ECHO
Environmental influences on Child Health Outcomes
A program supported by the NIH

IRB APPROVED
AS MODIFIED
Apr 20, 2020

Consent to Participate in a Research Study

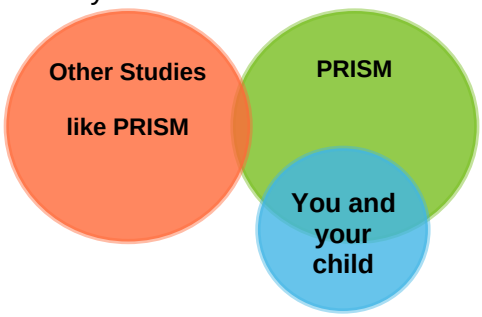
For Adult Participants

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
Investigator:	Rosalind J Wright, MD, MPH
Sub-Investigator:	Michelle Bosquet-Enlow, PhD
Research Site Address(es):	Boston Children's Hospital, 21 Autumn Street, 1st Floor Boston, MA 02115
Daytime Telephone Number(s):	Boston: 617-919-4680

Summary

Taking Part in the ECHO Program

- We are asking you and your child to join the ECHO Program to help understand how things that happen early in children's lives—even before they are born—affect their development, health, and wellbeing.
- This research program includes studies at about 200 locations in the United States.
- Rosalind Wright and Michelle Bosquet-Enlow lead the PRISM study at Boston Children's Hospital as part of the ECHO Program
- The ECHO Program will combine information from about 50,000 children and their families.
- With so many participants from many parts of the U.S., researchers can answer questions that the PRISM study cannot answer alone.



- The ECHO Program seeks to answer important childhood health questions. Some key questions are related to how the environment affects:
  - Mothers' and babies' health before, during, and after pregnancy
  - How children's airways develop and airways-related illnesses
  - Nutrition, physical activity, risks of being overweight, and weight-related illnesses
  - Brain development, including the ability to think and understand, social development, speech, attention, behavior, and emotions
  - Overall wellbeing, including things that strengthen the ability to adapt, satisfy needs, and achieve goals

Sponsor

The National Institutes of Health (NIH) supports this study.

Information and Samples

- We will ask you and your child for information and samples of blood, saliva, urine, hair, teeth, and toenail clippings. Blood and saliva will be used for DNA analysis.
- The exact information and samples will be different for each study location.
- We will collect information and samples through visits, phone calls, mail, online surveys, or other ways.

Risk

- As with all research studies, it is possible that someone might see information that identifies you when they do not have permission. To lower this risk, we will use special codes to label samples, questionnaires, forms, and other information instead of names. However, we cannot completely remove this risk.

Taking Part in a Research Study

- Research studies include only people who agree to take part. You can decide whether or not to be in the study.
- Before agreeing to continue in this study, you should read this consent form carefully, and ask any questions you have. Take your time making a decision.
- Ask the study staff to explain anything in this form that you do not understand.
- You can leave the study at any time. You may also decide not to give certain samples or not to answer certain questions.
- When you finish reading and someone has answered all of your questions, please sign and date this form if you agree to take part in the study.

What Is the Purpose of the ECHO Program?

- ECHO is a nationwide research program whose mission is to improve the health of children for generations to come.
- The goal is to learn how the environment affects children's health and development, and how it interacts with genetic information.
- The environment includes things that children may experience, throughout their lives and even before they are born, like the air they breathe, foods they eat, interactions with other people, and the neighborhoods where they live.
- Looking at differences in genes, which are made of DNA, can help us learn how genes and the environment work together to influence children's health. Genes may affect how our bodies respond to the environment, and the environment may affect how our genes work.

What Will I Need to Do in the Study?

- You are already part of the PRISM study. Now the PRISM study is taking part in the ECHO Program and we are asking you to take part as well.
- We will ask you to share with ECHO some of the information and samples you already gave the PRISM study.
- We will ask you to complete questionnaires and other forms. You may be able to complete them on a computer or tablet, by mail, over the phone, or in person. We will also collect information from your and your child's medical records.
- We will collect information and samples from you and your child during several periods-- when your child is 1-5 years old, when your child is 6-11, and when your child is 12-18. Depending on how old your child is now, you and your child may not participate during all these times.
- Examples of information that we will collect include:
  - Dates of birth, race, sex, gender, language, household information including address history, and jobs
  - Children's development and their behavior
  - Childcare and school attendance
  - Child and family health history, medications, immunizations (vaccines), and health insurance status
  - Household environment and exposures to chemicals and smoke
  -- Pregnant women's health care and diet
  - Things that may cause stress in your life, relationships with family and other people, and what your neighborhood is like
  - How children who join ECHO behave, what their daily life is like, friendships, their school life, how much exercise they get, what they eat, how they sleep, and how healthy they are overall
- If you are a biological parent of a child in ECHO, we will ask to collect samples from you. We may collect samples during a study visit, or we may give you instructions and supplies to collect samples at home.
- Examples of samples we will ask to collect include: blood, saliva (spit), urine, hair, toenail clippings, and children's shed teeth.
- 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 other studies related to ECHO.

What Will the ECHO Program Do With All This Information?

- By participating in ECHO, you allow us to share your and your child's information and samples with qualified researchers within and outside the ECHO Program. This includes information and samples you gave to the PRISM study in the past as well as new information and samples.
- Researchers will use your and your child's samples and information to look at your and your child's surroundings and experiences, such as chemicals, smoke, and what you eat. We will also study things in your and your child's body, such as, hormones, genes, germs, and whether you have been exposed to medicines or drugs.
- Researchers will use some of your and your child's samples, like blood or saliva, to look at DNA. We will also measure molecules from your cells, proteins, and other factors in blood or cells.

How Long Will the ECHO Program Last?

- The ECHO Program will last until 2023, and may continue after that.
- The PRISM study will decide how long they would like you and your child to participate in the study.
- The PRISM study visits will continue and are described in the PRISM consent forms.
- The ECHO Program will store your and your child's information and samples for an unlimited period of time, so researchers can use them in future health research.
  - See *"How Will You Protect My Information and Samples?"* and "*Will You Share My Information and Samples"*.
- At any time, you or your child can choose to leave the study.
  - See "*What If I Want to Leave the Study?*"

What Are the Possible Benefits?

- The ECHO Program may help us learn things about health and wellbeing that could benefit children—including your children and grandchildren—in the years to come.
- Taking part in ECHO will not improve your or your child's health right now nor will it change anything about your current medical care.
- You or your child will not receive medical care or other direct benefits from being in the study.
- By being part of this study, you will help answer questions about how to improve the health of children.

What Are the Possible Risks?

- Providing information and samples for this study is low risk. This means any discomfort you or your child might experience in the study is small and is similar to what could occur in daily life or during a routine doctor's visit.
- You or your child may have pain and bruising from a needle prick when collecting a blood sample.
- You or your child may feel uncomfortable answering questions about things like stressful events.
- Your and your child's privacy and confidentiality are very important to us. As with all research studies, there is a possible risk of loss of confidentiality even though we will store your and your child's names and contact information separate from other research information. This means someone might see your information when they do not have permission. Also, it is possible that in the future someone could figure out how to use the health or genetic information to identify individuals.
- Our testing might find a gene which may put you or a relative at risk for a genetic disorder in the future. There might be social and economic disadvantages associated with genetic information. For example, genetic information provided to the wrong source could affect you and your family. A U.S. law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Under this law, health insurance companies, group health plans, and most employers may not request your genetic information that we get from this research. For more information about GINA, please see: http://www.eeoc.gov/laws/types/genetic.cfm. This law does not protect information for being used when applying for life or long term care insurance. We will do our best to keep all information confidential and only with your permission would we share this information with others.
- Some people involved in genetic studies feel anxious about the possibility of carrying a gene that places them at risk or that may be passed on to children. If these feelings arise at any time during the research, you may contact us and we will arrange for you to speak with a genetic counselor.
- In order to allow researchers to share results, the National Institutes of Health (NIH) and other central repositories have developed special sample/data (information) "banks" that collect the results and analyze samples/data from research studies, including genetic studies. These central banks may also analyze and store samples and health information from research conducted by Boston Children's Hospital. These central banks will store your genetic and health information and/or samples and give them to other qualified and approved researchers to do more studies. We do not think that there will be further risks to your privacy and confidentiality by sharing your health information, samples and/or genetic information with these banks. However, we cannot predict how genetic information will be used in the future. The samples and data will be sent with only your research code number attached. Your name or other directly identifiable information will not be given to these central banks. There are many safeguards in place to protect your privacy
  - See *"How Will You Protect My Information and Samples?"*.

How Will You Protect My Information and Samples?

- The PRISM study will store information we need to contact you (like names, phone numbers, and email addresses.
- The ECHO Data Analysis Center at Johns Hopkins University (Baltimore, MD) and RTI International (Research Triangle Park, NC) will store your date of birth, other dates, and address information separate from other research information and samples.
- See "*Will You Share My Information and Samples"*.
- We will keep all information and samples in locked rooms or cabinets or in secure computer systems.
- Federal laws protect the privacy, security, and authorized access of research records. However, we cannot guarantee that we will never have to give out information.
- Laws help protect your genetic information, making it illegal to use genetic information to discriminate against you for health insurance coverage and employment. These laws do not apply to use of genetic information for other types of insurance (such as life, disability, or long-term care).
- For added protection, we have a Certificate of Confidentiality, which helps us protect the identity of people in the study. In some cases, the Certificate helps us refuse to give out information that could identify you or your child in a court of law or to others not connected with the research.
- The Certificate does not prevent us from giving out information that may identify you or your child if:
  - We have to report information by law, such as child abuse or some infectious disease;
  - We learn of possible harm to yourself or others, or if you need medical help;
  - You or a family member chooses to share information about you or about your participation in ECHO;
  - Researchers use it for other scientific purposes, as allowed by rules that protect research participants; or
  - You give written approval to give out the information. This includes sharing research information and samples for this study or for future research as described in this form.

Will You Share Our Information and Samples?

- The PRISM study and the ECHO Data Analysis Center will maintain ECHO information in secure databases. The information in the databases (including addresses, dates of birth, dates of procedures and collections, and health information) is for research only. For example, we may link information about your samples and health to information about air or water quality where you live or work.
- In addition, we will place genetic and health information about you in controlled-access NIH supported research databases. We will not label the information in a way that could identify you.
- The PRISM study and the ECHO Program will store, or "bank," ECHO samples and will distribute them in the future to approved researchers. We will not store samples with information that could identify you.
- ECHO researchers can request access to your research information and samples so they can help answer health questions. This does not include identifiable information such as birthdates and addresses.
- Researchers outside ECHO can request access to research information and samples that do not identify you. These researchers could be from government, academic, non-profit, or for-profit organizations.
- You will not be informed of the details of specific research that is done with your medical information and biospecimens. That means that a research project might be done that you would not consent to if provided with the details of that research project.
- Researchers will share summaries of ECHO analyses through scientific articles or other public scientific resources, such as NIH or ECHO databases. We will not publicly share any participant's individual information.
- When needed, people involved in this research program, including those working on, funding, and overseeing the program, may view your personal information.
- Others that may view your identifiable information include the Mount Sinai's and/or Boston Children's Hospital's Institutional Review Board, other representatives of Mount Sinai and Boston Children's Hospital, the Program for the Protection of Human Subjects, the United States Department of Health and Human Services, and the Office of Human Research Protection and the NIH. If any of these groups review your research record, they may also need to review your entire medical record. They may review your records to protect participants' rights and meet federal or state regulations.
- If study staff members think you may harm yourself or others, they may share that information with authorities or take other steps to protect you or others.

Will I Find Out the Results of the Research?

- From time to time, we will make study results available to all ECHO participants through the ECHO website, newsletters, community presentations, and scientific papers. These results will not be specific to any individual person in ECHO, including you or your child.
- If important new findings come up during the course of the study that might change your decision to be in this study, we will give you information about those findings as soon as possible.
- ECHO is a research program and therefore does not provide medical care. You should always talk to your doctor if you have questions or concerns about your health.
- The results of the tests performed for research purposes will not be placed in your medical record. Because of this, it is unlikely that others within the hospital, an insurance company, or employer would ever learn of such results.

What Are the Costs?

- There will be no costs to you or your child to be in this study other than the time and effort to complete study activities.
- The ECHO Program or the PRISM study will pay any costs related to study activities and sample collection.

Will I Receive Compensation?

- If you decide to take part in this study, you will be compensated for completing questionnaire packets, providing samples and body measurements from you and your child, and for you and your child to complete study tasks. We will give you $20 per completed questionnaire packet, $15 per sample/measurement, and $20 for study tasks. If you provide your child's shed teeth, we will pay you $5 per tooth. If you come to our site for visits, we will reimburse you for travel costs. When we collect samples from your child, or your child completes a study task or questionnaire packet, we will give them a gift worth about $10, in addition to the money we give you. If your child wears an activity monitor on their wrist for one week, we will pay you $75.
- We will pay you cash for in person visits and gift cards for phone, mail, or email surveys.
- If there is any overlap in procedures for PRISM and ECHO, the procedure will be done once and you will be paid once.
- You will be paid for your time spent in the research. Since this amount may be greater than the minimum reporting requirements set by the Internal Revenue Service or IRS (greater than $600/year), Boston Children's Hospital must report this to the IRS and will give you a 1099 form because the payment you receive for this study will be considered taxable income. Boston Children's Hospital will not deduct taxes from this payment. You will be responsible for reporting this payment when you file your tax return. We will ask for your social security number for tax reporting purposes, but it will not be stored with any other research data.

What If I Want to Leave the Study?

- You and your child's participation is voluntary. You may choose not to take part in ECHO. If you do decide to take part, you can leave at any time for any reason.
- You or your child can skip any part. You can also take a break at any time during the study and come back later.
- If you decide not to take part or you decide to leave ECHO, it will not result in any penalty or affect any medical care or benefits you or your child are otherwise entitled to. Also, it will not affect your or your child's access to health care.
- If you decide to leave the study, we encourage you to talk to a study staff member about why you would like to leave. You can reach the PRISM study staff at the phone number listed on the first page of this form.
- If you decide to leave the study, we will keep the information and samples we have collected up to that point, but will not ask you for any more information or samples. We will continue to use and share the information and samples you and your child provided unless you ask us not to do so. In that case, you can notify the PRISM study staff and we will stop using the information and any remaining samples. We cannot get back information or samples already given to other researchers or placed in coded databases.

What Alternatives Are There to Taking Part in This Study?

- The alternative to taking part is to not take part.

Whom Do I Call If I Have Questions or Problems?

- If you have questions about the study or a research-related injury, or if you have problems, concerns, complaints, questions, or suggestions about the research, contact the research team at the phone number(s) listed on the first page.
- An Institutional Review Board (IRB) oversees this research. An IRB is a group of people who perform independent review of research studies to protect the rights and welfare of participants.
- You may talk to a BCH IRB Staff member at (617) 355-7052, IRB@childrens.harvard.edu or a non-BCH IRB staff member at (888)-303-2224, irb@cgirb.com if:
  - You have questions, concerns, or complaints and you are not getting answers from the research team.
  - You want to talk to someone else about the research.
  - You have questions about your rights as a research participant.

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 will collect your and your child's name, address, phone number, birthdate, email address. The researchers will also get information from your and your child's medical record at the hospital where your child was born and/or your child's doctor. During the study the researchers will gather information by completing the procedures described on this form.

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 the study hospital workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the Mount Sinai's Program for the Protection of Human Subjects 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 hospital's Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Your health information is protected by a law called the Health Information Portability and Accountability act (HIPAA). In general, anyone who is involved in this research, including those funding and regulating the study, may see the data, including information about you. For example, the following people might see information about you:

- Research staff at Boston Children's Hospital involved in this study;
- Medical staff at Boston Children's Hospital directly involved in your care that is related to the research o arises from it;
- Other researchers and centers that are a part of this study, including people who oversee research at that hospital;
- People at Boston Children's Hospital who oversee, advise, and evaluate research and care. This includes the ethics board and quality improvement program;
- People from agencies and organizations that provide accreditation and oversight of research;
- People that oversee the study information, such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others;
- Sponsors or others who fund the research, including the government or private sponsors.
- Companies that manufacture drugs or devices used in this research;
- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities;
- People or groups that are hired to provide services related to this research or research at Boston Children's Hospital, including services providers, such as laboratories and others;
- And/or your health insurer, for portions of the research and related care that are considered billable.

If some law or court requires us to share the information, we would have to follow that law or final ruling.

Some people or groups who get your health information might not have to follow the same privacy rules. Once your information is shared outside of Boston Children's Hospital, we cannot promise that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information. Other laws may or may not protect sharing of private health information. If you have a question about this, you may contact the Boston Children's Hospital Privacy Officer at (857) 218-4680, which is set up to help you understand privacy and confidentiality.

Because research is ongoing, we cannot give you an exact time when we will destroy this information. Researchers continue to use data for many years, so it is not possible to know when they will be done.

We will also create a code for the research information we collect about you so identifying information will not remain with the data and will be kept separately. The results of this research may be published in a medical book or journal or be used for teaching purposes. However, your name or identifying information will not be used without your specific permission.

Your privacy rights

If you want to participate in this research study, you must sign this form. If you do not sign this form, it will not affect your care at Boston Children's Hospital now or in the future and there will be no penalty or loss of benefits. You can withdraw from the study and end your permission for Boston Children's Hospital to use o share the protected information that was collected as part of the research; however you cannot get back information that was already shared with others. Once you remove your permission, no more private health information will be collected. If you wish to withdraw your health information, please contact the research team.

You may have the right to find out if information collected for this study was shared with others for research, treatment or payment. You may not be allowed to review the information, including information recorded in your medical record, until after the study is completed. When the study is over, you will have the right to access the information again. To request the information, please contact the Hospital's Privacy Officer at (857) 218-4680.

In almost all disclosures outside of the 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 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.

For how long will the study hospital 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 at the address on the first page. Even if you withdraw your permission, the Principal Investigator 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.

It is important for you to understand that once information is disclosed to others outside the study hospital, 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, the study hospital has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

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 to your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

Signature of Person Obtaining Consent | Date | Time

For office use: STUDY ID

Documentation of Informed Consent and Authorization

- I have read this consent form and was given enough time to consider the decision to participate in this research.
- This research has been satisfactorily explained to me, including possible risks and benefits.
- All my questions were satisfactorily answered.
- I understand that participation in this research is voluntary and that I can withdraw at any time.
- I am signing this consent form prior to participation in any research activities.
- I give permission for participation in this research and for the use of associated protected health information as described above (HIPAA).
    - My child will have a chance to provide assent on the consent form below, unless the study staff determines my child is unable to do so.
-

Printed Name of Participant

Parent/Legal Guardian Permission (if applicable)
If the child to be involved in this research is a foster child or a ward of the state please notify the researcher or their staff who is obtaining your consent.

■ Date (MM/DD/YEAR) | Signature of **Parent** or **Legal Guardian** | Relationship to child

Child Assent

■ Date (MM/DD/YEAR) | Signature of **Child/Adolescent Participant**

■ If child/adolescent's assent is **not** documented above, please indicate reason below (check one):
▭ Assent is documented on a separate IRB-approved assent form
▭ Child is too young
▭ Other reason (e.g. sedated), please specify: _____

Adult Participant (if applicable)

■ Date (MM/DD/YEAR) | Signature of **Adult Participant (***18+ years)*

Research Investigator /or Associate's Statement & Signature

- I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant /parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.
- I have provided a copy of the consent form signed by the participant / parent / guardian and a copy of the hospital's privacy notification (if requested).

■ _____ _____

Date (MM/DD/YEAR) Signature of **Research Investigator or Associate**

☐ I have explained the study to the extent compatible with the participant's capability, and the participant has agreed to be in the study.

OR

☐ The participant is not able to assent because the capability of the participant is so limited that the participant cannot reasonably be consulted.

_____ _____

Date (MM/DD/YEAR) Signature of Person Obtaining Assent

Witness Statement & Signature

A witness must be present for the entire consent process in the following situations (please check the appropriate box)

__ The individual cannot read and this consent document was read to the participant or legal guardian, **or**

__ The individual has certain communication impairments that limit the participant's ability to clearly express consent **or**

__ Situations where the IRB requests a witness be present: please specify _____

I confirm that the information in this consent form was accurately explained to the participant, parent or legal guardian, the individual appeared to understand the information and had the opportunity to ask questions, and that informed consent was given freely.

■ _____ _____

Date (MM/DD/YEAR) Signature of **Witness**

Or

☐ The individual is not English speaking and, through an interpreter, a short form consent document was presented orally to the participant or legal guardian and this consent document serves as the summary for such consent.

I confirm that the information in this consent form was presented orally to the participant, parent or legal guardian, in a language they could understand and the individual had the opportunity to ask questions.

■ _____ _____

Date (MM/DD/YEAR) Signature of **Witness**