PROTOCOL APPROVAL WITH MODIFICATIONS

DATE:	29 Jan 2020
TO:	Mickie Speers
PROTOCOL:	NHLBI - ICECAP: Influence of Cooling duration on Efficacy in Cardiac Arrest Patients (Pro00041076)
APPROVAL DATE:	7 Jan 2020
EXPIRATION DATE:	7 Jan 2021

IRB APPROVED DOCUMENTATION:

Protocol Version:

- Protocol Version d (Dated December 30, 2019)

Consent Template:

- Informed Consent Form (Advarra IRB Approved Version 27 Jan 2020)

Other Material:

- FDA Letter, Re: G160072/A001 (Dated June 09, 2016)
- Clinical Standardization Guidelines (Edited 12-30-2019)
- STUDY PROTOCOL - Appendices (Not Dated)
- Bayesian Adaptive Trial Design for the Influence of Cooling duration on Efficacy in Cardiac Arrest Patients (ICECAP) simulation report (Last Updated October 30, 2018)
- Standard Operating Procedure Electronic Informed Consent (Not Dated)

The IRB approved the above referenced protocol with the modifications listed below on 7 Jan 2020:

- **Modifications to the Informed Consent Form**

On 27 Jan 2020, the IRB reviewed and approved with modifications additional edits to the Informed Consent Form.

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

Please Note: Each Principal Investigator will receive a separate IRB Approval notice allowing them to conduct the study.

Based on the information available, the IRB determined that the device is a Significant Risk device.

The above referenced material is available on your Advarra CIRBI Platform under the "IRB Issued Documents" tab.

If there are any changes to the IRB approved material, IRB approval will be needed prior to use. This includes changes in relative size and type of font in the material to be viewed by potential subjects.

If the study is expected to last beyond the approval period, you must request and receive re-approval prior to the expiration date noted above. A report to the Board on the status of this study is due prior to the expiration date or at the time the study closes, whichever is earlier. It is recommended that you submit status reports at least 4 weeks prior to your expiration date to avoid any additional fees or lapses in approval.

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.

Please review the IRB Handbook located in the "Reference Materials" section of 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.

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