

KAISER FOUNDATION HOSPITALS
THE PERMANENTE MEDICAL GROUP, INC.
DIVISION OF RESEARCH

Consent to Participate in a Research Study

For Pregnant Participants

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)

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**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 about your pregnancy, and the birth and health of the baby (including dates of birth and addresses). We will also ask to collect samples like blood, urine, and hair from you and from the baby after birth.
- ECHO may also collect information and samples before a person becomes pregnant again to help understand how things that happen before pregnancy affect child health.
- The information and samples will be different at each stage of pregnancy and as the child gets older.
- 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 for you and the baby 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, 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 the Baby and I Need to Do in the Study?

- We will collect information from you twice during pregnancy and around the time of the baby's birth.
- We may also ask your partner to join ECHO, if they are available.
- We will ask you to complete questionnaires and other forms. You may complete them on a computer or tablet, by mail, over the phone, or in person. We will also collect information from medical records.
- We will collect body measurements like height, weight, and blood pressure, and perform other tests. Some we can measure while you are at home, some in person, or some using devices you can wear.
- We will ask to collect samples in person or we may give you instructions and supplies to collect samples at home.
- Examples of information and samples that we will collect 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
- After the baby is born, we will ask you, or another parent or guardian, to sign a form that says you agree for the child to continue in this study (parent consent).
- After pregnancy, we will continue to collect information and samples from you and the baby like what we collect while you are pregnant. We will collect things twice before the baby's first birthday, and once a year from the time your child is age 1, up until they turn 20 years old, or as long as ECHO continues. Examples include information about their 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.

- If you become pregnant again while you are part of ECHO, we may ask 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 and the baby's 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, smoke, and foods. We may also study things such as hormones, germs, and whether you or the baby have been exposed to medicines or drugs.
- Researchers may use some of the samples, like blood or saliva, 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 twice while you are pregnant and around the time the baby is born to complete study activities. After the baby is born, ECHO will contact you twice before the baby's first birthday, then each year to complete surveys, study visits, or provide samples. The amount of time to complete these activities will take about one to three hours of your and the child's time each time we contact you.
- 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 the Information and Samples?"* and *"Will You Share the 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 or the baby's health right now nor will it change anything about your or the baby's current medical care.
- You and the baby 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 and the baby might experience in the study is small and is similar to what either of you could experience in daily life or during a routine doctor's visit.
- You or the baby may have pain and bruising from a needle prick when collecting a blood sample.
- You may feel uncomfortable answering questions about things like stressful events.
- Your and the baby's 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 or the baby 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 the Information and Samples?"*.

How Will You Protect the 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 and the baby's 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 the 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 and the baby's 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 or your child.
- 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 eligibility for future medical care, membership in Kaiser Foundation Health Plan, or cost of your 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 or the baby 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 or the baby if:
 - We have to report information by law, such as child abuse or some infectious diseases;
 - We learn of possible harm to yourself, the baby, or others, or if you need medical help;
 - You or a family member chooses to share information about you or the baby 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 the Information and Samples?

- The ECHO Data Analysis Center will maintain secure databases with ECHO 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 and the baby's samples and health to information about air or water quality where you live, work, or get childcare.
- 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 and the baby 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 or the baby. 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 or the baby's identifiable information.
- Others that may view your and the baby's 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 others 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, the baby, 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 and the baby.
- If the researchers see results they believe are very important to your or the baby's 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 you, your pregnancy and/or the baby's health.
- No information from this study will be placed in your or your child's 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 your condition 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.
- **During pregnancy:** \$100 for completing surveys and \$100 for completing the research clinic visit at each time we contact you during pregnancy.
- **After your baby is born:**
 - When your baby is 0-5 months: \$100 for surveys and \$200 for the research clinic visit;
 - For each visit thereafter: \$100 for surveys and \$100 for the research clinic visit
- If you and your baby 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 and the baby 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.
- 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 and/or the baby are otherwise entitled. Also, it will not affect your or your child's 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 and/or the baby's rights as research participants.
- 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 and for the baby to be in ECHO when it is born.
- I understand that after the baby is born, ECHO will ask a parent to sign a new form giving permission for the baby to continue in the study.
- 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. I also give permission for the baby to take part in ECHO from birth to 6 months of age, or until a parent or legal guardian signs a new form.

Printed Name of Participant

Signature of Participant

Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date