CONSENT FORM – Read carefully, sign and give to the examiner

The Sister Study
Informed Consent Form

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Informed Consent Form

Title of Study:	The Sister Study: Environmental and Genetic Risk Factors for Breast Cancer
Principal Investigator:	Dale Sandler, PhD, Epidemiology Branch National Institute of Environmental Health Sciences (NIEHS)
Co-Investigator:	Clarice R. Weinberg, PhD, Biostatistics Branch, NIEHS

Consent to Participate in a Research Study

You are being asked to be in a research study of breast cancer among sisters. The National Institute of Environmental Health Sciences (NIEHS), one of the National Institutes of Health, Department of Health and Human Services, is conducting this research. This study will last at least 10 years. In all, about 50,000 sisters of women who had breast cancer will participate. It is very important that you read and understand the information below. This is called "informed consent."

Please read each page carefully. When you are done and are satisfied that your questions have been answered, please sign and date the form on the last page if you agree to participate in the study.

Purpose of Study

The purpose of this research is to look at the environmental, lifestyle, and genetic factors that may make some women more likely to develop breast cancer. We are studying sisters of women with breast cancer because sisters share some of the same genes and other characteristics, but may be different in other ways. Much can be learned by comparing the life histories of those women who get cancer in the future and those who do not. We will also study factors related to other health problems like heart disease and osteoporosis, and will use your information and specimens to help us study these other conditions.

Eligibility

You are eligible to be in this study if —

- You are a woman living in the United States or Puerto Rico
- You have never had breast cancer
- You are 35 to 74 years old, and
- A sister of yours was diagnosed with breast cancer.

Voluntary Participation

You may decide to participate in this study or not. You may decide to drop out at any time. Your decision will not affect the care you receive from any medical care provider or medical benefits to which you are entitled. If you decide to withdraw from the study at a later date, we will keep the information we have collected up to that point, but will not ask you for any more information. We will continue to use the data and specimens you provided up to that time unless we get a signed written request from you asking us not to do so. If you decide to withdraw from the study, you should call 1-877-4SISTER to tell the study staff of your decision. The investigators conducting the study may also decide to withdraw you from the study without your consent if it is determined that you are not actually eligible or are no longer able to complete the requirements of the study.

Our Research Team

NIEHS designed and conducts, and has overall responsibility for the Sister Study. Social and Scientific Systems (SSS), a professional services research firm, and their subcontractor Westat are responsible for the day-to-day study management. SSS operates the telephone center and the biological specimen laboratory; Westat provides web and data management. EMSI performs the home visits described below.

All of these research partners are following guidelines and procedures established by NIEHS and approved by the NIH Office of Human Subjects Research, which exists to protect persons who participate in research studies.

Procedures of Study

There are **seven** tasks you will be asked to complete if you agree to be in the study:

1. **Using Kits that we will provide, collect a sample of —**
   - Your urine
   - Your toenail clippings
   - Dust from your house

   We will use these samples at a later date to measure certain chemicals, hormones, vitamins, and environmental agents. At this time, the type and number of tests we perform on your samples have not been determined. We will not test for illegal drugs. Not all tests will be done for all women. Although your samples may be analyzed for some things that could be clinically relevant, it may be many years before your sample is analyzed. If you have specific concerns about your health, you should consult your own doctor to discuss the need for any diagnostic tests.

2. **Allow us to send someone to your home to draw a blood sample (about 3 tablespoons)**.

   The trained female examiner who draws your blood will ship it to us along with the other samples (urine, toenail clippings, dust) that we asked you to collect. We will store your blood in a freezer so that at a later date we can use it to measure certain hormones, vitamins, chemicals, other environmental agents, and measures of biological function. We also will look at genes and gene products that could increase or decrease the risk of breast cancer or other diseases. At this time, the specific type and number of tests we perform on your blood sample have not been determined. We will not test for illegal drugs. While at your home, the

examiner will also ask to weigh you and measure your height and waist and hip circumference over your clothes. The examiner will also check your blood pressure to see if it is safe for us to draw your blood.

3. **Complete a detailed phone interview that will last about 2 hours. This interview will be completed in two sessions.**

   The interview takes about 2 hours. The interview will be completed in two sessions at times that are convenient for you. If possible, these sessions will be no more than two weeks apart. We will ask you questions about places you have lived and worked, your medical and personal history, hobbies, and physical activities. Some questions will be about topics some women may find sensitive, like use of alcohol, sexual orientation and genetic testing. We will also ask for your Social Security number. You may refuse to answer any question.

4. **Complete a set of questionnaires that are included in this Kit**.

   These will take about 90 minutes of your time in all. The questionnaires will ask about your diet, family history of cancer, and use of personal care products.

5. **Provide change of address information and health status updates every year to let us know about important changes in your health and contact information.**

   We will mail you annual update forms and ask you to return them, even if there have not been any changes in your health or contact information. You will be given extra copies of the update forms so that you can also notify us about important changes as soon as they occur.

6. **Fill out a questionnaire or do a telephone interview every other year while the study continues. In addition to a questionnaire, you may be asked to provide samples of tap water or other environmental samples.**

7. **Over the course of the study, some women will develop breast cancer. If you are diagnosed with breast cancer in the future, we ask that you notify us. We also ask that you let us know of other major health changes.**

   We will ask you for information related to your diagnosis and ask your permission to get a report from your doctor. We may also ask you for permission to request a sample of the breast tumor tissue that your doctor or hospital has saved after making your diagnosis. In addition, we may ask you to provide another blood sample. If you are not able to provide a blood sample at that time, we may ask you to provide a sample of the cells inside your cheek that we would collect by asking you to simply rinse and spit a mouthful of mouthwash. The rinse samples can be used in some, but not all, of the tests where we would usually use a blood sample. **It will be your choice whether or not you are willing to provide the additional information and samples we request.**

Some women will have **other diseases or conditions** such as heart disease, diabetes, osteoporosis, or autoimmune diseases that are important for women. This study gives us the opportunity to learn more about these other conditions. In the future, we may ask for your permission to contact your doctor about the diagnosis and treatment of other medical conditions. We may also ask you for more information about these conditions or for another blood sample. It will be your choice whether or not you are willing to give the additional information or sample we request. To better track your health, we may periodically search state and national databases that record health information.

Length of Participation

Women in this study will be followed for at least ten years. The information that we collect becomes more valuable over time as women in the study experience changes in their health. We also want to learn if environmental, lifestyle, and genetic factors influence treatment outcomes, survival, and quality of life following breast cancer diagnosis. It will be important for us to follow all women, including those who develop breast cancer, for the full length of the study. We hope that you will participate in the full length of the study. However, participation is voluntary, and you are free to withdraw at any time.

Use of Information Collected

The information we gather from you will be for research purposes only, and is not part of any diagnosis or treatment. The results of any tests done on your samples and the information you provide in the interview and questionnaires will be combined with the information from other women in the study. Together, these combined summary results will be used to prepare statistical reports and summaries that will be the basis for scientific publications and presentations at scientific meetings. Your name or individual results will not appear in any publications or reports.

We will store your biological and environmental samples indefinitely in a secure building. The investigators may dispose of the specimens when they are no longer needed. We may use your samples for other studies, but the exact studies have not been determined yet. We may also share these samples with other researchers for related research on women's health. These researchers will be bound by the conditions established by the Sister Study for the protection of your privacy and rights as a participant. The specimens will only have a number attached to them. We will not give other researchers any information that would allow them to identify you. Samples and data will only be shared for scientifically valid studies that meet approved standards for good science and for protecting the rights of participants. Samples and data that are shared can be used only for the specific research described in an approved research proposal and may not be used for other purposes without approval from the Sister Study.

Results of Tests

By enrolling in this study, you understand that you will donate your specimens for research purposes, and that you will not be informed of any of the results of the tests that may be performed on your specimens, with the exception that we will send you a urine glucose (sugar) report. Further research may be necessary before these results are meaningful. While some tests we perform may have known clinical importance, not all tests will be done for every woman in the study, and it may be many years before your individual sample is analyzed. **If you have specific concerns about your health, you should consult with your own doctor to find out about tests that are available and appropriate for you.**

During the time frame of the study, it is likely that we will gain new knowledge about preventable or treatable risk factors for breast cancer or other diseases. Although we will not be able to provide you with your individual test results, we will share such information with all the study participants through newsletters, email, articles on our website or other means. You can discuss this information with your doctor. The Sister Study is not designed to provide medical diagnoses or treatment.

Benefits

You will not receive any direct benefits from participating in this study. However, by taking part you will help us learn more about the causes of breast cancer and other diseases, and perhaps ways to prevent breast cancer in the future.

Risks

There is a small risk of bruising or infection at the spot where blood is withdrawn. Signs of infection are swelling, redness, or tenderness. If you have signs of infection, please contact your doctor or the Sister Study examiner at the toll-free number you are given at the end of your home visit (1-877-SIS-EXAM). You can always contact the Sister Study through our toll-free number, 1-877-4SISTER, to report any concerns following your home visit.

There is a slight risk of accidental breach of confidentiality although we will do everything we can to see that this does not happen. The study has obtained a "Certificate of Confidentiality" (see below) so that we cannot be forced by anyone to give out information that could identify you.

Confidentiality

Every effort will be made to protect the identity of the participants in this study. All of the study questionnaires, blood and urine samples, and other study forms and specimens will use a special identification number so your name will not be part of these materials. Your name will not be revealed in any publication. All study materials will be stored in a locked building and secure computer files.

Your specimens and information may be shared with researchers from other institutions. Any request for use of your specimens or information will first be reviewed by appropriate scientific and institutional review boards that are responsible for ensuring that the proposed research is of the highest quality and that your rights have been safeguarded. Your name will not be shared with other researchers.

Records that identify you in this study are private. No one other than research staff can look at them unless you agree to it. This is because the study has been granted a Certificate of Confidentiality under a Federal law (Section 301(d) of the Public Health Service Act). The Certificate helps researchers protect the privacy of research participants. With a Certificate of Confidentiality, researchers cannot be forced by anyone to give out information that could identify you.

A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about a participant if it is considered necessary to protect the participant or someone else from serious harm. A Certificate of Confidentiality also does not prevent you or a member of your

family from voluntarily releasing information about yourself or your involvement in this research. If an insurer or employer learns about your participation from you and you consent in writing to having information about you released, then we cannot use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Financial Costs

There are no costs to you other than your time for participating in the study. Costs for the blood draw, telephone interview, and shipments to us will be paid by the study.

Payments to Participants

You will not be paid to participate in this study; however, you will receive a phone card or some other small token of appreciation of similar monetary value.

Persons to Contact for More Information

You have the right to ask and to have answered all of your questions about this research. If you have questions, please call the study staff toll-free at 1-877-474-7837 and ask to speak with a member of the staff or either of the investigators, Dr. Dale Sandler or Dr. Clarice Weinberg. If you have any questions about your rights as a research participant, please contact the NIEHS Institutional Review Board, at 1-919-541-3852.

Before making your decision, please ask any questions you have by contacting one of the people listed above.

Participant Statement

I have read the above and have had my questions answered. I understand the requirements, the risks and the benefits of the study. I understand that participation is voluntary and that I may withdraw from the study at any time. I understand that by agreeing to participate in this study, I do not waive any rights regarding access to and disclosure of my records.

I consent to participate in the Sister Study.

_____ _____

Signature of Participant Date

_____ Form approved through 09/10/09 by NIEHS IRB

Printed Name of Participant

PLEASE RETURN THE COPY YOU SIGN. KEEP ONE COPY FOR YOUR RECORDS.