

The Columbia Center for Children's Environmental influences on Child Health Outcomes (CCCEH-ECHO)

Mothers and Newborns – Sibling – Fair Start

Updates to Our Protocol

WHY AM I BEING CONSENTED AGAIN?

We are asking you to sign this new consent form as you and your child have recently participated in a study at the Columbia Center for Children's Environmental Health (CCCEH). CCCEH is now joining with ECHO, a nationwide research program whose mission is to improve the health of children, to look at how the environment affects children's development and health outcomes. We are now asking you to allow us to share your and your child's information with the ECHO Program. The ECHO Program will, like us, keep the information that could help identify you and your child and where you live (or have lived), in a secure environment, and they will not have your name or specific apartment number. Only qualified data analysts within the ECHO program will have access to information like your birthdate and street address, which is sometimes considered "identifiable data" even though it does not include your name, exact address, or telephone number. Below we list important changes that were made in this consent form since we last spoke so that you can review it.

WHAT HAS CHANGED SINCE I PARTICIPATED?

In Section 'How Will My Information Be Used And Stored' we have added:

- We are participating in ECHO, a nationwide research program whose mission is to improve the health of children. By partnering with this program, we can answer important questions about children's health that we cannot answer alone.
- By participating in CCCEH-ECHO, you allow us to share your and your child's information and samples with the ECHO Program. This includes the information and samples that you and your child gave to CCCEH in the past, as well as new information and samples. To protect your identity, we will give your information a unique code number and your name will not be linked to this number.
- The ECHO Data Analysis Center will store all your answers to questionnaires, results of tests and samples. They will also store *some* identifiable information – only your and your child's date of birth, dates of events and street addresses. They will not have access to your name or apartment number.
- We clarify that we will also study how your body works by looking at hormones, genes, germs, and whether you or your child have been exposed to medicines or drugs.
- We will use some of your and your child's samples to measure molecules from your and your child's cells, proteins, and other factors.
- We will store your and your child's information and samples for an unlimited period of time, so that qualified researchers affiliated with and outside the ECHO program can use them in future health research or to develop new scientific methods. These researchers will not be given access to information that could identify you or your child.



In Section 'What Are The Risk' we have added:

- Also, it is possible that in the future someone could figure out how to use the health or genetic information to identify individuals or their close biological relatives. The risk of this happening is currently very small.

In Section 'How Will My Confidentiality Be Protected' we have added:

- The addresses you lived in (no apartment number), the date of your birth, date of when you participate in ECHO and other dates will also be stored at the ECHO Data Analysis Center. We will give your information a unique code number and your name will not be linked to this code.
- In addition, we will place genetic and health information about you and your child in controlled-access research databases. We will not label the information in a way that could identify you or your child.
- The following people and/or agencies will be able to look at, copy, use, and share your research information which may include some identifiable information (date of birth, street address):
 - The investigators, study staff, and other professionals who may be evaluating the study at NYSPI, Columbia University, and the ECHO Program.
 - The Institutional Review Board ('IRB'). An IRB is a committee organized to protect the rights and welfare of people involved in research.
 - The Federal Office of Human Research Protections ('OHRP') *and/or the United States Food and Drug Administration ('FDA')*.
 - The sponsor of this study, *National Institutes of Health*, including persons or organizations working with or owned by the sponsor may review your data for accuracy but may not copy information with your name on it.
 - The ECHO Data Analysis Center at Johns Hopkins University (Baltimore, MD) and RTI International (Research Triangle Park, NC) which will maintain ECHO research information.



Columbia University IRB

IRB-AAAS3412 (Y01M02)
IRB Approval Date: 03/23/2020
For use until: 08/20/2020