Note on SIREN Informed Consent Forms

The Sponsor/Investigator of WINDSURFER does not allow edits to this central IRB approved main consent form for this multicenter trial. This is to ensure equity of the language across the enrolling sites. Your site may add site-specific content in a single contained section below the universal text if necessary. This section is limited to information that pertains specifically to your local institution.

Please note the process for submitting informed consent form for WINDSURFER as site submit ceding applications to local IRBs. All SIREN informed consent forms are approved by the Advarra Central IRB (ER-CIRB) with the parent protocol. The informed consent form is a completely locked down form, to be used consistently across WINDSURFER sites. Please submit this form to your local IRB as is, without making any site specific changes. The current ER-CIRB approved form to be used is located in the WINDSURFER workbench.

Where local site and study team contact information needs to be included. This will populate directly into the form after the site application is submitted to and approved by the ER-CIRB. In very limited circumstances, when institutionally required language is requested by the IRB, there is potential to add a separate site-specific section at the end of the form prior to the signature page. However, for the time being, please submit the form as is. Additions will only be considered per a request from the local IRB and will be discussed on a case by case basis. Should this request from the IRB be made, please provide at the earliest time the additional requested language in a separate document for review by the SIREN CCC. Please do not edit or insert language into the body of the trial-wide approved ICF.

Please note that while HIPAA language is already included in the body of the consent form, a separate local HIPAA form is acceptable for use. So long as it is signed and dated by subject/LAR.

We understand that this process differs from how the ICF review process has operated for other trials. We are happy to help as we move along with this process; please let us know if we can be of assistance. Please also note the statement below from Advarra regarding this process for SIREN trials.

As you know, Advarra is the single IRB for SIREN network trials. If your organization has a negotiated process in place with Advarra specifically as it pertains to the informed consent language, please note that the established process that has been in place with your site and Advarra is suspended for the SIREN network's trials. SIREN has their own IC process which Advarra will follow for these specific trials. Any non-SIREN trials will follow the established process you have in place with Advarra.

If you have any questions, please reach out to windsurfer-contact@umich.edu

Thank you for your attention to this matter.

Best Regards,

Note on SIREN Informed Consent Forms

The SIREN Team

Consent for Clinical Research Study
And
Authorization to Disclose Health Information
Continued participation of participants enrolled under EFIC

Sponsor / Study Title:	**The National Heart Lung and Blood Institute (NHLBI) / "WIN ratio analysis to Determine a strategy of non-invasive SUpport for Respiratory Failure in the EmeRgency Department (WINDSURFER)** **A multicenter, randomized clinical trial to identify the best non-invasive respiratory support (NIRS) strategy for emergency department (ED) patients with acute hypoxemic respiratory failure (AHRF)."**
Protocol Number:	**WINDSURFER**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

If you are acting as a representative for another person who is not able to consent for themselves, about that person's participation in this study, "you" throughout this document refers to that person.

This research study involves participants who may be unconscious and/or do not have the capacity to consent to take part in the study. In cases where the participant's representative gives consent to continue participation, the participant should be informed about the study to the extent possible. If the participant regains capacity, the participant will be informed about the study and may leave the study if desired.

SUMMARY OF KEY INFORMATION

You were having trouble breathing and required oxygen. This is called acute hypoxemic respiratory failure (AHRF). The doctors in the emergency department had to start you on oxygen quickly to help you breathe. You qualified for this emergency research study and were included in the study. We could not get your permission before enrolling because the emergency treatment for respiratory failure must begin immediately. Now that you have been assigned to a study treatment, we are asking you to continue participating in this study. You can choose whether or not you want to continue to participate. The study team and this form provide information to help you decide.

This type of research is called "planned emergency research," and in cases where consent cannot be obtained, participants are enrolled using a US Food and Drug Administration (FDA) approved process for emergency situations called Exception from Informed Consent requirements. In this type of research, there is not time to discuss the study and obtain permission to participate in advance, so the research team informed the community in which you live about the study and addressed community concerns and questions that were raised before the study started. The community was consulted because it is not possible to predict who may suffer from AHRF. The research team will continue to try to get consent, even after you have been included in the study.

If you would like to know more about the steps taken to inform and consult the public about this study before it started, please contact the study doctor listed on the first page of this form.

Acute hypoxemic respiratory failure (AHRF) makes it difficult to breathe and causes critically low levels of oxygen in the blood. Acute hypoxemic respiratory failure often gets better when treated with oxygen. The purpose of this study is to identify whether oxygen given through a special face mask, called non-invasive positive pressure ventilation (NIPPV), or oxygen given through a special tube that sits in front of the nose, called heated high flow nasal oxygen (HFNO) is better for treating acute hypoxemic respiratory failure and whether the study treatments are safe. Both require special breathing equipment to deliver the oxygen. NIPPV and HFNO are both standard care ways of giving oxygen to people in respiratory failure, but it is not known if one option is better than the other.

Everyone in this study will receive oxygen. Everyone will be randomly assigned to receive oxygen through either NIPPV or HFNO. Random means assigned by chance, like the flip of a coin. Most study participants will have blood collected and tested every day for their ongoing medical care. Additional blood and urine may be collected for this study up to three times over the first three days. You may have other measurements collected such as chest movements to understand how the body responds when oxygen is used. No other aspects of your routine medical care are affected by the study.

If you continue in the study, you will continue to get oxygen through the study treatment assigned by the study (NIPPV or HFNO) for up to 24 hours or as long as your regular doctor thinks you need it. If your doctors do not think the study treatment is treating you adequately, they will give you more intensive treatment as needed. We will follow your progress while you are in the hospital. Your participation in the study will last up to 28 days. By agreeing to continue in the study, you allow us to collect medical information about you and how you are doing until you are discharged from the hospital or until 28 days after you started oxygen. We may also review your medical records up to 3 months after you start in the study. Researchers may contact you after you leave the hospital to ask you to participate in other research activities.

Because we do not know which oxygen system is better, you may benefit from one of these study treatments, but this is not guaranteed. You may not get any added benefit from being in this study. However, the information we obtain from this study may benefit other patients in the future.

The medical risks and discomforts of being in the study are similar to standard medical care. Acute hypoxemic respiratory failure is associated with substantial medical risks. These risks are not affected by participation in the study. The oxygen systems used in this study are approved by the Food and Drug Administration (FDA) and commonly used in the emergency department and hospital.

The risks of the two oxygen systems are the same whether they are used for the study or outside of this study. The risks of NIPPV include skin damage, dry mouth, eye irritation, sinus problems, stomach bloating and potential anxiety or claustrophobia. The risks of HFNO include nasal dryness, nosebleeds or discomfort from the flow through the nasal prong interface. Other side effects of both systems may also include pneumonia, lung injury, shock, abnormal heart rhythms, headache or confusion (from carbon dioxide rebreathing), or difficulty swallowing. There may be other unknown risks as well. Both study treatments are commonly used to help people with low oxygen levels. However, how well each study treatment works can be different for each person.

There may be risks if you are pregnant which are described later in this form. Collection of blood may cause pain or bruising. Measurement of chest movements may cause skin irritation.

Continuing to participate in this study is voluntary. The alternative is to no longer take part in the study. If you decide not to continue, your decision will not affect your current or future medical care in any way. If you choose not to continue, we will not collect any further information about you. However, we may keep information or specimens collected before the point of your withdrawal from the study. You can stop participating at any time.

Medical records and data collected in the study will remain as private as possible. Records may be viewed by the study team here or from the study coordinating centers. Records may also be seen by those who review the safety and conduct of the study. Review is done by this hospital, government regulators, and study funders.

There is no payment for being in the study. There is no cost to being in the study. Charges for all standard medical care will be billed the same way whether or not you are in the study.

Please contact us for any questions about the study, your participant rights, or other concerns. Please carefully read this form. Additional details about each item just described are found on the following pages. Please listen to the study team. They will explain the study and this form to you. Please ask questions about anything that is not clear. If you consent, you will be asked to sign this form.

MORE DETAILED INFORMATION

Why am I being asked to participate?

You received a copy of this form because you were having trouble breathing and required oxygen. This is called acute hypoxemic respiratory failure (AHRF). You needed immediate treatment in the emergency department. The doctors had to start you on oxygen quickly to help you breathe. You qualified for and were included in this emergency research study. We could not get your permission before enrolling because the treatment for acute hypoxemic respiratory

failure must begin immediately to prevent organ injury and death. There was not enough time to explain the risks and benefits of the study.

We are now asking you to continue participating in this study. You can choose whether or not you want to continue participating in the study. In other words, your participation is voluntary. Before you can decide, you will need to know what the study is about, the risks and possible benefits of being in this study, and what you will have to do in this study. The study team will talk with you about the study and this consent form. This form gives you essential information about the study. Please take time to review this information carefully. You may find some of the medical words hard to understand. Please talk with the study doctor or the study team about this form and ask them any questions you have. You may also decide to discuss it with your family, friends, or family doctor. If you choose to continue participating in the study, we will ask you to sign this form.

What is the purpose of this research study?
Acute hypoxemic respiratory failure makes it difficult to breathe and causes critically low levels of oxygen in the blood. Acute hypoxemic respiratory failure often gets better when treated with oxygen. However, without treatment, acute hypoxemic respiratory failure may worsen, causing death or requiring treatment with a breathing tube and mechanical ventilator. The purpose of this study is to identify whether oxygen given through a special face mask, called non-invasive positive pressure ventilation (NIPPV), or oxygen given through a special tube that sits in front of the nose, called heated high flow nasal oxygen (HFNO) is better for treating acute hypoxemic respiratory failure and whether the study treatments are safe. Both require special breathing equipment to deliver the oxygen. Giving oxygen through NIPPV or HFNO is common in the emergency department and hospital. Both oxygen systems are approved by the Food and Drug Administration (FDA) to treat acute hypoxemic respiratory failure.

What happens in this study?
Everyone in this study gets oxygen to help them breathe. Everyone will be randomly assigned to receive oxygen through NIPPV or HFNO. Random means assigned by chance, like the flip of a coin. Blood and urine may be collected for the study. Measurements such as of movements of the chest through the skin may be made. Review of medical records will also occur. This information will help us to understand how the body responds when oxygen is used.

Here is what has happened so far:
A doctor examined you and treated you medically. The doctor found that you required oxygen and you did not have another reason for acute hypoxemic respiratory failure that needed to be managed in a different way. After the study team determined you were eligible , you were placed on NIPPV or HFNO at random. You were also given other treatments normally given to patients with acute hypoxemic respiratory failure, such as medications given through the vein that were not determined by the study. Some medical information about you and your condition was collected. Up to 30 milliliters (6 teaspoons) of blood and 15 milliliters (3 teaspoons) of urine total may have been collected for study purposes. Measurements such as movements of your chest through the skin may have been performed. No other aspect of your medical care was affected by your participation in this study.

What am I being asked to do?
Now that you have been assigned to a study treatment, we are asking you to decide whether or not to continue participating in this study. Continuing in the study does not involve getting any further medications or tests. If you decide to continue participating, you allow us to collect some medical information about you and how you are doing until you are discharged from the hospital. The information we have or will collect includes demographics (age, sex, race, ethnicity), your condition and treatment in the emergency department and hospital, medical history, oxygen use, results of some tests performed as part of your medical care, and findings during your hospitalization, including adverse events (side effects) and the dates of hospital admission and discharge. We may continue to collect measurements such as chest movements through the skin. Most participants in the study will have regular collection of blood and urine as part of their ongoing medical care. Additional blood and urine may be collected for the research study; this would be at most three times over the first three days. Your participation in the study will be up to 28 days. We may also review your medical records up to 3 months after you started the study.

How long will I be in the study? How many other people will be in the study?
If you continue participating, you will be in this study for up to 28 days. We will collect your medical information until you are discharged from the hospital or until 28 days from when you started oxygen, whichever comes first. We may contact you after you leave the hospital to see how you are doing. We may also review your medical records up to 3 months after you started the study.

A total of 500 participants at hospitals across the United States will participate in this study. Enrollment in the study will take place over 4 or more years. No one will be included or prevented from participating based on gender, race, color, economic status, or national origin.

What are the possible risks and discomforts?
The medical risks and discomforts of being in the study are similar to getting standard care. Acute hypoxemic respiratory failure is associated with substantial medical risks. These risks are not affected by participation in the study.

The risks of the two oxygen systems are the same whether they are used in the study or for treatment of acute hypoxemic respiratory failure outside of this study.

The risks of NIPPV include:

- Skin breakdown or facial sores due to mask
- Dry mouth
- Eye irritation
- Sinus problems (nasal congestion, runny nose, nosebleeds)
- Stomach bloating
- Potential anxiety or claustrophobia
- Hypotension (low blood pressure)
- Increase in intracranial pressure (pressure inside your skull)

The risks of HFNO include:

- Nasal dryness
- Nosebleeds
- Discomfort from the flow through the nasal prong interface

Other side effects of both systems may also include:

- Pneumonia
- Lung injury (such as pneumothorax, which is a collapsed lung)
- Aspiration (breathing foreign material into the airways or lungs)
- Shock (very low blood pressure)
- Abnormal heart rhythms
- Headache, confusion, or worsening respiratory function (from carbon dioxide rebreathing)
- Difficulty swallowing

As with any device that comes into contact with the body, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

There may be other unknown risks as well.

You were randomly assigned to receive either NIPPV or HFNO. Both study treatments are commonly used to help people with low oxygen levels. However, how well each study treatment works can be different for each person.

There may be other risks if you are pregnant. There are no known risks to the pregnancy from NIPPV or HFNO. There may be risks of the oxygen systems to a pregnant woman or a fetus that are not yet known. We are not enrolling women who are known to be pregnant in the study, but it will not be possible to obtain the results of a pregnancy test before enrollment because acute hypoxemic respiratory failure requires immediate treatment. You should inform the study team and your study doctor if you are pregnant.

Risks related to blood collection are rare. Blood may be drawn from an existing intravenous (IV) catheter or from a needle in a vein. Infection or inflammation from blood draws occurs in less

than 1% or less than 1 out of 100 patients. Drawing blood can cause slight discomfort, bruising or infection at the site. Measurements of chest movements through the skin may cause irritation to the skin.

There is also a risk of breach of confidentiality related to participation in the study. We will do our best to keep all medical information we collect confidential. We will keep your study information in a secure location during and after the study. Only the members of the study team and the persons and entities listed below will have access to your medical information for the study.

What are the possible benefits?
Because we do not know which oxygen system is better, you may benefit from receiving a more effective study treatment, but this is not guaranteed. You may not get any benefit from being in this study. However, the information that we obtain from this study may benefit patients in the future.

What happens if I choose not to continue in the study?
The alternative to continuing is to no longer take part in the study. If you decide not to continue, your decision will not affect your current or future medical care in any way. Being in this study is entirely voluntary. You can withdraw your consent to participate in the study at any time. If you choose not to continue, we will not collect any further information about you. However, we may keep information or specimens collected before the point of your withdrawal from the study. Your decision will not impact your medical care now or in the future. You may ask and will receive responses to any questions during the study. The study team may also remove you from the study if they feel it is not in your best interest to continue taking part.

What happens if I am injured or hurt during the study?
If you are injured or become ill from participating in this study, medical treatment will be available at this institution or elsewhere consistent with the care provided for any medical problem. Payment for this care will be billed the same as any other care for any medical problem. If the hospital where you are participating in the study has any additional answers to this question, this information is found at the bottom of this form.

In the event that you suffer injury as a result of your participation in this study, no compensation will be provided to you by the funding agency, the National Institutes of Health (NIH), the treating institution, or the researchers. You still have all of your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages. You will not be giving up any of your legal rights by signing and dating this consent form.

Will I have to pay anything?
There is no additional cost to participate in the study. Charges for all standard medical care will be billed in the same manner regardless of participation. Funds are not available to cover the costs of any ongoing medical care, and you remain responsible for the cost of non-research related care. For questions about your medical bills relative to study participation, contact the study doctor listed on the first page of this form.

Will I be paid for being in the study?
You will not be paid to be in the study.

Who could profit or financially benefit from the study results?
None of the researchers involved in this study have any financial interests in the outcome of this study. Companies that manufacture non-invasive positive pressure ventilation or high flow nasal oxygen systems may financially benefit from the study results.

AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

How will personal information be protected?
The study doctor and his/her collaborators will consider your personal information confidential to the extent permitted by law. "Personal Information" means information that can be used to identify you or health information about you. This includes name or initials, date of birth, gender, ethnic origin and medical and health-related information such as blood tests, diagnostic imaging and results, the results of physiological monitoring or tests, the results of physical examinations, medical history and hospital records, and information directly observed in the study. It may also include information recorded while you were in the emergency department and hospital.

Information about you collected for the study may be stored electronically or on paper. The information stored on the computer is kept in password protected files that are maintained on password protected computers. The information stored on paper is stored in a locked file cabinet in a locked office. Only the members of the study team and the persons and groups listed below will have access to your medical information for this study.

The government agencies responsible for making sure that studies are conducted and handled correctly, and other organizations involved in this research study may look at your study records in order to perform their duties. These include: the US National Institutes of Health (NIH), the US Office for Human Research Protections, the US FDA, representatives from The Strategies to Innovate Emergency Care Clinical Trials Network (SIREN) Clinical Coordinating Center at the University of Michigan, representatives from the SIREN Data Coordination Center at the Medical University of South Carolina, researchers at the Ohio State University and collaborating researchers at other institutions, the Advarra Institutional Review Board, and/or other agents of the study who will be bound by the same provisions of confidentiality. Information from this study will be submitted to the US FDA.

To help us protect your privacy, this research is covered by a Certificate of Confidentiality from the US NIH. With this Certificate, the investigators may not disclose or use information, or documents that may identify a participant in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, in the US unless the participant has consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if the participant has consented to the disclosure, including for the participant's medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research participants.

Disclosure is required, however, for audit or program evaluation requested by the NIH or when required by the FDA. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want research information released to someone, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose to which you have consented in this informed consent document.

Although every effort will be made to maintain confidentiality of your medical and health records, absolute confidentiality cannot be guaranteed. We will use a study number rather than your name on study records where we can. Your name and other facts that might point to you will not appear when we present this study or publish its results. Viewing or storing this electronic informed consent form on a personal electronic device may allow information provided on this form (such as names and email addresses) to be inadvertently shared with others if the device is lost, hacked, or otherwise compromised.

Information is only collected during this hospitalization. If you are transferred to another hospital to complete the current course of inpatient medical care, that is considered part of this hospitalization. Your signature on this document authorizes those facilities to release medical records to the researchers and staff of this study. Only medical records that refer to the current hospitalization, while you are in the study, are included in this authorization.

We will keep any records that we produce private to the extent we are allowed or required by law. Your records will be kept for as long as necessary for purposes of the study.

The study doctor and treating institution are required by law to protect your health information.

With this form, you authorize the study doctor to use and disclose your health information, as described in this section, in order to conduct this study. If you decide not to continue to take part in the study and do not sign this form, you will be withdrawn from the study and no additional information about you will be collected. You have the right to revoke this authorization, at any time, and can do so by writing to the study doctor at the address on the first page. Even if you revoke the authorization, the study doctor and/or sponsor may still use health information they have collected about you, if necessary, for the conduct of the study. However, no new information will be collected.

Your authorization does not have an expiration date unless indicated elsewhere. Those persons who receive your health information may not be required by US federal privacy laws (such as the Privacy Rule) to protect it and may share the information with others without your permission, if permitted by laws governing them.

By signing and dating this information and consent form, you consent to the continued collection, access, use and disclosure of your information as described above. State law or the enrolling institution may require an additional separate form on which you can authorize sharing

of your health information. If so, you will have to sign and date both forms for your authorization to be valid.

What are the participant rights?
Taking part in this study is voluntary. You may choose not to continue to take part or leave the study at any time. Leaving the study, or choosing not to continue to take part, will not result in any penalty or loss of benefits to which you are entitled.

Doctors caring for you during this hospitalization may also be researchers in this study. If so, the study doctors are interested both in your medical care and in the conduct of this research. There is no obligation to participate in any research study just because it is offered by your doctors.

Future research studies
Researchers may contact you after you leave the hospital to participate in other research activities.

Your study information, blood, and urine collected during this study may have identifiable private information removed. Deidentified information, blood, and urine samples may be used for future research studies or distributed to another investigator for future research studies without your additional consent.

Clinically relevant results
This study does not involve individual research results that are clinically relevant. Individual research results will not be disclosed to you.

Blood and urine samples
If blood and/or urine samples were collected from you, these samples will be labeled with a study number instead of your name or other information that would identify you directly. The blood samples will be used to determine how your body reacts when oxygen is used to help you breathe. There will be no individual results to share with you from the blood testing.

Commercial profit
There is no plan for your biospecimens collected during this study to be used for commercial profit (even if identifiers are removed). However, if your biospecimens collected during this study were used for commercial profit, you would not share in this profit.

Genome sequencing
Researchers can look closely at large amounts of your genetic information by sequencing, or "reading," every letter in your DNA (your genome). Reading a person's entire genetic code is called whole genome sequencing. This study does not involve any genetic testing of your biospecimens, so it **will not** include whole genome sequencing (for example, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Where can I get more information?
Visit the WINDSURFER Study website: **siren.network/trial/windsurfer**

We may also contact you with periodic updates about the study. We may also contact you after the study has been completed to share the overall results of the study.

You will also get a copy of this form. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

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 the Web site at any time.

How is contact information used and stored?
Contact information for you, your family members, close friends, and associates may be collected to make sure that we can provide you with further information and updates about the study, including the results of the research after the study is over. You may also be contacted about future available studies. The information is stored in a secure computer system, separate from other personal or health information collected in the study.

Whom to contact about this study
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724

- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00092316.

Site Specific Information

The below information is specific to <<insert site name>> and is in addition to what has already been presented to you earlier in the consent document.

Informed Consent to Continue Participation

SIGNATURES:
Sign below only if you understand the information given to you about the research and choose to continue.

Make sure that any questions have been answered and that you understand the study. If you decide to continue in this research study, a copy of this signed consent form will be given to you.

We are interested in your experience with this consent process and may ask to talk to you about it further now, or in the future, to ask you a few questions about it.

Participant's Name	Signature and Date/Time

OR

Name of Legally Authorized Representative	Signature and Date/Time

Authority of Legally Authorized Representative to Act on Behalf of Participant

Name of Person Obtaining Consent	Signature and Date/Time

Informed Withdrawal Addendum
(Attach to informed consent document only when a participant chooses to withdraw.)

SIGNATURES: Sign below if you understand the information given to you about the research and choose **not** to continue. Make sure that any questions have been answered and that you understand the study.

Although you are opting not to continue in the study, we are interested in your experience so that we can learn more about how patients feel about this type of medical research. We may ask to talk to you about your experience further now, or in the future, to answer a few questions about it.

Check here if you do not want to be asked. ☐

Participant's Name	Signature and Date/Time

OR

Name of Legally Authorized Representative	Signature and Date/Time

Authority of Legally Authorized Representative to Act on Behalf of Participant

Name of Person Obtaining Withdrawal	Signature and Date/Time