BOOST-3 Readiness Checklist

HUB	
SPOKE	
DATE OF READINESS CALL	
SITE PARTICIPANTS	Site PI: Site Co-Is: Site Primary Study Coordinator: Hub PI: Hub PM: Other Team Members:
BOOST-3 & SIREN PARTICIPANTS	(For CCC Use) BOOST-3 PI(s): Bill Barsan, Lori Shutter, Ramon Diaz-Arrastia SIREN CCC Staff: Robert Silbergleit, Will Meurer, Erin Bengelink, Carol VanHuysen, Deneil Harn Ruth Lewis, MUSC Staff: Protocol Trainers: Ava Puccio, Anita Fetzick, Carol Moore

Contract Status ***(Check if complete. If incomplete, please explain.)***

☐ Pending

☐ Complete

EFIC Forms ***(Check if complete. If incomplete, please explain.)*** If unknown, inquire: boost-contact@umich.edu)

☐ CC forms complete and locked for all CC events (BOOST > EFIC tile)

X PD forms complete and locked for all PD activities to date (BOOST > EFIC tile)

X EFIC Local Context Form complete (BOOST > EFIC tile)

cIRB Tables *(Check if complete. If incomplete, please explain.)*

X Site Overview (SIREN > Central IRB)

X Site Regulatory Inspection (SIREN > Central IRB)

X Initial Site Submission (BOOST > Central IRB)

cIRB STATUS (for CCC use) ☐ Pending ☐ Submitted X Approved

PEOPLE Documents *(Check if complete. If incomplete, please explain.)*

X CVs (Hub PI, Hub PM, PI, Co-I, Primary SC, Secondary SC, Blinded Outcomes Assessor)

X HSP Certification (Hub PI, Hub PM, PI, Co-I, Primary SC, Secondary SC, Reg Doc Coordinator, Blinded Outcomes Assessor)

X GCP Training (Hub PI, Hub PM, PI, Co-I, Primary SC, Secondary SC, Blinded Outcomes Assessor, Reg Doc Coordinator and other Data Collection/ Entry/Management Personnel)

X Medical License (Hub PI, Hub PM, PI, Co-I, Primary SC, Secondary SC, Blinded Outcomes Assessor)

☐ Protocol Training (Hub PI, Hub PM, PI, Co-I, Primary SC, Secondary SC) *(Awaiting Donovan, Sun)*

X Regulatory Document Management Training (Reg Doc Coordinator, Hub PM, Team members maintaining regulatory compliance)

X Data Training (Reg Doc Coordinator, Hub PM, Team members maintaining regulatory compliance)

☐ BOOST Outcomes Training (Blinded Outcomes Assessor) Needs to be completed (*Tina Robertson) We plan on having her complete training.after first enrollment.*

SPOKE Documents *(Check if complete. If incomplete, please explain.)*

X Federal Wide Assurance (FWA)

X CLIA Certification (CLIA)

X Attestation of Study Team Education and Training

X Ceding request to Local IRB (see additional Regulatory Document Approval Parameters' direction for Canadian Sites)

X Ceding Acknowledgement from Local IRB (see additional Regulatory Document Approval Parameters' direction for Canadian Sites)

X HSP Requirements

X Conflict of Interest Disclosure *(None)*

eDOA

X Electronic Delegation of Authority Log accepted by CCC is current for full study team list
(DCC to verify the two accounts that will be responsible for uploading the Moberg data)

BOOST-3 Training

X Clinic staff on key units and study staff trained in study procedures (PI Attestation of Study Team Education and Training)

eCONSENT Participant Link (for CCC use) ☐ Pending X Complete

Site Specific econsent: https://bit.ly/BOOST3Queens

Note: e.consent test link: http://bit.ly/BOOST3Test

Please consider each of the questions listed below. Using this document as a template, please enter a text response to each item. The completed document will serve as a summary of how you will be conducting the trial at your site.

If there are differences in how adults and pediatrics will be handled at your site, please differentiate these in your answers.

STUDY LOGISTICS

COVID-19 Restrictions

During the COVID-19 restrictions, will your site be able to begin the trial once released to enroll? If so, please share your plan to ensure coverage onsite and remotely. *We don't foresee any problems due to COVID-19 restrictions. Our research coordinators are on site Monday-Friday and available to come in off hours for coverage.*

Human Subjects Protection/EFIC (CC/PD)

What was your single best experience conducting EFIC activities for BOOST3?
We actually liked doing the virtual presentations because there was more dialogue with the participants than going to public events.

Screening and Enrollment

1. Do you expect to have competing trials (either trials that compete for subjects, e.g. HOBIT or other trials enrolling TBI patients). If so, how will you decide how to allocate patients between the trials?

No

2. Where will the study specific monitor/Moberg be kept and who will retrieve it? Have you practiced using the Moberg and ensure that the current version of the program is being used?

The Moberg unit will be stored in the Neuroscience ICU. We have been using the Moberg unit to gain clinical experience with it as a lead-up to the clinical trial.

3. Is the site using an Integra or Raumedic monitor?

We use Raumedic monitors

If an Integra monitor, does the site have the metal blinding screen cover?

Is the team trained to place and secure the cover on the monitor?

If a Raumedic monitor, is the team trained on how the blinding steps work?

We have not yet completed training on the blinding steps.

4. Describe your study team on-call coverage? (Who takes call? How are they activated? What are your expected response times?)

We have 4 neurointensivists on a rotating call schedule and 8 neurocritical care nurse practitioners who are in-house 24/7.

5. How will you ensure 24/7 coverage and what contingencies exist for gaps in coverage?

We have 4 neurointensivists on a rotating call schedule and 8 neurocritical care nurse practitioners who are in-house 24/7.

6. How (and by who) will a potential participant be identified?

Participants will be identified by the admitting team, including the neurointensivist and neurocritical care nurse practitioner. All patients patients with severe TBI are admitted to our closed, dedicated Neurosciences ICU so they will be readily identified by the team

7. How (and by who) will study team members be immediately notified about a potential participant and come in to complete the screening and pursue family to consent prior to probe placement?

The study team members are part of the subjects treating team, every TBI subject will be looked at for possible BOOST-3 enrollment. It is the treating team (NSI staff who request probe placement) If a subject looks like they qualify the study coordinators will be notified by the treatment team so verify and assist in locating LAR for consent.

8. Who will be responsible for performing the index GCS?

Neurointensivist or Neuro APRN

9. How many BOOST-3 subjects do you expect to enroll each month?

1

Consent

10. Describe your process for identifying the subject and locating an LAR prior to probe placement.

If the patient is not identified in the ED, we use the ED social workers to help identify them and find family or LAR.

11. Describe your process for notifying family and obtaining informed consent.

If the family is present, they will be taken to a private conference area and identified as the subject's LAR (this is self identified at our site). They are told of the patient's diagnosis and treatment plan. After that, the research study is explained and discussed. If they are not present, we will see if they have the capability for eConsent and perform the same process.

12. How will you be collaborating with social workers or other hospital resources to ID subjects and locate family prior to randomization and after?

We use social workers in the ED prior to randomization and after until family/LAR is located.

13. Have you had any opt-out requests and, if so, how many and how did you handle these?

We have had one.

14. Have you confirmed iPad internet accessibility in the ED/ICU for e.consent? Describe your process for e.consent. (Not applicable to Canadian sites).

We will not be using an iPAD. We will use a cell phone or computer in the ED for eConsent. Cell phone coverage is available in the ED/ICU.

Study Intervention

15. Describe how you expect the study team/study coordinators to interact with the clinical team in the ED/ICU.

The neurointensivists on-call are all investigators in the trial and are consulted for all severe TBI. Both study coordinators have worked in the Neuro ICU and have several other acute trials in the ICU. It is expected the study coordinators will have an active presence in the ICU during enrollment and daily monitoring of subjects.

16. Describe how the study PI and primary study coordinator will assist the clinical team in protocol implementation.

The clinical team is also the study team. We round with the clinical team and discuss study procedures, tier treatments and protocol implementation.

17. Who at your site will be responsible for the daily study visit of the BOOST participant? What will your plan be for the daily visit?

The daily visit will be done by study coordinators. We will use the BOOST3 daily checklist.

18. Describe how you will assure ongoing current contact information for the participants/LARs? Who will be conducting the monthly calls? What is your plan to prevent “lost to follow-ups”?

We always confirm contact information and get an alternate contact if possible. Study Coordinators will be conducting monthly calls. We will work to establish a relationship with the LAR/family during hospitalization and express the importance of monthly updates and 180 day follow up with the subject.

19. Describe your process for obtaining the 6 month outcomes? Have you identified a blinded outcomes assessor and added this team member to the eDOA log? Describe how the local outcome examiners at your site (for 6 month outcomes other than the GOSE) will maintain being blinded to the study treatment group.

The 6-month outcomes will be done in-person in our outpatient clinic when possible or by telemedicine. We will discuss the follow-up visit with LAR and family at enrollment, prior to discharge. We have identified a blinded assessor (Tina Robertson). She is on the eDOA log. Tina is a former research coordinator and currently is our Stroke Get with Guidelines coordinator and only assesses our stroke subjects. She does not access TBI subjects.

20. Who (name(s) & study role(s)) will be completing the eCRFs? Handling DCRs, etc.?

Tracy Stern and Kim Nguyen (both study coordinators) will be completing eCRFs and DCRs

21.How many PbtO2 monitors have been placed in TBI (or other) patients in the last 6 months? (BOOST3 requires that at least 3 PbtO2 monitors should have been placed in the past 6 months in any patients).

Approximately 14 PbtO2 monitors in the last 6 months.

22. Describe your typical use of PbtO2 probes and monitors in your ICU. Who places them? Who manages them?

Our on-call neurosurgeons all place the PbtO2 monitors. Our on-call neurointensivists and neurocritical care NPs manage the PbtO2 monitors.

Training

23. Describe initial and ongoing planned training of physicians, nurses, and respiratory therapists at your site.

Bedside training was completed with the Neuro ICU nursing staff and nurse practitioners. The neurointensivist physicians are all investigators on the study and have completed study-related training materials. We will have BOOST3 resources available at the bedside. We will also do ongoing bedside training at enrollment. We will need to conduct targeted training with the respiratory therapist staff.

24. When did you get your Moberg device and describe the training that you have completed on the BOOST-3 CNS monitor and Carepath software?

We have had the Moberg device for about a year, but had issues with compatibility with the current Phillips bedside monitors which significantly delayed implementation of the device. We acquired a loaner where we were able to use the CNS monitor and Carepath software.

25. Describe initial and ongoing training of BOOST study team members (e.g., watch videos from the BOOST-3 investigator meeting, read the protocol, watch enrollment and other training videos, etc.).

Study team members have reviewed the protocol and watched training videos. We will do a refresher review prior to the study kick-off.

Remote Source Document Verification Monitoring

26. What is your prior experience with remote monitoring at your site?

We have some experience remote monitoring with simple research trials. We do not have as much experience in remote monitoring with studies with this much data. We don't have experience with remote source documentation verification.

27. Discuss your process and timeline to arrange for BOOST-3 monitor access to the electronic health record.

We will generate a service request to our IT department to give the monitor access to the EMR. For remote access, there is some additional paperwork we will request the monitor to complete. Once we know who will need access to the EMR, we can request access. This process generally takes 2-3 weeks.

ACTIONS REQUIRED PRIOR TO START-UP	
Action	**Date Completed**
1. Protocol training certificates uploaded for last two team members.	
2. Additional local training/education (estimated 3/15).	

SITE ACTIVATION	
Date approved for activation	
Status changed in WebDCU	