OHSU SIREN NETWORK NEWS

Issue: December 2019

CALENDAR

12/3 1pm ET SIREN Study Coordinator – Bluejeans conference link in e-mail

12/12 3pm ET Finance Committee meeting

12/19 – ICECAP Webinar – more info coming

Coming up! OHSU All site meeting 1/7/2020 @10am PT Watch your e-mail for conference room details

For working group meeting times visit:

SIREN CCC Events Calendar

Contact us: Jenny Cook, Coordinator, 503.494.1230
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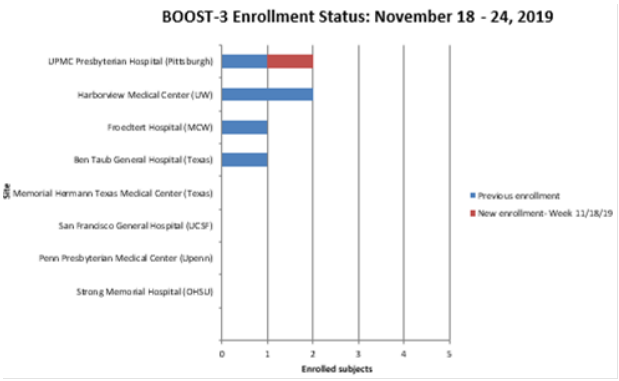
OHSU SIREN Website

Follow our research team on Twitter: @OHSU_CPREM

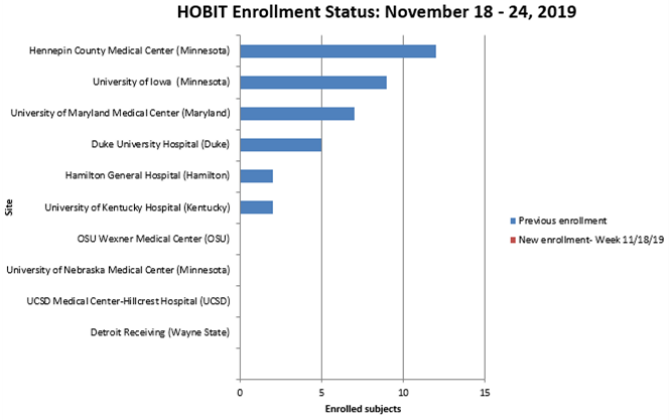
ONGOING TRIALS

BOOST 3 NEWS AND UPDATES



- **BOOST 3 enrollments: 6**
- Congrats to URMC who has been released to enroll!
- Site readiness: 8 sites have been released to enroll; 2 are approved, pending readiness; and many additional sites are ready for cIRB review (including OSU and OHSU)
- Moberg- at least 2 sites have encountered issues where the ICP values will not show up intermittently on the Moberg, but are still being recorded on their ICP monitor. Moberg is looking into this issue.

HOBIT – Hyperbaric Oxygen Brain Injury Treatment Trial



- Enrollment: 37 subjects (Goal:200)
  - 10 Active sites
- *HOBIT virtual investigators meeting* slides posted: Investigator Meetings
- IRB approval of EFIC is still pending – sites will be notified when approval is received.
- New MOP Section – 8.4 – be sure to review! Language in section 13.2 was also updated
- New chamber/resource log online- please use this new version going forward

REGULATORY TRAINING

A new WebDCU training video specific to the Regulatory Document Module is posted in the BOOST-3 and HOBIT Education and Training pages. This video is optional, but may be useful for your regulatory document management staff.

WORKGROUP SPOTLIGHT

Human Subjects Protection

BOOST3

- There was a consent protocol deviation at 1 site. The probe was placed before getting LAR consent when one was present at the facility. In this instance the LAR did consent to the study eventually, but the takeaway is: You MUST consent the LAR/family if present, and cannot use the EFIC process to enroll in these cases.
- EFIC review – despite the CCC review of these cases the cIRB reviews have not been consistent with each site. They have asked for different things from different sites. For example: some sites have been asked for their ED payer mix, but other sites are not. Requests have been varied and unpredictable. CCC is considering EFIC journal clubs where cIRB members and sites can participate, discuss and clarify issues that are being seen.
- Experience Supplement – Dr. Silbergleit & team are looking at BOOST cIRB reviews. There are aims surrounding cIRB they are looking to answer, and will be reaching out to sites for their detailed experiences with CC/PD/EFIC/cIRB
- AAHRPP and/or SCT proposal Discussion: these 2 groups are meeting at the same time in Baltimore and Dr. Silbergleit is looking for anyone interested in being involved in some of these proposals (Ketamine trial and HSP, CLOVERS trial controversy, Ischemia trial controversy, etc.). He is looking for someone who is interested in taking the lead on pulling a group together for further discussion. Interested? Let Jenny know.

Manuscripts

Ongoing

- ProTECT related: a look at ethnic and racial composition of people who had a LAR in the first hour versus those who did not (Kurt Denninghoff, Tomas Nuno)
  Dr. Tomas Nuno is accepting suggestions to his manuscript presented in Oct.2018. Please send your edits directly to Dr. Nuno at: tnuno@aemrc.arizona.edu
- ProTECT related: Timing of Consent into a Multicenter Randomized Controlled Traumatic Brain Injury Trial Conducted under Exception from Informed Consent. (Joshua Salzman et. al.) Submitted to AEM July 2016 and was denied.
  Last update in Jan 2018: Last circulated to Dr. Silbergleit to consider.

In the pipeline

- HSP-WG Methods paper – Previously: the discussion was that maybe this has already been written about in various other papers and no need or interest to write a standalone paper on the HSP-WG.
- HSP Manuscripts & meeting posters track is available here

EMS Working Group

- Will hold an in-person meeting at NAEMSP. This group is working on developing a survey of EMS/pre-hospital agencies to understand research capacity better.

JOURNAL CLUB

Miss journal club this month? Check out these articles and resources!

David Liu, MD will present: CRASH-3 Trial Collaborators. Effects of tranexamic acid on death, disability, vascular occlusive events and other morbidities in patients with acute traumatic brain injury (CRASH-3): a randomized, placebo-controlled trial. Lancet 2019;394:1713-23.

Corinne McGill, MPH will present: Goldacre B, Drysdale H, Dale A, Milosevic I, Slade E, Hartley P, et al. COMPare: a prospective cohort study correcting and monitoring 58 misreported trials in real time. Trials 2019;20:118-34.

https://compare-trials.org/project.html

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^{0}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 –Trial PI and primary coordinator should attend, others can go at site's expense.
- MOP and CRF's are in development and not ready to be circulated. Stay tuned.
- Webinar planned for 12/19 to discuss more trial logistics
- 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 indirect's.
- Preparation activities
    - Please check with your EMS agency partners about what cardiac arrest data you are able to obtain regularly.
    - Goals of care conversations will need to be performed as part of the enrollment process. This is an important point to discuss with your trial team, and providers who will be involved in patient care.

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)