

THE MOUNT SINAI HEALTH SYSTEM  
ADDENDUM TO CONSENT 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  
Mount Sinai Hospital, 5 East 98<sup>th</sup> Street, 10<sup>th</sup> Floor  
One Gustave L Levy Place Box 1198, NY, NY 10029  
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, 1<sup>st</sup> Floor  
Boston, MA 02115  
671-919-4680

**CONSENT ADDENDUM**

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

Please read this consent addendum carefully and take your time making your decision. As the study staff discusses this addendum with you, please ask him/her to explain any words or information that you do not clearly understand.

**PURPOSE OF THIS ADDENDUM:**

The purpose of this addendum is to describe a new part of the ECHO PEDS Study. The original consent form described study activities for you and your child between the ages of 2 and 8. This addendum will describe activities to happen when your child is 9-11 years of age. Except for the activities described in this addendum, the terms of your original consent form remain in full effect. If you choose not to participate in this study visit, it will not effect your previous participation in the study.

When your child is between 9 and 11 years old, we will ask you and your child to complete a study visit. The visit will be almost exactly the same as the ones we did when your child was younger. At each visit, you will answer questions about how you are coping with many of life's daily stressors, your

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health and your child's health, development, behaviors, and emotions, where you live and the address of your child's school, where he or she spends a lot of time.

We will ask you these questions during the study visit, or in a phone call before or after the visit, or through a survey. It will take about 1-1 ½ hours to finish these questions.

Study staff will collect samples (hair, urine, blood, and teeth) from your child so that they can look at markers of environmental factors, such as metals and chemicals, and markers of biological responses, such as changes in hormones, immune factors, or other proteins and molecules made in the body.

At each visit, study staff will measure both your and your child's height, weight, waist and hip circumference, and blood pressure.

Study staff will do behavior, learning, and memory tests with your child using an iPad. These games will involve activities like choosing different pictures by touching the screen and answering questions about pictures shown on the screen. These tests are done only for research. They are not meant to help you or your child's doctor or teacher with your child's care, and the results will not be shared with you.

If you agree to take part in this part of the research study, we will pay you for your time and effort as below. If the visits are completed at the hospital site, you will be reimbursed for your travel costs:

- \$75 and a small gift for your child
- \$15 for completing each of the following:
  - child spot blood collection,
  - child venous blood collection,
  - child hair collection,
  - child home urine collection,

Depending on your study site, you will be paid in either cash or gift cards.

**CONTACT PERSON(S):**

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator at phone number (212) 241-4947 (Dr. Rosalind Wright, MSHS), (617) 919-4680 (Dr. Michelle Bosquet Enlow, BCH), or (703) 798-1972 (Dr. Kathi Huddleston, GMU).

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System. You may call this number even if your hospital site is BCH or GMU.

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.



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- 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.

**Signature Block for Capable Adult**

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

\_\_\_\_\_  
Signature of subject/parent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of subject/parent

\_\_\_\_\_  
Printed name of child in study

**Person Explaining Study and Obtaining Consent**

\_\_\_\_\_  
Signature of person obtaining consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of person obtaining consent



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