May 1, 2025

BOOST-3 Bulletin

Brain Oxygen Optimization in Severe TBI Trial Newsletter

786 participants enrolled! Congratulations and thank you!

Top enrolling sites: #1Ben Taub, #2 Utah,
Froedtert and Strong are tied at #3, #4 Oregon, #5 UPMC

Neuro-monitoring devices not allowed

Add-on neuro-monitoring devices that are **not** acceptable include: NIRS, Jugular bulb saturation monitors, cerebral oximetry monitors, cerebral blood flow monitors, continuous transcranial doppler (TCD) monitoring, or quantitative EEG algorithms specific for cerebral hypoxia, as these can provide indirect information regarding brain tissue oxygenation. The occasional use of TCDs to confirm suspected vasospasm or assess autoregulation is allowed. The use of quantitative EEG for detection of seizures is acceptable.

Words of Wisdom from WebDCU by Zeke Lowell

Need help deleting a CRF or changing a visit date? Please email the DCU with the following format complete with information and we can get items removed for you:
Site Name:
Subject ID:

- CRF ID to delete:
- OR
- Visit to delete:
- OR
- Visit date to update:

Reason for change:

Thank you! WebDCU Team

May 1, 2025

REMINDERS from the BOOST PIs

+SCREENING Reports by Dr. Diaz-Arrastia

Please enter screen failures into WebDCU, so that it is evident that your site is actively screening patients. Otherwise, your site may look inactive.
Refer to the MOP Section 3.4 "Screening Report"
Screen results (failure or enrollment) should be entered into WebDCU within 5 days of screening.

The rule for Screening a patient is:
Screening should be inclusive of all patients admitted to an ICU with a TBI and placement of an intracranial monitoring device. Inclusion of patients on the screening log is independent of whether the study team was contacted on the day of service or not.

++DATA ENTRY Reminders by Renee Kasperek-Wynn

Opening Visit dates in casebook: Day 180 should be opened using the date of the last day 180 assessment. The EOS visit should be opened using the last date of the day 180 assessments. If the visit date needs to be corrected for either of these visits, reach out to the data managers to request a correction as you are unable to correct the visit date, once the visit has been opened.

End of Study CRF-Once the subject has ended participation in the study (completed the day 180 assessments, death, lost to follow-up, or consent withdrawal), please promptly submit the End of Study CRF(F126) to reflect the reason for study termination. This will require opening an End of Study visit.

Informed Consent Log CRF-

- When reporting outcome of Consent Obtained, please report the actual time consent was signed, rather than a general time or an estimated time when the discussion started.
- When consent has been obtained electronically, please remember that the time captured on the PDF record you receive via email is in EST, but the reported time of Consent Obtained on the CRF should be in your local time.
- When you have enrolled under EFIC, please document the status of consent attempt prior to proceeding with randomization. Please also work to submit the ICF log CRF ASAP after randomization. We will work to push any surveys needed to collect consent documentation, once it is reported that Consent has been obtained. We also will query if we do not see documentation of your attempts to get written consent on the ICF log CRF.

MOBERG MORSELS from Ryan Goldstein

1. When Discontinuing a Monitoring Session, **DO NOT unplug the Moberg CNS monitor** until the system is properly **shut down**!

2. If you are having problems with the Moberg, be sure to first check your connections and wall plug.

3. Call or email the trainer assigned to your site and let them know you are experiencing issues with your Moberg CNS. Photos are illustrative!

Moberg CNS Tips
1 Always use the "CNS Reader Admitted" shortcut.
2 After a patient is discharged, DO NOT leave the BOOST system running, instead make sure to shut down the system fully, and power it back up when you are ready to enroll a new patient.
3 If you see a "File Error" when opening the software, do NOT ignore it, instead make sure to shut down the system fully, power it back up, and readmit the patient as usual.

May 1, 2025

Some New Moberg CNS FAQs

Q: What if the Moberg CNS system alarms are not working?
A: If the monitoring session was not opened using the "CNS Reader Admitted" shortcut (rather, just "CNS Reader") then the monitoring session was not monitored by the software for abnormalities and would not have alarmed. If the "CNS Reader Admitted" shortcut was used, the title bar of the software will show the patient info as entered on the CNS Monitor and the admission time. If not, the CNS Reader should be closed, then the "CNS Reader Admitted" shortcut should be opened. Always use the "CNS Reader Admitted" shortcut.

Q: What does this File Error message on the Moberg CNS screen indicate and what should I do?

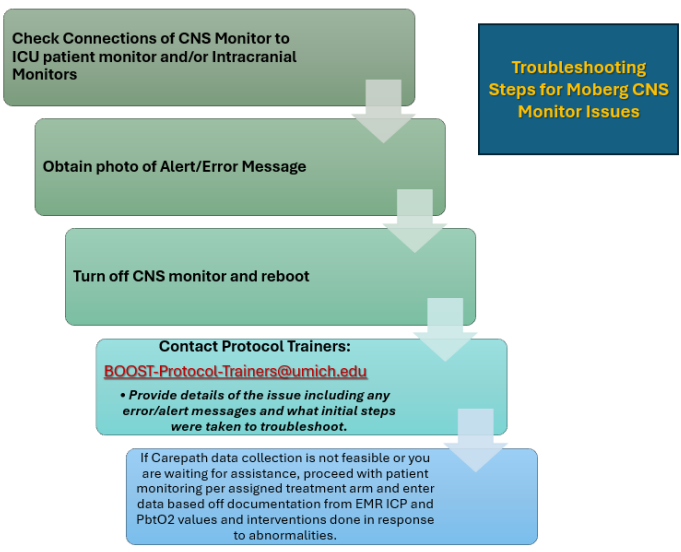
A: If this error is seen at any time, it means that

- the Events.xml file is locked,
- the software can't write to it, and
- the events will appear in the software but will not be saved.

The only way to resolve this issue is by

- shutting down the CNS Monitor entirely,
- unplugging it from the wall after the power LED goes out,
- plugging it back in,
- turning it back on,
- and readmit the patient as usual.

Don't leave the BOOST system running, but rather shut it down after the patient is discharged, then power it up when ready to enroll a new patient.



Other Frequently Asked Questions

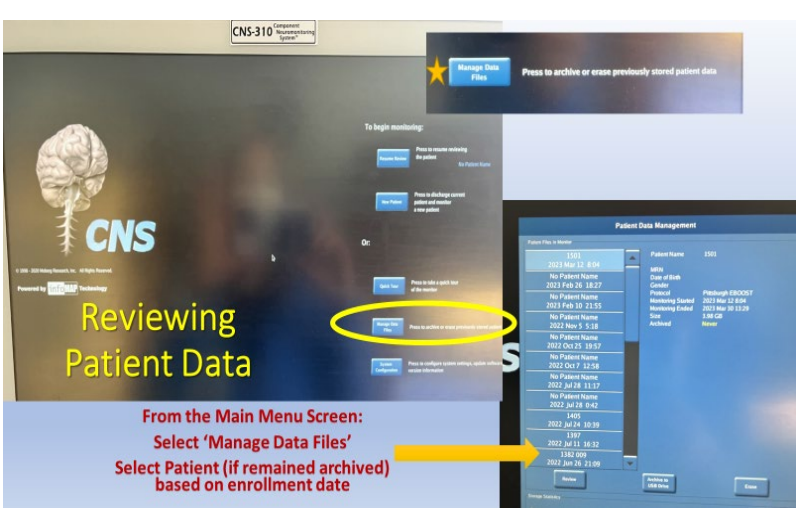
FiO2 Challenges

Q: How can you do an FiO2 challenge if the ventilator is already set at 100% FiO2?

A: If it is not feasible to lower the FiO2, consider doing a MAP or CO2 challenge to determine if that raises the PbtO2. **A MAP or CO2 challenge should not be performed in subjects in the ICP-only group.**

Data Retrieval

Q: How can I look back and retrieve participant data in Carepath?



A: From the "Main Menu" screen, select "Manage Data Files". Then select "Patient" (if the patient's data remained archived) based on the enrollment date of the patient. That will take you to the patient's data.

BOOST 3 Outcomes Updates by Kim Boase

Our overall follow-up rate is an incredible 95.7%! Thanks to all of our sites for making this happen. The 180-day follow-up is essential for the success of this trial.
A few reminders which will help us maintain this level of success.

1) Obtain multiple contacts when enrolling your participants and when meeting those who visit during the course of their hospitalization (Phone numbers and email addresses)
2) Monthly calls serve several purposes.
a. Maintain contact with the family and participant over time
b. Provide an opportunity to update missing demographic data
c. Identify any potential SAEs, hospitalizations
3) Schedule early in range if possible. The 180-day range is 180 days (+/- 30 days).
4) Try to coordinate the follow-up with another appointment.

The outcomes team is available to help with difficult scenarios. Please contact Kim with any questions kboase@uw.edu 206-849-4291.

Important Contacts for Help

- 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 and/or
  boost-protocol-trainers@umich.edu

May 1, 2025

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)

198 enrollments with 16 sites enrolling

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

Current Approved Sites	Enrolled
Baylor College of Medicine/Ben Taub Hospital	38
Oregon Health and Sciences University	30
University of Pittsburgh Medical Center	29
University of Utah	22
Strong Memorial Hospital	21
University of Chicago	19
Maine Medical Center	11
UC Davis	10
Penn Presbyterian Medical Center	6
University of Cincinnati	3
UF Health Shands Hospital	3
Detroit Receiving	2
VCU	1
University of North Carolina	1
Regions	1
OSU Wexner	1
Total enrollments	198

ELECTRO-BOOST

For Electro-BOOST, the total has risen from 26 to 177 since our last newsletter. Congratulations Electro-BOOST sites!

May 1, 2025

Total enrolled subjects: 177

Sites with Enrollments: 15

PIs: Eric Rosenthal, MD and Emily Gilmore, MD

Current Approved Sites	Enrolled
University of Pittsburgh Medical Center	33
Penn Presbyterian Medical Center	24
UC Davis	22
University of Chicago	17
University of Utah	15
Strong Memorial Hospital	13
Yale New Haven	12
UF Health Shands Hospital	9
Mass General Hospital	9
University of North Carolina	8
Oregon Health and Sciences University	6
UMass Memorial	4
Parkland	3
University of Texas Health Science, SA	1
University of Cincinnati	1
Total enrollments	177