



Use Plate or Print:

MRN#:

DOB:

Subject's Name:

Gender:

**Protocol Title: Hydrogen's Feasibility and Safety as a Therapy in ECPR (Hydrogen-FAST Trial)***BCH IRB Consent Template (February 2022 Version)***Principal Investigator: John Kheir, MD**

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This consent form gives you important information about a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care.

Please read this consent form carefully and take your time making a decision. The first section gives you an overview of the key information you should know about the research study. More detailed information about these topics may be found in the pages that follow.

The form may contain words that you do not understand. Please ask questions about anything you do not understand. We encourage you to talk to others (for example, your friends, family, or other doctors) before you decide to participate in this research study.

Please check one of the following:

You are an adult participant or an emancipated minor in this study.

You are the parent or guardian granting permission for a child in this study.

If the participant is a child the use of "you" refers to "your child".

### **Summary of Important Information**

We are asking you to participate in this research study. Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time. Your decision will not impact the clinical care you receive at Boston Children's Hospital. Because this is an emergency, the majority of patients enrolled in this trial are enrolled without informed consent.

In this research study we want to learn more about a new treatment for injury that can occur during a cardiac arrest that requires extracorporeal membrane oxygenator (ECMO) as a rescue treatment. We are trying to determine whether low concentrations of hydrogen gas protect the brain, kidney, and other organs from the damage that can occur after a cardiac arrest requiring ECMO support.

It is important to consider reasons why you would or would not want to participate in this research.



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Because ECPR is an emergency, your child has been/is being placed onto ECMO as a treatment for cardiac arrest that did not respond to medications. You do not have to be in this research study to be treated for cardiac arrest requiring ECMO rescue (known as ECPR). A cardiac arrest is an unexpected and rare event in which the heart stops effectively beating, causing blood in the body to stop flowing. It happens in ~1% of patients admitted to the cardiac ICU. This is a true medical emergency because the body requires a continuous supply of oxygen to keep cells healthy; when that does not happen, organ damage begins almost immediately. Standard treatments include CPR, placement of a breathing tube and administration of oxygen, and medications to help the heart start beating effectively again. When these efforts are ineffective, some patients have to be rescued using a heart-lung bypass machine known as ECMO. This process of rescuing a patient whose cardiac arrest does not get better using standard techniques using ECMO is ECPR. This requires the patient's room to be instantly transformed into an operating room. A surgical team performs emergency surgery on the blood vessels or on the heart itself to place large tubes that connect the ECMO machine to the circulation. Once turned on, the ECMO machine supplements the function of the heart and lungs, providing oxygen and warmth to the blood, and pumping it to the body. Even with the best treatments today, fewer than 50% of patients survive an ECPR event, largely due to the oxygen deprivation that occurs during the ECPR event itself.

Your healthcare provider has discussed with you what your clinical treatment options are and which clinical treatment(s) might be right for you considering your medical history. These clinical treatment options may include ECMO support, mechanical ventilation, sedation, monitoring for and treatment of seizures, brain imaging, dialysis, and perhaps others. Each of the clinical treatment options has known rates of being effective, known risks, as well as possible drawbacks.

The study treatment has not yet been proven to be safe and/or effective for the treatment of ECPR. The study treatment may work better, the same, or worse and may have less, more, and/or other risks compared to the clinical care options. It is important to consider the trade-offs of the clinical care options as well as this research study before you decide whether you take part or not take part in this research study.

If you decide to join this research study, the following things will happen: you will be randomly assigned to receive, or not to receive, 2% hydrogen gas through your ventilator and through the ECMO membrane for 72 hours. We will follow any signs or symptoms you have for 30 days, whether or not they are related to hydrogen. We will follow the labs that your clinical team orders and will also draw small samples of your blood periodically to help us understand whether hydrogen is decreasing the degree of brain injury you have. We will also examine your medical record for the same purpose.

The most important potential risk to know about are that administering hydrogen in the ECPR setting may have unknown negative effects. However, we have administered the same dose of hydrogen to 8 healthy adults and no negative effects were noted. If you are in the control group, you will not experience this risk.

The most important potential benefits to know about are that hydrogen may decrease your degree of brain injury (including your ability to function, eat, or talk, and the incidence of seizures) after an ECPR event. It may also decrease your kidney injury after an ECPR event. Taken together, these may improve your chances of surviving following an ECPR event. If you are in the control group, you will not experience this benefit.



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Patients in both groups will have some extra blood testing done to examine for injury over the first 30 days, and it is possible that you will benefit from this.

It will take you about 30 days to complete this study, not including a follow-up visit at 6 months. If you follow-up with your doctor at home, we can use information from that visit, or perform a videoconference to see how you are doing.

The research funds will cover costs associated with the study. We may bill your health insurer for routine items and services you would receive even if you did not take part in this research.

The medical conditions that result in e-CPR and the need for ECMO are extremely serious with high mortality. This research study cannot eliminate those risks which the clinical team will have communicated. The risks and possible benefits in this study need to be considered in that context.

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**How are individuals selected for this research study**

You are being asked to participate in this research study because you are having a cardiac arrest in a cardiac ICU at Boston Children's Hospital and are being cannulated to ECMO.

**Why is this research study being conducted?**

This study involves testing an investigational drug known as hydrogen gas. This means that hydrogen gas has not yet been approved by the Food and Drug Administration (FDA) and has not yet been proven to be safe and effective for the purpose we are studying. Information from this research may help decide whether the study drug/device should be approved by the FDA.

**Who is conducting this research study, and where is it being conducted?**

John Kheir, MD, a cardiac intensive care doctor at Boston Children's Hospital is leading this study. A grant from the National Heart, Lung and Blood Institute, a member of the National Institutes of Health will provide funding for this study.

Your health care provider may be a research investigator for this research study and as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another health care provider who is in no way associated with this project. You are not under any obligation to participate in any research project offered by your health care provider. If you choose not to participate or not to allow your child to participate, your care or your child's care at Boston Children's Hospital and/or with your health care provider will not be affected in any way at all.

**How many people will participate in this research study?**

Approximately 56 people will take part in this study at 2 different hospitals, and approximately 35 people will take part at Boston Children's Hospital.

**What do I have to do if I am in this research study?**

1. You will be randomly assigned to be – or not to be – treated with hydrogen administered through your ventilator and your ECMO machine for 72 hours, starting at the time of your cardiac arrest and ECPR event. Because no one knows whether hydrogen is effective, you will be “randomized” into one of the two study groups. One group will receive hydrogen and one group will not. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have a 2 out of 3 chance of being placed in the hydrogen group. Neither you nor the research investigator can choose what group you will be in.
2. For 30 days after the ECPR event, we will closely examine your medical record, and ask members of your clinical team, to determine whether you have experienced any negative effects related to hydrogen, and whether hydrogen helped to improve your recovery or survival from ECPR.
3. We will ensure that commonly measured blood tests – to look for damage to your liver, kidneys, heart, and other organs – are measured at least once every day for the first week after you are on ECMO, and then at least once per week for the next 3 weeks.

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4. We will collect a small amount of blood (1 mL total) at these same timepoints to measure new blood tests that will help us understand whether hydrogen helped to decrease your degree of brain injury. We estimate we will withdraw 5 mL of blood total for study purposes.
  5. We will follow-up with you at 6 months. If you follow-up with your doctor at home, we can use information from that visit, or perform a videoconference to see how you are doing.

**What are the risks of this research study? What could go wrong?*****Risks related to hydrogen administration***

The administration of hydrogen in the setting of ECPR may present risks that are not well-known or understood. Therefore, there may be unforeseeable risks associated with participating in this research. However, our investigative team, and others, have used a similar dose of hydrogen in animals in a similar setting and have not found any risks associated with its administration through the ventilator or through the ECMO machine, nor have we noted any impact on lung, heart, or other organ functions. We have also administered this dose of hydrogen to 8 healthy adults, none of whom reported any negative effects, and all blood testing was normal.

***Risks associated with blood testing***

Risks associated with a blood draw may include minor discomfort, bruising, fainting, and infection. In most cases, we will draw blood from a catheter that you already have to minimize the risk of painful needle sticks.

**What are the benefits of this research?**

If you are treated with hydrogen, it is possible that you will benefit. We and others have found that animals experiencing injuries like ECPR experience less brain injury, better cognitive functioning, fewer seizures, and smaller areas of injury on brain MRI when treated with hydrogen. They also experienced less kidney injury. Given that the likelihood of survival to discharge following ECPR varies between 42-48%, and that brain and kidney injury are important contributors to death in this setting, hydrogen treatment may be associated with improved survival.

Because we may measure additional labs that may uncover important changes in your recovery, it is possible that you may also have closer medical monitoring as a result of being in this study.

When we finish the research, we hope that we will know more about the safety of hydrogen in ECPR. This may help other children/adults with cardiac arrest, stroke, heart attacks, infections, or organ transplants in the future.

**Will I receive my study results?**

During this research we may learn information from the labs that we send which could be important for your health or your treatment. This information will be made available to you and your healthcare team as routinely ordered labs would be.

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We may also learn information from the special brain injury markers, but since we are not sure about how to interpret these labs yet, and since they will be run many months after your injury, we will not share this information with you or your care provider.

### **Will my samples/information be used for research in the future?**

We will gather samples about you as part of your participation in this research study, which may yield findings from the brain biomarker tests.

To advance science, medicine, and public health, we may share your samples with other researchers and one or more scientific databases but only after personal information that may identify you has been removed. Your samples will be labeled with a research code without identifiers so that you cannot be identified. These samples may be shared without getting additional consent from you.

The samples may be combined with other researcher's data to help understand, why diseases develop, how to best diagnose and treat diseases, and how to develop new medicines or medical devices. Your samples may be made broadly available for general research for multiple conditions or diseases.

If you have questions about storing samples or would like to request that samples be removed from storage, please let us know. It is not always possible to remove samples from storage or to retrieve samples from which identifiers have been removed and/or that have already been sent to other researchers.

Please check any that apply:

\_\_\_\_\_ I do not want you to draw any extra blood samples.

\_\_\_\_\_ I do not want you to use my child's samples for future research.

### **Are there costs associated with this research? Will I receive any payments?**

Although research funds will pay for some research-related items and services, we may bill your health insurer for routine items and services you would have received even if you did not take part in this research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the research staff.

We will offer you the care needed to treat any injury that directly results from taking part in this research. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.



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Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form. If you think you have been injured or have experienced a medical problem as a result of taking part in this research, tell the person in charge of the research as soon as possible. The researcher's name and phone number are listed in this consent form.

If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in this research. If possible, you should give them a copy of this consent form.

### **If I do not want to take part in this research, what are the other choices?**

If you do not join this research your doctor can discuss other healthcare choices with you. Your other choices may include continuing with general supportive intensive care, including mechanical ventilation, ECMO support. The only treatment to diminish injury after an ECPR event is to avoid fevers. Hydrogen is not available without being in this research protocol at this time.

### **Are there other things I should know about?**

As this research progresses, we may learn new information from data we have collected through other participants or from outcomes from other research studies. If this information could affect your health, safety or willingness to stay in this research, we will let you know as soon as possible.

### **Why would I be taken off the study early?**

The research investigator may take you out of this study at any time. This would happen if:

- You are not placed on ECMO within 2 hours of randomization.
- The research is stopped.
- The research investigator feels it is in your best interest to be taken out of this research.

If this happens, the research investigator will tell you.

### **Other information that may help you:**

Boston Children's Hospital is interested in hearing your comments, answering your questions, and responding to any concerns regarding clinical research. If you have questions or concerns, you may email [IRB@childrens.harvard.edu](mailto:IRB@childrens.harvard.edu) or call (617) 355-7052 between the hours of 8:30 and 5:00, Monday through Friday.

### **Who may see, use or share your health information?**

A copy of this consent form will not be placed in your medical record.

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Some of the information collected during this research will become part of your medical record, if the information is related to the care you receive at Boston Children's Hospital; this will include the results of any standard blood testing that is requested as part of the study protocol, but specifically not including the results of the brain injury marker blood testing. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Boston Children's Hospital and may be reviewed by Hospital staff when carrying out their responsibilities; however, they are required to maintain confidentiality in accordance with applicable laws and Hospital policies. Information contained in your medical record may not be given to anyone unaffiliated with Boston Children's Hospital in a way that could identify you without written consent, except as required or permitted by law.

The results of the brain injury blood testing 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.

The National Institutes of Health has issued (or we have applied to the NIH for) a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information that may identify you, even under a court order or subpoena unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you if required by law (such as to report child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or if it is used for other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. Any research information that is placed in your medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this web site at any time.

The Boston Children's Hospital standard is to send emails securely by encryption. If you prefer, we can send you regular non-encrypted emails. Unencrypted emails are sent directly to and can be opened from your personal email account.

We would also like to offer you the option of receiving study information and updates via SMS text message. Text messages are sent directly to the personal phone number you have provided. Text messages are sent from study-related Boston Children's Hospital phone numbers.

There is a potential risk of loss of confidentiality when using unencrypted e-mail and text messaging, as both are hosted by a third-party. Please be aware that these communications can be intercepted in transmission or misdirected.





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You acknowledge that you have been informed and understand that we cannot guarantee that regular non-encrypted email or text messages will be confidential. Please check below if you wish to receive non-encrypted emails or text messages.

\_\_\_\_\_  I wish to receive regular non-encrypted emails from the study team.

\_\_\_\_\_  I wish to receive text messages from the study team.

If, at any point, you no longer wish to receive unencrypted emails from us, you may indicate this by sending an email to [hydrogenfast@childrens.harvard.edu](mailto:hydrogenfast@childrens.harvard.edu) or calling this number 857-299-4233, and we will return to communicating via encrypted email. If you no longer wish to receive text messages from us, you may also reply STOP to a study text message and we will no longer send study text messages.

**Contact for Future Studies:** Your participation in any research is completely voluntary and you should feel no pressure to participate if you are contacted about another research study.

**Please check and initial one** of the options below regarding future contact about other research done by us or other researchers we are working with (collaborators).

\_\_\_\_\_  Yes, I may be contacted about participating in other research projects studying ECPR and brain injury or related conditions. I give permission for my contact information (name and mailing address and/or phone number) to be given to other researchers working with the study investigator at Boston Children's Hospital.

\_\_\_\_\_  No, I do not want to be contacted about other research projects. **Do not** give my contact information to the staff of any other research studies.

## **What should you know about HIPAA and confidentiality?**

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 or 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;



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- 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 or 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

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access the information again. To request the information, please contact the Hospital's Privacy Officer at (857) 218-4680.

## Contact Information

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study. I know:

 I can call...	 At	 If I have questions or concerns about
Investigator: John Kheir, MD	Phone: <b>857-636-8890</b> Pager: 617-355-7243 #4155	<ul style="list-style-type: none"> <li>▪ General questions about the research</li> <li>▪ Research-related injuries or emergencies</li> <li>▪ Any research-related concerns or complaints</li> </ul>
Research Contact	Phone: <b>857-299-4233</b>	<ul style="list-style-type: none"> <li>▪ General questions about the study</li> <li>▪ Research-related injuries or emergencies</li> <li>▪ Any research-related concerns or complaints</li> </ul>
Institutional Review Board	Phone: <b>617-355-7052</b>	<ul style="list-style-type: none"> <li>▪ Rights of a research participant</li> <li>▪ Use of protected health information.</li> <li>▪ Compensation in event of research-related injury</li> <li>▪ Any research-related concerns or complaints.</li> <li>▪ If investigator/research contact cannot be reached.</li> <li>▪ If I want to speak with someone other than the Investigator, Research Contact or research staff.</li> </ul>

## 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).

### Parent/Legal Guardian Permission (if applicable)

**Please let the researcher or staff know if the Massachusetts Department of Children and Families (DCF) has obtained temporary or permanent legal custody of the child to be involved in this research.**

■ \_\_\_\_\_  
 Date (MM/DD/YEAR)    Signature of **Parent #1** or **Legal Guardian**    Relationship to child



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■ \_\_\_\_\_  
Date (MM/DD/YEAR) Signature of **Parent #2** (if required) Relationship to child

CHECK if 2<sup>nd</sup> parent signature **not** obtained above. The PI must document in research records all attempts made to contact the second parent, as well as the reason why the 2<sup>nd</sup> parent signature was not obtained.

### 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)**

### Adult Participant: If decisionally impaired (if applicable)

### Legal Authorized Representative/Guardian

I give permission for the person I am authorized to represent to participate in this research and for the use of associated protected health information as described above (HIPAA).

■ \_\_\_\_\_  
Date (MM/DD/YEAR) Signature of **Legal Guardian** Print Name

■ Relationship to Participant \* (*This order must be followed. If there is a court appointed guardian, this is who needs to provide consent. If not, a health care proxy, followed by durable power of attorney and lastly, family members*)

- Court-Appointed Guardian
- Health Care Proxy (Attach Proxy and ensure there is express authority to make health care decisions inclusive of research.)
- Durable Power of Attorney (POA) (Durable POA may be limited to specific areas. Attach Durable POA and ensure that it covers research.)
- Family Member/Next of Kin, (in order of preference: spouses, parents, and adult children)



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Specify relationship \_\_\_\_\_

**Adult Assent (if applicable)**

■ \_\_\_\_\_  
Date (MM/DD/YEAR)      Signature of **Adult Participant**

CHECK if Adult Participant's assent **not** obtained above, and specify reason below:

**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**

**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 representative, **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 legally authorized representative, 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



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**Or**

The individual is not English speaking and, through an interpreter, a short form consent document was presented orally to the participant or legal representative 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 legally authorized representative, in a language they could understand and the individual had the opportunity to ask questions.

\_\_\_\_\_  
 Date (MM/DD/YEAR)                      Signature of Witness