



OHSU SIREN NETWORK NEWS

Issue: May 2020

CALENDAR

5/14 3-4pm ET – Finance Committee Call – Bluejeans link in e-mail

5/20 12-1pm ET Steering Committee Meeting – Bluejeans link in e-mail

5/20 1-2pm Journal Club – Bluejeans link in e-mail – articles still TBA

6/3 1pm Study Coordinator Meeting – Bluejeans link in e-mail

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

Twitter: [@OHSU CPREM](#)

Newsletter at a Glance

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COVID 19 & SIREN

As the country begins to ‘open’ again after the initial pandemic lockdown phase, many of our institutions are starting to loosen the restrictions on research. Clearly there is large variation in this across the board. Dr. Adler (URMC) discussed on the investigator call how they had received permission to continue BOOST 3 enrollment from their institution, but due to the clinical demands still being placed on the ICU’s at their site, they were still negotiating when BOOST 3 would restart enrollments. Other institutions have begun the process of ‘restarting’ many research activities

at their sites, citing low clinical burdens from the pandemic at this time.

Whatever boat you may be in right now, we are here to help you weather the storm. As the CCC updates policies or adds additional pandemic relevant information, we will be sure to pass it on. You may refer to current guidance here: <https://docs.google.com/document/d/1GrpnIBrARXNvx7ohgluy9aORgDIE6Sy-Kt64VslhIxo/edit?ts=5e726e90>

OHSU SIREN NETWORK TEAM CALL

Thank you for those who were able to join! Dr. Limkakeng (Duke), Dr. Adler (URMC), Dr. Zonies (OHSU), Dr. Ward (U. Wisc), Dr. Schreiber (OHSU), Margaret Carlson (Utah), Samantha Underwood (OHSU), Keeley McConnell (OHSU), Jenny Cook (OHSU), and Dr. Daya (Network PI).

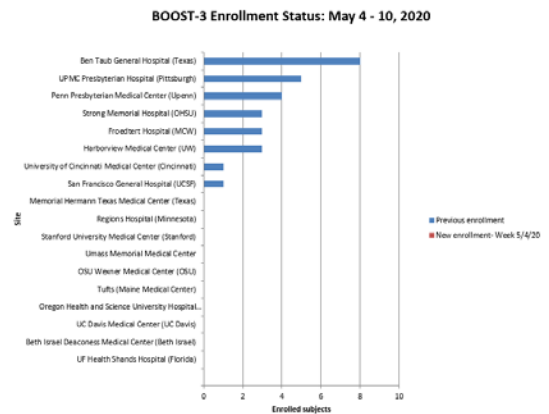
Despite the challenges we have all faced over the last few months, sites reported good progress on study activities that have been keeping them busy while enrollments have been halted. Utah’s BOOST 3 cIRB application is being reviewed this week, and Duke is expected to go to review in the near future. URMC and Utah have both had readiness calls for ICECAP and are prepared to launch once research resumes at their respective sites.

We also discussed 2 COVID-19 studies that may potentially run in the SIREN Network: an outpatient Losartan Trial, and an ED-based Convalescent Plasma study. Both studies are still in development and protocols have not yet been released. We know many of our network sites are interested in participating in these trials should they be approved. As soon as we receive more information we will share these details.

ONGOING TRIALS

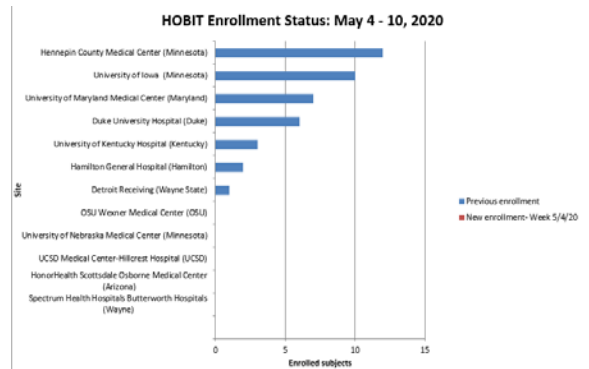
BOOST 3 NEWS AND UPDATES

- **BOOST 3 enrollments: 28** (Target enrollment 1094)
- **OHSU Network Enrollment: 3 – URM**
- **Released to enroll in our network:** OHSU, URM
- **Pending release:** Utah (currently in cIRB review), Duke – preparing cIRB application



HOBIT – Hyperbaric Oxygen Brain Injury Treatment Trial

- Enrollment: 41 (Goal:200)
- **OHSU Network enrollment: 7**
- Don't forget to check out the latest news from HOBIT in the newsletter from the CCC on 5/8/20
- Sites are encouraged to complete EFIC activities while research enrollment is suspended – see page 4!
- Duke's research restriction has been lifted, and they are once again in enrolling.



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

ICECAP study will enroll comatose (Comatose/unresponsive patient=GCS less than 8) 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.

- Sites that are able, may continue pre-study activities, and consider scheduling their readiness call.
- New site resources, FAQ's and information is being posted regularly to the ICECAP website – please be sure to visit often and update yourself and your team on the latest. <https://siren.network/clinical-trials/icecap>
- Readiness call completed: URM, Utah
- Pre-study preparation: UAB, Duke, OHSU, OSU

WORKING GROUPS

Currently the follow workgroups have monthly meetings scheduled: Education, Training & Collaboration; Trauma; Human Subjects Protection; Cardiovascular Emergencies; EMS; Electronic Data Capture. We are working to get updates on when additional groups will get started.

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 for benzodiazepine refractory status epilepticus.

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.

STAY AND STABILIZE vs. EARLY TRANSPORT – Cardiac arrest study being developed by Dr James Menegazzi from Pittsburgh

LEARNING OPPORTUNITIES

Journal Club: Wed, May 20, 2020 1:00 pm EDT; NOTE: BlueJeans Meeting ID provided in invitation email.

Click on journal images below for articles.



Dr. Jonathan Elmer will present: Elmer J, Coppler PJ, Solanki P, Westover B, Struck AF, Baldwin ME, et al. Sensitivity of Continuous Electroencephalography to Detect Ictal Activity After Cardiac Arrest. JAMA Network Open 2020;3(4):e203751.



Dr. Ramon Diaz-Arrastia will present: Launey Y, Fryer TD, Hong YT, Steiner LA, Nortje J, Veenith TV, et al. Spatial and Temporal Pattern of Ischemia and Abnormal Vascular Function Following Traumatic Brain Injury. JAMA Neurol. 2020;77(3):339-349.

Journal Club is a GREAT opportunity for early-stage investigators to present. Please reach out if you are interested in this opportunity!

Clinical Trials Methodology Course Webinar series: <https://siren.network/training/ctmc/ctmc-webinars>

Anyone who is interested is welcome to join the webinars – please visit the link above for more information, and to view the relevant ‘pre-webinar’ topic videos.

The NINDS Clinical Trials Methodology Course (CTMC) is an intensive, engaging program designed to help junior investigators develop scientifically rigorous, yet practical clinical trial protocols, and to focus on early consideration of funding mechanisms as a key trial planning activity. Click [here](#) to hear more from leadership and participants from the course.

HOBIT EFIC COMMUNITY CONSULTATION AND PUBLIC DISCLOSURE ACTIVITIES DURING THE PANDEMIC

Most importantly, we would like to have all sites without IRB approved EFIC plans to continue work on conducting their community consultation and public disclosure activities. The promotion of social distancing, and the widespread cancellation of many events and meetings poses particular challenges to SIREN sites currently conducting EFIC CC and PD activities for HOBIT. The pandemic does not change the regulatory obligations of sites with regard to these requirements and is unlikely to shift the criteria used by the IRB to assess adequacy of these measures. SIREN will work with sites to help come up with creative solutions to continue to conduct meaningful engagements with the community that ensure social distancing but remain consistent with the existing EFIC plans during this period. As always sites are encouraged to innovate, and then share successes peer to peer. We offer the following suggestions:

- a. Attend existing meetings by telephone. To the extent that meetings of community groups that investigators had planned to attend are canceled, this form of CC cannot be done. However, many community groups continue to meet using teleconferencing. If so, investigators can and should still join in on these existing meetings of community groups.
- b. Increased use of individual interviews. Substituting in-person encounters with teleconferencing may also be effective for one-on-one interactions between an investigator and selected community stakeholder leaders (political, religious, business, etc.).
- c. Focus groups. Although the dynamics of a focus group are better in person, a skilled facilitator can conduct successful carefully planned focus groups via teleconferencing, so this remains an option as well.
- d. Social media. Sites have often experienced difficulty getting extensive or representative feedback using social media, but some have generated lively interactions through optimized use of Twitter, Facebook, and other platforms. Sites are encouraged to share experiences on how to best use these resources in this period of social distancing.
- e. Random digit dialing surveys. Outsourcing community consultation to a survey vendor is an option in both SIREN EFIC plans. The relative merits and limitations of this technique are more favorable in a period of social distancing, and warrant reconsideration among sites that had previously planned to get this kind of broad cross sectional engagement from activities that can no longer be pursued.
- f. Booth events. In this period of social distancing, new events of this type will not be practical. These will have to be replaced with new activities in sites' lists of planned events.
- g. Most methods of public disclosure are already conducted without in-person events, so this should not be a significant barrier.

Ideally, we would like to have all sites with IRB approved EFIC activities (community consultation and public disclosure) by the time we are able to re-open sites for trial enrollment.

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)