

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT 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: 12/20/19

TITLE OF RESEARCH STUDY:

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

Mailing Address: Boston Children's Hospital, 300 Longwood Avenue, AT-120.3, Mailstop BCH 3199, Boston, MA 02115

Phone: 617-919-4680

WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that they don't know enough about. Being in a study may not help you or others.

People volunteer to be in a research study. You can decide whether or not to be in a study. You can also agree to take part now and later change your mind. No matter what you decide to do, it will not affect the care you receive at your health care system or hospital during this study or in the future.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. We will promptly tell you anything new we learn during this research study that might make you change your mind about being part of it.

Basic information about this study will appear on the website <http://www.ClinicalTrials.gov>. There are a few reasons for this: the National Institutes of Health (NIH) wants everyone doing research to post their research; some medical journals only accept articles if the research was posted on the website; and, since this is a study that the U.S. Food and Drug Administration (FDA) calls an "applicable clinical trials," a description of this clinical trial must be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

PURPOSE OF THIS RESEARCH STUDY:

The ECHO program is a national research study that will include participants at many sites across the United States. ECHO PEDS covers three of those sites -- George Mason University (GMU) in Virginia, Boston Children's Hospital (BCH) in Massachusetts, and Mount Sinai Health System (MSHS) in New York. Mount Sinai is coordinating ECHO PEDS. This consent form includes information about all three sites in ECHO PEDS.

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You qualify to take part in ECHO PEDS because you and your child have been participating in the PRogramming of Intergenerational Stress Mechanisms (PRISM) Study at either the MSHS or BCH, or the First 1000 Days of Life Study at Inova Translational Medical Institute.

The purpose of the ECHO PEDS study is to understand better how the environmental factors studied in PRISM and First 1000 Days affect your child's behavior and his or her cognitive development, for example learning and memory.

The purpose of the PRISM and First 1000 Days studies is still to understand how stress and other factors in your environment during pregnancy and in your child's environment as they grow up affect your child's health, growth and development. The researchers also want to understand better how changes in the body's responses to these factors, both during your pregnancy and in your child, influence child growth and health. They are examining how the body fights disease, how it responds to stress, and how your or your child's response to the environment may change in relation to your genes (the chemical structure that carries the information that determines your characteristics, such as height and eye color), and other responses.

Funds for this research are provided by the National Institutes of Health as part the Environmental Influences on Child Health Outcomes (ECHO) program.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

You and your child will take part in this phase of ECHO PEDS for about 7 years. There may be other phases of ECHO PEDS that you may qualify for and study staff will talk to you about those when they happen.

The number of people expected to take part in ECHO PEDS at MSHS and BCH is 1500, including 750 mothers and 750 children. The number of people expected to take part in ECHO PEDS at GMU is 3000, including 1500 mothers and 1500 children. The total number of people expected to take part in the whole ECHO program is 50,000 across the United States.

DESCRIPTION OF WHAT'S INVOLVED:

This form describes what you may need to do if you and your child agree to be in this research study. When your child is 7 years old or older, study staff will ask your child directly if he or she wishes to be in the study; this is also known as assent.

All the activities are done for research purposes only. Visits will take place at your home, at the clinical or laboratory sites at your hospital, over the phone, by mail, or by internet surveys.

In addition to the visits described below, the study team may contact you to talk about study procedures or other things related to your participation in this study, including taking part in later phases of ECHO PEDS.

Study staff will ask you and your child to complete up to three study visits in all, depending on how old your child is now. Visits will take place when your child is around 2, 4-5, and 7-8 years old. Study staff will try to schedule each visit at your study hospital. If they cannot do that, they will ask to come to

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your home to complete the visit. Each visit will take 1 ½ - 2 hours to complete. You may refuse to complete any of the procedures listed below and your refusal will not affect your ability to take part in the study.

Surveys

At each visit, you will answer questions about:

- how you are coping with many of life's daily stressors, such as challenges in parenting, emotions you have had, and your relationship with your child.
- your health and your child's health, development, behaviors, and emotions.
- where you live and the address of your child's school or day care, where he or she spends a lot of time.

Some of the questions ask about sensitive material. Study staff will try to complete them during your study visit. If it is not possible to complete them then, they will ask to call you to finish them over the phone, or you can complete them at home and return through the mail as soon as possible. The surveys should be finished within 1 week after your visit.

Sample Collection

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, they will ask to collect:

- a small amount of hair (about the diameter of a pencil eraser). They will cut the hair close to your child's scalp in a place that probably no one will be able to see.
- one sample of urine ("pee"). If this sample cannot be collected during the visit, they will show you how to collect the urine yourself and give you the supplies you will need. On the day the sample is collected, you will answer some questions about food your child ate or products he or she used. If needed, study staff will arrange to pick up the urine and questionnaire from you at your home or a place of your choosing.
- two blood samples. Trained staff members will get one blood sample by putting a small needle into a vein in your child's arm and taking out about 5 teaspoons of blood. For the second sample, a staff member will prick your child's finger with a needle, then massage it so that a few blood drops (less than 100 microliters, or 0.02 teaspoons) fall onto a blood filter paper sample card. You may allow the staff to get one or both blood samples, or you may refuse blood collection for your child.
- When your child begins to lose his or her baby teeth, study staff will ask you to send up to 5 teeth that have fallen out or been removed by the dentist. Study staff will contact you from time to time between study visits to see if you have any teeth to send. You will put the teeth in envelopes provided to you, fill out a short survey for each tooth, and mail the package to the study team using a stamped envelope.

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- When your child is about 2, we will also collect your child's nasal mucus by putting a swab in each nostril.

Body Measurements

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

Assessment of your child's behavior, learning, and memory.

When your child is 2 years old, study staff will ask you questions about his or her development. When your child is 4-5 and 7-8, they 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.

Research Record Review

The researchers will use your and your child's data (the information we collect from you) and samples from PRISM or First 1000 Days and from this ECHO PEDS study for this study and the whole ECHO program across the United States. Data and samples will be stored at Mount Sinai and the Mount Sinai ECHO team will manage any information that could be used to identify you. Your and your child's name or other directly identifiable information will not be shared with the national ECHO program. Your data and samples will be labeled only with a code number. The data and samples collected from you in ECHO PEDS will also be used in the original study you joined, PRISM or First 1000 Days.

Storage of Samples and Data

Your samples and data will be kept for as long as the researchers need them. When your child reaches the age of 18, the researchers will contact him/her and ask if he/she agrees to have his or her samples and data stored for as long as they need them. If your child agrees, he/she will be asked to give written consent at that time. If your child does not agree, then the rest of his/her remaining samples will be destroyed and no more testing of the samples will be done. If the researchers cannot contact your child because your child has moved or for any other reason, then the following will be done: all links to your child's identity will be removed from the remaining samples, and these nameless samples will continue to be used.

Scientific Databases

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by the study site, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called "dbGaP." A

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researcher who wants to study the information must apply to the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people. Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Researchers will always have a duty to protect your privacy and to keep your information confidential.

Future Use of Data or Samples

It is possible that the researchers will use your data or samples in the future for purposes related to this study or for unrelated uses. From time to time researchers outside of medicine and related sciences would like to use this information. This might be in the field of anthropology, human origins, mapping human migration patterns etc. If the data or samples are shared with researchers who are not involved in this study, any links to your identity will be removed.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, we will ask you to do the following things:

- attend study visits,
- complete study surveys,
- allow study staff to collect study samples.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you up to \$445 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 for the 2 year visit,
- \$75 and a small gift for your child for the 4-5 year visit,
- \$75 and a small gift for your child for the 7-8 year visit,
- \$15 for completing each of the following:
 - child spot blood collection at 2 years,
 - child venous blood collection at 2 years,
 - child hair collection at 2 years,
 - child home urine collection at 2 years,
 - child nasal mucus collection at 2 years,

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- child spot blood collection at 4-5 years,
- child venous blood collection at 4-5 years,
- child hair collection at 4-5 years,
- child home urine collection at 4-5 years,
- child spot blood collection at 7-8 years,
- child venous blood collection at 7-8 years,
- child hair collection at 7-8 years,
- child home urine collection at 7-8 years,
- \$5 gift card for each shed tooth you send us, up to \$25 for five teeth.

Depending on your study site, you will be paid in either cash or gift cards. Tax law may require your study hospital's finance department to report the amount of payment you receive from the study hospital to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if you receive payments that equal \$600 or more from the study hospital in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

You and your child are not expected to get any benefit from taking part in this research study. Others may not benefit either. However, possible benefits to others include increased knowledge of how environmental factors impact child growth and development.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Physical risks: The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw. For this reason, we always collect blood samples when your child is sitting down. The nasal swab may tickle or slightly irritate your child's nose. We may offer to use a numbing cream to put on your child's arm before the blood draw to reduce pain. There is a slight risk of side effects from the numbing cream, like redness, irritation, swelling, skin whiteness, itching, rash, change in how you sense skin temperature. If any of these occur, we will remove the cream immediately. Allergic reactions are rare, but we will not use the cream if your child has a family history of allergy to the ingredients in the cream.

Psychological risks: Your child may become bored or distressed when completing the learning or memory tasks. Each of the tasks was designed for young children. The tasks should not be more upsetting than situations your child may typically experience. If your child becomes very upset, the study will be stopped and you will be allowed to comfort your child. You may also end the procedure or withdraw from the study at any time.

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You may become upset when answering questions about emotional symptoms or stressors. You may refuse to answer any question you do not want to answer. You can stop the visit at any time by saying that you want to stop. You can withdraw from the study at any time. Stopping a visit or withdrawing from the study will not affect any care you may receive at any of the hospitals associated with this study. If you become very upset during the study, you will be referred for evaluation at your community clinic or the nearest emergency room. If you need continued treatment, you will be referred to an appropriate mental health professional in your community.

Privacy risks: There always exists the potential for loss of private information; however, there are procedures in place to minimize this risk. All of your answers to our questions and all of the information we gather about your child will be confidential and will be available only to the study staff. Information about your and your child's identity and links to your and your child's individual information will be kept in locked cabinets or securely stored electronically, only accessible to the study staff who will need to contact you for follow-up and analysis. Even with these precautions, we still cannot guarantee absolute confidentiality.

Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Since the database includes genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused, it is possible you would also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

Group Risks: Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most large employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you. If you choose not to take part in ECHO PEDS, you may continue to be in PRISM or First 1000 Days.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

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If you believe that you or your child has suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator at your hospital site.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You or your child may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at your hospital/ health care system any or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff at your hospital site.

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator (at your hospital site) at the mailing address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.

Withdrawal without your consent: The study Principal Investigators, the sponsor, or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If samples or data have been stored as part of the research study, they too can be destroyed without your consent.

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.
- 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.

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DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than \$5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at <http://icahn.mssm.edu/> where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project, it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use, and share that information.

What protected health information is collected and used in this study and might also be disclosed (shared) with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your and your child's name, address, telephone numbers, email address, birth date.

If you agree, the researchers will also get information from your PRISM or First 1000 Days of Life study file.

During the study, the researchers will gather information by completing the tests, procedures, questionnaires, and interviews explained in the description section of this consent.

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The research team and other authorized members of your study hospital's workforce may use and share your information to ensure that the research meets legal, institutional, or accreditation requirements. For example, your study hospital's Institutional Review Board is responsible for overseeing research on human subjects and may need to see your information. If you receive any payments for taking part in this study, the study hospital's Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.

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If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside your study hospital, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the study hospital workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project: Mount Sinai Hospital System, George Mason University, Boston Children's Hospital
- Research data coordinating office and/or their representative(s) who will be responsible for collecting results and findings from all the ECHO study sites: ECHO Data Coordinating Center at Duke University and the ECHO Data Analysis Center at Johns Hopkins University
- Outside laboratory who will be performing laboratory analysis for all the research centers involved in this project: NIH CHEAR Lab Hubs at Mount Sinai and other hospitals
- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: National Institutes of Health
- The United States Department of Health and Human Services and the Office of Human Research Protection.

In almost all disclosures outside of your study hospital, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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For how long will Mount Sinai, BCH, or GMU be able to use or disclose your protected health information? Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use, or share your health information?

NO! If you decide not to let us obtain, use, or share your health information, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator of your study hospital at the mailing address on the first page. Even if you withdraw your permission, the Principal Investigators for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

Certificate of Confidentiality: To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This Certificate does not mean that the Department of Health and Human Services approves of this research. Rather, it is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your research information with anyone who is not a member of the research team, including any family members or friends, other than to those identified above.

-----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

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT 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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However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

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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

Witness Section: For use when a witness is required to observe the consent process, document below (for example, subject is illiterate or visually impaired, or this accompanies a short form consent):

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process

Date

Printed name of person witnessing consent process

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