



# OHSU SIREN NETWORK NEWS

Issue: November 2019

## CALENDAR

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

11/14 3pm ET Finance Committee meeting

11/20 1pm ET [Journal Club](#)

11/22 10-12 or 2-4 ET HOBIT VIRTUAL INVESTIGATORS MEETING – PI and PSC MUST ATTEND one of these sessions

11/27 12pm ET SIREN Steering Committee - Bluejeans link in e-mail

12/3 1pm ET 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](mailto:cookjen@ohsu.edu)

[OHSU SIREN Website](#)

Follow our research team on Twitter: [@OHSU\\_CPREM](#)

## BOOST 3 NEWS AND UPDATES

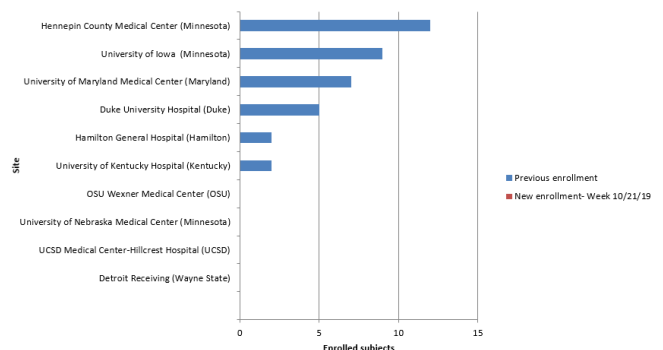
- **BOOST 3 enrollments: 3**
- Congrats to URMC for completing CC and their readiness call & OSU for completing CC as well!
- Site readiness: 5 sites have been released to enroll; 10 sites are currently pending cIRB review/readiness review and will be released in the near future.
- **Contracts:** Your new BOOST 3 no cost extension contract has been sent to your facility – **Please check with your contracts office to confirm your contract is being executed asap.**
- Feedback on first enrollment. The Harborview team had their first BOOST subject enrollment and had the following advice:
  - Review the CRF’s ahead of time, and determine where you can pull the info from – they specifically ran into an issue of having trouble determining the time of injury because the EMS chart was not available right away (what will you do if this is the case for one of your subjects??)
  - Moberg is LOUD –The Carepath page has a ‘pause data’ that will silence the alarm until patient is connected. The company is aware of this issue and is working on a resolution to the volume problem.
  - Community Consultation helpful hints: 1. Get out into your community! All your events cannot be at your facility or on your campus; this won’t pass muster with the cIRB. 2. Make sure you have some elderly individuals represented in your CC groups; this seems to be a point of emphasis with the cIRB. 3. Make sure your narratives give a flavor for the qualitative aspects of the event. The cIRB wants a feel for how your event went.

## ONGOING TRIALS

### HOBIT – Hyperbaric Oxygen Brain Injury Treatment Trial

- Enrollment: 37 subjects (Goal:200)
- Kudos to Duke for their recent enrollment!
- *Point of emphasis:* Monthly subject check-ins are critically important to staying in

HOBIT Enrollment Status: October 21 - 27, 2019



contact with the subject/LAR until the primary outcome can be collected. Please be diligent in completing these monthly contacts with all subjects.

- **HOBIT virtual investigators meeting**

- Reminder: HOBIT EFIC Virtual Investigators Meeting which will be held on **Friday, November 22nd from 10:00am – 12:00pm ET**; and on **Friday, November 22nd from 2:00pm – 4:00pm ET**.
- **Both the PI and Primary Study Coordinator or site designee from each site are required to attend one of the meetings.** Others are welcome to attend as well. Please register for the meeting via the link : [Bit.ly/HOBITmeeting2019](https://bit.ly/HOBITmeeting2019)

## WORKGROUP SPOTLIGHT

### Electronic Data Capture

This workgroup is working on a data harmonization project. Lisa Merck (committee chair) is working with a number of teams to put together a grant application that would create a curated library of imaging data with retrospective data from MISTIE and ProTECT, as well as prospective data from other trials moving forward.

### EMS

The EMS working group is wait to hear about the R34 that was submitted as a planning grant to help develop a study proposal looking at post ROSC stabilization for OHCA. The EMS WG also reviewed a draft proposal whose goal was to validate the findings of the EPIC TBI study from Arizona across SIREN EMS sites. This article was discussed at a recent SIREN JC.

## 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 to a target of 32-34°C. Enrolled subjects will be randomized to different cooling durations using an adaptive design. 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.

- Investigators meeting planned for 1/30-1/31 –place TBD
- Emails were sent out the week of October 21<sup>st</sup> to the first 50 sites expected to enroll in ICECAP. If you did not receive an e-mail and are interested in participating, contact us!
- DSMB meeting is taking place soon
- MOP is still in development and not ready to be circulated. Stay tuned.
- FINANCIAL:
  - There will be 5,000 in startup funds for the first 50 sites to enroll. If you have any spokes, or additional sites you want to bring on that are not in the current list, it is likely they will not receive startup funds.
  - Per subject payment will be \$10,000 inclusive of indirects.

## 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 ( $\geq 1$  mmol/L blood  $\beta$ -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 NIH review.

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

- **Chest Pain= Comparative Health Effectiveness of Strategies Testing Pain Assessment of Ischemia Noninvasively** : <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.
  - This grant has been moving forward – thank you to all who have answered e-mails and contributed ideas to this project in recent weeks.
  - There was a presentation on 10/23 by the HATRIC team to NHLBI to receive permission to move forward with the grant application

## **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)