June 4, 2020

BOOST-3 Bulletin

Brain Oxygen Optimization in Severe TBI Trial Newsletter

Congratulations to 9 enrolling sites - **30** subjects are enrolled!

Reminder:

The next SIREN Study Coordinator Meeting is on July 7th at 1pm EDT.

Ben Taub (9), UPMC (Pittsburgh) (5), University of Pennsylvania (4), Harborview (3), Strong Memorial (3), Foedtert (3), OHSU (Oregon) (1), UCSF (1), Cincinnati (1).

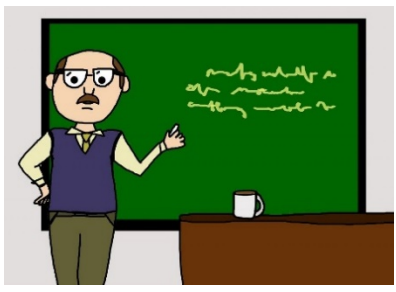
We thank your Herculean efforts!

21 sites open to enrollment are:
Univ. of Washington-Harborview, Ben Taub (Baylor-Houston), UPMC (Pittsburgh), Texas Medical Center/Memorial Hermann, Univ. of Pennsylvania, UCSF/San Francisco General Hospital, Regions Hospital (St. Paul), Strong Memorial (Rochester), Froedtert (Milwaukee), UF (Gainesville), UC Davis, Maine Medical Center, OSU Wexner (Columbus), Univ. of Cincinnati, OHSU(Oregon), Beth Israel Deaconess, Stanford, UMass Memorial, Univ. of Utah Healthcare, Yale, and Colorado.

Thank you for doing the hard work it took to get here!

Updated Protocol Training

The original Protocol training video on the BOOST 3 website was replaced with slides containing up-to-date information from the Protocol and MOP. Please review this training with your study teams.



Required 6-Month Re-training

If your site has not enrolled a participant in 6 months, your research staff is REQUIRED to engage in a refresher training session.

UPDATES TO REMEMBER

There have been some important changes to the protocol and MOP since the initial training which include the following:

1) Change in Duration of an Episode: 30 minutes of normal ICP or PbtO2 (originally 1 hour)
2) 5 Days of monitoring = 120 hours
3) Day 1 begins at the time of randomization and goes through midnight that day. Day 2 is a 24 hour period beginning after midnight of Day 1.
4) For all participants (unless they expire or are discharged before 120 hours) continue to collect applicable information through 120 hours on the Day 6 form in WebDCU.

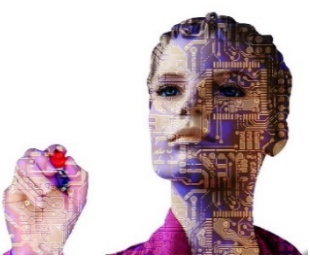
Alert: Please remember to fill in the participant's ID in Moberg!!

June 4, 2020

BREAKING NEWS

Research During a Pandemic

- Follow your institution's guidelines on performing research activities while COVID-19 restrictions are enforced.
- The COVID-19 SOP provides guidance when remote screening and enrollment must be implemented due to COVID-19 restrictions. This practice should be implemented at the discretion of your site PI and local policy at your institution.
- The SOP for screening and enrolling potential BOOST-3 subjects during COVID-19 restrictions can be found in the Toolbox on the BOOST-3 SIREN site.
- Site PIs should be proactive in selecting an on-site designee to assist the study coordinator with BOOST-3 related tasks such as Moberg setup, performing daily checks/FiO2 challenges on an enrolled subject during the monitoring period, and providing the clinical team with BOOST-3 reference materials.
- Study coordinators should have remote access to the EMR to allow for remote screening as well as daily review for potential adverse events or serious adverse events. Randomization and data entry may be performed remotely in WebDCU.



WebDCU Nuggets

1. **Counting number of burr holes:** The number of burr holes refers to the number drilled in order to place the PbtO2, ICP, AND EVD probes. If a probe is replaced, and the new probe requires a new burr hole, then record the number of **new** burr holes in WebDCU.
2. **BOOST Alerts tab reminder!**
   Please pay attention to the **Alerts** tab when you log into WebDCU. It will be outlined in **red** if there are any outstanding regulatory documents, DCRs, or CRFs that need to be addressed at your site. Queries should be addressed within 5 days.

New Frequently Asked Questions

FiO2 Challenges

Question: How can I do an FiO2 challenge if a patient's FiO2 is already set at 100%?

Answers:

1) Check blood gas and assess safety of temporarily lowering the FiO2 in order to do the challenge.
2) If the FiO2 challenge cannot be done for some reason, a MAP or CO2 challenge may be done where appropriate. Record in WebDCU that a MAP or CO2 challenge was performed. We are capturing this information. *NOTE: MAP/CO2 challenges can only be performed in the PbtO2/ICP treatment (unblinded) group.
3) If an FiO2 challenge cannot be performed, enter a note in general comments in WebDCU.

A request from leaders of the Follow-up examiners, Sureyya Dikmen, Nancy Temkin and Kim Boase:

Make sure your site has in place a plan for responding to any participant who endorses self-harm. This has come up early in the study and it is important to be prepared! Know how your institution handles this kind of situation both in clinic and off campus.

Questions about BOOST 3? Send to boost-contact@umich.edu