

## **CHILD HEALTH AND DEVELOPMENT STUDIES**

A project of the Public Health Institute

### **Consent to Authorize Use of Medical Information**

#### **Prenatal Environmental Determinants of Intergenerational Risk (PEDIGREE)**

##### **Why are you asking me to authorize use of my medical information?**

The Privacy Rule is a federal law designed to safeguard your Protected Health Information (PHI). Your PHI is individually identifiable information about you, including your physical or mental health, the receipt of health care, or payment for that care. The Privacy Rule requires that researchers obtain your written authorization to participate in the Prenatal Environmental Determinants of Intergenerational Risk (PEDIGREE) study being conducted by the Child Health and Development Studies (CHDS).

##### **What Medical Information am I authorizing the study to use?**

By signing this authorization, you will permit CHDS researchers to use and disclose your mammograms for the purpose of this research study. Your mammograms will only be used and disclosed as described in this authorization, except as otherwise required by law. **For the purposes of this study, your PHI refers to your mammogram film(s).**

##### **Who will use my mammograms?**

The CHDS and Columbia University research team will use your authorization to obtain a copy of your past mammogram film(s) from the facility where you received this service. Your mammograms may also be disclosed to persons assisting with this study or to others as required by law. In addition, your de-identified mammograms may be shared with scientists from other research organizations and universities in partnership with the CHDS. For more information please see the "What Researchers Will Do With Collected Materials" section on page 3 of the 3Gs and PEDIGREE consent form.

##### **What will the study use my mammograms for?**

CHDS researchers will use your mammograms to measure breast density, an indicator of breast health. One of the goals of the PEDIGREE study is to examine the relationship between early environmental exposures and breast health. In addition, others at the CHDS, for example the Institutional Review Board that approved the study, may also review your mammograms to monitor the study.

##### **When will this authorization expire?**

This authorization will expire at the end of the study.

**Can I withdraw this authorization?**

Yes, at any time during the study you may decide that you no longer want to have your mammograms used or disclosed as part of this study. If so, you must write a letter stating that you withdraw your authorization and send it to:

Barbara Cohn, PhD  
Child Health Development Studies  
1683 Shattuck Avenue, Suite B  
Berkeley, CA 94709

Even if you withdraw your authorization, CHDS researchers may be required by law to record and report anything that relates to your safety or the safety of others.

**What will happen to my mammogram after it is sent to the CHDS?**

The CHDS research team will use and disclose your mammograms only as described in this authorization. A potential risk would be the loss of privacy or confidentiality if unauthorized people obtain 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 on page 3 of the 3Gs and PEDIGREE study consent form.

**How will my mammogram be kept private?**

All identifying personal information associated with your mammograms will be removed and a study identification (ID) number will be applied to the mammogram film(s) and study data. All study information is stored in protected areas and is only accessible by study staff and is kept strictly confidential.

**Will I get a copy of this authorization?**

The researcher who is obtaining this authorization form must give you a copy of this form after you sign it.

**Authorization signatures**

This authorization has been explained to me, and all of my questions have been answered. By signing below, I am giving my permission to allow the use and disclosure of my PHI for the research study as described above.

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of Participant

\_\_\_\_\_  
Date