



# OHSU SIREN NETWORK NEWS

Issue: February/March 2020

## CALENDAR

3/3 1pm Study Coordinator Meeting – Bluejeans link in e-mail

3/12 3-4pm ET Finance Committee Meeting – Bluejeans link in e-mail

3/18 12-1pm ET Steering Committee Meeting – Bluejeans link in e-mail

3/18 1-2pm Journal Club – Bluejeans link in e-mail – articles still TBA

4/7 1-2pm ET - Study Coordinator Meeting – Bluejeans link in e-mail

4/9 3-4pm ET – Finance Committee Call – Bluejeans link in e-mail

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](#)

## WEBSITE LINKS NEEDED

• We are updating our network website, and currently have these links to our network partners:

### Our Network Partners

[Duke Emergency Medicine Research](#)

[OSU Emergency Medicine Research](#)

[OSU Neuroscience Research Institute](#)

• **Action Item:** Please send me a link to your site’s Research/team page so we can update this list. Thank you!

## ONGOING TRIALS

### BOOST 3 NEWS AND UPDATES

• **BOOST 3 enrollments: 21** (Target enrollment 1094)

• **OHSU Network Enrollment: 2 – URM**

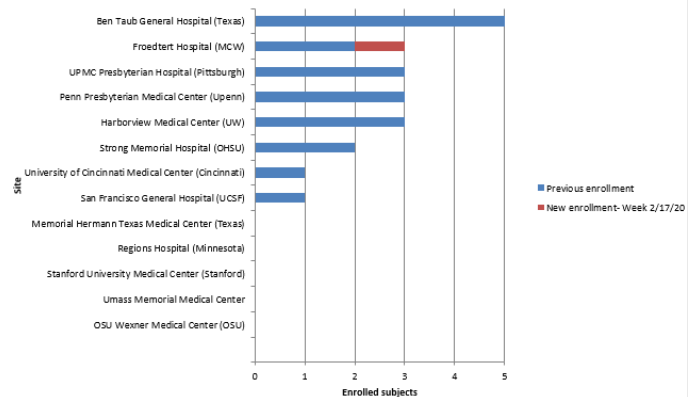
• **Helpful Hint from the URM team:**

CRF F269 – The

Abbreviated Injury

Scale states “The information on this form should be collected from the trauma registry”. Please make sure you have made the appropriate connections with your Trauma Registry to gather the requested data in a timely manner.

BOOST-3 Enrollment Status: February 17 - 23, 2020



- A Raumedic MPR2 Universal Quick Guide was posted to the [BOOST-3 Toolbox](#). Blinding information is included.

### HOBIT – Hyperbaric Oxygen Brain Injury Treatment Trial

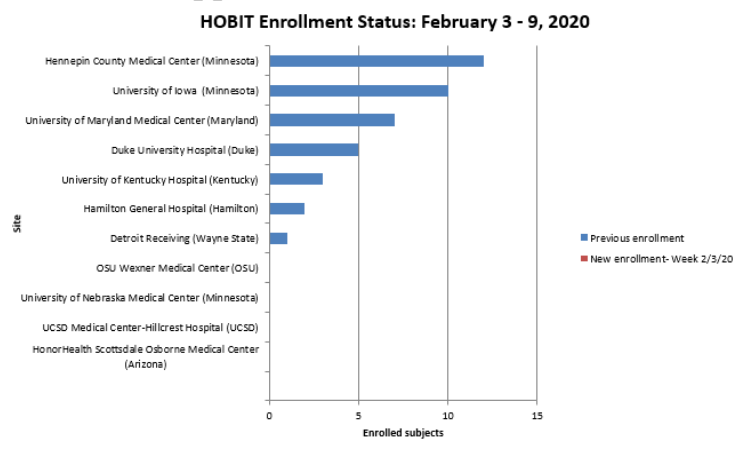
- Enrollment: 40 (Goal:200)
  - 11 Active sites
- Continuing Review approval: Advarra has approved HOBIT’s CR from 18Feb2020-18Feb2021. Site specific approval letters are available in WebDCU.

- **EFIC – Exception from Informed Consent has been approved for HOBIT!**

- **In order for your site to enroll patients under EFIC, you must seek individual cIRB approval.**

- To get started, please review the EFIC start-up activities and tasks outlined in the [HOBIT Milestone Document](#).
- The cIRB approved [EFIC plan](#) is available in the [EFIC Resources](#) tab of HOBITtrial.org
- **Use protocol version 5 until your site is approved for the EFIC process.**
- MOP Section Update – 3 Exception from Informed Consent– be sure to review!

- Have additional questions? Contact Natalie Fisher @ [brownnat@med.umich.edu](mailto:brownnat@med.umich.edu)



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

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.

- MOP draft released – Please review and comment if you find points that need clarification.
- OHSU Network sites participating in ICECAP – UAB, OSU, OHSU, URMC, Utah (Additional potential sites: Duke, Wake Forest)
- Please review notes from the investigator meeting below for more specifics!

### SIREN & ICECAP INVESTIGATOR MEETING

- ✓ Dr. Daya attended the SIREN investigator meeting. Here are some of the highlights:
  - SHINE (NETT Network trial) – The primary publication is out, and secondary publications are underway. The Public Use dataset will be available this summer.
  - ESETT (NETT Network trial) – The primary paper is published, post-trial public notification is in progress currently. Secondary papers are in development – proposals and the proposal submission form can be found at: <https://nett.umich.edu/clinical-trials/esett/esett-toolbox#Paper%20Ideas> (\*requires UM friend account login)
  - HOBIT – EFIC has been approved.
  - BOOST3 – Bio-BOOST has been funded. The primary site is UPenn, and there is an agreement executed with UMich.
  - cIRB – There is interest in getting our experience with the cIRB written up and out into the research community at large.
  - NIH workshop for 9/9-9/11 as part of its NINDS Advisory Meeting
  - Network notes
    - We are going to start year 4 of the funding cycle. We will need to start thinking about renewal the application.

- For this initial phase the goal was 4 studies started. So far, HOBIT, BOOST3 and ICECAP have started (or will very soon). HATTRIC is likely the next study if funded.
  - Discussion of need to develop and secure funding for newer trials for the next round of funding.
- ✓ Investigator Kick-off Meeting videos and slides are posted to the website under the [Investigator Meetings tab](#)

Here are a few highlights from the ICECAP Meeting:

- ✓ Initial cooling durations for the first 200 subjects = 12, 24, or 48hrs. After 200: If response curve is flat then 6hr duration will open. If response curve is positive then 60, 72hr durations will open.
- ✓ Time Zero = placement of definitive cooling device
- ✓ Subjects must be cooled to 34C within 4 hours
  - Recommended temperature management sources are esophageal, bladder or endovascular.
- ✓ Enrollment must occur within 6 hours of Time Zero
- ✓ Consent can be initiated prior to reaching 34C
  - Goals of Care is CRITICAL to consider during screening. LAR must agree to 96hrs of life support
    - Check for end of life documents (Advanced Directive, POLST/POST/MOLST, etc)
    - Check if subject has terminal illness
- ✓ Rewarming parameters: Controlled rewarming at 0.15C/hr for 24hours (or more)
  - Controlled rewarming for less than 24 hours = duration of hypothermia.
  - Duration of controlled normothermia will be at least 24 hrs with range of 36.5-37.5C.
  - Neurological prognostication should be done by an experienced and objective clinician after patient is weaned from all medications.
- ✓ Outcomes – 1 month follow up after ROSC to determine mRS will be via phone; 90-day follow up(+/-15 days) will be in person with a video conference call with a central reviewer.
- ✓ IRB – your local IRB must defer/rely on cIRB Advarra. Note that: contracts, COI, and continuing reviews will still be submitted to your local IRB.
- ✓ eConsent will be done via a tablet
- ✓ WebDCU will be used for all regulatory and study document storage and tracking.

## WORKING GROUPS

Have you joined a SIREN working group yet? Everyone is encouraged to join at least 1 group! To sign up visit this link: <https://siren.network/about-siren/working-groups>

Below is a list of the February meeting times for the working groups that are meeting. (Please note some groups are still in the development phase and have not yet set a regular meeting time.)

Education, Training & Collaboration 3/5 11-12 ET

EMS 3/18 4-5p ET

Trauma 3/10 4-5p ET

Cardiovascular Emergencies 3/23 1-2p ET

Human Subjects Protection 3/12 1-2p ET

Electronic Data Capture 3/26 12-1p ET

## **UPCOMING TRIALS/STUDIES IN DEVELOPMENT**

**HATTRIC – Planning grant: 1U34HL144374-01** was used to develop the study for submission this funding cycle. This study will examine the role of thrombolytics in submassive PE with evidence of right heart strain. The primary outcome will be resolution of right heart strain on echocardiography. Baseline and 24-hr echocardiogram measurements of RV/LV ratios will be needed. 5 doses are proposed, including a placebo. There is still discussion of POCUS vs FORMAL ECHOs. Several secondary outcomes have been proposed.

SEIZURE studies – the role of early EEG in the ED, also discussing the role of Ketamine as a secondary agent.

TARGET-TXA – TXA administration driven by TEG, excluding TBI patients

EPIC-TBI – Project findings were presented by Dr. Dan Spaite at the SIREN investigator meeting. A larger study to assess impact of these guidelines is under development.

## **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)