CHILD HEALTH AND DEVELOPMENT STUDIES
A project of the Public Health Institute

2nd Generation CHDS Daughter PEDIGREE

Prenatal Environmental Determinants of Intergenerational Risk (PEDIGREE)

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY BACKGROUND AND PURPOSE

You are being invited to participate in a research study being conducted by the Child Health and Development Studies (CHDS) in Berkeley, CA and Columbia University's Mailman School of Public Health. The study, Prenatal Environmental Determinants of Intergenerational Risk (PEDIGREE), is funded by the Breast Cancer and Research Environment Program, a joint effort of the National Institute of Environmental Health Sciences and the National Cancer Institute. You are being asked to participate in this study because you and your mother participated in the CHDS during your mother's pregnancy with you. The CHDS was a study of pregnancy and early child development that began over 50 years ago at Kaiser Permanente.

PEDIGREE is a study of the second generation of CHDS participants. The purpose of this study is to look at how the environment might affect health beginning in the womb, as people age, and at how it might play a role in the development of disease across generations. This study will help scientists learn about the relation between certain environmental factors, like chemicals in the environment, and the risk of developing breast cancer.

This study will be conducted by researchers at the CHDS, which is a part of the Public Health Institute, and researchers at Columbia University's Mailman School of Public Health. The Public Health Institute is a non-profit organization dedicated to promoting health and quality of life for people in California and throughout the world.

WHO IS BEING INVITED TO PARTICIPATE

The PEDIGREE study will ask about 400 women to give permission for the CHDS to obtain a copy of their past mammogram film(s) from the facility where they received this service. In addition, the study is requesting a saliva sample to examine genetic risk factors related to breast cancer.

STUDY PROCEDURES

By signing this consent form, you agree to participate in the PEDIGREE Study (mammogram collection and saliva collection). You may refuse to participate in any part of the visit and may withdraw from the study at any time.

If you decide to participate in the PEDIGREE study's mammogram and saliva collection:

1. You will be asked to sign mammogram authorization form(s), giving permission for the CHDS to obtain a copy of your past mammogram film(s) from the facility (or facilities if applicable) where you received this service.

You will be asked to provide a saliva sample by spitting into the Oragene collection container. The saliva sample will be tested to measure the amount of change in the chemical groups attached to DNA (DNA methylation) which measures gene activity.

USE AND STORAGE OF MAMMOGRAPHIC FILMS AND SALIVA SAMPLE

The saliva sample you provide will be stored at a secure laboratory facility with a protected, computerized inventory system. Your sample will be labeled with a study identification code; no personal identifiers such as your name, initials, or birth date will be used.

The saliva sample will be tested to measure the amount of change in the chemical groups attached to the DNA (DNA methylation) which measures gene activity. Your mammogram will be used to measure your breast density. Breast density is a measurable indicator of breast health, and can indicate future risk of breast cancer. The mammogram film will be scanned into a secure computer and software will be used to measure the breast density. The mammogram will not be used for diagnostic purposes. Original mammograms will be promptly returned to the lending hospital or radiological facility.

One of the purposes of these studies is to store DNA samples collected from saliva and mammogram films from study participants to use in the future for studies that are not yet planned. The CHDS has been able to contribute to scientific and medical knowledge because 50 years ago many of the mothers and fathers provided biological samples that were kept for future study. By adding your samples to this collection, you will enable researchers to expand the use of this resource to add to scientific and medical knowledge.

If you agree, your DNA sample and a copy of your mammogram film(s) will be stored for future research studies in areas such as women's health, environmental exposures, and genetics. In the future, features other than breast density that can be seen in your mammogram may be studied, for example, the structure of the breast.

CONFIDENTIALITY

All information obtained in this study will be kept strictly confidential. All study staff have signed a confidentiality agreement and have been specifically trained not to share information from any participant with anyone, including other members of the participant's family. Your information and samples will be assigned an ID number, and names, addresses, and phone numbers will be removed. The list of names and matching ID numbers will be stored separately from the other study information and they will only be available to the data collection team at the CHDS.

The results of future studies that use the study information may be published or presented to scientific groups, but information is presented in summary form and you will not be identified by name in these publications or presentations.

WHAT RESEARCHERS WILL DO WITH COLLECTED MATERIALS

In the future, scientists from other research organizations and universities may want to do research using the information (data) or de-identified samples. All research involving the testing of your samples will be carefully reviewed and approved by the CHDS scientists and the Institutional Review Board (a formal committee that reviews research studies to protect the rights of participants) at participating research institutions.

Research partners may include universities, as well as for-profit and non-profit research organizations. The CHDS will only approve projects with the potential to benefit the health of the public. It is possible that the results of the research performed on samples collected as part of the PEDIGREE study may someday lead to the development of a health test or other commercial product or service. You will not receive any personal financial benefit from any use of your samples.

Study scientists and research partners will be able to use information collected from your saliva sample and mammogram film(s), including that found in DNA (such as genes), together with the information you may have previously provided in questionnaires. This will help us learn more about how people's health is affected by things in the environment and behaviors, in combination with characteristics found in DNA.

Your consent at the end of this form allows you to specify if researchers can use your mammogram film(s), and if they can look, specifically, at your DNA collected through the saliva sample for such scientific purposes.

USE AND SHARING OF INFORMATION GAINED FROM THIS STUDY

By participating in this study, you give us your permission to use the information you provided in the DNA sample and mammogram film(s) collected during this study, which may be combined with past collected information, for future research studies in areas such as women's health, environmental exposures, and how health is related across the generations.

Your samples and information will be stored for as long as these studies are able to maintain them securely and they may continue to be used in research studies even after your death. In the event that the study can no longer store the samples securely, we will destroy them in accordance with standard protocols.

RESULTS OF THE STUDY

We plan to publish the findings of our studies in scientific journals. We are happy to provide you final study reports or reprints of any journal articles, when they are completed, at your request to the study director, Dr. Cohn. As the findings of the study are published, the CHDS website will be updated to include summaries of these results.

Testing of the collected samples will be done in a research lab and the tests are not for clinical use (meaning they are not intended to be used by doctors for diagnosing or treating medical problems). Your mammograms will be scanned into a computer and will then be used to measure the breast density by reading the mammogram film(s). If you wish, you will have the opportunity to learn how your results compare to other participants in this study. These results are not measured by a radiologist and should not be used to make decisions about your health care. If you are concerned, you can discuss these results with your doctor. You can show us your decision regarding this information by marking the check box on the final page of this document.

POSSIBLE RISKS

The procedures in this study are considered to be safe and pose minimal risk to you. We will not request mammogram films until they have been reviewed by a radiologist for breast abnormalities and all appropriate follow-up has occurred.

A potential risk would be the loss of privacy or confidentiality if unauthorized people had access to study records. The security measures we take make this a highly unlikely event. Information about how we maintain your privacy is described in greater detail in the "Confidentiality" section above. It is possible that mammograms or saliva samples could be mishandled in shipment. Mammograms and saliva samples will be shipped by FedEx or UPS, which have reliable systems for tracking materials in transit. The researchers are not aware that there have been any problems with shipping these kinds of films on other studies conducted.

POSSIBLE BENEFITS

There are no intended individual benefits from participating in this study. We do not expect the research results from these studies to be the kind of information that you, your doctor, or nurse practitioner would use to make decisions about your health care. Your participation in this study may add to overall understanding of how illness can be prevented, starting in early life. You may feel satisfaction having made an important contribution toward possible benefits to health of women in the future.

If you choose to receive results of the breast density score, you may decide to discuss the results with your doctor about your personal risk of breast cancer.

COMPENSATION

For your time and effort, you will receive $15 for completing the mammogram forms and saliva collection. At the conclusion of your participation in these studies, we will send you a check in the appropriate amount.

VOLUNTARY PARTICIPATION

Participation in this study is completely voluntary. You are free to refuse to participate in any part of the study. Your decision whether or not to participate in the study will not affect your medical care or health insurance in any way. Refusal to participate will involve no penalty or loss of benefits to which you would otherwise be entitled and you may discontinue participation at any time without penalty or loss of benefits to which you would otherwise be entitled.

If you participate now, but change your mind and wish to withdraw from the study at any time in the future, you may do so by sending written notification to the study director at the address provided at the end of this form. If you withdraw, we will destroy your sample and any information you provided as part of these studies, including your contact information. We will not be able to remove your information from studies already conducted on your samples or information, but any identifiable information and unused samples will be destroyed after your written notification of withdrawal is received.

FUTURE CONTACT

At some time in the future, we may want to contact you again to participate in other studies related to the CHDS. In these studies, we may ask you to fill out other surveys, complete an interview, or give new samples. If asked, you will be free to decline participation in future studies.

BILL OF RIGHTS OF STUDY PARTICIPANTS

California law requires that all research participants be informed of their rights.

As a study participant, you have the right:

- To be told about the nature and purpose of the study.
- To be told about the procedures in the study.
- To be told about any discomforts and risks to be expected from the study.
- To be told about benefits to be expected from the study.
- To be told of the other choices you have and how they may be better or worse than being in the study.
- To be told what sort of treatment is available if any complications arise.
- To be given the opportunity to ask questions about the study or the procedures.
- To be given the opportunity to withdraw from the study at any time.
- To receive a copy of the signed and dated consent form.
- To be free of pressure when considering whether you wish to agree to be in the study.

WHO TO CONTACT

For any questions concerning these studies, or if you are not satisfied with the manner in which these studies are being conducted, we encourage you to contact the study director, Dr. Barbara Cohn, by phone at (510) 649-6390, by email at bcohn@chdstudies.org, or by mail at the Child Health Development Studies, 1683 Shattuck Ave., Suite B, Berkeley, CA 94709.

Or you may report (without giving your name if you choose) any complaints to the Institutional Review Board by contacting Ms. Debora Pinkas, IRB Administrator at (510) 285-5500 or by addressing a letter to the Institutional Review Board, Public Health Institute, 555 12th Street, 10 Floor, Oakland, CA 94607.

STATEMENT OF CONSENT

I have read the above and am satisfied with my understanding of this study and the possible study benefits, risks, and alternatives. My questions about this study have been answered. I agree, or disagree, to the uses of my saliva sample and mammogram as indicated below:

I agree that the saliva samples I provided may be used to study my DNA; including genes and other information in my DNA that might be related to health. **Yes____ No____**

I agree that a copy of my mammogram film(s) may be stored, used and analyzed for the purposes of this research study and future as yet unnamed, research studies, as described in this consent form. **Yes____ No____**

If my mammogram film(s) are used for the PEDIGREE study, I want to receive a report of the study results. **Yes____ No____**

I hereby voluntarily consent to participation in the research study as described. I have been given a copy of this 6-page consent form to keep for my records.

_____ _____

Signature of Study Participant Date

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Printed Name of Study Participant