

# **Assent Form**

For Children Up to Age 11

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, ACCESS, and the First Thousand Days of Life and Beyond

Investigator: PRISM and ACCESS New York: Rosalind J Wright, MD, MPH

Sub-Investigators: PRISM Boston: Michelle Bosquet-Enlow, PhD

First 1000 Days: Rosemary D Higgins, MD and Kathi Huddleston, PhD

**Research Site Address(es):** PRISM and ACCESS New York: Mount Sinai Hospital,

5 East 98th Street, 10th Floor, New York, NY 10029

PRISM Boston: Boston Children's Hospital, 21 Autumn Street, 1st Floor, Boston, MA 02115

First 1000 Days: George Mason University

4400 University Drive, Population Health Center, Fairfax, Virginia 22030

Daytime Telephone Number(s): New York: 212-241-5287; Boston: 617-919-4680; Fairfax: 703-993-1952





## What is a research study?

Research is a way to help us learn new things and test new ideas. Being in research is your choice. Whatever you decide is OK. You can ask questions at any time.

## What is the name of this study?

Environmental influences on Child Health Outcomes, or ECHO for short.

# Who is in charge of this study?

A part of the government called the National Institutes of Health supports this study. The people in charge of the study are Rosalind Wright in New York, Michelle Bosquet-Enlow in Boston and Rosemary Higgins and Kathi Huddleston in Fairfax, Virginia.



#### What is this study about?

This study is trying to learn how to improve children's health in the United States. The study wants to find out how things in the world around us can change how children grow and how healthy they are.

#### What will happen to me in this study?

If you decide to be in this study, we will:

- Ask you to be in the study at least until the year 2023
- Ask you and your family to share information about you, your family, and the world around you
- Ask you to answer questions on a piece of paper, a cell phone, a computer, or a tablet
- Ask you for small amounts of things from your body, like hair, pee (urine), poop (stool), spit (saliva), blood, toenails, mucus from your nose, and a tooth if one falls out
- Look at notes from your doctor visits

# Could this study help me?

Being in this study may not help you right now. We do hope to learn important things from this study. And someday we hope it will help other kids be healthy.



## Could this study hurt me?

This study should not hurt you. You could feel a pinch or get a bruise from blood collection. You might feel uncomfortable about some questions you are asked. You don't have to answer all questions or give samples if you don't want to.

Version 01.20 Protocol ID: DCR2-18-209 Reference Date: 30Nov2018



# Do I have to be in this study? No, you don't. No one will be mad if you don't want to do this. Just tell us if you do or do not want to be in this study. And remember, you can say yes now and change your mind later. It is up to you. For office use: STUDY ID Statement of assent Printed Name of Participant OR I have explained the study to the The participant is not able to assent extent compatible with the participant's because the capability of the capability, and the participant has participant is so limited that the agreed to be in the study. participant cannot reasonably be consulted. Signature of Person Obtaining Assent Date Time

Version 01.20 Protocol ID: DCR2-18-209 Reference Date: 30Nov2018

Printed Name of Person Obtaining Assent