 1 ☐ Yes
 2 ☐ No (18)
 9 ☐ DK/ Refused (18)

Now we'd like to know some more specific information about your hair coloring patterns. If you used different types of dye or colors during different times in your life, please tell me about them separately, but remember to only include times that you colored your hair for at least one year.

	12. At what age did you (first/next) regularly start coloring your hair?	13. What shade of hair color did you use?	14. Did you use a home-kit or was it done in a salon?	15. At what age did you last dye your hair this color?	16. For how many months or years did you dye your hair this color?	17. On average, how often did you color your hair?
a	age _____	1 <input type="checkbox"/> Light (blonde, light brown) 2 <input type="checkbox"/> Medium (medium brown, red) 3 <input type="checkbox"/> Dark (dark brown, black)	1 <input type="checkbox"/> Home-kit: _____ (Brand name) <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 2 <input type="checkbox"/> Salon 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused	age _____	_____ (months) or _____ (years)	1 <input type="checkbox"/> 4-6 months 2 <input type="checkbox"/> 2-3 months 3 <input type="checkbox"/> 6-8 weeks 4 <input type="checkbox"/> 4-5 weeks 5 <input type="checkbox"/> More than every 4 weeks 9 <input type="checkbox"/> DK/Refused
b	age _____	1 <input type="checkbox"/> Light (blonde, light brown) 2 <input type="checkbox"/> Medium (medium brown, red) 3 <input type="checkbox"/> Dark (dark brown, black)	1 <input type="checkbox"/> Home-kit: _____ (Brand name) <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 2 <input type="checkbox"/> Salon 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused	age _____	_____ (months) or _____ (years)	1 <input type="checkbox"/> 4-6 months 2 <input type="checkbox"/> 2-3 months 3 <input type="checkbox"/> 6-8 weeks 4 <input type="checkbox"/> 4-5 weeks 5 <input type="checkbox"/> More than every 4 weeks 9 <input type="checkbox"/> DK/Refused

Show
Card

	12. At what age did you (first/next) regularly start coloring your hair?	13. What shade of hair color did you use?	14. Did you use a home-kit or was it done in a salon?	15. At what age did you last dye your hair this color?	16. For how many months or years did you dye your hair this color?	17. On average, how often did you color your hair?
c	____ age	1 <input type="checkbox"/> Light (blonde, light brown) 2 <input type="checkbox"/> Medium (medium brown, red) 3 <input type="checkbox"/> Dark (dark brown, black)	1 <input type="checkbox"/> Home-kit: (Brand name) _____ 2 <input type="checkbox"/> Salon 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused	____ age	____ (months) or ____ (years)	1 <input type="checkbox"/> 4-6 months 2 <input type="checkbox"/> 2-3 months 3 <input type="checkbox"/> 6-8 weeks 4 <input type="checkbox"/> 4-5 weeks 5 <input type="checkbox"/> More than every 4 weeks 9 <input type="checkbox"/> DK/Refused
d	____ age	1 <input type="checkbox"/> Light (blonde, light brown) 2 <input type="checkbox"/> Medium (medium brown, red) 3 <input type="checkbox"/> Dark (dark brown, black)	1 <input type="checkbox"/> Home-kit: (Brand name) _____ 2 <input type="checkbox"/> Salon 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused	____ age	____ (months) or ____ (years)	1 <input type="checkbox"/> 4-6 months 2 <input type="checkbox"/> 2-3 months 3 <input type="checkbox"/> 6-8 weeks 4 <input type="checkbox"/> 4-5 weeks 5 <input type="checkbox"/> More than every 4 weeks 9 <input type="checkbox"/> DK/Refused

Show
Card

18. Have you ever chemically relaxed or straightened your hair for at least one year?

- 1 ☐ Yes
 2 ☐ No (114)
 9 ☐ DK/ Refused (114)

Now we'd like to know some more specific information about the different ages you might have chemically relaxed or straightened your hair.

	19. When you were (age from 1 st column), did you ever relax your hair?	110. Between these ages, for how many months or years in total did you relax your hair?	111. Between these ages, on average, how often did you relax your hair? <div>Show Card</div>	112. Did you use lye or no-lye relaxers?	113. Did you use a home-kit or was it done in a salon?
a. 12 years old or younger	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (b) 9 <input type="checkbox"/> DK/Refused (b)	<u> </u> (Months) or <u> </u> (Years)	1 <input type="checkbox"/> 4-6 months 2 <input type="checkbox"/> 2-3 months 3 <input type="checkbox"/> 6-8 weeks 4 <input type="checkbox"/> 4-5 weeks 5 <input type="checkbox"/> More than every 4 weeks 9 <input type="checkbox"/> DK/Refused	1 <input type="checkbox"/> Lye 2 <input type="checkbox"/> No lye 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused	1 <input type="checkbox"/> Home-kit 2 <input type="checkbox"/> Salon 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused
b. Between 13 and 19 years old	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (c) 9 <input type="checkbox"/> DK/Refused (c)	<u> </u> (Months) or <u> </u> (Years)	1 <input type="checkbox"/> 4-6 months 2 <input type="checkbox"/> 2-3 months 3 <input type="checkbox"/> 6-8 weeks 4 <input type="checkbox"/> 4-5 weeks 5 <input type="checkbox"/> More than every 4 weeks 9 <input type="checkbox"/> DK/Refused	1 <input type="checkbox"/> Lye 2 <input type="checkbox"/> No lye 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused	1 <input type="checkbox"/> Home-kit 2 <input type="checkbox"/> Salon 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused
c. 20 years old up until now	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (114) 9 <input type="checkbox"/> DK/Refused (114)	<u> </u> (Months) or <u> </u> (Years)	1 <input type="checkbox"/> 4-6 months 2 <input type="checkbox"/> 2-3 months 3 <input type="checkbox"/> 6-8 weeks 4 <input type="checkbox"/> 4-5 weeks 5 <input type="checkbox"/> More than every 4 weeks 9 <input type="checkbox"/> DK/Refused	1 <input type="checkbox"/> Lye 2 <input type="checkbox"/> No lye 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused	1 <input type="checkbox"/> Home-kit 2 <input type="checkbox"/> Salon 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused

114. Have you ever used deep conditioning hair creams that contain cholesterol or placenta for at least one year?

- 1 ☐ Yes
 2 ☐ No (J1)
 9 ☐ DK/ Refused (J1)

Now we'd like to know some more specific information about the different ages you might have used deep conditioning hair creams that contain cholesterol or placenta.

	115. When you were (age from 1 st column), did you ever use cholesterol/placenta hair conditioner?	116. Between these ages, for how many months or years did you use these products?	117. During this age range, how often did you use these products?
a. 12 years old or younger	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (b) 9 <input type="checkbox"/> DK/Refused (b)	<u> </u> (Months) or <u> </u> (Years)	1 <input type="checkbox"/> Daily 2 <input type="checkbox"/> Several times/week 3 <input type="checkbox"/> Once/week 4 <input type="checkbox"/> Every 2 weeks 5 <input type="checkbox"/> Once/month 6 <input type="checkbox"/> 2-3 times a year 9 <input type="checkbox"/> DK/Refused
b. Between 13 and 19 years old	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (c) 9 <input type="checkbox"/> DK/Refused (c)	<u> </u> (Months) or <u> </u> (Years)	1 <input type="checkbox"/> Daily 2 <input type="checkbox"/> Several times/week 3 <input type="checkbox"/> Once/week 4 <input type="checkbox"/> Every 2 weeks 5 <input type="checkbox"/> Once/month 6 <input type="checkbox"/> 2-3 times a year 9 <input type="checkbox"/> DK/Refused
c. 20 years old old up until now.	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (J1) 9 <input type="checkbox"/> DK/Refused (J1)	<u> </u> (Months) or <u> </u> (Years)	1 <input type="checkbox"/> Daily 2 <input type="checkbox"/> Several times/week 3 <input type="checkbox"/> Once/week 4 <input type="checkbox"/> Every 2 weeks 5 <input type="checkbox"/> Once/month 6 <input type="checkbox"/> 2-3 times a year 9 <input type="checkbox"/> DK/Refused

Show
Card

J. LIVING ENVIRONMENT

For the next set of questions we would like to know about others who lived in your home when you grew up.

J1. Between birth and age 20, at what ages did you live with your (relative/person)?

a. BIOLOGICAL MOTHER

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Lived with																					

☐ Never lived with this person

☐ DK

b. BIOLOGICAL FATHER

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Lived with																					

☐ Never lived with this person

☐ DK

c. STEPMOTHER/Adoptive Mother (Or other mother figure)

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Lived with																					

☐ Never lived with this person

☐ DK

d. STEPFATHER/Adoptive Father (Or other father figure)

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Lived with																					

☐ Never lived with this person

☐ DK

e. ANY UNRELATED MALE >18 () ()

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Lived with																					

☐ Never lived with this person

☐ DK

f. ANY UNRELATED FEMALE >18 () ()

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Lived with																					

☐ Never lived with this person

☐ DK

K. PASSIVE SMOKING EXPOSURE

K1. During your life, have you ever lived with someone who smoked regularly inside your home? This could be parents or siblings when you grew up, or partners or roommates as an adult.

- 1 ☐ Yes
 2 ☐ No (L1)
 9 ☐ DK/Refused (L1)

K2. Beginning from the time you were born, please tell me about the number of people you lived with who smoked and at what ages you lived with them. Let's start with the first 10 years of your life. How many smokers did you live with from birth to age 10?

0-10 years

AGE	0	1	2	3	4	5	6	7	8	9	10
Passive Smoking											

99 ☐ DK/Refused

11-20 years

AGE	11	12	13	14	15	16	17	18	19	20
Passive Smoking										

99 ☐ DK/Refused

21-30 years

AGE	21	22	23	24	25	26	27	28	29	30
Passive Smoking										

99 ☐ DK/Refused

31-40 years

AGE	31	32	33	34	35	36	37	38	39	40
Passive Smoking										

99 ☐ DK/Refused

41-50 years

AGE	41	42	43	44	45	46	47	48	49	50
Passive Smoking										

99 ☐ DK/Refused

51-60 years

AGE	51	52	53	54	55	56	57	58	59	60
Passive Smoking										

99 ☐ DK/Refused

61-74 years

AGE	61	62	63	64	65	66	67	68	69	70	71	72	73	74
Passive Smoking														

99 ☐ DK/Refused

L. ALCOHOL CONSUMPTION

Now, we would like to know about what kinds of alcohol and how much you drank at different times in your life.

L1. Have you ever consumed alcoholic beverages, such as beer, wine or liquor at least once a week for 6 months or more?

- 1 ☐ Yes
 2 ☐ No (M1)
 9 ☐ DK/Refused (M1)

L2. When you were (age), did you drink alcoholic beverages at least once a week for 6 months or more?	L3. For how many years?	L4. How many drinks per day, week, month or year (did/do) you usually have when you were (age)?
a. Under 20 years of age 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (L2b)	_____ years	_____ drinks per 1 <input type="checkbox"/> Day 2 <input type="checkbox"/> Week 3 <input type="checkbox"/> Month 4 <input type="checkbox"/> Year
b. 20-29 years of age 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (L2c)	_____ years	_____ drinks per 1 <input type="checkbox"/> Day 2 <input type="checkbox"/> Week 3 <input type="checkbox"/> Month 4 <input type="checkbox"/> Year
c. 30-39 years of age 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (L2d) 3 <input type="checkbox"/> Not that old yet	_____ years	_____ drinks per 1 <input type="checkbox"/> Day 2 <input type="checkbox"/> Week 3 <input type="checkbox"/> Month 4 <input type="checkbox"/> Year
d. 40-49 years of age 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (L2e) 3 <input type="checkbox"/> Not that old yet	_____ years	_____ drinks per 1 <input type="checkbox"/> Day 2 <input type="checkbox"/> Week 3 <input type="checkbox"/> Month 4 <input type="checkbox"/> Year
e. 50-59 years of age 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (L2f) 3 <input type="checkbox"/> Not that old yet	_____ years	_____ drinks per 1 <input type="checkbox"/> Day 2 <input type="checkbox"/> Week 3 <input type="checkbox"/> Month 4 <input type="checkbox"/> Year
f. Age 60 or older 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (M1) 3 <input type="checkbox"/> Not that old yet	_____ years	_____ drinks per 1 <input type="checkbox"/> Day 2 <input type="checkbox"/> Week 3 <input type="checkbox"/> Month 4 <input type="checkbox"/> Year

M. DEVELOPMENTAL HISTORY

Now I am going to ask you a few questions about your height and weight.

M1. When you were (AGE), how did your height compare with other girls your age? Were you the shortest, much shorter, somewhat shorter, about the same, somewhat taller, much taller, or the tallest?

	A. SHORTEST	B. MUCH SHORTER	C. SOMEWHAT SHORTER	D. ABOUT THE SAME	E. SOMEWHAT TALLER	F. MUCH TALLER	G. TALLEST
a. 7 or 8 years old (2 nd or 3 rd grade)	1	2	3	4	5	6	7
b. AGE AT FIRST MENSTRUAL PERIOD ()	1	2	3	4	5	6	7
c. 15 or 16 years old (10 th or 11 th grade)	1	2	3	4	5	6	7

M2. When you were (AGE CATEGORY), how did your weight compare with other girls your age? Were you the thinnest, much thinner, somewhat thinner, about the same, somewhat heavier, much heavier, or the heaviest?

	A. THINNEST	B. MUCH THINNER	C. SOMEWHAT THINNER	D. ABOUT THE SAME	E. SOMEWHAT HEAVIER	F. MUCH HEAVIER	G. HEAVIEST
a. 7 or 8 years old (2 nd or 3 rd grade)	1	2	3	4	5	6	7
b. AGE AT FIRST MENSTRUAL PERIOD ()	1	2	3	4	5	6	7
c. 15 or 16 years old (10 th or 11 th grade)	1	2	3	4	5	6	7

M3. At age 20, how tall were you without shoes?

HT: _____

1 ☐ FEET, INCHES

2 ☐ CENTIMETERS

9 ☐ DK/Refused

M4. One year prior to (RD), how tall were you?

HT: _____

1 ☐ FEET, INCHES

2 ☐ CENTIMETERS

9 ☐ DK/Refused

M5. How much did you weigh when you were (AGE)? If you were pregnant or nursing at this age, how much did you weigh the year before the pregnancy?

a. 20 years old	WT: __ __ __	1 <input type="checkbox"/> Pounds 2 <input type="checkbox"/> Kilograms 9 <input type="checkbox"/> DK/Refused
b. 30 years old	WT: __ __ __	1 <input type="checkbox"/> Pounds 2 <input type="checkbox"/> Kilograms 9 <input type="checkbox"/> DK/Refused
c. 40 years old	WT: __ __ __	1 <input type="checkbox"/> Pounds 2 <input type="checkbox"/> Kilograms 9 <input type="checkbox"/> DK/Refused
d. 50 years old	WT: __ __ __	1 <input type="checkbox"/> Pounds 2 <input type="checkbox"/> Kilograms 9 <input type="checkbox"/> DK/Refused
e. 60 years old	WT: __ __ __	1 <input type="checkbox"/> Pounds 2 <input type="checkbox"/> Kilograms 9 <input type="checkbox"/> DK/Refused
f. 70 years old	WT: __ __ __	1 <input type="checkbox"/> Pounds 2 <input type="checkbox"/> Kilograms 9 <input type="checkbox"/> DK/Refused

M6. One year prior to (RD), how much did you weigh? If you were pregnant or nursing at this age, how much did you weigh the year before the pregnancy?

WEIGHT: ____

- 1 ☐ POUNDS
2 ☐ KILOGRAMS
9 ☐ DK/REFUSED

M7. Before (RD), when you gained weight, where on your body in general did you tend to gain it most easily? Do not include any times when you were pregnant or nursing.

CHECK ALL THAT APPLY.

- 01 ☐ NEVER GAIN WEIGHT
- 02 ☐ AROUND THE CHEST AND SHOULDERS
- 03 ☐ AROUND THE WAIST
- 04 ☐ AROUND THE STOMACH
- 05 ☐ AROUND THE HIPS
- 06 ☐ AROUND THE THIGHS
- 07 ☐ AROUND THE BUTTOCKS
- 08 ☐ EQUALLY ALL OVER
- 09 ☐ OTHER (SPECIFY) _____
- 99 ☐ DK/Refused

Show
Card

N. LIFETIME PHYSICAL ACTIVITY

Now I will be asking you about your physical activity patterns over your lifetime.

N1. When you were (AGE), how physically active were you compared to other girls your age? Would you describe yourself as being a lot more, a little more, about the same, a little less, or a lot less physically active than others?

	A. A LOT LESS	B. A LITTLE LESS	C. ABOUT THE SAME	D. A LITTLE MORE	E. A LOT MORE
a. 7 or 8 years old (2 nd or 3 rd grade)	1	2	3	4	5
b. AGE AT FIRST MENSTRUAL PERIOD	1	2	3	4	5
c. age 15 or 16 years old (10 th or 11 th grade)	1	2	3	4	5

Now I will ask you specifically about your occupation or volunteer work activities. Please consider every job, paid or unpaid, which you held for **at least 17 hours a week for 6 months or longer**.

N2. Have you ever worked for at least 17 hours a week for 6 months or longer in a year? This would include full-time or part-time, paid or unpaid work, and also any periods of self-employment.

1 ☐ Yes

2 ☐ No Go to O1

Now I am going to ask you some more detailed information about your jobs. Jobs should be reported separately if they required different physical effort. For example, changing from book keeping to construction work within the same company would be considered a two separate jobs.

N3. What was the title of the (first/next) paid or unpaid job you held?	N4. During a typical day at this job, which of the following would you consider your main activities? CHECK ALL THAT APPLY <div>SHOW CARD</div>	N4b. If R. provides more than one response for N4a ASK: What percent of time did you (ACTIVITY)?	N5. At what age or in what year, did you <u>start</u> working in this job?
<div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>01</div> </div>	01 <input type="checkbox"/> Sitting 02 <input type="checkbox"/> Standing 03 <input type="checkbox"/> Walking 04 <input type="checkbox"/> Lifting, carrying or pushing items less than 25 pounds (11 kilograms) 05 <input type="checkbox"/> Lifting, carrying or pushing items at least 25 pounds (11 kilograms) 06 <input type="checkbox"/> Some other activity (specify) _____	<div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div> <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div> <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div> <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div> <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div> <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div>	<div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>YEAR</div> </div> OR <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>AGE</div> </div>
<div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>02</div> </div>	01 <input type="checkbox"/> Sitting 02 <input type="checkbox"/> Standing 03 <input type="checkbox"/> Walking 04 <input type="checkbox"/> Lifting, carrying or pushing items less than 25 pounds (11 kilograms) 05 <input type="checkbox"/> Lifting, carrying or pushing items at least 25 pounds (11 kilograms) 06 <input type="checkbox"/> Some other activity (specify) _____	<div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div> <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div> <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div> <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div> <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div> <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div>	<div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>YEAR</div> </div> OR <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>AGE</div> </div>
<div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>03</div> </div>	01 <input type="checkbox"/> Sitting 02 <input type="checkbox"/> Standing 03 <input type="checkbox"/> Walking 04 <input type="checkbox"/> Lifting, carrying or pushing items less than 25 pounds (11 kilograms) 05 <input type="checkbox"/> Lifting, carrying or pushing items at least 25 pounds (11 kilograms) 06 <input type="checkbox"/> Some other activity (specify) _____	<div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div> <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div> <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div> <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div> <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div> <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>%</div> </div>	<div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>YEAR</div> </div> OR <div> <div> <div></div><div></div><div></div><div></div><div></div> </div> <div>AGE</div> </div>

	N6. When did you <u>stop</u> working in this job?	N7. For how many years did you work in this job?	N8. For how many months each year did you do this?	N9. On average, how many hours per week did you work at this job?
01	_ _ _ _ YEAR OR _ _ AGE 00 <input type="checkbox"/> still working	_ _ YEARS	_ _ MONTHS PER YEAR	_ _ HOURS PER WEEK
02	_ _ _ _ YEAR OR _ _ AGE 00 <input type="checkbox"/> still working	_ _ YEARS	_ _ MONTHS PER YEAR	_ _ HOURS PER WEEK
03	_ _ _ _ YEAR OR _ _ AGE 00 <input type="checkbox"/> still working	_ _ YEARS	_ _ MONTHS PER YEAR	_ _ HOURS PER WEEK

N3. What was the title of the (first/next) paid or unpaid job you held?	N4. During a typical day at this job, which of the following would you consider your main activities? CHECK ALL THAT APPLY	N4b. If R. provides more than one response for N4a ASK: What percent of time did you (ACTIVITY)?	N5. At what age or in what year, did you <u>start</u> working in this job?
<div>04</div> <div>_____</div>	01 <input type="checkbox"/> Sitting 02 <input type="checkbox"/> Standing 03 <input type="checkbox"/> Walking 04 <input type="checkbox"/> Lifting, carrying or pushing items less than 25 pounds (11 kilograms) 05 <input type="checkbox"/> Lifting, carrying or pushing items at least 25 pounds (11 kilograms) 06 <input type="checkbox"/> Some other activity (specify) _____	<div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div>	<div>____ ____ ____ OR ____ ____ </div> <div>YEAR AGE</div>
<div>05</div> <div>_____</div>	01 <input type="checkbox"/> Sitting 02 <input type="checkbox"/> Standing 03 <input type="checkbox"/> Walking 04 <input type="checkbox"/> Lifting, carrying or pushing items less than 25 pounds (11 kilograms) 05 <input type="checkbox"/> Lifting, carrying or pushing items at least 25 pounds (11 kilograms) 06 <input type="checkbox"/> Some other activity (specify) _____	<div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div>	<div>____ ____ ____ OR ____ ____ </div> <div>YEAR AGE</div>
<div>06</div> <div>_____</div>	01 <input type="checkbox"/> Sitting 02 <input type="checkbox"/> Standing 03 <input type="checkbox"/> Walking 04 <input type="checkbox"/> Lifting, carrying or pushing items less than 25 pounds (11 kilograms) 05 <input type="checkbox"/> Lifting, carrying or pushing items at least 25 pounds (11 kilograms) 06 <input type="checkbox"/> Some other activity (specify) _____	<div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div>	<div>____ ____ ____ OR ____ ____ </div> <div>YEAR AGE</div>

	N6. When did you <u>stop</u> working in this job?	N7. For how many years did you work in this job?	N8. For how many months each year did you do this?	N9. On average, how many hours per week did you work at this job?
04	_ _ _ _ YEAR OR _ _ AGE 00 <input type="checkbox"/> still working	_ _ YEARS	_ _ MONTHS PER YEAR	_ _ HOURS PER WEEK
05	_ _ _ _ YEAR OR _ _ AGE 00 <input type="checkbox"/> still working	_ _ YEARS	_ _ MONTHS PER YEAR	_ _ HOURS PER WEEK
06	_ _ _ _ YEAR OR _ _ AGE 00 <input type="checkbox"/> still working	_ _ YEARS	_ _ MONTHS PER YEAR	_ _ HOURS PER WEEK

N3. What was the title of the (first/next) paid or unpaid job you held?	N4. During a typical day at this job, which of the following would you consider your main activities? CHECK ALL THAT APPLY	N4b. If R. provides more than one response for N4a ASK: What percent of time did you (ACTIVITY)?	N5. At what age or in what year, did you <u>start</u> working in this job?
<div>07</div> <div>_____</div>	01 <input type="checkbox"/> Sitting 02 <input type="checkbox"/> Standing 03 <input type="checkbox"/> Walking 04 <input type="checkbox"/> Lifting, carrying or pushing items less than 25 pounds (11 kilograms) 05 <input type="checkbox"/> Lifting, carrying or pushing items at least 25 pounds (11 kilograms) 06 <input type="checkbox"/> Some other activity (specify) _____	<div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div>	<div>____ ____ ____ ____ OR ____ ____ </div> <div>YEAR AGE</div>
<div>08</div> <div>_____</div>	01 <input type="checkbox"/> Sitting 02 <input type="checkbox"/> Standing 03 <input type="checkbox"/> Walking 04 <input type="checkbox"/> Lifting, carrying or pushing items less than 25 pounds (11 kilograms) 05 <input type="checkbox"/> Lifting, carrying or pushing items at least 25 pounds (11 kilograms) 06 <input type="checkbox"/> Some other activity (specify) _____	<div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div>	<div>____ ____ ____ ____ OR ____ ____ </div> <div>YEAR AGE</div>
<div>09</div> <div>_____</div>	01 <input type="checkbox"/> Sitting 02 <input type="checkbox"/> Standing 03 <input type="checkbox"/> Walking 04 <input type="checkbox"/> Lifting, carrying or pushing items less than 25 pounds (11 kilograms) 05 <input type="checkbox"/> Lifting, carrying or pushing items at least 25 pounds (11 kilograms) 06 <input type="checkbox"/> Some other activity (specify) _____	<div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div>	<div>____ ____ ____ ____ OR ____ ____ </div> <div>YEAR AGE</div>

	N6. When did you <u>stop</u> working in this job?	N7. For how many years did you work in this job?	N8. For how many months each year did you do this?	N9. On average, how many hours per week did you work at this job?
07	_ _ _ _ YEAR OR _ _ AGE 00 <input type="checkbox"/> still working	_ _ YEARS	_ _ MONTHS PER YEAR	_ _ HOURS PER WEEK
08	_ _ _ _ YEAR OR _ _ AGE 00 <input type="checkbox"/> still working	_ _ YEARS	_ _ MONTHS PER YEAR	_ _ HOURS PER WEEK
09	_ _ _ _ YEAR OR _ _ AGE 00 <input type="checkbox"/> still working	_ _ YEARS	_ _ MONTHS PER YEAR	_ _ HOURS PER WEEK

O. EXERCISE, SPORTS AND LEISURE TIME PHYSICAL ACTIVITY

*Now I would like to know all of your exercise, sports, or leisure time activities that you did during your lifetime starting with your childhood and continuing to your (REFERENCE YEAR). Please consider any activities that you have participated in for **at least one hour per week for three months or more in any year**. In addition to sports and exercise, we are also interested in knowing whether you participated in exercise such as walking or biking to work or school.*

O1. Have you ever participated in any physical activities (exercise/sports) on a regular basis – that is, for at least one hour per week for 3 months or more in any year?

1 ☐ Yes

2 ☐ No (O8)

Let's go through these beginning with the activity you participated in at the youngest age, including your school years.

Ask all of the questions (O2-O7) for one exercise episode before asking about next episode. Seasonal activities done continuously (e.g. track every spring for four years) can be listed once. When activities were discontinued and then begun again later, code each interval of an activity separately so that activity patterns at various ages can be evaluated.

Activity	O2. In what activity did you (first/next) participate on a regular basis?	O3. At what age did you start (ACTIVITY) regularly?	O4. At what age did you stop (ACTIVITY)?	O5. For how many years in total did you (ACTIVITY) regularly?	O6. For how many months each year did you do this?	O7. On average, about how many hours per week did you actually (ACTIVITY)?
a	_ _ _ _ _ _ _ _ _	_ _ _ AGE	_ _ _ _ _ _ _ _ _ OR _ _ _ YEAR AGE 00 still doing	_ _ _ YEARS	_ _ _ _ _ MONTHS PER YEAR	_ _ _ _ _ _ _ _ _ HOURS MIN PER WEEK
b	_ _ _ _ _ _ _ _ _	_ _ _ AGE	_ _ _ _ _ _ _ _ _ OR _ _ _ YEAR AGE 00 still doing	_ _ _ YEARS	_ _ _ _ _ MONTHS PER YEAR	_ _ _ _ _ _ _ _ _ HOURS MIN PER WEEK
c	_ _ _ _ _ _ _ _ _	_ _ _ AGE	_ _ _ _ _ _ _ _ _ OR _ _ _ YEAR AGE 00 still doing	_ _ _ YEARS	_ _ _ _ _ MONTHS PER YEAR	_ _ _ _ _ _ _ _ _ HOURS MIN PER WEEK
d	_ _ _ _ _ _ _ _ _	_ _ _ AGE	_ _ _ _ _ _ _ _ _ OR _ _ _ YEAR AGE 00 still doing	_ _ _ YEARS	_ _ _ _ _ MONTHS PER YEAR	_ _ _ _ _ _ _ _ _ HOURS MIN PER WEEK
e	_ _ _ _ _ _ _ _ _	_ _ _ AGE	_ _ _ _ _ _ _ _ _ OR _ _ _ YEAR AGE 00 still doing	_ _ _ YEARS	_ _ _ _ _ MONTHS PER YEAR	_ _ _ _ _ _ _ _ _ HOURS MIN PER WEEK
f	_ _ _ _ _ _ _ _ _	_ _ _ AGE	_ _ _ _ _ _ _ _ _ OR _ _ _ YEAR AGE 00 still doing	_ _ _ YEARS	_ _ _ _ _ MONTHS PER YEAR	_ _ _ _ _ _ _ _ _ HOURS MIN PER WEEK

Activity	O2. In what activity did you (first/next) participate on a regular basis?	O3. At what age did you start (ACTIVITY) regularly?	O4. At what age did you stop (ACTIVITY)?	O5. For how many years in total did you (ACTIVITY) regularly?	O6. For how many months each year did you do this?	O7. On average, about how many hours per week did you actually (ACTIVITY)?
g	_ _ _ _ _ _ _ _ _	_ _ _ AGE	_ _ _ _ _ _ _ OR _ _ _ YEAR AGE 00 <input type="checkbox"/> still doing	_ _ _ YEARS	_ _ _ MONTHS PER YEAR	_ _ _ : _ _ _ HOURS MIN PER WEEK
h	_ _ _ _ _ _ _ _ _	_ _ _ AGE	_ _ _ _ _ _ _ OR _ _ _ YEAR AGE 00 <input type="checkbox"/> still doing	_ _ _ YEARS	_ _ _ MONTHS PER YEAR	_ _ _ : _ _ _ HOURS MIN PER WEEK
i	_ _ _ _ _ _ _ _ _	_ _ _ AGE	_ _ _ _ _ _ _ OR _ _ _ YEAR AGE 00 <input type="checkbox"/> still doing	_ _ _ YEARS	_ _ _ MONTHS PER YEAR	_ _ _ : _ _ _ HOURS MIN PER WEEK
j	_ _ _ _ _ _ _ _ _	_ _ _ AGE	_ _ _ _ _ _ _ OR _ _ _ YEAR AGE 00 <input type="checkbox"/> still doing	_ _ _ YEARS	_ _ _ MONTHS PER YEAR	_ _ _ : _ _ _ HOURS MIN PER WEEK
k	_ _ _ _ _ _ _ _ _	_ _ _ AGE	_ _ _ _ _ _ _ OR _ _ _ YEAR AGE 00 <input type="checkbox"/> still doing	_ _ _ YEARS	_ _ _ MONTHS PER YEAR	_ _ _ : _ _ _ HOURS MIN PER WEEK
l	_ _ _ _ _ _ _ _ _	_ _ _ AGE	_ _ _ _ _ _ _ OR _ _ _ YEAR AGE 00 <input type="checkbox"/> still doing	_ _ _ YEARS	_ _ _ MONTHS PER YEAR	_ _ _ : _ _ _ HOURS MIN PER WEEK

O8. Now, I would like to ask about your activities at home. Please, **do not include** activities you may do at your home or other people's home **for pay**. During the 12 months before (REFERENCE DATE), how much time did you spend (ACTIVITY)?

- a. Actively caring for a child or children **under 2 years of age** (includes activities such as feeding, dressing, bathing, playing, and carrying)

- 1 ☐ None or less than one hour a week
 2 ☐ 1-19 hours a week
 3 ☐ 20 or more hours a week
 9 ☐ DK/ Refused

Show
Card

- b. actively caring for a child or children **between 2 and 5 years of age**

- 1 ☐ None or less than one hour a week
 2 ☐ 1-19 hours a week
 3 ☐ 20 or more hours a week
 9 ☐ DK/ Refused

Show
Card

- c. actively caring for a disabled child or elderly person (only count time actually feeding, dressing, moving, etc.)

- 1 ☐ None or less than one hour a week
 2 ☐ 1-19 hours a week
 3 ☐ 20 or more hours a week
 9 ☐ DK/ Refused

Show
Card

- d. preparing meals or cleaning up from meals on **weekdays**

- 1 ☐ None or less than 30 minutes (1/2 hour) a day
 2 ☐ 30 to 59 minutes (less than 1 hour) a day
 3 ☐ 60 to 89 minutes (less than 1 1/2 hours) a day
 4 ☐ 90 to 119 minutes (less than 2 hours) a day
 5 ☐ 2 or more hours a day
 9 ☐ DK/ Refused

Show
Card

- e. preparing meals or cleaning up from meals on **weekends**

- 1 ☐ None or less than 30 minutes (1/2 hour) a day
 2 ☐ 30 to 59 minutes (less than 1 hour) a day
 3 ☐ 60 to 89 minutes (less than 1 1/2 hours) a day
 4 ☐ 90 to 119 minutes (less than 2 hours) a day
 5 ☐ 2 or more hours a day
 9 ☐ DK/ Refused

Show
Card

- f. doing major cleaning, such as shampooing carpets, waxing floors, or washing walls or windows

- 1 ☐ None or less than once a month
 2 ☐ Once a month
 3 ☐ 2-3 times a month
 4 ☐ Once a week
 5 ☐ More than once a week
 9 ☐ DK/ Refused

Show
Card

g. doing routine cleaning such as dusting, laundry, vacuuming, or changing linens

- 1 ☐ None or less than once a month
 2 ☐ Once a month
 3 ☐ 2-3 times a month
 4 ☐ Once a week
 5 ☐ More than once a week
 9 ☐ DK/ Refused

SHOW
CARD

h. going grocery shopping and pushing a shopping cart or carrying a basket

- 1 ☐ None or less than once a month
 2 ☐ Once a month
 3 ☐ 2-3 times a month
 4 ☐ Once a week
 5 ☐ More than once a week
 9 ☐ DK/ Refused

SHOW
CARD

i. doing gardening or yard work, such as mowing lawn or raking leaves

- 1 ☐ None or less than once a month
 2 ☐ Once a month
 3 ☐ 2-3 times a month
 4 ☐ Once a week
 5 ☐ More than once a week
 9 ☐ DK/ Refused

SHOW
CARD

j. doing heavy outdoor work, such as chopping wood, tilling soil, shoveling snow, or baling hay

- 1 ☐ None or less than once a month
 2 ☐ Once a month
 3 ☐ 2-3 times a month
 4 ☐ Once a week
 5 ☐ More than once a week
 9 ☐ DK/ Refused

SHOW
CARD

k. doing major home decoration or repair, such as plumbing, tiling, painting or building

- 1 ☐ None or less than once a month
 2 ☐ Once a month
 3 ☐ 2-3 times a month
 4 ☐ Once a week
 5 ☐ More than once a week
 9 ☐ DK/ Refused

SHOW
CARD

P. LIFE EVENTS

In this section, we want to know any and all years in which you experienced these life events up until you were 20 years old. Please indicate any and all years you witnessed or experienced...

P1. You witnessed or experienced a life threatening natural disaster or war.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Natural disaster																					

☐ Never witnessed or experienced

☐ DK

P2. You witnessed or experienced a life threatening accident.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Accident																					

☐ Never witnessed or experienced

☐ DK

P3. You witnessed or experienced a life threatening physical illness happening to you, a family member, or close friend.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Illness																					

☐ Never witnessed or experienced

☐ DK

P4. You witnessed or experienced the death of a close family member, or friend.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Death																					

☐ Never witnessed or experienced

☐ DK

P5. You witnessed or experienced mental illness happening to you, a close family member, or friend.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Mental Illness																					

☐ Never witnessed or experienced

☐ DK

P6. You witnessed or experienced a life threatening violent act, attack, or assault.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Violent Act																					

☐ Never witnessed or experienced

☐ DK

P7. Your living parents began living apart, got separated, or got divorced.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Parents Marital Status																					

☐ Never witnessed or experienced

☐ DK

P. LIFE EVENTS (cont'd)

P8. One or both of your parents lost their job, or was out of work.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Parents work history																					

☐ Never experienced

☐ DK

P9. You moved to a new neighborhood.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
New place																					

☐ Never experienced

☐ DK

P10. You had to leave home, or lived somewhere else.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Left Home																					

☐ Never experienced

☐ DK

P11. A close family member or friend had to spend time in jail or prison.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Prison life																					

☐ Never experienced

☐ DK

P12. A close family member or friend attempted or committed suicide.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Suicide																					

☐ Never witnessed or experienced

☐ DK

P13. You had a close physical relationship with a boyfriend.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Opposite Sex																					

☐ Never experienced

☐ DK

P14. You experienced sexual abuse (unwanted physical contact)

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Sexual abuse																					

☐ Never experienced

☐ DK

Q. OTHER DEMOGRAPHIC QUESTIONS

Q1. What is your marital status in the year before (RD)?

- 1 ☐ Married
- 2 ☐ Living as married
- 3 ☐ Widowed
- 4 ☐ Separated
- 5 ☐ Divorced
- 6 ☐ Single, never married or never lived as married. (Go to Q4)
- 9 ☐ DK/Refused

Q2. What was the highest grade of school that your SPOUSE/ PARTNER completed in the year before (RD)?

- 1 ☐ Less than 8th grade
- 2 ☐ 8th to 11th grade
- 3 ☐ High school graduate or equivalent (GED)
- 4 ☐ Technical or vocational school
- 5 ☐ Some college
- 6 ☐ College graduate
- 7 ☐ Post-graduate degree
- 9 ☐ DK/Refused

Q3. What was the usual occupation that your spouse/partner had in the year before (RD)?

Name of Job

□□□

Q4. What type of health insurance did you have in the year before (RD) ? (Check all that apply.)

- 01 ☐ Medicaid
- 02 ☐ Medicare
- 03 ☐ Employer-provided insurance (like Oxford, Blue Cross/Blue Shield, HIP)
- 04 ☐ Pay for insurance out of pocket
- 05 ☐ I do not have health insurance
- 06 ☐ Other (specify): _____
- 99 ☐ DK/Refused

□□□

If R is under 65 years of age, ask Q5. Otherwise continue to Q6.

Q5. Did you have a residential telephone on (RD)?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK/Refused

Q6. Including income provided by you, your spouse/partner, and any other person living in your household, which range of figures on this card comes closest to your total household income before taxes for the last calendar year?

- 1 ☐ Less than \$15,000
- 2 ☐ \$15,000-\$19,999
- 3 ☐ \$20,000-24,999
- 4 ☐ \$25,000-34,999
- 5 ☐ \$35,000-49,999
- 6 ☐ \$50,000-69,999
- 7 ☐ \$70,000-89,999
- 8 ☐ \$90,000 or more
- 9 ☐ DK / Refused

Show
Card

Q7. How many people, including yourself, were supported by this income during the last calendar year?

(Number of people)

Complete this section after you have thanked and left the participant

INTERVIEW QUALITY

1. Where was the interview conducted?

- 1 ☐ Respondent's Home
 2 ☐ Hospital or MD Office
 3 ☐ Nursing Home
 4 ☐ MSSM
 5 ☐ Somewhere else, specify _____ | | | |
-

2. Was the respondent's overall cooperation:

- 1 ☐ Very good
 2 ☐ Good
 3 ☐ Fair (3)
 4 ☐ Poor (3)

3. The main reason for the unsatisfactory or questionable quality of information is because: (Check all that apply).

- 1 ☐ Did not know enough information regarding the topic
 2 ☐ Did not want to be more specific
 3 ☐ Did not understand or speak english well
 4 ☐ Was bored or uninterested
 5 ☐ Was upset or depressed
 6 ☐ Had poor hearing or speech
 7 ☐ Was confused by frequent interruptions
 8 ☐ Was emotionally unstable (drunk etc)
 9 ☐ Was physically ill
 10 ☐ Did not comprehend content
 11 ☐ Gave conflicting responses
 12 ☐ Other (specify) _____ | | | |
-

4. Other interviewer comments.

- 1 ☐ No Comments
 2 ☐ Comments Below

_____ | | | |
 _____ | | | |

ANTHROPOMETRY MEASUREMENTS DATA FORM

Measurements will be made on your right side. Have you had any past or present injuries on your right side that might make these measurements uncomfortable?

YES (SPECIFY) _____ 1

NO.....2

CLOTHING WORN BY WOMAN DURING MEASUREMENTS:

MEASUREMENT	1 ST READING	2 ND READING	DIFFERENCE BETWEEN 1 ST & 2 ND READING	TOLERANCE	3 RD READING
HEIGHT (CM)					
MIDARM CIRCUMFERENCE (CM)				0.2 CM	
WAIST CIRCUMFERENCE (CM)				2.0 CM	
HIP CIRCUMFERENCE (CM)				2.0 CM	

Do you have an electronic internal medical device (such as a pacemaker, ventricular assistive device, or implantable cardioverter defibrillator)?

YES..... 1 (DO NOT USE THE TANITA MACHINE; SKIP TO COMMENTS)

NO.....2

Do you have any other implants, such as hip or knee replacements, breast implants or replacements?

YES (SPECIFY) 1

NO.....2

COMMENTS:

**ATTACH TANITA BODY COMPOSITION
ANALYZER STRIP HERE**

1. If we need to contact you in the future, it is helpful to know the name of an individual outside your household who will always know your whereabouts. Are you willing to provide us the name, address, and phone number of a close friend or relative who does not live with you?

- 1 ☐ Yes
2 ☐ No/Refused (2)

Name: _____

First name and last name

Street : _____

Apt. # _____

City _____

State _____

Zipcode _____

Telephone: (____) - ____ - ____
area code

1a. What is [NAME'S] relationship to you?

- | | |
|--|---|
| 1 <input type="checkbox"/> mother | 8 <input type="checkbox"/> step son |
| 2 <input type="checkbox"/> father | 9 <input type="checkbox"/> daughter-in-law |
| 3 <input type="checkbox"/> son | 10 <input type="checkbox"/> son-in-law |
| 4 <input type="checkbox"/> daughter | 11 <input type="checkbox"/> friend |
| 5 <input type="checkbox"/> brother | 12 <input type="checkbox"/> spouse |
| 6 <input type="checkbox"/> sister | 13 <input type="checkbox"/> other (specify) |
| 7 <input type="checkbox"/> step daughter | _____ |

2. What is your social security number?

_____ - _____ - _____

- 1 ☐ Does not have one
9 ☐ DK / Refused

3. Are you willing to be contacted for other studies in the future that you are eligible for?

- 1 ☐ Yes 2 ☐ No 9 ☐ DK

(participant initials)

Study ID: _____

Interviewer Initials: _____

SECTION R. DIAGNOSIS AND TREATMENT INFORMATION

For Cases Only:

R1. Please list all of the physicians and hospitals/clinics that are (or were) involved in diagnosing and treating your breast condition.

1. Doctor: _____ Phone: (____) - ____ - ____

Treatment (Circle one):

Surgery Radiation Chemotherapy Other _____

Affiliated Hospital/Clinic _____

Address _____

City _____ State _____ Zip _____

2. Doctor: _____ Phone: (____) - ____ - ____

Treatment (Circle one):

Surgery Radiation Chemotherapy Other _____

Affiliated Hospital/Clinic _____

Address _____

City _____ State _____ Zip _____

3. Doctor: _____ Phone: (____) - ____ - ____

Treatment (Circle one):

Surgery Radiation Chemotherapy Other _____

Affiliated Hospital/Clinic _____

Address _____

City _____ State _____ Zip _____

4. Doctor: _____ Phone: (____) - ____ - ____

Treatment (Circle one):

Surgery Radiation Chemotherapy Other _____

Affiliated Hospital/Clinic _____

Address _____

City _____ State _____ Zip _____

5. Doctor: _____ Phone: (____) - ____ - ____

Treatment (Circle one):

Surgery Radiation Chemotherapy Other _____

Affiliated Hospital/Clinic _____

Address _____

City _____ State _____ Zip _____

PROJECT 2

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

PROJECT 2

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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. However, research in genetic counseling has shown that many counselees have difficulty comprehending probability information. 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; however, 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 White women. However, 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 White 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 White 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. Newly diagnosed African American breast cancer patients 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:

As indicated in our Statement of Work, Goal was to start recruiting participants into the study in month seven of the grant. Therefore, during year two, we would have expected to continue to recruit and enroll participants into the study and to be collecting study data. However, we have not been able to accomplish that goal as we are still waiting to receive IRB approval from the Department of Defense. We therefore propose to modify the timeline of all subject related tasks to add 24 months. Of note, in the past year, we have trained interviewers and research assistants to administer questionnaires during both telephone and in-person interviews. We have developed study databases in which to store the research data once we are able to begin recruitment. We have also continually responded to the HSRRB's requests for information or protocol alterations in a timely fashion.

KEY RESEARCH ACCOMPLISHMENTS:

At this point in the research, with no approval by the HSRRB of the USAMRAA, no results are yet available.

REPORTABLE OUTCOMES:

We have a pending grant application at the DOD. The pending grant is designed to investigate the Emotional, Biological and Cognitive Impact of a Brief Expressive Writing Intervention for African American Women at Familial Breast Cancer Risk.

CONCLUSIONS:

To date, we have developed and pilot tested the culturally tailored genetic counseling intervention and all questionnaires have been prepared, finalized the study protocol, and trained key research personnel. As we have not received HSRRB approval from the Department of Defense, we have been unable to recruit participants into the study.

REFERENCES:

None

APPENDICES:

- Appendix 1. Culturally tailored counseling
- Appendix 2. Take home counseling material
- Appendix 3. Study questionnaires

TACT – Tri-State Women's Circle of Health Project 2
Initial Telephone Interview

Participant ID#: _____ **Interviewer:** _____

Date: _____ **Time of Interview:** _____

TACT Initial Phone Interview Packet

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Interviewer Script

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TACT – Tri-State Women's Circle of Health Project 2
Initial Telephone Interview

Participant ID#: _____ **Interviewer:** _____

Date: _____ **Time of Interview:** _____

Hello, may I please speak with ____?

Same interviewer as Project 1:
Hello, this is ____ calling from the
Mount Sinai School of Medicine.
How are you?

Different interviewer than Project 1:
Hello, this is ____ calling from the
Mount Sinai School of Medicine. I
work with ____ (Project 1
interviewer's name); I am another
interviewer for the study.

I am calling because ____ (Genetic Counselor) had spoken to you and set up this
time for your telephone interview for the TACT project. Is this still a good time?

If yes, continue.

*If no, reschedule. Try to reschedule for before participant's initial genetic
counseling session. If this is not possible, inform participant that the telephone
interview must be completed before she comes in for her genetic counseling
session. Tell her that you will have the genetic counselor call her to reschedule her
genetic counseling session.*

Before we get started, I would like to say thank you for your time and your
continued participation in our studies.

Did you receive the packet that ____ (Genetic Counselor) sent you in the mail?

If yes:
You will need the set of colored cards
that came with your packet. On these
cards are the answers that you will
choose from for the different
questionnaires that you will be
answering.

If no:
I will let ____ (Genetic Counselor)
know that you did not receive your
packet.
*Continue with the telephone
interview. Leave out the references to
the colored answer keys, as the
participant will not have them in front
of her.*

Today I am going to be asking you questions about how you have been feeling and
your attitudes, opinions, and feelings related to breast cancer and genetic testing.
You may decline to answer any question if you do not want to answer it. The first

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

question that I am going to ask you is about genetic testing. The answer choices are on the yellow card that says “Genetic Testing” on the top.

GO TO “INTENTION TO UNDERGO GENETIC TESTING” and continue through the packet until all questionnaires have been answered.

TACT – Tri-State Women's Circle of Health Project 2
Initial Telephone Interview

POSSIBLE PARTICIPANT QUESTIONS WITH INTERVIEWER RESPONSES

What is the TACT project about?

The TACT project is part of the Tri-State Women's Circle of Health program, the same research study that you completed the interview with me for. This part of the study, the TACT project, offers genetic counseling and testing for inherited cancer free of charge. The goals of the study are to provide African American women with both standard genetic counseling and culturally tailored genetic counseling. The culturally tailored genetic counseling is designed specifically for women of African ancestry. We want to explore which counseling helps women to better understand the information that is presented in the genetic counseling session.

What is a genetic counselor/genetic counseling?

A genetic counselor works with people and families who have an increased risk to inherit a certain disease or condition. In the TACT study, the genetic counselor works with women who have been diagnosed with breast cancer, and who have a history of breast or ovarian cancer in their family. The genetic counselor's job is to give you information about how cancer can sometimes be passed down in families. She will also talk to you about genetic testing that may be able to tell you whether or not the cancer in your family is being passed down. Just because you come in for the genetic counseling session, that does not mean that you have to get genetic testing. It is completely up to you whether or not to be tested.

How long will the telephone interview take?

The telephone interview should take about 30 minutes to complete.

How long is the genetic counseling session?

As ____ (Genetic Counselor) probably already told you, there are some questionnaires that you will be filling out with an interviewer before your counseling session. Also keep in mind that how long the session lasts can vary from one person to the next. The genetic counseling session will take approximately 1½ to 2½ hours to complete.

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

INTENTION TO UNDERGO GENETIC TESTING

In a small number of families, several family members develop breast cancer, often at younger ages. Scientists believe that, in some of these families, women who develop breast cancer have inherited an altered gene that makes them susceptible to cancer. This gene is passed down from generation to generation in these families. Some family members will inherit an altered gene and others will not. It is now possible to perform a blood test to determine which members of these families have inherited this altered gene.

Now that such a blood test is currently available, which of the following best describes what your intentions are?

- _____ I have already donated a blood sample for genetic testing
- _____ I plan to take the test as soon as possible
- _____ I plan to take the test sometime in the near future
- _____ I do not plan to take the test in the near future
- _____ I do not plan to take the test at all
- _____ Don’t Know/Refused

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

BSI

The answer choices for this next set of questions are on the orange card that says “BSI” on top.

I’m going to read you a list of problems and complaints that people sometimes have. Using the scale 1=not at all, 2=a little bit, 3=moderately, 4=quite a bit, and 5=extremely, please describe **how much discomfort that problem has caused you during the past week, including today.**

During the past week, how much were you distressed by:

	Not at all	A little bit	Moderately	Quite a Bit	Extremely	Don't Know/ Refused
1. Nervousness or shakiness inside	1	2	3	4	5	DK
2. Thoughts of ending your life	1	2	3	4	5	DK
3. Suddenly scared for no reason	1	2	3	4	5	DK
4. Feeling lonely	1	2	3	4	5	DK
5. Feeling fearful	1	2	3	4	5	DK
6. Feeling blue	1	2	3	4	5	DK
7. Feeling not interested in things	1	2	3	4	5	DK
8. Feeling tense or keyed up	1	2	3	4	5	DK
9. Spells of terror or panic	1	2	3	4	5	DK
10. Feeling hopeless about the future	1	2	3	4	5	DK
11. Feeling so restless you couldn't sit still	1	2	3	4	5	DK
12. Feeling of worthlessness	1	2	3	4	5	DK

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview
CESD

The answer choices for this next set of questions are on the white card that says “CESD” on top.

I’m going to read you a list of statements that describe ways people sometimes feel or behave. Using the scale 1=rarely or none of the time (less than 1 day), 2=some or a little of the time (1-2 days), 3=occasionally or a moderate amount of time (3-4 days) and 4=most or all of the time (5-7 days), please describe how often you felt or behaved this way **during the past week**.

	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)	Don’t Know/ Refused
--	--	---	---	--	---------------------------

During the past week:

- | | | | | | |
|--|---|---|---|---|----|
| 1. I was bothered by things that usually don’t bother me. | 1 | 2 | 3 | 4 | DK |
| 2. I did not feel like eating; my appetite was poor. | 1 | 2 | 3 | 4 | DK |
| 3. I felt that I could not shake off the blues even with the help of my family or friends. | 1 | 2 | 3 | 4 | DK |
| 4. I felt I was just as good as other people. | 1 | 2 | 3 | 4 | DK |
| 5. I had trouble keeping my mind on what I was doing. | 1 | 2 | 3 | 4 | DK |
| 6. I felt depressed. | 1 | 2 | 3 | 4 | DK |
| 7. I felt that everything I did was an effort. | 1 | 2 | 3 | 4 | DK |
| 8. I felt hopeful about the future. | 1 | 2 | 3 | 4 | DK |
| 9. I thought my life had been a failure. | 1 | 2 | 3 | 4 | DK |
| 10. I felt fearful. | 1 | 2 | 3 | 4 | DK |

Please continue on to the next page

TACT – Tri-State Women's Circle of Health Project 2
Initial Telephone Interview

CESD-Continued

	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)	Don't Know/ Refused
<u>During the past week:</u>					
11. My sleep was restless.	1	2	3	4	DK
12. I was happy.	1	2	3	4	DK
13. I talked less than usual.	1	2	3	4	DK
14. I felt lonely.	1	2	3	4	DK
15. People were unfriendly.	1	2	3	4	DK
16. I enjoyed life.	1	2	3	4	DK
17. I had crying spells.	1	2	3	4	DK
18. I felt sad.	1	2	3	4	DK
19. I felt that people disliked me.	1	2	3	4	DK
20. I could not get 'going'.	1	2	3	4	DK

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

IES

The answer choices for this next set of questions are on the lime green card that says “IES” on top.

I’m going to read you a list of comments made by people after stressful life events. Using the scale 1=not at all, 2= rarely, 3=sometimes, and 4=often, please indicate how frequently these comments were true for you about breast cancer DURING THE PAST WEEK, INCLUDING TODAY.

	Not at all	Rarely	Some- times	Often	Don’t Know/ Refused
1. I thought about it when I didn't mean to.	1	2	3	4	DK
2. I avoided letting myself get upset when I thought about it or was reminded of it.	1	2	3	4	DK
3. I tried to remove it from memory.	1	2	3	4	DK
4. I had trouble falling asleep or staying asleep.	1	2	3	4	DK
5. I had waves of strong feelings about it.	1	2	3	4	DK
6. I had dreams about it.	1	2	3	4	DK
7. I stayed away from reminders of it.	1	2	3	4	DK
8. I felt as if it was unreal.	1	2	3	4	DK
9. I tried not to talk about it.	1	2	3	4	DK
10. Pictures about it popped into my mind.	1	2	3	4	DK
11. Other things kept making me think about it.	1	2	3	4	DK
12. I was aware that I had a lot of feelings about it, but I didn't deal with them.	1	2	3	4	DK
13. I tried not to think about it.	1	2	3	4	DK
14. Any reminder brought back feelings about it.	1	2	3	4	DK
15. My feelings about it were kind of numb.	1	2	3	4	DK
** Have these experiences (#1-15, above) interfered with your daily activities?	1	2	3	4	DK

TACT – Tri-State Women’s Circle of Health Project 2

Initial Telephone Interview

Illness Perception

The answer choices for this next set of questions are on the turquoise card that says “Agree Scale (4)” on top.

We are interested in your own personal views of how you see your breast cancer. Research has shown that ideas about how illness develops are related to other health behaviors such as plans for treatment. Using the scale 1=strongly agree, 2=agree, 3=disagree, and 4=strongly disagree, please indicate how much you agree or disagree with the following statements that I will read to you:

		Strongly Agree	Agree	Disagree	Strongly Disagree	Don't Know/ Refused
1	A germ or virus caused my breast cancer	1	2	3	4	DK
2	Diet played a major role in causing my breast cancer	1	2	3	4	DK
3	Pollution of the environment caused my breast cancer	1	2	3	4	DK
4	My breast cancer is hereditary – it runs in my family	1	2	3	4	DK
5	It was just by chance that I developed breast cancer	1	2	3	4	DK
6	Stress was a major factor in causing my breast cancer	1	2	3	4	DK
7	My breast cancer is largely due to my own behavior	1	2	3	4	DK
8	Other people played a large role in causing my breast cancer	1	2	3	4	DK
9	My breast cancer was caused by poor medical care in the past	1	2	3	4	DK
10	My state of mind played a major part in causing my breast cancer	1	2	3	4	DK
11	A hex or a curse is responsible for my breast cancer	1	2	3	4	DK
12	Fate or destiny is responsible for my breast cancer	1	2	3	4	DK
13	Having a pessimistic or negative outlook on life caused me to develop breast cancer	1	2	3	4	DK
14	Injury to my breast(s), such as being hit, caused my breast cancer	1	2	3	4	DK
15	Drinking alcohol is a major cause of my breast cancer	1	2	3	4	DK

Please continue on to the next page.

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

Illness Perception-Continued

		Strongly Agree	Agree	Disagree	Strongly Disagree	Don’t Know/ Refused
16	Smoking is a major cause of my breast cancer	1	2	3	4	DK
17	Using street drugs played a major role in my breast cancer	1	2	3	4	DK
18	Failing to live in harmony with nature is what caused my breast cancer	1	2	3	4	DK
19	My breast cancer is a punishment from God	1	2	3	4	DK
20	Toxins in my food caused my breast cancer	1	2	3	4	DK
21	Having sex is what caused my breast cancer	1	2	3	4	DK
22	Taking birth control pills played a major role in my breast cancer	1	2	3	4	DK
23	I don’t know what caused my breast cancer	1	2	3	4	DK

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

Time Orientation

For the next set of statements that I will be reading to you, please indicate how much you agree or disagree with each statement using the scale 1=strongly agree, 2=agree, 3=disagree, and 4=strongly disagree. You will again be using the answer choices on the turquoise card that says “Agree Scale (4)” on top.

	Strongly Agree	Agree	Disagree	Strongly Disagree	Don’t Know/Refused
1. My day-to-day life is too busy to think about the future.	1	2	3	4	DK
2. If I want something now, I always buy it no matter what the price.	1	2	3	4	DK
3. There’s no sense in thinking about the future before it gets here.	1	2	3	4	DK
4. What happens to me in the future is out of my control.	1	2	3	4	DK
5. As long as I feel good now, I don’t worry about having health problems later in life.	1	2	3	4	DK
6. I have a plan for what I want to do in the next 5 years of my life.	1	2	3	4	DK
7. I often save money or use layaway to buy things I can’t afford right now.	1	2	3	4	DK
8. The choices I have made in life clearly show that I think about the future.	1	2	3	4	DK
9. When I plan a party or get-together, I always start weeks ahead of time.	1	2	3	4	DK
10. I often think about how my actions today will affect my health when I am older.	1	2	3	4	DK

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

Attitudes Towards Genetic Testing

The next set of statements that I will be reading to you relate to your feelings towards genetic testing. You will still be using the answers on the pink card to indicate how much you agree or disagree with each statement.

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't Know/ Refused
1. The results of genetic tests are used to treat certain people unfairly.	1	2	3	4	5	DK
2. Genetic testing allows doctors and scientists to “play God.”	1	2	3	4	5	DK
3. Genetic testing is used to show that my ethnic or racial group is not as good as other groups.	1	2	3	4	5	DK
4. Genetic testing is used to interfere with the way God intended people to be.	1	2	3	4	5	DK
5. Genetic testing is used to interfere with the “natural order” of life.	1	2	3	4	5	DK

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview
Genetic Testing Pros and Cons

I am now going to read you a list of statements about your attitudes toward genetic testing for cancer. You will still be using the answers on the pink card to indicate how much you agree or disagree with each statement.

		Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't Know/Refused
1	My concerns about getting breast cancer again would be reduced if I knew I did not carry the gene mutation.	1	2	3	4	5	DK
2	Knowing whether I had the gene mutation would increase my sense of personal control.	1	2	3	4	5	DK
3	Knowing whether I have the gene mutation or not would help me make important life decisions (e.g., getting married, having children).	1	2	3	4	5	DK
4	If the test showed that my risk is high, my family members might have trouble getting health insurance.	1	2	3	4	5	DK
5	I believe that genetic testing may be harmful to me or my family.	1	2	3	4	5	DK
6	If I were found to carry the gene mutation, it would help my daughter(s) or sister(s) decide whether to undergo genetic testing.	1	2	3	4	5	DK
7	My genetic test results could give my family members useful information about their risk of getting cancer.	1	2	3	4	5	DK
8	My genetic test results could help my family members make better decisions about how to take care of their health.	1	2	3	4	5	DK
9	Genetic testing would help me learn if my children were at increased risk for getting breast cancer.	1	2	3	4	5	DK

Please continue on to the next page

TACT – Tri-State Women's Circle of Health Project 2
Initial Telephone Interview

Genetic Testing Pros and Cons - Continued

		Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't Know/ Refused
10	If I underwent genetic testing for cancer, I would be concerned about the effect it would have on my family.	1	2	3	4	5	DK
11	If I were found to carry the gene mutation for breast cancer, I would worry about passing the gene to my children.	1	2	3	4	5	DK
12	Knowing that I carry the gene mutation would cause me to worry more about other family members who could be carriers (e.g., mother, sisters, daughters).	1	2	3	4	5	DK
13	If I were found to carry the gene mutation for breast cancer, I would feel guilty if my daughter(s) developed breast cancer.	1	2	3	4	5	DK
14	I would feel guilty if one of my relatives had the gene mutation and I did not.	1	2	3	4	5	DK
15	If I were found to carry a gene mutation for cancer, I would feel singled out.	1	2	3	4	5	DK
16	If I were found to carry a gene mutation for cancer, it would cause others to view me negatively.	1	2	3	4	5	DK
17	Knowing that I carry the gene mutation would cause me to feel less healthy than other people.	1	2	3	4	5	DK
18	I would be ashamed if I were found to carry the gene mutation.	1	2	3	4	5	DK
19	I would be frightened if I were found to carry the gene mutation.	1	2	3	4	5	DK
20	I would be angry if I were found to carry the gene mutation.	1	2	3	4	5	DK

Please continue on to the next page

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

Genetic Testing Pros and Cons - Continued

		Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't Know/Refused
21	Knowing that I carry the gene mutation would leave me in a state of hopelessness and despair.	1	2	3	4	5	DK
22	I would consider suicide if I were found to carry the gene mutation for breast cancer.	1	2	3	4	5	DK
23	If I underwent genetic testing for cancer, I would not be able to handle it emotionally.	1	2	3	4	5	DK
24	If I were found to carry the gene mutation, I would worry that the results would not stay confidential.	1	2	3	4	5	DK
25	Being tested for the gene mutation could jeopardize my insurance coverage.	1	2	3	4	5	DK
	As long as I am feeling good now, it is not important to obtain genetic testing for cancer.	1	2	3	4	5	DK
27	I don't have time to obtain genetic testing for cancer.	1	2	3	4	5	DK
28	Knowing that I carry the gene mutation would motivate me to perform breast self-examination more frequently.	1	2	3	4	5	DK
29	Knowing that I carry the gene mutation would help me decide whether to go for more frequent mammograms.	1	2	3	4	5	DK
30	Knowing that I carry the gene mutation would help me to decide whether to undergo bilateral mastectomy (an operation to remove both breasts).	1	2	3	4	5	DK

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

After questionnaires are complete:

Those are all of the questions that I had to ask you today. Thank you so much for taking the time to complete today’s interview. As a reminder, your genetic counseling session is scheduled for ____ (date) at ____ (time) with ____ (Genetic Counselor).

If participant indicates that she can no longer meet the genetic counselor at this time, tell her that the genetic counselor will call her to reschedule and then let the genetic counselor know that the participant needs to reschedule her appointment.

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

Participant ID#: _____ **Interviewer:** _____

Date: _____ **Time of Interview:** _____

TACT Pre-Counseling Interview Packet

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TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

Participant ID#: _____ **Interviewer:** _____

Date: _____ **Time of Interview:** _____

Introduction

Hello, my name is _____ and I am a (job title) for the TACT program.

Description of the Procedure

Before you complete the genetic counseling, we are asking you to complete another interview. The questions you will be asked are about ideas such as ethnic identity and beliefs and attitudes about the African American community. Because these ideas may not seem like they are related to breast cancer, we wanted to complete these questionnaires in person, so that you can have a chance to ask questions. Some people might find it surprising that we are asking about these ideas. Research shows that these beliefs and attitudes can be related to what people do regarding health, as well as their experiences with illness. There are also some questions that I will ask you about genetics.

So let's get started. If you have any questions as we go along, please just stop me.

GO TO "INTENTION TO UNDERGO GENETIC TESTING" and continue through the packet until all questionnaires have been answered.

TACT – Tri-State Women's Circle of Health Project 2
Initial Telephone Interview

POSSIBLE PARTICIPANT QUESTIONS WITH INTERVIEWER RESPONSES

What is the TACT project about?

The TACT project is part of the Tri-State Women's Circle of Health program, the same research study that you completed the interview with me for. This part of the study, the TACT project, offers genetic counseling and testing for inherited cancer free of charge. The goals of the study are to provide African American women with both standard genetic counseling and culturally tailored genetic counseling. The culturally tailored genetic counseling is designed specifically for women of African ancestry. We want to explore which counseling helps women to better understand the information that is presented in the genetic counseling session.

What is a genetic counselor/genetic counseling?

A genetic counselor works with people and families who have an increased risk to inherit a certain disease or condition. In the TACT study, the genetic counselor works with women who have been diagnosed with breast cancer, and who have a history of breast or ovarian cancer in their family. The genetic counselor's job is to give you information about how cancer can sometimes be passed down in families. She will also talk to you about genetic testing that may be able to tell you whether or not the cancer in your family is being passed down. Just because you come in for the genetic counseling session, that does not mean that you have to get genetic testing. It is completely up to you whether or not to be tested.

How long will this interview take?

This interview should take about 30 minutes to complete.

How long is the genetic counseling session?

As ____ (Genetic Counselor) probably already told you, there are some questionnaires that you will be filling out with an interviewer before your counseling session. Also keep in mind that how long the session lasts can vary from one person to the next. The genetic counseling session will take approximately 1½ to 2½ hours to complete.

TACT – Tri-State Women's Circle of Health Project 2

Initial Telephone Interview

Coping #1

We are interested in what strategies you have been using to cope with your diagnosis of breast cancer. Using the scale 1=did not use or not applicable, 2=used a little, 3=used a lot, and 4=used a great deal, please indicate how much you have used the following strategies.

		Did not use or N/A	Used a little	Used a lot	Used a great deal	Don't know/ Refused
1	Prayed that things would work themselves out	1	2	3	4	DK
2	Got a group of family or friends together to help	1	2	3	4	DK
3	Shared my feelings with a friend or family member	1	2	3	4	DK
4	Remembered what a parent (or other relative) once said about dealing with these kinds of situations	1	2	3	4	DK
5	Tried to forget about it	1	2	3	4	DK
6	Went to church (or other religious meeting) to get help from the group	1	2	3	4	DK
7	Thought of all the struggles Black people have had to endure and this gave me strength to deal with it	1	2	3	4	DK
8	To keep from thinking about it I found other things to keep me busy	1	2	3	4	DK
9	Sought advice about how to handle it from an older person in my family or community	1	2	3	4	DK
10	Read a scripture from the Bible (or similar book) for comfort and/or guidance	1	2	3	4	DK
11	Asked for suggestions on how to deal with the situation during a meeting of my organization or club	1	2	3	4	DK
12	Tried to convince myself that it wasn't that bad	1	2	3	4	DK
13	Asked someone to pray for me	1	2	3	4	DK

TACT – Tri-State Women’s Circle of Health Project 2

Initial Telephone Interview

Coping #1 (continued)

14	Spent more time than usual doing things with friends or family	1	2	3	4	DK
15	Hoped that things would get better with time	1	2	3	4	DK
16	Spent more time than usual doing group activities	1	2	3	4	DK
17	Sought out people I thought would make me laugh	1	2	3	4	DK
18	Got dressed up in my best clothing	1	2	3	4	DK
19	Attended a social event (dance, party, movie) to reduce stress	1	2	3	4	DK
20	Read passage from a daily meditation book	1	2	3	4	DK
21	Asked for blessings from a spiritual or religious person	1	2	3	4	DK
22	Sung a song to myself to help reduce the stress	1	2	3	4	DK
23	Helped others with their problems	1	2	3	4	DK
24	Sought emotional support from family and friends	1	2	3	4	DK
25	Lit a candle for strength or guidance	1	2	3	4	DK
26	Burned incense for strength or guidance	1	2	3	4	DK
27	Found myself watching more comedy shows on TV	1	2	3	4	DK
28	Left matters in God’s hands	1	2	3	4	DK
29	Used a cross or other object for its special powers	1	2	3	4	DK

TACT – Tri-State Women’s Circle of Health Project 2

Initial Telephone Interview

Medical Mistrust

These questions ask about your beliefs about the care you and other people of your racial and ethnic group receive from doctors, nurses, and other staff people in the health care system. Using the scale 1=strongly agree, 2=agree, 3=neither agree nor disagree, 4=disagree, and 5=strongly disagree, please indicate how much you agree or disagree with the following statements.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't Know/ Refused
1. Doctors and health care workers sometimes hide information from patients who belong to my ethnic group.	1	2	3	4	5	DK
2. Doctors have the best interests of people of my ethnic group in mind.	1	2	3	4	5	DK
3. People of my ethnic group should not confide in doctors and health care workers because it will be used against them.	1	2	3	4	5	DK
4. People of my ethnic group should be suspicious of information from doctors and health care workers.	1	2	3	4	5	DK
5. People of my ethnic group cannot trust doctors and health care workers.	1	2	3	4	5	DK
6. I prefer to see doctors and health care workers who belong to my ethnic group.	1	2	3	4	5	DK
7. People of my ethnic group should be suspicious of modern medicine.	1	2	3	4	5	DK
8. Doctors and health care workers treat people of my ethnic group like “guinea pigs”.	1	2	3	4	5	DK
9. People of my ethnic group receive the same medical care from doctors and health care workers as people from other groups.	1	2	3	4	5	DK
10. Doctors and health care workers do not take the medical complaints of people of my ethnic group seriously.	1	2	3	4	5	DK
11. People of my ethnic group are treated the same as people of other groups by doctors and health care workers.	1	2	3	4	5	DK

TACT – Tri-State Women’s Circle of Health Project 2

Initial Telephone Interview

Medical Mistrust (Continued)

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don’t Know/ Refused
12. I don’t feel comfortable with doctors or health care workers who don’t belong to my ethnic group.	1	2	3	4	5	DK
13. In most hospitals, people of different ethnic groups receive the same kind of care.	1	2	3	4	5	DK
14. I have personally been treated poorly or unfairly by doctors or health care workers because of my ethnicity.	1	2	3	4	5	DK

Please think of your primary care physician or the doctor you see most often. Which of the following would best describe the doctor’s racial or ethnic background?

- 1 Black American/African American
- 2 Afro-Caribbean/West Indian
- 3 African
- 4 Hispanic
- 5 White
- 6 Asian
- 7 Other _____

How much would you say that you trust that doctor?

- 1 Not at all
- 2 A little bit
- 3 A moderate amount
- 4 Very much
- 5 Completely

TACT – Tri-State Women's Circle of Health Project 2

Initial Telephone Interview

Identity

Every person is born into an ethnic group, or sometimes more than one, but people differ on how important their ethnicity is to them, how they feel about it, and how much their behavior is affected by it. These questions are about your ethnic group and how you feel about it or react to it. Using the scale 1=strongly agree, 2=agree, 3=disagree and 4=strongly disagree, please indicate how much you agree or disagree with the following statements.

		Strongly Agree	Agree	Disagree	Strongly Disagree	Don't Know/ Refused
1	I have spent time trying to find out more about my own ethnic group, such as its history, traditions, and customs.	1	2	3	4	DK
2	I am active in organizations or social groups that include mostly members of my own ethnic group.	1	2	3	4	DK
3	I have a clear sense of my ethnic background and what it means for me.	1	2	3	4	DK
4	I like meeting and getting to know people from ethnic groups other than my own.	1	2	3	4	DK
5	I think a lot about how my life will be affected by my ethnic group membership.	1	2	3	4	DK
6	I am happy that I am a member of the group I belong to.	1	2	3	4	DK
7	I sometimes feel it would be better if different ethnic groups didn't try to mix together.	1	2	3	4	DK
8	I am not very clear about the role of ethnicity in my life.	1	2	3	4	DK
9	I often spend time with people from ethnic groups other than my own.	1	2	3	4	DK
10	I really have not spent much time trying to learn more about the culture and history of my ethnic group.	1	2	3	4	DK
11	I have a strong sense of belonging to my own ethnic group.	1	2	3	4	DK
12	I understand pretty well what my ethnic group membership means to me, in terms of how to relate to my own group and other groups.	1	2	3	4	DK
13	In order to learn more about my ethnic background, I have often talked to other people about my ethnic group.	1	2	3	4	DK
14	I have a lot of pride in my ethnic group and its accomplishments.	1	2	3	4	DK
15	I don't try to become friends with people from other ethnic groups.	1	2	3	4	DK
16	I participate in cultural practices of my own group, such as special food, music, or customs.	1	2	3	4	DK
17	I am involved in activities with people from other ethnic groups.	1	2	3	4	DK
18	I feel a strong attachment towards my own ethnic group.	1	2	3	4	DK
19	I enjoy being around people from ethnic groups other than my own.	1	2	3	4	DK
20	I feel good about my cultural or ethnic background.	1	2	3	4	DK

TACT – Tri-State Women's Circle of Health Project 2

Initial Telephone Interview

Identity (Continued)

21	Overall, being Black has very little to do with how I feel about myself.	1	2	3	4	DK
22	In general, being Black is an important part of my self-image.	1	2	3	4	DK
23	My destiny is tied to the destiny of other Black people.	1	2	3	4	DK
24	Being Black is unimportant to my sense of what kind of person I am.	1	2	3	4	DK
25	I have a strong sense of belonging to Black people.	1	2	3	4	DK
26	I have a strong attachment to other Black people.	1	2	3	4	DK
27	Being Black is an important reflection of who I am.	1	2	3	4	DK
28	Being Black is not a major factor in my social relationships.	1	2	3	4	DK

TACT – Tri-State Women's Circle of Health Project 2
Initial Telephone Interview
Africentrism

Answer each item by telling me the number which best reflects **your** feelings.

Strongly Agree = 1

Agree = 2

Disagree = 3

Strongly Disagree = 4

- | | | | | |
|--|---|---|---|---|
| 1. Black people should make their community better than it was when they found it. | 1 | 2 | 3 | 4 |
| 2. The problems of other Blacks are their problems, not mine. | 1 | 2 | 3 | 4 |
| 3. The unity of the African race is very important to me | 1 | 2 | 3 | 4 |
| 4. I am more concerned with reaching my own goals than with working for the Black community. | 1 | 2 | 3 | 4 |
| 5. I have very little faith in Black people. | 1 | 2 | 3 | 4 |
| 6. I owe something to Black people who suffered before me. | 1 | 2 | 3 | 4 |
| 7. Black people need to stop worrying so much about "the community" and take care of their own needs. | 1 | 2 | 3 | 4 |
| 8. I am doing a lot to improve my neighborhood. | 1 | 2 | 3 | 4 |
| 9. The success I have had is mainly because of me, not anyone else. | 1 | 2 | 3 | 4 |
| 10. I have more confidence in White professionals, like doctors and teachers, than in Black professionals. | 1 | 2 | 3 | 4 |
| 11. Black people should build and maintain their own communities. | 1 | 2 | 3 | 4 |
| 12. I must do all I can to restore Black people to their position of respect in the world. | 1 | 2 | 3 | 4 |

TACT – Tri-State Women’s Circle of Health Project 2

Initial Telephone Interview

Africentrism (continued)

Strongly Agree =1

Agree = 2

Disagree = 3

Strongly Disagree = 4

- | | | | | |
|---|---|---|---|---|
| 13. I make it a point to shop at Black businesses and use Black-owned services. | 1 | 2 | 3 | 4 |
| 14. It hurts me when I see another Black person discriminated against. | 1 | 2 | 3 | 4 |
| 15. It is important that Black people decide for themselves what to be called and what their needs are. | 1 | 2 | 3 | 4 |

TACT – Tri-State Women’s Circle of Health Project 2

Initial Telephone Interview

Genetic Knowledge

The next of questions are about genetics and cancer. For each statement that I read to you, please tell me whether you think the statement is true, false, or if you don’t know the answer.

		True	False	Don’t Know
1.	50% of inherited genetic information (about breast cancer risk) is passed down from a person’s mother.	T	F	DK
2.	25% of inherited genetic information (about breast cancer risk) is passed down from a person’s father.	T	F	DK
3.	There is more than one gene that can increase the risk of breast cancer.	T	F	DK
4.	A woman who has a sister with a breast cancer gene mutation has a 1 in 4 chance of having a gene mutation herself.	T	F	DK
5.	A father can pass down a breast cancer gene mutation to his daughters.	T	F	DK
6.	One in 10 women has a breast cancer gene mutation.	T	F	DK
7.	All women who have a breast cancer gene mutation will get cancer.	T	F	DK
	If the currently available genetic tests were to indicate that a woman has a breast cancer gene mutation, she is at increased risk for:			
8.	Breast cancer	T	F	DK
9.	Ovarian cancer	T	F	DK
10.	Lung cancer	T	F	DK
11.	Bladder cancer	T	F	DK
	If a woman who already had breast cancer was found to have a breast cancer gene mutation, she is at increased risk for developing:			
12.	Another breast cancer	T	F	DK
13.	Ovarian cancer	T	F	DK
14.	Lung cancer	T	F	DK
15.	Bladder cancer	T	F	DK
16.	Women who test positive for breast cancer gene mutations are generally more likely to develop breast cancer at a young age.	T	F	DK

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

	<i>Genetic Knowledge, Continued...</i>	True	False	Don't Know
17.	A man who carries a breast cancer gene mutation has an increased risk of developing breast cancer himself.	T	F	DK
18.	If a woman tests positive for a breast cancer gene mutation, her male relatives' risk for developing prostate cancer are lowered.	T	F	DK
19.	A woman may be at greater risk for developing ovarian cancer if she has several close relatives with ovarian cancer.	T	F	DK
20.	A woman may be at greater risk for developing ovarian cancer if she has several close relatives with breast cancer.	T	F	DK
21.	A woman who has her healthy ovaries removed will definitely not get ovarian cancer.	T	F	DK
22.	A woman who has her breasts removed will definitely not get breast cancer.	T	F	DK
23.	Screening for ovarian cancer often does not detect a tumor until it is more advanced.	T	F	DK

24. How many copies of a non-working breast cancer gene must one inherit to be at inherited risk for breast cancer?
- a. 0
 - b. 1
 - c. 2
 - d. 3
 - e. Don't know
25. What is the approximate risk that the average woman in the United States will develop breast cancer in her lifetime?
- a. 12%
 - b. 24%
 - c. 58%
 - d. 72%
 - e. Don't know
26. If a genetic test were to indicate that a woman inherited a breast cancer gene mutation, then how likely is she to develop breast cancer in her lifetime?
- a. up to 15% chance
 - b. up to 25% chance
 - c. up to 40% chance
 - d. up to 50% chance
 - e. up to 85% chance
 - f. Don't know
27. Select the procedure that is NOT appropriate for the detection of ovarian cancer:
- a. ultrasound
 - b. pap smear
 - c. CA-125 blood test
 - d. pelvic examination
 - e. Don't know

TACT – Tri-State Women's Circle of Health Project 2
Initial Telephone Interview

After questionnaires are complete:

Those are all of the questions that I had to ask you today. Thank you so much for taking the time to complete today's interview. Now you will meet with ____ (Genetic Counselor) for your genetic counseling session.

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

Participant ID#: _____ **Interviewer:** _____

Date: _____ **Time of Interview:** _____

TACT Follow-Up Phone Interview Packet

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g. Genetic Testing Pros and Cons

13-15

h. Satisfaction with Decision Making

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i. Adherence

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j. Results Disclosure to Family Members

20-21

TACT – Tri-State Women's Circle of Health Project 2
Initial Telephone Interview

Participant ID#: _____ **Interviewer:** _____

Date: _____ **Time of Interview:** _____

Hello, may I please speak with _____?

Same interviewer as Initial Telephone Interview or Project 1 Interview:
Hello, this is _____ calling from the Mount Sinai School of Medicine. How are you?

Different interviewer than Initial Telephone Interview or Project 1 Interview:
Hello, this is _____ calling from the Mount Sinai School of Medicine. I work with _____ (genetic counselor's name) on the TACT study.

I am calling because _____ (Genetic Counselor) had spoken to you and set up this time for your telephone interview for the TACT project. Is this still a good time?

If yes, continue.

If no, reschedule.

Before we get started, I would like to say thank you for your time and your continued participation in our studies.

Did you receive the packet that _____ (Genetic Counselor) sent you in the mail?

If yes:
You will need the set of colored cards that came with your packet. On these cards are the answers that you will choose from for the different questionnaires that you will be answering.

If no:
I will let _____ (Genetic Counselor) know that you did not receive your packet. *Continue with the telephone interview. Leave out the references to the colored answer keys, as the participant will not have them in front of her.*

Today I am going to be asking you questions about how you have been feeling and your attitudes, opinions, and feelings related to breast cancer and genetic testing. You may decline to answer any question if you do not want to answer it. For the first set of questions that I am going to ask you, the answer choices are on the orange card that says "BSI" on top.

GO TO "BSI" and continue through the packet until all questionnaires have been answered.

TACT – Tri-State Women's Circle of Health Project 2
Initial Telephone Interview

Potential Participant Questions

How long will the telephone interview take?

The telephone interview should take about 45 minutes to complete.

After today's interview, am I finished with the study?

Once you have completed today's phone interview and you have sent back the packet of questionnaires that ____ (Genetic Counselor) mailed to you, then you will be finished with the study.

If participant has not received packet of questionnaires, inform genetic counselor.

If participant has any questions regarding the genetic counseling session or genetic testing results, tell the participant that you will have the genetic counselor call her back and inform the genetic counselor of the inquiry.

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

BSI

The answer choices for this next set of questions are on the orange card that says “BSI” on top.

I’m going to read you a list of problems and complaints that people sometimes have. Using the scale 1=not at all, 2=a little bit, 3=moderately, 4=quite a bit, and 5=extremely, please describe **how much discomfort that problem has caused you during the past week, including today.**

During the past week, how much were you distressed by:

	Not at all	A little bit	Moderately	Quite a Bit	Extremely	Don’t Know/ Refused
1. Nervousness or shakiness inside	1	2	3	4	5	DK
2. Thoughts of ending your life	1	2	3	4	5	DK
3. Suddenly scared for no reason	1	2	3	4	5	DK
4. Feeling lonely	1	2	3	4	5	DK
5. Feeling fearful	1	2	3	4	5	DK
6. Feeling blue	1	2	3	4	5	DK
7. Feeling not interested in things	1	2	3	4	5	DK
8. Feeling tense or keyed up	1	2	3	4	5	DK
9. Spells of terror or panic	1	2	3	4	5	DK
10. Feeling hopeless about the future	1	2	3	4	5	DK
11. Feeling so restless you couldn’t sit still	1	2	3	4	5	DK
12. Feeling of worthlessness	1	2	3	4	5	DK

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview
CESD

The answer choices for this next set of questions are on the white card that says “CESD” on top.

I’m going to read you a list of statements that describe ways people sometimes feel or behave. Using the scale 1=rarely or none of the time (less than 1 day), 2=some or a little of the time (1-2 days), 3=occasionally or a moderate amount of time (3-4 days) and 4=most or all of the time (5-7 days), please describe how often you felt or behaved this way **during the past week**.

Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)	Don’t Know/ Refused
--	---	---	--	---------------------------

During the past week:

1. I was bothered by things that usually don’t bother me.	1	2	3	4	DK
2. I did not feel like eating; my appetite was poor.	1	2	3	4	DK
3. I felt that I could not shake off the blues even with the help of my family or friends.	1	2	3	4	DK
4. I felt I was just as good as other people.	1	2	3	4	DK
5. I had trouble keeping my mind on what I was doing.	1	2	3	4	DK
6. I felt depressed.	1	2	3	4	DK
7. I felt that everything I did was an effort.	1	2	3	4	DK
8. I felt hopeful about the future.	1	2	3	4	DK
9. I thought my life had been a failure.	1	2	3	4	DK
10. I felt fearful.	1	2	3	4	DK

Please continue on to the next page

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview
CESD-Continued

	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)	Don’t Know/ Refused
--	--	---	---	--	---------------------------

During the past week:

11. My sleep was restless.	1	2	3	4	DK
12. I was happy.	1	2	3	4	DK
13. I talked less than usual.	1	2	3	4	DK
14. I felt lonely.	1	2	3	4	DK
15. People were unfriendly.	1	2	3	4	DK
16. I enjoyed life.	1	2	3	4	DK
17. I had crying spells.	1	2	3	4	DK
18. I felt sad.	1	2	3	4	DK
19. I felt that people disliked me.	1	2	3	4	DK
20. I could not get ‘going’.	1	2	3	4	DK

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview
IES

The answer choices for this next set of questions are on the lime green card that says “IES” on top.

I’m going to read you a list of comments made by people after stressful life events. Using the scale 1=not at all, 2= rarely, 3=sometimes, and 4=often, please indicate how frequently these comments were true for you about breast cancer DURING THE PAST WEEK, INCLUDING TODAY.

	Not at all	Rarely	Some- times	Often	Don’t Know/ Refused
1. I thought about it when I didn't mean to.	1	2	3	4	DK
2. I avoided letting myself get upset when I thought about it or was reminded of it.	1	2	3	4	DK
3. I tried to remove it from memory.	1	2	3	4	DK
4. I had trouble falling asleep or staying asleep.	1	2	3	4	DK
5. I had waves of strong feelings about it.	1	2	3	4	DK
6. I had dreams about it.	1	2	3	4	DK
7. I stayed away from reminders of it.	1	2	3	4	DK
8. I felt as if it was unreal.	1	2	3	4	DK
9. I tried not to talk about it.	1	2	3	4	DK
10. Pictures about it popped into my mind.	1	2	3	4	DK
11. Other things kept making me think about it.	1	2	3	4	DK
12. I was aware that I had a lot of feelings about it, but I didn't deal with them.	1	2	3	4	DK
13. I tried not to think about it.	1	2	3	4	DK
14. Any reminder brought back feelings about it.	1	2	3	4	DK
15. My feelings about it were kind of numb.	1	2	3	4	DK
** Have these experiences (#1-15, above) interfered with your daily activities?	1	2	3	4	DK

TACT – Tri-State Women’s Circle of Health Project 2

Initial Telephone Interview

Illness Perception

The answer choices for this next set of questions are on the turquoise card that says “Agree Scale (4)” on top.

We are interested in your own personal views of how you see your breast cancer. Research has shown that ideas about how illness develops are related to other health behaviors such as plans for treatment. Using the scale 1=strongly agree, 2=agree, 3=disagree, and 4=strongly disagree, please indicate how much you agree or disagree with the following statements that I will read to you:

		Strongly Agree	Agree	Disagree	Strongly Disagree	Don't Know/ Refused
1	A germ or virus caused my breast cancer	1	2	3	4	DK
2	Diet played a major role in causing my breast cancer	1	2	3	4	DK
3	Pollution of the environment caused my breast cancer	1	2	3	4	DK
4	My breast cancer is hereditary – it runs in my family	1	2	3	4	DK
5	It was just by chance that I developed breast cancer	1	2	3	4	DK
6	Stress was a major factor in causing my breast cancer	1	2	3	4	DK
7	My breast cancer is largely due to my own behavior	1	2	3	4	DK
8	Other people played a large role in causing my breast cancer	1	2	3	4	DK
9	My breast cancer was caused by poor medical care in the past	1	2	3	4	DK
10	My state of mind played a major part in causing my breast cancer	1	2	3	4	DK
11	A hex or a curse is responsible for my breast cancer	1	2	3	4	DK
12	Fate or destiny is responsible for my breast cancer	1	2	3	4	DK
13	Having a pessimistic or negative outlook on life caused me to develop breast cancer	1	2	3	4	DK
14	Injury to my breast(s), such as being hit, caused my breast cancer	1	2	3	4	DK
15	Drinking alcohol is a major cause of my breast cancer	1	2	3	4	DK

Please continue on to the next page.

TACT – Tri-State Women’s Circle of Health Project 2

Initial Telephone Interview

Illness Perception-Continued

		Strongly Agree	Agree	Disagree	Strongly Disagree	Don't Know/ Refused
16	Smoking is a major cause of my breast cancer	1	2	3	4	DK
17	Using street drugs played a major role in my breast cancer	1	2	3	4	DK
18	Failing to live in harmony with nature is what caused my breast cancer	1	2	3	4	DK
19	My breast cancer is a punishment from God	1	2	3	4	DK
20	Toxins in my food caused my breast cancer	1	2	3	4	DK
21	Having sex is what caused my breast cancer	1	2	3	4	DK
22	Taking birth control pills played a major role in my breast cancer	1	2	3	4	DK
23	I don't know what caused my breast cancer	1	2	3	4	DK

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

Genetic Knowledge

The next of questions are about genetics and cancer. For each statement that I read to you, please tell me whether you think the statement is true, false, or if you don’t know the answer.

		True	False	Don't Know
1.	50% of inherited genetic information (about breast cancer risk) is passed down from a person’s mother.	T	F	DK
2.	25% of inherited genetic information (about breast cancer risk) is passed down from a person’s father.	T	F	DK
3.	There is more than one gene that can increase the risk of breast cancer.	T	F	DK
4.	A woman who has a sister with a breast cancer gene mutation has a 1 in 4 chance of having a gene mutation herself.	T	F	DK
5.	A father can pass down a breast cancer gene mutation to his daughters.	T	F	DK
6.	One in 10 women has a breast cancer gene mutation.	T	F	DK
7.	All women who have a breast cancer gene mutation will get cancer.	T	F	DK
	If the currently available genetic tests were to indicate that a woman has a breast cancer gene mutation, she is at increased risk for:			
8.	Breast cancer	T	F	DK
9.	Ovarian cancer	T	F	DK
10.	Lung cancer	T	F	DK
11.	Bladder cancer	T	F	DK
	If a woman who already had breast cancer was found to have a breast cancer gene mutation, she is at increased risk for developing:			
12.	Another breast cancer	T	F	DK
13.	Ovarian cancer	T	F	DK
14.	Lung cancer	T	F	DK
15.	Bladder cancer	T	F	DK
16.	Women who test positive for breast cancer gene mutations are generally more likely to develop breast cancer at a young age.	T	F	DK

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

	<i>Genetic Knowledge, Continued...</i>	True	False	Don't Know
17.	A man who carries a breast cancer gene mutation has an increased risk of developing breast cancer himself.	T	F	DK
18.	If a woman tests positive for a breast cancer gene mutation, her male relatives' risk for developing prostate cancer are lowered.	T	F	DK
19.	A woman may be at greater risk for developing ovarian cancer if she has several close relatives with ovarian cancer.	T	F	DK
20.	A woman may be at greater risk for developing ovarian cancer if she has several close relatives with breast cancer.	T	F	DK
21.	A woman who has her healthy ovaries removed will definitely not get ovarian cancer.	T	F	DK
22.	A woman who has her breasts removed will definitely not get breast cancer.	T	F	DK
23.	Screening for ovarian cancer often does not detect a tumor until it is more advanced.	T	F	DK

24. How many copies of a non-working breast cancer gene must one inherit to be at inherited risk for breast cancer?

- a. 0
- b. 1
- c. 2
- d. 3
- e. Don't know

25. What is the approximate risk that the average woman in the United States will develop breast cancer in her lifetime?

- a. 12%
- b. 24%
- c. 58%
- d. 72%
- e. Don't know

26. If a genetic test were to indicate that a woman inherited a breast cancer gene mutation, then how likely is she to develop breast cancer in her lifetime?

- a. up to 15% chance
- b. up to 25% chance
- c. up to 40% chance
- d. up to 50% chance
- e. up to 85% chance
- f. Don't know

27. Select the procedure that is NOT appropriate for the detection of ovarian cancer:

- a. ultrasound
- b. pap smear
- c. CA-125 blood test
- d. pelvic examination
- e. Don't know

TACT – Tri-State Women’s Circle of Health Project 2

Initial Telephone Interview

Attitudes Towards Genetic Testing

The next set of statements that I will be reading to you relate to your feelings towards genetic testing. You will still be using the answers on the pink card to indicate how much you agree or disagree with each statement.

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't Know/ Refused
1. The results of genetic tests are used to treat certain people unfairly.	1	2	3	4	5	DK
2. Genetic testing allows doctors and scientists to “play God.”	1	2	3	4	5	DK
3. Genetic testing is used to show that my ethnic or racial group is not as good as other groups.	1	2	3	4	5	DK
4. Genetic testing is used to interfere with the way God intended people to be.	1	2	3	4	5	DK
5. Genetic testing is used to interfere with the “natural order” of life.	1	2	3	4	5	DK

TACT – Tri-State Women’s Circle of Health Project 2

Initial Telephone Interview

Genetic Testing Pros and Cons

I am now going to read you a list of statements about your attitudes toward genetic testing for cancer. You will still be using the answers on the pink card to indicate how much you agree or disagree with each statement.

		Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't Know/Refused
1	My concerns about getting breast cancer again would be reduced if I knew I did not carry the gene mutation.	1	2	3	4	5	DK
2	Knowing whether I had the gene mutation would increase my sense of personal control.	1	2	3	4	5	DK
3	Knowing whether I have the gene mutation or not would help me make important life decisions (e.g., getting married, having children).	1	2	3	4	5	DK
	If the test showed that my risk is high, my family members might have trouble getting health insurance.	1	2	3	4	5	DK
5	I believe that genetic testing may be harmful to me or my family.	1	2	3	4	5	DK
6	If I were found to carry the gene mutation, it would help my daughter(s) or sister(s) decide whether to undergo genetic testing.	1	2	3	4	5	DK
7	My genetic test results could give my family members useful information about their risk of getting cancer.	1	2	3	4	5	DK
8	My genetic test results could help my family members make better decisions about how to take care of their health.	1	2	3	4	5	DK
9	Genetic testing would help me learn if my children were at increased risk for getting breast cancer.	1	2	3	4	5	DK

Please continue on to the next page

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

Genetic Testing Pros and Cons - Continued

		Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't Know/Refused
10	If I underwent genetic testing for cancer, I would be concerned about the effect it would have on my family.	1	2	3	4	5	DK
11	If I were found to carry the gene mutation for breast cancer, I would worry about passing the gene to my children.	1	2	3	4	5	DK
12	Knowing that I carry the gene mutation would cause me to worry more about other family members who could be carriers (e.g., mother, sisters, daughters).	1	2	3	4	5	DK
13	If I were found to carry the gene mutation for breast cancer, I would feel guilty if my daughter(s) developed breast cancer.	1	2	3	4	5	DK
14	I would feel guilty if one of my relatives had the gene mutation and I did not.	1	2	3	4	5	DK
15	If I were found to carry a gene mutation for cancer, I would feel singled out.	1	2	3	4	5	DK
16	If I were found to carry a gene mutation for cancer, it would cause others to view me negatively.	1	2	3	4	5	DK
17	Knowing that I carry the gene mutation would cause me to feel less healthy than other people.	1	2	3	4	5	DK
18	I would be ashamed if I were found to carry the gene mutation.	1	2	3	4	5	DK
19	I would be frightened if I were found to carry the gene mutation.	1	2	3	4	5	DK
20	I would be angry if I were found to carry the gene mutation.	1	2	3	4	5	DK

Please continue on to the next page

TACT – Tri-State Women’s Circle of Health Project 2

Initial Telephone Interview

Genetic Testing Pros and Cons - Continued

		Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't Know/Refused
21	Knowing that I carry the gene mutation would leave me in a state of hopelessness and despair.	1	2	3	4	5	DK
22	I would consider suicide if I were found to carry the gene mutation for breast cancer.	1	2	3	4	5	DK
23	If I underwent genetic testing for cancer, I would not be able to handle it emotionally.	1	2	3	4	5	DK
24	If I were found to carry the gene mutation, I would worry that the results would not stay confidential.	1	2	3	4	5	DK
25	Being tested for the gene mutation could jeopardize my insurance coverage.	1	2	3	4	5	DK
	As long as I am feeling good now, it is not important to obtain genetic testing for cancer.	1	2	3	4	5	DK
27	I don't have time to obtain genetic testing for cancer.	1	2	3	4	5	DK
28	Knowing that I carry the gene mutation would motivate me to perform breast self-examination more frequently.	1	2	3	4	5	DK
29	Knowing that I carry the gene mutation would help me decide whether to go for more frequent mammograms.	1	2	3	4	5	DK
30	Knowing that I carry the gene mutation would help me to decide whether to undergo bilateral mastectomy (an operation to remove both breasts).	1	2	3	4	5	DK

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

Satisfaction With Decision Making

Now thinking about your decision to undergo genetic testing for BRCA1 and BRCA2 mutations, please listen to the following comments some people make about their decision. You will still be using the answers on the pink card to indicate how much you agree or disagree with each statement.

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	Don’t Know/ Refused
1. I am satisfied that I am adequately informed about the issues important to my decision regarding genetic testing.	1	2	3	4	5	DK
2. The decision I made about genetic testing was the best decision possible for me personally.	1	2	3	4	5	DK
3. I am satisfied that my decision about genetic testing was consistent with my personal values.	1	2	3	4	5	DK
4. I am satisfied that this was <u>my</u> decision to make.	1	2	3	4	5	DK
5. I am satisfied with my decision about genetic testing.	1	2	3	4	5	DK

TACT – Tri-State Women's Circle of Health Project 2
Initial Telephone Interview

ADHERENCE

BREAST SELF-EXAMINATION

Have you had bilateral mastectomy? _____ YES _____ NO
(If Yes please skip the following questions and go to the next page.)

How often do you perform breast self-examination?

- | | |
|----------------------|------------------------------|
| 1. Once a day | 6. Four or five times a year |
| 2. Once a week | 7. Two or three times a year |
| 3. Twice a month | 8. Once a year |
| 4. Once a month | 9. Never |
| 5. Every other month | |

CLINICAL BREAST EXAM

During a clinical breast exam, a health care provider checks the breasts for lumps.

When was your last clinical breast exam?

- | | |
|------------------------------|-------------------------------------|
| 1. Within the past year | 4. Over 3 years ago |
| 2. Between 1 and 2 years ago | 5. Never had a clinical breast exam |
| 3. Between 2 and 3 years ago | |

4. When are you planning to have your next clinical breast exam?

- _____ Within the next 6 months
_____ Within the next 12 months
_____ Within the next 2 years
_____ Within the next 3 years
_____ Never

MAMMOGRAPHY

How many mammograms have you had?

_____ None _____ One _____ Two _____ Three _____ Four _____ Five or more

Date of last mammogram: _____

When are you planning to have your next mammogram?

- _____ Within the next 6 months
_____ Within the next 12 months
_____ Within the next 2 years
_____ Within the next 3 years
_____ Never

TACT – Tri-State Women’s Circle of Health Project 2

Initial Telephone Interview

Adherence, continued

TRANSVAGINAL/TRANSABDOMINAL ULTRASOUND

Have you had an oophorectomy (surgical removal of the ovaries) or total hysterectomy (removal of both uterus and ovaries)? NO _____ YES _____

(If YES, please skip the following questions and go to the CA-125 questions on this page.)

When was your most recent pelvic/transvaginal ultrasound? (circle one)

- | | |
|--------------------------------|---|
| 1. Within the past month | 5. One to two years ago |
| 2. Within the past 3 months | 6. Over 2 years ago |
| 3. Within the past 6 months | 7. Never had a pelvic/transvaginal ultrasound |
| 4. Between 6 and 11 months ago | |

When are you going to have your next ultrasound?

- _____ Within the next 6 months
_____ Within the next 12 months
_____ Within the next 2 years
_____ Within the next 3 years
_____ Never

CA-125

CA-125 is a blood test that can indicate the presence of ovarian cancer or other conditions.

When was your most recent CA-125 blood test?

- | | |
|--------------------------------|----------------------------------|
| 1. Within the past months | 5. One to two years ago |
| 2. Within the past 3 months | 6. Over 2 years ago |
| 3. Within the past 6 months | 7. Never had a CA-125 blood test |
| 4. Between 6 and 11 months ago | |

When are you going to have your next CA-125 blood test?

- _____ Within the next 6 months
_____ Within the next 12 months
_____ Within the next 2 years
_____ Within the next 3 years
_____ Never

TACT – Tri-State Women's Circle of Health Project 2

Initial Telephone Interview

Adherence, continued

PROPHYLACTIC MASTECTOMY

Some women with a family history of cancer consider having prophylactic mastectomy (having their breasts removed to prevent cancer). Which statement best describes your intentions about prophylactic mastectomy?

I have already had a mastectomy ____ YES ____ NO (If Yes, please go to next section)

	Strongly Agree				Strongly Disagree
I am definitely going to have a mastectomy.	1	2	3	4	5

PROPHYLACTIC OOPHORECTOMY

Some women with a family history of cancer consider having prophylactic oophorectomy (having their ovaries removed to prevent cancer). Which statement best describes your intentions about prophylactic oophorectomy?

I have already had an oophorectomy ____ YES ____ NO (If Yes, end of questionnaire.)

	Strongly Agree				Strongly Disagree
I am definitely going to have an oophorectomy.	1	2	3	4	5

Impact of Culturally Tailored Counseling on Psychobehavioral Outcomes and BRCA Decision Making Among Women With Breast Cancer

We are interested in learning whom you did or did not tell about your genetic test results. For each of the following people, please indicate whether or not you told them your genetic test results. The answer choices for this set are on the orange card that says "BSI" on top. Please respond to the remaining items using the scale of 1 to 5 where 1 = not at all, 2 = a little bit, 3 = moderately, 4 = quite a bit, and 5 = extremely. Please indicate those relatives that are not relevant for you.

For example:

1. "Jane" told her mother her test results. Her mother became "moderately" distressed (1) and was "a little bit" supportive (2). It was "quite" difficult for Jane to tell her mother (4), whom she is "extremely" close to (5).
2. "Jane" did not tell her 18 year old daughter. Jane believed that she would become "a little bit" distressed (2), and would have been "quite" supportive (4). It would have been "extremely" hard for Jane to tell her daughter (5), whom she is "quite" close to (4).

1 = Not at all

2 = A little bit

3 = Moderately

4 = Quite a bit

5 = Extremely

DK (Don't Know/Refused)

Relative	Did you tell this person about your results? (YES or NO)	If YES, how distressed did that person become? If NO, how distressed do you believe that person would have become?	If YES, how supportive did you feel this person was? If NO, how supportive do you think they would have been?	If YES, how hard was it for you to tell this person? If NO, how hard would it have been for you to tell this person?	How close are you to this person?	DK
Example 1: Mother	YES	3	2	4	5	
Example 2: Daughter Age 18	NO	2	4	5	4	

Impact of Culturally Tailored Counseling on Psychobehavioral Outcomes and BRCA Decision Making Among Women With Breast Cancer

1 = Not at all 2 = A little bit 3 = Moderately 4 = Quite a bit 5 = Extremely DK (Don't Know/Refused)

Relative	Did you tell this person about your results? (YES or NO)	If YES, how distressed did that person become?	If YES, how supportive did you feel this person was?	If YES, how hard was it for you to tell this person?	How close are you to this person?	DK
Spouse						
Mother						
Father						
Siblings (Please list all)						
1.						
2.						
3.						
4.						
Children (Please list all)						
1.						
2.						
3.						
4.						

TACT – Tri-State Women’s Circle of Health Project 2
Initial Telephone Interview

After questionnaires are complete:

Those are all of the questions that I had to ask you today. Thank you so much for taking the time to complete today’s interview.

Decisional Conflict

You are about to make a choice regarding genetic testing for breast cancer. Please think about this choice now, and read the following comments some people make when deciding about these issues. Please circle the number that best describes how strongly you agree or disagree with each of the following comments.

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
1. The decision is hard for me to make.	1	2	3	4	5
2. I'm unsure what to do in this decision.	1	2	3	4	5
3. It's clear what choice is best for me.	1	2	3	4	5
4. I'm aware of the choices I have.	1	2	3	4	5
5. I feel I know the benefits of each option.	1	2	3	4	5
6. I feel I know the risks and side effects of each option.	1	2	3	4	5
7. I need more advice and information about choices.	1	2	3	4	5
8. I know how important the benefits of each option are to me in this decision.	1	2	3	4	5
9. It's hard to decide if the benefits are more important to me than the risks, or if the risks are more important than the benefits.	1	2	3	4	5
10. I feel pressure from others in making this decision.	1	2	3	4	5
11. I have the right amount of support from others in making this choice.	1	2	3	4	5
12. I feel I have made an informed choice.	1	2	3	4	5
13. My decision shows what is most important to me.	1	2	3	4	5
14. I expect to stick with my decision.	1	2	3	4	5
15. I am satisfied with my decision.	1	2	3	4	5

Collectivism

In your opinion, how important is it that you and your family...

	Not at all important	Unimportant	Important	Very Important
1. Let relatives stay with you for a short time when they need some help	1	2	3	4
2. Turn to each other in times of trouble	1	2	3	4
3. Raise each other's children whenever there is a need	1	2	3	4
4. Do everything you can to help each other move ahead in life	1	2	3	4
5. Take responsibility for caring for older family members	1	2	3	4
6. Call, write, or see each other often	1	2	3	4

We are interested in your experiences with racism. As you answer the questions below, please think about your ENTIRE life, from when you were a child to the present. For each question, please circle the number that best captures the things that have happened to you. Answer each question TWICE, once for what has happened to you IN THE PAST YEAR, and once for what YOUR ENTIRE LIFE HAS BEEN LIKE. Use these numbers:

Circle 1 = If this has NEVER happened to you

Circle 2 = If this has happened ONCE IN A WHILE (less than 10% of the time)

Circle 3 = If this has happened SOMETIMES (10%-25% of the time)

Circle 4 = If this has happened A LOT (26%-49% of the time)

Circle 5 = If this has happened MOST OF THE TIME (50%-70% of the time)

Circle 6 = If this has happened ALMOST ALL OF THE TIME (more than 70% of the time)

1. How many times have you been treated unfairly by *teachers and professors* because you are Black?

How many times in the past year? 1 2 3 4 5 6

How many times in your entire life? 1 2 3 4 5 6

Never

Almost all
the time

How stressful was this for you?

1 2 3 4 5

6
Extremely

2. How many times have you been treated unfairly by *employers, bosses and supervisors* because you are Black?

How many times in the past year? 1 2 3 4 5 6

How many times in your entire life? 1 2 3 4 5 6

Never

Almost all
the time

How stressful was this for you?

1 2 3 4 5

6
Extremely

3. How many times have you been treated unfairly by your *coworkers, fellow students and colleagues* because you are Black?

How many times in the past year? 1 2 3 4 5 6

How many times in your entire life? 1 2 3 4 5 6

Never
1
Not at all

How stressful was this for you?

2 3 4 5

Almost all
the time
6
Extremely

4. How many times have you been treated unfairly by people in *service jobs* (store clerks, waiters, bartenders, bank tellers, and others) because you are Black?

How many times in the past year? 1 2 3 4 5 6

How many times in your entire life? 1 2 3 4 5 6

Never
1
Not at all

How stressful was this for you?

2 3 4 5

Almost all
the time
6
Extremely

5. How many times have you been treated unfairly by *strangers* because you are Black?

How many times in the past year? 1 2 3 4 5 6

How many times in your entire life? 1 2 3 4 5 6

Never
1
Not at all

How stressful was this for you?

2 3 4 5

Almost all
the time
6
Extremely

6. How many times have you been treated unfairly by people in *helping jobs* (doctors, nurses, psychiatrists, psychologists, case workers, dentists, school counselors, therapists, social workers and others) because you are Black?

How many times in the past year? 1 2 3 4 5 6

How many times in your entire life? 1 2 3 4 5 6

Never
1
Not at all

How stressful was this for you?

2 3 4 5

Almost all
the time
6
Extremely

7. How many times have you been treated unfairly by *neighbors* because you are Black?

How many times in the past year? 1 2 3 4 5 6

How many times in your entire life? 1 2 3 4 5 6

Never
Almost all the time

How stressful was this for you? 1 2 3 4 5 6
Not at all
Extremely

8. How many times have you been treated unfairly by *institutions (schools, universities, law firms, the police, the courts, the Department of Social Services, the Unemployment Office and others)* because you are Black?

How many times in the past year? 1 2 3 4 5 6

How many times in your entire life? 1 2 3 4 5 6

Never
Almost all the time
How stressful was this for you? 1 2 3 4 5 6
Not at all
Extremely

9. How many times have you been treated unfairly by people you thought were your *friends* because you are Black?

How many times in the past year? 1 2 3 4 5 6

How many times in your entire life? 1 2 3 4 5 6

Never
Almost all the time
How stressful was this for you? 1 2 3 4 5 6
Not at all
Extremely

10. How many times have you been accused of doing something wrong (such as stealing, cheating, not doing your share of the work, or breaking the law) because you are Black?

How many times in the past year? 1 2 3 4 5 6

How many times in your entire life? 1 2 3 4 5 6

How stressful was this for you? 1 2 3 4 5 6

Never
1
Not at all

Almost all the time
6
Extremely

11. How many times have people misunderstood your intentions and motives because you are Black?

How many times in the past year? 1 2 3 4 5 6

How many times in your entire life? 1 2 3 4 5 6

Never
1
Not at all

Almost all the time
6
Extremely

12. How many times did you want to tell someone off for being racist but didn't say anything?

How many times in the past year? 1 2 3 4 5 6

How many times in your entire life? 1 2 3 4 5 6

Never
1
Not at all

Almost all the time
6
Extremely

13. How many times have you been really angry about something racist that was done to you?

How many times in the past year? 1 2 3 4 5 6

How many times in your entire life? 1 2 3 4 5 6

Never
1
Not at all

Almost all the time
6
Extremely

14. How many times were you forced to take drastic steps (such as filing a grievance, filing a lawsuit, quitting your job, moving away and other actions) to deal with some racist thing that was done to you?

How many times in the past year? 1 2 3 4 5 6
How many times in your entire life? 1 2 3 4 5 6

Never Almost all the time

How stressful was this for you? 1 2 3 4 5 6
Not at all Extremely

15. How many times have you been called a racist name like n____, coon, jungle bunny or other names?

How many times in the past year? 1 2 3 4 5 6
How many times in your entire life? 1 2 3 4 5 6

Never Almost all the time

How stressful was this for you? 1 2 3 4 5 6
Not at all Extremely

16. How many times have you gotten into an argument or a fight about something racist that was done to you or done to somebody else?

How many times in the past year? 1 2 3 4 5 6
How many times in your entire life? 1 2 3 4 5 6

Never Almost all the time

How stressful was this for you? 1 2 3 4 5 6
Not at all Extremely

17. How many times have you been made fun of, picked on, shoved, hit or threatened with harm because you are Black?

How many times in the past year? 1 2 3 4 5 6

How many times in your entire life? 1 2 3 4 5 6

Never Almost all

How stressful was this for you? 1 2 3 4 5 6

Not at all Extremely

18. How different would your life be now if you HAD NOT BEEN treated in a racist and unfair way?

In the past year?

Same as now	A little different	Different in a few ways	Different in a lot of ways	Different in most ways	Totally different
1	2	3	4	5	6

In your entire life?

Same as now	A little different	Different in a few ways	Different in a lot of ways	Different in most ways	Totally different
1	2	3	4	5	6

Why should I participate in the TACT program?

- You may learn valuable information about your chances of developing breast and ovarian cancer.
- You will learn information that will help you make decisions about your health care.
- You will help advance research on the best way to educate & counsel women of African descent.
- Your participation works toward the goal of reducing illness and death from these cancers.

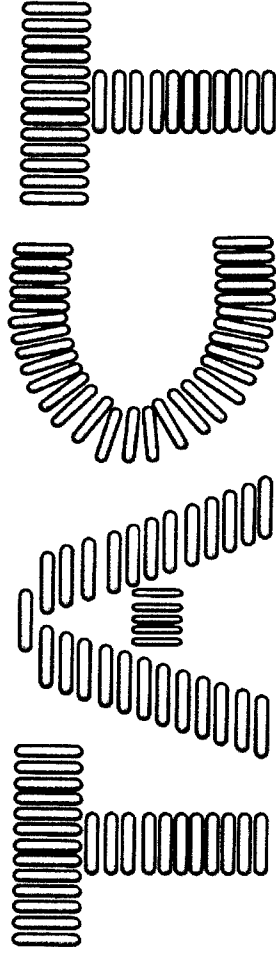
how to contact us

want to learn more?
wondering if you are eligible to participate?

Please call:

Erica Wahl, M.S., C.G.C.
Certified Genetic Counselor
(212) 659-5411

This genetic testing program is supported by research grants and is approved by the Mount Sinai Institutional Review Board (GCO# 00-0730) through ____ (date approved through)

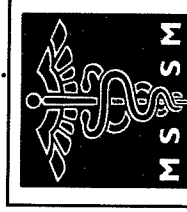


TALKING ABOUT COUNSELING & TESTING



have you been
diagnosed
with breast
cancer?

do you have a family
history of breast cancer?



MOUNT SINAI
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MEDICINE

here is your chance

to learn about breast and ovarian cancer susceptibility genes, such as BRCA1 and BRCA2

The Tri-State Women's Circle of Health study includes a genetic counseling and testing program called TACT. Through TACT, eligible women receive information and counseling about their chances for developing breast and ovarian cancer. These cancers may be related to genes that are passed down in families.

who is eligible for the TACT program?

If you are a woman of African descent (African, African-American, or African-Caribbean) who:

1. Currently has, or once had breast cancer,
- AND
2. Has a family history of breast and/or ovarian cancer,

you may be eligible to participate in TACT.

- We may contact you to see if you are interested
- You can also contact us if you would like to learn more!

All Information is Confidential

what happens in the TACT program?

Each woman in TACT will meet with a genetic counselor for about 1 to 2 hours, and will receive:

1. A detailed family history and outline of your chances of getting cancer.
2. Genetic education and counseling.
3. Guidelines for screening and prevention.
4. Choice for genetic testing at no cost (if eligible)
5. Information about cancer screening services and prevention trials.

Also, all participants will be asked to complete several questionnaires and telephone interviews. These will help us evaluate the program and make better programs in the future.

PROJECT 3

"Immune surveillance, stress and inherited susceptibility to breast cancer: a psychobiological analysis of the healthy daughters of breast cancer patients"

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:

Mutations in the autosomal dominant breast cancer susceptibility genes (BRCA1/BRCA2), account for less than half the attributable increased risk of breast cancer among first degree relatives of breast cancer patients. We hypothesize that deficits in immune surveillance mechanisms may contribute to the currently unexplained familial risk, based on initial evidence of reduced NK cell cytotoxicity in women at familial risk for breast cancer. On the other hand, heightened stress levels in women whose close relatives have had breast cancer raise the possibility that the lower levels of cytotoxic activity may be due to stress-induced immune suppression, rather than inherited deficits in immune surveillance. Our research investigates these two possible nonexclusive explanations for variability in NK cell cytotoxicity. The study also examines the possibility that the daughters of breast cancer patients may evidence a broader pattern of alterations in immune function, since NK cells play a central role in multiple aspects of immune surveillance. In addition to their role as cytotoxic effector cells in innate immune defenses, stimulated NK cells are early producers of key cytokines, which are known to have independent anti-cancer effects and to play a major role in eliciting and shaping additional immune defenses against cancer. Recent research indicating genetic influences (e.g., polymorphism studies) on these two key cytokines (TNF α , IFN γ) suggests another powerful approach to exploring the contribution of these cytokines to familial risk of breast cancer. Our longitudinal study is based on the Case Control design of Project 1 in the Center, in that daughters of both Cases and Controls will be recruited to Project 3. The daughters of Cases and Controls (Project 1) constitute the two Study Groups (final N=150/group). Each participating Case-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 (30 ml) collected. Blood samples are assayed for immune function and cytokine genotypes (Core C). Routine statistical analyses (Core B) will test study hypothesis after anticipated sample sizes are achieved. 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, the study could have profound implications for the eradication of breast cancer. 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.

BODY:

During the past year, we have continued to be engaged in interactions apparently required for the processing of HSRRB approval through the USAMRAA office for this Project, as well as for Project 1, which will be the entry point for recruitment for participants in the study (Project 3). Due to the many interactions required and delays in processing, we have fallen substantially behind our anticipated timeline for completion of the tasks listed in the Statement of Work. We therefore propose to modify our original Statement of Work, to include as a new Task (Months 0-30): Successful application for HSRRB approval through the USAMRAA office. Our most recent interactions were initiated in January of 2003 when Dr. Pranulis from the HSRRB of the USAMRAA provided us with 25 pages of detailed specific requests for further clarification/revisions to the Protocol, Consent forms and Questionnaires. We addressed these and submitted requested paperwork in March and as of this date (9/8/03) have not had a formal response. When we last

contacted Dr. Pranulis in August about these matters, we were informed that she had not yet had time to review our March response.

As allowable in the absence of approval by the HSRRB of the USAMRAA, we have focused our energies on required local Institutional Review Board requirements (all satisfied and approved), as well as Task 1: Setting up of Study 3 procedures, of our funded Project (Project 3). We have established productive interaction strategies with Core A, through weekly meetings and continuing e-mail interactions to address detailed issues concerning Project 3 recruitment and interviewing. This groundwork should enable us to move quickly to the next Tasks, as soon as approval from HSRRB is obtained. We have also prepared self-report assessment instruments, as well as establishing and validating tests for immune parameters assessed in the blood samples obtained after approval by the HSRRB of the USAMRAA. As we have husbanded our resources, we anticipate being able to address all proposed Tasks in a timely manner after approval by the HSRRB of the USAMRAA. Recognizing the late start date, and an anticipated request of a no-cost extension of the Center, we propose to modify the timeline of program of work to delay the start date for Tasks 2-6 by 16 months and the end dates by 12 months. For the additional 6 months delay anticipated, we plan to "make up for lost time" through enhanced recruitment efforts, and greater efficiencies in conducting the proposed research.

KEY RESEARCH ACOMPLISHMENTS:

At this point in the research, with no approval by the HSRRB of the USAMRAA, no results are yet available.

REPORTABLE OUTCOMES:

We have submitted one grant that will recruit the "graduates" of Project 3, as a follow-up to examine the impact of an intervention demonstrated to be effective with other populations with a history of major life stressors, and current chronic stress.

Source:	Department of the Army
Grant Number:	N/A
Project Title:	Emotional, Biological and Cognitive Impact of a Brief Expressive Writing Intervention for African American Women at Familial Breast Cancer Risk
Project Period:	7/01/04-6/30/08 Total Direct Costs: \$548,393/First Year: \$135,623
P.I.:	H. B. Valdimarsdottir
Co-P.I.:	D. H. Bovbjerg

CONCLUSIONS:

At this point in the research, no results are yet available. 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, the study could have profound implications for the eradication of breast cancer. 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.

REFERENCES:

N/A

APPENDICES:

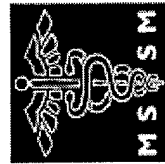
N/A

How can I get more information about the Circle of Life study?

If you have questions about the study or would like to take part, please call:

Attach Research Team
Member's business
card here.

This study has been approved by the Institutional Review Board of the Mount Sinai School of Medicine. GCO# 00-0730



Dr. Dana H. Bovbjerg
Program Head—Biobehavioral Medicine
Cancer Prevention and Control
Derald H. Ruttenberg Cancer Center
Mount Sinai School of Medicine
One Gustave L. Levy Place, Box 1130
New York, NY 10029-6574

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Circle of Life

Mothers, daughters and breast cancer



KEITH MALLETT, *Circle of Life*

Best Available Copy

Circle of Life is a research study of the daughters of women with or without breast cancer who participated in the Tri-State Women's Circle of Health Study.

Mothers influence their daughters in many ways. Daughters may have their mother's smile, sense of humor, or strength of character. *The purpose of the Circle of Life study* is to learn how a mother's illness or health affects her daughter, both emotionally and physically. The study will look at self-reported measures of stress as well as heart responses and the types and activity of cells in the blood.

Who is eligible for the Circle of Life study?

Daughters are eligible for this research study if:

- ✓ their mothers participated in the Tri-State Women's Circle of Health Study,
- ✓ they are 18 years or older,
- ✓ they have not had cancer or other major illness,
- ✓ they do not take medication, except hormone therapies, and
- ✓ they are not pregnant.

What happens in the Circle of Life study?

Daughters will meet with a member of the research team two times during a year. Each time they will

1. fill out questionnaires about their lives and feelings and how they cope with stress,
2. give a small blood sample (about two tablespoons),
3. wear a portable blood pressure monitor for 24 hours,
4. receive a small payment for their time and effort.

The Circle continues...

Daughters' participation in this study will help us better understand the relationship between stress and the body's ability to fight disease and possibly help other families dealing with cancer in the future.

Core A

"Recruitment, Tracking and Interviewing Core"

CORE A

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CORE A: "Recruitment, Tracking and Interviewing Core"

Principal Investigator: 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 the three projects of this Center. Breast Cancer survivors are utilized as Patient Advocates for Research Participation (PARPS), that is, as recruiters. Once a case or control has been identified, the PARP contacts her and schedules the first interview/assessment. The interviewers hired are culturally competent and have been trained 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, instruct participants in the use of the ambulatory blood pressure monitor, and track their involvement across and within the project. At times, the interviewers will also serve as recruiters at designated clinic sites.

BODY:

Consistent with the Statement of Work, as of this reporting period, we have addressed four major tasks. The first, involves the contact of identified cases and controls by Patient Advocates for Research Participation (PARPS). Fourteen PARPS have been recruited and trained. A recruiter manual (see appendix) has been developed and is continually updated. Second, in order to complete each interview or assessment, as outlined in the Overall Program, Research Interviewers have been hired and trained to complete the interviews/assessments for each Protocol. A manual for use by interviewers has been completed (see appendix) and is also updated as required. Since we have not received HSRRB approval, we have not begun the actual field work. The third task for this Core regards the education of physicians at the cooperating hospitals. We have made contact with the cooperating hospitals and key staff at each location has been identified. Meetings have been scheduled and standard procedures for the identification of cases has been established. A schedule for our Interviewers to be on-site at each cooperating hospital to assist with recruiting has been established. In addition, we have worked with the Patient Navigators/Research Nurses at the cooperating sites to ensure that they are aware of our procedures. Finally, this Core has the responsibility of tracking all of the participants in Projects 1, 2 and 3. Working with Core C, the tracking database has been completed. While we have not actively been recruiting participants, we have piloted the database, added fields as needed and designed the required reports for conducting this research.

KEY RESEARCH ACCOMPLISHMENTS:

There are no results available at this time.

REPORTABLE OUTCOMES:

There are no results available at this time.

CONCLUSIONS:

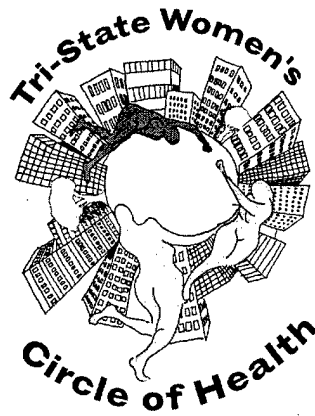
At this point in the research, no results are available. We have, however, in place all of the tools (assessments, tracking database, trained recruiters and interviewers) necessary to conduct the research.

REFERENCES:

There are no additional references to report at this time.

APPENDICES:

Copies of both the Recruiter and Interviewer Manuals are included.



Breast Study

Interviewer Training Manual

9/10/03

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I.

STUDY DESCRIPTION

Description of Breast Cancer Study

Breast Cancer Study Goals

Protocol Summary

About the Studies

Tri-State Women's Circle of Health Protocols

Flow Chart

DESCRIPTION OF BREAST CANCER STUDY

More and more women are being diagnosed with breast cancer. One out of every eight women will develop breast cancer in her lifetime. African-American women often develop breast cancer at an early age (before age 50) and sometimes the disease is more serious than in Caucasian women. For Hispanic women, breast cancer is the most commonly diagnosed cancer. This research project is to help us understand the causes of breast cancer. What people eat and drink and other lifestyle habits could affect their health. But not everyone with similar habits will get sick. This may be because of differences in how their bodies respond to things that they eat, drink, and smoke; and medications they take. In these studies, we will ask the same questions of women with breast cancer ("Cases") and women without cancer ("Controls"), who are the same age and live in the same area. They will be asked questions about eating, drinking, exercise and smoking habits, their medical and family histories, and other behaviors which may protect against or otherwise affect disease. Measurements will be taken, including height and weight. Comparisons between women with breast cancer and those without cancer will then be undertaken to determine differences.

Blood will also be drawn, (about 2 tablespoons). This blood will be processed to measure differences in how the body deals with things we eat, drink and smoke. Just like the answers to the questions, ways in which people break things down will also be compared between women with breast cancer and those without. From this study we hope that we will be able to see what some of the causes of breast cancer might be.

9/10/03

Reference: Study Description

Tri-State Women's Circle of Health

PROTOCOL SUMMARY FOR NEW AND CONTINUING PROTOCOLS

1. Provide a brief (200-250 word) summary of background information for physician/scientists:

African American women are more often diagnosed with breast cancer at an early age and have more aggressive disease. They are also more likely to experience menarche at an earlier age and to have higher estrogen levels. We hypothesize that earlier, more aggressive disease is related to earlier menarche and to lifetime hormonal exposures, and that both breast cancer risk and age at menarche are related to genetic, behavioral and reproductive factors. In a case-control study, we will evaluate relationships between breast cancer risk and a number of risk factors that will affect hormonal levels in African-American (e.g., lifetime physical activity patterns, alcohol consumption, smoking, diet, weight and weight change throughout the life, early life events, and hormonal and reproductive factors). Data will be collected through an in-person interview. We will also evaluate interindividual differences in hormone metabolism by studying genetic polymorphisms in enzymes in estrogen metabolism. The same factors, childhood body size, physical activity and early stressful events will also be evaluated in relation to age at menarche. We will identify African-American women with incident breast cancer at hospitals in NYC with the largest referral patterns for African-Americans, and controls using random digit dialing and Center for Medicare and Medicare Services lists. Both cases and controls will be recruited (n=1600) by culturally sensitive breast cancer survivors. In-person interviews will be conducted and a blood specimen drawn. Statistical analyses will be performed to address each of the aims. 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. In addition, to support our research on this topic we propose to collect preliminary data from 100 Caucasian breast cancer patients and matched controls (n=100), as well as 100 Hispanic breast cancer patients and matched controls (n=100).

2. State purpose of study:

The objectives of this molecular epidemiologic case-control study are to:

- 1) Evaluate relationships between breast cancer risk and a number of behavioral, reproductive and hormonal factors in African American women. An interview will be conducted with 800 women with breast cancer and 800 healthy controls, assessing lifetime physical activity patterns, alcohol consumption, smoking, diet, weight and weight change throughout the life, early life events, and hormonal and reproductive factors.
- 2) Evaluate the role of genetic variability in steroidogenesis and hormone metabolism on breast cancer risk and as a modifier of other risk factors by collection of a blood specimen, DNA extraction, and genotyping for polymorphisms in: CYP17, CYP19, CYP3A4, CYP1B1, CYP1A1, COMT, MnSOD, and UGT1A1. Main effects of the polymorphisms will be evaluated, as well as gene/environment interactions.
- 3) Determine the extent to which age at menarche is predicted by childhood body size and physical activity, stressful events in early life, and genetic polymorphisms in enzymes involved in steroidogenesis and hormone metabolism (CYP17, CYP3A4, CYP19, CYP1B1, CYP1A1).

Evaluate whether specific exposures, particularly early age at menarche, and/or genetic polymorphisms in hormone metabolizing enzymes, as well as gene/gene and gene/environment interactions, are related to earlier onset of breast cancer and more aggressive disease (delineated by stage, grade, ER/PR status, mitotic index).

3. Indicate number of subjects to be enrolled at this site: 165 African American, 80 Hispanic, and 80 White women with breast cancer over a 3-year period

Indicate total number of subjects to be enrolled, if multicenter study: 1600 African American women (800 with breast cancer and 800 controls), 200 Hispanic women (100 with breast cancer and 100 controls), and 200 White women (100 with breast cancer and 100 controls)

4. Indicate the characteristics of study population:

- (a) Gender: Males yes____ no X
 Females yes X no____
- (b) Age range: from 20 to 74
- (c) Racial and Ethnic Groups:
- | | | |
|------------------------|--------------|-------------|
| Caucasian | yes <u>X</u> | no____ |
| Black | yes <u>X</u> | no____ |
| Hispanic | yes <u>X</u> | no____ |
| American Indian | yes____ | no <u>X</u> |
| Alaskan Native | yes____ | no <u>X</u> |
| Asian/Pacific Islander | yes____ | no <u>X</u> |
| Other (specify) _____ | | |

(d) Justify any exclusion of specific gender, age, and racial or ethnic groups:

This study is designed to specifically focus on breast cancer in women.

Men are excluded because breast cancer in men, a rare disease, is likely to have different risk factors than breast cancer in women.

Children (those under age 20) are excluded for similar reasons. While breast cancer does rarely occur in women under 20, the risk factors and nature of the disease are likely to be different than that in older women. Incorporation of these two groups (men and women under 20) would likely introduce too much heterogeneity into the study population and mask associations. Women over age 74 are excluded because of the likelihood that there would be difficulty in recalling life events, and less reliability in questionnaire data.

5. State inclusion criteria for enrollment in study:

Cases will be African American, Caucasian, and Hispanic women between the ages of 20 and 74 who have newly diagnosed primary, incident, histologically-confirmed invasive or in situ breast cancer.

'African-American' will be those who self-identify as Black or Negro, consistent with guidelines of the New York State Tumor Registry, and with 1990 U.S. Census guidelines.

Controls will be African-American, Caucasian, and Hispanic women with no history of breast cancer, but who meet the other criteria as cases.

6. State exclusion criteria for enrollment in study:

Patients with a history of any cancer other than non-melanoma skin cancer are excluded, as are women with a documented or self-reported history of significant memory deficit. Cases under 65 years of age must have a residential telephone and those 65 and over must receive Medicare or Medicaid. Exclusion criteria for controls are the same as for cases.

7. Will vulnerable subjects be enrolled in this study? yes____ no X
- (a) Individuals with diminished mental capacity yes____ no X
- (b) children yes____ no X
- (c) pregnant women yes X no____
- (d) fetuses yes____ no X
- (e) economically or educationally disadvantaged persons yes X no____

(f) prisoners

yes_____ no__X__

8. If vulnerable subjects are to be enrolled, describe the special precautions that will be taken to ensure that consent is freely given and that the rights and welfare of the subjects are protected:

Participation is voluntary. All subjects will be treated equally. Minor incentives will be offered (a \$25.00 gift certificate). Participants will also be reimbursed (e.g., roundtrip metrocard) for travel expenses that they incur as part of their participation in this study. However, there will be no payment for participation. Since there is no danger to fetuses, pregnant women will not be excluded.

9. If the study involves children, will the MSSM Certification of Assent form be used to document that assent was freely given without coercion? yes_____ no N/A
If no, indicate how assent will be documented:

10. Indicate where and how research data will be stored to ensure confidentiality:

Procedures assuring confidentiality of data and samples will be followed, including labeling of all questionnaire data and biological samples with study ID only, and password-protection of computer data. From the time of interview, the participant will be referred to by ID number only. Identifiers will be stripped from all data, and codes linking those numbers to individuals, as well as signed consents, will be kept in a locked file to which only key personnel have access. Data will be analyzed in group aggregates only, and results reported only for by the entire case and control groups.

11. Will data (e.g. records, samples, specimens, databases, surveys, etc.) be **obtained** with identifiers that can be directly or indirectly linked back to the subjects?
yes__X__ no_____

12. Will data (e.g. records, samples, specimens, databases, surveys, etc.) be **stored** with identifiers that can be directly or indirectly linked back to the subjects?
yes__X__ no_____

13. Indicate who will have access to information about the subjects that is identifiable:

Key study personnel (principal investigator, project director, recruiter, interviewer) will have initial contact with study participants. However, no names will be attached to any identifiable data after it is collected. A file linking data to individuals will be kept separately and available only to the principal investigator.

14. Indicate how potential subjects will be identified and recruited for participation in the study:

Breast cancer cases will be confirmed by pathology reports for participating surgeons in hospitals and private doctor's offices. Eligible patients will be recruited in one of two ways. 1. Women identified as cases will be informed of the study by their surgeon or clinical staff member at a convenient time during an office/clinic appointment. Patients responding with interest in the study will be asked if they would like to be introduced to a member of the research team, who will describe study goals and discuss the study procedures. 2. A member of the study team will communicate regularly with staff members of participating surgeons offices on a pre-determined basis (e.g., weekly) to obtain the name of any newly diagnosed breast cancer cases

not previously approached about participating in the study. The physician of the potential participant will be contacted to confirm the diagnosis and diagnosis date, obtain consent to contact his/her patient and acquire contact information (e.g., home address). After confirmation and physician consent, a letter signed by their doctors (see attached) will be sent to patients briefly describing the study, along with a brochure regarding the study and contact information (e.g., phone number) to use if they are interested in learning more about participating in the study. Patients responding with interest in the study will then be mailed an introductory postcard with a photograph of their recruiter, explaining that she is a breast cancer survivor, and will be calling soon to discuss the study. During the subsequent phone, the recruiter will describe study goals and discuss the study procedures. A letter of invitation will be mailed to women who cannot be reached by telephone (see attached). African-American, Caucasian, and Hispanic breast cancer survivors will be trained as recruiters for this study (Patient Advocates for Research Participation (PARP)).

Approximately 1,200 potential controls will be identified and frequency matched to cases on the expected breast cancer case distribution (based on 1993-1997 data from the NY State Tumor Registry) by 5-year age groups and county of residence. Eligibility criteria will be the same as for cases, with the exclusion of breast cancer. Women under 64 years will be identified using random digit dialing (RDD) and those 65 and over will be randomly selected from Center Medicare and Medicaid (CMS) rosters. CMS lists of Medicare and Medicaid recipients are considered the most complete enumeration available for women over 65 years of age in the United States, and random selection from this list can be specifically tailored to create a representative control population. The telephone exchanges (area code plus first five digits) of the breast cancer cases receiving medical care at the participating hospitals will be used for sampling. Women indicating an interest in participating will receive the brochure describing the study, and an introductory postcard from the recruiter with a photograph of themselves to the potential participant, explaining that she is a breast cancer survivor and will be calling soon to discuss the breast cancer study. This card will be followed up by a phone call from the recruiter, who describes study goals and discusses the study procedure. A letter of invitation will be mailed to women who cannot be reached by telephone.

All women who participate in the study will be offered a \$25 gift certificate to Rite Aid Pharmacies or Pathmark Grocery Stores. Participants will also be reimbursed (e.g., roundtrip metrocard) for travel expenses related to their participation in this study. A thank you note will be mailed to participants following their interview (see attached).

15. Indicate when and where consent will be obtained:

The consent will be reviewed with the participant at the outset of the in-person interview. After responding to any questions the participant may have, informed consent will be obtained.

16. Indicate how you will determine whether the subjects (or their surrogates) understand the information that was provided in the consent document:

The interviewer will review the consent form with the participant and ask if they understand it and if they have any questions

17. Will the study include medical record review (hard copy of record or via computer)?
yes X no _____

If yes, list those individuals (e.g. co-investigators, fellows, research nurses, research coordinators, pharmaceutical company protocol monitors, etc.) who require access to the record:

<u>Title</u>	<u>Dept./Institution/Company</u>
Project Director	Ruttenberg Cancer Center, MSSM
Research Associate	Ruttenberg Cancer Center, MSSM
Research Nurse	Cancer Center, Queens Hospital Center

18. **Summarize**, in a **narrative** what actually will be done to the subjects during their participation in the study. Make certain that the following are included:

- (a) a clear description of what is being done for research purposes and what is being done as part of standard clinical care;

None of the procedures to be employed in this protocol are done as part of clinical care; all are for research purposes. Subjects will be interviewed in their homes or at another agreed-upon location. The interview will contain questions regarding lifestyle, reproductive, hormonal and demographic factors. A blood specimen will be (30 mL) will be obtained by a member of the study team or, if the participant prefers, by her physician. In the event that the woman prefers that blood be drawn by her doctor, tubes with ID labels will be provided with a self-addressed overnight mailer and instructions for handling.

- (b) a list of tests and procedures that will be performed for research purposes (e.g. blood tests, urine tests, cultures, interviews, questionnaires, surgical procedures, cardiac catheterization, pulmonary function tests, X-rays, scans, etc);

As described above, an interview will be administered to obtain information on known and suspected breast cancer risk factors. We will obtain demographic information, as well as information on reproductive and hormonal factors, such as age at menarche, age at first full-term pregnancy, age at menopause, oral contraceptive use, and hormone replacement therapy for postmenopausal women. For women with children, we will also inquire about breastfeeding practices. Information will be collected on presence of cancer in first-degree relatives. We will ask about physical activity and body size throughout the life span, as well as smoking and alcohol consumption. A brief food-frequency questionnaire will also be administered. Because we are hypothesizing that early childhood stressful events can result in early menarche, we will also administer a validated questionnaire regarding life events in the years preceding puberty.

A 30 mL blood specimen will be obtained and from it, DNA will be extracted and evaluated for genetic polymorphisms in specific genes involved in the metabolism of steroid hormones. These are genetic variants that are prevalent in the population (greater than 10% in our study), and that are not known to infer risk of disease in the absence of other moderating factors. They include: CYP17, CYP19, CYP3A4, CYP1B1, CYP1A1, COMT, MnSOD, and UGT1A1. A breast tumor specimen will also be obtained for future studies of molecular tumor characteristics.

- (c) a brief description of the analyses that will be performed on the biologic or non-biologic (i.e. questionnaires) samples collected;

The above listed genes will be subjected to allele-specific PCR to determine variant genotypes. Questionnaire data will be coded, entered into a database, cleaned, and variables of interest created. These will be evaluated as risk factors for breast cancer by comparing between cases and controls. Similarly, the effect of variant genotypes will also be tested using contingency tables and chi-square test statistic. The magnitude of risk associated with factors found to be significantly different between cases and controls will be estimated using unconditional logistic regression, adjusting for possible confounding variables. Gene/gene and gene/environment interactions will be calculated by performing stratified analyses, case-series analyses in which exposures are regressed on genotype status, reflecting the degree to which an exposure is associated with case status among those with 'low-risk' vs. 'high-risk' alleles. Interactions between genes and other factors that are thought to work together biologically will also be examined with cross-product terms in the logistic models. Dummy variables representing high-risk alleles and exposures they may modify will be entered into the regression and we will model the nature of the joint association. We will also evaluate the predictive role of a number of variables on age at menarche as the outcome variable. Finally, in cases only, we will categorize disease by degree of aggressiveness, and use techniques of logistic regression to estimate strength of association between another of predictive factors and markers of more aggressive disease.

- (d) a list of investigational drugs that will administered and indicate for each whether there is an IND or there is an application to the FDA for an IND;

No investigational drugs will be administered.

- (e) a list of investigational devices that will be used, indicate if they are classified as significant risk (SR) or non-significant risk (NSR) devices and whether there is an IDE or there is an application to the FDA for an IDE if the device is SR;

No investigational devices will be used.

- (f) a statement that defines who will be financially responsible for the costs associated with participation in the study (e.g. examinations, procedures, drugs, devices, etc.) and a statement that defines what will be provided without cost to the subjects; Costs associated with this study will be the responsibility of the PI, and there will be no expense to the subjects. In fact, they will receive a \$25 remuneration for their time given to the study. Participants will also be reimbursed for travel expenses related to their participation in this study.

- (g) your assessment of whether the research involves any physical, psychological, social and/or economic risk(s) and the magnitude of the risk(s); There will be little discomfort and risk from providing the blood specimen. In a small number of people, it is possible that some bruising may occur where the needle was

inserted for the blood draw. There is also a slight possibility that infection could occur, although this is rare due to all of the precautions taken. Some people may be made uncomfortable by some of the personal questions, and it is possible that trying to recall events in the past may frustrate some participants. There may be concerns regarding confidentiality, particularly with the genotyping date; it is stressed to the participant that all information is coded by ID number only, no names will be associated with results, and only key investigators have information that could link the participant with their data.

(h) your assessment of the risk/benefit ratio of the research;

Participants are given a \$25 gift certificate as compensation. It is likely that important information will be obtained in this study that could greatly benefit society. Risks are minimal, and society may benefit from the results of the study.

19. Will the study be monitored? yes_____ no__X__

If yes, indicate the frequency of monitoring, specify who will do the monitoring (e.g. regulatory monitors, an external data and safety monitoring board (DSMB), a DSMB composed of local individual(s) unaffiliated with the study and indicate to whom monitors will report in addition to the investigator (e.g. NIH, FDA, industry sponsor, IRB).

NOTE:

a) Data and patient safety monitoring: if required, a Data and Safety Monitoring Board (DSMB), which must be convened by the PI, can be made up of internal and/or external members who have the appropriate expertise and are totally independent of and unaffiliated with the study. The composition of the DSMB should be commensurate with the complexity of the proposed study and will be reviewed by the IRB. Approval of the DSMB by the IRB is required prior to initiating the clinical trial.

b) Regulatory monitoring: if required, independent regulatory monitors must be provided by the sponsor of a project. If the PI is also the sponsor, then it is the responsibility of the PI to obtain monitors. Monitors may be MSSM personnel with the requisite expertise (documented by their curriculum vitae and approved by the IRB) or external monitors (the IRB can assist in identifying external monitors), who are not directly affiliated with the proposed study.

20. Does the principal investigator or any of the co-investigators have a potential financial conflict of interest in relationship to this study? yes_____ no__X__

If yes, describe the nature of the potential conflict for each investigator.

21. Will research coordinators be employed for this study? yes__x__ no_____

a) How many coordinators will be employed for this study? __1__

b) Will the coordinator(s) work full time on this one project? yes_____ no__x__

If no, indicate if the coordinator(s) will work on other projects and describe the time allocation (in hours/week) of each coordinator.

c) Provide the name(s) of the coordinator(s) (if known) and indicate the number of subjects each coordinator will follow in this study.

Senaka Peter, MPH, is the coordinator for this study. She will work with the team of research recruiters and interviewers in Core A (Recruitment and Interview Core of the Center) to facilitate the identification and recruitment of 2000 participants over three years.

d) If more than one coordinator will be employed for this study, indicate the name of the senior coordinator _____ n/a _____

e) Provide a contact telephone number for the senior coordinator _____ n/a _____

f) If the research coordinator(s) will work on other projects indicate the total number of other projects each coordinator will work on, the number of subjects they will follow in each protocol, provide the name of the PIs and the GCO numbers other projects. (n/a)

g) Indicate if the individual(s) has prior experience as a research coordinator and briefly describe that experience. Include completed course work and credentials. If none, indicate your plans to formally educate and train the individual as a research coordinator.

This is not a clinical trial. The research coordinator will primarily deal with data collected through interview. This individual has been extensively trained.

22. Will private medical/psychiatric information be requested (e.g. in questionnaires) about individuals other than those who are the subjects who are enrolled in the study (e.g. family members)?
yes __X__ no _____

a) if yes, describe the topics that will be covered.

Family History of Cancer

for each topic indicate whether or not the questions would be considered part of a routine, complete medical history as would be obtained for standard clinical care.

The information that we request is information that would be gathered as part of standard clinical care during a complete and routine query of an individual's family medical history.

9/10/03

Reference: Study Description

ABOUT THE STUDIES

“Core A” is the name of the Recruiting and Interviewing portion of the three research projects, each of which addresses an important issue in breast cancer research.

Principal Investigator: Lina Jandorf, M.A.

These 4-year studies looking at critical psychological or behavioral issues will improve our understanding of the causes of breast cancer. The studies are:

Project 1: “Behavior, estrogen metabolism, and breast cancer risk: a molecular epidemiologic study.” Principal Investigator: Christine Ambrosone, Ph.D.

This is a study to understand why some women get breast cancer and others do not.

Project 2: “Impact of culturally tailored counseling on psychobehavioral outcomes and BRCA decision making among African-American women with breast cancer.” Principal Investigator: Heiddis Valdimarsdottir, Ph.D.

Women from Project 1 whose family history suggests that their cancer may be inherited will be offered genetic counseling and genetic testing at no cost. Such counseling may reduce distress and increase knowledge about breast cancer, genetic testing, and breast cancer prevention and surveillance options.

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

Principal Investigator: Dana Bovbjerg, Ph.D.

The adult daughters of women with breast cancer from Project 1 will be compared with the adult daughters of women without breast cancer to examine the possibility that inherited deficits in the immune system may be related to familial risk among daughters of patients whose cancers are not related to mutations in BRCA1 or BRCA2 genes.

9/10/03

Reference: Study Description

Tri-State Women's Circle of Health

Protocol	Idea - MSSM	Original DOD
Study Population	150 CA - 50 Black 50 White 3 CO/ 1 CA - RDD	800 CA - Black 800 CO - RDD
Hospital	Sinai, St. Luke's	All Hospitals
Age Range	20-64 years	20-64 years
Eligibility	<ul style="list-style-type: none"> ▪ CA: Incident & prevalent (1 yr) ▪ CO: NY metropolitan area ▪ English ▪ Match white CA on insurance 	<ul style="list-style-type: none"> ▪ CA<65 - telephone ▪ English only
Incentive	\$25 GC	\$25 GC
Contact & Recruiting	<ul style="list-style-type: none"> ▪ ID through hospital records or MD referral ▪ MD consent ▪ Letter from PI and MD w/ brochure and number to refuse contact ▪ PARP protocol - PPC ▪ Interview scheduled ▪ Blood (30mL) 	<ul style="list-style-type: none"> ▪ Identify through hospital reports or MD referral ▪ contact MD for OK & patient address ▪ Letter from MD with brochure ▪ PARP protocol-PPC ▪ Interview scheduled ▪ Blood (30 mL)

12/10/02

Reference: Study Description

TRI-STATE CIRCLE OF HEALTH FLOW CHART

	Subject Identification	Eligibility confirmed Via	Recruitment Letter/Brochure Sent/Given	Recruiter Activities Initiated **	Post-interview Questionnaire Review Prior to Hand-off to Core C
Hospital cases*	MD	Chart review by Project 1	Mailed by Project 1 (after MD approval) or given directly by MD	After eligibility confirmed by Project 1, Core A assigns Recruiter and sends post-card.	Core A (Interviewer) and Project 1 (SP).
	MD or staff	MD or staff	Brochure given by MD or staff.	Informed consent obtained by MD staff or interviewer on-site. Interviewer then schedules interview.	Ditto
RDD controls	phone list	RDD Company	Mailed by Project 1	After eligibility confirmed by Project 1, Core A assigns Recruiter and sends post-card.	Ditto

*3 month post-diagnosis time frame will be tracked through Eligible Applicants Data Base maintained by Project 1 (SP).

**Recruiter postcard sent by Core A; Recruiter Contact Form distributed to Interviewer for appointment confirmation, lab notification, interview, recruitment for additional studies. Core A to track : interviews needing to be scheduled; interviews scheduled; and specimens pending.

9/10/03

Reference: Study Description

II.

ROLE OF THE RECRUITER

Sequence of Subject Recruitment

Control Contacts

Case Contacts

Refuser Questionnaire

Sequence of Subject Recruitment

1. Cases are identified by:
 - physicians directly
2. Controls are identified by:
 - General public controls are identified by a RDD (random digit dialing) company through phone lists
3. For cases, a letter and brochure will be sent from the patient's doctor by MSSM staff, telling her about the study.
For controls, information will be sent by MSSM staff.
4. Cases may also be recruited by physicians' staff directly after their initial diagnosis. Informed consent is obtained and a blood draw may be done at that time, as well.
5. Cases and controls are assigned to recruiters. Packets are given to recruiters and include:
 - Contact sheet
 - Script for phone call
 - Reimbursement forms
 - Self-addressed stamped priority mail envelopes from MSSM
6. Post-cards with the recruiter's picture and name will be sent in envelopes by MSSM staff to the subject.
7. Recruiter will contact subjects within 14 days if possible.*
7. Recruiter notifies interviewer of interview date and location by phone or e-mail and interviewer forwards travel directions to participant, if needed.
8. Recruiters return the information (completed contact sheet) back to MSSM.
 - At any time, recruiters may call MSSM staff for assistance with subject phone numbers that may be incorrect. Interviewer will attempt to find current phone number and advise recruiter.

9/10/03

Reference: Role of the Recruiter

Date assigned _____

Date to notify MSSM staff
& return contact sheet

Date recruiter returned
contact sheet to MSSM

**MSSM BREAST CANCER RESEARCH
CONTROL CONTACT SHEET**

ID NUMBER: _____ REFERENCE DATE _____ AGE: _____

PARTICIPANT'S NAME: _____

PHONE NUMBER: _____ ETHNICITY: _____

PARTICIPANT'S ADDRESS: _____

BEST DAY TO CALL: _____ BEST TIME TO CALL: _____

REFERRED BY: RDD _____ HOSPITAL _____ (NAME)

RECRUITER'S NAME: _____

INTERVIEWER'S NAME: _____

SCHEDULED INTERVIEW DAY: _____ DATE: _____ TIME: _____

ATTEMPTS

Date	Time	Comments	Participation		Meeting Place		
			Yes	No	Home	Hospital	Other

Recruiter, please check the following words that apply to the participant you called. Also write down any additional comments that the participant made or your feelings about your conversation.

- | | | |
|--|------------------------------------|--|
| <input type="checkbox"/> Enthusiastic | <input type="checkbox"/> Nervous | <input type="checkbox"/> Not sure if they want to participate |
| <input type="checkbox"/> Excited | <input type="checkbox"/> Hesitant | <input type="checkbox"/> Would like more information about the study |
| <input type="checkbox"/> Willing to help | <input type="checkbox"/> Angry | <input type="checkbox"/> Questions for staff about the study |
| <input type="checkbox"/> Pleasant | <input type="checkbox"/> Depressed | |

Additional Comments: _____

If Answering Machine: "I'm calling regarding a study at Mount Sinai and I will call back (specific time) or you may reach Senaka Peter at Mount Sinai by calling 1-866-223-2219 or 212 659-5406."

9/10/03

Reference: Role of the Recruiter

ID NUMBER _____

REFERENCE DATE _____

Please attempt to call subjects at least once between 9-11 a.m.; 1-5 p.m.; and 7-8 p.m. before determining whether you can reach them. Please attempt to contact this subject at least 5 times before _____.

(return date)

PARTICIPANT RECRUITMENT FORM
[FORM FOR CONTROLS, WOMEN WITHOUT BREAST CANCER]

Hello, may I speak with _____
(WOMAN'S NAME)

(ONCE WOMAN IS ON THE PHONE):

Hello, my name is _____. I'm a breast cancer survivor (since _____ year of diagnosis, optional), involved with outreach for the Mount Sinai School of Medicine. A while back, you received a phone call from Kreider Research & Consulting regarding breast cancer research being conducted here. At that time, you agreed to be called to learn more about an on-going study about breast cancer and that is why I'm calling today. By now, you should also have received a brochure and letter from researchers here, as well as a postcard from me, about this important study at Mount Sinai. If you have time now, I would like to tell you more about it.

If no:

ASK FOR A BETTER TIME TO CALL BACK. TIME: _____

If yes:

Before we go on, it is important that you know we are only looking for women who have not had any form of cancer other than basal cell or squamous cell skin cancer. If you feel that this describes you, we can go on. Should I continue? (Note to Recruiters: We are looking for women who have not had any cancer other than basal cell or squamous cell skin cancer).

If no:

Would you be willing to tell me why you think this does not describe you? (IF WILLING, WRITE DOWN THE ANSWER ON THE CONTACT SHEET.)

Thank you for taking the time to be willing to receive information about the study but if you do not qualify there is no reason to take any more of your time. If you want to learn more about the study, I would be glad to answer your questions if I can or you can always check the website for the study, which is listed on the brochure you received in the mail. The website also has information links about cancer care and treatment.

If yes, they have not had any cancer other than the above skin cancers:

I would like to verify that you live in New York City six or more months out of the year. (If they ask why, explain that in order for our results to scientifically be valid, participants must reside in NYC six or more months out of the year.) **If no, let them know they do not qualify for the study and thank them for their time. If yes, then continue:**

I'll just take a minute to give you some background information: Doctors and researchers are concerned, because breast cancer is becoming more common in women, and not much is known about what causes it or how to prevent it. Scientists at the Cancer Center are running a study to try to learn some of the causes of breast cancer. This study will compare women who have had breast cancer to women who have not, to learn why some get cancer and others do not.

I want to tell you right at the start that there is no cost to you. In fact, you will receive a \$25 gift certificate to either Pathmark or Rite Aide as our way of thanking you for participating in our study. And I want you to know

that your privacy is always protected. Only limited study personnel will be aware of your name. From the time of the interview, only an identification number that has been assigned to you will be used, not your name. Do you have any questions for me so far?

I would like to schedule an appointment for you to meet with a female interviewer from the Cancer Center at one of our interview sites and we will, of course, provide a Metrocard to cover travel expenses. At the interview, you will be asked questions about your diet, health history, and other lifestyle habits. Also, a small blood sample and body measurements, such as height and weight, will be taken. This will probably take about two hours. (Offer Mount Sinai to all women and, as an alternative, a hospital in their borough) The interview can be conducted in **Manhattan** at either Mount Sinai Hospital, 98 St. & Fifth Ave. or St. Luke's Roosevelt Hospital, 59 St. & 9th Ave.; in **Queens** at Queens Hospital Center, 164th St. Jamaica, in **Brooklyn** at Kings County Hospital in Brooklyn (primarily Mondays and Fridays), or in the **Bronx** at either Montefiore Medical Center, East 210th St. or Albert Einstein College of Medicine on Eastchester Road (primarily Wednesdays or Fridays), whichever is more convenient for you. That's all there is to it. So, do you have any questions?

If the hospital sites are not acceptable, offer to have the interview done in their home.

(IF THEY HAVE QUESTIONS THAT YOU DO NOT KNOW THE ANSWER TO, TELL THEM AN INTERVIEWER WILL CALL BACK TO ANSWER THEIR QUESTIONS).

Do you think you would be able to participate in this study? (YES)_____ (NO)_____

(IF NO, TRY TO FIND OUT WHY AND TRY TO RESPOND TO HER CONCERNS. IF IT WOULD HELP, REFER TO Q&A NUMBER 5 REGARDING CANCER HISTORY. IF THEY STILL SAY NO, ASK): May I ask you just a few short questions about your socioeconomic background and medical and reproductive history on the phone? The information you would provide will help the researchers to determine whether there is a difference between the women who agree to participate in the study and those who do not agree to participate. Your name will not be attached to your comments and I will be the only person who knows who says what.

Do you agree to participate in this short telephone survey? (YES)_____ (NO)_____

(If YES, See Refuser Questionnaire)

(IF THEY AGREE TO PARTICIPATE, SAY):

That's great. I will be happy to set up an appointment for you. Will you be coming to Mount Sinai or do you prefer _____ hospital? What is a good time and day for you?

INTERVIEW LOCATION: _____
DAY INTERVIEW SCHEDULED: _____ DATE: _____ TIME: _____

I will tell let the Interviewers know you are interested in being in the study, and one of them will call to confirm the interview appointment. Is this the best phone number at which to reach you?

(IF YES, WRITE DOWN THE PHONE NUMBER THAT YOU CALLED.
OR, IF THERE IS A BETTER NUMBER, WRITE IT DOWN HERE).

(_ _ _) _ _ - _ _ _ Is there a good time of day to call you? TIME: _____.

Ok, so one of our Interviewers will be calling you soon to confirm your interview appointment on _____ (Date) at _____ (Time) and she'll be meeting you at:

Home: _____ **Hospital:** _____ **Other:** _____
If Hospital/Other, indicate building/room number: _____

If you should want to speak with someone before the Interviewer calls, let me give you the name and phone number of a contact person: (interviewer's) phone number: _____.

Thank you so much for your time, and for agreeing to be in this study.

Date Directions Sent _____

9/10/03

Section: Recruitment Tools/Techniques

Date assigned _____

Date to notify MSSM staff
& return contact sheet

Date recruiter returned
contact sheet to MSSM

MSSM BREAST CANCER RESEARCH CASE CONTACT SHEET

ID NUMBER: _____ REFERENCE DATE _____ AGE: _____

PARTICIPANT'S NAME: _____

PHONE NUMBER: _____ ETHNICITY: _____

PARTICIPANT'S ADDRESS: _____

REFERRED BY: MD _____ HOSPITAL _____ (NAME)

RECRUITER'S NAME: _____

INTERVIEWER'S NAME: _____

SCHEDULED INTERVIEW DAY: _____ DATE: _____ TIME: _____

ATTEMPTS

Date	Time	Comments	Participation		Meeting Place		
			Yes	No	Home	Hospital	Other

Recruiter, please check the following words that apply to the participant you called. Also write down any additional comments that the participant made or your feelings about your conversation.

- | | | |
|--|------------------------------------|--|
| <input type="checkbox"/> Enthusiastic | <input type="checkbox"/> Nervous | <input type="checkbox"/> Not sure if they want to participate |
| <input type="checkbox"/> Excited | <input type="checkbox"/> Hesitant | <input type="checkbox"/> Would like more information about the study |
| <input type="checkbox"/> Willing to help | <input type="checkbox"/> Angry | <input type="checkbox"/> Questions for staff about the study |
| <input type="checkbox"/> Pleasant | <input type="checkbox"/> Depressed | |

Additional Comments: _____

If Answering Machine: "I'm calling regarding a study at Mount Sinai and I will call back (specific time) or you may reach Senaka Peter at Mount Sinai by calling 1-866-223-2219 or 212 659-5406."

9/10/03

Reference: Role of the Recruiter

ID NUMBER: _____ REFERENCE DATE: _____

Please attempt to call subjects at least once between 9-11 a.m.; 1-5 p.m.; and 7-8 p.m. before determining whether you can reach them. Please attempt to contact this subject at least 5 times before _____ (return date)

PARTICIPANT RECRUITMENT FORM

[FORM FOR CASES, WOMEN WITH BREAST CANCER]

Hello, may I speak with _____
(WOMAN'S NAME)

(ONCE WOMAN IS ON THE PHONE):

Hello, my name is _____. I'm a breast cancer survivor (since _____ year of diagnosis, optional), involved in outreach for the Mount Sinai School of Medicine. You should have received a letter from Dr. _____ and the researchers here, as well as a postcard from me, telling you about an important study on breast cancer taking place at Mount Sinai Medical Center (and REFERRING HOSPITAL). Your doctor told us that you have indicated an interest in meeting with one of the interviewers for this study. If you have time, I would like to tell you about the study to help you decide whether or not you want to participate.

If no:

ASK FOR A BETTER TIME TO CALL BACK. TIME: _____

If yes:

I'll just take a minute to give you some background information:

Doctors and researchers are concerned, because breast cancer is becoming more common in women, and not much is known about what causes it or how to prevent it. Doctors at the Cancer Center are running a study to try to learn some of the causes of breast cancer. This study will compare women who have had breast cancer to women who have not, to learn why some get cancer and others do not. Before being diagnosed with this recent breast cancer, did you ever have breast cancer before, or any form of cancer other than basal cell or squamous cell skin cancer? **IF YES, FIND OUT WHAT TYPE OF CANCER, LET THEM KNOW THEY DO NOT QUALIFY FOR THE STUDY AND THANK THEM FOR THEIR TIME.**

IF THEY HAVE NOT HAD OTHER THAN THE ABOVE SKIN CANCERS, CONTINUE:

I would like to verify that you live in New York City six or more months out of the year. (If they ask why, explain that in order for our results to scientifically be valid, participants must reside in NYC six or more months out of the year.) **If no, let them know they do not qualify for the study and thank them for their time. If yes, then continue:**

I want to tell you right at the start that you do not have to agree to participate. If you do decide to participate, it will not cost you anything. People who agree to participate will be given a \$25 gift certificate from either Pathmark or Rite Aide as our way of thanking you for participating in our study. We will also provide a Metrocard for participants who need to travel in order to participate in this study. The privacy of everyone who participates will always be protected. No one other than the researchers will know who participated or who said what. Any information that is obtained will have a code number on it, not a name. You should also know that this is not a treatment study. If you decide to participate, it will not interfere with any treatment you may be having now or in the future. This study involves being interviewed by a woman who is a trained interviewer. She will be asking questions about diet, health history, and life style habits. She will take some measures of height, weight, and body size and will take a small sample of blood. These procedures will take about two hours. Do you have any questions for me so far?

(IF THEY HAVE QUESTIONS THAT YOU DO NOT KNOW THE ANSWER TO, TELL THEM AN INTERVIEWER WILL CALL BACK TO ANSWER THEIR QUESTIONS).

Do you think you would be interested in participating or at least learning more about the study before you decide? (YES)_____ (NO)_____

(IF NO, TRY TO FIND OUT WHY AND TRY TO CHANGE THEIR MIND. IF IT WOULD HELP, REFER TO Q&A NUMBER 5 REGARDING CANCER HISTORY. IF THEY STILL SAY NO, ASK): May I ask you just a few short questions about your medical history and socioeconomic background on the phone? (See Refuser Questionnaire)

(IF THEY AGREE TO PARTICIPATE, SAY):

That's great. I would like to schedule an appointment for you to meet with a female interviewer from the Cancer Center at one of our interview sites. **(Offer Mount Sinai to all women and, as an alternative, a hospital in their borough)** The interview can be conducted in **Manhattan** at either Mount Sinai Hospital, 98 St. & Fifth Ave. or St. Luke's Roosevelt Hospital, 59 St. & 9th Ave.; in **Queens** at Queens Hospital Center, 164th St. Jamaica, in **Brooklyn** at Kings County Hospital in Brooklyn (primarily Mondays and Fridays), or in the **Bronx** at either Montefiore Medical Center, East 210th St. or Albert Einstein College of Medicine on Eastchester Road (primarily Wednesdays or Fridays), whichever is more convenient for you. That's all there is to it. So, do you have any questions?

If the hospital sites are not acceptable, offer to have the interview done in their home.

I will be happy to set up an appointment for you. Will you be coming to Mount Sinai or do you prefer _____ hospital? What is a good time and day for you?

INTERVIEW LOCATION: _____
DAY INTERVIEW SCHEDULED: _____ DATE: _____ TIME: _____

I will tell let the Interviewers know you are interested in being in the study, and one of them will call to confirm the interview appointment. Keep in mind that even though you agreed to meet with the interviewer that you can change your mind at any time – even after you start the interview. But I am hoping that you will participate. Is this the best phone number at which to reach you?

(IF YES, WRITE DOWN THE PHONE NUMBER THAT YOU CALLED.
OR, IF THERE IS A BETTER NUMBER, WRITE IT DOWN HERE).

(____)____-____ Is there a good time of day to call you? TIME: _____.

Ok, so one of our Interviewers will be calling you soon to confirm your interview appointment on _____ (Date)at _____ (Time) and she'll be meeting you at:

Home: _____ Hospital: _____ Other: _____
If Hospital/Other, indicate building/room number: _____

If you should want to speak with someone before the Interviewer calls, let me give you the name and phone number of a contact person: (interviewer's) phone number: _____.
Thank you so much for your time, and for agreeing to be in this study.

Date Directions Sent _____
9/10/03 Section: Recruitment Tools/Techniques

REFUSER QUESTIONNAIRE

1. What is your date of birth?

____/____/____
Month Day Year

2. Do you consider yourself to be of Latina or Hispanic origin?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused



If **YES**: Do you consider yourself to be any of the following?
(Check all that apply)

- 1 ☐ Mexican/Mexican American/Chicano
2 ☐ Puerto Rican
3 ☐ Cuban
4 ☐ Caribbean or West Indian
5 ☐ Dominican
6 ☐ Other (please specify): _____

3. What is your race?

- 1 ☐ White
2 ☐ Black/African American
3 ☐ Black-Other
4 ☐ Black-West Indian / Caribbean
5 ☐ American Indian or Alaska Native
6 ☐ Asian Indian
7 ☐ Chinese
8 ☐ Filipino
9 ☐ Korean
10 ☐ Vietnamese
11 ☐ Other Asian
12 ☐ Native Hawaiian
13 ☐ Guamanian or Chamorro
14 ☐ Samoan
15 ☐ Other pacific Islander
16 ☐ Some other race

4. What is the highest grade or year of school you have completed?

- 1 ☐ Less than 8th grade
- 2 ☐ 8th to 11th grade
- 3 ☐ High school graduate or equivalent (GED)
- 4 ☐ Technical or vocational school
- 5 ☐ Some college
- 6 ☐ College graduate
- 7 ☐ Post-graduate degree
- 9 ☐ DK/Refused

5. Have you had a mother, sister or daughter that has had breast cancer?

- 1 ☐ Yes
 - 2 ☐ No
 - 9 ☐ DK /Refused
-

6. Have you ever had a mammogram?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK /Refused

7. During your whole lifetime, how many mammograms have you ever had?

____ (number)

8. What type of health insurance do you have?

- 1 ☐ Medicaid
- 2 ☐ Medicare
- 3 ☐ Employer-provided insurance (Oxford, Blue Cross/Blue Sheild, HIP)
- 4 ☐ Pay for insurance out of pocket
- 5 ☐ I do not have health insurance
- 6 ☐ Other: _____
- 9 ☐ DK/Refused

9. How old were you when you had your first menstrual period?

____ (years)

10. How many SONS do you have? _____ (number of sons)

11. How many DAUGHTERS do you have? _____ (number of daughters)

12. Have you gone through menopause, or the change of life?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

13. Have you ever taken birth control pills?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

14. Have you ever taken hormone replacement therapy?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

15. Do you currently smoke cigarettes?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

↓
If no, did you ever smoke regularly?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

16. In the past year, how many times in a typical week did you participate in moderate physical activity for at least 30 minutes per day?

____ (number of times)

17. One year ago, how much did you weigh?

WEIGHT:

POUNDS.....1
KILOGRAMS.....2

12/10/02
Reference: Role of the Recruiter

III.

ROLE OF THE INTERVIEWER

Overview

Interviewer Training Outline

Interview Confirmation Script

Interviewer's Contact Sheet

Travel Safety Tips

OVERVIEW OF INTERVIEWER ROLE

This section provides a brief overview of the tasks you are expected to perform as an interviewer. Each is discussed in detail in later sections of this manual.

1. After the successful completion of training, you will be given an assignment of cases and/or controls. These women will have already agreed to participate in the study and the recruiter will have set up an interview appointment. Your first job is **to send directions to the participant and confirm** the date, time and location for the interview.
2. If the interview is off-site, you will call-in upon arrival. You will then begin by obtaining a signed **consent form** for the interview and then administering the **main interview** and the **Food Frequency Questionnaire**. After this, you will introduce the **Early Life Experiences, IES, Behavior Change and How I Feel Scales** to the participant; while they finish these measures, you will **review** the main interview questionnaire and the FFQ for completeness and prepare to take the Anthropometry measurements.
3. When the FFQ has been completed, you will take the **Anthropometry measurements**.
4. The next task in the interview process will be to complete the **Blood Specimen Data Form** and then collect the blood specimen. (If this is not possible, a **DNA sample** will be collected). Material will be given to participant for their physician to do the blood draw, if they prefer. However, a DNA sample will still be taken in such cases.
5. You will give the participant the \$25 **gift certificate** and note the certificate number on the consent form.
6. You will very briefly **introduce the 2nd and 3rd projects** to women meeting criteria for participation (discussed in later sections of the manual) and obtain consent for the telephone interview for Project 2, if appropriate.
7. You will **deliver** blood specimens to the GCRC lab and document in the **Lab Book**.
8. You will **record each contact** (via telephone or in person) with the participant from interview confirmation through completion in the "Interviewer Contacts" section of the **database**.
9. You will **enter all data** related to the interview process from confirmation of the interview appointment ("Participant Status" section) through completion of the interview ("Post-Interview Checklist" and "MHI") **within 24 hours** of the interview completion.
10. You will **edit** each questionnaire, reviewing all items for completeness and legibility prior to passing on for data entry
11. You will **report in person** to your supervisor for regularly scheduled conferences.
12. All work will be reviewed for accuracy and completeness. **Interviews will be validated** periodically by re-contacting respondents.

9/10/03 Reference: Role of the Interviewer

Interview Confirmation Script

Hello, Ms. _____; my name is _____ and I work with Dr. Ambrosone at Mount Sinai School of Medicine. _____ (Recruiter) told me she spoke with you about our breast cancer study and that you agreed to participate, which is great.

If you were originally scheduled for the interview:

I'm just calling to confirm our appointment on (Day) _____ (Date) _____ at (Time) _____. Do you have a moment to talk?

If you were not originally scheduled for the interview:

I know _____ (Recruiter) said _____ (Interviewer) would be doing the interview with you. However, _____ (Interviewer) is not able to meet with you on that day so I will be doing the interview, instead. So I just wanted to introduce myself and confirm the appointment, if you have a moment to talk?

If no, ask for a better time to contact them and write it here _____.

If yes: I'd like to take a moment to tell you a bit more about the study.

You may remember that _____ (recruiter) told you that the study will look for things that may cause breast cancer by comparing women who have had breast cancer to women who have not. Understanding things that may cause breast cancer will help us teach women how to change their lifestyle habits to help them stay well. Do you have any questions about the interview?

If needed: The interview will include questions about your work, family, health, and diet history. You will also be asked to give a small blood sample at the time of your scheduled appointment and measurements will be taken, such as your height and weight. The entire process will take only about 2 hours. As an appreciation for your time and effort, I will be bringing the \$25 gift certificate for (Pathmark or Rite Aid) with me.

Ok, then, I'd like to confirm that we're meeting at:

Place of interview: _____

Address of location: _____

Brief directions to location (if needed): _____

I just have one suggestion for you in terms of the interview: **if you could wear comfortable, light, loose-fitting clothing, such as slacks and a short-sleeve shirt and socks or knee highs instead of stockings, it would make it much easier to take the body measurements, ok?**

Thank you Ms. _____, for taking time to talk with me today. I look forward to seeing you on (Day) _____ (Date) _____ (Time) _____ at (Location) _____. If you have a pen handy, I can give you my phone number in case you have any questions beforehand or need to change your appointment; ok, ready? My name is _____ and you can reach me at Mount Sinai at 212 659- _____ or my cell phone number, which is: _____.

9/10/03

Reference: Role of the Interviewer

Participant ID: _____
Reference Date: _____

Interviewer ID : _____

INTERVIEWER'S CONTACT SHEET

PARTICIPANT'S NAME _____

PHONE NUMBER _____

1. DATE: ____/____/____ RESULT: _____
TIME: _____

STATUS: _____

2. DATE: ____/____/____ RESULT: _____
TIME: _____

STATUS: _____

3. DATE: ____/____/____ RESULT: _____
TIME: _____

STATUS: _____

4. DATE: ____/____/____ RESULT: _____
TIME: _____

STATUS: _____

5. DATE: ____/____/____ RESULT: _____
TIME: _____

STATUS: _____

INTERVIEW CONFIRMED: _____ RESCHEDULED DATE/TIME: _____

DIRECTIONS SENT _____

INTERVIEW REFUSED: _____ REASON: _____

DATE INTERVIEW HELD: _____

9/10/03

Reference: Role of the Interviewer

INTERVIEWER TRAINING OUTLINE

These are case-control studies of women with breast cancer (cases), women similar to cases with regard to age and place of residence, but who do not have cancer (controls), and the adult healthy daughters of both the cases and controls.

These studies are designed to examine the genetic and environmental risk factors, the interest in genetic counseling and testing for BRCA testing, and the immunologic parameters of African American women recently diagnosed with breast cancer.

WHY INTERVIEW SUBJECTS IN PERSON?

1. More people will agree to answer questions when asked by another person, than will agree to respond to a questionnaire sent in the mail.
2. People are more likely to choose a specific response to a question if they are asked to respond by an interviewer, as opposed to saying, 'I don't know'. Interviewers can help subjects think through a question to provide an answer.
3. Interviewers can help clarify questions that the respondent doesn't understand.
4. Interviewers can observe respondents, noting information that might not be easily ascertained in a questionnaire, like a person's dress or grooming, surroundings, and her ability to read, write, or speak English.

INTERVIEWER ROLE

Goal: *The interviewer's role is to make sure that each question means the same thing to each respondent.*

The interviewer's presence should affect neither a respondent's perception of a question nor the answer given. The interviewer must always remain neutral.

MANDATORY INTERVIEWER CHARACTERISTICS

- Neat, well groomed
- Well-spoken
- Relaxed (but professional)
- Friendly (but not clingy)

LEARNING THE QUESTIONNAIRE

- Study each question carefully
- Practice reading the questions aloud
- Practice the questionnaire first on people you know well

QUESTIONNAIRE MASTERY

- No errors when reading questions

- Smooth, natural delivery, consistent across interviews

RECORDING RESPONSES

1. Record the answers to open-ended questions exactly as they are given. Do not simplify, interpret or correct grammar in responses.
2. Write comments that explain response when ever possible (e.g., a respondent appears to be embarrassed about answering, a respondent seemed offended by the question).
3. Probe for responses by asking for more information or by remaining silent and letting the respondent clarify his or her response spontaneously. **PROBES MUST BE COMPLETELY NEUTRAL.**

9/10/03

Reference: Role of the Interviewer

Division of Core A Responsibilities

(August 2003)

Lina Jandorf:

- Monitoring Interviewers' comp time status.
- Tracking time for questionnaire and self-reports completion.
- Coordinating interview scheduling among interviewers when scheduling conflicts exist.
- Assigning Recruiters/Interviewers.
- Coordination between Core A and Center Grant Projects.
- Interviewing and training recruiters.
- Interviewing and training new Interviewers.

Rose Bialecki:

- Developing agenda and minutes for weekly Core A Meeting.
- Developing agenda and handouts for Recruiter Meetings.
- Producing recruiter newsletter after Recruiter Meeting.
- Telephone screening, interviewing and training recruiters and tracking processing of volunteer paperwork.
- On-going updating of Interviewer/Recruiter Manuals.
- Reserve SLR and Beth Israel interview space.
- Maintain Anthropometry supplies.
- Maintain Klingenstein supplies
- Develop recruiter postcards
- Maintain supply of direction sheets to various hospitals

Sherly Jacob:

- Reserve KC and Queens Hospital interview space.
- Maintain supplies in KC and Queens Hospital.
- Maintain clerical supplies, including gift certificates, postage, metro cards, forms, etc.
- Update interviewer information cards.
- Update Show Cards
- Track supply of Project 1 Questionnaires (for reordering)

Melissa Solis:

- Reserve Weiler and Moses interview space.
- Maintain supplies in Weiler/Moses.
- Notify GCRC and lab weekly re interviews.
- Maintain blood draw supplies, including FedEx.
- On-site recruitment at Weiler/Moses.
- Weekly reports for Core A meeting.
- Maintain supply of consents, HIPAA forms, etc.

Yahaira Gutierrez:

- Perform all Interviewer functions on an as-needed basis.

Meredith Grossman:

- Perform all Interviewer functions on an as-needed basis.
- Project 3 batching, tracking, reports and assigning calls to Interviewers

All Interviewers:

- Complete Project 1 Interviews.
- Reserve rooms at Klingenstein.
- Send out recruiter mailings.
- Maintain weekly contact with Recruiters.
- Attend Recruiter/Interviewer Meetings.
- Maintain database on a daily basis.
- Re-schedule interviews.
- Train new Interviewers
- On-site recruitment at Kings County and other clinic sites.
- Project 2 and 3 Interviews

9/10/03

Reference: Role of the interviewer

TRAVEL SAFETY TIPS

BODY LANGUAGE

- Look Confident and sure about your destination. Take a copy of confirmed directions with you.
- Wear clothing that blends in well.
- If you must wear jewelry, moderation is the rule.
- Wear sneakers or comfortable shoes.
- Walk confident and make good eye contact.

AUTOMATED TELLERS

- Use only in well-lit areas.
- Be aware of what's going on around you.

SUBWAY SAFETY

- Travel during peak hours, whenever possible.
- Sit in subway car where motorman is located.
- Wait for trains near token booth.

TRAVELING

- Confirm your destination ahead of time and make sure a supervisor has a copy of your travel plans.
- Call when you arrive at interview location and before you leave. It's always a good idea for another party to know your time schedule.
- Use cellular phone to call for assistance at any time.
- Always remember that no matter what the situation:
 - REMAIN CALM
 - USE COMMON SENSE
 - IF IT DOESN'T:
 - Feel right
 - Look right
 - Sound right-**DON'T DO IT!!**

9/10/03

Reference: Role of the Interviewer

IV.

Interview Process

Mount Sinai Hospital

St. Luke's Roosevelt Hospital

Kings County Hospital

Montefiore Medical Centers

Queens Hospital Center

In-Home

All Interviews

HIPAA & Consent Procedures

Flow of Interviews

GCRC Admission Form

INTERVIEWS AT MOUNT SINAI HOSPITAL

Scheduling Blood Processing at the GCRC

After confirming the interview date, time and location, the GCRC will be notified by Meredith Grossman via e-mail (Schedule-CRC) of the scheduled interview and the approximate time for the blood draw and/or blood processing. All blood draws performed at the GCRC will be done by GCRC staff nurse practitioners. If an interview is cancelled or no blood specimen obtained, Interviewer will notify both Shen and Rui, as well as the GCRC at x46041, not to expect a blood specimen. If this occurs on a Friday after 5:00pm or any time Saturday, in addition to GCRC, Shen and Rui, the Interviewer will also notify Abbie Iyare at 917-447-1999.

○

Scheduling the Interview at the Klingenstein Pavilion

A sign-up book will be maintained in Room 16-52, East Building, in which to reserve an interview room at 1176 Fifth Ave., after confirmation of the appointment. The participant will be met in the lobby and accompanied to Suite 5, first floor. See "Hospital Info." Section for details.

INTERVIEWS AT ST. LUKE'S ROOSEVELT HOSPITAL

After confirming the interview date, time and location, Rose Bialecki should be notified that a room is needed at SLR. She will contact Mary Pepin (212 523-7177) and confirm that a room is available for the interview to take place. Directions will be sent to the participant, if needed. Blood draw and processing will follow the same procedure as for Mount Sinai. See "Hospital Info." Section for details.

INTERVIEWS AT KINGS COUNTY HOSPITAL

At a minimum, one Interviewer will be assigned to Kings County to both recruit and interview. Other Brooklyn patients can also be scheduled by additional recruiters at Kings County; after confirmation, Interviewer will advise Sherly Jacob who will arrange for interview space with Deborah Bristol (718-245-4779/4737; DFYB1963@aol.com). Blood specimens will be returned to the GCRC for processing, either by the Interviewer or via Federal Express, with the same procedures as Mount Sinai. See "Hospital Info." Section for details.

INTERVIEWS AT MONTEFIORE MEDICAL CENTERS

At a minimum, one Interviewer will be assigned to Montefiore/Einstein/Jacobi for two days per week. Nursing staff, including Una Hopkins at Weiler (718 405-8522) and Cathy Sarta at Moses (718 920-2059), and Interviewer will serve as Recruiters and schedule the appointments which will take place in an office at the hospitals. Consent will be obtained and blood drawn prior to the interview by hospital staff. Other Bronx patients can also be scheduled by additional recruiters at the 3 Bronx sites; after confirmation, Interviewer will advise Meredith Grossman who will arrange for interview space. Blood specimens will be returned to the GCRC for

processing, either by the Interviewer or via Federal Express, with the same procedures as Mount Sinai. See "Hospital Info." Section for details.

INTERVIEWS AT QUEENS HOSPITAL CENTER

After confirming the interview date, time and location, Sherly Jacob should be notified that a room is needed. She will contact Sharyn Parness (718 883-3751; 718 223-1908 PIN 24790) and confirm that a room is available for the interview to take place. Directions will be sent to the participant, if needed. Blood draw and processing will follow the same procedure as for Mount Sinai. See "Hospital Info." Section for details.

IN – HOME INTERVIEWS

Introduction at the Door

Once you have located the participant's home (using the Participant Recruitment Form and street map) you are ready to contact her. (Should you feel uncomfortable in the neighborhood and/or interview setting, advise the participant that you are unable to complete the interview and reschedule at a time when you can be accompanied by another interviewer). Upon arrival, activate your cell phone and notify the office you are at the participant's home. Although in most cases you have already introduced yourself and the study during the telephone call to confirm the appointment, you should be prepared to repeat all or part of that introduction if necessary. Always have your **ID** badge visible and have a copy of the brochure for reference. Be prepared to answer any questions asked briefly, to the point, and accurately.

Setting of the Interview

Find a comfortable, well-lighted and private place in the home. Ideally, this would include a table and two chairs so you can be face to face during the interview. However, keep in mind that you must accommodate to her home, and family situation. You may suggest an ideal interview setting but you must comply with her wishes (e.g., wants to have spouse or daughter participate, has no private space in home, etc). You may suggest that there are some parts of the interview which she may prefer to keep private, if possible.

ALL INTERVIEWS

HIPAA & Consent Procedures

HIPAA is the acronym for the Health Insurance Portability and Accountability Act. It was passed in 1996 and was made effective April 14, 2003. These federal regulations are intended to ensure patients' privacy requirements. Because of this change in policy, participants will now receive a HIPPA notification form that they will need to sign stating that they received it. In addition, participants will be asked to sign a consent form and a HIPPA authorization form for this study.

Cases:

All cases should receive HIPAA notification, HIPAA authorization, and informed consent from the hospital which referred them, regardless of the location of the interview.

- 1. Ask participant if they have received the HIPAA notification form from their referring hospital.**
 - a. If yes, go to #3**
 - b. If no, go to #2**
- 2. Give participant HIPAA notification form from their referring hospital and ask them to sign that they received it.**
- 3. Ask participant to read over and sign the HIPAA authorization form from their referring hospital.**
- 4. Go over informed consent from their referring hospital and ask them to sign it ONLY after you are sure they understand the consent completely.**

**** If the case from a hospital other than Mount Sinai needs to have blood drawn at Mount Sinai by GCRC, the interviewer needs to go through steps 1 – 4 again with Mount Sinai HIPAA notification, Mount Sinai HIPAA authorization, and Mount Sinai informed consent. In addition, GCRC needs a copy of the signed Mount Sinai consent form every time they draw blood for this study.**

**** If a case from any hospital other than Moses or Weiler is interviewed at Moses or Weiler, their staff must draw blood. If Moses or Weiler staff draws blood, the interviewer needs to go through steps 1 – 4 again with the Montefiore HIPAA notification, Montefiore HIPAA authorization, and Montefiore informed consent. The interviewer should take the original informed consent and leave a copy for Una Hopkins (if at Weiler) or Cathy Sarta (if at Moses).**

Controls:

All controls should receive HIPAA notification, HIPAA authorization, and informed consent from the hospital where the interview is taking place. If the interview is conducted at the participant's home, Mount Sinai HIPAA notification, HIPAA authorization, and informed consent should be used.

- 1. Ask participant if they have received the HIPAA notification form from the site where the interview is taking place.**
 - a. If yes, go to #3**
 - b. If no, go to #2**
- 2. Give participant HIPAA notification form from the site where the interview is taking place and ask them to sign that they received it.**
- 3. Ask participant to read over and sign the HIPAA authorization form from site where the interview is taking place.**
- 4. Go over informed consent from the site where the interview is taking place and ask them to sign it ONLY after you are sure they understand the consent completely.**

**** If a control is interviewed at Moses or Weiler, their staff must draw blood. The interviewer should take the original HIPAA notification page that was signed, HIPAA authorization & informed consent and leave a copy for Una Hopkins (if at Weiler) or Cathy Sarta (if at Moses).**

Obtaining Informed Consent

After you have gained cooperation and before you begin any data collection activities, you will need to obtain the participant's informed consent. Informed consent involves telling the participant exactly what her participation entails as well as her rights as a research participant. If participant indicates an inability to understand the consent process, either due to mental impairment or language barrier, the interview cannot proceed because the participant cannot consent in an informed manner. Likewise, if the participant exhibits an inability to complete the interview for any reason, including physical discomfort or symptoms, the interview can be abbreviated and, if possible, completed at another time.

The consent form provides the following information:

- A brief description of the study;
- A list of the study components for which consent is being sought;
- Information on the voluntary nature of participation;
- A description of the steps the researchers will take to maintain confidentiality and assurances that the data will be used for research purposes only; and
- The name and number of study researchers to call if there are any questions about the individual's rights as a research participant.

Remember it is critical that each consent form be presented to the participant prior to undertaking the specific tasks stated in each form and that the appropriate consent form be used for each participating institution, i.e., Mount Sinai, St. Luke's Roosevelt, etc. After the participant signs and dates two consent forms and initials each page, give the copy of the completed form to her. The remaining copy will be attached to the questionnaire when you turn in the completed participant materials. **All controls will be consented under the consent of the hospital where the interview takes place. If it is done in the home, the Mount Sinai consent will be used. Cases will be consented under the consent of the referring hospital.**

The goal for cases and controls is to administer all the study components in one visit, in the following order:

- HIPAA notification and authorization;
- Consent Form;
- Main Questionnaire;
- Food Frequency Questionnaire
- Behavior Change, Early Life Experiences, IES, How I Feel Scale (all self-administered);
- Anthropometry measures;
- Blood Draw;
- Introduction of Projects 2 and 3

- Consent for Project 2 Telephone Interview, if applicable.

If the participant cannot complete the interview at one appointment due to time constraints, take the Anthropometry measures and blood draw at the first interview; complete the remainder of the questionnaires at the next one.

FLOW OF INTERVIEWS

- Administer **HIPAA notification and authorization, consent** followed by **main questionnaire**. Show cards help the questionnaire go by quicker.
- Help the participant get started with the **FFQ**. You can sit next to her and ask her the first few items in order to orient her to the form and also to get a sense of her reading ability. If you feel she is not understanding the FFQ or she can't read well, then please ask her the questions. Otherwise, get her started and then let her finish it up. After she gets done with the FFQ, look over it to be sure she filled everything out correctly, and hand her the **Behavior Change Questionnaire, Early Life Experiences, Impact of Events, How I Feel Scale**(assuming she can read and is receptive).
- While she is doing these final questionnaires, please do the following:
 1. **Code the "activities"** in the physical activity section.
 2. **Review questionnaire** and check answers to make sure everything is filled out properly. (It is important to do this while you are still with the participant in case you realize that a question was not asked, or section was skipped so you can ask her any remaining things!) While reviewing, **check eligibility** for Projects 2 and 3.
 3. **Set up** for anthropometry and blood draw.
- Before the blood draw, have participant fill out the **Blood Specimen Checklist**. (This questionnaire deals with what she ate, drank or took in the past 2 days. This is so we know what to expect in the blood samples).
- Administer Project 2 Telephone Interview Consent for all African American cases.

9/10/03

Reference: Interview Process



**Mount Sinai School of Medicine
General Clinical Research Center**

Request for Admission

GCO# 00-0730

PROTOCOL TITLE Behavior, Estrogen Metabolism and Breast Cancer Risk: a Molecular Epidemiologic Study

Name(s) of Investigator(s):	Dept.	Office#	Home#	Beeper#
1. (PI) Christine Ambrosone, Ph.D.	Cancer Center	212-659-5552		
2. Julie Britton, Ph.D.	Cancer Center	212-241-5488		
3. Margaret McGovern, MD, Ph.D.	Human Genetics	212-249-9234		

Please circle the number before the name of the attending physician

Name of patient (Last, First, M.I.) _____ **Sex**

(circle): M / F

Birth Date: _____ **Birthplace:** _____ **Marital Status:** _____ **Religion:** _____

Ethnicity (circle): Black Hispanic White Asian/Pacific Islander Native American Other/Unknown

Patient's Street Address: _____

Tel. #: _____

Next of Kin: (name) _____ **Relationship:** _____

Address: _____ **Tel. #:** _____

In Case of Emergency Contact: _____ **Relationship:** _____

Address: _____ **Tel. #:** _____

Date of Admission: ____ / ____ / **Estimated Length of Stay:** _____ Days, or 2 _____ Hours

Admission Type (circle): Inpatient/Scatter-Bed/Off-Site/Outpatient **Time of Admission:** _____ am _____ pm

Prior Registration at Mount Sinai? (Circle): No / Yes, Unit # _____

Admitting Diagnosis: _____

Justification For Admission Under This Study: _____

Activity Level ():

☐ Normal ambulatory ☐ Ambulates with assistance ☐ Assistance transferring bed to chair ☐ complete assistance

Dietary (): ☐ Regular Diet ☐ mg Sodium Diet _____ ☐ Diabetic, (Calories _____) ☐ Kosher

☐ Low Cholesterol ☐ Low MAO Diet ☐ 1,000 Cal. ☐ Other N/A _____

I have determined that this patient/subject is a suitable candidate for this research protocol. I estimate the proportion of the admission that will be:

(a) Research 100 % (b) routine care _____ %

Signature of Investigator

Date

The final determination for evaluating what fraction of the admission was for research or routine patient care is made by the Program Direction Staff at the time of discharge.

Request Approved, GCRC

Date

9/10/03

Reference: Interview Process

V.

QUESTIONNAIRE ADMINISTRATION

Interview Topic Outline

Averting Refusals

Interviewer Questions and Answers

Questionnaire Reminders

Emotional Reactivity

9/10/03

INTERVIEW TOPIC OUTLINE

- **DEMOGRAPHICS:** Personal, demographic information.
- **FAMILY HEALTH HISTORY:** Cancer history of all immediate blood relatives: parents, siblings, children.
- **PRENATAL EXPOSURES:** Few questions on mother's pregnancy.
- **MENSTRUAL HISTORY:** Reproductive and medical history including childbirth, breastfeeding practices for each child, oral contraceptives and Hormone Replacement Therapy (HRT).
- **MEDICAL HISTORY:** A few questions on specific diseases, medications and mammography screening.
- **SMOKING HISTORY:** Few questions on cigarette smoking and passive smoking exposure.
- **DEVELOPMENTAL HISTORY/ PHYSICAL ACTIVITY:** Height and weight, physical activity patterns including history and job related physical activities.
- **STRESSOR EVENTS:** Lifetime history of stressful events, such as unemployment, death, moving etc.
- **LIFESTYLE:** Questions about living environment, alcohol consumption, household income, spirituality.
- **BEHAVIOR CHANGE:** Change in behaviors since reference date.
- **SENSITIVE QUESTIONS:** Regarding childhood.
- **EMOTIONAL STATUS:** Present and cancer related.

9/10/03

Reference: Questionnaire Admin.

Questionnaire Reminders

Questionnaire – See QxQ for question by question directions.

Rounding: Round up if more than $\frac{1}{2}$ (See QxQ).

Probe for specific responses, if participant unsure. Ranges are not appropriate.

Check only one response unless indicated otherwise.

Check questionnaire for missing page numbers.

Check questionnaire for consistency in response, i.e., respondent has 3 children but only two names are listed.

Check questionnaire for accuracy, i.e., 20 years exercising started at age 17; if the respondent is now 34, that's incorrect.

Self-Reports

FFQ: make sure all bubbles are completely filled out in pencil.

Reference date must be included; refers to one year prior to the questionnaire reference date.

Never or less than 1x/month does not need an amount.

Blood Specimen Checklist: remove last page with a control. Complete Interviewer information.

Behavior Change: "other" should not be checked for no change.

All: Review self-reports for missing or conflicting responses and clarify answers.

Self-reports can be done over the phone, if the respondent has not returned via mail.

If returned by mail and today's date is missing, use the date returned, less 2 days.

9/10/03

Reference: Questionnaire Admin.

AVERTING REFUSALS

1. **BE EMPATHETIC WITH YOUR SUBJECT.** How would you feel if someone you didn't know wanted to interview you? What would make you feel at ease with a stranger who wants both your time and a lot of personal information?
 - **BE SENSITIVE** to the participant's perspective on life. Get a sense of what she finds is important, pay attention to her living situation and her limitations.
 - **ESTABLISH RAPPORT.** Start off on the right foot. Offer a compliment about her house/apartment. Be careful not to appear condescending or say anything that may influence her answers during the interview. Treat her with the respect she deserves.
 - **BODY LANGUAGE IS IMPORTANT.** Present a calm, professional, pleasant demeanor. Your sense of confidence and competence will be communicated by your positive attitude.
 - **ASK "YES" ANSWER QUESTIONS.** If you get to a stage at the introduction and think a refusal is pending, ask questions that will elicit a "Yes" response. If she starts agreeing with you, it will be harder for her to refuse later. For example:

"Breast cancer is an important health issue facing women today, don't you agree?"

"To improve the health care system we all need to help out, don't you think?"
 - **FOCUS ON THE PARTICIPANT.** Don't be self-conscious. Use eye contact (when in-person) to draw out her concerns. Be a good listener.
 - **IGNORE NEGATIVE COMMENTS.** This is not as hard to do as you may think. Don't take negative comments personally; they are not directed at you. If she says something negative, say "uh huh" or nothing, and wait. The pause will let her know she has said something inappropriate.
 - **START THE STUDY TASKS QUICKLY.** Once you begin conducting the various activities, the participant will see that her fears are unfounded.
2. **STOP BEFORE THE PARTICIPANT REFUSES.** If you still find that you cannot convince a woman to participate in the study, **leave the door open for someone else to make a further attempt.** Try to leave on a friendly note. If the situation allows, ask her to think about the study and suggest something like:

"Why don't you think about it for a few days. My supervisor or another study interviewer will contact you at another time. This study has great value."

Exit gracefully and leave the person receptive to the efforts of a different interviewer.

9/10/03

Reference: Questionnaire Admin.

INTERVIEWER QUESTIONS/ANSWERS

1. I don't have time/interview is too long:

I know that this takes a bit of time but there are still many things that health educators and researchers don't know about women and breast cancer. This information is important in helping us to better address the needs of local communities. In order to complete the interview, we can work around your schedule. Your help is so important to us because the information you give us about your lifestyle and family and medical history could help us to reduce the number of people who develop and die from breast cancer.

2. I don't know how this information is going to be used/don't know who will see my answers:

All the information you provide will be confidential. Your interview answers will not be marked with your name, but with a code number. Any personal information we obtain from you will be separated from your interview answers. Your help is so important to us because the information you give us about your lifestyle and family and medical history could help us to reduce the number of people who develop and die from breast cancer.

3. Why are you asking questions about my parents, children and other relatives?

There are differences in the incidence of breast cancer between ethnic groups, e.g., Hispanic women have less breast cancer than African American and White women, so researchers are looking at both genes and the environment to help understand why these differences occur.

4. I'm receiving chemotherapy right now/just finished treatment; can I still participate?

This is not a treatment study and your involvement will not interfere with any treatment you may be undergoing/have recently completed. The study consists of a one-time interview, at which we would take a small blood sample, as well as body measurements. That's all there is to it.

5. Why do you need to take my blood; what will you do with it?

The purpose of the study is to try to understand why some women get breast cancer and others do not. Not everyone with similar habits or characteristics will get breast cancer. This may be because of individual differences in how our bodies make the substances needed to keep everything working right. Just as people differ from one another in how they look, they also differ in what goes on inside their bodies and in how their bodies respond to things they eat, drink and smoke, as well as medications they take. In this study, we will compare some of these factors between women with breast cancer and women without.

6. Why are you asking about whether I was breastfed or whether I breastfed my children?

Breastfeeding has been shown to provide protection against certain autoimmune diseases, such as diabetes; researchers are interested in any differences in women who have had breast cancer and those who have not so this is one area they are looking at.

7. Why are you asking about age at menstruation/age of first pregnancy?

Some research has shown a relationship between age of menstruation (age of first pregnancy) and frequency of breast cancer so this is one area researchers are interested in.

8. Why are you asking about oral contraceptives and HRT?

Estrogen has been linked to some types of breast cancer; researchers are looking at the amount of estrogen a woman has been exposed to during her lifetime to see if that is related to whether or not women develop breast cancer.

9. Why are you asking about ex-ray treatments?

Radiation exposure has been linked to certain types of cancer so researchers are looking at such exposure to see if it may be related to breast cancer, as well.

10. Why are you interested in how much aspirin, etc. I take?

Aspirin has been shown to be protective in certain circumstances against heart disease but can cause other physical problems, such as stomach irritation. Researchers are interested in whether aspirin or other over the counter medications may be related to differences in who develops breast cancer and who doesn't.

11. Why do you want to know if I dye my hair?

Researchers are looking at whether hair dye is related to who gets or who doesn't get breast cancer.

12. Why are you asking about the people I lived with when I was growing up?

Researchers are interested in whether our environment, including things like radiation exposure, as well as other household conditions such as the size of the family, is related to who gets or who doesn't get breast cancer.

13. Why are you interested in my height and weight growing up?

Researchers are looking at ways in which our bodies change over time and whether those changes are related to those who get and those who don't get breast cancer.

14. Why are you asking about the jobs I've had/amount of physical activity?

Some studies have shown exercise to be related to less risk of breast cancer; researchers are interested in looking at women's lifetime physical activity to see if there is a difference between women who have developed breast cancer and those who have not.

15. Why are you asking about my childhood experiences (abuse, trauma, poverty)?

These are standardized questionnaires. Researchers don't really know much about how our early experiences may or may not affect our adult health; it is hoped these questions will help them start to understand whether or not this is the case.

16. I had skin cancer but I don't know which kind I had.

Basal cell or squamous cell carcinoma rarely metastasize in contrast to melanoma which may result in metastasis.

Patient refuses a second time

Thank you for listening. Please take my number or card in case you change your mind. Would you mind answering just a few questions? Proceed to Refuser Questionnaire.

9/10/03

Reference: Questionnaire Admin.

Emotional Reactivity

During a Project 1 Interview

It is possible that the experience of undergoing an interview may reveal some negative feelings related to having breast cancer or some other life event or circumstance. Interviewers should observe respondents carefully throughout the interview for both verbal and non-verbal cues that distress is being experienced, and to respond appropriately. Depending on the amount and nature of the distress, the Interviewer may:

- suggest a short break;
- offer to postpone completion of the interview to another day;
- ask if assistance from a family member is wanted;
- contact Lina Jandorf or Anne Fatone for assistance.

In reviewing the "How I Feel " Scale, if more than one question is answered with the indicated response, or if depression (question 9) or emotional instability (question 18) are answered in the affirmative, the Interviewer should ascertain whether the participant is currently seeing a therapist. If not, let them know that either Lina Jandorf or Anne Fatone may be contacting them post-interview, as a normal follow-up. If respondent does not presently have a therapist but is interested in locating someone, the following resources can be offered:

Ann Webster, Ph.D. (clinical psychologist): 212 799-5449

Jane Karp, M.D. (psychiatrist): 212 772-0025

Robin Zarel, CSW (social worker) 212 247-4206

Mount Sinai Breast Health Resource Center (cases only): 212 987-3063
(services are free at the Resource Center only).

After the interview, Interviewers complete the Mental Health Index Summary section of the Post-Interview Checklist field in the database. If responses indicate the need for follow-up and the respondent does not have a therapist, the Mental Health Index Summary Sheet will be completed and given to Lina Jandorf or Anne Fatone for follow-up within 24 hours of interview. If follow-up is not indicated, data will be entered indicating depressive symptomatology criteria was not met and respondent does not need to be contacted.

9/10/03

Reference: Questionnaire Admin.

Interview Date: _____

Location: _____

**Mental Health Inventory Summary Sheet
(How I Feel Scale)**

<u>Question</u>	<u>Response</u>	<u>Yes*</u>	<u>No</u>
HIFS2	1	___	___
HIFS4	6	___	___
HIFS9	1 or 2	___	___
HIFS16	1 or 2	___	___
HIFS18	6	___	___

***If yes response to two or more, or yes response to either 9 or 18, MIH Summary Sheet given to:**

L. Jandorf _____ Date: _____

A. Fatone _____ Date: _____

Place ID label here:

9/10/03

Reference: Questionnaire Admin.

VI.

Blood Draw

Phlebotomy Training Protocol

Practice Log Sheet

Interviewer Tracking

Introduction to Blood Draw

Biosafety

Blood Draw Protocols

Physician Blood Draw

Procedure for Spinning Blood

Blood Draw Procedures

Unusual Occurrences

Incident/Emergency Report Form

Needlestick/Sharps Injury Procedures

Phlebotomy Training Protocol

1. Trainee must attend a 3-hour vascular module sponsored by the MSMC Nursing Department.
2. Once the 3-hour vascular module has been completed, the trainee is required to successfully complete 6 blood draws in a controlled setting, before entering the field. The subjects of the blood draw should sign the Phlebotomy Practice Log Sheet.

Note: the more practice the more confident the trainee will become, therefore, it is suggested that the trainee compete more than the 6 required blood draws.

3. Once the trainee has successfully completed the 6 required blood draws, the Phlebotomy Practice Log Sheet will be kept on file.
4. Efforts should be made to perform the blood draws on an ethnically-diverse group of women. Reflecting the population of the study, this should include at least two African American women.

9/10/03

Reference: Blood Draw

PHLEBOTOMY PRACTICE LOG SHEET

Interviewer Name: _____

Phlebotomy Training Date: _____ *

Name of Volunteer	Date of Blood Draw	Volunteer's Signature

Supervisor's Signature: _____

*6 Blood Draws must be completed as part of Interviewer Training

9/10/03

Reference: Blood Draw

Interviewer Tracking

Name of Interviewer: _____

Phlebotomy Training: _____
(Contact: Sylvia McBirney x47050)

Phlebotomy Practice Complete: _____

CPR Training: _____
(Contact: Sylvia McBirney)

Anthropometry Training: _____
(Contact: Julie Britton, Ph.D., x45488)

GCRC Orientation: _____

9/10/03

Reference: Blood Draw

Introduction to Blood Draw

To gain cooperation, you must be prepared to address the subject's concerns effectively. Therefore, be sure you are familiar with the following information about the procedures to be used for the study:

- You must be able to describe the tubes that are to be drawn and summarize the testing that will be done by the researchers at MSSM. Stress that this is not a multi-stick procedure; all three tubes will be drawn with one venipuncture.
- The blood draw will only cause minimal discomfort. The body manufactures blood daily and this small volume of blood (24 ml) will be completely replaced within 24 hours.
- The supplies used for the blood draw are completely sterile, and they are used only once. After use they are destroyed. There is absolutely no possibility of the subject being infected by any blood-borne disease, such as hepatitis or AIDS, as a result of participating in the Tri-State Women's Circle of Health Breast Cancer Study Project.

Gaining the cooperation of the subject will be easier if the atmosphere is pleasant and you make the subject feel comfortable. Below is a list of suggestions for creating a pleasant atmosphere.

- Maintain a clean and uncluttered work surface. This is especially important because of today's concern with blood-borne infectious diseases, such as hepatitis and AIDS.
- Be aware of your body language: a positive body image inspires confidence. Maintain a tidy appearance, erect posture, and a pleasant expression.
- Speak face-to-face with the subject and maintain eye contact. Staring at other areas in the room may cause the subject some uneasiness since it implies that she is not important and you are not interested in performing the blood draw.
- Avoid nervous behaviors, such as squirming and tapping, which can distract you and the subject. The subject may begin to feel nervous, hurried, and anxious as a result of such behaviors.
- Avoid distractions such as TV, radio, or food cooking on the stove. At times you may need to request that you move the blood draw into a room which would give you complete privacy.

9/10/03

Reference: Blood Draw

BIOSAFETY

Overview

Standard laboratory precautions to minimize the spread of infectious disease must be followed. These recommendations have been developed and compiled by **CDC**.

- All blood samples are considered to be potentially infectious and must be handled with extreme care.
- Extraordinary care must be taken to avoid accidental needle sticks or cuts from broken glass. This can occur as a result of careless technique and improper disposal of used needles and blood drawing equipment. Extraordinary care must be taken to dispose of needles immediately after use in a puncture proof box.
- Gloves must be worn during venipuncture and at all times when handling the blood samples and contaminated material. Cuts or abrasions should be protected under the gloves.
- Hands should be washed with soap and water or antibacterial handwipe before and after each blood draw. A new pair of gloves should be worn for each subject.
- Work surfaces should be covered with Chuks at all times.
- Blood spills should be cleaned promptly with absorbent material, using a 1:10 dilution of bleach and water or antibacterial handwipe.
- All needles or blood collection sets are sterile and are to be used only once.
- All needles or blood collection sets must be disposed of immediately after use, in a puncture-proof sharps container clearly marked "Biohazard." Needles are never to be re-capped, bent, or cut.
- Broken glass should be disposed of in the puncture proof sharps box.
- Never leave any material at a drawing site.
- All contaminated material should be disposed of in a sturdy closeable bag clearly marked **BIOHAZARD**.
- Only authorized personnel are to handle the supplies, equipment and samples.
- Eating, drinking or smoking is prohibited in areas where blood is processed or stored.

9/10/03

Reference: Blood Draw

PROTOCOL FOR COLLECTION OF BLOOD SAMPLES

1. After anthropometry, have participant complete Specimen Collection Checklist and then collect blood (24 ml.):

1-10ml. Red-top tube for serum and blood clots.

1- 4ml. Purple-top tube(EDTA) for DNA extraction.

1-10ml. Green-top tube (sodium heparin additive) for plasma and buffy coat.

Blood should be collected in the following order: 1 red, 1 purple, 1 green.

2. Specimens are inserted into either a bio-hazard bag (on-site interview) or styrofoam transport (off-site interview). Wrap one sheet of labels stapled to the Physician Order Sheet around the bio-hazard bag or styrofoam transport using a rubber band. Protect specimens from light.
3. Blood specimens will be taken to the General Clinical Research Center (GCRC) at 1184 Fifth Avenue, 2nd floor, for initial processing by Core C. The purple vial will be left in biohazard bag, with a copy of the Specimen Collection Record, in a basket in room 296 of the Molecular Biology Core laboratory, 1184 Fifth Ave. The red and green vials will be taken to the GCRC, also with a copy of the Specimen Collection Record. After 5:00 PM weekdays or on weekends, all tubes will be taken to the GCRC, with both copies of the Specimen Collection Record. The date and time of specimen delivery will be recorded in the GCRC Log Book. A voice message will be left for Shen and Rui, x85483, advising them of the specimen collection. If after 5:00 on Friday or any time Saturday, Abbie Iyare, the lab technician, will also be notified at 917-447-1999.
4. There may be participants who prefer to have blood drawn by their own physician. In order to accommodate this request, the following process will be followed:
 - Label the Specimen Checklist.
 - Label the empty vials before placing them in the Styrofoam box, then in the cardboard box and, finally, in the Diagnostic Specimen Envelope.
 - Complete the recipient part of the FedEx USA Airbill as follows:
 - Mount Sinai School of Medicine, 1425 Madison Ave., Suite 1670, New York, N.Y. 10029; Attention: Lina Jandorf/Anne Fatone-Center Grant; check recipient for payment and put our account number: 2519-4716-3; check 4a (Priority Overnight).
 - Attach the filled out FedEx USA Airbill to the Diagnostic Specimen Envelope.
 - Place the Specimen Checklist and the Instructions for Physicians in the Diagnostic Specimen Envelope.
 - Give this material to the participant for them to bring to their physician. Remind participant to complete Specimen Checklist prior to the blood draw. Let participant know

that **blood cannot be drawn on a Friday** because blood processing may not be available until Monday. So their physician can draw their blood on from Monday through Thurs.

The Interviewer is responsible for following up with the participant and/or her physician and notifying Lab personnel when to expect the specimen shipment.

- If an interview is cancelled or no blood specimen obtained, Interviewer will notify both Shen and Rui, as well as the GCRC at x46041, not to expect a blood specimen. If this occurs on a Friday after 5:00pm or any time Saturday, in addition to GCRC, Shen and Rui, the Interviewer will also notify Abbie Iyare at 917-447-1999.

9/10/03

Reference: Blood Draw

**Tri-State Women's Circle of Health
Breast Cancer Research Project**

Instructions to Participants and Physicians

Your patient is taking part in the Tri State Women's Circle of Health Breast Cancer Research being conducted throughout the metropolitan area. She has asked that you, rather than study personnel, draw the blood sample needed for the study. Please follow the steps outlined below which are designed to simplify this process for you and your patient.

- The participant should complete the Specimen Checklist prior to the blood draw.
- There are three vials in the Styrofoam box, 1 red, 1 purple, 1 green. Please fill all three.
- Place the vials back in the Styrofoam box and then in the cardboard box. Finally, place the cardboard box in the Diagnostic Specimen Envelope from FedEx, along with the Specimen Checklist.
- Complete the sender part of the FedEx USA Airbill. Mount Sinai School of Medicine, as recipient, will be billed for the shipment.
- Call FedEx at 1-800-463-3339 for same day pick-up of the specimen on **Monday-Thursday**. Specimens cannot be picked up on Fridays.

If it is not convenient to have the Diagnostic Specimen Envelope containing the specimen picked up, it can also be taken to a Federal Express Drop Box on **Monday-Thursday**.

It is important that the blood specimen be returned the same day it is drawn.

Participant:

On the day of the shipment Please call Senaka Peter at 212 659-5406 to notify her that a blood specimen has been sent. This will ensure that the specimen will be followed-up on with FedEx should a problem develop.

Thank you for helping with this important research project!

9/10/03

Reference: Blood Draw

BLOOD DRAW PROCEDURES

The blood draw should take place in a location which is well-lit and has no carpet. If carpeted, protect the floor with a Chuks. The participant should be comfortable and should be in a place where she will not be injured if she faints, e.g., the couch or chair.

Next, prepare your work area. Carefully drape the area you will be working in because any spills outside the draped area must be cleaned with an antibacterial wipe. Place only the supplies you need for the draw for this subject on the covering. This would include the tourniquet, needles, tubes, alcohol wipes, gauze strips, and band-aids. Keep the Blood Specimen Data Sheet and a pen on the table and complete each section as you proceed.

A. Follow the steps outlined below to **prepare the puncture site**:

- Wash your hands thoroughly with soap and water or use handiwipes, if necessary. Dispose of towels or wipes in a waste biohazard bag.
- Put on gloves.
- Ask which arm the participant prefers to be used for the blood draw.
- Instruct the subject to extend her arm palm up and straight at the elbow so that the veins are accessible and you are able to work in a comfortable position. Be sure that the arm is in a downward position to prevent backflow.
- Inspect the arm you plan to use. The veins of choice are located in the antecubital area. It is preferred that you do not draw blood from the back of the hand.
 - Do not draw blood from an arm which has a rash, open sores, is swollen, or has evidence of a recent blood draw or hematoma.
- Apply the tourniquet about 3-4 inches above the elbow.
- Select a vein which is palpable and well-fixed. Palpate even when the vein can be seen. Avoid veins which feel hard or show signs of scarring.
- If the veins do not distend quickly,
 - Ask the subject to open and close her hand several times;
 - Massage the arm from the wrist up to the elbow;
 - Apply a warm compress for about 10 minutes;
 - Tap the area two or three times; and

- Examine the other arm. Sometimes veins in one arm are larger than in the other.
- If the tourniquet has been applied for more than one minutes while the vein is selected, release it for at least five minutes before re-applying.
- Cleanse the puncture site with an alcohol wipe, working in a circular motion out from the puncture site.
- Dry the area using a sterile 2 x 2" gauze. The area should be dry.

You will make one attempt at drawing the participant's blood. If you are unsuccessful with one needlestick, ask the subject if you can try again. If you are unsuccessful with two needlesticks, you will stop and clean-up the blood draw materials. You will then document the problem. If the interviewee is a patient at a participating hospital, ask permission to contact her at her next doctor's appointment.

B. You will attempt to **collect three tubes**, one red, purple and green for each participant using the following technique:

- Assemble the butterfly with the vacutainer holder.
- Ask the participant to make a fist.
- Remove the shield from the butterfly needle and approach the vein in the same direction the vein runs, holding the needle with the bevel up and at a 15°angle, about ½" below the proposed point of entry to the vein.
- Pinching the butterfly "wings" together, push the needle firmly into the skin and then into the vein. When you are firmly in the vein, blood will appear in the tubing of the butterfly.
- Quickly push the red test tube onto the butterfly needle in the holder puncturing the stopper of the tube. The tube must be punctured in the center of the stopper.

If no blood appears in the tubing, attempt to re-position the needle. If blood does not appear, release the tourniquet and remove the needle, placing a sterile gauze pad over the puncture site.

Ask the participant if you may attempt a second draw. If she agrees, make a second attempt on the other arm with a sterile collection set and new test tubes. Two attempts are allowed, only after verbal consent by the participant.

- Hold the tube with the stopper in an upright position so that the contents of the tube do not touch the stopper.
- When the first tube is full, remove it from the holder and place succeeding green tubes in holder.
 - If tubes are slow in filling, re-apply the tourniquet and ask the participant to open and close her hand slowly. Release the tourniquet when blood flow has been established.
 - If at any time during the blood draw procedure a hematoma appears, terminate the blood draw.
- **Remove the tourniquet when the third tube is partially full.** The participant should open her fist.
- Immediately invert the tubes to ensure proper mixing of blood and anticoagulant. Note: the ratio of blood to anticoagulant in these tubes has been determined for maximum test sensitivity so be sure to fill the tube as completely as possible.
- If the subject shows any adverse affects or states she does not feel well, terminate the blood draw and follow emergency procedures as necessary.

C. The following procedures will be followed in **concluding the blood draw.**

- When the last tube is filled and gently inverted, quickly withdraw the needle holding a gauze pad over the puncture site and applying slight pressure only when the needle is withdrawn.
- Ask the participant to hold the gauze pad with moderate pressure and raise the arm straight up in the air for 2 minutes. Do not flex the arm. If the participant is using a blood thinning medication other than aspirin, have her apply pressure to the area for a few extra minutes.
- IMMEDIATELY, disconnect the butterfly assembly from the vacutainer holder and discard it in the sharps container. The holder is reusable.
 - If the holder becomes visibly soiled, discard it in the biohazard bag.
- **Label each tube with an ID label. If the label overlaps itself, be sure that the ID number can easily be read.**
- Check the puncture site and apply a band-aid over a sterile 2x2" gauze pad when bleeding has stopped.
 - Keep continued pressure on the site for a few more minutes if bleeding continues.
- Closely monitor the subject for any adverse reactions to the blood draw for ten minutes.

- Discard all used material in the waste biohazard bag.
- Dispose of needles in a sharps container and the gloves, table covering, and handiwipes in the waste biohazard bag.
- Wash your hands with soap and water or an antibacterial handwipe.

NOTE: If blood has spilled on an area outside of the table covering, the area must be washed with an antiseptic wipe. The towels must be disposed of in the waste biohazard bag.

9/10/03

Reference: Blood Draw

UNUSUAL OCCURRENCES

When a problem occurs during the venipuncture, it is important to document this in the comment section of the Blood Specimen Data Form. For example:

- Unsuccessful draw: reasons, how many attempt, etc.;
- Quantity not sufficient;
- Two sticks required;
- Tourniquet left on too long;
- Hematoma developed;
- Subject became ill or fainted;
- Subject requested blood draw be stopped;
- Sample hemolyzed, lipemic, icteric, or clotted;
- Vial cracked;
- Sample leaked; and
- Problems transporting blood to laboratories.

Specimen Storage

There may be times when you are unable to deliver the blood specimens to the GCRC on the day they are collected. In those instances, you will need to store the blood until the next day. Blood specimens are to be stored in a specimen biohazard bag and refrigerated.

Venipuncture Complications

Hematomas

Hematomas are the most common complication of venipuncture. They are masses produced by coagulation of extravasated blood in a tissue or cavity. They may result from through-and-through puncture to the vein or from incomplete insertion of the needle into the lumen of the vein, allowing the blood to leak into the tissue by way of the bevel of the needle. In the latter case, correction may be made by advancing the needle into the vein. At first sign of uncontrollable bleeding, the tourniquet should be released and the needle withdrawn. Mild pressure to the puncture site should be applied immediately. Hematomas also result from the application of the tourniquet after an unsuccessful attempt has been made to draw blood.

Hematomas most frequently result from insufficient time spent in applying the pressure, from failure to apply pressure, and from the bad habit of flexing the arm to stop bleeding. Once the venipuncture is complete, the subject should be instructed to apply mild pressure to the puncture site and raise her arm straight in the air for about two minutes. Constant pressure should always be maintained until the bleeding stops. Pressure should be applied with dry, sterile gauze; a wet sponge encourages bleeding. Band-aids do not take the place of pressure and, if used, are not to be applied until after the bleeding stops.

Arms covered with ecchymoses (escape of blood into the tissues, producing a large and blotchy area of superficial discoloration; bruises) demonstrate poor technique or a haphazard manner. Proper techniques must be employed at all times to prevent unnecessary hematomas.

Syncope (Fainting)

Syncope, or fainting, is a sudden loss of strength or temporary loss of consciousness and is caused by decreased blood flow to the brain. To prevent injury of any subject who might faint, always perform the venipuncture when the subject is in a seated, relaxed position with feet flat on the ground. Warning signs include: the subject may become pale and begins to perspire heavily; the subject may feel dizzy and hot, and may begin to pant (hyperventilate); and/or the subject may feel nauseated.

When the subject has any of the above signs, terminate the venipuncture. Instruct the subject not to watch the procedure. Have the seated subject put her head down between her knees, and carefully prevent her from falling. Have her take slow, deep breaths. Keep talking to the subject in a calm, reassuring manner. Call for a family member or co-worker, if available.

If the subject faints, gently ease the subject to a lying position and elevate her feet. Check radial pulse. After the subject regains consciousness, give her fluids, i.e., water. Stay with the subject until you are assured that she has recovered.

Continued Bleeding

Some subjects are receiving certain drug therapies or have bleeding disorders that may cause them to continue to bleed after the venipuncture. To prevent bleeding, it may be necessary to apply pressure to the puncture site for an extended period of time. If the subject continues to bleed after ten minutes, call her physician for appropriate care.

Thrombosis

Thrombosis is the formation of blood clots (thrombi) inside a blood vessel or inside the chambers of the heart. They can occur as a result of venipuncture when the endothelial lining of the vein is injured. A thrombosed vein should not be used for venipuncture. A thrombosed vein can be detected by palpation prior to the venipuncture. The vein with a thrombosis lacks resilience, feels hard and cord-like, and rolls easily. Remember only the veins in the arms will be used for the venipuncture procedure. Veins in the lower extremities may have poor circulation, which leads to the formation of thrombi.

To prevent thrombosis, subsequent venipunctures should be performed at sites proximal to previous puncture sites.

Sclerosis

Sclerosis is an indication of hardening of blood vessels. It can occur as a result of inflammation, excessive venipuncture, or poor technique. A vein that feels hard when palpated should not be used for venipuncture. Prevention of sclerosis can be accomplished by the skillful performance of venipuncture technique.

Embolus

An embolism is transfer of a mass, blood clot or object within the vascular system, from its point of origin or entrance to a distant site, causing an obstruction of blood flow. The embolus is most often a blood clot, but it may be a fat globule, an air bubble, a piece of tissue, or a clump of bacteria. Embolisms are usually fatal, and can be prevented by performing the venipuncture procedure using skillful technique.

Medical Emergencies Overview

The blood specimen collection component is designed to be safe for all eligible subjects. However, it is possible that an incident or medical emergency may occur when you are conducting a blood draw.

All life-threatening emergencies that may occur during a home visit, such as acute myocardial infarction, should be referred for immediate evaluation at an acute care facility, with emergency measures taken, as needed, prior to departure. Minor emergencies, such as hypotension or fainting, should receive treatment and then the subject should be assisted to contact their physician to determine if further evaluation is needed. Although, most emergencies are of a less severe nature, you should be prepared for both types.

When a serious or life-threatening event occurs during a home visit, your primary goal is to stabilize the subject and assist her to the nearest medical facility. If possible, contact the subject's physician and/or the next-of-kin. If the situation is urgent, 911 should be called and the subject transported to an emergency room. When in doubt, call 911 and report the incident; the emergency personnel will determine whether transport is necessary. As soon as possible, notify Lina Jandorf or Anne Fatone.

In the event of a medical emergency in which the subject remains conscious, you must obtain the consent of the subject to contact emergency medical services. If the subject refuses to consent, the subject or the subject's guardian must be asked to sign a release form which states that the subject does not wish to contact an emergency medical service for follow up medical attention against the advice of the MSSM technician. If a family member or a neighbor is present, they should be asked to witness the subject's signature by signing the release form.

For incidents requiring the use of emergency medical services, even if the subject was not transported to an emergency care facility, you should meet with your supervisor to discuss the incident.

9/10/03

Reference: Blood Draw

MSSM BREAST CANCER STUDY

INCIDENT/EMERGENCY REPORT

1. Date of Incident/Emergency: _____ Time of Incident/Emergency: _____ AM/PM	2. ID Number: <table border="1" style="display: inline-table; width: 100px; height: 20px; vertical-align: middle;"></table> Subject's Age: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>
3. Subject's Symptoms (Please list.) _____ _____ _____ _____	4. Medical/Emergency Procedures Followed: <div style="text-align: right;"><input type="checkbox"/> N/A</div>
5. Emergency Equipment Used (Please list.) _____ _____ _____ _____	6. Outcome of Medical Procedures Used: <div style="text-align: right;"><input type="checkbox"/> N/A</div>
7. Identification of Emergency Services Used: <input type="checkbox"/> N/A <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> A. _____ _____ _____ () _____ </div> <div style="width: 45%;"> B. _____ _____ _____ () _____ </div> </div>	
8. Identification of Medical Facility to Which Subject Was Taken: <input type="checkbox"/> N/A _____ _____ _____ () _____ <div style="float: right; margin-top: 10px;"> Accompanied Subject to Facility Y N Personal Belongings Sent with Subject Y N </div>	
1. Physician Contacted on: _____ Next-of-Kin Contacted on: _____ Specify Next-of-Kin: _____ Supervisor Contacted on: _____	
Any other comments:	Research Interviewer Signature: _____ Date: _____

9/10/03

Reference: Blood Draw

To complete the form, you should include the following information:

- Month, day, year and time of the incident or emergency.
- Subject's ID number.
- Subject's age (enter number of months or years).
- Subject's symptoms (list specific symptoms separately like shortness of breath, dizziness, chest pain, etc).
- Medical/emergency procedures followed (briefly describe what was done in the order in which it was done; if not applicable enter "N/A"; vital sign measurements would be recorded here if applicable).
- Emergency equipment (list all equipment's used; if not applicable, enter "N/A.")
- Outcomes (briefly describe outcomes of the incident/emergency by relating them to individual procedures performed; if not applicable, enter "N/A.")
- Identification of emergency services used (list specific name, address and telephone number, including area code, of hospital ambulance service or police, fire, county or local rescue squad used; if not applicable, enter "N/A.")
- Identification of medical facility to which participant was taken; if not applicable, enter "N/A.")
- Phlebotomist accompanied (circle appropriate response for whether you accompanied subject to the medical facility).
- Personal belongings (circle appropriate response for whether personal belongings were sent with the subject).
- Month, day and year you contacted the subject's physician/clinic, if known; if not applicable, enter "N/A").
- Month, day, year you contacted next-of-kin.
- Name of next-of-kin contacted.
- Lina Jandorf or Anne Fatone contacted.
- Your ID (Initials).
- Comment section should include a summary statement of your impression of what occurred with the subject and any additional information that warrants documentation on the report.

9/10/03

Reference: Blood Draw

PROCEDURE TO FOLLOW IN THE EVENT OF NEEDLESTICK/SHARPS INJURY OR OTHER BLOOD/BODY FLUID EXPOSURE

An **exposure** is defined as:

- A percutaneous injury (e.g., needlestick, cut with a sharp object, bite);
- Contact of blood or body fluids with mucous membranes;
- Contact of blood or body fluids with skin that is chapped, abraded, or otherwise not intact;
- Contact of blood or body fluids with intact skin when the contact is prolonged and involves an extensive area of skin.

1. **Wash** the exposed area immediately with soap and water. If mucous membranes were exposed, e.g. eye splash, **Flush** with water.
2. Immediately **report** the exposure to:

<u>Beeper</u>	<u>Office</u>	<u>Cell</u>
Lina Jandorf:	917-424-0702	212 659-5506 917-650-3751
<u>or</u> Rose Bialecki		212 659-5473 917-607-3195
3. **During regular business hours**, Lina or Rose contacts the **Needlestick Coordinator**, Beeper 4118; from outside MSMC: 212-241-5581 and asks for beeper 4118. Needlestick Coordinator will complete **Risk Assessment Checklist** and review **consent for HIV testing** with participant over the phone.
4. **If not regular business hours**, Lina or Rose contacts the Page Operator at 212-241-6500 to beep the **Nursing Administrator on call for the Dept. of Medicine**. Either she or they complete the **Risk Assessment Checklist** and review **consent for HIV testing** with participant over the phone; also **obtain control participant's physician's name and phone number**.
5. Needlestick Coordinator, Lina or Rose will **notify the lab** to expect the blood sample at the following 659 extensions: 8168;8161;8162 or 8145. Obtain name of contact person.
6. Employee **obtains signature for Informed Consent** for HIV testing and offers copy to participant.
7. Employee draws a blood sample using the **red top test tube** and writes participant's name, DOB and sex on blank specimen label. Blood will be tested for Hepatitis and, if consent obtained, HIV status.
8. Employee reports **within one hour** to Employee Health Service with red top tube or the **nearest Emergency Room. Do not leave red tube in ER**. If not during regular business hours, employee will take red top tube to lab on the 8th floor of the East Building, L8-72.
9. Supervisor will complete **Blood/Body Fluid Worksheet**. If not regular business hours, Supervisor will also complete 2 green **Microbiology Lab Virology/Serology requisition forms** and bring to lab in East Building, L8-72. If during regular hours, Needlestick Coordinator will complete forms. Blue copy of forms will be kept on file.

9/10/03

Reference: Blood Draw

VII.
DNA COLLECTION

Procedure

Materials

9/10/03

DNA Collection Procedure

In the event a participant does not agree to provide a blood sample, or if **less than 2** vials of blood can be successfully obtained, a DNA collection procedure will be undertaken, with the consent of the participant. The purpose of this simple procedure is to collect some loose cells from the mouth of the participant.

If blood cannot be obtained from either a Case or Control, they will be asked if they would be willing to have their physician draw the blood during a routine visit. (See procedures for Physician Blood Draw in previous section.) Whether or not they agree to have their physician obtain a blood sample, DNA should be taken as a precaution.

Preferably, the participant will not have had anything to eat or drink other than water an hour before the following procedure.

1. 10 ml. of Scope will be pre-measured into a specimen jar. Instruct the participant to pour the mouthwash from the jar into her mouth, **without swallowing**.
2. Tell her to swish (gargle) the mouthwash around in her mouth vigorously for 60 seconds. **Watch the clock while she does this.** It is important that you do not shorten the time, but there is no harm in doing it for longer than 60 seconds.
3. Have the participant spit the mouthwash back into the jar. Replace the cover on the jar and screw it on **tightly**.
4. Write the date the saliva sample was taken on the label affixed to the specimen cup.
5. Place the container with the sample into the plastic bag. **Push the air out of the bag before sealing it.**
6. Specimen will be delivered to Room 296, 1184 Fifth Ave., and left in the basket between 9:00am and 5:00pm. After 5:00pm and on weekends, specimen will be delivered to the -20 freezer next to the carbon dioxide tanks in L 16-07, East Building, and placed in the door of the freezer. Delivery will be noted in the Specimen Logbook and Shen and Rui, x85483, informed via voicemail of the specimen collection.

9/10/03

Reference:DNA

DNA COLLECTION MATERIALS

- Peppermint Scope mouth wash
- A specimen jar with 10 ml. of Scope pre-measured into the jar.
- A plastic biohazard specimen bag
- Freezer-resistant label with ID and name of the participant printed on it

9/10/03
Reference:DNA

VIII.

Personnel Resources

Buddy System

Staff Listing

9/10/03

BUDDY SYSTEM

The “buddy system” was developed to enhance communication between interviewers and recruiters throughout the recruitment phase. Therefore, each interviewer is matched to a recruiter. If recruitment packets are mailed to recruiters, interviewers will contact recruiters to inform the recruiters of how many potential subjects they are mailing to the recruiter as well as how many are **priority**.

Neon labels will be attached to those cases which must be contacted immediately (within 48 hrs). If a recruiter cannot reach a priority case within this amount of time, they need to contact their interviewer buddy, to let them know. This way, the interviewer can assist the recruiter. It is imperative that we do not lose any potential subjects, due to the late diagnosis date.

Whether or not there are new subjects packets to send, interviewers will contact their recruiter buddies once per week, to see how they are, to ask about recruitment progress, and to see if they have any questions or problems.

Recruiters have **14 days** from the “mail date” to contact their potential subjects. After 14 days, recruiters should return the information in the postage paid envelope

9/10/03

Reference:Personnel Resources

RECRUITER/INTERVIEWER BUDDIES

Recruiters/Interviewers

Interviewer: Rose Bialecki	Sherly Jacob	Melissa Solis
Recruiters:		
Marcia Butler 718-937-4220	Carol Copeland 212-864-0867(H) 212 234-1447	Eileen Abiola 718-816-1655
	Glorie Browne 212-368-3868 917-913-0120(cell)	Medina Byars 718-430-4167/9(W) 718-542-0288 (H)
Iris Mendez 718-798-5345 917-447-3976 (cell)	Beverly Coll 717-484-4263 (H) 718-812-1020 (cell)	Alice Jaworsky 718-721-1355
	Pat Drew 212-410-1309	Cathy Williams (718) 981-1673 (H) (347) 217-8899 (cell) (718) 981-8680 (W)
Active Recruiters listed in bold		

Back-up Interviewers

Yahaira Gutierrez
Meredith Grossman

9/10/03

Reference: Personnel Resources

STAFF LISTING

	<u>Office Number</u>	<u>Mobile Phone</u>	<u>Beeper</u>
Lina Jandorf, M.A., Principal Investigator, Core A	659-5506	917 650-3751	917-424-0702
Christine Ambrosone, Ph.D., Principal Investigator, Project 1	866-223-2219		
Heiddis Valdimarsdottir, Ph.D., Principal Investigator, Project 2	659-5559		
Dana Bovbjerg, Ph.D., Principal Investigator, Project 3	659-5562		
Julie Britton, Ph.D. Co-Investigator, Project 1	241-5488		
Helena Furberg, Ph.D., Project Director	659-5523		
Senaka Peter, M.P.H., Project Coordinator	659-5406		
Anne Fatone, Ph.D., Research Fellow	659-5407	917 776-4875	917-919-3565
Sherly Jacob, B.A., B.S., Research Interviewer	659-5405	917 650-4835	
Meredith Grossman, B.A., Research Interviewer	659-5474	917-519-9425	
Rose Bialecki, B.A., Research Interviewer	659-5473	917-607-3195	
Yahaira Gutierrez, B.A., Research Interviewer	659-5482		
Linda Lumpkin, Administrative Assistant	659-5546		

All office exchanges are in Area Code 212.

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Reference: Personnel Resources

X.

INTERVIEWER CHECKLISTS

Checklist

Post-Interview Checklist

9/10/03

INTERVIEW CHECKLIST

PRE-INTERVIEW

- ☐ Call participants prior to interview to confirm
- ☐ Maintain interview schedule in database daily.
- ☐ Mail directions, if needed
- ☐ E-mail changes in weekly schedule to: L. Jandorf, A. Fatone, M. Grossman, Shen, Rui
- ☐ Reserve interview room
- ☐ Charge Phone and Check Battery
- ☐ Call office upon arrival if location off-site
- ☐ If interview cancelled: Notify GCRC Nurse Practitioner at X46041; Shen and Rui, x85483; and notate in Interview Room Reservation Book. If interview at another hospital site, notify appropriate personnel. If after 5:00pm Friday or Saturday any time, also notify Abbie Iyare at 917-447-1999.

BAGCHECK

- ☐ ID badge
- ☐ Phone
- ☐ Business Cards
- ☐ Interviewer Organizer
- ☐ Interviewer Folio
- ☐ Metrocard
- ☐ Street Map
- ☐ Directions to Interview Location
- ☐ Laminated Primary & Secondary Contact Information
- ☐ Gift certificate
- ☐ Brochures, including Projects 2, 3
- ☐ Participant ID labels (2 sheets/interviewee)
- ☐ Pencils
- ☐ Pens
- ☐ Rubber Bands
- ☐ Pack of "flags"
- ☐ Small note pad
- ☐ Federal Express envelopes
- ☐ Anthropometry Measurement Tools:
 - ☐ Anthropometry Training Manual
 - ☐ Mastik tape
 - ☐ Gulick II Tape Measure
 - ☐ Triangle
 - ☐ Tanita Scale
 - ☐ Washable pens
 - ☐ Extension cord
- ☐ Blood draw items:
 - ☐ Tourniquet

- ☐ Chuks pads
- ☐ Test Tubes (1 red, 1 purple, 1 green); **take extras**
- ☐ Vacutainer Holder
- ☐ Alcohol pads
- ☐ Gauze
- ☐ Band-aids
- ☐ Butterflies
- ☐ Gloves
- ☐ Sharps container
- ☐ Biohazard Disposal trash bags
- ☐ Non-biohazard trash bags
- ☐ Styrofoam Transport Box
- ☐ Paper Towels
- ☐ Antibacterial Wipes
- ☐ DNA items:
 - ☐ Specimen jar with 10ml. Peppermint Scope
 - ☐ Biohazard Bag
- ☐ Forms
 - ☐ Project 1 Consent; Project 2 Telephone Consent
 - ☐ Interview Questionnaire; include extra Physical Activity Sheets
 - ☐ List of Activity Codes
 - ☐ Show Cards
 - ☐ Food Frequency Questionnaire
 - ☐ Early Life Experiences
 - ☐ Behavior Change
 - ☐ IES
 - ☐ How I Feel Scale
 - ☐ Anthropometry Measurements Data Form
 - ☐ Specimen Collection Checklist
 - ☐ Specimen Collection Record
 - ☐ Projects 2 and 3 brochures
 - ☐ GCRC Admission Form
 - ☐ GCRC Orders Form
 - ☐ Envelopes, stamped/addressed to MSSM for self-report scales
 - ☐ Incident Report Form
 - ☐ HIV Test Consent
 - ☐ Mental Health Inventory Summary Sheet

POST-INTERVIEW

- ☐ Notify office of departure (if offsite)
- ☐ Bring blood specimen to GCRC and Lab Rm. 296 and DNA to Lab Rm. 296 or East Building, Rm.16-07
- ☐ Record specimen transport and delivery time/date in GCRC Logbook; notify Lab, x85483
- ☐ Review questionnaires for completion and accuracy
- ☐ Enter Post-Interview Checklist into database
- ☐ Complete Mental Health Inventory Summary Sheet; distribute and enter in database.
- ☐ Distribute consent form and questionnaires to Senaka Peter, including those of Partial Interviews.
- ☐ Shred Interviewer copy of Contact Sheet
- ☐ Re-stock carry-all and/or interview room

POST-INTERVIEW CHECKLIST

Interviewer ID: _____

Date: _____

Participant's ID: _____ Date Interview Completed _____

Location of Interview:

MSMC Department:

GCRC _____

1176 _____

East Bldg. _____

Other _____

Hospital:

St. Luke's _____

Kings County _____

Queens-Mt. Sinai _____

Einstein/Monte/Jacobi _____

Columbia-Presbyterian _____

Beth Israel _____

Participant's Home: _____ Other: _____

Interview Sections:

1 - Complete

2 - Partial

3 - None

4 - Missing

____ Consent Form and Contact Sheet

____ Main Questionnaire

____ FFQ

____ Behavior Change

____ Early Life Experiences

____ IES

____ How I Feel Scale

____ Blood Draw

____ DNA

____ Anthropometry Measurements

____ Incident Report on File

Date Submitted:TO

SP

SP

SP

SP

SP

SP

SP

GCRC; Rm. 296

15-76, East Bldg.

SP

LJ

Interview Status:

1 _____ Completed

2 _____ Partial, Pending Completion

3 _____ Partial, Final

EligibleMaterial GivenSigned ConsentProject 2

Project 3

Gift Card Serial Number: _____ **Metrocard: Yes** ____ **No** ____

Date Thank You Mailed: _____

9/10/03

Reference: Interviewer Checklists

XI.

Hospital Information

9/10/03

XII.

Projects 2 and 3

XIII.

Addendum

Consent Forms

Questionnaires

Question by Question Specifications

Show Cards

Physical Activity Codes

Specimen Checklist

Physicians' Orders

Field Materials

Primary/Secondary Contact Information

Needlestick Paperwork

Anthropometry Training Manual



Breast Study

Recruiter Training Manual

9/9/03

Recruiter Training Program

Agenda

5:30-5:45	Introductions
5:45-6:00	Volunteer Office
6:00-6:15	Overview of Project
6:15-6:30	Interviewers' Role <ul style="list-style-type: none">- Buddy System
6:30-7:00	Recruiters' Role <ul style="list-style-type: none">- Confidentiality- Contact List- Paper Trail- Resource Guide
7:00-7:30	Role Playing

Thank you for your willingness to participate and help us with our study!

II.

Why This Study?

Program Description

9/9/03

Reference: Study Description/Goals

DESCRIPTION OF BREAST CANCER STUDY

More and more women are being diagnosed with breast cancer. One out of every eight women will develop breast cancer in her lifetime. African-American women often develop breast cancer at an early age (before age 50) and sometimes the disease is more serious than in Caucasian women. For Hispanic women, breast cancer is the most commonly diagnosed cancer. This research project is to help us understand the causes of breast cancer. What people eat and drink and other lifestyle habits could affect their health. But not everyone with similar habits will get sick. This may be because of differences in how their bodies respond to things that they eat, drink, and smoke; and medications they take. In these studies, we will ask the same questions of women with breast cancer ("Cases") and women without cancer ("Controls"), who are the same age and live in the same area. They will be asked questions about eating, drinking, exercise and smoking habits, their medical and family histories, and other behaviors which may protect against or otherwise affect disease. Measurements will be taken, including height and weight. Comparisons between women with breast cancer and those without cancer will then be undertaken to determine differences.

Blood will also be drawn, (about 2 tablespoons). This blood will be processed to measure differences in how the body deals with things we eat, drink and smoke. Just like the answers to the questions, ways in which people break things down will also be compared between women with breast cancer and those without. From this study we hope that we will be able to see what some of the causes of breast cancer might be.

9/9/03

Reference: Study Description/Goals

Tri-State Women's Circle of Health

BREAST CANCER STUDY

GOALS

To find out more about

1. Why some women get cancer and others do not
2. Why some women have cancers that make them die sooner than other women
3. Why some women get the disease at young ages (less than age 50)
4. What things in the environment, in our diets, and in our genes affect these outcomes
5. Effective ways to encourage women to participate in the study

9/9/03

Reference: Study Description/Goals

ABOUT THE STUDIES

“Core A” is the name of the Recruiting and Interviewing portion of the three research projects, each of which addresses an important issue in breast cancer research.

Principal Investigator: Lina Jandorf, M.A.

These 4-year studies looking at critical psychological or behavioral issues will improve our understanding of the causes of breast cancer. The studies are:

Project 1: “Behavior, estrogen metabolism, and breast cancer risk: a molecular epidemiologic study.” Principal Investigator: Christine Ambrosone, Ph.D.

This is a study to understand why some women get breast cancer and others do not.

Project 2: “Impact of culturally tailored counseling on psychobehavioral outcomes and BRCA decision making among African-American women with breast cancer.” Principal Investigator: Heiddis Valdimarsdottir, Ph.D.

Women from Project 1 whose family history suggests that their cancer may be inherited will be offered genetic counseling and genetic testing at no cost. Such counseling may reduce distress and increase knowledge about breast cancer, genetic testing, and breast cancer prevention and surveillance options.

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

Principal Investigator: Dana Bovbjerg, Ph.D.

The adult daughters of women with breast cancer from Project 1 will be compared with the adult daughters of women without breast cancer to examine the possibility that inherited deficits in the immune system may be related to familial risk among daughters of patients whose cancers are not related to mutations in BRCA1 or BRCA2 genes.

9/9/03

Reference: Study Description/Goals

What Will You Do?

Barriers to Participation in Research Studies
Benefits to Participation

Your Message to Participants:
“DIB”

Decisions, Involvement, Benefits

Counseling Guidelines

9/9/03

Reference: Role of the Recruiter

BARRIERS TO PARTICIPATION IN STUDIES AND RESEARCH

- Poverty; lack of education
- Time and hassle from patient's perspective
- Negative personal and family attitudes
- Not feeling well, too overwhelmed
- Inadequate evidence of benefits
- Protocol too invasive (e.g. blood draws)
- Too much time required to participate
- Fearful about research, being a "guinea pig"
- Information about the study is too technical and too complex to be easily understood

BENEFITS TO PARTICIPATION IN RESEARCH

- Help ourselves by facilitating breast cancer research
- Help our children/grandchildren
- Knowledge – research is the key to opening doors for more information, particularly for women from minority ethnic groups who have been under-represented in research in the past. For example, African-American women with breast cancer are frequently diagnosed at a younger age, with more advanced, aggressive tumors. There are many possible reasons for this but only research will help give us the answers why and allow us to begin to identify means of prevention.
- Participating in research is an opportunity to give something back to others, in particular, other women.

9/9/03

Reference: Role of the Recruiter

YOUR MESSAGE TO PARTICIPANTS AND MATCHED HEALTHY WOMEN

“DIB”

DECISION, INVOLVEMENT, BENEFITS

Decision

When you talk with women, one of the areas you will discuss is why they may choose to participate in the research and what is their decision-making process.

Guidelines:

- Focus on the experience – What will she consider in deciding?
- Share the important fact that influenced you – Who or what things helped you decide that it is important to know WHY women get cancer?
Why YOU or SHE got cancer.
- Share the difficulties and issues. What are the issues that may affect their decision?

Reasons you would want to participate:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

Other reasons given during discussion:

Involvement

It is important for you to share with patients and controls what is **involved** in the study experience – the issues which affect her decision to participate in a study.

Guidelines:

- Give the patient a “picture” of the experience – don’t frighten them, but let them know the kinds of things involved in the study experience.
- Help them feel informed about what to expect

List some of the things that are involved in the research process:

Benefits

Be sure to tell the patients all of the good things about the research, and what you perceive to be benefits of participating in a study like this.

Guidelines:

Mention two or three of the most important things – what do you consider to be the top three benefits?

List the benefits of participating in this study:

1.

2.

3.

4.

5.

9/9/03

Reference: Role of the Recruiter

Recruiting for Studies

How to Give Advice and be Listened to: Counseling Guidelines

As a breast cancer survivor, you may know a lot about your cancer experience and treatment, but recruiting other patients and women to participate in research about the cause of cancer may require new skills for you. You may get into discussions with women that require some counseling skills. Here are a few tips on how to counsel effectively. Some of these suggestions you may already know. Others may be new to you.

Counseling/Recruiting Guidelines

- Be supportive and non-judgmental-nothing she says is bad or stupid.
- Ask open-ended questions that can't be answered with yes or no. Questions that begin with why, what, or how for example, will give fuller answers.
- Make sure the questions you ask are ones you can and would answer yourself. Don't ask questions that are too technical or too personal.
- If there is a disagreement, don't defend or argue. Ask more questions to broaden the perspectives. For example, *why do you think that...? Are you worried/afraid that...?*
- Because you are a survivor, she might want you to tell her what to do. It is not your role and you will not be trained to counsel regarding treatment or how to cope.
- Reflect back to her what she has said, especially if you are unsure about what she means or if she seems unsure of herself. For example, *So you feel/think that....*

9/9/03

Reference: Role of the Recruiter

Recruiter Role

How to Give Information and be Listened to: Research Study Discussion

The guidelines on the previous page help create a sense of trust and a positive tone in a discussion session. It is also important to direct the discussion in such a way that you know what kind of information is needed. Here are some guidelines for directing your discussion:

- Find out what concerns she already has
- Find out what she knows about research or epidemiological studies. Does she worry about being a “guinea pig”? Does she think it is risky? What does she know about others’ experience?
- Find out how she feels about participating in research in general. Does she have any fears about the blood drawing or contamination of her blood?
- Use the DIB guidelines – Decision, Involvement, and Benefits
- Encourage her to think about the issues and talk with you and the study staff about them.
- Leave her with information and a phone number to call. Tell her you’ll check back with her in a week or so (if appropriate) and encourage her to call Anne Fatone, Ph.D. about questions: (212) 659-5407.

Talk about the different kinds of questions suggested here. A good recruiting session will:

- get the facts
- discuss feelings and give emotional support
- give facts/informational assistance
- help solve problems
- guide a decision

9/9/03

Reference: Role of the Recruiter

Recruiting Techniques Exercise

Working in groups of two or three, fill in the spaces provided with one or two additional questions that will help you reach the counseling goal listed to the left.

<u>Goal</u>	<u>Questions or Statement</u>
1. Get the facts	<p>What do you understand about this study?</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
2. Discuss feeling and give emotional support	<p>How do you feel about participation in this kind of research?</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
3. Give facts/informational assistance	<p>I am a survivor. We are all interested in knowing more about what causes cancer. This study can help us understand why some of us have cancer and other women don't.</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
4. Help solve problems	<p>Do you have enough time to participate?</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
5. Guide a decision	<p>Do you have questions I can answer?</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>

9/9/03.

Reference: Role of the Recruiter

IV.

How Will You Do It?

General Telephone Techniques

Contact Issues

Questions/Answers

Sequence of Actions

Tri-State Women's Circle of Health Flow Chart

Contact Sheets

Participant Recruitment Forms (Cases/Controls)

Questionnaire for non-Participants

9/9/03

Reference: Recruiting Tools/Techniques

General Telephone Techniques

Since your first contact with prospective participants will be a brief telephone conversation, it is especially important that you strike the correct tone within the first few minutes. This section contains a discussion of the techniques to use and procedures to follow when making your first contact by telephone.

When you visit people in person, your body language and your appearance help you communicate and maintain cooperation. By your posture, facial expressions, gestures, and other body language you present a non-threatening, neutral, yet supportive impression. Similarly, when interviewing in person, you have the opportunity to observe the woman's facial expressions and body language to see how she is reacting.

When you are contacting people over the telephone, you do not have these advantages. You cannot observe the woman and she knows only your voice. Because of this, you may find telephone work to be more challenging than in-person work.

To be successful during a telephone contact, **you need to develop a professional telephone manner and use your voice effectively.** You want to be confident, enthusiastic, warm, and sincere. You want your voice to sound pleasant, and have variety in both the rate at which you speak and also the inflection of your voice. In this way, you can establish and maintain rapport without being there in person.

Several characteristics make up a professional telephone-interviewing manner. They are:

- **Being "On the Job".** It is important for you to be well prepared before starting the conversation. This includes having a quiet, private place from which to call, as well as the time needed to make the call effective. Setting the stage for your contact with this person so you are calm, organized and unhurried will get you off to the best possible start.
- **Voice Quality.** This is how you sound to a listener. Over the telephone, your voice is all that represents you, the study sponsors, and the study to the woman with whom you're speaking. What will a listener hear? Do you have a voice that is clear, pleasant, and easy to understand? Do you speak at a comfortable pace for a listener? Do you speak in a monotone or do you sound like you are interested in the person? Before you begin your telephone calls, think about the sound of your voice and how you might improve it.
- **Concentration.** You need to listen to and concentrate on what the contact is saying so that you won't lose track of where you are in the interview. It is easy to be distracted by noise and also by thinking about what you need to do next. Try to concentrate on the response and let the questionnaire guide you.
- **Enthusiasm.** If you sound like you are truly interested in the study and in each person, she will sense this. The listener may be more likely to think that it is important that she participate.

- **Neutrality and Tact.** Although you want to sound interested in the person, remain neutral and objective. An overly friendly manner can give the listener the impression that you are trying to sell them something.

When you read an introduction, make sure that you do not insert question marks at the ends of sentences that do not have question marks. Introduce yourself quickly and continue with a description of the study. Do not pause long enough for the contact to start to refuse or ask questions until you have the full introduction.

If a woman begins to digress, be attentive to the individual's needs, but don't be **overly** empathetic or sympathetic. Get back to the subject matter at hand by showing her that you have heard and understood what she has said, but not by expressing a personal view or attitude.

Do not react negatively or abruptly to the listener's statements. An unpleasant telephone manner may disrupt the climate of the conversation and damage the rapport that has been established. No matter what situation arises the Recruiter must always come across as a responsible person **doing her job.**

The following points summarize all that has been said. These points should serve as a quick guide to a more effective and professional telephone personality.

- **BE PROFESSIONAL.** Be prepared by focusing on the work at hand, with materials ready, time available and privacy assured.
- **BE EXPRESSIVE.** Speak at a moderate rate and volume, but vary the tone of your voice to add vitality and emphasis to what you say.
- **BE DISTINCT.** Pronounce your words clearly and carefully. Always speak directly into the telephone.
- **BE ALERT.** Be cheerful and wide-awake, and listen. This sets the tone of any conversation and shows you are listening.
- **BE NATURAL.** Use simple language. Avoid slang and technical terms when answering subject questions.
- **BE PLEASANT.** Show that you are interested. However, never get too personal.
- **BE COURTEOUS.** Good telephone habits are good manners.

9/9/03

Reference: Recruiting Tools/Techniques

CONTACT ISSUES

A major concern of this and other important research efforts is achieving high response rates. In general, high response rates suggest that more confidence can be placed in the data results. The issues covered here help track and promote response/cooperation.

Completing the Record of Calls

It is important that you are thorough and precise in recording all attempts to contact the case/control whether or not you are able to reach her. The Breast Study Contact Sheet is the principle form designed to document the results of all contact attempts.

Handling Refusals and Other Nonresponse

Overview

You will find that most individuals are very willing to participate in the study. Some will not refuse outright, but will express hesitancy, reservation, or even some initial hostility. Others will put off scheduling an appointment, or habitually cancel their appointment. Still others may leave their house on the day of the appointment to avoid being interviewed. Some individuals will express interest in the study, but will be unwilling to arrange an appointment because of a specific conflict (e.g., vacation plans).

With experience comes sensitivity to the various ways women say "No" and to the manner and wording they use that provide clues to the firmness of a refusal. The more you are aware of these differences, the better you will be able to deal with resistance. The better you understand how cases/controls view you and the study, the better able you will be to reassure them and respond to their objections. It is often the way you handle questions (either verbalized or implied) that makes the difference between getting cooperation or a refusal. Your job is to "read" (during your initial and follow-up contact) the various types of women selected for the study and decide on an appropriate course of action.

Breast Cancer Patients

We believe that breast cancer cases will be very motivated to participate in the study. Any reluctance by cases to participate may come from the timing of the study – not the study itself. Certainly, this is a difficult time for these women. However, **we believe that several reasons will motivate/promote case participation.** They are:

1. The importance of breast cancer to women across the country;
2. The high incidence of breast cancer among African American and Hispanic women;
3. The fact that "case" physicians have provided consent; and

4. You – experienced breast cancer survivors, trained in telephone recruiting.

On the other hand, we know that some cases will express emotions from surprise to tears to anger about being contacted so quickly after their diagnosis. Some cases may not have shared their condition with their friends or family yet. For others, this diagnosis may be an additional concern added to other problems they face. Furthermore, they may be in the process of selecting the type of cancer treatment they will undergo or actually be in the midst of treatment. Your task is to be aware and sensitive to these issues while still endeavoring to follow the study protocol – to obtain agreement to participate in the study.

Controls

Obtaining participation from individuals who are controls present a unique challenge. Population- based controls have fewer motivations than cases for donating their time for research purposes. Therefore, to obtain cooperation, you should appeal to:

1. Their interest in contribution directly to the general advancement of breast cancer research;
2. The specific goal of understanding the role of selected environmental and biological factors in the development of breast cancer among women.
3. Their altruism; and
4. The fact the most respondents enjoy and value their participation.

Remember that the initial telephone contact with prospective participants is your first opportunity to begin to **establish rapport and secure compliance!**

Averting Refusals

There are a number of key suggestions to help you avoid refusals:

In the participant's eyes, you are the study. If they have good feelings about you, they will participate in the study. Encourage positive feelings as follows:

- Be enthusiastic about the study;
- Make it clear you are committed to the project and that you think it is worthwhile;
- Refer to the sponsorship of the study. Mention the letter;
- Emphasize that you are not selling anything or soliciting for any charity;
- Know the study. If you are confident and knowledgeable, your contact will trust you.

9/9/03

Reference: Recruiting Tools/Techniques

QUESTIONS/ANSWERS

1. I don't have time/interview is too long:

I know that this takes a bit of time but there are still many things that health educators and researchers don't know about women and breast cancer. This information is important in helping us to better address the needs of communities like yours. In order to complete the interview, we can work around your schedule. Your help is so important to us because the information you give us about your lifestyle and family and medical history could help us to reduce the number of people who develop and die from breast cancer.

2. I don't have breast cancer; this doesn't really apply to me:

You do not have to have breast cancer to be eligible to complete this interview. We are asking healthy women to participate so we can understand the differences between women who develop breast cancer and those who do not. Your help is so important to us because the information you give us about your lifestyle and family and medical history could help us to reduce the number of people who develop and die from breast cancer.

3. I had a bad experience with (their doctor or a hospital).

I'm sorry to hear that. Problems in getting health care are some of the most frustrating ones, but we hope to interview people like you who have had bad experiences with these health care centers. We need to know if experiences like that can keep people from getting the care they need, such as cancer tests. Your help is so important to us because the information you give us about your lifestyle and family and medical history could help us to reduce the number of people who develop and die from breast cancer.

4. I don't know how this information is going to be used/don't know who will see my answers:

All the information you give to will be confidential. Your interview answers will not be marked with your name, but with a code number. Any personal information we obtain from you will be separated from your interview answers. Your help is so important to us because the information you give us about your lifestyle and family and medical history could help us to reduce the number of people who develop and die from breast cancer.

5. I'm not interested:

I don't know if you've had any family members or friends who have had breast cancer, but the lifetime risk for women to develop this disease is 1 in 8. So even though you wouldn't benefit yourself from this study, your help is so important to us because the information you give us about your lifestyle and family and medical

history could help us to reduce the number of people who develop and die from breast cancer.

6. I don't feel well enough/don't want to travel to any of the hospitals.

If you are unable to come to the hospital, I can arrange for an interviewer to meet you, either at your doctor's office or even to come to your home.

7. I work Monday-Friday; can you do the interview on a weekend or in the evening?

Absolutely. I can schedule a weekend or evening appointment for you with one of our interviewers.

8. Why do you need to take my blood; what will you do with it?

The purpose of the study is to try to understand why some women get breast cancer and others do not. Not everyone with similar habits or characteristics will get breast cancer. This may be because of individual differences in how our bodies make the substances needed to keep everything working right. Just as people differ from one another in how they look, they also differ in what goes on inside their bodies and in how their bodies respond to things they eat, drink and smoke, as well as medications they take. In this study, we will compare some of these factors between women with breast cancer and women without.

9. I'm receiving chemotherapy right now/just finished treatment; can I still participate?

This is not a treatment study and your involvement will not interfere with any treatment you may be undergoing/have recently completed. The study consists of a one-time interview, at which we would take a small blood sample, as well as body measurements. That's all there is to it.

10. I'm not sure what kind of skin cancer I had.

Basal cell or squamous cell carcinoma rarely metastasize in contrast to melanoma which may result in metastasis.

9/9/03

Reference: Recruiting Tools/Techniques

Sequence of Subject Recruitment

1. Cases are identified by: physicians directly
2. Controls are identified by: General public controls are identified by a RDD (random digit dialing) company through phone lists
3. For cases, a letter and brochure will be sent from the patient's doctor by MSSM staff, telling her about the study.
For controls, information will be sent by MSSM staff.
4. Cases may also be recruited by physicians' staff directly after their initial diagnosis. Informed consent is obtained and a blood draw may be done at that time, as well.
5. Cases and controls are assigned to recruiters. Packets are given to recruiters and include:
 - Contact sheet
 - Script for phone call
 - Reimbursement forms
 - Self-addressed stamped priority mail envelopes from MSSM
6. Post-cards with the recruiter's picture and name will be sent in envelopes by MSSM staff to the subject.
7. Recruiter will contact subjects within 14 days if possible.*
8. Recruiter notifies interviewer of interview date and location by phone or e-mail and interviewer forwards travel directions to participant, if needed.
9. Recruiters return the information (completed contact sheet) back to MSSM.
 - **At any time, recruiters may call MSSM staff for assistance with subject phone numbers that may be incorrect. Interviewer will attempt to find current phone number and advise recruiter.**

9/9/03

Reference: Recruiting Tools/Techniques

TRI-STATE CIRCLE OF HEALTH FLOW CHART

	Subject Identification	Recruitment Letter/Brochure Sent/Given	Recruiter Activities Step 1 **	Recruiter Activities Step 2	Recruiter Activities Step 3
Hospital cases	Pathology Reports or MD	Mailed by Project 1 (after MD approval) or given directly by MD	After eligibility confirmed by Project 1, AF assigns Recruiter and sends postcard	AF sends contact information to Recruiters who call to arrange interview appointments.	Recruiters notify Interviewer; return Recruitment and Reimbursement Forms to AF
RDD controls	HCFA/phone list	Mailed by Project 1	Ditto	Ditto	Ditto

After completion by Recruiter, Recruiter Contact Form distributed to Interviewer by AF for appointment confirmation, lab notification, interview, recruitment for additional studies.

9/9/03

Reference: Recruiting Tools/Techniques

Date assigned _____

Date to notify MSSM staff
& return contact sheet

Date recruiter returned
contact sheet to MSSM

**MSSM BREAST CANCER RESEARCH
CONTROL CONTACT SHEET**

ID NUMBER: _____ REFERENCE DATE _____ AGE: _____

PARTICIPANT'S NAME: _____

PHONE NUMBER: _____ ETHNICITY: _____

PARTICIPANT'S ADDRESS: _____

BEST DAY TO CALL: _____ BEST TIME TO CALL: _____

REFERRED BY: RDD _____ FRIEND _____ HOSPITAL _____ (NAME)

RECRUITER'S NAME: _____

INTERVIEWER'S NAME: _____

SCHEDULED INTERVIEW DAY: _____ DATE: _____ TIME: _____

ATTEMPTS

Date	Time	Comments	Participation		Meeting Place		
			Yes	No	Home	Hospital	Other

Recruiter, please check the following words that apply to the participant you called. Also write down any additional comments that the participant made or your feelings about your conversation.

- | | | |
|--|------------------------------------|--|
| <input type="checkbox"/> Enthusiastic | <input type="checkbox"/> Nervous | <input type="checkbox"/> Not sure if they want to participate |
| <input type="checkbox"/> Excited | <input type="checkbox"/> Hesitant | <input type="checkbox"/> Would like more information about the study |
| <input type="checkbox"/> Willing to help | <input type="checkbox"/> Angry | <input type="checkbox"/> Questions for staff about the study |
| <input type="checkbox"/> Pleasant | <input type="checkbox"/> Depressed | |

Additional Comments: _____

If Answering Machine: "I'm calling regarding a study at Mount Sinai and I will call back (specific time) or you may reach Senaka Peter at Mount Sinai by calling 1-866-223-2219 or 212 659-5406."

9/9/03

Reference: Recruitment Tools/Techniques

ID NUMBER _____

REFERENCE DATE _____

Please attempt to call subjects at least once between 9-11a.m.; 1-5p.m.; and 7-8 p.m. before determining whether you can reach them. Please attempt to contact this subject at least 5 times before _____.
(return date)

PARTICIPANT RECRUITMENT FORM
[FORM FOR CONTROLS, WOMEN WITHOUT BREAST CANCER]

Hello, may I speak with _____
(WOMAN'S NAME)

(ONCE WOMAN IS ON THE PHONE):

Hello, my name is _____. I'm a breast cancer survivor (since _____ year of diagnosis, optional), involved with outreach for the Mount Sinai School of Medicine. A while back, you received a phone call from Kreider Research & Consulting regarding breast cancer research being conducted here. At that time, you agreed to be called to learn more about an on-going study about breast cancer and that is why I'm calling today. By now, you should also have received a brochure and letter from researchers here, as well as a postcard from me, about this important study at Mount Sinai. If you have time now, I would like to tell you more about it.

If no:

ASK FOR A BETTER TIME TO CALL BACK. TIME: _____

If yes:

Before we go on, it is important that you know we are only looking for women who have not had any form of cancer other than basal cell or squamous cell skin cancer. If you feel that this describes you, we can go on. Should I continue? (Note to Recruiters: We are looking for women who have not had any cancer other than basal cell or squamous cell skin cancer).

If no:

Would you be willing to tell me why you think this does not describe you? (IF WILLING, WRITE DOWN THE ANSWER ON THE CONTACT SHEET.)

Thank you for taking the time to be willing to receive information about the study but if you do not qualify there is no reason to take any more of your time. If you want to learn more about the study, I would be glad to answer your questions if I can or you can always check the website for the study, which is listed on the brochure you received in the mail. The website also has information links about cancer care and treatment.

If yes, they have not had any cancer other than the above skin cancers:

I would like to verify that you live in New York City six or more months out of the year. (If they ask why, explain that in order for our results to scientifically be valid, participants must reside in NYC six or more months out of the year.) **If no, let them know they do not qualify for the study and thank them for their time. If yes, then continue:**

I'll just take a minute to give you some background information: Doctors and researchers are concerned, because breast cancer is becoming more common in women, and not much is known about what causes it or how to prevent it. Scientists at the Cancer Center are running a study to try to learn some of the causes of breast cancer. This study will compare women who have had breast cancer to women who have not, to learn why some get cancer and others do not.

I want to tell you right at the start that there is no cost to you. In fact, you will receive a \$25 gift certificate to either Pathmark or Rite Aide as our way of thanking you for participating in our study. And I want you to know that your privacy is always protected. Only limited study personnel will be aware of your name.

From the time of the interview, only an identification number that has been assigned to you will be used, not your name. Do you have any questions for me so far?

I would like to schedule an appointment for you to meet with a female interviewer from the Cancer Center at one of our interview sites and we will, of course, provide a Metrocard to cover travel expenses. At the interview, you will be asked questions about your diet, health history, and other lifestyle habits. Also, a small blood sample and body measurements, such as height and weight, will be taken. This will probably take about two hours. **(Offer Mount Sinai to all women and, as an alternative, a hospital in their borough)** The interview can be conducted in **Manhattan** at either Mount Sinai Hospital, 98 St. & Fifth Ave. or St. Luke's Roosevelt Hospital, 59 St. & 9th Ave.; in **Queens** at Queens Hospital Center, 164th St. Jamaica, in **Brooklyn** at Kings County Hospital in Brooklyn (primarily Mondays and Fridays), or in **the Bronx** at either Montefiore Medical Center, East 210th St. or Albert Einstein College of Medicine on Eastchester Road (primarily Wednesdays or Fridays), whichever is more convenient for you. That's all there is to it. So, do you have any questions?

If the hospital sites are not acceptable, offer to have the interview done in their home.

(IF THEY HAVE QUESTIONS THAT YOU DO NOT KNOW THE ANSWER TO, TELL THEM AN INTERVIEWER WILL CALL BACK TO ANSWER THEIR QUESTIONS).

Do you think you would be able to participate in this study? **(YES)**_____ **(NO)**_____

(IF NO, TRY TO **FIND OUT WHY** AND TRY TO RESPOND TO HER CONCERNS. **IF IT WOULD HELP**, REFER TO Q&A NUMBER 5 REGARDING CANCER HISTORY. IF THEY STILL SAY NO, ASK):

May I ask you just a few short questions about your socioeconomic background and medical and reproductive history on the phone? The information you would provide will help the researchers to determine whether there is a difference between the women who agree to participate in the study and those who do not agree to participate. Your name will not be attached to your comments and I will be the only person who knows who says what.

Do you agree to participate in this short telephone survey? **(YES)**_____ **(NO)**_____

(If YES, See Refuser Questionnaire)

(IF THEY AGREE TO PARTICIPATE, SAY):

That's great. I will be happy to set up an appointment for you. Will you be coming to Mount Sinai or do you prefer _____ hospital? What is a good time and day for you?

INTERVIEW LOCATION: _____
DAY INTERVIEW SCHEDULED: _____ DATE: _____ TIME: _____

I will tell let the Interviewers know you are interested in being in the study, and one of them will call to confirm the interview appointment. Is this the best phone number at which to reach you?

(IF YES, WRITE DOWN THE PHONE NUMBER THAT YOU CALLED.
OR, IF THERE IS A BETTER NUMBER, WRITE IT DOWN HERE).

(____)____-____ Is there a good time of day to call you? **TIME:** _____.

Ok, so one of our Interviewers will be calling you soon to confirm your interview appointment on _____ (Date) at _____ (Time) and she'll be meeting you at:

Home: _____ Hospital: _____ Other: _____

If Hospital/Other, indicate building/room number: _____

If you should want to speak with someone before the Interviewer calls, let me give you the name and phone number of a contact person: (interviewer's) phone number: _____.

Thank you so much for your time, and for agreeing to be in this study.

Date Directions Sent _____

9/9/03

Section: Recruitment Tools/Techniques

Date assigned _____

Date to notify MSSM staff
& return contact sheet

Date recruiter returned
contact sheet to MSSM

MSSM BREAST CANCER RESEARCH CASE CONTACT SHEET

ID NUMBER: _____ REFERENCE DATE _____ AGE: _____

PARTICIPANT'S NAME: _____

PHONE NUMBER: _____ ETHNICITY: _____

PARTICIPANT'S ADDRESS: _____

REFERRED BY: MD _____ HOSPITAL _____ (NAME)

RECRUITER'S NAME: _____

INTERVIEWER'S NAME: _____

SCHEDULED INTERVIEW DAY: _____ DATE: _____ TIME: _____

ATTEMPTS

Date	Time	Comments	Participation		Meeting Place		
			Yes	No	Home	Hospital	Other

Recruiter, please check the following words that apply to the participant you called. Also write down any additional comments that the participant made or your feelings about your conversation.

- | | | |
|--|------------------------------------|--|
| <input type="checkbox"/> Enthusiastic | <input type="checkbox"/> Nervous | <input type="checkbox"/> Not sure if they want to participate |
| <input type="checkbox"/> Excited | <input type="checkbox"/> Hesitant | <input type="checkbox"/> Would like more information about the study |
| <input type="checkbox"/> Willing to help | <input type="checkbox"/> Angry | <input type="checkbox"/> Questions for staff about the study |
| <input type="checkbox"/> Pleasant | <input type="checkbox"/> Depressed | |

Additional Comments: _____

If Answering Machine: "I'm calling regarding a study at Mount Sinai and I will call back (specific time) or you may reach Senaka Peter at Mount Sinai by calling 1-866-223-2219 or 212 659-5406."

9/9/03

Reference: Recruitment Tools/Techniques

ID NUMBER: _____ REFERENCE DATE: _____

Please attempt to call subjects at least once between 9-11 a.m.; 1-5 p.m.; and 7-8 p.m. before determining whether you can reach them. Please attempt to contact this subject at least 5 times before _____ (return date)

PARTICIPANT RECRUITMENT FORM

[FORM FOR CASES, WOMEN WITH BREAST CANCER]

Hello, may I speak with _____

(WOMAN'S NAME)

(ONCE WOMAN IS ON THE PHONE):

Hello, my name is _____. I'm a breast cancer survivor (since _____ year of diagnosis, optional), involved in outreach for the Mount Sinai School of Medicine. You should have received a letter from Dr. _____ and the researchers here, as well as a postcard from me, telling you about an important study on breast cancer taking place at Mount Sinai Medical Center (and REFERRING HOSPITAL). Your doctor told us that you have indicated an interest in meeting with one of the interviewers for this study. If you have time, I would like to tell you about the study to help you decide whether or not you want to participate.

If **no**:

ASK FOR A BETTER TIME TO CALL BACK. TIME: _____

If **yes**:

I'll just take a minute to give you some background information:

Doctors and researchers are concerned, because breast cancer is becoming more common in women, and not much is known about what causes it or how to prevent it. Doctors at the Cancer Center are running a study to try to learn some of the causes of breast cancer. This study will compare women who have had breast cancer to women who have not, to learn why some get cancer and others do not. Before being diagnosed with this recent breast cancer, did you ever have breast cancer before, or any form of cancer other than basal cell or squamous cell skin cancer? **IF YES, FIND OUT WHAT TYPE OF CANCER, LET THEM KNOW THEY DO NOT QUALIFY FOR THE STUDY AND THANK THEM FOR THEIR TIME.**

IF THEY HAVE NOT HAD OTHER THAN THE ABOVE SKIN CANCERS, CONTINUE:

I would like to verify that you live in New York City six or more months out of the year. (If they ask why, explain that in order for our results to scientifically be valid, participants must reside in NYC six or more months out of the year.) **If no, let them know they do not qualify for the study and thank them for their time. If yes, then continue:**

I want to tell you right at the start that you do not have to agree to participate. If you do decide to participate, it will not cost you anything. People who agree to participate will be given a \$25 gift certificate from either Pathmark or Rite Aide as our way of thanking you for participating in our study. We will also provide a Metrocard for participants who need to travel in order to participate in this study. The privacy of everyone who participates will always be protected. No one other than the researchers will know who participated or who said what. Any information that is obtained will have a code number on it, not a name. You should also know that this is not a treatment study. If you decide to participate, it will not interfere with any treatment you may be having now or in the future. This study involves being interviewed by a woman who is a trained interviewer. She will be asking questions about diet, health history, and life style habits. She will take some measures of height, weight, and body size and will take a small sample of blood. These procedures will take about two hours. Do you have any questions for me so far?

(IF THEY HAVE QUESTIONS THAT YOU DO NOT KNOW THE ANSWER TO, TELL THEM AN INTERVIEWER WILL CALL BACK TO ANSWER THEIR QUESTIONS).

Do you think you would be interested in participating or at least learning more about the study before you decide? (YES)_____ (NO)_____

(IF NO, TRY TO FIND OUT WHY AND TRY TO CHANGE THEIR MIND. IF IT WOULD HELP, REFER TO Q&A NUMBER 5 REGARDING CANCER HISTORY. IF THEY STILL SAY NO, ASK): May I ask you just a few short questions about your medical history and socioeconomic background on the phone? (See Refuser Questionnaire)

(IF THEY AGREE TO PARTICIPATE, SAY):

That's great. I would like to schedule an appointment for you to meet with a female interviewer from the Cancer Center at one of our interview sites. **(Offer Mount Sinai to all women and, as an alternative, a hospital in their borough)** The interview can be conducted in **Manhattan** at either Mount Sinai Hospital, 98 St. & Fifth Ave. or St. Luke's Roosevelt Hospital, 59 St. & 9th Ave.; in **Queens** at Queens Hospital Center, 164th St. Jamaica, in **Brooklyn** at Kings County Hospital in Brooklyn (primarily Mondays and Fridays), or in **the Bronx** at either Montefiore Medical Center, East 210th St. or Albert Einstein College of Medicine on Eastchester Road (primarily Wednesdays or Fridays), whichever is more convenient for you. That's all there is to it. So, do you have any questions?

If the hospital sites are not acceptable, offer to have the interview done in their home.

I will be happy to set up an appointment for you. Will you be coming to Mount Sinai or do you prefer _____ hospital? What is a good time and day for you?

INTERVIEW LOCATION: _____
DAY INTERVIEW SCHEDULED: _____ DATE: _____ TIME: _____

I will tell let the Interviewers know you are interested in being in the study, and one of them will call to confirm the interview appointment. Keep in mind that even though you agreed to meet with the interviewer that you can change your mind at any time – even after you start the interview. But I am hoping that you will participate. Is this the best phone number at which to reach you?

(IF YES, WRITE DOWN THE PHONE NUMBER THAT YOU CALLED.
OR, IF THERE IS A BETTER NUMBER, WRITE IT DOWN HERE).

(____)____-____ Is there a good time of day to call you? TIME: _____.

Ok, so one of our Interviewers will be calling you soon to confirm your interview appointment on _____ (Date) at _____ (Time) and she'll be meeting you at:

Home: _____ Hospital: _____ Other: _____
If Hospital/Other, indicate building/room number: _____

If you should want to speak with someone before the Interviewer calls, let me give you the name and phone number of a contact person: (interviewer's) phone number: _____.

Thank you so much for your time, and for agreeing to be in this study.

Date Directions Sent _____

9/9/03

Section: Recruitment Tools/Techniques

REFUSER QUESTIONNAIRE

1. What is your date of birth?

____/____/____
Month Day Year

2. Do you consider yourself to be of Latina or Hispanic origin?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused



If YES: Do you consider yourself to be any of the following?
(Check all that apply)

- 1 ☐ Mexican/Mexican American/Chicano
2 ☐ Puerto Rican
3 ☐ Cuban
4 ☐ Caribbean or West Indian
5 ☐ Dominican
6 ☐ Other (please specify): _____

3. What is your race?

- 1 ☐ White
2 ☐ Black/African American
3 ☐ Black-Other
4 ☐ Black-West Indian / Caribbean
5 ☐ American Indian or Alaska Native
6 ☐ Asian Indian
7 ☐ Chinese
8 ☐ Filipino
9 ☐ Korean
10 ☐ Vietnamese
11 ☐ Other Asian
12 ☐ Native Hawaiian
13 ☐ Guamanian or Chamorro
14 ☐ Samoan
15 ☐ Other pacific Islander
16 ☐ Some other race

4. What is the highest grade or year of school you have completed?

- 1 ☐ Less than 8th grade
- 2 ☐ 8th to 11th grade
- 3 ☐ High school graduate or equivalent (GED)
- 4 ☐ Technical or vocational school
- 5 ☐ Some college
- 6 ☐ College graduate
- 7 ☐ Post-graduate degree
- 9 ☐ DK/Refused

5. Have you had a mother, sister or daughter that has had breast cancer?

- 1 ☐ Yes
 - 2 ☐ No
 - 9 ☐ DK /Refused
-

6. Have you ever had a mammogram?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK /Refused

7. During your whole lifetime, how many mammograms have you ever had?

____ (number)

8. What type of health insurance do you have?

- 1 ☐ Medicaid
- 2 ☐ Medicare
- 3 ☐ Employer-provided insurance (Oxford, Blue Cross/Blue Sheild, HIP)
- 4 ☐ Pay for insurance out of pocket
- 5 ☐ I do not have health insurance
- 6 ☐ Other: _____
- 9 ☐ DK/Refused

9. How old were you when you had your first menstrual period?

____ (years)

10. How many SONS do you have? _____ (number of sons)

11. How many DAUGHTERS do you have? _____ (number of daughters)

12. Have you gone through menopause, or the change of life?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

13. Have you ever taken birth control pills?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

14. Have you ever taken hormone replacement therapy?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

15. Do you currently smoke cigarettes?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused



If no, did you ever smoke regularly?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

16. In the past year, how many times in a typical week did you participate in moderate physical activity for at least 30 minutes per day?

___ ___ (number of times)

17. One year ago, how much did you weigh?

WEIGHT:

POUNDS.....1
KILOGRAMS.....2

6/24/02

V.

Resources

Buddy System

Expense Report Forms

Staff Listing

Sample Recruiter Post-Card

Sample Brochure

Women's Health Resources

BUDDY SYSTEM

The “buddy system” was developed to enhance communication between interviewers and recruiters throughout the recruitment phase. Therefore, each interviewer is matched to a recruiter. If recruitment packets are mailed to recruiters, interviewers will contact recruiters to inform the recruiters of how many potential subjects they are mailing to the recruiter as well as how many are **priority**.

Neon labels will be attached to those cases which must be contacted immediately (within 48 hrs). If a recruiter cannot reach a priority case within this amount of time, they need to contact their interviewer buddy, to let them know. This way, the interviewer can assist the recruiter. It is imperative that we do not lose any potential subjects, due to the late diagnosis date.

Whether or not there are new subjects packets to send, interviewers will contact their recruiter buddies once per week, to see how they are, to ask about recruitment progress, and to see if they have any questions or problems.

Recruiters have **14 days** from the “mail date” to contact their potential subjects. After 14 days, recruiters should return the information in the postage paid envelope.

Section: Resources
9/9/03.

RECRUITER/INTERVIEWER BUDDIES

Recruiters/Interviewers

Interviewer: Rose Bialecki	Sherly Jacob	Melissa Solis
Recruiters:		
Marcia Butler 718-937-4220	Carol Copeland 212-864-0867(H) 212 234-1447	Eileen Abiola 718-816-1655
	Glorie Browne 212-368-3868 917-913-0120(cell)	Medina Byars 718-430-4167/9(W) 718-542-0288 (H)
Iris Mendez 718-798-5345 917-447-3976 (cell)	Beverly Coll 717-484-4263 (H) 718-812-1020 (cell)	Alice Jaworsky 718-721-1355
	Pat Drew 212-410-1309	Cathy Williams (718) 981-1673 (H) (347) 217-8899 (cell) (718) 981-8680 (W)

Back-up Interviewers

Yahaira Gutierrez
Meredith Grossman

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Reference: Resources

Mount Sinai Recruiter Reimbursement Form

Name (Please Print)

Social Security Number

Your Complete Mailing Address

Your Signature:

Date:

Date	ID #	Participate		Interviewer	Scheduled Interview Date	Interviewed (Staff Only)
		Yes	No			

BELOW IS TO BE COMPLETED BY STAFF

_____ x \$5 = _____
of contacts who **will not** participate per contact

_____ x \$15 = _____
of contacts who **will** participate per contact

50 Scheduled Interviews Completed: x \$50 = _____

Total Reimbursement = _____

11/18/02

STAFF LISTING

	<u>Office Number</u>	<u>Mobile Phone</u>	<u>Beeper</u>
Lina Jandorf, M.A., Principal Investigator, Core A	659-5506	917 650-3751	917-424-0702
Christine Ambrosone, Ph.D., Principal Investigator, Project 1	866-223-2219		
Heiddis Valdimarsdottir, Ph.D., Principal Investigator, Project 2	659-5559		
Dana Bovbjerg, Ph.D., Principal Investigator, Project 3	659-5562		
Julie Britton, Ph.D. Co-Investigator, Project 1	241-5488		
Helena Furberg, Ph.D., Project Director	659-5523		
Senaka Peter, M.P.H., Project Coordinator	659-5406		
Anne Fatone, Ph.D., Research Fellow	659-5407	917 776-4875	917-919-3565
Sherly Jacob, B.A., B.S., Research Interviewer	659-5405	917 650-4835	
Meredith Grossman, B.A., Research Interviewer	659-5474	917-519-9425	
Rose Bialecki, B.A., Research Interviewer	659-5473	917-607-3195	

All office exchanges are in Area Code 212.

9/9/03

Reference: Resources



Women's Health Resources

Support & Social Services

American Cancer Society

Service(s): Screenings, Education, and Support Groups

National

Telephone: (800) ACS-2345 (800-227-2345)

Local

Location: Brooklyn: 148 Pierrepont Street, Brooklyn, NY

Telephone: (718) 237-7850

Location: Harlem: 271 West 125th Street b/w 7th & 8th Avenue; Rm. 210, New York, NY

Telephone: (212) 586-8700

Location: Queens: 97044 Queens Boulevard, Suite 110- Rego Park, NY

Telephone: (718) 263-2224

Location: Staten Island: 58 New Dorp Plaza

Telephone: (718) 987-8871

Web address: www.cancer.org

Arthur Ashe Institute for Urban Health/Black Pearls Program

Service(s): Breast-health literature and workshops for African-American women

Location: 450 Clarkson Avenue, Box 1232- Brooklyn, NY

Telephone: (718) 270-3101

Camp Good Days and Special Times, Inc.

Services: Vacation for survivors and their families

Telephone: 1-800-735-2135

CancerCare

Services: Counseling, education, support groups general information and referral and direct financial assistance for all cancers

Hours: Monday-Thursday: 9:00-7:00; Friday: 9:00-5:00

Location: call for details

Telephone: (212) 302-2400 or (800) 813-HOPE (800-813-4673)

Web address: www.cancercare.org

Cancer Hope Network

Services: Provides opportunity to talk with another cancer survivor based on same or similar type of cancer, stage, treatment, age, gender, ethnicity, etc.

Telephone: (877) 467-3638

Web address: Info@cancerhopenetwork.org

Cancer Information Service (CIS)- National Cancer Institute:

Service(s): Telephone-based cancer information and written literature on various cancer topics and issues
Telephone: (800) 4 Cancer (800-422-6237)
Web address: www.cancer.gov

Gilda's Club- New York

Service(s): Education, support groups, stress management and social events
Hours: Monday-Friday: 9:00-5:00
Location: 195 West Houston Street- New York, NY
Telephone: (212) 647-9700
Web address: www.gildasclubnyc.org

Partnership of Cancer Centers of Beth Israel & St. Luke's/Roosevelt & SHARE

Service(s): Yoga, Meditation, Ongoing Breast Support
Location: call for details and to register
Telephone: Cancer Centers of St. Luke's/Roosevelt Hospitals: (212) 523-7082
Beth Israel Cancer Center: (212) 844-6022

Project S.H.E. (Support· Heal· Educate)

Service(s): Education and information
Location: 467 West 143rd Street, Suite 3; New York, NY
Email: projectshe@yahoo.com
Web address: www.projectshe.org

Community Outreach Program, Albert Einstein College of Medicine

Service(s): Individual and group counseling; research, education
Location: 1300 Morris Park Avenue, Bronx, N.Y. 11461
Telephone: (718) 430-2696
Web address: www.aecom.yu.edu/cancer/outreach

SHARE (Self-help for women with Breast or Ovarian Cancer)

Service(s): Support groups for survivors, relatives and exercise and wellness programs
Location: 1501 Broadway, Suite 1720; New York, NY 10036
Telephone: (212) 719-0364; (800) 891-2392

SHAREing & CAREing

Service(s): Support groups, volunteer services, information, financial counseling, childcare and advocacy
Location: 30-60 Crescent St., Suite B, Astoria, NY 11102
Telephone: (718) 777-5766

Sister's Network

A national African-American Breast Cancer Survivors' Organization

(731) 781-0255 phone national headquarters

Web address: www.sistersnetworkinc.org

Mahogany Sister's Network- Queens New York Chapter

Location: P.O. Box 204- Brooklyn, NY 11207

Telephone: (718) 723-5879

Sister's Network-Long Island New York Chapter

Location: 734 Franklin Avenue- Garden City, NY

Telephone: (516) 538-8086

The Jean Sindab African American Breast Cancer Project- New York –Presbyterian Hospital, Columbia Presbyterian Center
Service(s): Research, Education and information
Telephone: (212) 305-6816
Web address: www.sindab.org

The National Black Women's Health Project
Local Office: 485 Lenox Avenue- New York, NY
Telephone: (212) 368-1602; national office: (202) 543-9311
Web address: www.nbwhp.org

The Susan G. Komen Breast Cancer Foundation
Service(s): funding for breast cancer research, information and education
New York Affiliate:
341 West 38th Street, 10th floor; New York, NY 10018
(212) 560-9590 phone or 800-I'M AWARE (800-462-9273)
Web address: www.komen.org

Y-Me National Breast Cancer Organization
Service(s): Education, support services and newsletter
Location: 212 West Van Buren, 5th fl; Chicago, IL 60607-3908
Telephone: (800) 241-2141
(800) 986-9505 en espagnol
Web address: www.y-me.org

Young Survival Coalition (Young Women against Breast Cancer)
Seeks to increase awareness of breast cancer and to advocate for increased funding and technological advancement with a particular focus on young women
Service(s): Support Groups, Education, and Advocacy
Telephone: (212) 916-7667
Web address: www.youngsurvival.org

Encore^{PLUS®} YWCA of the United States of America
Service(s): Exercise and recreation
Target: women recovering from breast surgery
Location: call for details
Telephone: (212) 735-9797

Post-Mastectomy Retail Stores

Underneath It All
Service(s): A post breast surgery comprehensive shopping service
Hours: Monday-Thursday: 10:00-6:00
Location: 444 East 75th Street- New York, NY
Telephone: (212) 717-1976

Yvette Lingerie and Post-Mastectomy Boutique
Service(s): Counseling and products for women with breast cancer
Location: 40-13 Bell Boulevard- Bayside, NY
Telephone: (718) 229-5724

Email: YvetteLingerie@aol.com
Web address: www.YvetteLingerie.com

Paulette Gay

Service(s): Scarves, head wraps, workshops
Location: 408 Lenox Avenue, New York, N.Y. 10039
Telephone: 212 862-7369

▪ **My Secret**

Services: Products for women with breast cancer
Location: 86th Street and Columbus Ave., New York, N.Y.

Financial/Health Insurance

Health Insurance Association of America

Service(s): hotline for general consumer information
Fee: Free
Telephone: (202) 824-1600

Medical Assistance Research Program of New York City

Service(s): eligibility information about Medicaid
Telephone: (212) 273-0047/49

Resource Entitlement and Advocacy Program (REAP)

Service(s): advocacy, assistance with entitlements
Location: Mount Sinai Medical Center
2403-05 Madison Avenue at 97th Street; New York, NY
Telephone: (212) 423-2800

**The Health Insurance Information, Counseling & Assistance Program (HICAP)
Insurance Help**

Service(s): advocacy, assistance with Insurance counseling, assistance and information
Telephone: (212) 869-3850; (800) 333-4114

Breast and Cervical Cancer Screening

American Italian Cancer Foundation

Service(s): Breast health and Screenings, Mobile van service
Fee: free
Hours: Monday-Friday: 9:00-5:00
Location: call for details
Telephone: (800) 564-6868 or (212) 628-9090
Web address: www.aicfonline.org

Bronx Breast-Health Partnership- Bronx Lebanon Hospital Center:

Service(s): Breast and Cervical Health and Screenings
Fee: low or no cost
Location: 1650 Grand Concourse-Bronx, NY
Telephone: (718) 920-1724

Brooklyn Breast- Health Partnership:

Service(s): Breast Screenings and Cervical Examinations
Fee: low or no cost
Location: 30 Third Avenue, Brooklyn
Telephone: (718) 875-1019

Boriken Neighborhood Health Center:

Service(s): Clinical Breast and Cervical Examinations, General Health and Social Services
Fee: sliding scale
Hours: Monday & Wednesday: 8:30-7:00; Tuesday, Thursday & Friday: 8:30-5:00
Location: 2253 Third Avenue, Third floor b/w 122nd and 123rd Streets, New York, NY
Telephone: (212) 289-6500

Breast Examination Center of Harlem (BECH)- Memorial Sloan-Kettering Cancer Center

Service(s): Breast & Cervical Health, Screenings, Education and Support Services
Fee: free
Hours: Monday-Friday: 8:30-4:00
Location: State Office Building-163 West 125th Street, corner of Adam Clayton Powell, Jr. (7th Avenue), 4th floor
Telephone: (212) 531-8000
Web address: www.mskcc.org

Callen-Lorde Community Health Center

Service(s): Breast and Cervical health and senior wellness programs
Location: 356 West 18th Street b/w 8th and 9th Avenues- New York
Hours: M: 12:30-8p; W: 8:30a-8p; T, Th & F: 9a-4:30p
Telephone: (212) 271-7200

Cancer Institute of Brooklyn at Maimonides Medical Center

Service(s): Breast Health and screenings, social and support services, community outreach
Language: English, Spanish, Russian and Chinese
Telephone: (718) 283-6955

Columbia University Breast-Cancer Screening Partnership:

Service(s): Breast Health and Screenings
Fee: low or no cost
Location: Columbia Presbyterian Center- Atchley Pavilion, 10th floor; 161 Fort Washington Avenue, New York, NY
Telephone: (212) 305-0163

Continuum Health Partners

Beth Israel- St. Luke's Roosevelt- Long Island College- NY Eye & Ear Infirmary
Service(s): Mammography screening
Fee: Free
Target: women 50 and over with and without insurance
Location: call for details and to make appointment
Telephone: (212) 844-8772

Cumberland Diagnostic & Treatment Center

Service(s): Breast and Cervical Health, Cancer Screenings, Counseling and Education

Location: 100 North Portland Avenue- Brooklyn, NY
Telephone: (718) 260-7500

Kings County Hospital Center

Services (s): Breast and Cervical Health and General Health
Telephone: (718) 245-3267

Lenox Hill Hospital Health Education Center

Service(s): Breast Health, Education and Information
Fee: low or no cost
Location: 1080 Lexington Avenue- New York, NY
Telephone: (212) 434-2980
Web address: www.lenoxhillhospital.org

Manhattan Breast Health Partnership:

Service(s): Breast Health and Screenings
Fee: low or no cost
Location: call for details
Telephone: (212) 586-8700

Metropolitan Hospital Center- Women's Health Clinic

Service(s): Breast & Cervical Health, General Health and Support Groups
Fee: call for details
Hours: Monday-Friday: 9:00-4:00
Location: 1901 First Avenue b/w First and Second Avenues New York, NY

Mount Sinai /NYU Health

Service(s): Breast and Cervical Examinations, General Health, Genetic Testing and Education
Fees: call for details
Location: 1190 Fifth Avenue, New York, NY
Telephone: (800) MD-SINAI (800-637-4624)

Mount Sinai Breast Health Resource Program

Service(s): Support, counseling, stress management, health education, information and screening referrals
Fees: call for details
Location: 16 East 98th Street- New York, NY
Telephone: (212) 987-3063

National Black Leadership Initiative on Cancer- Cancer Control Center of Harlem Hospital

Service(s): Breast and Cervical Health and Screenings
Fee: Free
Hours: Thursdays: 12:00-3:00; Saturdays: 9:00-12 noon
Location: Harlem Hospital Center- Ronald H. Brown Pavilion
530 Lenox Avenue at West 137th Street b/w Lenox and Fifth Avenues New York, NY
Telephone: (212) 939-8034 or (212) 939-8051

Queens Healthy Women Partnership:

Service(s): Breast Health and Screenings
Fee: low or no cost

Location: ACS Queens- 97044 Queens Boulevard, Suite 110- Rego Park, NY
Telephone: (718) 263-2224

Settlement Health

Service(s): Clinical Breast and Cervical Examinations, General Health and Social Services
Fee: sliding scale
Hours: Monday & Friday: 9-4:45; Wednesday: 10-4:45; Tuesday & Thursday: 9-6:45;
Saturday 9-12:45
Location: 212 East 106th Street b/w Third and Second Avenues, New York, NY
Telephone: (212) 360-2600

Sister-to-Sister Full Circle of Care Breast Cancer Program

Service(s): Breast Health and Screenings, Education and Social Services
Fee: low or no cost
Hours: call for details
Location: ACS Brooklyn & ACS Harlem
Telephone: (212) 663-8800 or (718) 237-7850

St. Luke's Roosevelt Hospital Breast Clinic- Breast Health Partnership

Service(s): Breast Health and screenings
Fee: Low or no cost
Location: 1111 Amsterdam Avenue- New York, NY
Telephone: (212) 573-4000

Staten Island Breast Health Partnership

Service(s): Breast & Cervical Health and screenings
Fee: Low or no cost
Location: 58 New Dorp Plaza- Staten Island, NY
Telephone: (718) 987-8871

The William F. Ryan Community Center

Service(s): Breast and Cervical Health and Screening
Fee: sliding scale
Hours: Monday & Thursday: 9:00-1:30; Tuesday, Wednesday & Friday: 9:00-5:00
Location: 110 West 97th Street, New York, NY
Telephone: (212) 749-4820

World Wide Web Based Information & Resources

AVON- Avon Breast Cancer Crusade

Web address: www.avoncompany.com/women/avoncrusade

CancerCare

Web address: www.cancercare.org

Cancer Information Service (CIS)- National Cancer Institute

Web address: www.cancer.gov

Gynecologic Cancer Foundation

Web address: www.wcn.org

Look Good...Feel Better

Web address: www.lookgoodfeelbetter.org

National Alliance of Breast Cancer Organizations

Web address: www.nabco.org

Sister's Network

Web address: www.sistersnetworkinc.org

The Breast Cancer Site

Web address: www.thebreastcancersite.com

The Susan G. Komen Breast Cancer Foundation

Web address: www.komen.org or www.breastinfo.org

Y-Me National Breast Cancer Organization

Web address: www.y-me.org

Young Survival Coalition (Young Women against Breast Cancer)

Web address: www.youngsurvival.org

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Reference: Resources

Core B

"Molecular, Diagnostics and Research Core"

CORE B

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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 will provide expert molecular studies to identify: 1) molecular changes in two genes, BRCA 1 and 2, which are associated with breast cancer; and 2) molecular changes in DNA that are associated with variability in level of production of certain proteins that are normally found in the body that also may effect cancer risk. These analyses will permit 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 Molecular Diagnostic and Research Core investigators will 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. The Core directors will work closely with the center investigators in developing cost efficient protocols for the molecular testing.

BODY:

Task 1. To establish the methodology for complete sequencing of BRCA 1 and 2

The methodology for the full sequencing of BRCA 1 and 2 has been established in the core laboratory. In addition QA and QC measures have been established and both normal control and know mutation carriers have been sequenced.

Task 2. To establish the methodology for the determination of the genotype of r 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 3. Sequencing of BRCA 1 and 2 genes using DNA from subjects recruited from Project 2

No specimens have been received for sequencing.

Task 4. Determination of genotypes for estrogen receptor polymorphisms.

No specimens have been received by the core laboratory to date.

Task 5. Determination of the genotype for polymorphisms in TNFa

No specimens have been received by the Core Laboratory to data.

Task 6. 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 also is offering a course in the Spring 2004, which is open to trainees and investigators. This course, entitled "Laboratory Science 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. The laboratory has worked with the project PIs in the establishment of a system for the storage of specimens in a 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"

CORE C

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Core C: "Biostatistics and Data Management Core"

Principal Investigator: Dr. James H. Godbold

INTRODUCTION:

The three projects in this Center project will each collect 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.

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.

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 ACOMPLISHMENTS:

Below are listed (A) the tasks to be addressed in Year 1 by the Biostatistics and Data Management Core for which work continued into Year 2, and (B) the tasks planned for Year 2 along with the accomplishments associated with that task.

A. Tasks for Year 1, on which work continued into Year 2:

1. Design databases for data to be collected in Projects 1, 2, and 3.

Questionnaires for Projects 2 and 3 were finalized.

2. Write programs to establish databases for Projects 1, 2, and 3.

Programs in ACCESS[®] were completed to produce screens for entering data from the questionnaires for Projects 1, 2, and 3. The screens appear exactly like the layout of the questionnaire pages.

3. Validate databases by entering hypothetical data, some of which is correct and some of which has deliberate errors to see if the database will prevent erroneous values from being entered while allowing for the entry of correct values.

This validation has been done for the databases designed to contain the scientific data to be collected from Projects 1, 2, and 3.

B. Tasks for Year 2:

1. Enter data into databases for Projects 1, 2, and 3.

No data has been gathered pending HSRRB approval. Thus, data entry has not yet begun.

2. Monitor data collection activities in Projects 1, 2, and 3.

No data has been gathered pending HSRRB approval.

3. Generate quarterly reports on subject enrollment and data collection for Projects 1, 2, and 3 for use by Core A.

Programs were written to produce graphical flowcharts that show the number of subjects at each stage of the recruitment/interview process. A single flow chart can be generated for all subjects overall; and separate flow charts can be generated for each recruitment site. These charts will be generated on a weekly basis.

4. Generate queries for data that fail range and logic checks at time of entry to the database.

Work is in progress on generation of these queries.

5. Monitor status of data queries.

This activity awaits the completion of the query-generation program.

Another activity of work during Year 2, which does not fall into any of the above categories, was the generation of lists of telephone prefixes for retrospective cases recruited at each hospital to be used in Random Digit Dialing to recruit age-matched controls for Project 1.

REPORTABLE OUTCOMES:

None

CONCLUSIONS:

None

REFERENCES:

None

APPENDICES:

None

Core D

"Training Core"

CORE D

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Core D: "Training Core"

Principal Investigator: Dr. Dana H. Bovbjerg

INTRODUCTION:

Despite the recent encouraging news that cancer incidence and mortality rates have inched downward in the past decade, breast cancer continues to be a preeminent cause of morbidity and mortality among American women. 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:

Since we are still waiting for HSRRB review of our repeatedly amended (at the request of Dr. Pranulis, Human Subjects Protection Scientist, AMDEX) applications for approval through the USAMRAA office for Project 1, 2, or 3, which were intended to provide the research experience for the Trainees supported by this Core (See reports for each Project above), we have intentionally delayed our timeline for completion of the training tasks listed in the Statement of Work of the funded Core (D). In the past year we have, however, begun to address Task 1: a) recruiting applications (more than 20 received); b) evaluating potential trainees (done for all received); c) developing and scheduling Foundations Curriculum (done for Epidemiology and Behavioral modules); d) coordinating training with ongoing Cancer Center Training Programs (done); e) schedule seminar series (done); f) run Foundations and Seminar Series (done); g) establish hands-on research experience for each Trainee (not done, since HSRRB approval not received); h) schedule and run Luncheon Lecture Series (replaced by weekly Journal Club – done); subsections i) through l) have not been completed due to the delays imposed by the HSRRB review (Dr. Pranulis). However, with two postdoctoral Trainees now recruited to the Program, we propose for this next year, to continue our attempts obtain HSRRB approval required to conduct our research, which would allow us to complete Task 1. While awaiting review of our amended applications, we propose to engage the Trainees in related research approved by the Mt Sinai Institutional Review Board for protection of human subjects, and funded by other sources. This report constitutes Completion of Task 2 for this Core. We propose to delay initiation of Task 3 by 6 months. We anticipate requesting a no-cost extension of the Center grant, and with expedited implementation of Task 3, we foresee completion of Tasks 3 and 4 by month 60.

KEY RESEARCH ACOMPLISHMENTS:

At this point in the research, with no approval by the HSRRB of the USAMRAA, no results are yet

available.

REPORTABLE OUTCOMES:

None at this time.

CONCLUSIONS:

At this point in the research, no results are yet available. We have recruited Trainees and initiated a broad-based postdoctoral training program to prepare those Trainees for interdisciplinary research in biobehavioral approaches to breast cancer. At the end of the program the Trainees should be ready to pursue independent research careers investigating biobehavioral processes involved in breast cancer and their interactions with minority culture. As a long term benefit of the Core, we anticipate the Trainees' efforts will cumulatively result in a series of research articles addressing some of the more critical minority issues in biobehavioral aspects of breast cancer with potential clinical implications for cancer prevention, screening, diagnosis, treatment, and survival in this underserved population.

REFERENCES:

N/A

APPENDICES:

N/A