



OHSU SIREN NETWORK NEWS

Issue: June 2019

CALENDAR

6/4 1pm EDT SIREN Study
Coordinator – Bluejeans
conference link in e-mail

6/13 3pm Finance Committee
meeting

6/19 1pm EST SIREN
Journal Club [click here](#) to join

6/26 12pm EST SIREN
Steering Committee -
Bluejeans link in e-mail

7/2 1pm EDT Study
Coordinator Call

[SIREN CCC Events Calendar](#)

Contact us: Jenny Cook,
Coordinator, 503.494.1230
cookjen@ohsu.edu
[OHSU SIREN Website](#)

BOOST 3 NEWS AND UPDATES

- Reminder: Keep your CC events up to date in WebDCU. Weekly summaries will be sent to you with the info you submit.
- The BOOST-3 Protocol Training is posted on the BOOST-3 website's [Education and Training page](#). Please take note of the following:
 - You are exempt from this training **ONLY IF**:
 - You attended the in-person investigator kick-off meeting in Atlanta **OR**
 - You attended a group protocol training session conducted by Trial Leadership.
 - *Team members who met these requirements will have their training added by the CCC once they are in the approved eDOA*
 - There are 3 requirements to complete the protocol training:
 - 1) Review the Protocol,
 - 2) Watch the protocol training video (slides accompany the video for reference), **AND**
 - 3) Take the protocol certification test (you must get 16/19 correct to pass).
 - Upon successful completion of the test you will receive an email with your Protocol Certification enclosed in the body of the email. Save this email as a **PDF** and send it to your Study Coordinator to upload to WebDCU. There is no expiration for this certification.
 - **BOOST eICF form** - the BOOST eICF test link is once again available to anyone interested in testing out how the eICF works: <http://bit.ly/BOOST3Test>

- *The test link does not contain the study team email notification function, which is set up unique to site personnel listed on the eDOA with ICF responsibilities. This function will be applied on the participant approved eICF link generated once a site is released to enroll. Individual sites will receive more information about this during your site readiness call.*
- University of Minnesota's E-Consent Lessons Learned presentation from May's Study Coordinator Meeting is posted to the SIREN website under [Presentations](#).
 - **Readiness Call Checklist:** The Readiness Call Checklist is posted under the [Getting Started](#) tab on the BOOST-3 website. This document lists the items that need to be completed prior to the readiness call (the last step before being released to enroll).
 - The SIREN Electronic Informed Consent SOP was posted to BOOST-3 [Toolbox](#) under the [Consent link](#).
 - NOTE: For a complete list of all the SIREN SOPs click [here](#).

SAEM OHSU NETWORK MEETING

Thank you to those who were able to join us at SAEM for our informal investigator meeting. We discussed the current and future (potential) trials; and individual site progress, challenges, and successes.

WORKGROUP RUNDOWN

Wondering if your workgroup has started yet? Here's the breakdown of the groups already meeting the ones still to come.

Meeting currently:

EMS WG Update (3rd Wednesday of the month, 4-5pm EDT)

HSP WG Update (2nd Thursday of the month 1-2pm EDT)

EDC WG Update (4th Thursday of the month 12-1pm EDT)

Cardiovascular Emergencies/Registry based trials WG (3rd Wednesday of the month 1-2pm EDT)

Trauma WG (2nd Tuesday of the month 4-5pm EDT)

To be convened:

Intensivist Investigators

Outcomes

Training and mentoring

Workgroup updates:

Cardiovascular Emergencies/ Registry Based Randomized Trials

- The Cardiovascular Emergencies Working Group is focused on creating ancillary and new cardiovascular SIREN network projects. Currently the group is developing cardiovascular research questions ancillary to the BOOST-3 trial. The group is also beginning to generate ideas for and will be developing new proposals for funding which are either ancillary to an existing SIREN studies or stand-alone projects. The group currently has over 20 active members and would welcome additional members interested in cardiovascular outcomes research. Michelle Minix is the working group admin from the SIREN CCC.
 - Cardiovascular ancillary studies being thought for BOOST3 study
 - Generated 4 study questions/projects
 - Done with existing data or minimal additional data
 - Hx of prior CVS disease is associated poorer outcomes
 - ECG and monitor data to look at dysrhythmia's after TBI
 - Types and also incidence and comparing between treatments
 - HR variability between treatment arms

Human Subjects Protection workgroup

HSP is working on a paper recounting a mixed methods paper on the use of a novel iPad delivered interactive video and knowledge assessment for informed consent in the SHINE trial.

EMS Working Group

EMS working group is planning to submit a planning grant application to the NIH to look at field stabilization post-ROSC vs. load and go once ROSC achieved (project being led by Jim Mennegazzi). Also looking at potential value of collecting blood from OHCA patients for genomic and proteomic analysis for PEA OHCA.

Electronic Data Capture Group

BOOST 3 is looking to perform some ancillary studies of continuous monitoring data. There are a few groups looking into funding, and feasibility. Approximately 30% of BOOST 3 sites have the capability of performing the data capture needed for these ancillary studies. If you are interested in participating, or know of potential funding sources contact Jenny so she can put you in touch with Emily Gilmore, Yale, who is leading these efforts. They are specifically looking into real-time analytics, and how to fund this piece of the projects.

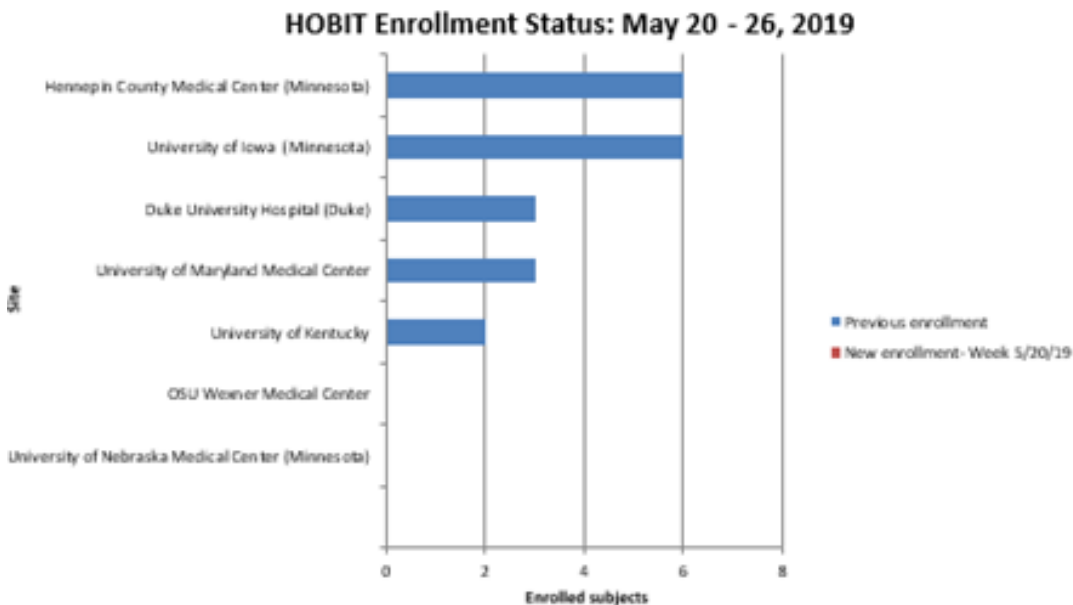
Other side notes (Please note neither of these trials will/are part of the SIREN network):

- The [ACCESS clinical trial](#) is looking for more study sites. If you are interested, contact the coordinating center.
- IMMEDIATE II clinical trial is being submitted to NHLBI, after the FDA requested a confirmation trial based on the results from the [IMMEDIATE](#) trial. IMMEDIATE II will be a very similar design to IMMEDIATE, however enrollment will occur in both the pre-hospital and ED settings.

ONGOING TRIALS

HOBIT

- Enrollment: 20 subjects (Goal:20)



POTENTIAL 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.

- Going to NHLBI council on 6/4 for funding decision
- Potential ancillary studies:
 - Karen Hirsch and Michael Kurz
 - Post cardiac arrest imaging and outcomes
 - Imaging to help predict long term outcomes
 - Looking at biomarkers, early and late to help drive therapies/guide neuroprognostification
 - Data driven as well as collecting samples for biorepository

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 β -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.

- Being submitted in June.

HATRIC = Having the dose of thrombolytics to reduce intracranial hemorrhage

- Sites should anticipate a survey soon regarding dose selection with regards to thrombolysis for pulmonary embolism
- The aim of the planning grant is to help design the larger RCT which will study thrombolysis in PE
- TNKase also being discussed as an option in addition to tPA as a thrombolytic agent