



# OHSU SIREN NETWORK NEWS

Issue: August 2019

## CALENDAR

8/6 1pm EDT SIREN Study  
Coordinator – Bluejeans  
conference link in e-mail

8/8 3pm EDT Finance  
Committee meeting

8/28 12pm EDT SIREN  
Steering Committee -  
Bluejeans link in e-mail

For working group meeting  
times visit:

[SIREN CCC Events Calendar](#)

\*Journal Club will resume in  
September. If you have not  
yet attended – try it out this  
fall!

Contact us: Jenny Cook,  
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[OHSU SIREN Website](#)

## BOOST 3 NEWS AND UPDATES

- BOOST 3 Milestones document – if you have not completed your milestones for payment #1 – please do so ASAP!
  - 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.
- Site readiness in WebDCU – new tutorial slides are available at <https://siren.network/clinical-trials/boost-3/getting-started> - scroll or click on “site readiness status navigation”
- EFIC CC template available: Also available on the getting started tab – there is more guidance available on [Preparing CC and Local Context Narratives](#)
  - The CCC developed this material based on feedback from the cIRB after the first 5 sites completed CC was available.
- New! BOOST 3 monthly newsletter. Newsletters will be sent out via e-mail, or you can visit to view current and past newsletter (and save the link) - [BOOST-3 Newsletter](#)
- New! A video on how to move the Moberg data into the IBM cloud account is posted in the BOOST-3 website's [Toolbox](#) under the [Moberg Device link](#).

## WORKGROUP SPOTLIGHT

Trauma – The Trauma workgroup has been meeting since Jan and 3 main themes have emerged:

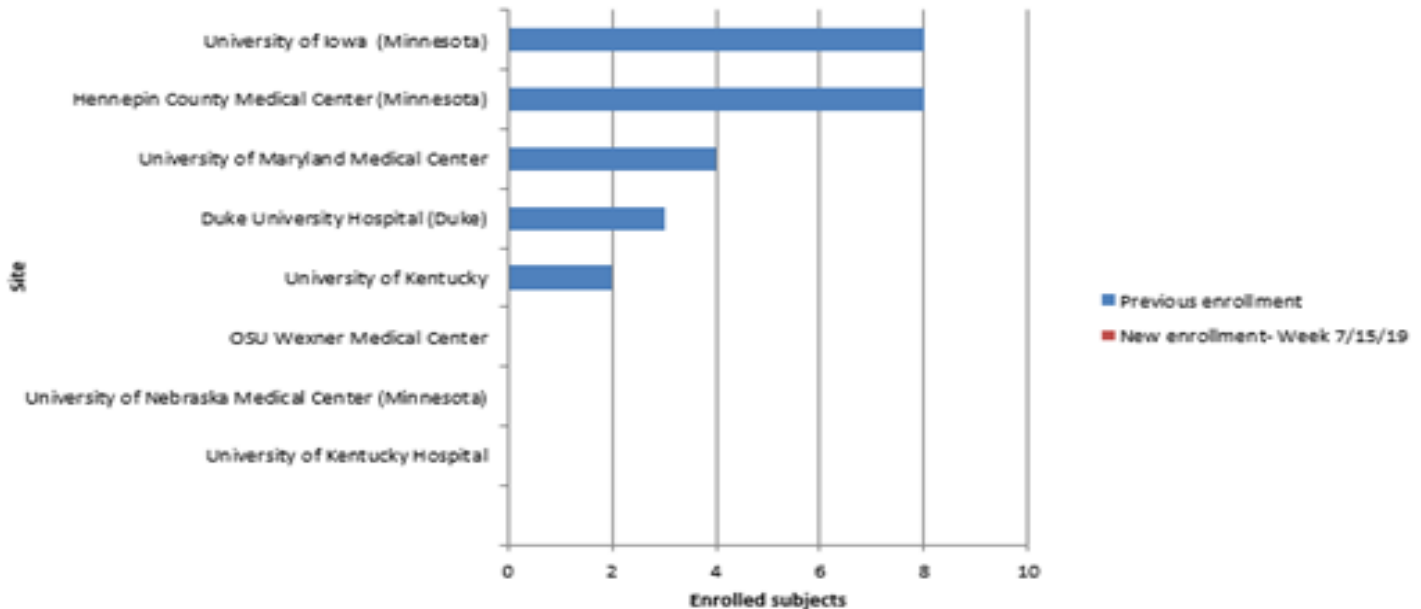
1. Creating an infrastructure for pre hospital data collection. There is concern over the quality as well as variability among metrics collected in pre-hospital registries, but the Trauma WG would like to create some standards so registry based clinical trials can be performed with rigor. The LITES network is currently in the development phase of a robust trauma database, and there may be opportunity to work with them.
2. Traumatic Hemorrhage – There is interest in running a platform trial for traumatic hemorrhage. Briefly, a platform trial would look at multiple treatments for a group of related diseases or subgroups of a single disease to discover optimal treatments.
3. Biomarker studies – The group is interested in developing standardizing protocols for the prehospital and hospital- based trial biomarker collection for analysis. There has also been discussion around Bio-repository storage protocols within the Trauma WG.

## ONGOING TRIALS

**HOBIT – Hyperbaric Oxygen Brain Injury Treatment Trial**

- Enrollment: 25 subjects (Goal:200)
- 8 Active sites – 5 have enrolled at least 1 subject to date
- Team reminder: It's OK for your study coordinator to work with, and talk to the GOSE blinded assessor. The SC just needs to be cognizant to not discuss which arm of the treatment protocol any given subject was enrolled in.
- The network must open all 12 sites this year to meet the milestone goal.

### HOBIT Enrollment Status: July 15 - 21, 2019



## 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.

- 7/29 – trial has been approved for funding.

*From the ICECAP leadership team (Will Meurer, Romer Geocadin, Robert Silbergleit)*

#### Here is what we know about some next steps:

- Protocol:
  - The ICECAP website <https://siren.network/clinical-trials/icecap>, on the SIREN website <https://siren.network/>, includes links to the trial protocol and other material.
  - Please take a moment to re-familiarize yourself with these posted study materials (since it's been a long time).
  - We already have an IDE from the FDA for this protocol.
  - The SIREN DSMB will review the protocol next.
  - Start thinking about implementation at your site now. How will eligible patients be rapidly identified? Is initiation of cooling as standard care in your system efficient enough to meet the eligibility criteria? Who are the key clinical team members from whom you need to get buy in?
- Notice of Award:
  - We have not received a Notice of Award yet.
  - When we do, we will start the site contracting process.

- The site contracting process will include a new rider for SIREN Hubs that already have a master agreement.
- The site contracting process will include new subcontracts to SIREN Spokes from their SIREN Hubs.
- Some of you are unsure of whether your site is a SIREN Hub or Spoke, and are unsure how to proceed.
- Your site may already be involved with SIREN but through different investigator groups, unbeknownst to you.
- We will work with each of you, one by one, to help understand your situation.
- **Central IRB:**
  - ICECAP will use the SIREN Emergency Research Central IRB (run by Advarra). Per NIH single IRB policy.
  - Most of your institutions have a pre-existing reliance agreement with Advarra.
  - Reliance agreements allow the CIRB to review for your institution in general, not for a specific trial.
  - We'll confirm existing reliance agreements and work on new ones for any sites where these are missing.
  - After the SIREN DSMB review and Notice of Award, we will submit the protocol to the ER-CIRB.
  - Sites will submit information to the SIREN CCC needed for site IRB applications.
  - Sites will submit an application to their local IRB's asking to cede review of this specific trial to the CIRB.
  - After CIRB approval of the protocol, the SIREN CCC will submit applications to CIRB on behalf of each site.
- **Investigators Meeting:**
  - Will be looking for dates and a location for a kick-off Investigator Meeting as soon as practical. Depending on the timing of the Notice of Award and other steps mentioned above, this might be late Fall or early Winter.
  - Stay tuned.
- Our email list for ICECAP investigators is imperfect. Please excuse duplicates of this email due to use of overlapping SIREN lists. Similarly, please feel free to forward this message to any overlooked ICECAP investigators or collaborators we inadvertently missed on our current list.

## 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 for review.

## **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)