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

3rd Generation Adult CHDS Granddaughter Age 18 & older

Three Generations Study

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. This study, called the Three Generations Study (3Gs), is funded by the California Breast Cancer Research Program. The CHDS was a study of pregnancy and early child development that began over 50 years ago at Kaiser Permanente. Your grandmother participated in the study when she was pregnant with your mom. Now you are being asked to participate in the 3Gs study because your mother is participating in the study.

3Gs is a study of the second generation of CHDS participants (your mother) and their daughters (you). The purpose of the study is to look at how the environment might affect health beginning in the womb, as people age, and how it might play a role in the development of disease across generations. The study will help scientists learn about the relation between certain environmental factors, like chemicals in the environment, and the risk of developing breast cancer and other important women's health conditions.

The study will be conducted by researchers at the CHDS, which is a part of the Public Health Institute, 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

More than 4000 women whose mothers were participants of the CHDS will be asked to participate in a telephone interview. About 1000 of these women will also be asked to participate in a second phase of the study which includes an in-person visit and bio-specimen (blood, urine and saliva) collection. Any daughter (you) age 9 or older of these 1000 women will also be invited to participate in the study by completing the visit with their mothers.

Your participation will add a third generation to the first and second generations of families already participating in the CHDS, allowing researchers to study health across multiple generations.

STUDY PROCEDURES

By signing this consent form, you agree to participate in this study. You may refuse to answer any question and refuse any part of the visit you do not wish to participate in. You may also withdraw from the study at any time.

If you decide to participate in this study:

1. Your mother will be contacted by phone to schedule the in-person visit. At this time, we can only conduct one visit per household. We ask that you speak with your mother to find a time that works best for both of you to complete the visit.

2. At the scheduled time, a member of the 3Gs team will visit you and your mother. The examiner will be a certified phlebotomist (a person who is certified to draw blood) or a licensed practical nurse. The visit will take about 30 minutes of your time. The examiner will have gone through a rigorous background check before being allowed to make visits. The person will show identification when s/he arrives.

3. S/he will ask to measure your blood pressure, height, weight, and waist size.

4. S/he will request a blood sample. If you agree, s/he will draw three 10 ml tubes of blood and one 2.5 ml tube (which is equal to a total of approximately two tablespoons) from a vein in your arm.

5. S/he will ask for a sample of your urine and will provide you with a urine cup.

6. S/he will ask for a sample of your saliva and will provide you with a saliva collection tube to spit in.

7. S/he will assist you with filling out a form which lists all current medications and supplements, like vitamins, herbs or other over-the-counter products, you are taking.

8. You will be asked to fill out a written questionnaire. You will be mailed a booklet with questions about health and health behaviors. We will also ask about your menstrual and reproductive history, birth control, nutrition and physical activity. This booklet can either be picked up at the time of the visit or can be mailed back to the study in the enclosed, postage-paid envelope. It will take about 20-30 minutes to fill out.

USE AND STORAGE OF BLOOD, URINE AND SALIVA SAMPLES

The samples (blood, urine, and saliva) you provide will be stored at a secure laboratory facility with a protected, computerized inventory system. Your samples will be labeled with a study identification code and no personal identifiers such as your name, initials or birthdate will be used.

The 3Gs study will create a collection of blood, urine, and saliva 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 families provided blood 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 samples will be stored for future research studies in areas such as women's health, environmental exposures, and how health is related across generations.

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 SAMPLES

In the future, scientists from other research organizations and universities may want to do research using the samples or information (data). 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 3Gs 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 the use of your sample.

Study scientists and research partners will be able to use information collected from your blood, urine, and saliva samples, including that found in DNA (such as genes), together with the information you 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 blood, urine, and saliva samples and if they can look, specifically, at your DNA 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 provide in the questionnaire and the samples 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 the study is 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 and 3Gs websites will be updated to include summaries of these results. There are no current plans to test the blood, urine, or saliva collected from you as part of the 3Gs study. In the future, researchers will apply for research funds that will allow us to use your samples for research as described above.

You will be provided with results from the measurements of your blood pressure, height, weight, and waist size. The examiner will give you these results at the conclusion of the visit. These results are for your information and are not to be used to assess your risk for disease or for diagnostic purposes. You may contact your health care provider with concerns.

POSSIBLE RISKS

The procedures in this study are considered to be safe and pose minimal risk to you. There may be some discomfort associated with routine blood drawing, such as minor bruising, the possibility of bleeding, or infection at the site where the blood was drawn. In rare cases, it can cause fainting. In the extremely unlikely event that you sustain an injury as a result of the blood draw, you will need to see your own doctor. The study will not be able to provide medical care or reimbursement for a research-related injury.

A potential risk would be 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 (or the "Certificate of Confidentiality" section below).

POSSIBLE BENEFITS

There are no intended individual benefits from participating in this study. We do not expect the research results from the study 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.

You will be provided with results from the measurements of your blood pressure, height, weight, and waist size. The examiner will give you these results when the visit is completed. These results are for your information only and are not to be used to assess your risk for disease. You may contact your health care provider with concerns.

COMPENSATION

For your time and effort, you will receive $25 for completing the written questionnaire and you will receive $50 for participating in the visit. At the conclusion of your participation in the study, we will send you a check in the appropriate amount, based on your level of participation ($25 for the written questionnaire and $50 for the visit).

VOLUNTARY PARTICIPATION

Participation in the study is completely voluntary. You are free to refuse to participate in any part of the study or to refuse to answer any questions. 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 from 3Gs, we will destroy your samples and any information you provided as part of this study 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.

CERTIFICATE OF CONFIDENTIALITY

To help keep information about you confidential, the research team has obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). This certificate adds special protection for research information about you. It will allow researchers to resist demands, such as those from a court order or subpoena, to release information that could identify you. However, there is no absolute guarantee that a court order could not compel our researchers to release information about your participation. You should also understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself and your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. Additionally, the Public Health Institute Institutional Review Board and other regulatory agencies may need to review research documents for purposes of data and quality control. The researchers may also release identifying information in some circumstances. For example, they may disclose medical information in cases of medical necessity, or take steps (including notifying authorities) to protect you or someone else from serious harm, including child abuse. In addition, federal agencies may review our records under limited circumstances, such as a DHHS request for information for an audit or program evaluation. This Certificate does not mean that the DHHS approves or disapproves of the project.

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 study participant, you have the following rights:

- 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 this study, or if you are not satisfied with the manner in which this study is 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., Ste 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 the study, its possible benefits, risks, and alternatives. My questions about the study have been answered. I agree, or disagree, to the specific uses of my blood, urine, and saliva samples as indicated below:

I agree that my blood sample 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____**

I agree that the sample of my urine may be stored and used for future, as yet unnamed, research studies. **Yes____ No____**

I agree that the sample of my saliva may be stored and used for future, as yet unnamed, research studies. **Yes____ No____**

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

_____ _____
Signature of Study Participant Date

_____
Printed Name of Study Participant

_____ _____
Signature of Witness Date