

**THE MOUNT SINAI HEALTH SYSTEM
ASSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai**

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Study ID #: 16-0904

Form Version Date: 11/25/19

TITLE OF RESEARCH STUDY:

Title: ECHO Perinatal Environment & Development Study (PEDS)

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Boston Children's Hospital Principal Investigator:

Name: Michelle Bosquet-Enlow, PhD

Physical Address: Boston Children's Hospital, 21 Autumn Street, 1st Floor

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Phone: 617-919-4680

DESCRIPTION OF THIS RESEARCH STUDY:

Since you were born, you and your mother have been part of a research study to learn if different things, like the air you breathe or being worried or upset, can change the way children grow, like how the lungs grow and if some children are more likely to have health problems like asthma. Now we want to see if these things affect how you think and learn, as you get older. We are asking you and other children to be in our research study. If you agree to be in this study, we will ask you to do these things:

Learning games:

- You will play some games on an iPad. You will do things like touching the screen to choose different pictures and answering questions about pictures shown on the screen. These games will show us how you learn. We want to find out which games you do well and which are harder.

Measuring your body size:

- You will get on a special scale to measure your weight and height.
- We will use a tape measure around your waist and hips.
- We will put a cuff around your arm to measure blood pressure.

Samples from your body:

- We will ask you for pee, hair, teeth, and blood so that we can see if there are things in your environment that might affect how your body works.
- We will ask you to pee into a cup.
- We will cut a small amount of your hair from the back of your head.

-----FOR IRB USE ONLY-----

Rev6.22.16

Icahn School of Medicine at Mount Sinai

Protocol: IRB-17-01498

Approved: 04/10/2020

Expires: 04/09/2021

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- We will ask your mother to give us five baby teeth that fell out.
- We will take blood by putting a needle in your arm and filling some small tubes with blood.
- We will also prick your fingertip with a needle and squeeze it gently to make some blood drip onto special paper.

You can say no to any of these things--the learning games, the measures we take like seeing how tall you are, and samples-- if you want to.

You might feel bored or tired during the learning games. We can take a break if you want to. When we collect your blood, it may sting a little bit and you might get a bruise where the needle pricks you. You might feel dizzy when we collect your blood, so we will ask you to sit down while we do that.

We will keep the measures and information we get about you locked up. Nobody will know who you are other than the people doing the study.

Your parent or guardian has to say it is OK for you to be in the study. After they decide, you get to choose if you want to do it too.

Before you decide to be in this study, we will answer any questions you have. You can also talk to your mom or dad. You do not have to be in this study, it is okay to say no. If you say yes, you can change your mind and stop being part of it at any time.

You can call us if you have any questions about the study or if you decide you do not want to be in the study any more. The phone number for your study hospital is on the first page.

The Mount Sinai Program for Protection of Human Subjects has checked this research study. You may call someone from that office at telephone number (212) 824-8200 if you do not want to talk to the researchers doing this study.

We will give you a copy of this form to keep for yourself.

If you decide to be in the study, please sign your name below.

Name

Date

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