# PROTOCOL APPROVAL WITH MODIFICATIONS

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| **DATE:** | 11 Jan 2024 |
| **TO:** | Natalie Fisher |
| **PROTOCOL:** | The National Institute of Neurological Disorders and Stroke (NINDS) and The National Heart, Lung, and Blood Institute (NHLBI) - POST-ICECAP, Patterns of Survivors Recovery Trajectories in the ICECAP Trial (POST-ICECAP) (Pro00075795) |
| **APPROVAL DATE:** | 10 Jan 2024 |

## IRB APPROVED DOCUMENTATION:

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| **Protocol Version(s):** | • Protocol (Version 1) |
| **Consent Template(s):** | • Main Informed Consent Form (Advarra IRB Approved Version 10 Jan 2024) |
| **Recruitment Material:** | • Flyer, poster, or bulletin board, "HELP RESEARCH ON CARDIAC ARREST RECOVERY" (Not Dated) |

The IRB approved the above referenced protocol with the modifications listed below on 10 Jan 2024:

- **Modifications to the Informed Consent Form template.**

**Please Note: This approval notice is for the IRB approval of the protocol only. The Principal Investigator for each site must complete a separate site submission to receive an IRB Approval notice allowing them to conduct the study.**

The above referenced recruitment/subject material is available on your Advarra CIRBI Platform workspace under the “IRB Issued Documents” tab.

Use of eConsent is Approved.

Based on the confirmations provided to the IRB, it is expected that:

1. The eConsent(s) will include the complete and exact contents of the most current, IRB approved study consent(s).
2. The eConsent process includes obtaining signature(s) in compliance with applicable law and a method to confirm the identity of the signer(s).

3. The stored eConsent(s) identify the signers and date (time, if applicable) of signing; signed eConsent(s) are stored with appropriate access, and all versions are retrievable.
4. The signers must review all consent contents prior to signing the eConsent (i.e., there is no function available to skip directly to the signature field(s)).
5. All subject-facing materials used during the eConsent process (e.g., web-linked materials, graphics, videos, glossary, etc.) will be submitted for IRB approval.
6. If CIRBI eConsent Attestation responses change, an eConsent Modification will be submitted to the IRB for review. Note: An eConsent Modification is not required when revisions are only to the IRB approved study consent document(s).

Individual sites using a different eConsent system/process (e.g., different app, vendor) or different eConsent subject-facing materials from the sponsor (e.g., Video Storyboard, Glossary of Terms, links, etc), require a site-level eConsent review (reviewed as part of the initial site/SSU submission or in a site eConsent Modification).

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**The IRB determined that the use of a Legally Authorized Representative (LAR) is approved for this study. During the course of the study, if the subject regains the capacity to consent, informed consent must be obtained from the subject and the subject must be offered the ability to leave the study if desired.**

There is no expiration date for this study, and it is not subject to requirements for continuing review under the revised Common Rule (2018 Requirements). However, a termination report must be submitted upon termination of the study.

If the study is in an FDA 30-day wait period, subjects **may not** be consented or screened, as consent would be required before study-specific screening activities may begin. However, some initial activities related to determining a potential subject's interest in the upcoming study may occur. Such activities should be limited to recruitment efforts to inform potential subjects, or a community that a study may soon begin on a given condition. However, screening subjects to determine eligibility would not be acceptable until the IND is in effect.

Audio/visual recruitment or subject material approved in script format only must be submitted in final format for the IRB to review what potential subjects will see or hear. The IRB does not review the content found in embedded links or QR codes, therefore this content must be submitted for review and approval separately, prior to use.

If you wish to appeal the IRB's determinations and/or imposed modifications, please submit supporting documentation to address the IRB's concerns by creating an Appeal Modification in CIRBI.

Approved investigators and sites are required to submit to Advarra for review, and await a response, prior to implementing any amendments or changes in the protocol; informed consents; advertisements or recruitment materials ("study-related materials"); investigators; or sites (primary and additional).

Approved investigators and sites are required to notify Advarra of the following reportable events, including, but not limited to unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study.

**Compliance Statement/REB Attestation (Applicable for research conducted in Canada):**

The IRB attests that this submission has been approved by an IRB whose membership complies with the requirements defined in Health Canada regulations, ICH GCP guidelines, FDA regulations at 21 CFR part 56,

and HHS regulations at 45 CFR part 46. The IRB carries out its functions in accordance with FDA regulations at 21 CFR parts 50, 56, 312, and 812; HHS regulations at 45 CFR part 46, subparts A-E; good clinical practices; Health Canada regulations; and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, as appropriate to the research.

Advarra IRB is registered with OHRP and FDA under IRB#00000971.

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for selecting Advarra IRB to provide oversight for your research project.

Sincerely,

Luke Gelinas, PhD
Executive Board Chair