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APPROVAL NOTICE

MOD01000491

DATE: 14 Jun 2021

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)

APPROVAL DATE: 12 Jun 2021

IRB APPROVED:

Documentation:

- Substudy Supplement (Version: June 11, 2021)

The IRB reviewed and approved the above referenced documentation.

The IRB determined there were no changes required to the current Consent Template(s). Sites will be instructed to continue using the Consent Form(s) electronically available on their Advarra CIRBI Platform workspace under the "IRB Issued Documents" tab.

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.