OHSU SIREN NETWORK NEWS

Issue: October 2019

CALENDAR

10/1 1pm EDT SIREN Study Coordinator – Bluejeans conference link in e-mail

10/10 3pm EDT Finance Committee meeting

10/16 1pm EDT Journal Club

10/23 12pm EDT SIREN Steering Committee - Bluejeans link in e-mail

11/5 1pm EDT SIREN Study Coordinator – Bluejeans conference link in e-mail

For working group meeting times visit:

SIREN CCC Events Calendar

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

Follow our research team on Twitter: @OHSU_CPREM

BOOST 3 NEWS AND UPDATES

- 1st BOOST 3 enrollment at Ben Taub, 5 sites are currently open for enrollment.
- *If you're having trouble completing a milestone – please reach out to us for assistance and advice. Getting sites up and running this year is a grant required milestone. Please help us all stay compliant. All tasks for you to receive your first milestone payment should be complete at this time. Please note that the CCC is now beginning to review the list of sites that have not received a milestone payment to see if they should be replaced by a site on the alternate list.*
- Ancillary studies:
  - Is your study planning to participate in BioBOOST? (an ancillary study to BOOST-3 which will fund the collection of blood and CSF for analysis of proteomic biomarker studies and other future uses.) Please e-mail Jenny if your site has been contacted about participating, has plans, or is interested in participating in BioBOOST.
  - ELECTROBOOST – an ancillary study proposal that is being submitted for funding consideration. Please let us know if your site has interest in being a part of this substudy.

- **Device Billing FAQ's:**
  - Q: Are we billing insurance for the device?
  - A: The ICP probe is standard of care and the cost of the probe should be billed to the 3rd party payers. The PbtO2 probe is the target of the study, and the cost of the probe is included in the per-patient capitated cost. There is no charge for the use of the Moberg CNS monitor.
  - Q: Will the sponsor pay for the device or procedure if insurance denies?
  - A: No. As placement of the probes is part of routine care, the cost for the procedure to place the probes and the ICP probe itself should be billed to insurance. The cost of the PbtO2 probe is covered by the sponsor. There is no cost associated with the monitoring device. As a reminder: Please discuss your local practices for intracranial monitoring with the treating neuro-intensivist or neurosurgeon at your site.
- The cIRB has requested that the CCC 'pre-review' the EFIC study packet sites are submitting prior to sending it to the cIRB to confirm completeness and diligence. The CCC will be testing this process with the next round of EFIC submissions. If you are submitting soon, please be aware the CCC may review your packet and request edits prior to sending it into the cIRB. Examples of EFIC summaries from sites that are approved have been shared as examples.
- OHSU hosted BOOST 3 webpage: As part of our SIREN Network information, we have added a page with BOOST 3 resources. Let us know if there are additional resources, links or information you would like to see added to this site. Feel free to share this resource!

- Contracts: The NIH has asked that BOOST 3 contracts be put into a no cost extension for year 1. The CCC is working to make this happen and will be in touch with sites to amend your contract once the details are approved.

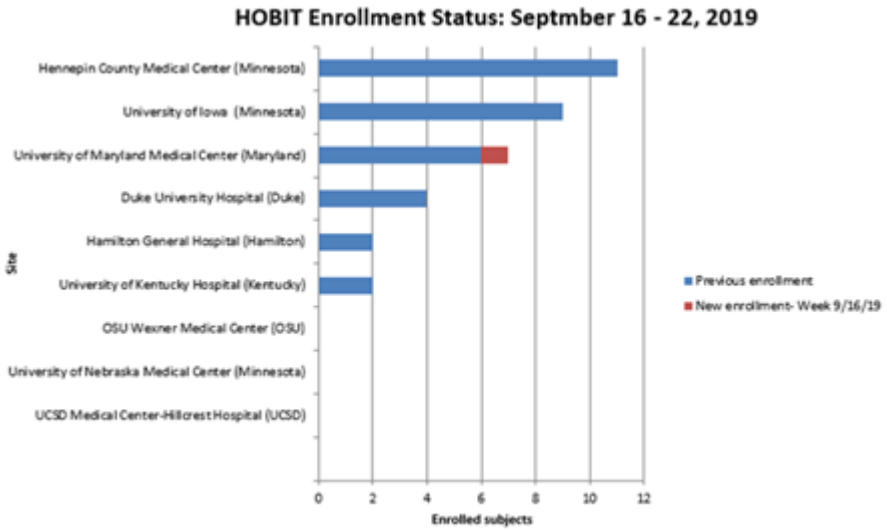
JOURNAL CLUB – EARLY CAREER INVESTIGATORS NEEDED

Do you have an early career investigator on your team who would be interested in presenting at an upcoming journal club meeting? Everyone is welcome to join, and presenters are always needed. Let us know if you'd like to present!

ONGOING TRIALS

HOBIT – Hyperbaric Oxygen Brain Injury Treatment Trial

- Enrollment: 35 subjects (Goal:200)
- 9 Active sites – 6 have enrolled at least 1 subject to date
- DSMB for HOBIT met in September. Study is currently under its enrollment to date target – stay tuned for DSMB findings



- NEW: The following Monoplace Safety Technical Bulletin was posted to the Toolbox under Chamber Resources: Ohmeda Battery Charging Cradle
- The following FAQ was posted on the FAQ page under Screening and Inclusion/Exclusion.
- **Q**: If a potential subject presents with a GCS of 3 - 8 but the GCS improves to >8 prior to randomization, should that potential subject be included in the screening log?
    - **A**: Yes. The screening log should include all patients 16 - 65 years of age who presented to the enrolling institution within 18 hours of blunt head trauma, had a GCS of 3 - 8, and were hospitalized but not randomized. When completing the screening log, select "Improved GCS" as the reason for screen failure.
- The following FAQ was posted on the FAQ page under HBO Treatment.
- **Q**: What should I do if a subject is randomized with the intent to get the initial treatment within the prescribed time window, but is unable to?
    - **A**: Once a subject is randomized, they are in the trial whether they receive the treatment or not. This event should be reported in WebDCU as a protocol deviation, however, the subject is still eligible to receive subsequent HBO treatments if feasible. Treatment should be initiated as soon as feasible.

WORKGROUP SPOTLIGHT

Human Subjects Protection

BOOST 3 Discussion: Last meeting from HSP discussed the cIRB approach to approval of sites for EFIC for BOOST 3.

- The cIRB does not want to review these reports twice for each site so going forward, the reports will go to a designated group at the CCC to review and make sure it meets the cIRB requirements before sending it to cIRB for final review and approval.
- Selected sites may be collecting additional physiological data and may need to include this into their consent form, but this is all still up in the air so not much info to share at this point.

There was a bit of a discussion about recent events at Hennepin with regards to emergency research and a planned proposal for a session at SAEM 2020.

UPCOMING TRIALS

ICECAP = The Influence of Cooling duration on Efficacy in Cardiac Arrest Patients

Brief summary: ICECAP study will enroll comatose adult survivors of out of hospital cardiac arrest that have already been rapidly cooled using a definitive temperature control method. Those with and without initial shockable rhythms will be studied as distinct populations (maximum of 1800 subjects over four years). ICECAP will determine if identifying an optimal duration of cooling can improve outcomes, and if development of a duration response curve can substantiate efficacy in a wider patient population.

- **NOGA has been received.**
- Investigator meeting planned for 1/30-1/31 –place TBD

OHSU SIREN network sites

- The following sites from our network are anticipated to participate in ICECAP
  - University of Alabama
  - University of Rochester Medical Center
  - The Ohio State University
  - University of Utah
  - OHSU

If your site is interested in participating in ICECAP, but is not listed, please fill out the survey on the ICECAP webpage: https://siren.network/clinical-trials/icecap

FUTURE POTENTIAL TRIALS

KETOSIS = Ketogenic Emergency Treatment of Status epilepticus In Siren

This is a proposal for a phase II multicenter, double-blind, placebo-controlled, restricted Bayesian response adaptive randomization clinical trial designed to determine the ketogenic formula specifications needed to safely induce ketonemia (≥ 1 mmol/L blood ß-hydroxybutyrate) within 24 hours in patients with established refractory status epilepticus (requiring general anesthesia to suppress ongoing status epilepticus), as an adjunct to standard medical care.

- Submitted in June 2019 for review.

There are plans to submit/resubmit 2 grants in the winter funding cycle:

- **Chest Pain= C**omparative **H**ealth **E**ffectiveness of **S**trategies **T**esting **P**ain **A**ssessment of **I**schemia **N**oninvasively : https://siren.network/clinical-trials/chest-pain
- **HAT-TRIC=Dose finding trial of Fibrinolytics for Acute Pulmonary Embolism:** HAT-TRIC will find the lowest effective dose of fibrinolytic that provides adequate treatment effect for acute submassive PE. With a PE, acute pulmonary hypertension causes dilation of the right ventricle (RV) relative to the left ventricle. We will use the ratio of RV/LV diameters at 24 hours as an endpoint to see if fibrinolytic is producing its intended biological effect. Normal RV/LV ratio is <0.9, but during an acute PE, RV/LV ratio may be 1.3 or higher. Patients will only be enrolled in HAT-TRIC if RV/LV ratio is elevated.

GLOSSARY OF FREQUENTLY USED ABBREVIATIONS

CCC = Central Coordinating Center (i.e. University of Michigan)
EFIC= Exception from informed consent
CC = Community Consultation
PD = Public Disclosure
cIRB = Central IRB (in this case Advarra)