

THE MOUNT SINAI HEALTH SYSTEM
ADDENDUM TO ASSENT FORM
Icahn School of Medicine at Mount Sinai

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Study ID #: 16-0904

Form Version Date: 4/7/2021

TITLE OF RESEARCH STUDY:

ECHO Perinatal Environment & Development Study (PEDS)

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Mount Sinai Principal Investigator:

Rosalind J. Wright, MD, MPH
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212-241-5287

George Mason University Principal Investigator:

Kathi Huddleston, PhD
George Mason University, Population Health Center
4400 University Drive
Fairfax, Virginia 22030
703-993-1952

Boston Children's Hospital Principal Investigator:

Michelle Bosquet-Enlow, PhD
Boston Children's Hospital
21 Autumn Street, 1st Floor
Boston, MA 02115
671-919-4680

CONSENT ADDENDUM

You are being asked to sign this assent addendum because you and your mother are participating in the ECHO PEDS Study at Mount Sinai or Boston Children's Hospital or George Mason University.

The study staff will explain this form to you. Please ask him/her to explain any words or information that you do not clearly understand.

PURPOSE OF THIS ADDENDUM:

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. You have done activities, answered questions, and given samples when you were younger. Now we are asking you to do them again, now that you're 9-11 years old. If you agree to do this visit, we will ask you to do the same things you did before:

Learning games:

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- 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.
- 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.

Your parent or guardian has to say it is OK for you to do this visit. After they decide, you get to choose if you want to do it too.

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.

- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

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

Name

Date



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