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

IRB APPROVED
AS MODIFIED
Apr 20, 2020

# Consent to Participate in a Research Study

## For Adult Participants

| | |
|---|---|
| **Name of Research Study:** | Environmental influences on Child Health Outcomes (ECHO)-wide Cohort Data Collection Protocol |
| **Protocol No.:** | None; WIRB® Protocol #20181210 |
| **Sponsor:** | National Institutes of Health (NIH) |
| **Local Study Names:** | PRISM, ACCESS, and the First Thousand Days of Life and Beyond |
| **Investigator:** | PRISM and ACCESS New York: Rosalind J Wright, MD, MPH |
| **Sub-Investigators:** | First 1000 Days**:** Rosemary D Higgins, MD and Kathi Huddleston, PhD |
| **Research Site Address(es):** | PRISM and ACCESS New York: Mount Sinai Hospital<br>5 East 98th Street, 10th Floor<br>New York, NY 10029<br><br>First 1000 Days: George Mason University, Population Health Center<br>4400 University Drive<br>Fairfax, Virginia 22030 |
| **Daytime Telephone Number(s):** | New York: 212-241-5287; Fairfax: 703-993-1952 |

# Summary

## Taking Part in the ECHO Program

- We are asking you and your child to join the ECHO Program to help understand how things that happen early in children's lives—even before they are born—affect their development, health, and wellbeing.
- This research program includes studies at about 200 locations in the United States.
- Rosalind Wright leads the PRISM and ACCESS studies at Mount Sinai as part of the ECHO Program.
- Rosemary Higgins and Kathi Huddleston lead the First 1000 Days of Live Study at George Mason as part of the ECHO Program.
- The ECHO Program will combine information from about 50,000 children and their families.

- With so many participants from many parts of the U.S., researchers can answer questions that the PRISM, ACCESS, and First 1000 Days studies cannot answer alone.
- The ECHO Program seeks to answer important childhood health questions. Some key questions are related to how the environment affects:
  - Mothers' and babies' health before, during, and after pregnancy
  - How children's airways develop and airways-related illnesses
  - Nutrition, physical activity, risks of being overweight, and weight-related illnesses
  - Brain development, including the ability to think and understand, social development, speech, attention, behavior, and emotions
  - Overall wellbeing, including things that strengthen the ability to adapt, satisfy needs, and achieve goals

### Sponsor

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

### Information and Samples

- We will ask you and your child for information (including dates of birth and addresses) and samples of blood, saliva, urine, hair, stool, birth samples (placenta and cord blood), teeth, and toenail clippings. Blood and saliva will be used for DNA analysis.
- The exact information and samples will be different for each study location.
- We will collect information and samples through visits, 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 continue 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.

## What Is the Purpose of the ECHO Program?

- ECHO is a nationwide research program whose mission is to improve 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 may experience, throughout their lives and even before they are born, like the air they breathe, foods they eat, 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 influence children's growth, development, and health before and after birth, throughout childhood, and into adulthood. 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?

- You are already part of the PRISM, ACCESS, and First 1000 Days studies. Now these studies are taking part in the ECHO Program and we are asking you to take part as well.
- We will ask you to share with ECHO some of the information you already gave the PRISM, ACCESS, or First 1000 Days studies.
- 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. We will also collect information from your and your child's medical records.
- We will collect information and samples from you and your child during several periods--while you are pregnant, when your child is less than 1 year old, when your child is 1-5 years old, when your child is 6-11, and when your child is 12-18. Depending on how old your child is now, you and your child may not participate during all these times.
- Examples of information that we will collect include:

  - Dates of birth, race, sex, gender, language, household information including address history, and jobs
  - Children's development and their behavior
  - Childcare and school attendance
  - Child and family health history, medications, immunizations (vaccines), and health insurance status
  - Household environment and exposures to chemicals and smoke
  - Pregnant women's health care and diet
  - Things that may cause stress in your life, relationships with family and other people, and what your neighborhood is like
  - How children who join ECHO behave, what their daily life is like, friendships, their school life, how much exercise they get, what they eat, how they sleep, and how healthy they are overall

- If you are a biological parent of a child in ECHO, we will ask to collect samples from you. We may collect samples during a study visit. For other samples, we may give you instructions and supplies to collect samples at home.
- Examples of samples we will ask to collect include : blood, saliva (spit), urine, hair, toenail clippings, placenta, blood from the umbilical cord after childbirth, stool, breast milk, nasal mucus, and children's shed teeth.
- In addition to the visits described below, the study team may contact you to talk about study procedures or other things related to your participation in this study, including taking part in other studies related to ECHO.

## What Will the ECHO Program Do With All This Information?

- By participating in ECHO, you allow us to share your and your child's information and samples with qualified researchers within and outside the ECHO Program. This includes information and samples you and your child gave to the PRISM, ACCESS, and First 1000 Days studies in the past as well as new information and samples.
- Researchers will use your and your child's samples and information to look at your and your child's surroundings and experiences, such as chemicals, smoke, and what you eat. We will also study things in your and your child's body, such as hormones, genes, germs, and whether you or your child have been exposed to medicines or drugs.
- Researchers will use some of your and your child's samples, like blood or saliva, to look at DNA. We will also measure molecules from your cells, proteins, and other factors in blood or cells.

## How Long Will the ECHO Program Last?

- The ECHO Program will last until 2023, and may continue after that.
- The PRISM, ACCESS, and First 1000 Days studies will decide how long they would like you and your child to participate in the study.
- The other study visits will continue and are described in the consent forms for those studies.
- The ECHO Program will store your and your child's information and samples 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"* .
- At any time, you or your child can choose to leave the study.
  - See "*What If I Want to Leave the Study?*"

## What Are the Possible Benefits?

- The ECHO Program may help us learn things about health and wellbeing that could benefit children—including your children and grandchildren—in the years to come.
- Taking part in ECHO will not improve your or your child's health right now nor will it change anything about your current medical care.
- You or your child 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 or your child 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 or your child may have pain and bruising from a needle prick when collecting a blood sample.
- You or your child may feel uncomfortable answering questions about things like stressful events.
- Your and your child'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 your information that identifies you when they do not have permission. 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?

- The ACCESS, PRISM, and First 1000 Days studies will store information we need to contact you (like names, phone numbers, and email addresses).
- The ECHO Data Analysis Center at Johns Hopkins University (Baltimore, MD) and RTI International (Research Triangle Park, NC) will store your date of birth, other dates, and address information separate from other research information and samples.
- 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.
- Laws help protect your and your child's genetic information, make it illegal to use genetic information to discriminate against you and/or your child for health insurance coverage and employment. These laws do not apply to other types of insurance (such as life, disability, or long-term care).
- For added protection, we have a Certificate of Confidentiality, which helps us protect the identity of people in the study. In some cases, the Certificate helps us refuse to give out information that could identify you or your child 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 your child if:
  - We have to report information by law, such as child abuse or some infectious disease;
  - 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 research information and samples for this study or for future research as described in this form.

## Will You Share Our Information and Samples?

- The PRISM, ACCESS, and First 1000 Days studies and the ECHO Data Analysis Center will maintain ECHO information in secure databases. The information in the databases (including addresses, dates of birth, dates of procedures and collections, and health information) is for research only. For example, we may link information about your samples and health to information about air or water quality where you live or work.
- In addition, we will place genetic and health information about you in controlled-access NIH-supported research databases. We will not label the information in a way that could identify you.
- The study sites in NYC and Fairfax, and the ECHO Program will store, or "bank," ECHO samples and will distribute them in the future to approved researchers. We will not store samples with information that could identify you.
- ECHO researchers can request access to your research information and samples so they can answer health questions. This does not include identifiable information such as birthdates and addresses.
- Researchers outside ECHO can request access to research information and samples that do not identify you.
- Researchers will share summaries of ECHO analyses, including genetics, through scientific articles or other public scientific resources, such as NIH or ECHO resources. We will not publicly share any participant's individual information.
- 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 Program for the Protection of Human Subjects, Mount Sinai's institutional review board, the United States Department of Health and Human Services, and the Office of Human Research Protection.
- 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 or your child.
- 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.

## What Are the Costs?

- There will be no costs to you or your child to be in this study other than the time and effort to complete study activities.
- The ECHO Program or the PRISM, ACCESS, and First 1000 Days studies will pay any costs related to study activities and sample collection.

## Will I Receive Compensation?

- If you decide to take part in this study, you will be compensated for completing questionnaire packets, providing samples and body measurements from you and your child, and for you and your child to complete study tasks. We will give you $20 per completed questionnaire packet, $15 per sample/measurement, and $20 for study tasks. If we collect samples at your child's birth—placenta, umbilical cord blood, meconium—we will pay you $75. If you provide your child's shed teeth, we will pay you $5 per tooth. If you come to our site for visits, we will reimburse you for travel costs. When we collect samples from your child, or your child completes a study task or questionnaire packet, we will give them a gift worth about $10, in addition to the money we give you. If you child wears an activity monitor on their wrist for one week, we will pay you $75.
- We will pay you cash for in person visits and gift cards for phone, mail, or email surveys.
- If there is any overlap in procedures for the other studies and ECHO, the procedure will be done once and you will be paid once.
- Tax law may require your study hospital's finance department to report the amount of payment you receive from the study hospital to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if you receive payments that equal $600 or more from the study hospital in a calendar year. You would be responsible for the payment of any tax that may be due.
- 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 and your child's participation is voluntary. 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 or your child can skip any part. You can also take a break at any time during the study and come back later.
- If you decide not to take part or you decide to leave ECHO, it will not result in any penalty or affect any medical care or benefits to which you or your child are otherwise entitled to. Also, it will not affect your or your child's access to health care.
- 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 study staff at the phone number(s) listed on the first page of this form.
- If you decide to leave the study, we will keep the information and samples we have collected up to that point, but will not ask you for any more information or samples. We will continue to use and share the information and samples you and your child provided unless you ask us not to do so. In that case, you can notify the study staff and we will stop using the information and any remaining samples. We cannot get back information or samples already given to other researchers or placed in coded databases.

## What Alternatives Are There to Taking Part in This Study?

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

## 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 on the first page.
- In case of injury during testing procedures, the research team may provide basic first aid. If appropriate, the staff will call the emergency response team at 911. Neither the site nor the investigators have funds available for payment of medical treatment for injuries that you may sustain while participating in this research. Should you need medical care, you or your insurance carrier will be responsible for payment of the expenses required for medical treatment.
- 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 talk to an IRB staff member at (888)-303-2224, irb@cgirb.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.

## Maintaining Confidentiality – HIPAA Authorization:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be disclosed (shared) with others?

As part of this research project, the research team will collect your and your child's name, address, phone number, birthdate, email address. The researchers will also get information from your and your child's medical record at the hospital where your child was born and/or your child's doctor. During the study the researchers will gather information by completing the procedures described on page 3 of this form.

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The research team and other authorized members of the study hospital workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the Mount Sinai's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the hospital's Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the study hospital workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project: Mount Sinai Hospital System, George Mason University, Boston Children's Hospital, and National Institutes of Health (NIH)
- Research data coordinating office and/or their representative(s) who will be responsible for collecting results and findings from all the ECHO study sites: ECHO Data Coordinating Center at Duke University and the ECHO Data Analysis Center at Johns Hopkins University
- Outside laboratory who will be performing laboratory analysis for all the research centers involved in this project: Fisher BioServices Thermo Fisher Scientific and NIH CHEAR Lab Hubs at Mount Sinai and other hospitals
- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: The United States Department of Health and Human Services, the Office of Human Research Protection, and National Institutes of Health (NIH)

- Western Institutional Review Board® (WIRB®)

In almost all disclosures outside of the study hospital you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services will be granted direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will the study hospital be able to use or disclose your protected health information?
Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?
NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

It is important for you to understand that once information is disclosed to others outside the study hospital, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, the study hospital has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or

questions about your medical history or conditions, then the following section may be ignored.

## Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

## Disclosure of Financial Interests

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk to your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

## Statement of Consent

| For office use: STUDY ID |
|---|
| |

- 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.
- My child will have a chance to sign a separate assent form, unless the study staff determines my child is unable to do so.

**I agree to take part and for my child to take part in the ECHO Program.**

_____
Printed Name of Participant (Adult)

_____ _____ _____
Signature of Participant (Adult) Date Time

*Please use this box **only** if the parent/guardian has declined participation for themselves but is consenting for the child.*

_____
Printed Name of Child's Parent/Legal Guardian

_____ _____ _____
Signature of Child's Parent/Legal Guardian Date Time

_____
Printed Name of Person Obtaining Consent

_____ _____ _____
Signature of Person Obtaining Consent Date Time