SIREN Informed Consent Forms

The Sponsor/Investigator of POST-ICECAP 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 forms for POST-ICECAP as sites 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 POST-ICECAP 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 POST-ICECAP Toolbox and the Getting Started page.

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 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 below statement from Advarra regarding this process for SIREN trials.

As you know, Advarra is the single IRB for the 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 already have in place with Advarra.

If you have any questions regarding this please contact POST-ICECAP-contact@umich.edu

Thank you for your attention with this matter,
Best regards,
Advarra Institutional Services Team & SIREN

SIREN

POST-ICECAP

CONSENT FOR CLINICAL RESEARCH STUDY AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title:	**The National Institute of Neurological Disorders and Stroke (NINDS) and The National Heart, Lung, and Blood Institute (NHLBI) / "Patterns Of Survivors' Recovery Trajectories in the ICECAP Trial (POST-ICECAP)"**
Protocol Number:	**POST-ICECAP**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

This study is for people who survived cardiac arrest. If you are well enough, you can decide whether or not to join. If you are not well enough yet to decide for yourself, a representative can consent for you. Anyone can leave whenever they want, especially if they regain the ability to decide during the study.

SUMMARY OF KEY INFORMATION

Because you have survived a cardiac arrest, you might be able to join a research study. After cardiac arrest, some people find it hard to go back to work or get back into social activities. This study wants to understand how different survivors recover mentally, emotionally, and in terms of their quality of life. We are curious if treatments during hospitalization or what happens after leaving (like rehabilitation) or their social environment affects recovery. This information could help us better help others who have had cardiac arrest.

For the first year after a cardiac arrest, we will check in with participants or their caregivers every three months by phone or in person. We will ask questions and do some puzzles to see how their brains are recovering. We will also look at their medical records. About 1,000 people from around 50 hospitals will take part.

Being in the study will not directly benefit participants, but it will help us understand how to give the best care to people who have had cardiac arrest. The study involves minimal risk—no treatments, just answering questions on paper, computer, or the phone. There might be mild inconveniences or a bit of anxiety, but they should go away quickly. We will keep personal information as private as possible.

Participants will not get paid for being in the study, but they might get some compensation for their time and expenses during follow-up visits. Being in the study will not cost anything, and medical care charges will stay the same whether in the study or not.

Joining the study is up to the individual, and they can quit at any time without penalty. If there are any questions or concerns, they can contact the study team.

The study team will explain everything, and answer questions, and if you agree, you can sign and date the form.

MORE DETAILED INFORMATION

Why am I (or the person I represent) being asked to participate?
We are doing this research to understand how people recover after a cardiac arrest, both physically and mentally. We are curious whether what happens in the weeks and months after the cardiac arrest influences this recovery. We are inviting people who are at least 18 years old, understand English or Spanish, and have survived a cardiac arrest to join us in this study.

What is a cardiac arrest?
Cardiac arrest happens when the heart suddenly stops beating, usually due to issues like abnormal heart rhythms, heart attacks, or other medical conditions. This stoppage means no blood flows to vital organs including the brain, leading to loss of consciousness and no pulse. Without quick treatment, it can result in death within minutes. Medical care focuses on helping recovery from these injuries and preventing them from happening again.

This differs from a heart attack, where the heart still beats, but there's a block in blood flow to the heart.

Why is this study being done?
This study wants to understand how life is for people who survived a cardiac arrest—both physically and mentally. We are checking how recovery goes over the year after the cardiac arrest.

We are also looking into whether the treatments given during or after hospitalization influence long-term recovery. People get different amounts of rehabilitation and medical help, and we are trying to find out if that affects how well they recover.

Besides medical conditions, we are looking at how social support, caregivers, and the environment play a role in recovery. Participants will be asked about their resources and everyday experiences to see if they influence recovery.

How many people will take part in the study?
This study plans to include about 1,000 people from all over the United States. It will take around 4 years and involve over 50 hospitals. Anyone can join—no matter their age, gender, sexual orientation, race, color, socioeconomic status, or where they are from.

What is involved in the study?
When people join the study, a study team member will explain everything and answer questions. Participants will go through the consent form and sign it. We will also get their contact information.

After that, we will check the participant's medical records and ask about the participant's background and health before the cardiac arrest.

Over the next year (at 1, 3, 6, 9, and 12 months), we will meet to discuss recovery. Participants can choose how we schedule our meetings — call, email, or text.

At 1, 6, and 9 months, we will meet over the phone or in-person to see how they are doing and if they got rehabilitation or medical care. At 3 and 12 months, we will meet in person to measure recovery. They will do a questionnaire and some brain exercises, like games. It will probably take 1 to 2 hours. If the participant is already doing these exercises for another study, we will not repeat them.

If an in-person visit is not possible, or we cannot cover everything, we will call by phone. The phone call will gather the same information as the visit, except for the brain exercises. It might take about 1 hour.

How long does participation in the study last?
Participation in the study will last for 12 months.

What are the risks of the study?
There might be some mild feelings of anxiety (fear or uneasiness) or distress when answering questions, but they usually go away quickly. If these feelings persist, our study team is here to talk and provide care. Participants can also stop anytime.

There is a small risk of participants' information being seen by someone outside the study, but we are committed to keeping it confidential.

Are there benefits to taking part in the study?
Taking part will not directly benefit participants. The hope is that what we learn can help others in the future.

What other options are there?
This research study is for research purposes only. The only alternative is to not participate in this study. Joining is voluntary, and there is no penalty for choosing not to.

AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

How will personal information be protected?

The study investigator and collaborators will consider the participants' personal information confidential to the extent permitted by law. "Personal Information" means information that can be used to identify the participant or health information about the participant. 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.

We will store information about the participants electronically in password-protected files that are maintained on password-protected computers. Only the members of the study team and the persons and groups listed below will have access to the participants' information.

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 the participant's 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 Food and Drug Administration (FDA), representatives from The Strategies to Innovate Emergency Care Clinical Trials Network (SIREN) Clinical Coordinating Center at the University of Michigan, representatives from the Data Coordination Unit at the Medical University of South Carolina, the Central Institutional Review Board, and/or other agents of the study. These agents will be bound by the same provisions of confidentiality.

To help us protect the participant's privacy, this research is covered by a Certificate of Confidentiality from the US National Institutes of Health. With this Certificate, the investigators may not disclose or use information, or documents that may identify the 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 the participant from voluntarily releasing information about themselves or their involvement in this research. If the participant wants research information released to someone, the participant 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 the participant's medical and health records, absolute confidentiality cannot be guaranteed. We will use a study number rather than the participant's name on study records where we can. The participant's name and other facts that might point to the participant will not appear when we present this study or publish its results.

Viewing or storing this electronic informed consent form on your 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.

When ready to leave the hospital, the participant may go to a rehabilitation or nursing facility. The participant might also be readmitted to another medical facility later. Your signature on this document authorizes those facilities to release medical records to the researchers and research staff of this study. Only medical records that refer to the time while the participant is 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. The participant's records will be kept for as long as necessary for the purposes of the research study.

The study doctor and treating institution are required by law to protect the study participants' health information. With this form, you authorize the study doctor to use and disclose the participant's health information, as described in this section, in order to conduct this research study. 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 the study participant, 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. You do not have to sign and date this information and consent form, but if you do not, you or the person you represent will not be able to take part in this research study. Those persons who receive the participant's 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 collection, access, use and disclosure of the participant's information as described above. State law or the enrolling institution may require an additional separate form on which you can authorize sharing of the participant's health information. If so, you will have to sign and date both forms for your authorization to be valid.

How is the contact information stored?
We will collect contact information for participants and their family members, close friends, and associates in order to stay in contact about their condition, share the research results, and provide updates. We will keep this information safe in a separate, secure computer system, away from other personal and health details collected in the study.

Will the participant have to pay anything?
There is no additional cost to participate in the study.

Will the participant be paid for being in the study?
No. We will not pay participants for being in the study. Some compensation may be available to reimburse them for the time and expense of follow-up study visits.

What if the participant is injured as a result of being in this study?
If a participant is injured or becomes ill from participating in the study, they may get medical treatment 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 at which the participant was enrolled has any additional answers to this question, this information is found at the bottom of this form.

In the event that the participant suffers injury as a result of their participation in this research study, no compensation will be provided to the participant by the granting agency (NIH), the treating institution, or the researchers. The participant still has all of their legal rights. Nothing said here about treatment or compensation in any way alters the participants' right to recover damages. Participants will not be giving up any of their legal rights by signing and dating this

consent form.

Who could profit or financially benefit from the study results?
Researchers in this project will not gain financially from the study's outcome.

What are the participant's rights?
Participants have rights. Joining is voluntary, and they can leave anytime without penalties or losing entitled benefits. Doctors caring for them may also be researchers, but there's no pressure to join any study offered by these doctors.

Future research studies
In the future, after removing the participant's identifiable private information, researchers may use the data collected for more research without obtaining new consent. Researchers might reach out to ask about future studies, but privacy and contact information will be strictly confidential.

Clinically relevant results
This study will not share individual research results with the participants. They will not get personal research updates.

Where can I get more information?
You will get a copy of this form. We will keep participants informed about anything new that could impact their health, well-being, or their decision to stay in the study. Expect periodic updates during and after the study, including the overall results once it's done.

Whom to contact about this study

During the study, if you have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document.

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, and/or concerns or complaints regarding this research study, 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: Pro00075795.

ADDITIONAL SITE-SPECIFIC INFORMATION

Any additional information provided by this site is included in the following box.

CONSENT STATEMENTS

PARTICIPANT'S CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

SIGNATURES

_____

Printed Name of Participant

_____ _____ at _____

Participant's Signature Date and Time

STATEMENT OF LEGALLY AUTHORIZED REPRESENTATIVE

You should feel that you have been told enough about this study to give your informed consent before signing and dating this form. Signing and dating this form does not waive any legal rights to which you or the participant are entitled. You will receive a copy of this form after it is signed and dated.

If you want your family member (or the person you represent) to participate in this study, please sign and date below.

_____

Printed Name of Participant

_____

Printed name of Legally Authorized Representative

_____

Relationship to Participant

_____ _____ at _____

Legally Authorized Representative Signature Date and Time

Printed Name of Principal Investigator/Designee	Title
Principal Investigator/Designee Signature	_____ at _____ Date and Time