



OHSU SIREN NETWORK NEWS

Issue: September 2018

CALENDAR

9/4 1pm EDT NETT/SIREN
Study Coordinator Call: 888-
330-1716 / 5967697 web [click here](#)

9/13 1pm EDT Human
Subjects Protection Working
group

9/13 3pm EDT Finance
Committee meeting

9/19 1pm EDT SIREN/NETT
Journal Club [click here](#)

9/26 12pm EST NETT/SIREN
Steering Committee Call in:
888-330-1716 / 5967697 web
[click here](#)

10/2 1pm EDT NETT/SIREN
Study Coordinator Call: 888-
330-1716 / 5967697 web [click here](#)

Contact us: Jenny Cook,
Coordinator, 503.494.1230
cookjen@ohsu.edu

SIREN WORK GROUP SIGN UP

Network goal – 1 representative from each site participates on a workgroup.

Sign up today! <https://siren.network/about-siren/working-groups>

We encourage all SIREN team members to participate in one working group which will help guide trials, designs, and network processes. Thank you in advance for signing up!

HOBIT – HYPERBARIC OXYGEN BRAIN INJURY TREATMENT TRIAL

- ✓ Congrats to Duke, 1 of 3 sites now enrolling subjects.
- ✓ Hennepin has created some helpful hint documents (attached to this e-mail.) These are also located on the HOBIT website under Toolbox → Clinical Resources.
- ✓ *The Hennepin site has enrolled the first 2 subjects, and highly recommends making sure you do a good simulation to help prepare your team for this very time/resource intensive trial!*
- ✓ Readiness checklist was recently updated. Check out the latest version!
- ✓ Reminder: All study resources can be found at hobittrial.org

BOOST III: BRAIN OXYGEN OPTIMIZATION IN SEVERE TBI - PHASE III UPDATES – IMPORTANT SURVEY [CLICK HERE](#)

- ✓ BOOST FAQ's are listed on pages 2-3 of this newsletter. Please read carefully if your site is interested in participating. There are some very important pieces of info in these FAQ's!

The BOOST III Notice of Grant award has been issued. This means:

- ✓ Hub sites participating in BOOST III, will receive a master contract from University of Michigan in the coming weeks (if you haven't already).

- ✓ BOOST III riders (e.g. study specific contract) will be drafted and University of Michigan will be rolling those out to sites in the coming months.
- ✓ If you are an OHSU spoke site, we will be drafting your subcontract once we receive our BOOST III rider.
- ✓ <https://siren.network/clinical-trials/boost-3> for study resources.

cIRB RELIANCE AGREEMENTS

There is a new guidance document from the CCC regarding the nuts and bolts of the cIRB processes – also attached to this newsletter and titled: “SIREN – Resources and Steps for Relying on the SIREN ER-cIRB. **Please review this document and follow the applicable steps on pages 2-3** (if you have not done so already). This information is also on the [SIREN website](#) → Resources tab → “ER-cIRB page”

BOOST III FAQ's

- Q1:** Who are the personnel at the SIREN CCC and who should we communicate with for various trial related questions?
A1: The easiest way to reach out to the SIREN CCC is to use the BOOST-contact@umich.edu. This will ensure that your message gets to the appropriate team member who can provide a prompt response.
- Q2:** How can we confirm prospective trial sites, affiliated SIREN Hubs and critical study team member contact information with the SIREN CCC?
A2: This is a great question, as we want to be sure that we have the contact information to reach all critical study team members at all prospective BOOST 3 sites. If there have been any changes to your site's Hub affiliation, BOOST 3 PI, or BOOST 3 Primary Study Coordinator since you completed the initial survey, please let us know. We are happy to work with you to confirm this information.
- Q3:** How will sites be rolling out and how many sites will participate in the study?
A3: While taking all sites into consideration, we will be prioritizing sites based on experience with placement and management of PbtO2 monitors. We will be contacting the highest priority sites no later than September 10. BOOST will only include sites that use PbtO2 monitors. For sites who do not currently have or use PbtO2 monitors but intend to, you will need to demonstrate experience in using brain tissue oxygen monitors for patient care in TBI patients. Our expectation is that sites should have successfully placed and used PbtO2 monitors at least 3 times in the past 6 months to be considered as a BOOST site. After your site has placed at least 3 PbtO2 monitors, the site PI should contact Dr. Shutter (shutterla@upmc.edu) to confirm this information. We encourage all sites to begin preparations now, and will move forward with sites as they complete this process and are ready to get started. We budgeted for 45 actively enrolling sites in BOOST3.
- Q4:** What will be involved in the process of ceding to the central IRB (Advarra)?
A4: Consistent with NIH guidelines, BOOST 3 will be using a central IRB. The answer to this question and others about cIRB can be found on the following SIREN page: [Resources and Steps for Relying on the SIREN ER-CIRB](#)
- Q5:** My site IRB uses Smart IRB for reliance agreements. How does that work?
A5: Please contact your IRB for assistance with this. You can also reference instructions from Advarra: [Using Smart IRB](#)
- Q6:** What is expected of each site for the EFIC process for this trial?
A6: Sites with experience conducting EFIC activities can expect to propose community consultation and public disclosure (CC/PD) activities similar to the efforts undertaken in previous trials. However, the cIRB may yet request the overall trial EFIC plan to have some additional or different requirements. An EFIC plan for sites to use to build out your local CC/PD plan will be made available as soon as it has been cIRB approved. Centrally, the CCC will create CC/PD related resources and templates for local use, e.g. videos, brochures, ads, flyers, slide sets, self-administered survey instruments, etc. CC and PD results and event data will be collected centrally in WebDCU™ for generating reports for the cIRB. There will be startup funds allocated to perform the required EFIC activities. If you have additional questions please contact Deneil Harney dkolk@umich.edu 734-232-2132
- Q7:** How will BOOST 3 data be managed?
A7: The BOOST 3 database is currently being built in the WebDCU™ clinical trial management system. WebDCU is housed at the Data Coordination Center (DCC) at the Medical University of South Carolina (MUSC). All trial data will be maintained in this secured system, including CRFs, regulatory requirements, and EFIC CC and PD activities. The central IRB application process will also take place in this system. Training and instructional materials will be provided to facilitate use of each component of the database.
- Q8:** How will local site training take place?
A8: Sites will be responsible for training their local study teams and clinical staff initially and throughout the course of the trial. The SIREN CCC will provide training materials, available online for easy access (protocol training, in-service slides, etc.), as well as study materials to be distributed locally (e.g. pocket cards, trial posters, etc.). As sites develop their own materials, we encourage sharing across the network and can post these materials in the BOOST 3 Toolbox.

Q9: What trial equipment will be provided to sites?

A9: The SIREN CCC will be lending Moberg CNS monitors (CNS-310) to all enrolling sites. So long as sites continue to enroll, the devices will remain on site. Should sites discontinue enrollment, the devices will be returned to the SIREN CCC. PbtO2 monitors will not be provided by the SIREN CCC. For enrolling sites, startup payments will include some funds to partially offset the cost of site's PbtO2 ownership. The cost of probes is built into per subject payments.

Q10: What is the per subject reimbursement?

A10: The per subject reimbursement has not yet been finalized. However, it is expected to be approximately \$12,500, which is inclusive of indirects. Per subject reimbursement will be milestone driven.

Q11: Will there be an initial BOOST 3 Investigator Meeting?

A11: Yes. We anticipate that this will take place in the first quarter of 2019. Meeting details and location will be distributed as soon as we have further information.

Please feel to share these FAQs and other study information with your local study teams. We are happy to field additional questions as they arise, so please do not hesitate to reach out to us: BOOST-contact@umich.edu