

## Assent Form

For Children Ages 12 – 18

**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 Name:** PRISM and ACCESS

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## What is the name of this study?

Environmental influences on Child Health Outcomes (ECHO), or the ECHO Program

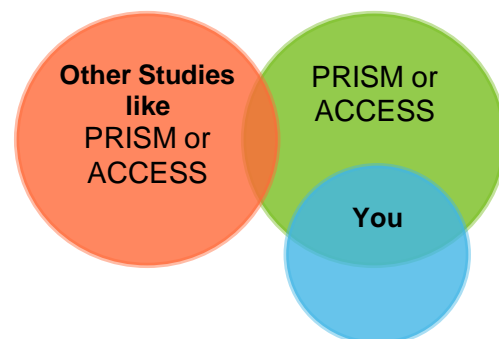
## What is the purpose of the ECHO Program?

- The purpose is to improve children's health for generations to come.
- We want to learn how genes and the things around us work together to affect children's development, health, and wellbeing.
- ECHO will focus mainly on health issues like:
  - What happens before, around the time of, and after a baby is born
  - Children's breathing problems and breathing-related illnesses
  - Nutrition, physical activity, and related illnesses
  - The way children's brains develop, including how they think, feel, understand, speak, and behave
  - Overall health and wellbeing



## Who will take part in ECHO?

- The ECHO Program includes many research studies that work together.
- You are already part of one of these studies, the PRISM or ACCESS study.
- ECHO includes studies at about 200 locations around the United States.
- ECHO will combine information from about 50,000 children and their families.



### Taking part in a research study

- Research studies include only people who agree to be in them.
- Before you decide to be in this study, you should read this whole form and ask questions so we can answer them. You can also talk to your family about joining the study.
- Being in research is your choice. You do not have to be in this study and whatever you decide is ok.
- If you decide to be in this study, you can change your mind and leave the study at any time. If you want to leave the study, please tell the research team. You can also say no to some parts of the study.
- If the study is still going, someone will contact you when you turn 18 years old or when you reach the age your state considers an adult. We will ask you to complete the adult form that will allow you to stay in the study. If you do not complete the adult form, we will consider your participation ended.
- ***When you finish reading, and have answers to all your questions, please sign and date the last page if you agree to join the study. We will give you a signed copy to keep for yourself.***
- If you want to read more about the study, ask for a copy of the form that adults read and sign.

### Who is paying for this study?

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

### What do I need to do for this study?

- We will ask you and your family to share information and give samples at different times in your life, at least until 2023.
- We might collect information during a study visit, using paper forms, phone calls, or by asking you or a family member to answer questions on a computer or tablet.
- We will also use some information from your doctor visits.
- We will ask you to donate (give) blood, spit (saliva), pee (urine), poop (stool), hair, teeth you lose, mucus from your nose, or toenail clippings. We call these things we collect “samples.”

### What will the ECHO Program do with all this information?

- We will use the information and samples you provide to answer important scientific questions about children’s health and human development.
- We will share your information and samples with researchers who will look at things in your life and your body.
- We plan to look at differences in genes and other things in the body, which may make children more or less likely to stay healthy.

### What are the benefits to me?

- The study may help us learn things about health and wellbeing that could benefit children – including your children and grandchildren – in the future.
- By being part of this study, you will help answer questions about how to improve the health of children.
- Taking part in the study will not improve your health and you will not receive medical care or other direct benefits from being in the study.

### Are there any risks to me?

- The risks to you are very small. You might feel a pinch if we use a needle to get some blood.
- The blood test could leave a bruise where the needle goes into your body. You could also feel uncomfortable answering questions about stressful things that happen to you or people you know.
- There is a possible risk that someone might see your information when they do not have permission.

### Will you keep my information safe?

- We will keep information and samples we collect during this study locked up. We will do everything we can to make sure nobody will know who you are except the people doing the research.
- We will enter and store your information in locked rooms or cabinets and on secure computer systems. We will give your samples a secret ID number and place them in locked storage to use in research later on.
- We can use or share your information and samples in ways that nobody can tell it came from you.
- If we write a research paper about what we learn from the study, we will not use your name.

### Will I find out any results of the study?

- We will make study results available through the ECHO website, newsletters, community presentations, and scientific papers.
- This information will not be specific to any individual person in ECHO, including you.
- If we learn something new that might change your decision to be in this study, we will give you that information as soon as possible.

## Statement of assent

For office use: STUDY ID

A study staff member explained this study to me in a way that I understand. I had the chance to ask questions. I read this form and I choose to be in this study. I understand I can stop being in this study at any time. I will get a signed and dated copy of this form.

\_\_\_\_\_  
Signature of Participant (if 12 years or older), as able

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Printed Name of Participant

☐ I have explained the study to the extent compatible with the participant's capability, and the participant has agreed to be in the study.

OR

☐ The participant is not able to assent because the capability of the participant is so limited that the participant cannot reasonably be consulted.

\_\_\_\_\_  
Signature of Person Obtaining Assent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Printed Name of Person Obtaining Assent