NIH SIREN Emergency Trials Network

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BOOST-3 Protocol Revision: BOOST-3 Study Protocol Version 3

This revision of the BOOST-3 clinical trial protocol does not involve any substantive changes to the research or the safety or experiences of human subjects. Rather this new version is just intended to clarify several items in the protocol about which we have been answering questions and providing additional training since the protocol was initiated. It also corrects some minor mistakes, and numerous typographical, formatting, and grammatical errors that we have accumulated over time. Important clarifications in the eligibility criteria include a more specific description of how to implement the exclusion for poor bilateral pupillary response, and correction of the intended PF ratio threshold for exclusion. Both of these changes in the protocol simply clarify or correct the protocol to reconcile it with, and reinforce, the study team training that has already been used since the start of the trial. Extensive clarifications in the tier treatment descriptions better reflect the wording and descriptions of the clinical interventions as used in practice, but do not actually alter the treatments recommended to be used to respond to ICP or brain tissue hypoxia events.

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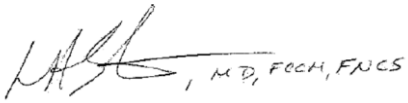

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