AUTHORIZATION TO USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

STUDY TITLE: Environmental influences on Child Health Outcomes (ECHO) Cohort Data and Biospecimen Collection Protocol

SPONSOR: National Institutes of Health (NIH)

PRINCIPAL INVESTIGATOR: Monique Hedderson, PhD

STUDY CONTACT PHONE NUMBER: (866)-405-2312

Why is this authorization required?

The Privacy Rule is a federal law designed to safeguard your Protected Health Information (PHI). You and your child's PHI is individually identifiable information about you, some of which includes your physical or mental health, the receipt or provision of health care, or payment for that care. The Privacy Rule requires that researchers obtain your written authorization (approval) for us to use and disclose (release) your PHI. A disclosure of PHI means communicating that information to a person or research facility/company outside of Kaiser Permanente Northern California.

By signing this authorization, you will permit Kaiser Permanente researchers to use and disclose your PHI for the purpose of the research study named above. Your PHI will only be used and disclosed as described in this authorization, except as otherwise required by law.

What is the purpose of the use or disclosure of my PHI?

Kaiser Permanente researchers will use your PHI, including your research and/or medical record, to conduct the study and determine research results. In addition, others at Kaiser Permanente may also review your research or medical record, or both, to monitor the study. This will include the Institutional Review Board.

What information will be used or disclosed?

To do this study, we will look at or collect information about you and your health, and that of your baby (after birth). Examples of information we will use or disclose include:

- Dates of birth, race, sex, gender, language, household information including address history, and jobs
- Health history, medications, immunizations (vaccines), and health insurance status
- Household environment and exposures to chemicals, drugs, and smoke
- Your health care, diet, and sleep
- Things that may cause stress in your life, relationships with family and other people, and what your neighborhood is like
- Blood, saliva (spit), urine, hair, placenta, and blood from the umbilical cord after childbirth
- Information about your child's behavior, diet, sleep, breathing, overall health, childcare and education, development, and relationships. We will also collect samples from the child like blood, urine, hair, stool, and teeth that fall out.

We will use and disclose your information electronically, by phone, or on paper.

The following identifiable private information about you will be used and disclosed:

- Name
- Address
- Dates, including birth date, admission date, discharge date, date of death
- Telephone numbers
- Electronic mail addresses
- Internet Protocol (IP) address numbers
- Medical record number
- Any other unique identifying number, characteristic, or code.

Must I agree to this authorization to participate in the research?

Yes, in order to participate in this research study, you must agree to the uses and disclosures of your PHI as described in this authorization.

Who will use or disclose my PHI?

Kaiser Permanente researchers and the research team will use your PHI for the purposes of this study as described in the consent form.

The Kaiser Permanente research team may also disclose your PHI to others outside of Kaiser Permanente. Your PHI may be viewed by or sent to the following: the ECHO Data Analysis Center at Johns Hopkins University and RTI International, collaborating investigators in the national ECHO program, including researchers at outside laboratories participating in ECHO, National Institutes of Health (NIH) representatives, the Department of Health and Human Services (DHHS), and other qualified approved researchers, including data consultants and laboratory staff.

Your PHI may also be sent to persons outside of Kaiser Permanente Northern California assisting with this study or to others as required by law.

How will the confidentiality of my information be protected?

Kaiser Permanente is committed to protecting your personal health information. State and federal law also require Kaiser Permanente to maintain privacy and security of your information in this study. To protect the confidentiality of your information, we will use a special code to label samples, questionnaires, forms, and other information instead of using names. The research study staff will keep the key to the code secure. We will store information needed to contact you separate from your research information and samples. We will keep all information and samples in locked rooms or cabinets or in secure computer systems.

When will this authorization expire?

All data collected for this study will be used for an indefinite period of time. As a result, there is no expiration for this authorization.

Can I withdraw this authorization?

If at any time you want to withdraw from this agreement, you must notify us in writing:

Monique Hedderson, PhD
Mosswood Pediatric Building
3505 Broadway
Oakland, California 94611
United States

After we receive your notification, we will continue to use only data that we have already looked at or disclosed, unless we need to monitor your data for your safety.

What will happen to my PHI after it is disclosed?

The Kaiser Permanente research team will use and disclose your PHI only as described in this authorization. However, if someone receives your PHI from Kaiser Permanente and then discloses it again to someone else, it may no longer be protected by this authorization.

Will I get a copy of this authorization?

The researcher who is obtaining this authorization from you 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.			
Participant Signature:		Date:	
Participant Printed Name:			
Signature of Person Explaining the Authorization			
I attest that I discussed this authorization with the participant named above, and the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.			
Person Explaining Signature		Date:	
Person Explaining Printed Name			