March 15, 2021

# BOOST-3 Bulletin

Brain Oxygen Optimization in Severe TBI Trial Newsletter

**146 participants enrolled! Congratulations and thank you!**

**There are 35 sites open to enrollment**

## 25 - Sites have enrolled at least one subject

| | |
|---|---|
| Ben Taub General Hospital, Houston, TX | (21) |
| University of Utah Healthcare, Salt Lake City, UT | (17) |
| Froedtert Hospital, Milwaukee, WI | (16) |
| Strong Memorial Hospital, Rochester, NY | (13) |
| Penn Presbyterian Medical Center, Philadelphia, PA | (13) |
| Oregon Health & Science University Hospital, Portland, OR | (12) |
| Harborview Medical Center, Seattle, WA | (9) |
| UPMC Presbyterian Hospital, Pittsburgh, PA | (6) |
| University of Cincinnati, Cincinnati, OH | (6) |
| UF Health Shands Hospital, Gainesville, FL | (4) |
| Mass General Hospital | (4) |
| Yale New Haven Hospital, New Haven, CT | (4) |
| Cooper, New Jersey | (3) |
| Univ. of Massachusetts | (2) |
| Maine Medical Center, Portland, ME | (2) |
| San Francisco General Hospital, San Francisco, CA | (1) |

**----------First enrollments since the last newsletter----------**

| | |
|---|---|
| University of Chicago Medical Center, Chicago, IL | (2) |
| UC Davis Medical Center, Sacramento, CA | (2) |
| UNC - University of North Carolina Medical Center, Chapel Hill | (2) |
| OSU Wexner Medical Center, Columbus, OH | (2) |
| Detroit Receiving Hospital, Detroit, MI | (1) |
| WVU Healthcare Ruby Memorial Hospital, Morgantown, WV | (1) |
| Regions Hospital, St Paul, MN | (1) |
| CIUSSS-NIM Hôpital du Sacré-Cœur de Montréal, QC, CAN | (1) |
| University of New Mexico Hospital, Albuquerque, NM | (1) |

## HELP! Important Phone Numbers

- For immediate emergency assistance (enrollment, clinical, protocol, adverse events, etc.), please use the 24/7 BOOST 3 Principal Investigator Hotline: 855-4-BOOST3 (855-426 -6783).
- For urgent WebDCU randomization questions call: 1-866-450-2016
- WebDCU: Zeke Lowell (lowelle@musc.edu) or Sara Butler (butlers@musc.edu).
- Questions about BOOST 3? Send to boost-contact@umich.edu

### ANSWER TO A FREQUENTLY ASKED QUESTION

**What do you do if the ICP and/or PbtO2 abnormality is refractory?**

If an ICP and/or PbtO2 abnormality persists after treatments have been administered from Tiers 1 and 2 without ever normalizing, no more treatments are required to be attempted by the study. Tier 3 treatments are optional. If the attending physician chooses to attempt further treatments, record those treatments in the CRFs with results in the "Comments" section in WebDCU.

If the values normalize prior to probe removal, record "End of Episode". Additional treatments are then required, unless, in the judgement of the medical staff, further treatment is contraindicated. Reasons for no further treatment in both cases must be documented in WebDCU under "Comments".

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**Additionally**, when probes are removed, record the final ICP and PbtO2 values in the "Daily Vitals" that are done close to the time of probe removal and enter information that describes the refractory values and treatment decisions in "Comments"

## Hot Topic: Monthly Telephone Follow-Ups

To maintain engagement and prevent subjects being lost to follow up, follow-up phone calls are important. Study Day (approx.) 30, 60, 90, 120, and 150 and are added into the Subject CRF binder as a Study Visit.
Collect: current living situation, return to work/school status, or any readmissions to the hospital and/or Serious Adverse Events. *Remember to review the Baseline Form to fill in missing data.*
Day 30 may occur prior to Hospital Discharge. Indicate on the CRF F507 that the patient remains hospitalized.
*Some Tips for Successful Engagement:*
You may visit the subject/LAR if they are returning to your hospital/clinic to collect the information needed to complete the monthly form.
Planning and confirmation for the Day 180 visit should occur around the time of the Day 150 Follow Up. The Central Outcomes team at UW will contact each site as participants first come into the 180-day window. Scheduling the follow-up visit will be coordinated directly with the assigned Central Examiner.


## Important reminders:

## MOBERG PAUSE: TAKING THE PATIENT TO IMAGING

**Follow these Steps**

1) Make sure you're on the CNS Monitor display (black background)
2) Press the bottom step on the left side of the screen ("Stop Monitoring"),
3) Then on the dialog that appears, press "Pause Monitoring".
4) Switch displays and mark "Data Paused" in Reader/CarePath as well, although that isn't necessarily required - just makes it easier to see what happened when reviewing the data later.
5) When you return, press "Resume Monitoring"!!!!!!!!!! Don't forget!

**OR, another option:**

Another way to leave and return: **Just disconnect** and take patient to imaging, and **reconnect** when patient returns. Moberg will just stop collecting data and will resume when reconnected. BUT be sure to document *why there was a disruption* in data collection.

## WebDCU Nuggets

### F514 Follow-Up CT Scan for Probe Placement and *Optional* Forms

*Some CRFs can be optional*. Optional forms can be left blank and will not impact your site's timeliness on data entry. Form F514 "Follow-up CT Scan" for probe placement may be optional. This form is required to be completed during the Day 1 visit and should only be completed on Day 2 through Day 6 if an additional CT scan for probe placement is performed. This form should be filled out by the physician reviewing the CT scan.
If there is no CT scan *for probe placement* on days 2-6, you do not need to fill out this form on those days.

If there are any questions regarding this CRF, other data entry items, or any other aspect of WebDCU, please reach out to Zeke Lowell (lowelle@musc.edu) or Sara Butler (butlers@musc.edu).

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# BIO-BOOST

**Biomarkers in the Brain Oxygen Optimization in Severe Traumatic Brain Injury Trial**

**A multicenter, observational study examining the longitudinal changes of brain physiologic parameters in target molecular biomarker levels (serum, plasma, CSF, DNA and RNA)**

**PIs: Frederick Korley, MD, PhD and Ramon Diaz-Arrastia, MD, PhD**

| Current Approved Sites | Trained | Enrolled | Screened |
|---|---|---|---|
| Oregon Health and Sciences University | Yes | 4 | 4 |
| Baylor College of Medicine/Ben Taub Hospital | Yes | 0 | 3 |
| University of Pittsburgh Medical Center | Yes | - | - |
| Maine Medical Center | Yes | - | - |
| Temple University | No | - | - |
| University of Cincinnati | Yes | - | - |
| Penn Presbyterian Medical Center | Yes | - | - |
| Detroit Receiving Hospital | No | - | - |
| University of Florida/Shands Hospital | Yes | - | - |
| Utah | No | | |
| Strong Memorial Hospital | Yes | | |