ECHO
Environmental influences on Child Health Outcomes
A program supported by the NIH

Consent to Participate in a Research Study

For Partners

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

PROTOCOL NO: None
WCG IRB Protocol #20181210
2093753

SPONSOR: National Institutes of Health (NIH)

INVESTIGATOR: Monique Marie Hedderson, PhD, MPH
Division of Research
2000 Broadway
Oakland, California 94612
United States

STUDY-RELATED PHONE NUMBER(S): (866) 405-2312 (24 hours)

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

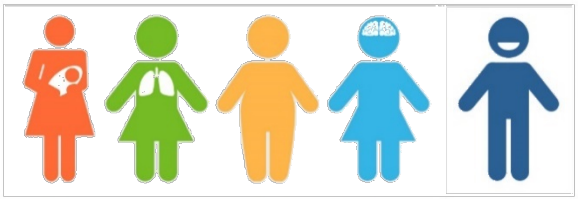
If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

BEFORE YOU READ THIS CONSENT FORM, YOU SHOULD HAVE READ THE KAISER PERMANENTE MEDICAL CARE PROGRAM, RESEARCH PARTICIPANTS' BILL OF RIGHTS. ASK THE STUDY STAFF FOR A COPY OF THIS DOCUMENT IF YOU HAVEN'T ALREADY RECEIVED ONE.

Summary

Taking Part in ECHO

- We are asking you to be part of ECHO to help understand how the environment and things that happen early in children's lives—even before they are born—affect their development, health, and well-being.
- This research program includes study sites at many locations in the United States.
- Dr. Monique Hedderson leads the ECHO study site where you are.
- ECHO will combine information from about 20,000 pregnant participants, more than 50,000 children, and their families.
- With so many participants from many parts of the U.S., researchers can answer questions that are important for children across the country.
- ECHO seeks to answer important childhood health questions. Some key questions are related to how the environment affects:
  - Pregnant people's and babies' health before, during, and after pregnancy
  - Children's breathing problems and breathing-related illnesses
  - Nutrition, physical activity, risks of becoming overweight, and weight-related illnesses
  - Brain development, including the ability to think and understand, social development, speech, attention, behavior, and emotions
  - Overall health, the ability to handle life's stresses, and general life satisfaction



Sponsor

The United States National Institutes of Health (NIH) supports this study.

Information and Samples

- We will ask for information like date of birth, jobs, and medical history and samples like saliva, urine, or sperm.
- ECHO will also collect information and samples before a person becomes pregnant again to help understand how things that happen before pregnancy affect child health.
- We will collect information and samples in person, through phone calls, mail, online surveys, or other ways.

Risk

- As with all research studies, it is possible that someone might see information that identifies you when they do not have permission. To lower this risk, we will use special codes to label samples, questionnaires, forms, and other information instead of names. However, we cannot completely remove this risk.

Taking Part in a Research Study

- Research studies include only people who agree to take part. You can decide whether or not to be in the study.
- Before agreeing to be in this study, you should read this consent form carefully, and ask any questions you have. Take your time making a decision.
- Ask the study staff to explain anything in this form that you do not understand.
- You can leave the study at any time. You may also decide not to give certain samples or not to answer certain questions.
- When you finish reading and someone has answered all of your questions, please sign and date this form if you agree to take part in the study.
- You will also be asked to sign a separate Authorization Form, which will describe how your personal health information, and that of your baby, may be used or disclosed by the researchers in the study.

What Is the Purpose of ECHO?

- ECHO is a nationwide research program whose mission is to enhance the health of children for generations to come.
- The goal is to learn how the environment affects children's health and development, and how it acts together with genetic information.
- The environment includes things that children or their parents may experience throughout their lives and even before they are born or become pregnant, like the air they breathe, foods they eat, medicines and drugs, interactions with other people, and the neighborhoods where they live.
- Looking at differences in genes, which are made of DNA, can help us learn how genes and the environment work together to affect children's growth, development, and health before and after birth, throughout childhood, and into adulthood. DNA is short for deoxyribonucleic acid. It is in every cell of every living thing and it carries information about a person's characteristics, for example, eye color. Each piece of information is carried on a different section of the DNA. These sections are called genes. Genes may affect how our bodies respond to the environment, and the environment may affect how our genes work.

What Will I Need to Do in the Study?

- We will collect information from you over approximately six months.
- We will ask you to complete questionnaires and other forms. You may be able to complete them on a computer or tablet, by mail, over the phone, or in person.
- Examples of information that we will collect from you include:
  - Date of birth, race, sex, gender, language, household information including address history, and jobs
  - Height and weight, health history, medications, immunizations (vaccines), and health insurance status
  - Household environment and exposures to chemicals, drugs, and smoke
  - Things that may cause stress in your life and relationships with family and other people
- We may ask to collect samples from you like saliva (spit), sperm, or urine. We may collect samples in person or give you instructions and supplies to collect samples at home.
- If your partner becomes pregnant again while part of ECHO, we may ask you to provide these things again. We may ask your partner to collect information and samples about that pregnancy, and from that baby when it is born.

What Will ECHO Do With All This Information?

- By participating in ECHO, you allow us to share your information and samples with qualified researchers within and outside ECHO.
- Researchers may use the samples and information to study your surroundings and experiences, such as chemicals and smoke. We may also study things such as hormones, germs, and whether parents have been exposed to medicines or drugs.
- Researchers may use some of the samples, like saliva or sperm, to look at DNA (your genes). We may also measure molecules from cells, proteins, and other factors in blood or cells.
- One method of studying DNA may include genome sequencing. This is a way of studying nearly all of a person's DNA. Every person's genome sequence is different; it is unique to them, like a fingerprint.

How Long Will ECHO Last?

- ECHO will last at least until 2030, and may continue after that.
- ECHO will contact you to complete surveys, study visits, or provide samples. This will take about one to two hours of your time.
- If your partner becomes pregnant again, we may ask you to complete these things a second time.
- ECHO will store the information and samples we collect for research for an unlimited period of time, so researchers can use them in future health research or in developing new scientific methods.
  - See *"How Will You Protect My Information and Samples?"* and "*Will You Share My Information and Samples"*.
- You can choose to leave the study at any time.
  - See "*What If I Want to Leave the Study?*".

What Are the Possible Benefits?

- ECHO may help us learn things about health and well-being that could benefit children—including your children and grandchildren—in the years to come.
- Taking part in ECHO will not improve your health right now nor will it change anything about your current medical care.
- You will not receive medical care or other direct benefits from being in the study.
- By being part of this study, you will help answer questions about how to improve the health of children.

What Are the Possible Risks?

- Providing information and samples for this study is low risk. This means any discomfort you might experience in the study is small and is similar to what could occur in daily life or during a routine doctor's visit.
- You may feel uncomfortable answering questions about things like stressful events or providing a sperm sample.
- Your privacy and confidentiality are very important to us. As with all research studies, there is a possible risk of loss of confidentiality. This means someone might see information that identifies you when they do not have permission. We will make every effort to keep your personal information secure. However, we cannot completely remove this risk. Also, it is possible that in the future someone could figure out how to use the health or genetic information to identify individuals or their close biological relatives. The risk of this happening is very small, but may grow in the future.
  - See *"How Will You Protect My Information and Samples?"*.

How Will You Protect My Information and Samples?

- Monique Hedderson, the study staff where you are, and the Data Analysis Center will store information we need to contact you (like names, phone numbers, and email addresses) so they can send you ECHO surveys and reminders.
- The ECHO Data Analysis Center at Johns Hopkins University (Baltimore, MD) and RTI International (Research Triangle Park, NC) will store your address and contact information separate from other research information and samples. This information will not be shared outside of the Data Analysis Center.
    - See "*Will You Share My Information and Samples"*.
- We will keep all information and samples in locked rooms or cabinets or in secure computer systems.
- Federal laws protect the privacy, security, and authorized access of research records. However, we cannot guarantee that we will never have to give out information.
- Your samples will be sent to research laboratories for measurements. The samples will be identified by the date of collection and a study ID, but will not include personal information that identifies you.
- Risks related to genetic research: A federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for employers, health insurers and group health plans to discriminate against you based on your genetic information. GINA limits the way these parties can use genetic information. Be aware that GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. If you agree to take part in genetic testing, the genetic information we collect or obtain through this research will not affect your eligibility for future medical care, membership in Kaiser Foundation Health Plan, or the cost of your premiums or benefits.
- In California, state law (CalGINA) requires that employers with 5 or more employees may not use your genetic information, obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. The genetic information we collect through this research will not affect your or your child's eligibility for future medical care, membership in Kaiser Foundation Health Plan, or cost of your or your child's premiums or benefits. Be aware that these laws do not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.
- For added protection, we have a Certificate of Confidentiality, which helps us protect the identity of people in the study. In most cases, the Certificate helps us refuse to give out information that could identify you in a court of law or to others not connected with the research.
- The Certificate does not prevent us from giving out information that may identify you if:
    - We have to report information by law, such as child abuse or some infectious diseases;
    - We learn of possible harm to yourself or others, or if you need medical help;
    - You or a family member chooses to share information about you or about your participation in ECHO;
    - Researchers use it for other scientific purposes, as allowed by rules that protect research participants; or
    - You give written approval to give out the information. This includes sharing information and samples for this study or for future research as described in this form.
- Under California law, the researchers must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may be required to report such information to the appropriate authorities.

Will You Share My Information and Samples?

- The ECHO Data Analysis Center will maintain secure databases with research information, including addresses, dates of birth, dates of procedures and collections, and health information. Only the ECHO Data Analysis Center will access addresses that could identify you. For example, we may link information about your samples and health to information about air or water quality where you live or work.
- ECHO researchers can request access to research information and samples – including dates that could identify you – so they can help answer questions about children's health.
- In addition, we will place genetic and health information about you in controlled-access NIH-supported research databases where researchers outside ECHO may apply for and get permission to use it. We will not label the information in a way that could identify you. Researchers approved to access this information must agree not to try to identify you.
- Researchers will share summaries of study information or analyses through scientific articles or other public scientific resources, such as data sharing resources that provide broad or unrestricted access to the information. Some examples of information that may be shared include how different genes are associated with different traits or diseases across many participants, or how often certain gene changes are seen across participants from many studies. The risk of anyone identifying you with this is very low.
- When needed, people involved in this research program, including those working on, funding, and overseeing the program, may view your identifiable information.
- Others that may view your identifiable information include the Kaiser Permanente Northern California Institutional Review Board (a formal committee that reviews research studies to protect the rights and welfare of participants), or the IRB that reviewed this research; other representatives of Kaiser Permanente, Kaiser Foundation Research Institute, and other at Kaiser Permanente responsible for monitoring research; the NIH and/or its authorized representatives and the Department of Health and Human Services.
- If study staff members think you may harm yourself or others, they may share that information with authorities or take other steps to protect you or others.

Will I Find Out the Results of the Research?

- From time to time, we will make study results available to all ECHO participants through the ECHO website, newsletters, community presentations, and scientific papers. These results will not be specific to any individual person in ECHO, including you.
- If the researchers see results they believe are very important to your health or medical care, we will give you a report with the information and an explanation of what each result means. We will also let you know if we think you should share the results with a doctor or other health professional.
- We will not tell you about any of the genetic results.
- If important new findings come up during the course of the study that might change your decision to be in this study, we will give you information about those findings as soon as possible.
- ECHO is a research program and therefore does not provide medical care. You should always talk to your doctor if you have questions or concerns about your health.
- No information from this study will be placed in your medical record or shared with the Kaiser Foundation Health Plan.

What Are the Costs to Me?

- There will be no costs to you to be in this study other than the time, effort, and a means of transportation to the clinic to complete study activities.
- ECHO or the study site where you are will pay any costs for study activities and sample collection.
- The study-related tests and procedures that are not part of standard of care for you will be provided to you free of charge while you are participating in this study.
- All aspects of your standard medical care will continue to be provided to you according to the terms of your plan benefits described in your applicable plan Evidence of Coverage or Summary Plan Description, which may include copayments, coinsurance, and deductibles.

Will I Receive Compensation?

- You will receive electronic gift cards for completing study activities, including surveys and research clinic visits at each time point throughout the study.
- You will receive $25 for completing surveys and $25 for completing biospecimen collection activities either in-person at the research clinic visit or remotely at home.
- If you leave the study early, you will be paid only for the components you have completed. Payment for participation in a study is taxable income.
- If this research produces any new products, tests, or discoveries that someone might be able to sell for profit, you will not share in this profit.

What If I Want to Leave the Study?

- You may choose not to take part in ECHO. If you do decide to take part, you can leave at any time for any reason.
- You can skip any part and still take part in ECHO. You can also take a break at any time during the study and come back later.
- ECHO may have you stop taking part if you and the ECHO participant who had a recent pregnancy are no longer partners.
- If you decide not to take part in ECHO or you decide to leave ECHO, it will not affect any medical care or result in any penalty or loss of benefits to which you are otherwise entitled. Also, it will not affect your medical care or eligibility for future care or membership in Kaiser Foundation Health Plan.
- If you decide to leave the study, we encourage you to talk to a study staff member about why you would like to leave. You can reach the ECHO study staff at the phone number(s) listed at the beginning of this form.
- If you decide to leave the study, we will keep all the information and samples we have collected up to that point. We will continue to use and share the information and samples you provided unless you ask us not to do so. In that case, you can notify the ECHO study staff and we will stop using the information and any remaining samples. We may not be able to get back information or samples we have already given to other researchers or placed in research databases.

What Alternatives Are There to Taking Part in This Study?

- The alternative to taking part is to not take part.

What if I or My Baby Become Injured While Taking Part in the Study?

- Any injury or condition experienced by a member of Kaiser Foundation Health Plan Inc. as a result of being in this study will be covered as described in your Health Plan Evidence of Coverage. No free medical care or other form of compensation will be offered by Kaiser Foundation Health Plan Inc., Kaiser Foundation Hospitals, The Permanente Medical Group Inc., or the Kaiser Permanente staff conducting the study. Your consent to participate in this research study does not take away any legal rights which you may have in the case of negligence or legal fault of anyone who is involved with this study.

Whom Do I Call If I Have Questions or Problems?

- If you have questions about the study or a research-related injury, or if you have problems, concerns, complaints, questions, or suggestions about the research, contact the research team at the phone number(s) listed at the beginning of this form.
- An Institutional Review Board (IRB) oversees this research. An IRB is a group of people who perform independent review of research studies to protect the rights and welfare of participants.
- You may contact an IRB staff member by phone at (855) 818-2289, or by email at clientcare@wcgclinical.com if:
  - You have questions, concerns, or complaints and you are not getting answers from the research team.
  - You want to talk to someone else about the research.
  - You have questions about your rights as a research participant.
- Questions about your rights as a study participant, and questions, concerns, comments or complaints about the study may also be presented to the Kaiser Permanente Northern California Institutional Review Board 1800 Harrison Street, Oakland. CA 94612, or 1-866-241-0690.

Statement of Consent

- A study staff member explained to me the study purpose, what may happen during the study, risks, and benefits.
- A study staff member answered my questions with all the information I needed.
- I know whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to get information or offer input about the research.
- I read this consent form and agree to be in ECHO.
- I understand I may withdraw any time.
- I will receive a signed and dated copy of this consent form.

For office use: STUDY ID

I agree to take part in ECHO.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

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). Your 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 Boad.

What information will be used or disclosed?

To do this study, we will look at or collect information about you and your health.

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
- Saliva (spit), urine, semen

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 (if applicable)
- 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 Printed Name:			
Participant Signature:		Date:	
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 Printed Name			
Person Explaining Signature		Date:	

Human Research Participant Protection Program

Research Participants' Bill of Rights

The following rights and privileges are guaranteed to all participants in medical research conducted within the Kaiser Permanente Medical Care Program. If you have questions about these rights, please call the Institutional Review Board toll-free at 1 866-241-0690.

Please note that items 5 and 6 below apply to clinical trials and may not apply to the research in which you are participating.

If you participate in medical research, you are entitled to certain rights that include but are not limited to the right to be:

1. Informed of the nature and purpose of the research.
2. Given an explanation of the procedures to be followed in the research and a description of any drug or device to be used.
3. Informed of any related discomforts and risks that can reasonably be expected from participation in the research.
4. Told of any benefits that can reasonably be expected from participation in the research.
5. Informed of any appropriate alternative procedures, drugs, or devices that might be advantageous to you and the relative risks and benefits of these alternatives.
6. If complications arise, informed of the availability of medical treatment, if any, after the medical research.
7. Given an opportunity to ask any questions concerning the research or about the procedures involved.
8. Told that you can decide to withdraw your consent to participate at any time with no effect on your health care benefits or medical care provided by Kaiser Permanente.
9. Given a copy of the signed and dated written consent form.
10. Allowed to decide for yourself whether to participate in research without any force, fraud, deceit, duress, coercion, or undue influence by anyone.