December 20, 2019

# BOOST-3 Bulletin

Brain Oxygen Optimization in Severe TBI Trial Newsletter

## Enrollment has begun!

Congratulations to our first enrollers:

Ben Taub (2) Harborview (2)

Pittsburgh (2) Froedtert (1) Strong Memorial (1)

We thank your Herculean efforts!

**Reminder:**

**The next SIREN Study Coordinator Meeting is on January 8th at 1pm EST.**

Other sites open to enrollment are:

University of Pennsylvania
U Texas-Houston/Memorial Hermann
UCSF/San Francisco General Hospital
Regions Hospital

Soon to be released to enroll after their readiness call:

Detroit Receiving

Thank you! It took so much hard work to get here - many sites are close!

## Important news as of December 2019:

Change in Duration of an Episode: 30 minutes of normal ICP or PbtO2 (see FAQs below)

Clarification of "5 Days": "5 Days" means 120 hours for both monitoring a participant and for collecting data for CRFs.
Day 1 begins at the time of randomization and goes through midnight that day. (Count the number of hours you have in Day 1 which presumably will be fewer than 24 hours.)
Day 2 is a 24 hour period beginning after midnight of Day 1.
And so on with 24 hour periods = 1 day. If the probes are remaining in place for 5 days, ensure that you are capturing 120 hours of ICP/PbtO2 data so you will most likely go into Day 6 to make up for the fewer than 24 hours on Day 1.
If the monitor is removed prior to Day 5 because of other reasons, continue to collect applicable information through Day 6 forms in WebDCU.

BREAKING NEWS

WE HEARD YOU! No More Earplugs Required!!!!

The **nuclear alarm** that currently *BLARES* from the Moberg CNS and seems to alert everyone to take shelter when there is an ICP or PbtO2 abnormality is being changed! The Moberg group is going to provide the study sites with the ability to turn down the volume or even change to a different sound.

December 20, 2019

# BOOST-3 Updates

## New Frequently Asked Questions

**Q. When does an Episode end? (This is a revision to the former FAQ)**
**A.** An Episode may end when an abnormality is treated and resolves for **30 minutes**.

If another abnormality begins after 30 minutes of normality, a new Episode begins and the treatment team should again begin in Tier 1. (Tier 1 examples, drain CSF raise HOB for a high ICP.)

Rule for moving to Tier 2: If an abnormality is sustained for 1 hour, you MUST move to a Tier 2 treatment by the end of the hour. Tier 2 treatments can be initiated as soon as the treatment team desires as long as a Tier 1 intervention has been attempted. They do not have to wait an hour to try something from Tier 2.

**Q. What if an FiO2 challenge must be done AFTER the required 2 hour limit?**
**A.** This happens sometimes because the patient is in the ED a long time, waiting for a bed, or still in the OR. Just do it as soon as you can and document the reason for a late challenge under "ISSUES" in WebDCU. It is a protocol deviation but cannot be helped so just document why this happened later than within the 2 hour window.

Important Randomization Requirements:
Q. At what point can we randomize under EFIC and when to enroll with LAR written consent?
A. If there is an LAR present in the hospital PRIOR to probe placement, you must get written consent. Do NOT enroll under EFIC. Do not randomize until you have WRITTEN consent.


EFIC enrollment rule: If there is no LAR available (*check and check again!*) prior to probe placement, you CAN enroll with EFIC and randomize. Randomization must occur after probe placement or it will constitute a protocol violation.
Before you randomize, check the time of probe placement and the time an LAR arrived at the hospital. The time of probe placement in the CRFs must be documented in source documents, and can be the start of the insertion procedure. If the LAR arrived prior to the recorded time of probe placement, you must obtain written consent.
Continue to try to locate an LAR for written consent or refusal after EFIC enrollment. Enter attempts to locate an LAR in WebDCU because the monitors are looking for this information.

**Some Studies ok for Co-enrollment with BOOST-3**

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|---|---|
| Spreading -Depolarizations II | Bio-BOOST |
| EPIBios4 Rx | PPROWER |
| ITCOM (but not ok with Bio-BOOST) | PRECISE |
| Prevent-Clot | PACT |
| Pro-Focci | |

**Have a question about BOOST-3?**

**Email**

**boost-contact@umich.edu**