July 2019

BOOST-3 BITES

Brain Oxygen Optimization in Severe TBI Trial Newsletter

Reminders:

August 6th at 1pm EDT

NETT/SIREN Study Coordinator Meeting

Way to go Pittsburgh, Ben Taub and Memorial Hermann (Houston), and University of California, San Francisco General Hospital!

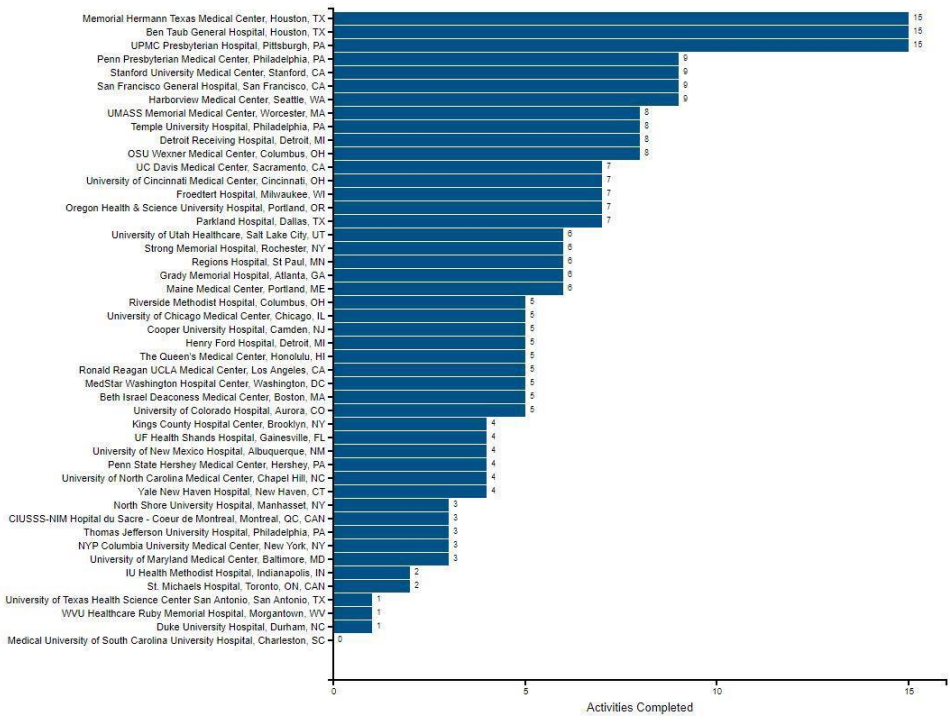
These four sites are our first sites to receive **IRB approval**! Big congrats to **Drs. Shutter, Okonkwo, Puccio, and Anita Fetzick, RN (Pittsburgh); Drs. Robertson and Cruz-Navarro, and Santhosh Sadsivan (Ben Taub); Drs. Kitagawa, Jones, and Choi, and Misty Ottman (Memorial Hermann); and Dr. Hemphill and Jeany Duncan at UCSF!**

The first three sites to be **released to enroll** are: **Pittsburgh, Ben Taub and Memorial Hermann!**

Kudos to the other sites that are VERY close to begin enrollment, as well. Site Readiness calls will be scheduled soon.

It is all finally coming together. Thank you all for your hard work and dedication to TBI research.

Site Readiness Activities Completed by Site



Have a question about BOOST-3?

Email

boost-contact@umich.edu

July 2019

BOOST-3 Updates

EFIC

Everything you ever wanted to know about Exception from Informed Consent (EFIC) is in the **Getting Started** page of the BOOST-3 website (http://boost3trial.org). This is a great resource for those who need to complete EFIC activities.

The Central IRB is requiring additional information from all sites regarding EFIC activities. The cIRB has asked that each site write a short narrative describing the following for each Community Consultation activity:

- Demographics of the audience (approx. age ranges and ethnicity percentages),
- Kinds of questions asked, and
- Comments from the audience.

A space for this narrative has been added in WEBDCU. The Local Context Narrative needs to be completed as well. Please reference *Preparing CC and Local Context Narratives* for further instructions.

Toolbox

New documents are often being added to the **Toolbox** on the BOOST-3 website. Please familiarize yourself with the Toolbox and its contents. If you have any tools that you find useful at your site please email them to boost-contact@umich.edu and we will have them posted in the Toolbox. You will always be notified of new postings.

FAQS

Two of the new questions ask if it is ok to disable the PbtO2 or ICP alarms or to lower or raise the thresholds. These were added because it was observed that during trial runs, some treatment staff had disabled the alarms or changed thresholds because they did not want the alarms going off too often. (Yes, alarms can be annoying!) Nevertheless, it is **NOT** ok to disable the alarms (except in the blinded arm) or change thresholds in this trial because abnormalities will be missed. A major part of this study includes timing--from the beginning of an abnormality to the initiation of a treatment. Therefore, coordinators and investigators, please check the monitors every morning to make sure they are alarmed and ready!

MOBERG CNS Monitor

New Video on how to use the Moberg CNS monitor is now available. Dr. Anna Rodriguez, (anna@moberg.com), Director of Research at Moberg ICU Solutions, has provided an excellent video, self-explanatory, and simple to follow on using the Moberg CNS monitor. Please review the video and practice using the CNS monitor (more than once) to get the hang of it.

WEBDCU CRFs

The CRFs in WebDCU are ready to launch! Thank you **Drs. Sharon Yeatts and Wenle Zhao, Jodie Riley, Catherine Dillon, Sara Butler, Chris Arnaud, Keith Pauls, and Abby Teklehaimanot** for your brilliance.