OHSU SIREN NETWORK NEWS

Issue: January 2019

CALENDAR

1/8 1pm EST NETT/SIREN Study Coordinator web click here

1/10 1pm EST Human Subjects Protection Working group

1/16 1pm EST SIREN Journal Club click here to join

1/23 12pm EST NETT/SIREN Steering Committee Call: 888-330-1716 / 5967697 web click here

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

HOBIT – HYPERBARIC OXYGEN BRAIN INJURY TREATMENT TRIAL

- ✓ Enrollment: 13 subjects (Goal: 200)
- ✓ The OHSU Network has 3 potential HOBIT sites. Duke and OSU have started enrolling subjects. UAB is working diligently on their study start up milestones, and expect to be released to enroll in the near future.
- ✓ Please review the e-mail from Natalie Fisher Brown on 1/2/19 titled: **HOBIT eConsent - Verify Local Site Contact Information is Displayed**

BOOST3 INFO

- ✓ **cIRB approval expected soon.** BOOST3 study documents and approval to begin site preparation should be received in early January. Watch your inboxes for the documents and announcement. This should come directly from the CCC.
- ✓ **Site preparation:** If your site is not a regular user of the Licox monitor, you must demonstrate successful placement of 3 Licox probes with monitoring prior to being released to enroll. To demonstrate success, you will need to submit the following:
  - Head CT confirming placement
  - Brief patient Hx (eg 24yo F post MVC with GCS of 6)
  - The goal of demonstrating successful placement of these monitors is to give all staff familiarity with using them. Experience with the monitors is needed from all bedside providers – the MDs, RNs, APPs, RTs, etc. You do not have to use them to guide therapy, but the team needs experience with managing them and how to do physiological challenges.
- ✓ **BOOST3 investigator meeting**: Mar 19-20, 2019 – Atlanta, GA
  - Plan to: Arrive on 3/18. Meet all day on 3/19, dinner will be on your own that evening, 3/20 will be part-day meeting, so attendees can fly home that evening.
  - On 1/3 Valerie Stevenson sent an e-mail with more details on signing up. Check you inbox!

- ✓ Please review at your earliest convenience
  - The Draft of the BOOST3 Protocol
  - Getting Started steps
  - BOOST3 Milestones Document

DEC 10 - OHSU SIREN CALL MINUTES

- ✓ Thank you to all who were able to participate in the OHSU Network call last month. Topics discussed were:
  - BOOST3 Phillips monitor compatibility issue some sites are experiencing issues. Please check to see if this an issue at your institution.
  - Contracts for BOOST3 should have been received by your site in late Nov – contact Jenny ASAP if you are a BOOST3 site and do not have your contract in house.
  - cIRB ceding – this process is still a little unclear, but the CCC insists that what you will need is a letter (of any form amenable by your site) from your IRB to the study PI stating that they are willing to cede oversight of the study (or studies that are part of the SIREN network) to the cIRB (Advarra). We suggest contacting your IRB now to discuss this so that you can understand their process for creating these documents. Your IRB likely has a process in place for this, but the length of time, and requirements for ceding can be different from site to site, so check with your local!
  - Working groups
    - Some of the working groups are up and running – Operations committee (Mo Daya), Human Subject Protection (HSP – Alex Limkakeng, Denise Griffiths), Electronic Data Capture (Tom Terndrup, Jenny Cook), EMS (Mo Daya), Cardiovascular Emergencies (Simon Maher, Bory Kea), Trauma (David Zonies, Jan Jansen).
    - Information about committee business will be shared in upcoming newsletters. Please let me know if you have notes to share.
    - Not all working groups have been organized yet. If you have not heard from the CCC yet, your working group is still forming, and will be in touch once they have established a chair for your committee.

EFIC / IRB SITE MILESTONES FOR BOOST3

START-UP ACTIVITIES for SIREN Sites

Task 1: Inform your institution that you plan to participate in BOOST3 and that your institution's participation requires relying upon the SIREN central IRB managed by Advarra. The form of this communication may vary from site to site, but is some kind of ceding application by the site investigator to the local IRB requesting an acknowledgement from the local IRB that they are aware of this particular trial and agree to cede the review and oversight to Advarra. Demonstrate completion of this task by uploading this ceding application that was sent by the site investigator to your local IRB or research office. Upload the document into BOOST3 WebDCU, under the regulatory document titled: **Ceding Request to Local IRB**

Note: The materials that your local IRB may require you to include with this ceding application may vary from site to site as well, but will typically include the study protocol and consent form, the sponsor's Notice of IRB Approval for the protocol and consent form from Advarra, and other materials, which should be submitted locally exactly as they have been provided by the sponsor. Exception from Informed Consent (EFIC) material and the consent form will have placeholders to incorporate local contact information. Any other edits (requested by the local research office), are discouraged in the interest of equity and require a discussion between the site investigator, the local research office and the sponsor. Such a meeting can be requested by emailing BOOST-Contact@umich.edu.

Task 1a: If Applicable, Submit (non-template) site specific Community Consultation (CC) and Public Disclosure (PD) materials to Deneil Harney (dkolk@umich.edu) for review/approval. Initial review will occur within 2 business days.

Task 2: Add all known Study Team Members to the Study Team Member Request Table in BOOST3. Enter eDOA log to include PI, Primary Study Coordinator, and any other team members involved with EFIC activities, including their respective responsibilities. Include all contact information including email and phone number.

Task 3: Upload your local research office ceding approval letter into BOOST3 WebDCU, under the regulatory document titled: **Ceding Acknowledgment from Local IRB**

Milestone 1 Payment **(contingent on completion and approval of tasks 1-3)**	**$30,000** **(total payment, includes F&A)**

Task 4: Complete a Supplemental EFIC Local Context Form in BOOST 3 WebDCU.

Task 5: Generate a new CC and PD form for each proposed EFIC event via the Community Consultation (CC) and the Public Disclosure (PD) form in the BOOST 3 WebDCU.

Task 6: Conduct CC and complete the CC form for each CC event. All queries related to CC data must be reconciled for task eligibility. Contact Deneil Harney (dkolk@umich.edu) for approval.

Task 7: Begin PD activities and enter related PD data, including a PDF of the source as it appeared in print, was heard, seen, etc. PD activity will be ongoing throughout the trial, but sites should show results for events completed prior to beginning enrollment to receive credit for this task. Queries related to PD forms completed

prior to enrollment must be reconciled for task eligibility. Contact Deneil Harney (dkolk@umich.edu) for approval.

Task 8: Complete and have CCC approved for submission to Advarra a cIRB **Initial Site Application** form and affiliated regulatory documents, in SIREN and BOOST3 WebDCU.

Task 9: Update eDOA log to include all study team members with their respective responsibilities. Have all regulatory and training requirements reconciled and approved in WebDCU. Contact the SIREN CCC at BOOST-Contact@umich.edu for final approval of this task.

Task 10: Complete a readiness checklist and call, and be released to enroll by the CCC & Sponsor. A site should plan a readiness call, which corresponds with the completion of: All study-staff training being complete, site and study team regulatory compliant, contracts finalized, and when ready to begin enrollment immediately. Email BOOST-Contact@umich.edu for more information and to set up your readiness call.

NOTE: Two weeks' notice is desirable to coordinate a date and time that will work for everyone that needs to attend. The date a hub/spoke/site is released to enroll by the CCC in WebDCU will be used to verify the date this task was completed.

Milestone 2 Payment **(contingent on completion and approval of tasks 4-10)**	**$10,000** **(total payment, includes F&A)**

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TOTAL for MILESTONES 1, 2 = $40,000

NOTE: Post trial public disclosure will occur after the trial is completed. There will be a separate document describing that milestone and payment at a future time.

How to Request Information/Clarification Regarding Task Completion and Milestone Payments: All email correspondence regarding task and milestone completion should be sent to the SIREN CCC at BOOST-Contact@umich.edu

The SIREN CCC will send a confirmation email to the Hub & BOOST PI once all the tasks for a given milestone have been verified as complete. The Hub PI is then eligible to request payment by submitting an institutional acceptable invoice document to the SIREN CCC via email to BOOST-Contact@umich.edu.

The following resources have been developed to assist you with successfully completing WebDCU documentation milestone tasks accurately and promptly.

✓ Instructions for acceptable regulatory documentation parameters, including unique circumstances, deferrals, waivers, and documents that apply to more than one spoke:
BOOST 3 Regulatory Document Approval Parameters for WebDCU pdf
Available in WebDCU: BOOST 3>Toolbox > Project Documents

✓ Instructions for completing CC and PD data-entry in BOOST 3 WebDCU (tasks 5 - 7 above). **CCS Form Guide** & **the BOOST 3 Instruments – CCS Key** pdf, and **PDS Form Guide** pdf. Available in WebDCU: BOOST 3 > Toolbox > Project Documents