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

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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

I. Center Grant Overall Report

II. Project 1 Report

III. Project 2 Report

IV. Project 3 Report

V. Core A Report

VI. Core B Report

VII. Core C Report

VIII. Core D Report

CENTER GRANT

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

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:

As we have yet to receive official notification of approval of the HSRRB of the USAMRAA for any of the proposed three Projects, 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 (detailed for each Projects and Cores in separate sections, below). Our primary goal for the next year is thus to obtain approval from the HSRRB for each of the Projects so that we can begin the research. Our responses to requested clarifications/revisions for Project 1 and Project 2 have been under review by the HSRRB since February 2002. For Project 3, we are currently preparing further clarifications/revisions recently (10/04/02) requested by the HSRRB and plan to submit those by 11/1/02. Based on the time required for processing previous clarifications/revisions (2-10 months [and counting]), we are thus optimistic that we can complete the required review process prior to the second 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 of the HSRRB of the USAMRAA. While awaiting HSRRB approval, our second goal for the next year is to complete initiate all Tasks that can be completed without such approval. We thus propose to 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 anticipate being allowed by the HSRRB to initiate the proposed research. 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.

REFERENCES:

None

APPENDICES:

None

PROJECT 1

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

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 and Health Care Finance Administration (Center for Medicaid and Medicare Services) lists. 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

As per our proposed statement of work, the past year has been devoted to study start-up and organizational tasks. We have developed 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 have also pilot tested and refined our questionnaire and developed study-related instruments and forms to facilitate data collection and tracking. Materials for the training of interviewers and maintenance of data quality have been designed. To date, three interviewers have been hired and trained. The textual content for participant letters and a brochure introducing the study has been finalized and will be (has been) submitted for IRB review. A database in ACCESS® has been designed for subject tracking.

None of the seven subsequent tasks have been performed while we wait for Army IRB 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:

- Establishment of infrastructure for molecular epidemiologic study (questionnaire development, protocols and equipment for blood processing and specimen banking, interviewing hiring and training, development of 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: 42,385,555
P.I.: C. Ambrosone

Source: K07/NCI (Pending)
Grant Number: N/A
Project Title: Telomerase and Breast Cancer Etiology in African Americans
Project Period: 7/01/03-6/30/08 Total Direct Costs: $616,875
P.I.: H. Furberg

CONCLUSIONS:

At this time no participants have been recruited to this study because we have not received Army IRB 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

Study ID#: _____

TRI-STATE 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
Has participant previously been consented?	☐ Yes ☐ No
Was blood drawn prior to date of interview?	☐ Yes ☐ No
Does participant want study results?	☐ Yes ☐ No
Was a continuation booklet used?	☐ Yes ☐ No

	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, probe to assess 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?

____ ____ / ____ ____ / ____ ____ ____ ____ 99☐ DK/Refused
Month Day Year

A2. What is your current age?

_____ _____ age 99 ☐ DK/Refused

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

_____ 99 ☐ DK/Refused |__|__|__|

(Name of state or country)

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

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

Show Card

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

Show Card

A6a. Interviewer observation: Based on above, 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

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)

Show Card

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

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

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

_____ 99 ☐ DK/Refused |__|__|__|

(Name of country)

A15. In what country was your MOTHER'S FATHER (maternal grandfather) born?

_____ 99 ☐ DK/Refused |__|__|__|

(Name of country)

A16. In what U.S. state or foreign country was your FATHER born?

_____ 99 ☐ DK/Refused |__|__|__|

(Name of country)

A17. Is your FATHER of Latino or Hispanic origin?

1 ☐ Yes
2 ☐ No
9 ☐ DK/Refused

Show Card

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

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

Show Card

- 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

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

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 ☐ Yes → 2 ☐ No (B5) 9 ☐ DK/Refused (B5)	a. ⌊_⌊_⌊_⌋ b. ⌊_⌊_⌊_⌋ c. ⌊_⌊_⌊_⌋	a. ___ ___ age b. ___ ___ age 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 ☐ Yes → 2 ☐ No (B9) 9 ☐ DK/R (B9)	a. ⌊_⌊_⌊_⌋ b. ⌊_⌊_⌊_⌋ c. ⌊_⌊_⌊_⌋	a. ___ ___ age b. ___ ___ age 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 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (b) 9 ☐ DK/Refused (b)	a. ___ ___ ___ b. ___ ___ ___ c. ___ ___ ___	a. ___ ___ age b. ___ ___ age c. ___ ___ age
b		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (c) 9 ☐ DK/Refused (c)	a. ___ ___ ___ b. ___ ___ ___ c. ___ ___ ___	a. ___ ___ age b. ___ ___ age c. ___ ___ age
c		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (d) 9 ☐ DK/Refused (d)	a. ___ ___ ___ b. ___ ___ ___ c. ___ ___ ___	a. ___ ___ age b. ___ ___ age c. ___ ___ age
d		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (e) 9 ☐ DK/Refused (e)	a. ___ ___ ___ b. ___ ___ ___ c. ___ ___ ___	a. ___ ___ age b. ___ ___ age c. ___ ___ age
e		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (B18) 9 ☐ DK/Refused (B18)	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 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (g) 9 ☐ DK/Refused (g)	a. ☐☐☐ b. ☐☐☐ c. ☐☐☐	a. ___ ___ age b. ___ ___ age c. ___ ___ age
g		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (h) 9 ☐ DK/Refused (h)	a. ☐☐☐ b. ☐☐☐ c. ☐☐☐	a. ___ ___ age b. ___ ___ age c. ___ ___ age
h		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (i) 9 ☐ DK/Refused (i)	a. ☐☐☐ b. ☐☐☐ c. ☐☐☐	a. ___ ___ age b. ___ ___ age c. ___ ___ age
i		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (j) 9 ☐ DK/Refused (j))	a. ☐☐☐ b. ☐☐☐ c. ☐☐☐	a. ___ ___ age b. ___ ___ age c. ___ ___ age
j		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (B26) 9 ☐ DK/Refused (B26)	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]?	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 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (b) 9 ☐ DK/Refused (b)	a. ___ ___ b. ___ ___ c. ___ ___	a. ___ ___ age b. ___ ___ age c. ___ ___ age
b		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (c) 9 ☐ DK/Refused (c)	a. ___ ___ b. ___ ___ c. ___ ___	a. ___ ___ age b. ___ ___ age c. ___ ___ age
c		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (d) 9 ☐ DK/Refused (d)	a. ___ ___ b. ___ ___ c. ___ ___	a. ___ ___ age b. ___ ___ age c. ___ ___ age
d		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (e) 9 ☐ DK/Refused (e)	a. ___ ___ b. ___ ___ c. ___ ___	a. ___ ___ age b. ___ ___ age c. ___ ___ age
e		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (f) 9 ☐ 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 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (g) 9 ☐ DK/Refused (g)	a. ___ ___ ___ b. ___ ___ ___ c. ___ ___ ___	a. ___ ___ age b. ___ ___ age c. ___ ___ age
g		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (h) 9 ☐ DK/Refused (h)	a. ___ ___ ___ b. ___ ___ ___ c. ___ ___ ___	a. ___ ___ age b. ___ ___ age c. ___ ___ age
h		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (i) 9 ☐ DK/Refused (i)	a. ___ ___ ___ b. ___ ___ ___ c. ___ ___ ___	a. ___ ___ age b. ___ ___ age c. ___ ___ age
i		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No (j) 9 ☐ DK/Refused (j)	a. ___ ___ ___ b. ___ ___ ___ c. ___ ___ ___	a. ___ ___ age b. ___ ___ age c. ___ ___ age
j		1 ☐ Male 2 ☐ Female	1 ☐ Yes 2 ☐ No 9 ☐ DK/R	___ ___ age	1 ☐ Yes → 2 ☐ No 9 ☐ 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 <u>breast</u> or <u>ovarian</u> cancer?

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

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

01 ☐ None	
02 ☐ Mother's mother	
03 ☐ Father's mother	
04 ☐ Mother's sister(s)	**a.** How many with breast cancer? _____
05 ☐ Father's sister(s)	**b.** How many with breast cancer? _____
06 ☐ My maternal half sister(s)	**c.** How many with breast cancer? _____
07 ☐ My paternal half sister(s)	**d.** How many with breast cancer? _____
08 ☐ Maternal male relatives	**e.** How many with breast cancer? _____
09 ☐ Paternal male relatives	**f.** How many with breast cancer? _____
10 ☐ Other relative(s)	**g.** Please specify who:_____ |_|_|_| _____ |_|_|_|
99 ☐ DK/Refused	

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

01 ☐ None	
02 ☐ Mother's mother	
03 ☐ Father's mother	
04 ☐ Mother's sister(s)	**a.** How many with ovarian cancer? _____
05 ☐ Father's sister(s)	**b.** How many with ovarian cancer? _____
06 ☐ My maternal half sister(s)	**c.** How many with ovarian cancer? _____
07 ☐ My paternal half sister(s)	**d.** How many with ovarian cancer? _____
08 ☐ Other relative(s)	**e.** Please specify who:_____ |_|_|_| _____ |_|_|_|
99 ☐ 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 → **C5a. What was your weight?** ___ ___ pounds ___ ___ ounces
2 ☐ No
9 ☐ DK/Refused

If birthweight is known, skip to question C6.

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 → **C8a. How long did she breastfeed you?** ___ ___ months
2 ☐ Yes probably/possibly 99 ☐ DK/Refused
3 ☐ No
9 ☐ 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)?

Show Card

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

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.)*

Show Card

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): _____ |__|__|__|
99 ☐ DK/Refused

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☐Single live birth 2☐Multiple birth, any living	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	1 ☐ Yes E6a. How long? ↓ ___ ___ Months 2 ☐ No 9 ☐ DK/Refused
	3☐Multiple birth, none living 4☐Stillbirth 5☐Spontaneous miscarriage 6☐Induced abortion 7☐Tubal or ectopic pregnancy 8☐Other (specify): _____ ☐☐☐	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	
b	1☐Single live birth 2☐Multiple birth, any living	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	1 ☐ Yes E6b. How long? ↓ ___ ___ Months 2 ☐ No 9 ☐ DK/Refused
	3☐Multiple birth, none living 4☐Stillbirth 5☐Spontaneous miscarriage 6☐Induced abortion 7☐Tubal or ectopic pregnancy 8☐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?
c	1 ☐ Single live birth 2 ☐ Multiple birth, any living	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	1 ☐ Yes E6c. How long? ↓ ___ ___ Months 2 ☐ No 9 ☐ DK/Refused
	3 ☐ Multiple birth, none living 4 ☐ Stillbirth 5 ☐ Spontaneous miscarriage 6 ☐ Induced abortion 7 ☐ Tubal or ectopic pregnancy 8 ☐ Other (specify): ___ ___ ___	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	
d	1 ☐ Single live birth 2 ☐ Multiple birth, any living	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	1 ☐ Yes E6d. How long? ↓ ___ ___ Months 2 ☐ No 9 ☐ DK/Refused
	3 ☐ Multiple birth, none living 4 ☐ Stillbirth 5 ☐ Spontaneous miscarriage 6 ☐ Induced abortion 7 ☐ Tubal or ectopic pregnancy 8 ☐ Other (specify): ___ ___ ___	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	
e	1 ☐ Single live birth 2 ☐ Multiple birth, any living	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	1 ☐ Yes E6e. How long? ↓ ___ ___ Months 2 ☐ No 9 ☐ DK/Refused
	3 ☐ Multiple birth, none living 4 ☐ Stillbirth 5 ☐ Spontaneous miscarriage 6 ☐ Induced abortion 7 ☐ Tubal or ectopic pregnancy 8 ☐ 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?
f	1 ☐ Single live birth 2 ☐ Multiple birth, any living	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	1 ☐ Yes E6f. How long? ↓ ___ ___ Months 2 ☐ No 9 ☐ DK/Refused
	3 ☐ Multiple birth, none living 4 ☐ Stillbirth 5 ☐ Spontaneous miscarriage 6 ☐ Induced abortion 7 ☐ Tubal or ectopic pregnancy 8 ☐ Other (specify): ___ ___ ___	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	
g	1 ☐ Single live birth 2 ☐ Multiple birth, any living	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	1 ☐ Yes E6g. How long? ↓ ___ ___ Months 2 ☐ No 9 ☐ DK/Refused
	3 ☐ Multiple birth, none living 4 ☐ Stillbirth 5 ☐ Spontaneous miscarriage 6 ☐ Induced abortion 7 ☐ Tubal or ectopic pregnancy 8 ☐ Other (specify): ___ ___ ___	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	
h	1 ☐ Single live birth 2 ☐ Multiple birth, any living	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	1 ☐ Yes E6h. How long? ↓ ___ ___ Months 2 ☐ No 9 ☐ DK/Refused
	3 ☐ Multiple birth, none living 4 ☐ Stillbirth 5 ☐ Spontaneous miscarriage 6 ☐ Induced abortion 7 ☐ Tubal or ectopic pregnancy 8 ☐ 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 ☐ Single live birth 2 ☐ Multiple birth, any living	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	1 ☐ Yes E6i. How long? ___ ___ Months 2 ☐ No 9 ☐ DK/Refused
	3 ☐ Multiple birth, none living 4 ☐ Stillbirth 5 ☐ Spontaneous miscarriage 6 ☐ Induced abortion 7 ☐ Tubal or ectopic pregnancy 8 ☐ Other (specify): ___	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	
j	1 ☐ Single live birth 2 ☐ Multiple birth, any living	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	1 ☐ Yes E6j. How long? ___ ___ Months 2 ☐ No 9 ☐ DK/Refused
	3 ☐ Multiple birth, none living 4 ☐ Stillbirth 5 ☐ Spontaneous miscarriage 6 ☐ Induced abortion 7 ☐ Tubal or ectopic pregnancy 8 ☐ Other (specify): ___	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	
k	1 ☐ Single live birth 2 ☐ Multiple birth, any living	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	1 ☐ Yes E6k. How long? ___ ___ Months 2 ☐ No 9 ☐ DK/Refused
	3 ☐ Multiple birth, none living 4 ☐ Stillbirth 5 ☐ Spontaneous miscarriage 6 ☐ Induced abortion 7 ☐ Tubal or ectopic pregnancy 8 ☐ 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 ☐ Single live birth 2 ☐ Multiple birth, any living	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	1 ☐ Yes E6l. How long? ↓ ___ ___ Months 2 ☐ No 9 ☐ DK/Refused
	3 ☐ Multiple birth, none living 4 ☐ Stillbirth 5 ☐ Spontaneous miscarriage 6 ☐ Induced abortion 7 ☐ Tubal or ectopic pregnancy 8 ☐ Other (specify): ___ ___ ___	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	
m	1 ☐ Single live birth 2 ☐ Multiple birth, any living	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	1 ☐ Yes E6m. How long? ↓ ___ ___ Months 2 ☐ No 9 ☐ DK/Refused
	3 ☐ Multiple birth, none living 4 ☐ Stillbirth 5 ☐ Spontaneous miscarriage 6 ☐ Induced abortion 7 ☐ Tubal or ectopic pregnancy 8 ☐ Other (specify): ___ ___ ___	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	
n	1 ☐ Single live birth 2 ☐ Multiple birth, any living	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	1 ☐ Yes E6n. How long? ↓ ___ ___ Months 2 ☐ No 9 ☐ DK/Refused
	3 ☐ Multiple birth, none living 4 ☐ Stillbirth 5 ☐ Spontaneous miscarriage 6 ☐ Induced abortion 7 ☐ Tubal or ectopic pregnancy 8 ☐ Other (specify): ___ ___ ___	___ ___ Months Or ___ ___ Weeks	___ ___ / ___ ___ ___ ___ Month Year	

	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 ☐ Yes → 2 ☐ No (E7b) 9 ☐ 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 <u>and</u> protein in your urine.** 1 ☐ Yes → 2 ☐ No (E7c) 9 ☐ DK/Refused (E7c)	a. _____ (Pregnancy letter) b. _____ (Pregnancy letter) c. _____ (Pregnancy letter) d. _____ (Pregnancy letter)
c	**Diabetes or high blood sugar?** 1 ☐ Yes → 2 ☐ No (F1) 9 ☐ 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? Show Card	F7. What type of hormones did you use? Show Card	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 ☐ Yes (specify):_____ (F8) |_|_|_| 2 ☐ No (F7)	1 ☐ Estrogen only 2 ☐ Progestin only 3 ☐ Both Estrogen and Progestin 9 ☐ DK/Refused	____ year OR ____ age	____ year OR ____ age 00 ☐ still taking	____ months OR ____ years
b	1 ☐ Yes (specify):_____ (F8) |_|_|_| 2 ☐ No (F7)	1 ☐ Estrogen only 2 ☐ Progestin only 3 ☐ Both Estrogen and Progestin 9 ☐ DK/Refused	____ year OR ____ age	____ year OR ____ age 00 ☐ still taking	____ months OR ____ years
c	1 ☐ Yes (specify):_____ (F8) |_|_|_| 2 ☐ No (F7)	1 ☐ Estrogen only 2 ☐ Progestin only 3 ☐ Both Estrogen and Progestin 9 ☐ DK/Refused	____ year OR ____ age	____ year OR ____ age 00 ☐ still taking	____ months OR ____ years

	F6. Do you recall the name of the hormone that you (first/next) used? Show Card	F7. What type of hormones did you use? Show Card	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 ☐ Yes (specify):_____ (F8) |_|_|_| 2 ☐ No (F7)	1 ☐ Estrogen only 2 ☐ Progestin only 3 ☐ Both Estrogen and Progestin 9 ☐ DK/Refused	____ year OR ____ age	____ year OR ____ age 00 ☐ still taking	___ months OR ___ years
e	1 ☐ Yes (specify):_____ (F8) |_|_|_| 2 ☐ No (F7)	1 ☐ Estrogen only 2 ☐ Progestin only 3 ☐ Both Estrogen and Progestin 9 ☐ DK/Refused	____ year OR ____ age	____ year OR ____ age 00 ☐ still taking	___ months OR ___ years
f	1 ☐ Yes (specify):_____ (F8) |_|_|_| 2 ☐ No (F7)	1 ☐ Estrogen only 2 ☐ Progestin only 3 ☐ Both Estrogen and Progestin 9 ☐ DK/Refused	____ year OR ____ age	____ year OR ____ age 00 ☐ 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?

___ ___ Age OR ___ ___ ___ ___ 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?

___ ___ Age OR ___ ___ Month / ___ ___ ___ ___ Year

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

1 ☐ Yes →

2 ☐ No (G7)

9 ☐ DK/Refused (G7)

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)

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 H

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.

I1. 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 (I8)
9 ☐ DK/ Refused (I8)

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.

	I2. At what age did you (first/next) regularly start coloring your hair?	I3. What shade of hair color did you use?	I4. Did you use a home-kit or was it done in a salon?	I5. At what age did you last dye your hair this color?	I6. For how many months or years did you dye your hair this color?	I7. On average, how often did you color your hair?
a	___ ___ age	1 ☐ Light (blonde, light brown) 2 ☐ Medium (medium brown, red) 3 ☐ Dark (dark brown, black)	1 ☐ Home-kit:_____ (Brand name.) |_|_|_| 2 ☐ Salon 3 ☐ Both 9 ☐ DK/Refused	___ ___ age	___ ___ (months) or ___ ___ (years)	1☐4-6 months 2☐2-3 months 3☐6-8 weeks 4☐4-5 weeks 5☐More than every 4 weeks 9☐DK/Refused
b	___ ___ age	1 ☐ Light (blonde, light brown) 2 ☐ Medium (medium brown, red) 3 ☐ Dark (dark brown, black)	1 ☐ Home-kit:_____ (Brand name) |_|_|_| 2 ☐ Salon 3 ☐ Both 9 ☐ DK/Refused	___ ___ age	___ ___ (months) or ___ ___ (years)	1☐4-6 months 2☐2-3 months 3☐6-8 weeks 4☐4-5 weeks 5☐More than every 4 weeks 9☐DK/Refused

	I2. At what age did you (first/next) regularly start coloring your hair?	I3. What shade of hair color did you use?	I4. Did you use a home-kit or was it done in a salon?	I5. At what age did you last dye your hair this color?	I6. For how many months or years did you dye your hair this color?	I7. On average, how often did you color your hair?
c	___ ___ age	1 ☐ Light (blonde, light brown) 2 ☐ Medium (medium brown, red) 3 ☐ Dark (dark brown, black)	1 ☐ Home-kit:_____ (Brand name) |_|_|_| 2 ☐ Salon 3 ☐ Both 9 ☐ DK/Refused	___ ___ age	___ ___ (months) or ___ ___ (years)	1☐4-6 months 2☐2-3 months 3☐6-8 weeks 4☐4-5 weeks 5☐More than every 4 weeks 9☐DK/Refused
d	___ ___ age	1 ☐ Light (blonde, light brown) 2 ☐ Medium (medium brown, red) 3 ☐ Dark (dark brown, black)	1 ☐ Home-kit:_____ (Brand name) |_|_|_| 2 ☐ Salon 3 ☐ Both 9 ☐ DK/Refused	___ ___ age	___ ___ (months) or ___ ___ (years)	1☐4-6 months 2☐2-3 months 3☐6-8 weeks 4☐4-5 weeks 5☐More than every 4 weeks 9☐DK/Refused

I8. Have you ever chemically relaxed or straightened your hair for at least one year?

1 ☐ Yes
2 ☐ No (I14)
9 ☐ DK/ Refused (I14)

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

	I9. When you were (age from 1st column), did you ever relax your hair?	I10. Between these ages, for how many months or years in total did you relax your hair?	I11. Between these ages, on average, how often did you relax your hair?	I12. Did you use lye or no-lye relaxers?	I13. Did you use a home-kit or was it done in a salon?
a. 12 years old or younger	1☐Yes 2☐No (b) 9☐DK/Refused (b)	___ ___ (Months) or ___ ___ (Years)	1☐4-6 months 2☐2-3 months 3☐6-8 weeks 4☐4-5 weeks 5☐More than every 4 weeks 9☐DK/Refused	1☐Lye 2☐No lye 3☐Both 9☐DK/Refused	1☐Home-kit 2☐Salon 3☐Both 9☐DK/Refused
b. Between 13 and 19 years old	1☐Yes 2☐No (c) 9☐DK/Refused (c)	___ ___ (Months) or ___ ___ (Years)	1☐4-6 months 2☐2-3 months 3☐6-8 weeks 4☐4-5 weeks 5☐More than every 4 weeks 9☐DK/Refused	1☐Lye 2☐No lye 3☐Both 9☐DK/Refused	1☐Home-kit 2☐Salon 3☐Both 9☐DK/Refused
c. 20 years old up until now	1☐Yes 2☐No (I14) 9☐DK/Refused (I14)	___ ___ (Months) or ___ ___ (Years)	1☐4-6 months 2☐2-3 months 3☐6-8 weeks 4☐4-5 weeks 5☐More than every 4 weeks 9☐DK/Refused	1☐Lye 2☐No lye 3☐Both 9☐DK/Refused	1☐Home-kit 2☐Salon 3☐Both 9☐DK/Refused

I14. 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 cholesterol hair creams.

	I15. When you were (age from 1st column), did you ever use cholesterol/placenta hair conditioner?	I16. Between these ages, for how many months or years did you use these products?	I17. During this age range, how often did you use these products?
a. 12 years old or younger	1☐Yes 2☐No (b) 9☐DK/Refused (b)	___ ___ (Months) or ___ ___ (Years)	1☐Daily 2☐Several times/week 3☐Once/week 4☐Every 2 weeks 5☐Once/month 6☐2-3 times a year 9☐DK/Refused
b. Between 13 and 19 years old	1☐Yes 2☐No (c) 9☐DK/Refused (c)	___ ___ (Months) or ___ ___ (Years)	1☐Daily 2☐Several times/week 3☐Once/week 4☐Every 2 weeks 5☐Once/month 6☐2-3 times a year 9☐DK/Refused
c. 20 years old old up until now.	1☐Yes 2☐No (J1) 9☐DK/Refused (J1)	___ ___ (Months) or ___ ___ (Years)	1☐Daily 2☐Several times/week 3☐Once/week 4☐Every 2 weeks 5☐Once/month 6☐2-3 times a year 9☐DK/Refused

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

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

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

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

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

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

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 <u>number of people</u> you lived with who smoked and <u>at what ages</u> 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 ☐ Yes 2 ☐ No (L2b)	____ ____ years	____ ____ drinks per 1 ☐ Day 2 ☐ Week 3 ☐ Month 4 ☐ Year
b. 20-29 years of age 1 ☐ Yes 2 ☐ No (L2c)	____ ____ years	____ ____ drinks per 1 ☐ Day 2 ☐ Week 3 ☐ Month 4 ☐ Year
c. 30-39 years of age 1 ☐ Yes 2 ☐ No (L2d) 3 ☐ Not that old yet	____ ____ years	____ ____ drinks per 1 ☐ Day 2 ☐ Week 3 ☐ Month 4 ☐ Year
d. 40-49 years of age 1 ☐ Yes 2 ☐ No (L2e) 3 ☐ Not that old yet	____ ____ years	____ ____ drinks per 1 ☐ Day 2 ☐ Week 3 ☐ Month 4 ☐ Year
e. 50-59 years of age 1 ☐ Yes 2 ☐ No (L2f) 3 ☐ Not that old yet	____ ____ years	____ ____ drinks per 1 ☐ Day 2 ☐ Week 3 ☐ Month 4 ☐ Year
f. Age 60 or older 1 ☐ Yes 2 ☐ No (M1) 3 ☐ Not that old yet	____ ____ years	____ ____ drinks per 1 ☐ Day 2 ☐ Week 3 ☐ Month 4 ☐ 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 <u>height</u> 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 (2nd or 3rd 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 (10th or 11th grade)	1	2	3	4	5	6	7

M2. When you were (AGE CATEGORY), how did your <u>weight</u> 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 (2nd or 3rd 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 (10th or 11th 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 ☐ Pounds 2 ☐ Kilograms 9 ☐ DK/Refused
b. 30 years old	WT: |__|__|__|	1 ☐ Pounds 2 ☐ Kilograms 9 ☐ DK/Refused
c. 40 years old	WT: |__|__|__|	1 ☐ Pounds 2 ☐ Kilograms 9 ☐ DK/Refused
d. 50 years old	WT: |__|__|__|	1 ☐ Pounds 2 ☐ Kilograms 9 ☐ DK/Refused
e. 60 years old	WT: |__|__|__|	1 ☐ Pounds 2 ☐ Kilograms 9 ☐ DK/Refused
f. 70 years old	WT: |__|__|__|	1 ☐ Pounds 2 ☐ Kilograms 9 ☐ 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

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****. Jobs should be reported separately if they required <u>different</u> physical effort. For example, changing from book keeping to construction work within the same company would be considered a "change in job".*

N2. Have you ever worked or volunteered for <u>at least 17 hours a week for 6 months or longer</u> 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

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? If R. chooses more than one activity ask : What percent of the time did you do (ACTIVITY)?	N5. At what age or in what year, did you start working in this job?
01	01 ☐ Sitting |_|_|_|% 02 ☐ Standing |_|_|_|% 03 ☐ Walking |_|_|_|% 04 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items<25lbs. (11 kg) |_|_|_|% 05 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items >25lbs. (11 kg) |_|_|_|% 06 ☐ Some other activity (specify)_____ |_|_|_|%	|_|_|_|_| YEAR OR |_|_| AGE
02	01 ☐ Sitting |_|_|_|% 02 ☐ Standing |_|_|_|% 03 ☐ Walking |_|_|_|% 04 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items <25lbs. (11 kg) |_|_|_|% 05 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items >25lbs. (11 kg) |_|_|_|% 06 ☐ Some other activity (specify)_____ |_|_|_|%	|_|_|_|_| YEAR OR |_|_| AGE
03	01 ☐ Sitting |_|_|_|% 02 ☐ Standing |_|_|_|% 03 ☐ Walking |_|_|_|% 04 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items <25lbs. (11 kg) |_|_|_|% 05 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items >25lbs. (11 kg) |_|_|_|% 06 ☐ Some other activity (specify)_____ |_|_|_|%	|_|_|_|_| YEAR OR |_|_| AGE

	N6. When did you stop 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☐ still working	___ YEARS	___ MONTHS PER YEAR	___ HOURS PER WEEK
02	____ YEAR OR ___ AGE 00☐ still working	___ YEARS	___ MONTHS PER YEAR	___ HOURS PER WEEK
03	____ YEAR OR ___ AGE 00☐ 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? If R. chooses more than one activity ask What percent of the time did you do (ACTIVITY)?	N5. At what age or in what year, did you start working in this job?
04	01 ☐ Sitting |_|_|_|% 02 ☐ Standing |_|_|_|% 03 ☐ Walking |_|_|_|% 04 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items<25lbs. (11 kg) |_|_|_|% 05 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items >25lbs. (11 kg) |_|_|_|% 06 ☐ Some other activity (specify)_____ |_|_|_|%	|_|_|_|_| YEAR OR |_|_| AGE
05	01 ☐ Sitting |_|_|_|% 02 ☐ Standing |_|_|_|% 03 ☐ Walking |_|_|_|% 04 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items<25lbs. (11 kg) |_|_|_|% 05 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items >25lbs. (11 kg) |_|_|_|% 06 ☐ Some other activity (specify)_____ |_|_|_|%	|_|_|_|_| YEAR OR |_|_| AGE
06	01 ☐ Sitting |_|_|_|% 02 ☐ Standing |_|_|_|% 03 ☐ Walking |_|_|_|% 04 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items<25lbs. (11 kg) |_|_|_|% 05 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items >25lbs. (11 kg) |_|_|_|% 06 ☐ Some other activity (specify)_____ |_|_|_|%	|_|_|_|_| YEAR OR |_|_| AGE

	N6. When did you stop 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☐ still working	__ YEARS	__ MONTHS PER YEAR	__ HOURS PER WEEK
05	____ YEAR OR ___ AGE 00☐ still working	__ YEARS	__ MONTHS PER YEAR	__ HOURS PER WEEK
06	____ YEAR OR ___ AGE 00☐ 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? If R. chooses more than one activity ask What percent of the time did you do (ACTIVITY)?	N5. At what age or in what year, did you start working in this job?
07		01 ☐ Sitting |_|_|_|% 02 ☐ Standing |_|_|_|% 03 ☐ Walking |_|_|_|% 04 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items<25lbs. (11 kg) |_|_|_|% 05 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items >25lbs. (11 kg) |_|_|_|% 06 ☐ Some other activity (specify)_____ |_|_|_|%	|_|_|_|_| YEAR OR |_|_| AGE
08		01 ☐ Sitting |_|_|_|% 02 ☐ Standing |_|_|_|% 03 ☐ Walking |_|_|_|% 04 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items<25lbs. (11 kg) |_|_|_|% 05 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items >25lbs. (11 kg) |_|_|_|% 06 ☐ Some other activity (specify)_____ |_|_|_|%	|_|_|_|_| YEAR OR |_|_| AGE
09		01 ☐ Sitting |_|_|_|% 02 ☐ Standing |_|_|_|% 03 ☐ Walking |_|_|_|% 04 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items<25lbs. (11 kg) |_|_|_|% 05 ☐ Sitting, standing, or walking while lifting/carrying/ or pushing items >25lbs. (11 kg) |_|_|_|% 06 ☐ Some other activity (specify)_____ |_|_|_|%	|_|_|_|_| YEAR OR |_|_| AGE

	N6. When did you stop 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☐ still working	__ YEARS	__ MONTHS PER YEAR	__ HOURS PER WEEK
08	____ YEAR OR ___ AGE 00☐ still working	__ YEARS	__ MONTHS PER YEAR	__ HOURS PER WEEK
09	____ YEAR OR ___ AGE 00☐ 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. Seasonal activities done continuously (e.g. track every spring for four years) can be listed once. When activites were discontinued and then begun again later, code each interval of an activity separately so that activity patterns at various ages can be evaluated.

Ask all of the questions (O2-O7) for one exercise episode before asking about next episode

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	____ YEAR OR __ AGE 00☐ still doing	__ YEARS	__ MONTHS PER YEAR	__:__ HOURS MIN PER WEEK
b	_____	__ AGE	____ YEAR OR __ AGE 00☐ still doing	__ YEARS	__ MONTHS PER YEAR	__:__ HOURS MIN PER WEEK
c	_____	__ AGE	____ YEAR OR __ AGE 00☐ still doing	__ YEARS	__ MONTHS PER YEAR	__:__ HOURS MIN PER WEEK
d	_____	__ AGE	____ YEAR OR __ AGE 00☐ still doing	__ YEARS	__ MONTHS PER YEAR	__:__ HOURS MIN PER WEEK
e	_____	__ AGE	____ YEAR OR __ AGE 00☐ still doing	__ YEARS	__ MONTHS PER YEAR	__:__ HOURS MIN PER WEEK
f	_____	__ AGE	____ YEAR OR __ 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	____ YEAR OR __ AGE 00☐ still doing	__ YEARS	__ MONTHS PER YEAR	__:__ HOURS MIN PER WEEK
h	_____	__ AGE	____ YEAR OR __ AGE 00☐ still doing	__ YEARS	__ MONTHS PER YEAR	__:__ HOURS MIN PER WEEK
i	_____	__ AGE	____ YEAR OR __ AGE 00☐ still doing	__ YEARS	__ MONTHS PER YEAR	__:__ HOURS MIN PER WEEK
j	_____	__ AGE	____ YEAR OR __ AGE 00☐ still doing	__ YEARS	__ MONTHS PER YEAR	__:__ HOURS MIN PER WEEK
k	_____	__ AGE	____ YEAR OR __ AGE 00☐ still doing	__ YEARS	__ MONTHS PER YEAR	__:__ HOURS MIN PER W7EEK
l	_____	__ AGE	____ YEAR OR __ AGE 00☐ still doing	__ YEARS	__ MONTHS PER YEAR	__:__ HOURS MIN PER WEEK

Next, I would like to ask about some specific household and gardening activities that you may have done around your home. I am only interested in those activities that you have participated in for at least 2 hours per week for three months or more in any year. It may help to consider what a typical day or week is like for you.

NOTE: Activities done for pay should be recorded under occupational activities.

O8. Have you ever participated for at least 2 hours per week for three months or more in any year in (ACTIVITY)?	O9. At what age did you start (ACTIVITY) regularly?	O10. At what age did you stop (ACTIVITY)?	O11. Considering that you may have started & stopped several times for how many years in total did you (ACTIVITY) regularly?	O12. For how many months each year did you do this?	O13. On average, about how many hours per week did you actually perform (ACTIVITY) on weekdays and on weekends?
a. Actively caring for a child or children under 2 years of age (only count time actually spent in activities such as feeding, dressing, bathing, playing, and carrying) 1 ☐ Yes 2 ☐ No (8b)	___ AGE	___ AGE 00☐ currently doing	___ YEARS	___ MONTHS PER YEAR	__:__ HOURS MIN PER WEEK ☐ Full time
b. Actively caring for a child or children between 2 and 5 years of age 1 ☐ Yes 2 ☐ No (8c)	___ AGE	___ AGE 00☐ currently doing	___ YEARS	___ MONTHS PER YEAR	__:__ HOURS MIN PER WEEK ☐ Full time
c. Actively caring for a disabled child or elderly person (only count time actually spent in feeding, dressing, moving, etc.) 1 ☐ Yes 2 ☐ No (8d)	___ AGE	___ AGE 00☐ currently doing	___ YEARS	___ MONTHS PER YEAR	__:__ HOURS MIN PER WEEK ☐ Full time
d. Preparing or cleaning up from meals on weekdays and weekends. Please tell me about weekdays and weekends separately. 1 ☐ Yes 2 ☐ No (8e)	___ AGE	___ AGE 00☐ currently doing	___ YEARS	___ MONTHS PER YEAR	d1. WEEKDAYS __:__ HOURS MIN d2. WEEKENDS __:__ HOURS MIN

O8. Have you ever participated for at least 2 hours per week for three months or more in any year In (ACTIVITY)?	O9. At what age did you start (ACTIVITY) regularly?	O10. At what age did you stop (ACTIVITY)?	O11. Considering that you may have started & stopped several times for how many years total did you (ACTIVITY)?	O12. For how many months each year did you do this?	O13. On average, about how many hours per week did you actually perform (ACTIVITY) on weekdays and on weekends?
e. Doing major cleaning, such as shampooing carpets, waxing floors, or washing walls or windows 1 ☐ Yes 2 ☐ No (8f)	____ AGE	____ AGE 00☐ currently doing	____ YEARS	____ MONTHS PER YEAR	____:____ HOURS MIN PER WEEK
f. Doing other cleaning, such as dusting, laundry, vacuuming, or changing linens 1 ☐ Yes 2 ☐ No (8g)	____ AGE	____ AGE 00☐ currently doing	____ YEARS	____ MONTHS PER YEAR	____:____ HOURS MIN PER WEEK
g. Gardening or doing yard work, such as mowing the lawn or raking leaves. 1 ☐ Yes 2 ☐ No (8h)	____ AGE	____ AGE 00☐ currently doing	____ YEARS	____ MONTHS PER YEAR	____:____ HOURS MIN PER WEEK
h. Doing heavy outdoor work, such as chopping wood, tilling soil, shoveling snow, or baling hay 1 ☐ Yes 2 ☐ No (go to next section)	____ AGE	____ AGE 00☐ currently doing	____ YEARS	____ MONTHS PER YEAR	____:____ HOURS MIN PER WEEK

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...

Show Card

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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?

Show Card

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

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

__ __ (Number of people)

THIS SHOULD BE A TEAR OUT SHEET OR A SEPARATE SHEET SINCE IT HAS CONFIDENTIAL TRACKING INFORMATION ON IT.

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 ☐ mother
2 ☐ father
3 ☐ son
4 ☐ daughter
5 ☐ brother
6 ☐ sister
7 ☐ step daughter
8 ☐ step son
9 ☐ daughter-in-law
10 ☐ son-in-law
11 ☐ friend
12 ☐ spouse
13 ☐ other (specify) _____ |_|_|_|

2. What is your social security number?

___ ___ ___ - ___ ___ - ___ ___ ___ ___

9 ☐ DK / Refused

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☐ Other [specify] |_|_|_|

BEHAVIOR CHANGE SECTION

In this next section we would like to know about how your behavior might have changed since (Month / year).

BC1. Since (Month / year), have you increased, decreased or not changed your intake of the following dietary items? If you never ate these foods, check the "~~do not eat~~ never ate" box	Never ate	Increased	Decreased	No Change	Not Sure
a. Amount of food eaten	☐	☐	☐	☐	☐
b. Fats	☐	☐	☐	☐	☐
c. Fruits	☐	☐	☐	☐	☐
d. Vegetables	☐	☐	☐	☐	☐
e. Cruciferous vegetables (broccoli, cabbage, kale, brussels sprouts)	☐	☐	☐	☐	☐
f. Total calories	☐	☐	☐	☐	☐
g. Salt	☐	☐	☐	☐	☐
h. Number of fast foods	☐	☐	☐	☐	☐
i. Olive oil	☐	☐	☐	☐	☐
j. Canola oil	☐	☐	☐	☐	☐
k. Butter, margarine, or shortening	☐	☐	☐	☐	☐
l. Whole grain bread and pasta	☐	☐	☐	☐	☐
m. Soy products	☐	☐	☐	☐	☐
n. Meat	☐	☐	☐	☐	☐
o. Fish	☐	☐	☐	☐	☐
p. Chicken	☐	☐	☐	☐	☐
q. Other (specify)_____	☐	☐	☐	☐	☐

BC2. Since (Month / year), have you increased, decreased or not changed your intake of the following dietary supplements?	Never took	Increased	Decreased	No Change	Not Sure
a. Multivitamins	☐	☐	☐	☐	☐
b. Vitamin A	☐	☐	☐	☐	☐
c. Vitamin C	☐	☐	☐	☐	☐
d. Vitamin D	☐	☐	☐	☐	☐
e. Vitamin E	☐	☐	☐	☐	☐
f. Antioxidant tablets	☐	☐	☐	☐	☐
g. Beta Carotene	☐	☐	☐	☐	☐
h. Melatonin	☐	☐	☐	☐	☐
i. Co-enzyme Q10	☐	☐	☐	☐	☐
j. Alpha-lipoic acid	☐	☐	☐	☐	☐
k. Calcium	☐	☐	☐	☐	☐
l. DHEA	☐	☐	☐	☐	☐
m. Fiber supplements	☐	☐	☐	☐	☐
n. Selenium	☐	☐	☐	☐	☐
o. Other (specify)_____	☐	☐	☐	☐	☐

BC3. Since (Month / year), have you been on any special diets?

1 ☐ Yes **(Go to BC3a)**
2 ☐ No **(Go to BC4)**
9 ☐ Do Not Know/Refused **(Go to BC4)**

BC3a. If YES, which ones? (Check all that apply)

1☐ Low fat diet
2☐ Vegetarian diet
3☐ Macrobiotic diet
4☐ Asian diet
5☐ Mediterranean
6☐ OTHER (SPECIFY) _____

BC4. Since (Month / year), have you ever taken any herbal or alternative medicine remedies?

1 ☐ Yes **(Go to BC4a)**
2 ☐ No **(Go to BC5)**
9 ☐ Do Not Know/Refused **(Go to BC5)**

BC4a. If YES, which ones? (Check all that apply)

01☐Alfalfa
02☐Bee Pollen
03☐Black Cohosh
04☐Blue Cohosh
05☐Cats Claw
06☐Chaste berries
07☐Dong Quai
08☐Echinacea
09☐Evening primrose
10☐False unicorn
11☐Flax seed oil
12☐Fo ti teng
13☐Garlic
14☐Ginkgo biloba
15☐Ginseng
16☐Green tea
17☐Gotukola
18☐Licorice root
19☐Motherwort
20☐Nux Vomic
21☐Pulsatilla
22☐Red clover
23☐Red raspberry
24☐Royal jelly
25☐ Sage tea
26☐Sasaparilla
27☐Saw palmetto
28☐Sephia
29☐Shark cartilage
30☐Soy supplements
31☐Genistein
32☐St. John's Wort
33☐Valerian root
34☐Wild Yam/Mexican Yam
35☐Essiac tea
36☐Glucosamine
37☐Others: _____

BC5. Since (Month / year) have you sought out any other type of complimentary care, such as mental or physical therapies?

1 ☐ Yes **(Go to 5a)**
2 ☐ No **(Go to Bc6)**
9 ☐ Do Not Know/Refused **(Go to BC6)**

BC5a. If YES, which ones? (Check all that apply)

01 ☐ Massage therapy
02 ☐ Chiropractic care
03 ☐ Hydrotherapy
04 ☐ Herbal therapy
05 ☐ Naturopathy
06 ☐ Chinese medicine
07 ☐ Shiatsu
08 ☐ Ayurveda
09 ☐ Homeopathy
10 ☐ Acupressure
11 ☐ Acupuncture
12 ☐ Prayer
13 ☐ New age
14 ☐ Faith Healing
15 ☐ Psychotherapy/counseling
16 ☐ Support Groups
17 ☐ Other (specify):_____

BC6. Since (*Month / year*), has your smoking behavior changed?

1 ☐ Yes
2 ☐ No
3 ☐ No, never smoked
9 ☐ Do Not Know/Refused

BC6a. If Yes, do you:
1 ☐ Smoke more
2 ☐ Smoke less
3 ☐ Quit smoking altogether

BC7. Since (*Month / year*), has your alcohol consumption patterns changed?

1 ☐ Yes
2 ☐ No
3 ☐ No, never drank
9 ☐ Do Not Know/Refused

BC7a. If Yes, do you:
1 ☐ Drink more
2 ☐ Drink less
3 ☐ Quit drinking altogether

BC8. Since (*Month / year*) has your participation in household activities...

1 ☐ Remained the same
2 ☐ Decreased
3 ☐ Increased
9 ☐ Do Not Know/Refused

BC9. Since (*Month / year*) has your participation in exercise, leisure or sport activites...

1 ☐ Remained the same
2 ☐ Decreased
3 ☐ Increased
9 ☐ Do Not Know/Refused

BC10. Since (Month / year) has your participation in occupation or volunteer activities...

1 ☐ Remained the same
2 ☐ Decreased
3 ☐ Increased
9 ☐ Do Not Know/Refused

BC11. At any time since (Month / year), has your weight changed, this would include losing as well as gaining weight?

1 ☐ Yes
2 ☐ No **(Go to question BC17)**
9 ☐ Do Not Know/Refused **(Go to question BC17)**

BC12. At any time since (Month / year), did you gain weight?

1 ☐ Yes
2 ☐ No **(Go to question BC15)**
9 ☐ Do Not Know/Refused **(Go to question BC15)**

BC13. What is the heaviest you have been since (Month / year)?

WEIGHT: |__|__|__|

1 ☐ Pounds
2 ☐ Kilograms
9 ☐ Do Not Know/Refused

BC14. Have you lost any of the weight that you gained since (Month / year)?

1 ☐ Yes
2 ☐ No
9 ☐ Do Not Know/Refused

BC15. At any time since (Month / year), have you weighed less than you weighed on that date?

1 ☐ Yes
2 ☐ No **(Go to question BC17)**
9 ☐ Do Not Know/Refused **(Go to question BC17)**

BC16. What is the least you have weighed since (Month / year)?

WEIGHT: |__|__|__|

1 ☐ Pounds
2 ☐ Kilograms
9 ☐ DK/Refused

BC17. Since (Month / year), have you started taking any prescription or over the counter medications? (PLEASE DO NOT INCLUDE DRUGS PRESCRIBED AS PART OF YOUR BREAST CANCER TREATMENT).

1 ☐ Yes
2 ☐ No
9 ☐ Do Not Know/Refused

BC17a. If YES, what types? (Check all that apply)

01 ☐ Anti-anxiety, anti-depression medications
02 ☐ Non-steroidal anti-inflammatory drugs
03 ☐ Acetominophen
04 ☐ Other (Specify) : _____

BC18. Since (Month / year), have you taken hormone replacement therapy?

1 ☐ Yes
2 ☐ No
9 ☐ Do Not Know/Refused

EARLY LIFE EXPERIENCES

Your name does not appear with any information that you provide in this study. For statistical purposes it is important to answer each question.

Before my first period,	Never True	Rarely True	Sometimes True	Often True	Very Often True
1. I didn't have enough to eat.	☐	☐	☐	☐	☐
2. I knew that there was someone to take care of me and protect me.	☐	☐	☐	☐	☐
3. People in my family called me things like "stupid", "lazy" or "ugly".	☐	☐	☐	☐	☐
4. My parents were too drunk or high to take care of the family.	☐	☐	☐	☐	☐
5. There was someone in my family who helped me feel that I was important or special.	☐	☐	☐	☐	☐
6. I had to wear dirty clothes.	☐	☐	☐	☐	☐
7. I felt loved.	☐	☐	☐	☐	☐
8. I thought my parents wished I had never been born.	☐	☐	☐	☐	☐
9. I got hit so hard by someone in my family that I had to see a doctor or go to the hospital.	☐	☐	☐	☐	☐
10. There was nothing I wanted to change about my family.	☐	☐	☐	☐	☐
11. People in my family hit me so hard that it left me with bruises or marks.	☐	☐	☐	☐	☐
12. I was punished with a belt, a board, a cord, or some hard object.	☐	☐	☐	☐	☐
13. People in my family looked out for each other.	☐	☐	☐	☐	☐
14. People in my family said hurtful or insulting things to me.	☐	☐	☐	☐	☐
15. I believe that I was physically abused.	☐	☐	☐	☐	☐
16. I had the perfect childhood.	☐	☐	☐	☐	☐
17. I got hit or beaten so badly that it was noticed by someone like a teacher, neighbor or doctor.	☐	☐	☐	☐	☐
18. I felt that someone in my family hated me.	☐	☐	☐	☐	☐
19. People in my family felt close to each other.	☐	☐	☐	☐	☐
20. Someone tried to touch me in a sexual way, or tried to make me touch them.	☐	☐	☐	☐	☐
21. I had the best family in the world.	☐	☐	☐	☐	☐
22. Someone tried to make me do sexual things or watch sexual things.	☐	☐	☐	☐	☐
23. Someone molested me.	☐	☐	☐	☐	☐
24. I believe that I was emotionally abused.	☐	☐	☐	☐	☐
25. There was someone to take me to the doctor if I needed it.	☐	☐	☐	☐	☐
26. I believe that I was sexually abused.	☐	☐	☐	☐	☐
27. My family was a source of strength and support.	☐	☐	☐	☐	☐
28. One of the adults in the household pushed, grabbed, shoved, or slapped me.	☐	☐	☐	☐	☐

EARLY LIFE EXPERIENCES (cont'd)

Before my first period,	Never True	Rarely True	Sometimes True	Often True	Very Often True
29. I lived with someone who was a problem drinker, or alcoholic.	☐	☐	☐	☐	☐
30. My mother/stepmother, hugged me, held my hand, or gave me physical affection.	☐	☐	☐	☐	☐
31. Someone in the household was depressed or mentally ill.	☐	☐	☐	☐	☐
32. My relationship wth my father/stepfather was warm and supportive.	☐	☐	☐	☐	☐
33. My father or stepfather was threatened with or hurt by violent acts, hitting, pushing, slapping.	☐	☐	☐	☐	☐
34. My father/stepfather was delighted when I learned a new skill or accomplished something.	☐	☐	☐	☐	☐
35. My mother or stepmother was threatened with or hurt by violent acts, hitting, pushing, slapping.	☐	☐	☐	☐	☐
36. My father/stepfather, hugged me, held my hand, or gave me physical affection.	☐	☐	☐	☐	☐
37. I lived with someone who used street drugs.	☐	☐	☐	☐	☐
38. My relationship with my mother/stepmother was warm and supportive.	☐	☐	☐	☐	☐
39. There were problems paying the bills or money problems in my household.	☐	☐	☐	☐	☐
40. I attended church or religious institution.	☐	☐	☐	☐	☐
41. I felt depressed.	☐	☐	☐	☐	☐
42. I kept regular hours, going to bed and getting up at the same time from day to day.	☐	☐	☐	☐	☐
43. I had friends that I could talk to about anything.	☐	☐	☐	☐	☐
44. I felt hopeless.	☐	☐	☐	☐	☐
45. My mother/stepmother was delighted when I learned a new skill or accomplished something.	☐	☐	☐	☐	☐

IES

Below is a list of comments made by people about stressful events. **IN THE PAST TWO WEEKS INCLUDING TODAY. PLEASE INDICATE HOW FREQUENTLY THESE COMMENTS WERE TRUE FOR YOU ABOUT BREAST CANCER.** If the item did not occur, please mark the "not at all" column.

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

How I Feel Scale

INSTRUCTIONS: Below is a list of questions about how you feel, and how things have been going for you during the past two weeks. For each question, please circle number for the one answer that comes closest to the way you have been feeling.

During the past two weeks:

HIFS1. How happy, satisfied, or pleased have you been with your personal life?

a. Extremely happy, could not have been more satisfied or pleased
b. Very happy most of the time
c. Generally satisfied, pleased
d. Sometimes fairly satisfied, sometimes fairly unhappy
e. Generally dissatisfied, unhappy
f. Very dissatisfied, unhappy most of the time

HIFS2. How much of the time have you felt lonely?

a. All of the time
b. Most of the time
c. A good bit of the time
d. Some of the time
e. A little of the time
f. None of the time

HIFS 3. How often did you become nervous or jumpy when faced with excitement or unexpected situations?

a. Always
b. Very often
c. Fairly often
d. Sometimes
e. Almost never
f. Never

HIFS 4. How much of the time have you felt that the future looks hopeful and promising?

a. All of the time
b. Most of the time
c. A good bit of the time
d. Some of the time
e. A little of the time
f. None of the time

HIFS 5. How much of the time has your daily life been full of things that were interesting to you?

a. All of the time
b. Most of the time
c. A good bit of the time
d. Some of the time
e. A little of the time
f. None of the time

HIFS 6. How much of the time did you feel relaxed and free of tension?

a. All of the time
b. Most of the time
c. A good bit of the time
d. Some of the time
e. A little of the time
f. None of the time

HIFS 7. How much of the time have you generally enjoyed the things you do?

a. All of the time
b. Most of the time
c. A good bit of the time
d. Some of the time
e. A little of the time
f. None of the time

HIFS 8. Have you had any reason to wonder if you are losing your mind, or losing control over the way you act, talk, think, feel or of your memory?

a. No, not at all
b. Maybe a little
c. Yes, but not enough to be concerned or worried about it
d. Yes, and I have been a bit concerned
e. Yes, and I am quite concerned
f. Yes, and I am very much concerned about it

HIFS 9. Did you feel depressed?

a. Yes, to the point that I did not care about anything for days at a time
b. Yes, very depressed almost every day
c. Yes, quite depressed several times
d. Yes, a little depressed now and then
e. No, never depressed at all

HIFS 10. How much of the time have you felt loved and wanted?

a. All of the time
b. Most of the time
c. A good bit of the time
d. Some of the time
e. A little of the time
f. None of the time

HIFS 11. How much of the time have you been a very nervous person?

a. All of the time
b. Most of the time
c. A good bit of the time
d. Some of the time
e. A little of the time
f. None of the time

HIFS 12. When you got up in the mornings, about how often did you expect to have an interesting day?

a. Always
b. Very often
c. Fairly often
d. Sometimes
e. Almost never

HIFS 13. How much of the time have you felt tense or "high-strung"?

a. All of the time
b. Most of the time
c. A good bit of the time
d. Some of the time
e. A little of the time
f. None of the time

HIFS 14. Have you been in firm control of your behavior, thoughts, emotions, feelings?

a. Yes, very definitely
b. Yes, for the most part
c. Yes, I guess so
d. No, not too well
e. No, and I am somewhat disturbed
f. No, and I am very disturbed

HIFS 15. How often did your hands shake when you tried to do something?

a. All of the time
b. Most of the time
c. A good bit of the time
d. Some of the time
e. A little of the time
f. None of the time

HIFS 16. How often did you feel that you had nothing to look forward to?

a. All of the time
b. Most of the time
c. A good bit of the time
d. Some of the time
e. A little of the time
f. None of the time

HIFS 17. How much of the time have you felt calm and peaceful?

a. All of the time
b. Most of the time
c. A good bit of the time
d. Some of the time
e. A little of the time
f. None of the time

HIFS 18. How much of the time have you felt emotionally stable?

a. All of the time
b. Most of the time
c. A good bit of the time
d. Some of the time
e. A little of the time
f. None of the time

PROJECT 2

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

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, our Aim during the fist six months of the grant was to train personnel, develop the culturally tailored intervention, and to prepare the questionnaires. This goal has been accomplished. First, a genetic counselor, Erica Wahl, has been hired and trained to counsel women considering BRCA testing. Second, the culturally tailored intervention has been developed and pilot tested (see Appendix 1). In addition, we modified and simplified our take home counseling manual (see Appendix 2). Third, the questionnaires designed to assess our study hypothesis has been developed for both the baseline and the follow-up assessment (see Appendix 3). Our Goal was to start recruiting participants into the study in month seven of the grant. 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 12 months.

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 the baseline and the follow-up questionnaires have been prepared. As we have not received IRB 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

September 26, 2002

Culturally-Tailored Genetic Counseling for TACT

for families at increased risk for BRCA1/2 associated hereditary breast and ovarian cancer

*Given the nature of the TACT research project and our recruitment methods, all TACT participants will be women of African ancestry, age 18 or older, who have been diagnosed with breast cancer.

- Pre-counseling information gathering
  - Gather brief family history of cancer prior to genetic counseling session. All information will be reviewed in the session.
  - Inform patient they may bring someone to session with them if they are interested (family member, friend, etc.)
- Genetic counseling session
  - Contracting
    - Introductions are made. Genetic counselor explains to patient what will be discussed in the session and ascertains patient's agenda.
    - Review research study and consent form
      - "Today's visit will involve a discussion of your medical and family histories and the genetics of inherited cancer. We will also be discussing the possibility of genetic testing. The decision whether or not to have genetic testing is a personal one; this testing is not right for everyone. Hopefully the information that you will learn in our discussion today will help you to make this decision. But before we talk about these things, we need to review the consent form that was sent to you in the mail. Signing this consent form means that you agree to participate in the TACT program. It does not require you to have genetic testing."
      - Explain goals of TACT
        - "TACT is part of the Tri-State Women's Circle of Health research project. The goal of the TACT program is to provide African American women with both standard genetic counseling and culturally tailored genetic counseling that is designed specifically for women of African ancestry, and then explore which counseling helped women to better understand the information presented."

        > "A lot of African Americans have concerns about research...what are your concerns?"
        > Prompt participant about concerns regarding *genetic* research (if this does not come up in their response)

      - Explain benefits, risks, and alternatives of participation
      - Explain protections offered by TACT (confidentiality – NIH certificate, IRB protections, etc.)
    - Obtain written informed consent

- Review personal medical history
  - Patients are asked about their personal history of cancer in addition to general questions about their health and medical care.
  - For all patients, ascertain:
    - Age at menarche
    - Menopause status (pre/peri/post, age at menopause)
    - Number of pregnancies
    - Number of children
    - Age at first live birth
    - Use of oral contraceptives
    - Other hormone use
    - Cancer history:
      - Type of cancer
      - Age at diagnosis
      - How the cancer was detected
      - Size of cancer
      - Stage at diagnosis
      - Treatment history (including alternative treatments, how treatment decisions were made, etc.)
    - Total number of breast biopsies
    - Surgical history
    - Hospitalizations
    - Chronic illnesses
    - Use of medications
    - Smoking/alcohol use
    - Allergies
    - Environmental/occupational exposures
      - "What factors do you think may have played a role in your development of cancer?"
        "What factors do you think play the largest role in your chances of developing breast cancer again?"
    - Assess patient's current cancer screening practices with regard to breast, ovarian, and colon cancers
  - During discussion of cancer history, assess how patient coped with cancer diagnosis (this information will be helpful for discussion later in the session re: decisions about genetic testing, decisions about cancer screening/prevention, etc.)
    - "How are you doing now?"

      - "How helpful were your health care providers in administering your care and providing you with advice since your diagnosis of breast cancer?"
        "Did your health care providers help you cope with your diagnosis?"
        "Certain factors can affect a person's relationship with their healthcare providers. I'd like to ask you about a few of these. How important is it to you to work with someone the same sex as you? How important is it to you to work with someone the same race as you? How important is it to you to work with someone the same age as you? Are there any other factors that I haven't mentioned that are important to you?"

"Do you consider yourself to be a spiritual person?"
If yes..."Did your faith help you to cope with your diagnosis?"
If yes or no... "Do you see this affecting your thoughts/decision about genetic testing?"

- Review family history
  - A three-generation pedigree is constructed – includes information about patient's first-, second- and third- degree relatives as well as all first-degree relatives of all affected individuals. Patient is asked about each relative's age, medical history (with a focus on cancer), and if relative is deceased, cause of/age at death. Careful attention should be paid to all cancer diagnoses, pre-cancerous conditions and findings associated with cancer syndromes. Ethnic background/ancestry is recorded.
    - Information to collect for cancer diagnoses (if possible):
      - Sites of primary cancers
      - Specific diagnosis
      - Age at/year of diagnosis
      - Treatments (including surgical history)

Were any alternative treatments used?
(Counselor should remain neutral about alternative treatments, i.e. should not endorse/support alternative treatments)

      - If individual is deceased, age at/year of death
      - Name of institution(s) where individual received medical care
        - This will be helpful in the event that it is decided to obtain documentation of cancer diagnosis (i.e. pathology report)

- At this time, explore patient's relationships with family members (this information will be helpful for discussion later in the session re: sharing genetic counseling and testing information with family members, decisions about cancer screening/preventive options, etc.)
  - "Did your family history of cancer make you worry about your chances to develop cancer?"
    "Were you aware that having a family history of cancer put you at an increased risk to develop cancer yourself?"
  - "What was your family's response to your diagnosis?"
    "How did your friends respond to hearing about your diagnosis?"
    "Did members of your family and your friends help you to cope with the diagnosis? Were they available as a source of support?"
    "Was your faith community available as a source of support?"
    "Were any of your family members or friends involved in your care?"
    "Did they help you to make decisions regarding treatment/surgery?"
  - Inquire about other family members diagnosed with cancer:
    - "Were you involved in <u>So-and-so's</u> care?"

- Perform risk assessment
  - Assess likelihood that cancer is hereditary and due to a BRCA1/2 mutation
    - "Now we are going to talk about how cancer can sometimes be inherited in families. How familiar are you with genetics? Before hearing about this research study, how much did you know about the BRCA1 and BRCA2 genes?"
    - Certain findings within a family increase the likelihood of a hereditary breast/ovarian cancer syndrome: (Visual aid – Pedigree with cartoon photos)
      - Multiple family members with same or related cancers
      - Cancer found in multiple generations
      - Earlier than average ages of onset
      - More than one primary cancer in the same individual
      - Rare cancers (i.e. breast cancer in males)
  - (The following information is not necessary to include in all sessions – include if patient inquires about specific risk to inherit BRCA mutation or if pertinent):
    Information gathered from medical and family histories can be entered into models or compared against empiric data to come up with an estimate of the likelihood that cancer is inherited and to assess the risk of cancer in an unaffected individual

    "These models are based on studies of mostly white women, and the estimates that they come up with may not be appropriate for AA women."

- Review incidence of breast and ovarian cancer
  - Breast cancer is common; the lifetime risk for women in the general population to develop breast cancer is about 12% (1 in 8)

    - Provide information about breast cancer specific to AA women
      - Visual aid – bar graph showing the differences between different groups of women (AA, whites, Hispanics, Asians) and the frequency of breast cancer diagnoses
      - Breast cancer is diagnosed at younger ages in AA women than white women

  - Lifetime risk for women in the general population to develop ovarian cancer is about 1-2%
  - Approximately 5-10% of all cases of breast and ovarian cancer are inherited (Visual aid – 1 in 10 women)
    - Explain that this statistic is based on studies of mostly white women
- Review breast and ovarian cancer genetics
  - Review chromosomes and genes (Visual aid - chromosomes)

- BRCA1/BRCA2
  - Function as tumor suppressor genes
  - Inherited BRCA1/2 mutations account for many cases of hereditary breast and ovarian cancer
    - Review incidence of cancer in individuals with BRCA1/2 mutations
    - Review risk of a second cancer for affected individuals with BRCA1/2 mutations
  - Review autosomal dominant inheritance (Visual aid – Daryl and Linda)
    - Explore patient's thoughts about the possibility of passing on a mutation to her children

> "If the cancer in your family is, in fact, hereditary, how much would you worry about passing on a mutation to your children?"
> "How much would you worry about your daughters or other relatives who might have a mutation?"
> "Some people feel personally responsible or a sense of guilt about the possibility of passing along a mutation to their children. How true do you feel this would be for you?"

➢ Review options for cancer surveillance and prevention for individuals with or at risk for BRCA1/2 mutation
- Make a clear distinction between detection and prevention
- "If you choose to undergo genetic testing at this time, here are some options that you can consider based on the results of your testing."
- Screening for breast, ovarian, colon and prostate cancers
  - Emphasize efficacy of breast and colon cancer screening (good prognosis if detected early)
  - Explore patient's past screening practices
- Preventive surgical options – "prophylactic" surgery
  - Bilateral mastectomy
  - Oophorectomy
  - Present pros and cons of both surgical options
- Chemoprevention (i.e. Tamoxifen)
- Healthy living (i.e. exercise, diet, etc.)
- Review the limited efficacy of each option presented

> Emphasize the importance this information has for patient and/or family members NOW – i.e. current screening methods may need to be altered, some family members may need to start a program of cancer surveillance; best to implement changes now to maximizes chances for early detection

- Explore why patient is interested in genetic testing at this time.
  - "How important is genetic testing to you at this time?"
    "Why are you interested in genetic testing at this point?"
    "How do you think having genetic testing may help you and family now?"
    "How do you think it may affect you and your family in the future?"

- "What would you do differently if you knew you had a mutation?" …

> "How much will the test results affect your medical decisions now? How much do you think they will affect your medical decisions in the future?"

- "After what we've discussed today, how much do you think genetic testing would help reduce your chances of getting breast cancer again?"
- "While this information can be relevant immediately, there are certainly other factors related to your cancer diagnosis that you are dealing with right now. It may be important to keep these other factors in mind when you are deciding whether to have testing. You can always wait and have the testing at a later time."

▪ Explore patient's feelings towards surveillance/preventive options – which option(s) does patient feel comfortable with?

> Will patient discuss options with family members/friends? Will they be involved in decision-making? Will patient turn to spiritual faith to help her with decision? Etc.

Counselor can draw upon information that already been gathered.

➢ Review genetic testing for BRCA1/2
  ▪ Emphasize that testing is an OPTION – it is not a requirement of the study. Ensure that patient is aware of the option to return for a second visit for testing if she wishes to discuss option of genetic testing with family/friends or if she needs additional time to think it over
  ▪ Ideally, the first individual in a family to receive testing should be affected and the one most likely to carry a BRCA1/2 mutation (i.e. early age at onset, 2 primary cancers, etc.)
  ▪ Blood test requiring 1-2 teaspoons of blood
    - Review risk of blood draw – bruising, bleeding, infection
  ▪ Describe testing options
    - Full sequencing
    - Single-site analysis
    - Will utilize 2 separate consent forms – one for patients undergoing full sequencing, one for patients undergoing single-site analysis
    - Review risk of laboratory error
  ▪ Describe possible testing outcomes:
    - Positive – presence of mutation known to cause cancer
      ♦ Explore patient's possible reactions if she tests positive
        ➢ "How well do you think you will be able to handle your feelings related to testing? How will you cope with these issues?"

"Having a mutation makes some people feel less healthy than others. How true would this be for you?"
"Do you think having a mutation would affect how others view you? If so, why? How do you think they would view you?"
"Some people feel singled out or ashamed when they learn they have a mutation. How true would this be for you?"

- ♦ Review psychosocial risks associated with positive results (i.e. burden of positive result – worry, guilt, fear, depression; family issues, etc.)
- ♦ Review psychosocial benefits associated with positive results (i.e. relief from uncertainly surrounding results, knowing results enables some women to feel more "in control", more confident about medical decisions, etc.)

- Negative – mutation is absent
  - ♦ Review psychosocial risks associated with negative results (i.e. "survivor guilt", regret about earlier decisions, family issues, false sense of reassurance, etc.)
  - ♦ Review psychosocial benefits associated with negative results (i.e. relief, knowing results enables some women to feel more "in control", more confident about medical decisions, etc.)
- Review other benefits of both positive and negative results (i.e. opportunity to make informed decisions about medical care, test results are useful information for family members, etc.)
- Inconclusive results – variant of unknown significance

Explain that this result has been seen more frequently in AA women (Visual aid - train)

- Explore how patient feels she would handle the results emotionally

- Describe limitations of testing
  - A negative result is only fully informative if a familial mutation is known.
  - A variant of unknown significance indicates that a mutation is found within BRCA1/2, but it is unknown if this particular mutation affects cancer risk.
  - A "true negative" test result (familial mutation is known) does not guarantee that an individual will not develop breast or ovarian cancer due to the remaining general population risk.
  - BRCA1/2 mutations demonstrate incomplete penetrance and variable expressivity. Therefore, one cannot predict when or if an individual with a mutation will develop cancer, or what type of cancer this may be.
- Explore how testing would affect patient psychologically
  - Sense of control, sense of relief

"Undergoing testing can be very emotional. People may feel angry, scared or depressed. How do you think that genetic testing might affect you emotionally?"

"How much useful information do you think genetic testing will provide your family members?"
"Are other family members considering testing?"
"How do you think genetic testing will affect your family?"

"How comfortable would you be discussing/relaying this information to your family members?"
"Do you think the results of genetic testing may affect your family financially?"
"What are other concerns about how genetic testing might affect your family?"

- Discuss risks of testing:
  - Concerns about discrimination (health/life insurance coverage, employment opportunities) and confidentiality
    - Explore patient's feelings regarding discrimination, stigma, confidentiality concerns regarding genetic counseling/testing – for all of these areas, distinguish personal vs. family vs. community concerns
      - "How concerned are you that your test results would not stay confidential?"

"How concerned are you that the testing results could be used to treat you unfairly?...to treat your family unfairly?...to treat AA as a group unfairly?" Relate to issues of health insurance, employment, etc.

    - Explore any financial concerns the patient may have in regards to testing (i.e. ability to get insurance, etc.)
- Assess patient's attitudes towards testing at this point. "What are you thinking about testing now?, What do you consider to be the pros of testing for you?, What do you consider to be the cons of testing for you?, Do you think that testing makes sense for you?"
- Assess patient's interest in testing

"How confident do you feel in genetic testing and the results of testing?"

    - If patient is interested, written informed consent is obtained prior to drawing a blood sample.
    - Test results are delivered in person approximately four weeks later.
    - If unsure, patients are encouraged to think testing over/discuss with family/friends before making a decision.
    - If patient uninterested, plan appropriate surveillance and/or prevention based on family and medical history.

- Assessment of patient's understanding and emotions
  - Throughout the session, the counselor should assess the patient's understanding of the material being presented to insure that the patient has a

clear understanding. Additionally, the counselor should be assessing and inquiring about the patient's emotional state.

- Conclusion
  - Elicit and address any additional questions or concerns.
  - Provide patient with contact information.
  - Make referrals as necessary.
  - Agree on plan for follow-up.

September 26, 2002

Addendum to TACT counselor manual – potential TACT participant responses to counselor inquiries/research protocol, and possible counselor responses:

Counselor question/topic #1:
A lot of African Americans have concerns about research…what are your concerns?
Potential participant responses *(to this question about research in general, and more specifically regarding the TACT research project and its procedures):*

- Researchers are not honest; researchers do things to participants that the participants do not give them permission to do
  - ***Counselor response:***
    - Understandable to have these concerns, as these types of situations did occur in the past
    - Important to know that in response to these circumstances that arose in the past, laws have been passed to protect research participants
      - ✓ IRB
      - ✓ Consent form
        - Point out phone #s (IRB, HV)
        - Point out "voluntary participation" – participant can withdraw at any time
- "I don't know which group I'm in." (Standard vs. culturally-tailored genetic counseling)
  - ***Counselor response:***
    - Participants are not informed of their group
    - All of the important information that is needed is the same in both groups, it is how the information is delivered that is different
    - Once participant has completed the TACT study, the researchers can disclose this information
- Researches are "trying out" a new delivery method in the culturally-tailored session, participant feels like a "guinea pig"
  - ***Counselor response:***
    - The goal is that the delivery method will make for an improved experience
    - The design of the delivery method is based on published studies and other information present in the literature
    - Ultimately, it is the participant who will be deciding whether or not the new delivery method is helpful

Introduction to counselor question/topic #2:
"Certain factors can affect a person's relationship with their health care providers. I'd like to ask you about a few of these."

Question 2a: "How important is it to you to work with someone the same sex as you? "

Potential participant responses:

- "I prefer to work with a woman health care provider."

- ***Counselor response:***
  - "What is it about women health care providers that you prefer?"
  - After response to above question… "I can understand your feelings and why you would be more comfortable with a woman health care provider, in fact, may women feel the same way you do."
- "I prefer to work with male health care providers."
  - ***Counselor response:***
    - "What is it about male health care providers that you prefer?"
    - After participant response to above question… "I can understand your feelings, and although I know that it can't be the same experience that you're used to, that [what participant has just described] is what I would like to do for you today."

Question 2b: "How important is it to you to work with someone the same race as you?"

Potential participant responses:

- "I prefer to work with African American health care providers."
  - ***Counselor response:***
    - "What is it about African American health care providers that you prefer?"
    - After participant response to above question… "I can certainly understand why you would feel that way. And while we do come from different backgrounds, I want you to know that I am here today to help you in any way that I can, and if at any time you feel that I am not correctly understanding your thoughts or experiences, please let me know."
- "I prefer to work with African American health care providers because other health care providers are racist."
  - ***Counselor response:***
    - "It is unfortunate that this continues to be the case in some situations, I can certainly understand why this is a concern for you. I want you to know that I am here today to work with you in a fair way, and if at any point you feel that I am not respecting you, please let me know."

Question 2c: "How important is it to you to work with someone the same age as you?"

Potential participant responses:

- "I prefer to work with someone who is older/closer to my age/has more experience."
  - ***Counselor response:***
    - "I can understand your concern, but I feel that it's important for you to know all genetic counselors have gone through the same extensive training, and that I have worked with people of all ages. Also, if you have any questions or concerns that I can't answer, I will find out the information for you."

Question 2d: "Are there any other factors that I haven't mentioned that are important to you?"

Potential participant responses:

- "I prefer to work with someone who has been through the same experience [i.e. breast cancer] as I have."
  - ***Counselor response:***
    - "I understand how it may be easier for you to speak about this with someone who has been through your experience; however, I feel that it is important for you to know that I have worked with a number of women with breast cancer in the past who have provided me with a lot of insight. But I want to be sure that I truly understand your experience, so please let me know at any time if there is a way that I could better understand your situation."

Counselor question/topic #3:

Discussion of family issues and risk to children.

Potential participant responses:

- "Do you have any children?"
  - ***Counselor response:***
    - "No, actually, I don't have any children, but I'm wondering why that is important to you?"

Counselor question/topic #4:

Discussion of family/friends availability as source of support

Potential participant responses:

- "My family and friends were not available to me as a source of support/did not help me to cope with my diagnosis."
  - ***Counselor response:***
    - Acknowledge that this must have been difficult for the participant
    - Inquire what the participant did to cope with the diagnosis on her own
    - Compliment participant on her strength and her ability to come up with a coping strategy

Counselor question/topic #5:

Discussion of breast cancer information specific to AA women – bar graph illustrating differences in frequency of breast cancer diagnoses among different groups (AA, white, Hispanic, and Asian women), breast cancer diagnosed at younger ages in AA women than white women.

Potential participant responses:

- Although the above discussion does not touch upon AA women more likely to be diagnosed at later stages, having a higher mortality rate, the participant may be aware of this information and bring it up during the session.
  - ***Counselor response:***

- Confirm that it is true that AA women are more likely to be diagnosed at a later stage and that the mortality rate it higher
- Explain that these statistics are based on the group as a whole (all AA women diagnosed with breast cancer)
- Emphasize that the survival rate for a woman diagnosed with breast cancer is based on many individual factors that are specific to her diagnosis
- If participant inquires specifically about what her survival rate is, explain that this is information best discussed with her oncologist

Counselor question/topic #6:
Having a mutation makes some people feel less healthy/singled out or ashamed/that people will view them differently…how true would this be for you?
Potential participant responses:

- "I already feel less healthy because of my cancer diagnosis."
  - ***Counselor response:***
    - Do you feel that learning you have a mutation would make a difference in how healthy you feel?
- "Yes, I would feel less healthy/singled out/ashamed/etc. if I found out I had a mutation." (or "No, I would not…")
  - ***Counselor response:***
    - This is important to know/for you to think about because this information can help you make your decision whether or not to be tested.

Counselor question/topic #7:
How concerned are you that the testing results could be used to treat you unfairly?…to treat your family unfairly?…to treat AA as a group unfairly?
Counselor will relate to issues of health insurance, employment, etc.
Potential participant responses:

- "It seems like for some of the possible testing results the medical community really doesn't understand what the results mean, and I worry about this because this result is more common in the African American community."
  - ***Counselor response:***
    - Acknowledge that the medical community does not have as much insight regarding results interpretation for the African American community
    - Explain that one goal of this research is to help improve this understanding

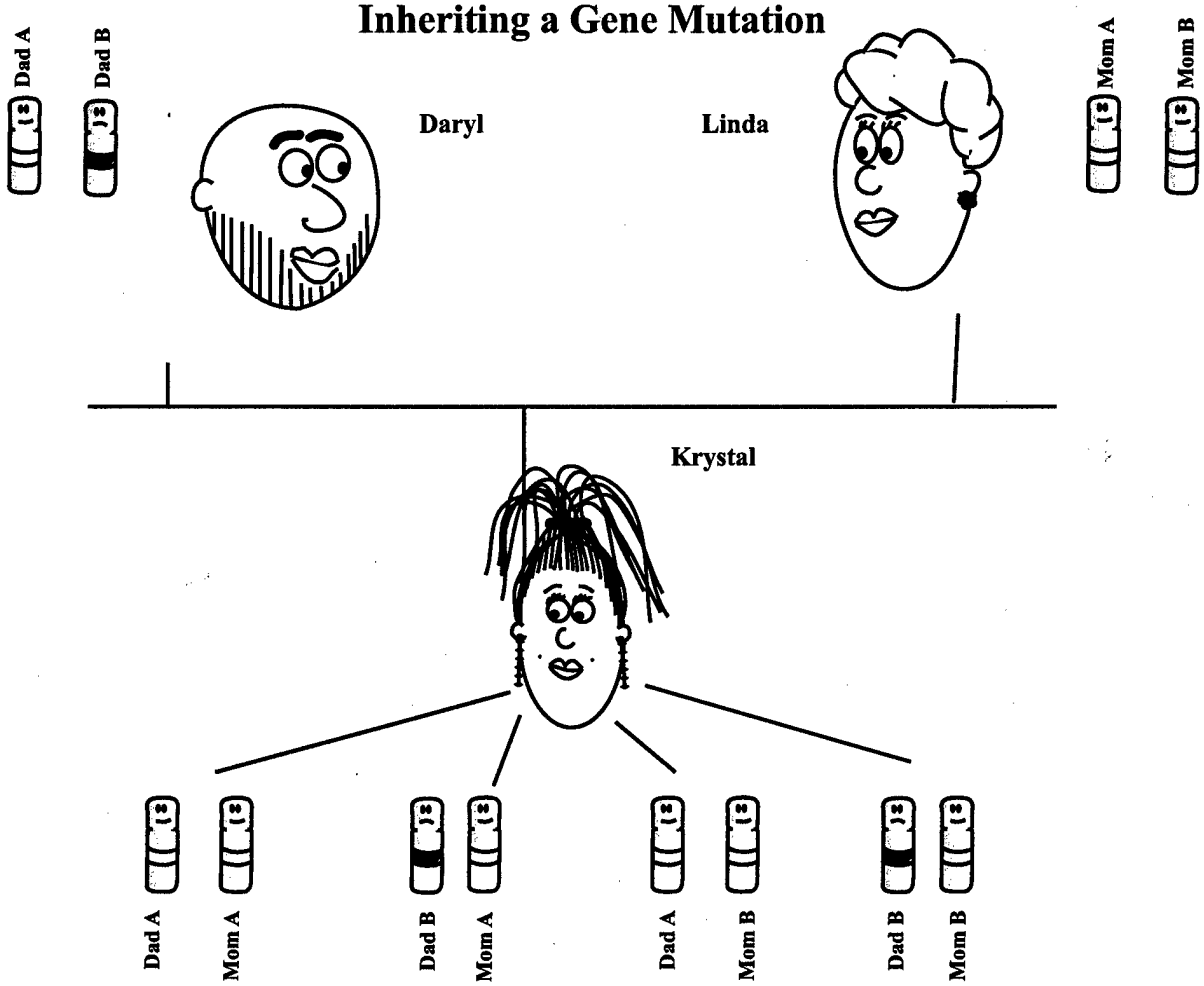
Counselor question/topic #8:
How confident do you feel in genetic testing and the results of testing?
Potential participant responses:

- "It's difficult for me to feel confident because it sounds like even if I get tested, depending on what the results are I still may not know if the cancer in my family is inherited."

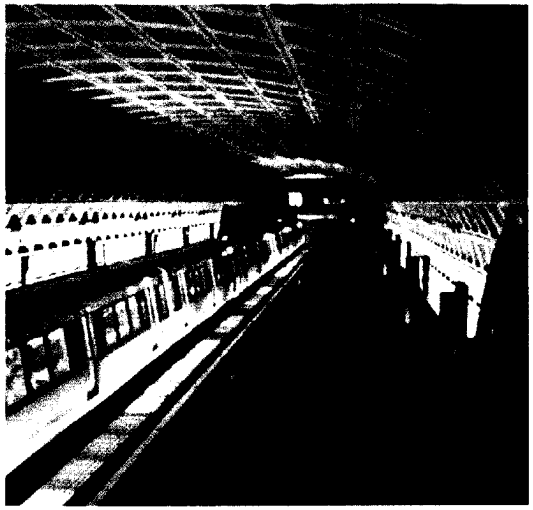
"It's difficult for me to feel confident because it seems as though the information is always changing."

- ***Counselor response:***
  - Acknowledge that this could certainly be the case, but express that new information is coming out at a rapid rate, and for those people whose test results are variants/inconclusive, etc. this new information may help us to better understand the meaning of these results. Encourage the participant to check in with the genetic counselor every once in a while to check up on new advances made in the field.

Inheriting a Gene Mutation



Daryl and Linda will pass down one gene of each pair to every child they have. So, each child has a 50/50 (1 in 2) chance of having the gene mutation passed down to them.
Look at the possible combinations of genes Krystal could get from her parents. Every child Daryl and Linda had, boy or girl, will have one of these possible combinations.



T

Express to Central St

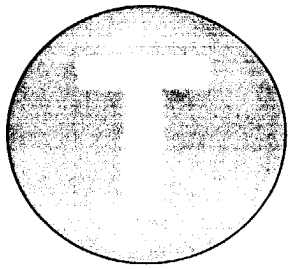
Let's say you have an appointment on Main Street, and you have to arrive on time. To get there you take the T train, which goes express. If the train runs normally, you know you will arrive on time.

But imagine

3 different changes that could happen to the train.

Each change makes you whether you will arrive on time

Let's compare the **3** train situtations to genetic test results.



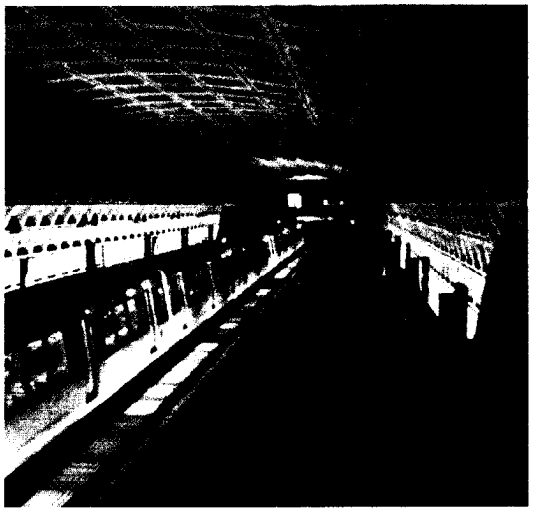
The conductor announces,
"This train is delayed. Please be patient".

What does that mean? Are you only going to be delayed a few minutes? Or is the train going to be stuck for half an hour? Here, you just don't know if you are going to make it on time.

In genetic testing, this situation would get the label

because the train delay is:

Situation #1



Express to Central St.

The conductor announces, "The T train will be running local to Main St".

Here, it may take you a little longer, but you will probably make it to your appointment on time.

In genetic testing, this situation would get the label

because the train delay is:

Situation #2

Express to Central St.

The conductor announces, "The T train will be skipping the Main St. stop. Passengers must ride to Central St. and go backwards."

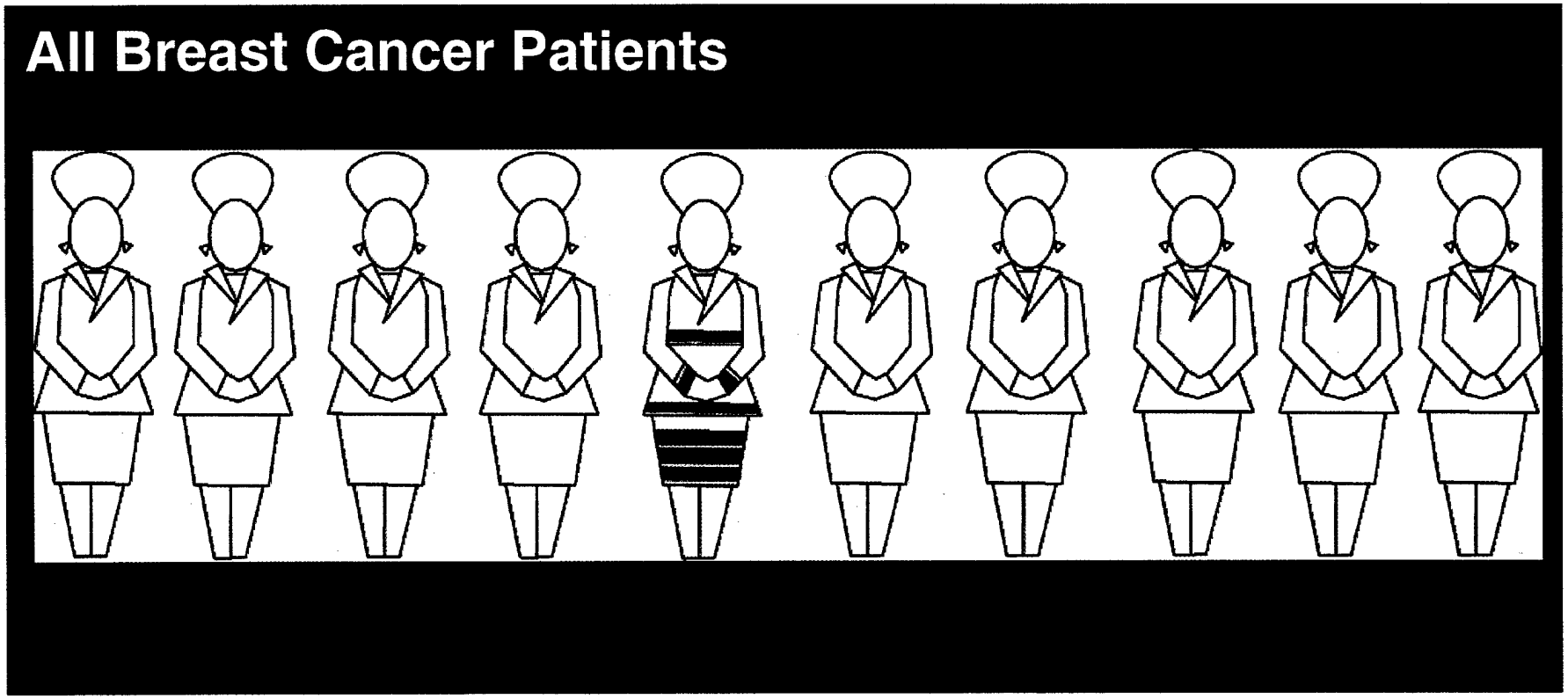
Here, the conductor has said the train won't be going to Main St. at all! You feel pretty sure you are going to be late for your appointment now.

In genetic testing, this situation would get the label

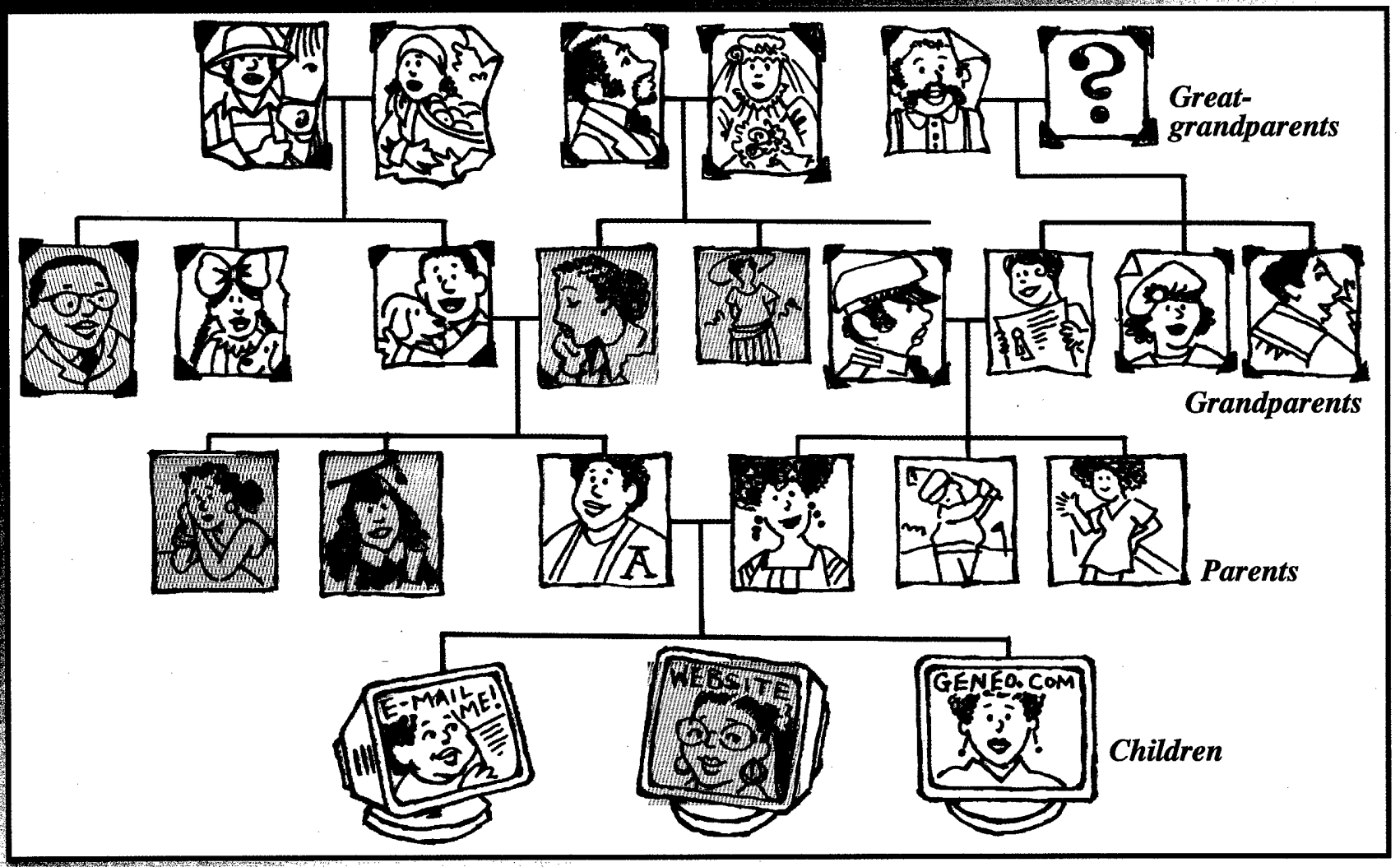
because the train delay is:

Situation #3

Most Cancer is Not Inherited



PATERNAL MATERNAL



Prostate Cancer

Ovarian Cancer

Breast Cancer before 50

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Talking About Counseling and Testing

April 2002
Ruttenberg Cancer Center
Department of Human Genetics

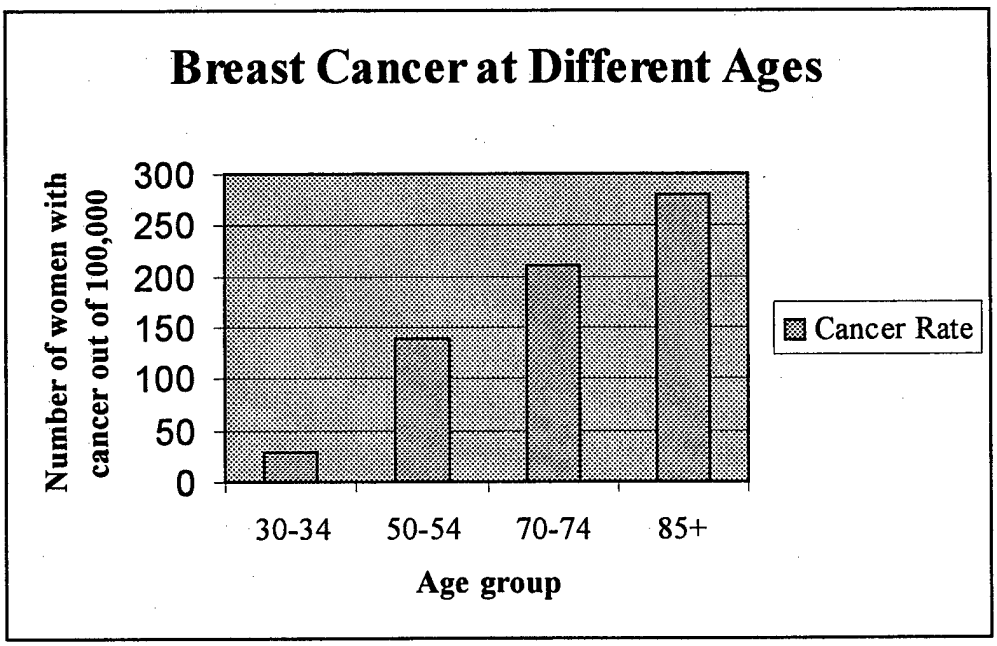
Major Risk Factors for Breast and Ovarian Cancer

All women have a chance of developing breast **cancer** or ovarian cancer at some point in their life. Breast cancer is a common disease. Did you know that in the United States, over 190,000 women are diagnosed with the disease every year? Ovarian cancer is a much rarer disease. Only about 25,000 women develop the disease in a year.

But what causes these diseases? It is not one single thing. Breast or ovarian cancer results from a combination of things, such as **genetic** and **environmental factors**. Genetics deals with what is passed down from one generation to another in families, like brown eyes. Environmental factors means anything else that happens to a person that is not passed down in the family. Let's talk about environmental factors next.

- **AGE**

  Age is a very important factor in whether a woman gets breast or ovarian cancer. The older a woman is, the higher the chances that she could develop cancer.



Look at this chart that shows how often women of different ages get breast cancer. The chart shows that if you walked down the street, and asked 100,000 women aged 30-34 to step into one big room, less than 50 of them would have breast cancer. But if you asked women who were 85 or older, almost 300 of them would have breast cancer. As you can see, the number of women with breast cancer increases as age increases.

BUT, because of genetics, some women are more likely to develop cancer at younger ages, such as in their 30s and 40s. We will talk more about this later.

- **FAMILY HISTORY OF CANCER**

A family history of cancer is another factor that affects whether women develop breast or ovarian cancer.

- Women with one or more close relatives (like a mother or sister) who have breast cancer have a greater chance of developing breast cancer themselves. In fact, the chance can be even greater if the relative's cancer was diagnosed at a young age, or if the cancer was in both breasts.

- **PERSONAL HISTORY OF CANCER**

If you have breast cancer once, you have a higher chance of developing it again. So, if a woman has a **mastectomy** (removing ~~a br~~east) to treat her cancer, then she could develop cancer in the other breast. She could even develop it in the same breast again, if she had the lump removed. Also, women who have had breast cancer before have a slightly higher chance of developing ovarian cancer than other women.

Other risk factors for breast cancer and ovarian cancer

We just talked about some of the main factors that affect whether a woman develops breast or ovarian cancer. There are a few more to mention here. It is important to know that these factors are for women in the general population. Scientists do not yet know how the factors below affect women who have a mutation passed down to them.

Reproductive Factors

- The hormones related to menstruation and pregnancy play a role in breast cancer.
- Having periods before the age of 12, or having menopause after age 55 increase your chances.
- Never having children or having your first child after age 30 increases your chances of breast cancer.
- Never having children increases the chances of ovarian cancer.

Birth Control Pills (Oral Contraceptives)

- The use of birth control pills has not been found to be related to a higher risk of breast cancer for most women.
- But, women under age 25 who use the pill for long periods of time may have a slightly higher chance of developing breast cancer at a young age.
- Use of birth control pills reduces the chance of ovarian cancer.

Hormone replacement therapy

- Long-term use of **hormone replacement** (like estrogen) increases your chances of breast cancer.
- And, your chances might be even higher if it is estrogen plus progesterone.
- But, hormone replacement can give you some health benefits, like relief of menopause symptoms, and protection from **osteoporosis** (a bone disease).

Other factors

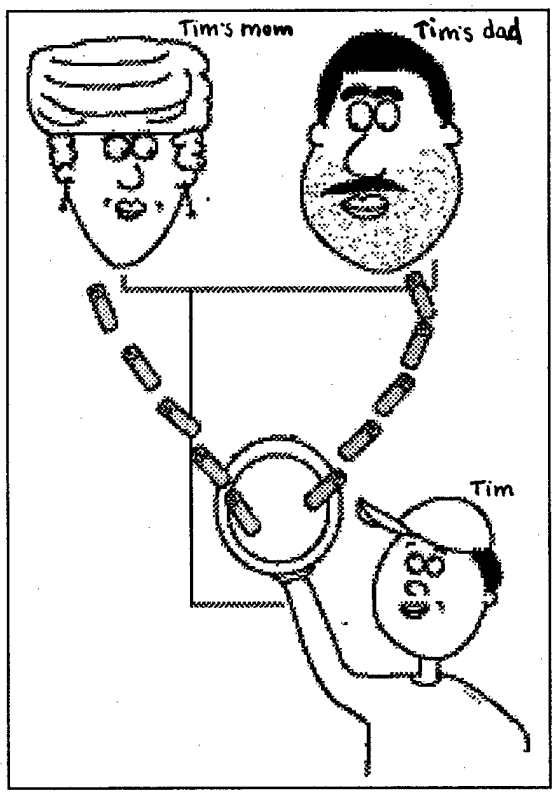
- Right now, scientists are not sure whether fat in your diet plays a role in breast cancer. They do know cutting down the fat in your diet will lower your chances of other diseases and other types of cancer.
- Drinking alcohol is related to slightly higher chances of breast cancer. And, the amount you drink over a period of years is also important.
- Some results from breast **biopsies** may mean that a woman has a greater chance of developing breast cancer. A breast biopsy is when tissue is removed from the breast and examined for changes.

Genetics

In order to understand why some people have a higher chance of developing cancer, it is helpful to know some basics about **genetics**.

First, let's look at **chromosomes**. As you probably know, the human body is made up of cells. Each cell has a **nucleus**, which is the control center. Chromosomes live in the nucleus. Chromosomes hardly get any elbow room – 46 of them live together in 1 nucleus!

But at least each one has its own partner. Chromosomes come in pairs. As you can see below, one of each pair is passed down from our mother and the other is passed down from our father.



Now, it is time to look at the **genes**. The genes live on the chromosomes.

Since chromosomes come in pairs, so do genes. Like the chromosomes, every gene has a partner. One gene of each pair is passed down from our mother, and the other is passed down from our father. Genes have a very important job. They are responsible for the instructions that control how the body develops, grows, and works. Several genes are related to the chances of getting cancer.

When genes are working properly, our bodies develop properly and work smoothly. But sometimes genes have **mutations**. A mutation is a change to a gene that may make it work incorrectly. This can happen because the gene's material gets rearranged, has more than usual, or too little of what is supposed to be there.

When genes are not working correctly, the cell where the genes live can start to have trouble working correctly. For example, the cell could start growing

in an "out of control" way and a cancer could develop. It turns out that not all gene mutations have a harmful effect. In fact, every person has several gene mutations that do not lead to changes you can notice. But sometimes, gene mutations do lead to the development of a disease.

Passing Down a Greater Chance of Cancer

Now you know the basics of what genes are and what they do. The way a tendency to develop breast cancer is passed down is called "**dominant inheritance**". Let's talk about what that means. Have you ever talked with someone who dominates, or controls, the whole conversation? You can hardly get a word in edgewise? Well, some genes dominate their partners too. Remember that genes come in pairs, one from each parent. Each gene in a pair does the same job. With dominant inheritance, when only one gene in the pair has a mutation, the body may not work properly. It doesn't matter if the other gene is just fine.

Scientists have discovered two genes so far that deal with breast cancer. They are called BRCA1 and BRCA2. BRCA stands for BReast CAncer. When someone receives a non-working BRCA1 or BRCA2 gene from a parent, that non-working gene always dominates over its normal partner.

How these genes work

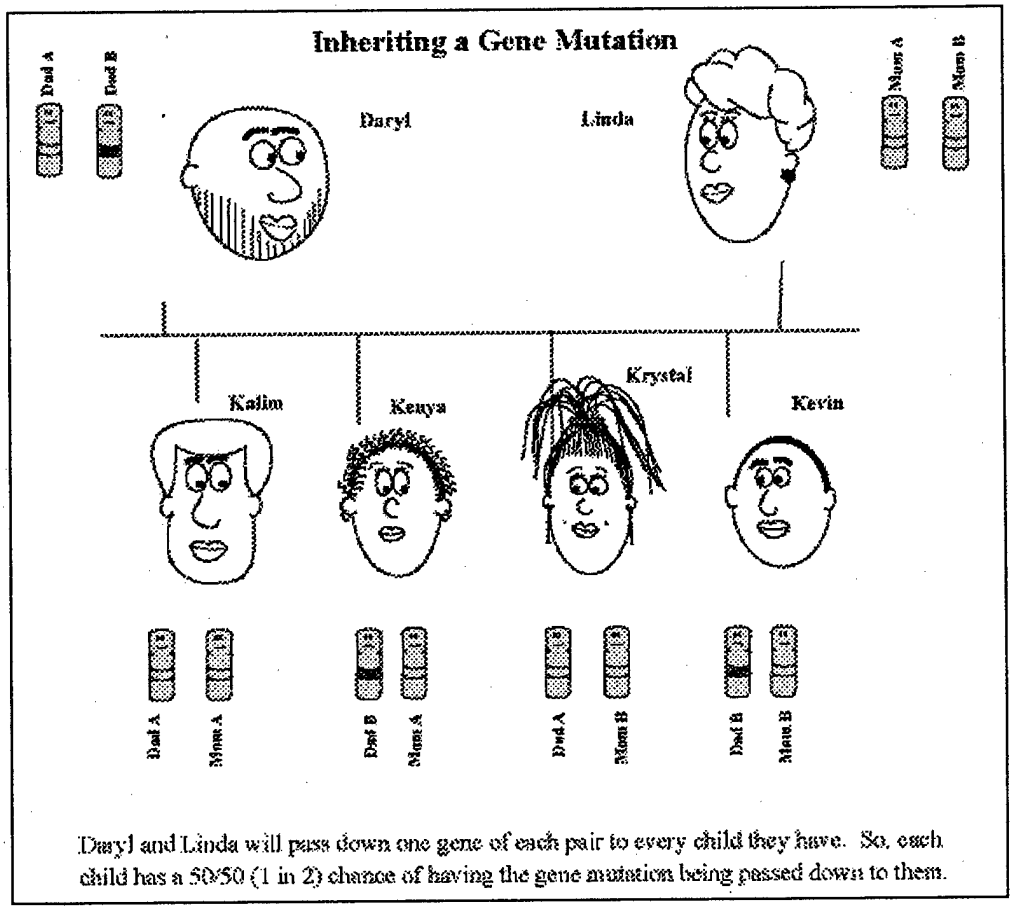
Scientists think that BRCA1 and BRCA2 are responsible for many breast and ovarian cancers **that are passed down in families**. Remember, not all cancer is **hereditary**, or passed down. It is not known how many people have changes in these genes. But scientists think only about 1 person out of 800 have a changed BRCA1 gene, and changes in BRCA2 are even more rare.

The family tree on the next page shows how Daryl and Linda's kids have a BRCA gene passed down to them. As you can see, Daryl has a mutation in one of his BRCA genes.

There is no way to tell which child might receive the non-working gene. Things like birth order, the sex of the child, or how much the child looks like the parent with the non-working gene **do not give clues** about who will

receive the non-working gene. Neither does whether the child was born before or after your cancer.

You can have genetic testing to see if you have a mutation in your BRCA1 or BRCA2 genes.



Daryl and Linda will pass down one gene of each pair to every child they have. So, each child has a 50/50 (1 in 2) chance of having the gene mutation being passed down to them.

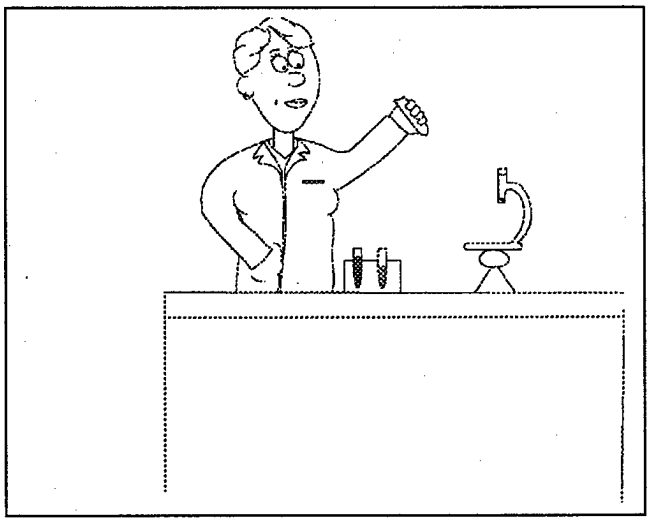
How Genetic Testing Works

Genetic tests are different from other medical tests. Usually, medical tests are **diagnostic**. That means they tell you whether you have a certain condition or not. For example, a pregnancy test will tell you whether you are pregnant or not, and an x-ray can tell you whether you have a broken bone or not. But genetic tests for cancer do not work that way. They don't tell you whether you have cancer or not. They just tell you whether you have a **predisposition** to cancer. A predisposition is just another way of saying you have a greater chance than most people for developing the disease.

Let's use an example. Everyone has a chance of slipping and falling when they are walking around their house. But imagine if all of your floors had a sheet of ice over them. You would have a greater chance of slipping in your house than would someone with plain floors.

Genetic tests can tell whether you have a mutation. Let's talk about how genetic tests work and why they are so complicated.

To do the test, a small blood sample is needed. Then, the genetic material in the blood cells is examined, to see if there are any mutations. The genetic material is called **DNA.** (Look back at page 4 to see examples of how to think about changes in genetic material.) Scientists have many ways of looking for genetic mutations.



The most thorough way is called **sequencing**. What this means is that the "chemical alphabet" of a person's DNA is examined, and compared to DNA that is normal. But this is a very hard thing to do. It's like looking for *one single spelling mistake* in a book that has 3,000 pages!

That is why genetic testing is a very difficult process, and takes a lot of time.

Now, let's talk about the results you get from genetic testing for BRCA1 and BRCA2. Genetic tests need to be interpreted. Some genetic test results give more information than others.

Positive Test Results

► As you read before, having mutations in the BRCA1 and BRCA2 genes makes people more likely to develop breast or ovarian cancer. A positive test means that **a genetic mutation that increases the chances of cancer was found.** You may hear this result described as a "deleterious mutation". This means a **mutation** that makes you more likely to develop cancer.

What does a positive result mean for my family?

Once a significant change in the BRCA1 or BRCA2 gene is found in one family member, it is easier to test other family members. For example, if "Dana" gets a positive result, then other family members would only be tested for the particular change that Dana has. It would not be necessary to look for every single possible change. In the case of the spelling example, this would be like finding the one spelling mistake in a 3,000-page book. Now for everyone else in the family who wants to be tested, we know on which page, in which paragraph, in which sentence, and in which word to look for the spelling mistake. That is why it is quicker and easier to test other family members once a mutation has been found in a family.

Negative Test Results

►**A negative result means that no mutation was found.** If a person gets back a negative test, AND they already know that someone else in the family has a mutation, then that person can be sure they don't have the mutation. So, their chances of getting cancer are like everyone else's. They have a similar chance of getting cancer as anyone in the **general population**. And, they cannot pass the mutation on to their children, because they don't have it.

There are also "unclear" negative test results. This kind of test result means the person **did not show** a genetic mutation in BRCA1 or BRCA2 – *but*, it is not possible to be 100% sure there are no changes there. Let's use the example of looking for a spelling mistake to understand why:

▶ It could be that the methods that are currently available are not sensitive enough to find a mutation in the BRCA1 or BRCA2 gene. For example, the change may be in a part of the gene that is hard to examine. In the spelling example, let's say the only way we are able to look for mistakes is to just move our eyes over the page. Maybe that would work well in chapters with lots of pictures and not too many words. But in a chapter that has 500 words per page, maybe a magnifying glass would work better. Since we don't have a magnifying glass, the test comes back negative – no spelling mistakes.

▶ It could be that **there is a change present**, but it is in a different gene, one that was not tested. Scientists know that there are other genes related to **cancer**. But these **genes** are rare or not even discovered yet. In the spelling example, this would mean that we are looking for spelling mistakes in one book, because we know that book is related to cancer. If we don't find any, the test comes back negative. But what if there is a second book that is also related to **cancer**, and we didn't even know it existed? Since we never even looked for mistakes in the second book, it's not 100% certain that there are no important changes.

What does all that mean for me? If you get an unclear negative result:

1. You could possibly get more genetic testing when more genes are discovered.
2. Family members would not be tested after you get your result. Why? Because if the test doesn't show that you have a non-working gene, you can't pass along something you don't have. So it would not be appropriate to start testing other family members.

Variant of Uncertain Significance

▶ In some cases, a mutation may be found, but it is of unclear clinical significance. Basically what that means is there *is* a slight change in the gene, but scientists have not found that it is *definitely* related to higher chances of getting breast and ovarian cancer.

Let's use an example to understand this. Let's say you have an appointment on Main Street, and you have to arrive on time. To get there you take the T train, which goes express.
This is the standard way the train works.

But imagine 3 different things that could happen to the train. You can see that in each situation, something different has happened. You know that if the T train goes express to Main Street, you will make it to your appointment on time. But in each of the 3 examples, you are not sure if you will arrive on time. If this were a genetic test, these changes would be of "unclear significance". Let's compare the train examples to genetic test results.

1. The train is delayed:
   The conductor announces, "We hope to be moving shortly".

   #1: The train is delayed
   What does that mean? Are you only going to be delayed a few minutes? Or is the train going to be stuck for half an hour? This result means, "there is a change that could mean something, but we're not sure". In genetic testing, this would get the label, **variant of unknown significance**.

2. The train goes slower:
   The conductor announces, "The T train will be running local to Main Street."

   #2: The train goes slower
   You can't say for sure what time you will arrive, but you will probably make it to your appointment on time. So this result means, "this change probably doesn't mean anything." In genetic testing, this would get the label, **variant of unknown significance, favor polymorphism**.

3. The train changes its route:
   The conductor announces, "The T train will be skipping the Main Street stop. Passengers must ride to Central Street and go backwards."

#3: The train changes its route
Here, the conductor has said that the train won't be stopping at Main Street at all! You feel pretty sure that you are going to be late for your appointment now. So, this result means, "there is a change here, and most likely it means something—we doubt that it means nothing." In genetic testing, this would get the label, **variant of unknown significance, favor deleterious**.

Now you have an idea about the kinds of results that are of uncertain significance. Some results suggest that the changes in the gene could really mean something about your cancer risk, and others seem unlikely to have anything to do with that.

What does a variant result mean for my family?

If a person is found to have a variant genetic test result, it may be possible to test family members to find out more about what the variant result really means.

What does it mean if I have a BRCA mutation?

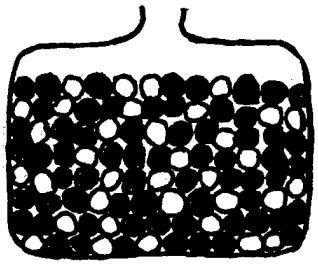
Both women and men with a BRCA mutation have a greater chance to get cancer. Scientists have studied many families with BRCA mutations. These studies helped them to understand whether these families have a higher chance to develop certain cancers. The studies also helped them understand the chances that a person with a BRCA mutation would develop cancer at some point in their life.

Let's talk about a person's chance to develop cancer if they have a BRCA1 or BRCA2 mutation. It is important to know that the chance to develop **cancer** varies from person to person. It also varies from family to family. Because of this, the numbers provided are not exact. Below you can read about the lifetime chance people with a BRCA mutation have to develop cancer.

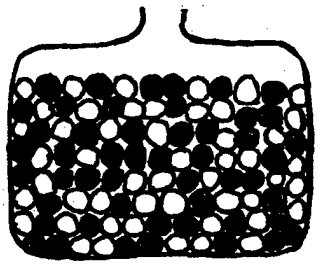
Breast Cancer Risks

A woman with a BRCA mutation has a higher chance of developing breast and ovarian cancer at a younger age. In general, she has a 55% to 85% chance to develop breast cancer over her lifetime. But this only applies to women who have never had a diagnosis of breast cancer. For a woman who has already had breast cancer, the numbers are different.

These pictures are about a woman with a BRCA mutation who already had breast cancer. The pictures show the chances of her developing breast cancer again. Her chances are higher than for women in the general population. You should notice that we show the chances for both BRCA1 *and* BRCA2.



Here we see that for a woman with a BRCA1 mutation, her chance to get breast cancer (in her other breast) is up to 65%.

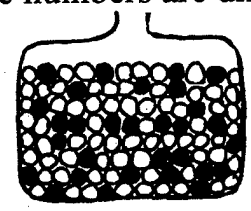


With a BRCA2 mutation, this chance is up to 50%.

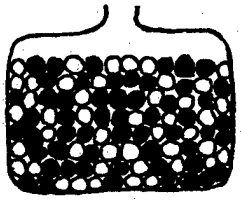
A woman with a BRCA mutation who has had ovarian cancer also has a greater chance to get breast cancer.

Ovarian Cancer Risks

In general, if a woman has a BRCA1 mutation, she has a 15% to 60% chance to develop ovarian cancer over her lifetime. For a woman with a BRCA2 mutation, she has a 15%-25% chance to develop ovarian cancer over her lifetime. But this only applies to women who have never had a diagnosis of breast cancer. For a woman who has already had breast cancer, the numbers are different.

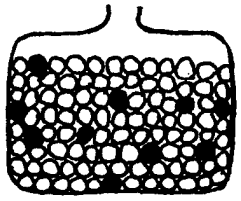


30% to

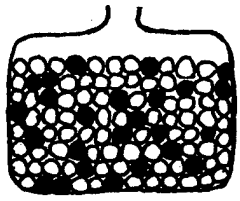


55%

For a woman with a BRCA1 mutation who has already had breast cancer, her chance to get ovarian cancer is between 30% and 55%.

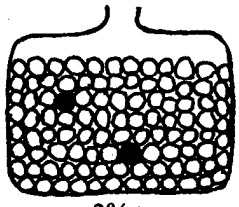


10% to

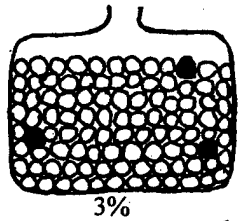


25%

With a BRCA2 mutation, this chance is between 10% and 25%.



2% to



3%

This is compared to the general population risk of 2% to 3%. ____

Cancer Risks for Men

A man with a BRCA mutation has a greater chance to get prostate cancer. He may also be at an increased risk to get male breast cancer.

Colon Cancer Risks

Scientists are not sure if people with BRCA mutations have a greater chance to get colon cancer. Some studies have shown that there is a greater chance, while other studies have not.

Risks for Other Cancers

Men and women who have a BRCA2 mutation have a greater chance to get other cancers. The chance to get these cancers is less than 10%, much lower than the chances to get breast, ovarian, or prostate cancer. Men and women with a BRCA2 mutation may have a greater chance to get cancer of the pancreas, gallbladder, bile duct, stomach, and skin (melanoma).

Next we will talk about what a person with a BRCA mutation can do to manage their cancer risks.

What Can I Do if I Have a BRCA Mutation?

If you are found to have a BRCA mutation, or if you are not but you have a very strong family history of cancer... **Keep a watchful eye on developing cancer and protect your health!**

Breast and ovarian cancer **screening** are ways to possibly pick up cancer at an early stage. If you have a BRCA1 or BRCA2 mutation, there are also ways to prevent breast or ovarian cancer or at least lower your chances of developing these cancers.

If someone has a BRCA mutation, or if they have a very strong family history of cancer, they should follow the screening guidelines discussed below.

Screening for female breast cancer:

- **Breast self-exams** every month.
- **Clinical breast examinations** (when a health care professional examines your breasts) 2-4 times a year, starting around age 25-35.
- **Mammography** (an x-ray of the breasts) once a year, starting around age 25-35.
- Sometimes **ultrasound** and **MRI** are also used to look for changes in breast tissue. These are other ways to make a picture of the breast tissue.

Screening for ovarian cancer:

- **Pelvic exam** twice a year.
- Vaginal ultrasound twice a year, starting around age 25-35.
- **CA-125 blood test** twice a year, starting around age 25-35. This test looks for special markers in the blood that may tell if a woman has ovarian cancer.

These screening tests for ovarian cancer are currently the best tests available. But, they have not been proven to find ovarian cancer in its early stages. This means that these tests can be normal when there is cancer present.

Screening for colon cancer:

- **Fecal occult blood test** (a test to see if there is any blood in your stool) and **digital rectal exam** (done by your doctor) once per year, beginning by age 50, AND
- **Sigmoidoscopy** (a test that lets your health care professional look into the lower part of your colon) every 3-5 years, beginning by age 50.

OR

- **Colonoscopy** (a test that lets your health care professional look at your entire colon) every 5-10 years, beginning by age 50.

All men and women should start watching out for colon cancer at age 50. If you have a BRCA mutation or you are at increased risk for inherited breast and/or ovarian cancer, you may have an increased risk to develop colon cancer. Therefore, it may be recommended that you start this screening before age 50. It may also be recommended that you have more frequent screening.

Sometimes more frequent colon screening is recommended for other reasons. If someone has already had colon cancer, or if they have had colon polyps, they should receive more frequent screening. Also, if someone has a family history of colon cancer, it may be recommended that they begin screening at an earlier age and have screening more often.

Screening for skin cancer:

- Check your skin regularly for growths, sores that do not heal, changes in the size, shape or color of any moles, or any other changes in the skin. Report any changes to your health care professional right away.
- Do not stay in the sun for long periods of time.
- Use sunscreen for added protection.
- Have exams of your skin during regular checkups with your health care professional.
- Men and women who have a BRCA2 mutation should have an annual skin examination with a dermatologist.

FOR MALE RELATIVES:

Screening for prostate cancer:

- **PSA blood test** once a year, starting at age 50. This test looks for special markers in the blood that may tell if a man has prostate cancer.
- Digital rectal exam (done by your doctor) once a year, starting at age 50.

Screening for male breast cancer:

Right now, there are no standard screening recommendations for men who have an greater chance to develop breast cancer. But, it is important that these men report any changes in their breast tissue to their health care professional.

Preventing Breast and Ovarian Cancer

Now we will discuss some of the ways to prevent breast or ovarian cancer, or at least lower your chances of developing these cancers, including **preventive surgery** and **chemoprevention.**

Preventive Surgery for Breast Cancer

Women who have a BRCA1 or BRCA2 mutation have a greater chance of getting breast cancer. Some of these women think about having a healthy breast removed in order to try to prevent breast cancer. This is known as **prophylactic mastectomy**. In this surgery, the entire breast is removed, including the nipple, but some breast tissue remains after this surgery. For that reason, there is still a small chance of developing breast cancer after having prophylactic mastectomy. Even if you have already had a mastectomy because of breast cancer, this surgery can reduce the chance of a new breast cancer again in the other breast.

Preventive Surgery for Ovarian Cancer

Women who have a BRCA1 or BRCA2 mutation also have a greater chance of getting ovarian cancer. Some of these women may think about having their ovaries removed in order to prevent ovarian cancer. This surgery is known as a **prophylactic oophorectomy**. This surgery greatly lowers the chance of developing ovarian cancer. But, even after the surgery, there is still a small chance of developing an ovarian-like cancer. Women may be more interested in this surgery if they have decided not to have children or have finished having children. Also, younger women who have this surgery will go through early **menopause**. Menopause is the change of life when your menstrual period ends. This surgery may reduce the chance of getting ovarian cancer by 97%. It is important to know that for women who are younger than 50, it may also lower your chances of getting breast cancer, too.

Deciding to Have Preventive Surgery

If you have a BRCA1 or BRCA2 mutation, there is no right or wrong decision about having preventive surgery. There are many things to consider before having surgery, including:

- How comfortable you are using breast and ovarian screening tests (like a mammogram or ultrasound) versus having preventive surgery.

- How comfortable you are with how much preventive surgery would lower your chances of developing breast and ovarian cancer.

- How surgery would affect you emotionally.

- Other medical conditions you may have that might affect surgery.

- The financial costs involved in preventive surgery.

Before making a decision, all of these issues should be discussed with your doctors.

Chemoprevention

Chemoprevention means medication that may reduce cancer risk. There are different medications in this group. One common one is called **tamoxifen**. This is a medication that affects hormones. Tamoxifen is often used by some women who have already had breast cancer. This is because tamoxifen can prevent the cancer from spreading. It also reduces the chance of getting a new breast cancer. Your doctor can tell you if tamoxifen is right for you.

For women who have had breast cancer and who also have a BRCA1 or BRCA2 mutation, scientists are not yet sure whether tamoxifen reduces the chances of getting breast cancer again.

Remember, even if you decide to use chemoprevention, you must still get breast and ovarian cancer screening as described on page 15.

Is Genetic Testing Right For You?

There are possible benefits ("pros") to having genetic testing. There are also possible risks ("cons"). Each woman needs to think carefully about the pros and the cons in order to make her own decision about being tested.

Pros

Genetic testing can help you learn whether or not you have a BRCA1 or BRCA2 mutation. Some people decide to participate in genetic testing because:

- It can give you more knowledge and information about your chance for getting a second, new cancer.
- It can help you make better healthcare decisions, especially about cancer screening tests (like how often to have them) and preventive surgery.
- It can provide important information for your family members, especially your children, sisters and brothers. For example, if you learn you have a BRCA1 or BRCA2 mutation, that may help your family members decide whether they want to be tested, too, since these mutations run in families.
- It can help you emotionally. If you learn that you have a BRCA1 or BRCA2 mutation, you may have more peace of mind because you are more certain about your chance of getting cancer. If you learn that you do not have a mutation, you may be relieved.
- It can give you a chance to help scientists understand more about inherited cancer and add to the research.

Cons

Some people decide not to participate in genetic testing because:

- It is sometimes hard to make sense of test results because they can be difficult to interpret (go back to page X for more information).

- Genetic testing can be hard emotionally. People who learn that they have a BRCA1 or BRCA2 mutation may feel sad, angry or worried.

- Learning test results may put a strain on family relationships because people react differently to genetic testing. Family members may feel guilty about test results. For example, a person may feel badly if she learns that she does not have the mutation but her sister does. Sometimes, psychological counseling and support may be helpful.

- Genetic counselors do as much as possible to keep your genetic results private. But, if other members of your family decide to be tested, they may learn or figure out your test results based on your cancer history and position in the family tree.

- Genetic test results can lead to discrimination or unfair treatment by employers or companies that provide health, life, or disability insurance.

Protection from Genetic Discrimination

There are laws that help protect people who undergo genetic testing from discrimination or unfair treatment.

The Health Insurance Portability and Accountability Act (HIPAA) says that genetic information is protected medical information. For example, what if someone needs to change insurance? HIPAA does not allow group health providers to deny health care to people who have a genetic mutation in BRCA1 or BRCA2. But, the HIPAA rules **do not apply** to people who are covered by private insurance. It also does not apply to disability and life insurance.

The Americans with Disabilities Act protects employees from genetic discrimination through the U.S. Equal Employment Opportunity Commission. But, these guidelines are not clear when it comes to genetic test results. Therefore, it may be hard to prove that an employer has acted against these guidelines.

An executive order signed by President Clinton in February 2000 makes it illegal for departments and agencies in the federal government from using genetic information in their hiring or promotion decisions. This is a good start but it does not apply to employees who do not work for the federal government.

Different states may also provide protection against genetic discrimination. For more information about laws in New York, New Jersey, and other states, go to the website....

Although these laws do not protect everyone completely, they are important steps in protecting people who decide to have genetic testing.

Summary

This educational packet provides a lot of information about hereditary breast and ovarian cancer and genetic testing. Deciding whether to have genetic testing is a personal decision that must be carefully considered. There are no right or wrong answers. You may want to ask yourself if the information you could gain from genetic testing would be useful to you. What would you do with this information? Would this information change any of your current health care practices? You may also want to talk about the information provided in the packet with your health care providers, family, and friends. This information provided in this packet may help you to make this decision.

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

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? Please check one

_____ 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

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

BSI

The following is 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 and 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

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

CESD

w is a list of statements that describe ways people sometimes feel or behave. Please circle the number for each ment which best describes 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**
<u>During the past week:</u>					
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
11. My sleep was restless.	1	2	3	4	DK

Please continue on to the next page

	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:					
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

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

IES

The following is 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

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

Decisional Conflict

You have now made a decision whether or not to donate blood today for genetic testing. Please thing about this choice now and describe how strongly you agree or disagree with each of the following comments using this scale: 1=strongly agree, 2=agree, 3=neither agree nor disagree, 4=disagree, and 5=strongly agree.

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	Don't Know/ Refused
1. The decision was easy for me to make.	1	2	3	4	5	DK
2. I'm sure what to do in this decision.	1	2	3	4	5	DK
3. It's clear what choice is best for me.	1	2	3	4	5	DK
4. I'm aware of the options I have in this decision.	1	2	3	4	5	DK
5. I feel I know the advantages of each option.	1	2	3	4	5	DK
6. I feel I know the disadvantages of each option.	1	2	3	4	5	DK
7. I am clear about <u>how important</u> the advantages are to me in this decision.	1	2	3	4	5	DK
8. I am clear about <u>how important</u> the disadvantages are to me in this decision.	1	2	3	4	5	DK
9. For the main options I considered, I am clear about which is <u>more</u> important to me (the advantages or disadvantages).	1	2	3	4	5	DK
10. I made this choice without any pressure from others.	1	2	3	4	5	DK
11. I had the right amount of support from others in making this choice.	1	2	3	4	5	DK
12. I had enough advice about the options.	1	2	3	4	5	DK
13. I feel I have made an informed choice.	1	2	3	4	5	DK
14. My decision shows what is important to me.	1	2	3	4	5	DK
15. I expect to stick with my decision.	1	2	3	4	5	DK
16. I am satisfied with my decision.	1	2	3	4	5	DK

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

Satisfaction With Decision Making

Thinking about your decision regarding BRCA testing, please indicate how strongly you agree or disagree with the following comments using this scale: 1=strongly agree, 2=agree, 3=neither agree nor disagree, 4=disagree, and 5=strongly agree.

	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

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

Genetic Knowledge Questionnaire

We are interested in how much you already know about cancer and genetics. Please indicate whether the following statements about cancer and genetics are true or false, or if you don't know the answer.

1	A woman is at a greater risk for developing breast cancer if she has several close relatives with breast cancer.	True	False	Don't Know
2	If a woman who already has had breast cancer is found to have inherited a breast cancer gene mutation, she is at increased risk for developing:			
a)	Breast cancer in her other breast	True	False	Don't Know
b)	Ovarian cancer	True	False	Don't Know
c)	Lung cancer	True	False	Don't Know
d)	Bladder cancer	True	False	Don't Know
3	Breast cancer in an older woman is more likely to be associated with a breast cancer gene mutation than is breast cancer diagnosed in a young woman.	True	False	Don't Know
4	A woman who has a mother or sister with a breast cancer gene mutation has a 50% chance of also having the mutation.	True	False	Don't Know
5	A woman who does not have a breast cancer gene mutation can still get breast cancer.	True	False	Don't Know
6	A father can pass down a breast cancer gene mutation to his daughters.	True	False	Don't Know
7	Most breast cancer is not hereditary.	True	False	Don't Know
8	All women who have a breast cancer gene mutation will at some point get cancer.	True	False	Don't Know
9	A woman who has inherited a breast cancer gene mutation should be screened for cancer more often.	True	False	Don't Know
10	A woman who has her healthy ovaries removed in an effort to prevent ovarian cancer will definitely not get ovarian cancer.	True	False	Don't Know
11	A woman who has had breast cancer and has many relatives affected with breast cancer will definitely have a breast cancer gene mutation.	True	False	Don't Know

Genetic Knowledge - Continued

12	Even if a woman does not have a breast cancer gene mutation, her children can still get it from their grandmother (their mother's mother).	True	False	Don't Know

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

Africentrism

These questions are related to your feelings about issues related to the Black community. Research has shown that ideas and beliefs about these issues are related to health. Using the scale 1=strongly agree, 2=agree, 3=disagree, and 4=strongly disagree, please indicated how much you agree or disagree with the following statements.

	Strongly Agree	**Agree**	**Disagree**	**Strongly Disagree**	**Don't Know/ Refused**
1. My family's needs are more important to me than my own needs.	1	2	3	4	DK
2. Black people should make their community better than it was when they found it.	1	2	3	4	DK
3. The problems of other Blacks are their problems, not mine.	1	2	3	4	DK
4. The unity of the African race is very important to me.	1	2	3	4	DK
5. I am more concerned with reaching my own goals than with working for the Black community.	1	2	3	4	DK
6. I have very little faith in Black people.	1	2	3	4	DK
7. I owe something to Black people who suffered before me.	1	2	3	4	DK
8. Black people need to stop worrying so much about "the community" and take care of their own needs.	1	2	3	4	DK
9. I am doing a lot to improve my neighborhood.	1	2	3	4	DK
10. The success I have had is mainly because of me, not anyone else.	1	2	3	4	DK
11. I have more confidence in White professionals, like doctors and teachers, than in Black professionals.	1	2	3	4	DK
12. Black people should build and maintain their own communities.	1	2	3	4	DK
13. I must do all I can to restore Black people to their position of respect in the world.	1	2	3	4	DK
14. I make it a point to shop at Black businesses and use Black-owned services.	1	2	3	4	DK
15. It hurts me when I see another Black person discriminated against.	1	2	3	4	DK
16. It is important that Black people decide for themselves what to be called and what their needs are.	1	2	3	4	DK
17. The Black community would be better off if people just worked on their own goals.	1	2	3	4	DK

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

Illness Perception

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.

		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
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

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Africultural Coping

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
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

Africultural Coping (continued)

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

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LOT-R

Please indicate how strongly you agree or disagree with the following comments using this scale: 1=strongly agree, 2=agree, 3=neither agree nor disagree, 4=disagree, and 5=strongly disagree. Don't let your answer to one question influence another.

		Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	Don't Know/ Refused
1	In uncertain times I usually expect the best.	1	2	3	4	5	DK
2	It's easy for me to relax.	1	2	3	4	5	DK
3	If something can go wrong for me, it will.	1	2	3	4	5	DK
4	I'm always optimistic about my future.	1	2	3	4	5	DK
5	I enjoy my friends a lot.	1	2	3	4	5	DK
6	It's important for me to keep busy.	1	2	3	4	5	DK
7	I hardly ever expect things to go my way.	1	2	3	4	5	DK
8	I don't get upset too easily.	1	2	3	4	5	DK
9	I rarely count on good things happening to me.	1	2	3	4	5	DK
10	Overall, I expect more good things to happen to me than bad.	1	2	3	4	5	DK

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Self-Esteem

The following are ten statements about yourself. 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 each of the statements.

		Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	Don't Know/ Refused
1	I feel that I'm a person of worth, at least on an equal basis with others.	1	2	3	4	5	DK
2	I feel that I have a number of good qualities.	1	2	3	4	5	DK
3	All in all, I am inclined to feel that I am a failure.	1	2	3	4	5	DK
4	I am able to do things as well as most other people.	1	2	3	4	5	DK
5	I feel I do not have much to be proud of.	1	2	3	4	5	DK
6	I take a positive attitude with myself.	1	2	3	4	5	DK
7	On the whole, I am satisfied with myself.	1	2	3	4	5	DK
8	I wish I could have more respect for myself.	1	2	3	4	5	DK
9	I certainly feel useless at times.	1	2	3	4	5	DK
10	At times I think I am no good at all.	1	2	3	4	5	DK

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Brief COPE (COPE-S)

We are interested in how people respond when they confront difficult or stressful events in their lives. There are lots of ways to try to deal with stress. This questionnaire asks you to indicate what you generally do and feel, when you experience stressful events. Obviously, different events bring out somewhat different responses, but think about what you usually do when you are under a lot of stress.

Please respond to each of the following items using the scale 1=I haven't been doing this at all, 2=I've been doing this a little bit, 3= I've been doing this a medium amount, and 4=I've been doing this a lot. Please try to respond to each item separately in your mind from each other item. Choose your answers thoughtfully, and make your answers as true FOR YOU as you can. There are no "right" or "wrong" answers, so choose the most accurate answer for YOU – not what you think "most people" would say or do. Indicate what YOU usually do when YOU experience a stressful event.

		I haven't been doing this at all	**I've been doing this a little bit**	**I've been doing this a medium amount**	**I've been doing this a lot**	**Don't Know/ Refused**
1	I've been turning to work or other activities to take my mind off things.	1	2	3	4	DK
2	I've been concentrating my efforts on doing something about the situation I'm in.	1	2	3	4	DK
3	I've been saying to myself "this isn't real".	1	2	3	4	DK
4	I've been using alcohol or other drugs to make myself feel better.	1	2	3	4	DK
5	I've been getting emotional support from others.	1	2	3	4	DK
6	I've been giving up trying to deal with it.	1	2	3	4	DK
7	I've been taking action to try to make the situation better.	1	2	3	4	DK
8	I've been refusing to believe that it has happened.	1	2	3	4	DK
9	I've been saying things to let my unpleasant feelings	1	2	3	4	DK
10	I've been getting help and advice from other people.	1	2	3	4	DK
11	I've been using alcohol or other drugs to help me get through it.	1	2	3	4	DK
12	I've been trying to see it in a different light, to make it seem more positive.	1	2	3	4	DK
13	I've been criticizing myself.	1	2	3	4	DK
14	I've been trying to come up with a strategy about what to do.	1	2	3	4	DK
15	I've been getting comfort and understanding from someone.	1	2	3	4	DK
16	I've been giving up the attempt to cope.	1	2	3	4	DK
17	I've been looking for something good in what is happening.	1	2	3	4	DK
18	I've been making jokes about it.	1	2	3	4	DK
19	I've been doing something to think about it less, such as going to movies, watching TV, reading, daydreaming, sleeping, or shopping.	1	2	3	4	DK
20	I've been accepting the reality of the fact that it has happened.	1	2	3	4	DK
21	I've been expressing my negative feelings.	1	2	3	4	DK
22	I've been trying to find comfort in my religion or spiritual beliefs.	1	2	3	4	DK

Brief COPE (COPE-S) Continued

23	I've been trying to get advice or help from other people about what to do.	1	2	3	4	DK
24	I've been learning to live with it.	1	2	3	4	DK
25	I've been thinking hard about what steps to take.	1	2	3	4	DK
26	I've been blaming myself for things that happened.	1	2	3	4	DK
27	I've been praying or meditating.	1	2	3	4	DK
28	I've been making fun of the situation.	1	2	3	4	DK

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Attitudes Towards Genetic Testing

	Strongly Agree		Neither agree nor 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 "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

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Genetic Testing Pros and Cons

These questions ask about your attitudes toward genetic testing for cancer. Please indicate how strongly you agree or disagree with the following statements based on this scale: 1=strongly agree, 2=agree, 3=neither agree nor disagree, 4=disagree, and 5=strongly disagree.

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't Know/ Refused
1. My concerns about getting breast cancer again would by 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
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
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

26. 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

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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

Medical Mistrust (Continued)

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

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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
21	Overall, being Black has very little to do with how I feel about myself.	1	2	3	4	DK

Identity (Continued)

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

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Collectivism

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

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

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Time Orientation

Using the scale 1=strongly agree, 2=agree, 3=disagree, 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. 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

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Spirituality

1. Are you a member of a church or other place of worship?
   1. Yes
   2. No

2. How often do you attend church or other religious services?
   1. More than once per week
   2. Once a week
   3. A few times a month
   4. A few times a year
   5. Once a year or less
   6. Never

3. How often do you spend time in private religious activities, such as prayer, meditation, or Bible study?
   1. More than once per week
   2. Once a week
   3. A few times a month
   4. A few times a year
   5. Once a year or less
   6. Never

Do you agree or disagree with the following statements?

		Strongly agree	**Agree**	**Disagree**	**Strongly Disagree**	**Don't Know/ Refused**
4	Religion or spirituality is important in my day-to-day life.	1	2	3	4	DK
5	Prayer or mediation has helped me cope during times of serious illness.	1	2	3	4	DK
6	I enjoy attending religious functions held by my religious or spiritual group.	1	2	3	4	DK
7	I feel certain that God in some form exists.	1	2	3	4	DK
8	When I need suggestions on how to deal with problems, I know someone in my religious or spiritual community that I can turn to.	1	2	3	4	DK
9	I believe God will not give me a burden I cannot carry.	1	2	3	4	DK
10	I enjoy or meeting or talking often with people who share my religious or spiritual beliefs.	1	2	3	4	DK
11	During times of illness, my religious or spiritual beliefs have been strengthened.	1	2	3	4	DK

Spirituality (Continued)

12	When I feel lonely, I rely on people who share my spiritual or religious beliefs for support.	1	2	3	4	DK
13	I have experienced a sense of hope as a result of my religious or spiritual beliefs.	1	2	3	4	DK
14	I have experienced peace of mind through my prayers and meditations.	1	2	3	4	DK
15	One's life and death follows a plan from God.	1	2	3	4	DK
16	I seek out people in my religious or spiritual community when I need help.	1	2	3	4	DK
17	I believe God protects me from harm.	1	2	3	4	DK
18	I pray for help during bad times.	1	2	3	4	DK
19	I talk openly about my faith with others.	1	2	3	4	DK
20	I often read religious books, magazines, or pamphlets.	1	2	3	4	DK
21	I often watch or listen to religious programs on television or radio.	1	2	3	4	DK
22	My spiritual beliefs are the foundation of my whole approach to life.	1	2	3	4	DK
23	I am often aware of the presence of God in my life.	1	2	3	4	DK
24	I have a personal relationship with God.	1	2	3	4	DK
25	When I am ill, I pray for healing.	1	2	3	4	DK
26	I pray often.	1	2	3	4	DK
27	I rely on God to keep me in good health.	1	2	3	4	DK

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. 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?	NA
Example 1: Mother	YES	3	2	4	5	
Example 2: Daughter Age 18	NO	2	4	5	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?	NA
Spouse						
Mother						
Father						
Siblings (Please list all) 1.						
2.						
3.						
4.						
Children (Please list all) 1.						
2.						
3.						
4.						

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

Schedule of Racist Events

We are interested in your experiences with racism. As you answer the following questions, please think about your ENTIRE life, from when you were a child to the present. For each question, please indicate how often these things that have happened to you using the scale 1 = If this has NEVER happened to you, 2 = If this has happened ONCE IN A WHILE (less than 10% of the time), 3 = If this has happened SOMETIMES (10%-25% of the time), 4 = If this has happened A LOT (26%-49% of the time), 5 = If this has happened MOST OF THE TIME (50%-70% of the time), 6 = If this has happened ALMOST ALL OF THE TIME (more than 70% of the time), and DK if you Don't Know or if you do not want to answer the question. Answer each question for what has happened to you IN YOUR ENTIRE LIFE.

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

How many times in your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

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

How many times in your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

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

How many times in your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

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 your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

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

How many times in your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

Schedule of Racist Events - Continued

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 your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

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

How many times in your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

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 your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

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

How many times in your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

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 your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

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

How many times in your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

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

How many times in your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

Schedule of Racist Events - Continued

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

How many times in your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

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 your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

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

How many times in your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

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 your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

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 your entire life?	**1**	**2**	**3**	**4**	**5**	**6**	**DK**
	Never					Almost all the time	

PROJECT 3

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

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:

The increased risk of breast cancer among the first degree relatives of breast cancer patients can only rarely be attributed to mutations in the autosomal dominant breast cancer susceptibility genes (BRCA1/BRCA2). Based on initial evidence of reduced NK cell cytotoxicity in first degree relatives of breast cancer patients, it has been hypothesized that deficits in immune surveillance mechanisms may account for the residual familial risk. On the other hand, heightened stress levels reported in individuals whose close relatives had breast cancer raise the possibility that the lower levels of cytotoxic activity may be due to stress-induced immune suppression. The proposed research will investigate these two possible nonexclusive explanations for variability in NK cell cytotoxicity. The proposed study will also examine the possibility that the daughters of breast cancer patients may evidence a broader pattern of alterations in immune function, as 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 (TNFa, IFNg) suggests another powerful approach to exploring the contribution of these cytokines to familial risk of breast cancer. The proposed longitudinal study will be based on the Case Control design of Project 1, in that daughters of both Cases and Controls will be recruited to the Project. The daughters of Cases and Controls (Project 1) will constitute the two Study Groups (final N=150/group). Each participating Case-daughter will be assessed (Core A) on two separate occasions (at the same time of day), following their mother's diagnosis (after completion of initial treatment) and approximately three months later. At each assessment standardized self-report measures will be completed and, following at least 20 minutes of quiet rest, a blood sample (30 ml) will be collected. Ambulatory cardiovascular activity will be assessed to provide an objective indicator of stress. Blood samples will be assayed for immune function and cytokine genotypes (Core C). Routine statistical analyses (Core B) will test study hypothesis. 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.

BODY:

As we have yet to receive official notification of HSRRB approval through the USAMRAA office for this Project, or for Project 1, which will be the entry point for recruitment for participants in the study, 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 0-18): Successful application for HSRRB approval through the USAMRAA office. To date we have submitted responses to 9 requests for revisions to the Protocol, responses to 23 requests for revisions to the Consent forms, and two revisions to the Questionnaires. We have recently (10/4/02) been provided by the HSRRB of the USAMRAA with 16 pages of detailed specific requests for further clarification/revisions to the Protocol, Consent forms and Questionnaires, which we propose to address by the end of this month. Given the 2-10 month time period required for turn around of such materials by the HSRRB of the USAMRAA after previous submissions for Projects 1, 2 and 3, we anticipate approval by 2003.

As allowable in the absence of approval by the HSRRB of the USAMRAA, we have focused our energies on completion of required local Institutional Review Board requirements, 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 in collaboration with all investigators and consultants, as well as establishing tests for proposed immune parameters that will be 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: Psychological, Biological and Cognitive Impact of a Brief Expressive Writing intervention for African American Women at Familial Breast Cancer Risk
Project Period: 1/01/03-12/21/03 Total Direct Costs: $490,832/First Year Costs: $120,160
P.I.: H. Valdimarsdottir
Co-Investigator: D. 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:

Recruitment brochure

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 Coordinator's business card here.

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

IRB approved from
9/15/02 to 9/14/03

MOUNT SINAI SCHOOL OF MEDICINE

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Circle of Life

Mothers, daughters and breast cancer

KEITH MALLET, *Circle of Life*

Core A

"Recruitment, Tracking and Interviewing Core"

CORE A: "Recruitment, Tracking and Interviewing Core"

Principal Investigator: Ms. Lina Jandorf

INTRODUCTION:

This Core has responsibility for 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 will be utilized as Patient Advocates for Research Participation (PARPS), that is, as recruiters. Once a Case or Control has been identified, the PARP will contact her and schedule the first interview/assessment. In addition, culturally competent interviewers will be trained and ready: to conduct each assessment/interview, to collect blood specimens, to contact the Cases for Project 2, to contact the healthy adult daughters of both Cases and Controls for Project 3. For Project 3, they will also instruct participants in the use of the ambulatory blood pressure monitor, and track their involvement across and within the project.

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 in anticipation of Army IRB approval. A recruiter guide (see appendix) has been developed. Second, in order to compete each interview or assessment, as outlined in the Overall Program, two Research Interviewers have been hired and trained to complete the interviews/assessments for each Project. A manual for use by interviewers has been completed (see appendix). Since we have not received Army IRB approval, we have not begun the actual field work. The third goal for this Core regards the education of physicians at the cooperating hospitals. We have made contact with the cooperating hospitals. Key staff at each location have been identified. Meetings have been scheduled, standard procedures for the identification of cases has been established. A schedule for our Interviewers to be on hand at each site has been established. Finally, this Core has the responsibility of tracking all of the participants in Projects 1, 2 and 3. Working with Core C, a tracking database has been completed. While we have not actively been recruiting participants, we have tested the database and designed the needed reports for the conducting of this research.

KEY RESEARCH ACCOMPLISHMENTS:

At this point in time, no results are available, as Army IRB approval to recruit participants has not yet been received.

REPORTABLE OUTCOMES:

At this point in time, no results are available.

CONCLUSIONS:

At this point in the research, no results are yet 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

1/29/02

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I.

STUDY DESCRIPTION

Description of Breast Cancer Study

Breast Cancer Study Goals

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.

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

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.

Tri-State Women's Circle of Health

Protocol	Idea - MSSM	Idea DOD	Original DOD	Original DOD – MSSM
Study Population	150 CA - 50 Black 50 Hispanic 50 White 3 CO/ 1 CA - RDD, hospital, friend	150 CA - 50 Black 50 Hispanic 50 White 3 CO/ 1 CA - RDD, hospital, friend	800 CA - Black 800 CO - RDD, HCFA	800 CA – Black 100 CA – White 100 CA – Hisp 800B, 100W, 100H CO - RDD, HCFA
Hospital	Sinai, St. Luke's	Sinai	All Hospitals	All Hospitals
Age Range	20-74 years	20-74 years	20-74 years	20-74 years
Eligibility	▪ CA: Incident & prevalent (1 yr) ▪ CO: NY Tri-State area ▪ English/Spanish ▪ Match white CA on insurance	▪ CA: Incident & prevalent (1 yr) ▪ CO: NYC Metro area ▪ English only ▪ Match white CA on insurance	▪ CA<65 - telephone ▪ CA>65-medicare/aid ▪ English only	▪ CA< 65 – telephone ▪ CA>65 - Medicare/aid ▪ English only
Incentive	$25 GC	1Week ($17) Metrocard	$25 GC	$25 GC
Contact & Recruiting	▪ ID through path reports or office records ▪ MD consent ▪ Letter from PI and MD w/ brochure and number to refuse contact ▪ PARP protocol - PPC ▪ Interview scheduled ▪ Blood (30mL)	▪ Identify through path reports ▪ ask MD to verify diagnosis and give OK to contact ▪ PARP protocol – Lottery ▪ Interview scheduled ▪ Blood (30mL)	▪ Identify through path reports and at private MD offices ▪ contact MD for OK & patient address ▪ Letter from MD with brochure ▪ PARP protocol-PPC ▪ Interview scheduled ▪ Blood (23 mL)	▪ ID through path reports at hosp. And "at private doctor's offices" ▪ New cases: MDs tell about study **or** ▪ contact MD, get consent to contact & contact info ▪ RA sends letters, puts in tracking d-base ▪ Letter from doc w/ brochure ▪ PARP protocol-PPC ▪ Interview (Travel Reimb)* ▪ Blood (30 mL) ▪ Tumor Block/Chart Rev*

* pending IRB approval

7/29/02

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*	Pathology Reports or 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 (AF) assigns Recruiter and sends post-card	Core A (Interviewer) and Project 1 (TB)
RDD controls	HCFA/phone list	RDD Company	Mailed by Project 1	Ditto	Ditto

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

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

10/8/02

Reference:Study Description

II.

ROLE OF THE RECRUITER

Sequence of Subject Recruitment

Control Contacts

Case Contacts

Sequence of Subject Recruitment

1. Cases are identified by:
   - physicians directly or through pathology reports, followed by physician approval to contact patients.

2. Controls are identified by:
   - General public controls are identified by a RDD (random digit dialing) company through phone lists or HCFA listing for Medicare.

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 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

5. Post-cards with the recruiter's picture and name
   will be sent in envelopes by MSSM staff to the subject.

6. 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.

7/29/02
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_____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.

- ☐ Enthusiastic
- ☐ Excited
- ☐ Willing to help
- ☐ Pleasant
- ☐ Nervous
- ☐ Hesitant
- ☐ Angry
- ☐ Depressed
- ☐ Not sure if they want to participate
- ☐ Would like more information about the study
- ☐ Questions for staff about the study

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 Seneka Peter at Mount Sinai by calling 1-866-223-2219 or 212 659-5406."

7/29/02
Reference: Role of the Recruiter

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**:
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. Have you ever had any form of cancer other than basal cell or squamous cell skin cancer? IF YES, FIND OUT WHAT KIND, 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 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 and can be conducted at either Mount Sinai Hospital, 98 St. & Fifth Ave.; St. Luke's Roosevelt Hospital, 59 St. & 9th Ave., Queens Hospital

Center, 164th St. Jamaica, or Kings County Hospital in Brooklyn (Tuesdays and Fridays only), whichever is more convenient for you. That's all there is to it. So, do you have any questions?

If the hospital locations are not acceptable, offer to have the interviewer conduct the interview 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 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 on the phone?
(SEE QUESTIONS FOR NON-PARTICIPANTS ON LAST PAGE)

(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 another hospital? What is a good time and day for you?

INTERVIEW LOCATION:_____
DAY INTERVIEW SCHEDULED:_____DATE:_____TIME:_____

I will tell _____, the Interviewer who will be meeting you, that you are interested in being in the study, and she 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(interviewer) 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 her before she calls, let me give you (interviewer's) phone number: _____.

Thank you so much for your time, and for agreeing to be in this study.
Date Directions Sent _____
8/20/02 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.

- ☐ Enthusiastic
- ☐ Excited
- ☐ Willing to help
- ☐ Pleasant
- ☐ Nervous
- ☐ Hesitant
- ☐ Angry
- ☐ Depressed
- ☐ Not sure if they want to participate
- ☐ Would like more information about the study
- ☐ Questions for staff about the study

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 Seneka Peter at Mount Sinai by calling 1-866-223-2219 or 212 659-5406."

7/29/02

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 there gave the study director your name. If you have time, I would like to tell you about the study.

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 want to tell you right at the start that there is no cost to you. In fact, you will receive a $25 gift certificate from either Pathmark or Rite Aide as our way of thanking you for participating in our study. I also want you to know that your privacy will always be 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. Also, this is not a treatment study and your involvement will not interfere with any treatment you may be undergoing. 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 and can be conducted at either Mount Sinai Hospital, 98 St. & Fifth Ave.; St. Luke's Roosevelt Hospital, 59 St. & 9th Ave., Queens Hospital

Center, 164th St. Jamaica, or Kings County Hospital in Brooklyn (on Tuesdays and Fridays only), whichever is more convenient for you. That's all there is to it.
So, do you have any questions?

If the hospital locations are not acceptable, offer to have the interviewer conduct the interview 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 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 on the phone?
(SEE QUESTIONS FOR NON-PARTICIPANTS ON THE LAST PAGE)

(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 another hospital? What is a good time and day for you?

INTERVIEW LOCATION:_____
DAY INTERVIEW SCHEDULED:_____DATE:_____TIME:_____

I will tell _____, the Interviewer who will be meeting you, that you are interested in being in the study, and she 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(interviewer) 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 her before she calls, let me give you (interviewer's) phone number: _____.
Thank you so much for your time, and for agreeing to be in this study.
Date Directions Sent _____
8/20/02Section: Recruitment Tools/Techniques

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).

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).

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 on the **Interviewer's Contact Sheet** from interview confirmation through completion.

9. You will **enter all data** related to the interview process from confirmation of the interview appointment through completion of the interview within 24 hours of the interview completion and refer eligible participants for Projects 2 and 3.

10. You will **edit** each questionnaire, reviewing all items for completeness and legibility prior to passing on for data entry and complete the **Post-Interview Checklist** within 24 hours of the interview completion.

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.

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 1 ½ to 2 hours and is a one time thing. As an appreciation for your time and effort, I will be bringing the $25 gift certificate for (K-mart 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 212 659-_____.

7/29/02
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:_____

7/29/02
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.**

Participation instructions

I will be asking you many different questions about your background, including family and medical history. I will also be asking you about your lifestyle, such as physical activity and food preferences, because these areas influence health. If, at any time, you feel uncomfortable with a question and do not wish to answer it, just let me know. You do not have to answer any questions you don't want to. Please remember that what you tell me is confidential, so answer each question to the best of your ability and as honestly as you can. Also, if you begin to feel tired or feel like you are not able to pay attention or concentrate, let me know. We can either take a short break or try to finish at another time. However, it is probably easier to finish the entire interview now than to try to finish it hours from now or on another day. Lastly, if you have any questions at all about any part of the interview, do not hesitate to ask.

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!!**

7/29/02
Reference:Role of the Interviewer

IV.

Interview Process

Mount Sinai Hospital

St. Luke's Roosevelt Hospital

Kings County Hospital

In-Home

All Interviews

Flow of Interviews

GCRC Admission Form

INTERVIEWS AT MOUNT SINAI HOSPITAL

Scheduling the Interview at the GCRC:

After confirming the interview date, time and location, the GCRC will be notified by Anne Fatone via e-mail 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. Meet the participant in the lobby of 1184 Fifth Avenue and accompany her to the GCRC.

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. This is a good opportunity to engage in "small talk" with the participant to establish rapport and put her at ease.

INTERVIEWS AT ST. LUKE'S ROOSEVELT HOSPITAL

Scheduling the Interview at St. Luke's Roosevelt Hospital

After confirming the interview date, time and location, Anne Fatone should be notified that a room is needed at SLR. She will contact Legia Colon via e-mail and confirm that a room is available for the interview to take place. Directions will be sent to the participant, if needed. Interviews will be held at 425 West 59th Street, Suite 7A on the 7th floor. Blood draw and processing will follow the same procedure as for Mount Sinai.

INTERVIEWS AT KINGS COUNTY HOSPITAL

Scheduling the Interview at Kings County Hospital

At a minimum, one Interviewer will be assigned to Kings County for one day per week. Debbie Bristol will serve as Recruiter for Kings County patients and schedule the appointments which will take place in an office at the hospital. Other Brooklyn patients can also be scheduled by additional recruiters at Kings County; after confirmation, Interviewer will advise Anne Fatone 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.

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

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.

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.

The goal for cases and controls is to administer all the study components in one visit, in the following order:

- 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

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 **consent** followed by **main questionnaire**. Show cards should 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).

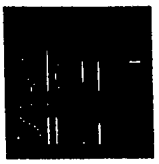
- While she is doing these final questionnaires, please do the following:

  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).



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**

7/29/02
Reference: Interview Process

V.

QUESTIONNAIRE ADMINISTRATION

Interview Topic Outline

Averting Refusals

Interviewer Questions and Answers

Questionnaire Reminders

Emotional Reactivity

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.

7/29/02
Reference:Questionnaire Admin.

Questionnaire Reminders

Questionnaire

Section D

Postmenopause refers to any woman who is no longer getting her period, for whatever reason, natural or surgical.

Section F

If different estrogens taken, list them separately.

Section G

List arthritis medications separately

Section H

Hospital: List borough if in New York City; otherwise, indicate city and state.

Section K

Check off if never lived with this person.
If unrelated male or female, indicate who person was.
If woman was adopted, indicate father under "Stepfather".

Section L

Indicate number of people lived with who smoked and at what ages.

Section O

Physical activity must total 100% for each job.
Regarding night shifts, if less than one shift/week, the answer is no. Night shift must begin after 7:00 pm and end by 9:00 am.

If still doing activity, do not complete age.

Section P

Indicate all years in which the even occurred. If never, check-off.

Section Q

Skip Q3 if woman single, never married or lived as married.

Page 56

Put ID sticker on this page.

Page 57

If cooperation fair or poor, answer question 3.

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.

General Comments

Rounding: Round up if more than ½ (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.

7/29/02
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.

7/29/02
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 note 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 carcinoma rarely metastasizes 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.

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 symptomotology criteria was not met and respondent does not need to be contacted.

10/8/02
Reference: Questionnaire Admin.

Interview Date:_____ Location:_____

Mental Health Inventory Summary Sheet
(How I Feel Scale)

Question	Response	Yes*	No
HIFS2	A	___	___
HIFS4	F	___	___
HIFS9	**A or B**	___	___
HIFS16	A or B	___	___
HIFS18	**F**	___	___

***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:

7/29/02
Reference: Questionnaire Admin.

VI.

Blood Draw

Phlebotomy Training Protocol

Practice Log Sheet

Interviewer Tracking

Introduction to Blood Draw

Biosafety

Blood Draw Protocols

Specimen Collection Record

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.

7/29/02
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

7/29/02
Reference: Blood Draw

Interviewer Tracking

Name of Interviewer: _____

Phlebotomy Training:_____

Phlebotomy Practice Complete:_____

CPR Training:_____

Anthropometry Training:_____

_____

_____

GCRC Orientation:_____

7/29/02
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 (30 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-born 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.

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 handiwipe.
- 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.

7/29/02
Reference: Blood Draw

PROTOCOL FOR COLLECTION OF BLOOD SAMPLES

1. After anthropometry, have participant complete Specimen Collection Checklist and then collect blood (30 ml.):

   2-10ml. Green-top tubes (sodium heparin additive) for plasma and buffy coat.
   1-10ml. Red-top tube for serum and blood clots.

   Blood should be collected in the following order: 1 green, 1 red, 1 more 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. If specimens cannot be delivered directly to the GCRC, follow the procedure for blood spinning. The date and time of specimen delivery will be recorded in the GCRC Log Book. A voice message will be left for Ildiko Libertini, x85567, advising her of the specimen collection.

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; check recipient for payment and put our account number: 2519-4716-3; check 4a (Express Package Service).
   - 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 Thursday.

   The Interviewer is responsible for following up with the participant and/or her physician and notifying Ildiko when to expect the specimen shipment.

Please Note: GCRC nurse practitioners can draw blood using a portacath, if necessary. GGCR Admission Form and Physicians Orders required. Also, patients receiving chemotherapy or radiation can have blood drawn at the time of interview or after treatment is completed, if they prefer.

10/8/02

Procedure for Spinning Blood
(To be used when GCRC does not process blood)

- Blood is transported to lab in room 16-02 East Building.
- Rubber gloves (Diamond Grip) to be worn at all times.
- Use 3 15ml. tubes with a blue top. Label the tubes "red" and "green", along with date and Study ID number.
- Carefully remove top of blood vials and pour blood into correct tubes. Dispose of vials in red biohazard bag.
- Close top of tubes tightly and place in centrifuge diagonally across from each other.
- Balance with one tube of water, to make 4 tubes.
- Put tubes in holders on scale and adjust amount of water until balanced.
- Return to centrifuge, align white markers with central knob, and lock centrifuge.
- Set speed at 1000 RPM and timer for 20 minutes.
- Remove from centrifuge holding steadily to avoid mixing.
- Place in tray and refrigerate.
- Leave a voice message for Ildiko Libertini, x85567.

7/29/02
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 <u>downward</u> position to prevent backflow.
- Inspect the arm you plan to use. The veins of choice are located in the anticubital 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. <u>The area should be dry.</u>

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 <u>three</u> 10 ml. tubes**, one green, one red and the final 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 <u>15°angle</u>, 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 first green 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 red and 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 text 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 handiwipe.

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.

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.

7/29/02
Reference: Blood Draw

MSSM BREAST CANCER STUDY

INCIDENT/EMERGENCY REPORT

1. Date of Incident/Emergency: _____ Time of Incident/Emergency: _____AM/PM	2. ID Number: ☐☐☐☐☐ Subject's Age: ☐☐☐
3. Subject's Symptoms (Please list.) _____ _____ _____ _____ _____	4. Medical/Emergency Procedures Followed: ☐ N/A
5. Emergency Equipment Used (Please list.) _____ _____ _____ _____ _____	6. Outcome of Medical Procedures Used: ☐ N/A
7. Identification of Emergency Services Used: ☐ N/A A. _____ _____ _____ (____)_____	B. _____ _____ _____ (____)_____
8. Identification of Medical Facility to Which Subject Was Taken: ☐ N/A _____ _____ _____ (____)_____	Accompanied Subject to Facility Y N Personal Belongings Sent with Subject Y N
1. Physician Contacted on: _____ Next-of-Kin Contacted on: _____ Supervisor Contacted on: _____	Specify Next-of-Kin: _____

Any other comments:	Research Interviewer Signature: _____ Date: _____

7/29/02
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.

7/29/02
Reference: Blood Draw

Mt. Sinai Hospital Department of Infection Control

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 mucus 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.

PROCEDURE

1. **Wash** the exposed area immediately with soap and water. (If mucous membranes were exposed, flushed with water.)
2. Immediately **report** the exposure to your supervisor.
3. **During regular business hours,** Supervisor contacts the **Needlestick Coordinator,** Beeper 4118; from outside MSMC: 241-5581 and ask for beeper 4118. Needlestick Coordinator will complete **Risk Assessment Checklist.**
4. **If not regular business hours,** employee completes **Risk Assessment Checklist.** Employee attempts to **obtain Informed Consent** for HIV testing.
5. If consent obtained, employee draws a blood sample using the **red test tube.**

6. Employee reports **within one hour** to Employee Health Service or the **nearest** Emergency Room.

7. Supervisor will complete **Blood/Body Fluid Worksheet.**

7/29/02
Reference: Blood Draw

VII.

DNA COLLECTION

Procedure

Materials

DNA Collection Procedure

In the event a participant does not agree to provide a blood sample, or if a sample cannot 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.

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. Place the container with the sample into the plastic bag. **Push the air out of the bag before sealing it.**

5. Specimen will be delivered to freezer in Room 16-02, East Building. Delivery will be noted in the Specimen Logbook and Ildiko Libertini, x85567, informed via voicemail of the specimen collection.

10/8/02
Reference:DNA

7/29/02
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

7/29/02
Reference:DNA

VIII.

ANTHROPOMETRY MEASUREMENTS

ANTHROPOMETRY TRAINING MANUAL
ADOPTED FROM:
The manual prepared by Irwin J. Shorr for the Women's Interview Study of Health.

7/29/02

Methods of Measurement
Anthropometry

The study and technique of measurements of the human body is called anthropometry. The training program is designed to help ensure that you take anthropometric measurements for this study using standard techniques. Body size characteristics such as weight, height, and waist-to-hip ratios have been linked with breast cancer risk among Caucasians and these relationships appear to vary by menopausal status. We are undertaking this study to examine whether the same associations exist among African-American women.

Anthropometry measurement data form

Record all measurements on this form, which contains the following information:

INJURIES ON THE RIGHT SIDE: Read the question verbatim and circle the appropriate response. If "yes", please specify the type of injury. See general guideline #1 for further instructions.

TIME: Enter the time that you begin the physical measurements.

TIME LAST EATEN: Enter the time the participant last ate.

TIME LAST CONSUMED LIQUID: Enter the time the participant last consumed fluid.

CLOTHING: Briefly describe the clothing worn by the subject during the measurements

The next part of the form is used for recording the measurements. The measurements are listed in the order that they should be taken. The first two columns are for recording the measurements taken. In the third column, the absolute difference (result of subtraction ignoring the sign) between the two measurements is calculated. The forth column shows the tolerance level. The fifth column is available should it be necessary to take a third measurement (this is discussed in more detail below).

INTERNAL MEDICAL DEVICE: The body composition machine cannot be used if an individual is wearing an **internal electronic medical device** such as a pacemaker, ventricular assistive device, or implantable cardioverter defibullator.

IMPLANTS: Implants will skew the readings from the Tanita machine. Ask the question verbatim and circle the appropriate response. If "yes", please specify the type of implant. For example "hip replacement, "knee replacements", "breast implants", or "breast replacement/augmentation". Women with internal implants (including those which are metal or plastic) that are NOT electronic can use the machine. However, you should circle "yes" to the response about any other implants. Please SPECIFY where (location on the body, e.g., breast, knee, etc.) and what type of implant (e.g., metal or plastic) the woman has.

TANITA OUTPUT: Attach the body composition machine output in this location.

COMMENTS: Explain any problems that you may have had. Enter any pertinent comments. Measurement skills and efficiency will improve with practice. Do not be discouraged if it takes a few minutes longer to do these measurement in the beginning of the data collection.

Preparing the participant for the measurements

At the time the interview is scheduled, participants will be asked to wear comfortable, light, loose-fitting clothing, e.g., slacks or shorts and a loose shirt or blouse. The circumference measurements as well as the Tanita machine (which resembles a scale) will probably be new experiences for the participant.

Before you begin, you should explain to them exactly what you will be doing.

The instruments are not designed for very obese persons. The limit of the tape measure used for the circumferences is 180 centimeters or 71 inches. The limit of the body composition machine is 200 kilograms or 440 pounds. For an obese participant, please take as many measurements as you can.

Record the reason for not taking a measurement in the comment section of the form.

Measurements will be taken toward the end of the interview to ensure that all of the participants have engaged in no heavy physical activity as well as had no food or fluid equivalent to the amount of a full meal for at least one hour prior to the measurements. Interviewers will begin by recording the study ID, interviewer ID, date, time of day as well as any the time of last food and fluid (including water) consumption on the data form.

Remember that some of the women will have cancer. You must be authoritative yet gentle when taking your measurements. Your own sense of calm, sensitivity, professionalism and self confidence will be felt by the women.

General guidelines:

1. All the measurements are being taken from the right side of the subject. After you have explained what measurements you will be taking, ask the woman if she has any past or present injuries that might make these measurements uncomfortable.

   Measurements should be made on the left side of the body if:

a. The participant reports surgery of the right breast.

b. The participant currently or in the past has had a right arm injury, e.g., broken bones, sprains, surgery, that results in pain, swelling, or deformity.

c. The participant, for any reason, requests that you not make measurements on the right side.

If measurements are made on the left side, this should be noted in the comments section. Else, it will be assumed that they were made on the right side. Example: "Measurements taken on left side – right side lumpectomy".

If you begin measurements on the right side and switch to the left side for a specific measurement, remember to switch back to the right side for the remainder of the measures.

2. After you take a circumference at a certain location, you should repeat the entire measurement at the same location. Begin, by re-locating the appropriate spot to make the measurement. Do not assume that the spot you located the first time is correct.

3. Before taking the mid-upper arm, waist, and thigh circumference measurements, determine the right spot by marking it with a washable pen (small dots or "x").

4. Circumferences and height will be measured and recorded in metric units. The folding yard stick is only in metric units. The circumference tape is in both metric and English units. Please only use the metric side.

   a. Each centimeter (cm) is divided into ten gradations that are 0.1 cm (1 millimeter (mm)). The line at five mm is slightly longer.

Reading and recording measurements:
It is critical that you keep the "Anthropometry Measurements Data Form" next to you so that a measurement is recorded immediately after it is taken. Even a few seconds time in between the completion of a measurement and recording it can cause an error.

To help minimize error during the reading and recording of measurements, follow these steps:

1. Immediately call the measurement out loud. The units of the measurement, i.e., centimeters, should not be read aloud. Example: 83.6 should be read as "Eighty-three point six" not as "Eight three point six".

2. Immediately record the measurement. Please use leading and trailing zeros. Make sure you do not leave any boxes empty. For instance: Midarm circumference is 21.0 cm.

Incorrect
21.

Incorrect
2 1 0 . 0

Incorrect
2 1 . 0

Correct
0 2 1 . 0

3. Check the measurement that you record to make sure it is accurate and legible.

Height

STEP 1. Locate an area in the home with a firm floor (preferably not heavy carpet).

STEP 2. Have the woman remove her shoes. Her hair should be as flat as possible (she may have to remove barrettes or combs, etc. or take down buns or hairpieces).

STEP 3. Have the woman stand erect. Have her stand with her back against the wall, with her heels against each other and both heels touching the wall, knees together, feet in a small "V". Her buttocks, shoulder blades, and heels should touch the wall. Sometimes it is impossible to position the woman's heels, buttocks, and shoulder blades against the wall and have her stand erect. If the back is arched due to large buttocks, move her forward and have only one part, usually the buttocks, in contact with the wall. See diagram on next page.

STEP 4. Feet should be flat on the floor, legs and back straight and arms hanging at her sides.

STEP 5. Ask the subject to stand up and to look straight ahead. Position the head so that the imaginary line drawn from the bottom of her eye socket through the midpoint of her ear forms a 90 degree angle with the wall. This is known as the Frankfort horizontal plane (chin slightly down, eyes and ears aligned when looking at the person from the side). The back of the head usually does not touch the wall. Note: you may have to assist the woman in adjusting her head into this position.

STEP 6. Stand in front of individual and verify positioning.

STEP 7. Tear off a small piece of tape and keep in one hand. Note: Only use the tape that you have been provided with, since it is designed to not pull paint off the wall.

STEP 8. Approach the woman on her right. With the drawing triangle, make a 90 degree angle with the top of the woman's head and wall. Place the piece of tape on the bottom corner of the triangle on the wall so that the bottom of the tape is aligned with the bottom of the triangle.

STEP 9. The woman can step aside after the tape is firmly on wall.

STEP 10. Unfold the folding ruler all the way into a straight line. Take the measurement from the floor to the lower edge of the tape you placed before. Take the reading shown on the folding ruler to the nearest 1 mm.

STEP 11. Read and call out the height measurement.

STEP 12. Immediately record the height measurement to the 0.1 cm on the data form. Check the recorded measurement for accuracy and legibility.

Tolerance. Standing height is only measured once.

Midarm Circumference

To determine the midpoint of the woman's arm, follow the steps outlined below. The midpoint is at the center of the arm length, which is the distance between the lateral projection of the acromion process of the scapula (shoulder) and the inferior margin of the olecranon process of the ulna (elbow).

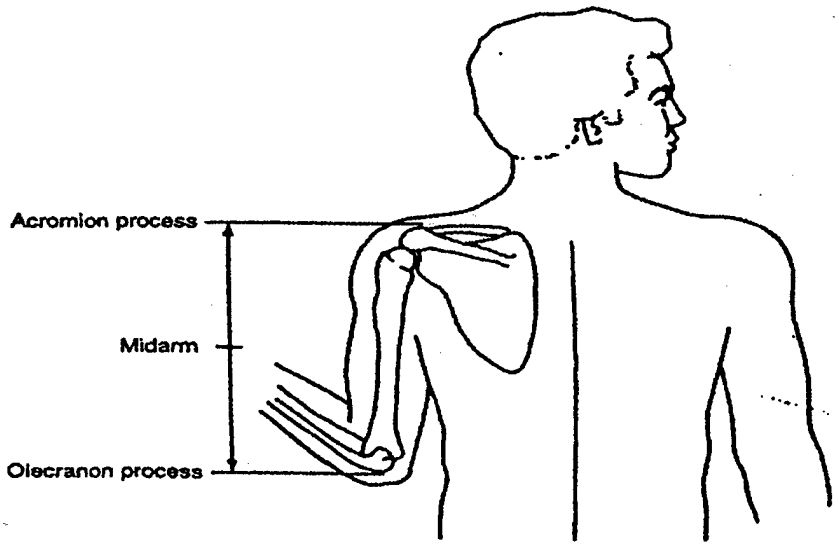


Illustration from:
Clinical Nutrition and Dietetics 2nd edition, by Frances J. Zeman.
Macmillan Publishing Company, 1991.

STEP 1. This measurement will be made on the bare arm.

STEP 2. Have the woman stand erect, with her right arm at a right angle (90 degrees) and the palm facing upward. You should be on the right side and slightly behind the subject.

STEP 3. Locate the shoulder with your finger tips. This is the body protrusion of the posterior of the upper shoulder at the end of the scapular ridge. To find the exact bone on the shoulder, have the subject move her arm forward and backward and find the joint between shoulder and upper arm. You can feel the movement of the joint. Mark the spot with the washable pen.

STEP 4. Locate the elbow. This is the bony point or tip of the mid-elbow. Mark the spot with the

washable pen.

STEP 5. Measure the length from the shoulder to the elbow. Make sure that you pull the tape straight down and do not bend it around the arm.

STEP 6. Read the number at the tip of the elbow to the nearest centimeter.

STEP 7. Divide the number by two. This is the midpoint of the upper arm. Hold the tape with one hand and mark the midpoint with the washable pen.

STEP 8. Now you are ready to determine the circumference. Ask the woman to drop her arm so that it hangs loosely and comfortably at the participant's side and the palm facing the thigh.

STEP 9. Hold the tape measure in your right hand. Pull out some of the tape with your left hand. Make sure you are using the side of the tape that is in metric units (the numbers in red). Line the zero line up with the midpoint spot on the woman's arm.

STEP 10. Bring the tape around the back of the woman's arm and place it below the zero end of the tape. Make sure the tape is flat against the woman's skin.

STEP 11. Shift the grip of your right hand to hold the tape and the grip of your left hand to hold the tension meter. Pull until you see the silver ring between the two red balls.

STEP 12. Verify that the tape is in the satisfactory position with the correct tension. When you are satisfied that the tape is correctly positioned, read and call out the arm circumference.

STEP 13. Immediately record the arm circumference measurement to the 0.1 cm on the data form.

Check the recorded measurement for accuracy and legibility.

Tolerance. The tolerance for the mid-arm circumference is 0.2 cm. If the absolute difference between your first and second measurement is greater than 0.2 cm, take a third measurement and record it on the spaces provided.

Waist Circumference

STEP 1. This measurement will be made directly on the skin if possible.

STEP 2. The subject stands erect with the abdomen relaxed, arms at the sides and feet together. You should be on the right side and slightly behind the subject.

STEP 3. Palpate the hip area for the right iliac crest and make a small mark with the washable pen.

This level is usually, but not always, at the level of the umbilicus (belly button). The correct measurement site is the intersection of LINE 1 (mid-axillary line) with LINE 2 (just above the hip bone).

LINE 1 divides the body into a front (anterior) and back (posterior). LINE 2 can be identified by locating the anterior superior iliac spine and following the bone back to the mid-axillary line. The mark should be made at the bone, but the tape should be placed directly above the bone/mark. To locate the iliac crest, it may be easier to locate the ribs first and then move down. NOTE: If you cannot locate this spot on a woman then you should use the narrowest part to make your measurement. This should be noted in the comment section. Example: "Measurement made at narrowest part – unable to locate iliac crest."

STEP 4. Use the technique described for the mid-arm circumference. Place the tape around the waist covering this mark in a horizontal plane indicated by the iliac crest.

STEP 5. Hold the tape snugly against the skin around the subject's waist, without compressing the skin.

Pull until you see the silver ring between the two red balls on the tension meter. **Ask the woman to help you hold the tape around her waist**. The tape should be level with the floor.

STEP 6. Watch the woman breathe. The measurement should be read at the end of a normal expiration.

When you are satisfied that the tape is correctly positioned, read and call out the waist circumference.
STEP 7. Immediately record the waist circumference measurement to the 0.1 cm on the data form.

Check the recorded measurement for accuracy and legibility.

Tolerance. The tolerance for the waist circumference is 2.0 cm. If the absolute difference between your first and second measurement is greater than 2.0 cm, take a third measurement and record it on the spaces provided.

Hip Circumference

STEP 1. This measurement will be made directly on the skin if possible. Else, make measurement with minimal clothing.

STEP 2. The subject stands erect, arms at the sides and feet together.

STEP 3. The observer squats at the right side of the subject so that the level of maximum extension of the buttocks can be seen.

STEP 4. Use the technique described for the mid-arm circumference. Place the tape around the

buttocks in a horizontal plane. The tape should be level with the floor.

STEP 5. Go up and down with the tape to find the widest spot. Pull until you see the silver ring between the two red balls on the tension meter.

STEP 6. When you are satisfied that the tape is correctly positioned, read and call out the hip circumference.

STEP 7. Immediately record the hip circumference measurement to the 0.1 cm on the data form. Check the recorded measurement for accuracy and legibility.

Tolerance: The tolerance for the hip circumference is 2.0 cm. If the absolute difference between your first and second measurement is greater than 2.0 cm, take a third measurement and record it on the spaces provided.

Weight and body composition:

NOTE: This device cannot be used by individuals who have a pacemaker or other internal medical device. Thus, before you take this machine out of the bag, you must ask the woman whether or not she has such a device. Ask the woman the question on the measurement form and circle the appropriate response. If "YES" then the anthropometry section of the interview is over.

STEP 1. Locate a flat or level surface, near an electrical outlet. To determine if surface is level, check the level gauge to make sure the air bubble is in the center of the red circle.

STEP 2. Set-up the unit. Connect the weighing platform to the control box. Then, connect the control box to the power outlet.

STEP 3. Turn on the power, by pressing the "ON/OFF" key. Note: do not have the woman stand of the platform.

STEP 4. Enter clothes weight, by using the numeric keys. The "CE" key can be used to correct a mistake, or to clear previously entered information.

We cannot ask a woman to remove her clothes so that we can weigh them. Thus, we have provided the following chart for you to determine how much to enter for the clothes weight. Only one weight is entered so you must locate the items that the woman is wearing and sum the weights to calculate the clothes weight. Use the rounding rule when necessary. Do not forget to describe the clothes the woman is wearing on the "clothing" section of the anthropometry form. Note: women should be asked to remove outer layers of clothing such as sweatshirts or sweaters. They must also remove their shoes and socks.

Clothing Weight (kilograms)
Shorts 0.4
Jeans 0.7
Cotton pants 0.3

All other pants (i.e., wool slacks, khakis) 0.4
Dress 0.5
Skirt 0.2
Chenille or heavy top 0.5
Silk blouse (long or short sleeve) 0.1
Long or short sleeve blouses or shirts (not in previous 2 categories) 0.3

STEP 5. Enter either "Female/Standard" or "Female/Athletic". "Athlete" is defined as a person involved in intense activity for at least 10 hours per week.

STEP 6. Enter age, using the numeric keys.

STEP 7. Enter height, using the numeric keys. Enter the height, in centimeters, from the measurement form. Height it entered rounded to the nearest centimeters.

The Rounding Rule

□If a number is less than half, round down.

□If a number is more than half, round up.

□If a number is exactly half, round up.

Therefore, if the answer is 152.3 centimeters, you would round down to 152. If it is 152.8 centimeters, you would round up to 153. But, if it is 152.5 you would round up to 153.

STEP 8. Ask the woman to remove her shoes and socks, and any heavy or outer clothing (e.g., jacket or sweater).

STEP 9. When the flashing arrow appears next to "STEP ON", ask the woman step on the weighing platform in bare feet. Make sure the heels are placed on the posterior electrodes, and the front part of the feet are in contact with the anterior electrodes. Ask the subject to stand still on the platform, body weight evenly distributed, head erect, arms down at the side, and eyes looking straight. This is required for approximately one minute.

STEP 10. You will now see the woman's weight, in kilograms, displayed. This will be followed by four "bubbles" on the bottom half of the LCD. The bubbles will disappear one by one. The woman should remain on the platform until the final bubble has disappeared, and the display emits a short beep.

After the beep the woman can step off the platform and put back on her shoes.

STEP 11. Weight and percent body fat will be displayed on the LCD, then the results will automatically print out.

STEP 12. Attach the print-out SECURELY to the anthropometry measurement form.

STEP 13. Press the "ON/OFF" key to turn the power off.

Clean-up

STEP 1. Wipe the weighing platform of the body composition machine with an alcohol wipe.

STEP 2. Disassemble the machine and pack it up.

STEP 3. Wipe the circumference tape with an alcohol wipe. Allow it to air dry for a few minutes and then role up.

IX.

Personnel Resources

Buddy System

Staff Listing

7/29/02

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

Recruiters/Interviewers

Interviwer: Lucia Dettenborn	**Sherly Jacob**	**Meredith Grossman**
Recruiters:		
Marcia Butler 718-937-4220	Debbie Bristol Kings County Hospital 718-245-4737	Eileen Abiola 718-816-1655
Valerie Ingoglia 718-728-1867 (H) 718 706-5395 (W)	Glorie Browne 212-368-3868	Medina Byars 718-430-4166 (W) 718-863-1799 (H)
Iris Mendez 718-798-5345	Beverly Coll 718-627-9245 (H) 718-812-1020 (cell)	Carol Copeland 212-864-0867
Layda Rodriguez 212-831-4967(H) 646-831-8032 (cell)	Pat Drew 212-410-1309	Alice Jaworsky 718-721-1355

Back-up Interviewers

Yahaira Gutierrez
Anne Fatone

10/8/02
Reference: Personnel Resources

STAFF LISTING

	Office Number	Mobile Phone	Beeper
Lina Jandorf, M.A., Principal Investigator, Core A	659-5506	917 650-3751	917-424-0702
Christine Ambrosone, Ph.D., Principal Investigator, Project 1	659-5552		
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		
Senaka Peter, M.P.H., Project Coordinator	659-5406		
Anne Fatone, Ph.D., Research Fellow	659-5407	917 837-0106	917-919-3565
Lucia Dettenborn, M.S., Research Interviewer	659-5473	917 607-3195	
Sherly Jacob, B.A., B.S., Research Interviewer	659-5405	917 650-4835	
Meredith Grossman, B.A., Research Interviewer	659-5474	917-519-9425	
Yahaira Gutierrez, B.A., Research Interviewer	659-5482		
Linda Lumpkin, Administrative Assistant	659-5546		

All office exchanges are in Area Code 212.

10/8/02
Reference: Personnel Resources

X.

INTERVIEWER CHECKLISTS

Checklist

Post-Interview Checklist

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, L. Dettenborn, I. Libertini
- ☐ 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; Ildiko Libertini x85567; and notate in Interview Room Reservation Book. If interview at another hospital site, notify appropriate personnel.

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
    - ☐ Tape Measure
    - ☐ Washable pens
    - ☐ Extension cord
- ☐ Blood draw items:
    - ☐ Tourniquet
    - ☐ Chuks pads
    - ☐ Test Tubes (2 green, 1 red); **take extras**
    - ☐ Vacutainer Holder

- [ ] Alcohol pads
- [ ] Gauze
- [ ] Bandaids
- [ ] 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
- [ ] 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 material
- [ ] GCRC Admission Form
- [ ] GCRC Orders Form
- [ ] Envelopes, stamped/addressed to MSSM for self-report scales
- [ ] Incident Report Form
- [ ] HIV Test Consent
- [ ] Risk Assessment Form
- [ ] Mental Health Inventory Summary Sheet

POST-INTERVIEW

- [ ] Notify office of departure (if offsite)
- [ ] Bring blood specimen to GCRC or DNA to East Building, Room 16-02
- [ ] Record specimen transport and delivery time/date in GCRC Logbook; notify Ildiko x85567
- [ ] 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
- [ ] Shred Interviewer copy of Contact Sheet
- [ ] Re-stock carry-all and/or interview room

10/8/02

Reference:Interviewer Checklists

	Eligible	Material Given	Signed Consent
Project 2	_____	_____	_____
Project 3	_____	_____	_____

Gift Card Serial Number:_____**Metrocard:Yes**____**No**____
Date Thank You Mailed:_____
7/29/02
Reference: Interviewer Checklists

XI.

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

Blood Draw Instructions to Physicians

Breast Study Recruiter Training Manual

Recruiter Training Program

Agenda

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 - Buddy System
6:30-7:00	Recruiters' Role - 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!

8/14/02
Reference: Agenda

II.

Why This Study?

Program Description

8/14/02
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.

8/14/02
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

8/14/02

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.

8/14/02

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

8/14/02
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.

8/14/02
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. _____

8/14/02
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....*

8/14/02
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 is 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

8/14/02
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.

Goal	Questions or Statement
1. **Get the facts**	**What do you understand about this study?**
2. **Discuss feeling and give emotional support**	**How do you feel about participation in this kind of research?**
3. **Give facts/informational assistance**	**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.**
4. **Help solve problems**	**Do you have enough time to participate?**
5. **Guide a decision**	**Do you have questions I can answer?**

8/14/02

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

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 infection 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.

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.

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 note 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.

Sequence of Subject Recruitment

1. Cases are identified by:
   - Physicians directly or through pathology reports, followed by physician approval to contact patients.

2. Controls are identified by:
   - General public controls are identified by a RDD (random digit dialing) company through phone lists or HCFA listing for Medicare.

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 and controls are assigned to recruiters. Packets are given to recruiters and include:

- Contact sheet
- Script for phone call
- Reimbursement forms
- Self-addressed stamped envelopes from MSSM

5. Post-cards with the recruiter's picture and name
   will be sent in envelopes by MSSM staff to the subject.

6. Recruiter will contact subjects within 14 days if possible.*

7. Recruiter notifies interviewer of interview date and location and interviewer forwards directions to participant.

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.**

8/14/02
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.

8/14/02
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.

- ☐ Enthusiastic
- ☐ Excited
- ☐ Willing to help
- ☐ Pleasant
- ☐ Nervous
- ☐ Hesitant
- ☐ Angry
- ☐ Depressed
- ☐ Not sure if they want to participate
- ☐ Would like more information about the study
- ☐ Questions for staff about the study

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 Seneka Peter at Mount Sinai by calling 1-866-223-2219 or 212 659-5406."

8/14/02

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**:
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. Have you ever had any form of cancer other than basal cell or squamous cell skin cancer? IF YES, FIND OUT WHAT KIND, 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 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 and can be conducted at either Mount Sinai Hospital, 98 St. & Fifth Ave.; St. Luke's Roosevelt Hospital, 59 St. & 9th Ave., Queens Hospital Center, 164th St. Jamaica, or Kings County Hospital in

Brooklyn (Tuesdays and Fridays only), whichever is more convenient for you. That's all there is to it. So, do you have any questions?

If the hospital locations are not acceptable, offer to have the interviewer conduct the interview 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 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 on the phone?
(SEE QUESTIONS FOR NON-PARTICIPANTS ON LAST PAGE)

(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 another hospital? What is a good time and day for you?

INTERVIEW LOCATION:_____
DAY INTERVIEW SCHEDULED:_____DATE:_____TIME:_____

I will tell _____, the Interviewer who will be meeting you, that you are interested in being in the study, and she 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(interviewer) 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 her before she calls, let me give you (interviewer's) phone number: _____.
Thank you so much for your time, and for agreeing to be in this study.
Date Directions Sent _____
8/20/02 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.

- ☐ Enthusiastic
- ☐ Excited
- ☐ Willing to help
- ☐ Pleasant
- ☐ Nervous
- ☐ Hesitant
- ☐ Angry
- ☐ Depressed
- ☐ Not sure if they want to participate
- ☐ Would like more information about the study
- ☐ Questions for staff about the study

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 Seneka Peter at Mount Sinai by calling 1-866-223-2219 or 212 659-5406."

7/24/02

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 there gave the study director your name. If you have time, I would like to tell you about the study.

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 want to tell you right at the start that there is no cost to you. In fact, you will receive a $25 gift certificate from either Pathmark or Rite Aide as our way of thanking you for participating in our study. I also want you to know that your privacy will always be 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. Also, this is not a treatment study and your involvement will not interfere with any treatment you may be undergoing. 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 and can be conducted at either Mount Sinai Hospital, 98 St. & Fifth Ave.; St. Luke's Roosevelt Hospital, 59 St. & 9th Ave.,

Queens Hospital Center, 164th St. Jamaica, or Kings County Hospital in Brooklyn (on Tuesdays and Fridays only), whichever is more convenient for you. That's all there is to it. So, do you have any questions?

If the hospital locations are not acceptable, offer to have the interviewer conduct the interview 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 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 on the phone?
(SEE QUESTIONS FOR NON-PARTICIPANTS).

(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 another hospital? What is a good time and day for you?

INTERVIEW LOCATION:_____
DAY INTERVIEW SCHEDULED:_____DATE:_____TIME:_____

I will tell _____, the Interviewer who will be meeting you, that you are interested in being in the study, and she 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(interviewer) 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 her before she calls, let me give you (interviewer's) phone number: _____.
Thank you so much for your time, and for agreeing to be in this study.
Date Directions Sent _____
8/20/02

STUDY ID: _____ **DATE:** _____
INTERVIEWER ID: _____

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/African
4 ☐ Black- West Indian / Caribbean
5 ☐ Black- Other
6 ☐ American Indian or Alaska Native
7 ☐ Asian Indian
8 ☐ Chinese
9 ☐ 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 ☐ Don't know/Refused

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

1 ☐ Less than 8th grade
2 ☐ 8th to 11th grade
3 ☐ High school graduate
4 ☐ Some college/college graduate/professional degree
9 ☐ Don't know/Refused

5. Do you have a mother, sister or daughter that has been diagnosed with breast cancer?

1 ☐ Yes
2 ☐ No
9 ☐ Don't know/Refused

6. Have you ever had a mammogram?

1 ☐ Yes
2 ☐ No
9 ☐ Don't know/Refused

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

___ ___ (number of mammograms)

8. What type of health insurance do you have?

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

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

___ ___. ___ (age in 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 ☐ Don't know/Refused

13. Have you ever taken birth control pills?

1 ☐ Yes
2 ☐ No
9 ☐ Don't know/Refused

14. Have you ever taken hormone replacement therapy?

1 ☐ Yes
2 ☐ No
9 ☐ Don't know/Refused

15. Do you currently smoke cigarettes?

1 ☐ Yes
2 ☐ No
9 ☐ Don't know/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

1 ☐ Pounds
2 ☐ Kilograms

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
8/14/02

RECRUITER/INTERVIEWER BUDDIES

Recruiters/Interviewers

Interviwer: Lucia Dettenborn	**Sherly Jacob**	**Meredith Grossman**
Recruiters:		
Marcia Butler 718-937-4220	Debbie Bristol Kings County Hospital 718-245-4737	Eileen Abiola 718-816-1655
Valerie Ingoglia 718-728-1867 (H) 718 706-5395 (W)	Glorie Browne 212-368-3868	Medina Byars 718-430-4166 (W) 718-863-1799 (H)
Iris Mendez 718-798-5345	Beverly Coll 718-627-9245 (H) 718-812-1020 (cell)	Carol Copeland 212-864-0867
Layda Rodriguez 212-831-4967(H) 646-831-8032 (cell)	Pat Drew 212-410-1309	Alice Jaworsky 718-721-1355

Back-up Interviewers

Yahaira Gutierrez
Anne Fatone

10/10/02
Reference: Resources

Mount Sinai Recruiter Reimbursement Form

_____ _____

Name (Please Print) **Your Signature**

_____

_____

Your Complete Mailing Address

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 Total

_____ x $10 = _____

# of contacts who **will** participate per contact Total

Total Reimbursement = _____

8/14/02

STAFF LISTING

	Office Number	Mobile Phone	Beeper
Lina Jandorf, M.A., Principal Investigator, Core A	659-5506	917 650-3751	917-424-0702
Christine Ambrosone, Ph.D., Principal Investigator, Project 1	659-5552		
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		
Senaka Peter, M.P.H., Project Coordinator	659-5406		
Anne Fatone, Ph.D., Research Fellow	659-5407	917 837-0106	917-919-3565
Lucia Dettenborn, M.S., Research Interviewer	659-5473	917 607-3195	
Sherly Jacob, B.A., B.S., Research Interviewer	659-5405	917 650-4835	
Meredith Grossman, B.A., Research Interviewer	659-5474	917-519-9425	
Yahaira Gutierrez, B.A., Research Interviewer	659-5482		
Linda Lumpkin, Administrative Assistant	659-5546		

All office exchanges are in Area Code 212.

10/10/02
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

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

Core B

"Molecular, Diagnostics and Research Core"

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 primers required for the amplification of the BRCA 1 and 2 coding regions have been selected and synthesized. Using these primers 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 2003, 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: "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 the tasks to be addressed in Year 1 by the Biostatistics and Data Management Core, along with the accomplishments associated with that task.

1. Design databases for data to be collected in Projects 1, 2, and 3.

   Members of Core C have worked with the investigators in each project in the designing of the questionnaires to be used for data collection. Suggestions have been made on the questionnaires to facilitate data storage and data retrieval. A database in ACCESS® has been designed for Project 1. Work is still on-going with investigators in Projects 2 and 3 in developing the questionnaires for data collection.

2. Write programs to establish databases for Projects 1, 2, and 3.

   A program in ACCESS® is under development to produce screens for entering data from the Project 1 questionnaire. The screens appear exactly like the layout of the questionnaire pages. Work on this program began as soon as the questionnaire was finalized.

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 form being entered while allowing for the entry of correct values.

For the tracking database (see task 4 below) this validation process has been done. Items for specific fields have been range-tested and logic-tested. Also, the security status has been tested so that persons with read-only privileges have been confirmed not to be able to make changes to the database; and persons with access to only certain modules of the database have been confirmed not to be able to be able to see or modify data in the restricted modules. Once the databases for the scientific data associated with Projects 1, 2, and 3, are complete, they will likewise be validated.

4. Develop a tracking system for data collected in Projects 1, 2, and 3 for use by Core A.

   An extensive Tracking Database for Project 1 has been completed in ACCESS®. This tracking database captures data on recruitment, enrollment, and on follow-up once individuals are enrolled in the study. Reports are generated for the Principal Investigator of Core A to be used in planning the workload of recruiters and interviewers. Reports are also generated to monitor the recruitment status by hospital site and by age group of eligible women.

5. Establish Master Logs for biological specimens.
   A database as been established in ACCESS® to capture information associated with each biological specimen. In this database, as in all other databases, there are no variables containing personal identifiers or confidential information. The specimens are identified only by the Study ID Number. The link between the Study ID and the name of the subject is maintained in a separate database that contains no other information and is password-protected.

REPORTABLE OUTCOMES:
None

CONCLUSIONS:
No data has been gathered and no analyses have been performed pending Army IRB approval. Thus, no findings can be reported at this time.

REFERENCES:
None

APPENDICES:
None

Core D

"Training Core"

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 during the 1990's, breast cancer continues to be a preeminent cause of morbidity and mortality among American women. This 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 postdoctoral 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:

As we have yet to receive official notification of HSRRB approval through the USAMRAA office for Project 1, 2, or 3, which will provide the research experience for the Trainees supported by this Core, we have intentionally delayed our previous timeline for completion of the training tasks listed in the Statement of Work of the funded Core (D). We have therefore only recently initiated efforts to address Task 1 and have little progress to report. We therefore propose for this next year, to modify our original Statement of Work, to delay the start dates of Task 1 and Task 3 by 9 months. In anticipation of a no-cost extension of the Center grant, we also propose to delay the end dates for these Tasks by 9 months. The current report itself, constitutes completion of Task 2.

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 initiated recruitment of Trainees and 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