



OHSU SIREN NETWORK NEWS

Issue: July 2019

CALENDAR

7/1 6:30p SIREN/BOOST gathering @ neurotrauma conference

7/9 1pm EDT SIREN Study Coordinator – Bluejeans conference link in e-mail

7/11 3pm EDT Finance Committee meeting

7/24 12pm EDT SIREN Steering Committee - Bluejeans link in e-mail

[SIREN CCC Events Calendar](#)

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[OHSU SIREN Website](#)

BOOST 3 NEWS AND UPDATES

- Please review your BOOST 3 Milestones document regularly to confirm you are on track with pre-study preparation
- EFIC documentation in WebDCU
 - The first 5 sites to complete EFIC CC activities were submitted to the cIRB, and some feedback was received:
 - Additional qualitative data is requested by the cIRB. There are now additional fields in the CC forms where you need to enter additional information describing your impressions of the overall event. Also adding in detail such as “A 15 minute presentation was given followed by 20 minute discussion with the group or individuals about their questions. These are the themes that emerged in the discussion....” You do not need to include every single question asked, but a summary of your impressions is needed. The cIRB is looking for confirmation that the events allowed for interaction and understanding from participants which helps to show you have met the burden of CC as outlined in the CRF’s.
 - Some sites did not have enough ‘diversity’ in their events (i.e. all took place in the medical community or a diversity of age ranges was not represented). Consider reaching out to retirement facilities to capture the older adult population, and make sure any racial/ethnic groups in your area are well represented.
 - The ‘standard’ report the CCC generates for the cIRB will be available for sites to download and submit to their local IRB’s as needed.
- Additional information/guidance will be posted to the BOOST-3 website

WORKGROUP RUNDOWN

There is an Education/Training/Collaborations workgroup starting which is looking for early stage and junior investigators to get involved! Sign up today <https://siren.network/about-siren/working-groups>

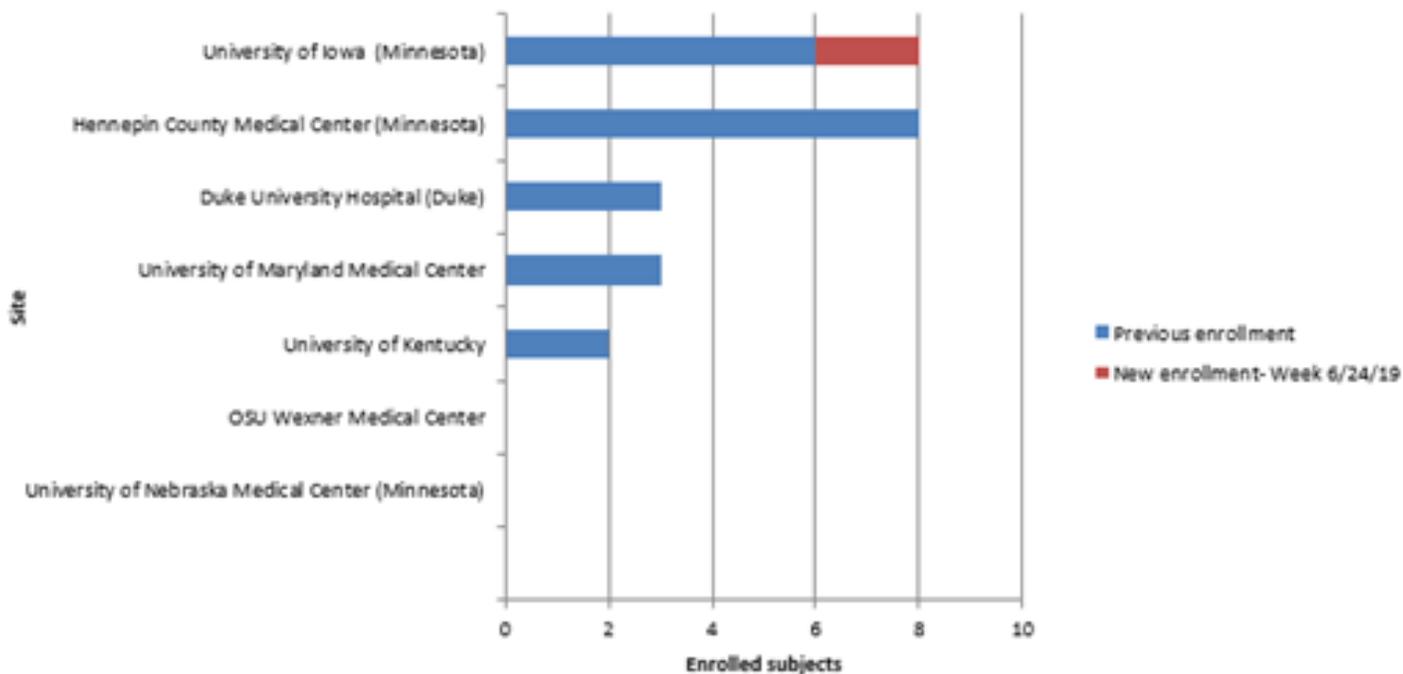
ONGOING TRIALS

HOBIT – Hyperbaric Oxygen Brain Injury Treatment Trial

- Enrollment: 24 subjects (Goal:200)
- [MOP update to section 3.4](#) - Re: subjects enrolled in HBO +NBH and NBH only! Please read!
- Thank you to everyone who attended the virtual meeting – slides and materials are online and can be used for training and education as needed. <https://siren.network/clinical-trials/hobit/investigator-meetings>
- [FAQ update](#)
 - **Q: Should death be considered an SAE? (NEW 6-28-19)**
A: No. Death is considered an outcome. The event causing death should be reported as the

SAE. For instance, if fulminant sepsis causes the death, sepsis should be considered the SAE. If the subject dies after being withdrawn from life support and placed on comfort care secondary to their neurological injury, that should be reported in one of 2 ways. 1) If they were deteriorating neurologically, the SAE should be reported as “neurological deterioration.” In the vast majority of cases, the death should be reported this way. 2) In the unusual circumstance that the subject remained neurologically stable or improved, the SAE may be reported as “withdrawn from life support.” The GCS at the time of enrollment and the one closest to withdrawal from life support should be included in the SAE narrative.

HOBIT Enrollment Status: June 24 - 30, 2019



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.

- Went to council on 6/4 – still waiting for decision.

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 = HALving the dose of Thrombolytics To Reduce Intracranial Hemorrhage

- **Site Survey due 7/5**
- 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