CONTINUING REVIEW APPROVAL

CR00585299

DATE:	30 Sep 2024
TO:	Erin Bengelink
PROTOCOL:	National Institute of Neurological Disorders and Stroke, NIH - BOOST3, Brain Oxygen Optimization in Severe Traumatic Brain Injury - Phase 3 (BOOST-3): A multicenter, randomized, blinded-endpoint, comparative effectiveness study of goal-directed critical care based upon monitoring of brain tissue oxygen and intracranial pressure versus monitoring of intracranial pressure alone in patients with severe traumatic brain injury. (Pro00030585)
CONTINUING REVIEW APPROVAL DATE:	30 Sep 2024
EXPIRATION DATE:	30 Sep 2025

Thank you for providing the information required for Advarra IRB to conduct continuing review of the protocol.

In addition to the information you provided, the IRB reviewed the current protocol referenced above, the Consent Template(s) for the study, and other supporting information.

The IRB approved continuation of the above referenced protocol. The IRB determined there were no changes required to the current Consent Form(s). The IRB determined there were no changes to the previous device risk or status. The IRB determined there were no changes to the previous pediatric risk determination.

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

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; consent documents; 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 continuing to use Advarra IRB to provide oversight for your research project.

Sincerely,

Luke Gelinas, PhD
Executive Board Chair