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

**3rd Generation
Minor CHDS
Granddaughter Assent
and Parental Consent**

Three Generations Study

PARENTAL CONSENT AND MINOR ASSENT TO PARTICIPATE IN A RESEARCH STUDY

This form is to be signed by the second generation CHDS participant and her minor daughter.

STUDY BACKGROUND AND PURPOSE

Your daughter is 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 mother participated in the study when she was pregnant with you. Now your daughter is being asked to participate in the 3Gs study because you are participating in the study.

3Gs is a study of the second generation of CHDS participants and their daughters. The purpose of the study is to look at how the environment might affect health as people age and at 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 age 9 or older of these 1000 women will also be invited to participate in the study by completing the in-person visit with their mothers. The study is planned to last for five years.

Your daughter's 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 parental consent form, you agree to allow your daughter to participate in this study. You may refuse, on your daughter's behalf, to allow her participation in any part of the visit or to answer any question asked of her. She may also withdraw from the study at any time.

If you agree to allow your daughter to participate in this study:

1. Be sure that your daughter will available at the same visit that you (mom) schedule for yourself.

2. At the scheduled time, a member of the 3Gs team will visit you and your daughter. The examiner will be a certified phlebotomist (a person who is certified to draw blood) or a licensed practical nurse. Your daughter's segment of the visit will take about 30 minutes of her 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 daughter's blood pressure, height, weight, and waist size.

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

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

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

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

8. S/he will ask you and your daughter a few questions about your daughter's current health and development.

USE AND STORAGE OF BLOOD, URINE AND SALIVA SAMPLES

The samples (blood, urine, and saliva) your daughter provides will be stored at a secure laboratory facility with a protected, computerized inventory system. Her samples will be labeled with a study identification code and no personal identifiers such as her 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 her 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, her 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 daughter's 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 your daughter 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 3Gs 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. Your daughter will not receive any personal financial benefit from the use of her sample.

Study scientists and research partners will be able to use information collected from your daughter's blood, urine, and saliva samples, including that found in DNA (such as genes), together with the information 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 permission at the end of this form allows you to specify if researchers can use your daughter's blood, urine, and saliva samples and if they can look, specifically, at her DNA for such scientific purposes.

USE AND SHARING OF INFORMATION GAINED FROM THIS STUDY

By allowing your daughter to participate in this study, you give us your permission to use the health information and samples collected from her 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 daughter's samples and information will be stored for as long as the study is able to maintain them securely and may continue to be used in research studies even after her death. In the event that the study can no longer store the samples securely, we will destroy them in accordance with standard biological materials disposal 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 your daughter as part of the 3Gs study. In the future, researchers will apply for research funds that will allow us to use her samples for research as described above.

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

POSSIBLE RISKS

The procedures in this study are considered to be safe and pose minimal risk to your daughter. 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 she sustains an injury as a result of the blood draw, you will need to take her to see her 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 privacy is described in greater detail in the “Confidentiality” section above (and the “Certificate of Confidentiality” section below).

POSSIBLE BENEFITS

There are no intended individual benefits to you or your child from participating in this study. However, your participation in this study may somehow benefit all girls and women by helping us understand how illness can be prevented, starting in early life. Your daughter may feel satisfaction having made an important contribution toward the possible benefit to the health of women in the future.

You will be provided with results from the measurements of your daughter’s 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 risk for disease. You may contact your daughter’s health care provider with concerns.

COMPENSATION

For her time and effort, your daughter will receive a $50 check for participating in the in-person visit. We will mail your daughter the check, made out to her, to your address.

VOLUNTARY PARTICIPATION

Participation in the study is completely voluntary. Your daughter is free to refuse to participate in any part of the study or to refuse to answer any questions. Your decision whether or not to allow your daughter to participate in the study will not affect her medical care.

If your daughter participates now, but you or she feel differently later and wish to withdraw her from the study at any time in the future, you/she may do so by sending written notification to the study director at the address provided at the end of this form. If your daughter withdraws from 3Gs, we will destroy her identifiable samples and any information she provided as part of this study including contact information. We will not be able to remove her information from studies already conducted on her samples or information, but any identifiable information and unused samples will be destroyed after written notification is received.

CERTIFICATE OF CONFIDENTIALITY

To help keep information about your daughter 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 your daughter. It will allow researchers to resist demands, such as those from a court order or subpoena, to release information that could identify her. However, there is no absolute guarantee that a court order could not compel our researchers to release information about her participation. You should also understand that a Certificate of Confidentiality does not prevent her or a member of your family from voluntarily releasing information about her and her involvement in this research. If an insurer, employer, or other person obtains her and/or 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 her 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 your daughter again to participate in other studies related to the CHDS. In these studies, we may ask you and/or your daughter to fill out other surveys, complete an interview or give new samples. If asked, your daughter (or you, if she is under 18 at that time) 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, your daughter has 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 and agree to allow your daughter 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 AND PERMISSION

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 that my daughter may participate in this study. I know my daughter's participation in this study is our choice. By having my daughter also sign this form, the CHDS and I recognize her autonomy and will respect her privacy in the course of this study. I agree, or disagree, to the specific uses of my daughter's blood, urine, and saliva samples, if she so chooses, as indicated below:

I agree that my daughter's blood sample may be stored and used for the purposes of future, as yet unnamed, research studies, as described in this consent form. **Yes____ No____**

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

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

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

Statement of Assent

Signing my name here means that I have read the Three Generations Study Assent Information Sheet and that I agree to be in this study. My parents and I have our own copy of this form to keep.

______________________________	______________________________	____________
Printed Name of Child	Signature of Child	Date

Parental Consent

I agree to allow my daughter ____ to participate in this study.
printed name of daughter
I have been given a copy of this 6-page consent form to keep for my records.

______________________________	______________________________	____________
Printed Name of Parent	Signature of Parent	Date

Witness Signature

______________________________	______________________________	____________
Signature of Witness	Printed Name of Witness	Date