



OHSU SIREN NETWORK NEWS

Issue: April 2020

CALENDAR

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

4/15 12-1pm ET Steering Committee Meeting – Bluejeans link in e-mail

4/15 1-2pm Journal Club – Bluejeans link in e-mail – articles still TBA

5/5 1pm Study Coordinator Meeting – Bluejeans link in e-mail

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

5/20 3-4pm ET Finance Committee 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

There’s no getting around it, COVID-19 has affected all of us. Our personal and professional lives, our research and our world. We have all had to rapidly adapt to new technologies, new processes, and new ways of thinking about teams, collaboration, and how to function when we need to also practice social distancing. While all of this has been hard, and is bound to bring us new unforeseen challenges over the next many weeks and months, we at the same time, have seen unprecedented levels of collaboration, understanding, and support coming out of this global pandemic crisis. We want to reiterate: **We are here to support you and thank you for all that you do since many of you are on the frontline of this battle.**

We understand that research operations may have been suspended at your institution until further notice, and simply ask that you keep us updated when your site resumes research activities. We will likely need to report

this data centrally and want to make sure we are ready to help if you need any assistance resuming studies. Below is the current status we have for your site. If any of the information needs to be updated, please contact [Jenny Cook](#).

- OHSU – Began modified operations 3/23. BOOST 3 approved to continue; ICECAP pre-study activities continue, but site readiness call delayed.
- University of Utah – BOOST 3 & ICECAP pre-study activities still progressing; still TBD if either study can start during the COVID19

- Duke University – 3/16 all “non-essential” clinical trial enrollment suspended; HOBIT enrollment suspended; BOOST 3 pre-study activities continue, and TBD if enrollment can begin during COVID19
- OSU – 3/17 Enrollment activities for BOOST3 and HOBIT suspended until further notice
- URMC – 3/16 BOOST 3 enrollment suspended; ICECAP pre-study activities are continuing.
- UAB, Birmingham – ICECAP pre-study activities continuing.
- Wake Forest & UW-Madison – status update requested Thank you all for your partnerships, dedication, and collaboration. We truly could not be here without all of you. Once again, if we can support you in some way, please reach out.

ACTION ITEM SPECIAL REQUEST: SIREN EMS SURVEY

The intent of this survey is to help guide EMS studies in SIREN. Thank you for taking the time to complete.

Dear Colleagues,

Many of you (25 actually) filled out the SIREN EMS survey as it was still being developed. Thank you for that, and for the very valuable feedback that we received during the developmental process.

Unfortunately, important new questions have since been added and others have been modified. So we are unable to use those data.

Therefore, we kindly and respectfully ask that you complete the new survey. Like the previous survey, this survey is streamlined and should not take too much of your time.

https://pitt.co1.qualtrics.com/jfe/form/SV_e3vYVIXxAoXtNEF

Thanks and best regards,

Jim

James J. Menegazzi, PhD

Research Professor of Emergency Medicine

Nancy L. Caroline Endowed Professor of Resuscitation Research

Department of Emergency Medicine

University of Pittsburgh School of Medicine

ACTION ITEM SPECIAL REQUEST: POTENTIAL TRIAL SURVEY

From Bill Barsen:

We are currently looking at two possible Covid19 trials for the SIREN network. I mentioned on the last steering committee call about the losartan study. Conversations with NIH are going on and as soon as we have word about funding, we will be in touch immediately.

The second trial is what I need your input on now. The Blood Division at NHLBI approached us about performing a trial utilizing convalescent plasma in patients discharged from the ED. The subjects would be ED patients who present with likely Covid19 infection who are felt good enough to go home. After confirmation of a + Covid19 test, they would be randomized to receive either FFP or Convalescent plasma. They would then be discharged home and have phone follow up every other day with minimal data collection. The primary endpoint would be hospitalization within 15 days. We will likely only be enrolling subjects at higher risk for readmission but the exact inclusions/exclusions have not been determined.

Enclosed is a Qualtrics link to a short, 3 question survey. We want to get an idea of how many of you are able to get the results of Covid testing in the ED and whether you think you could participate in this study. I know that many of you are unable to do testing that returns to you in the ED but I also know many of you are probably working on getting tests soon. We're trying to get a head count of how many sites are able to potentially do this trial starting 2 weeks from today. We would like the answers back in the next 2 days as we are actively planning this with NHLBI and they would like enrollment to start in 2 weeks. Thanks so much!

https://umich.qualtrics.com/jfe/form/SV_50T4WsUDem7Hu4t

ACTION ITEM SPECIAL REQUEST: COVID-19 HEALTHCARE WORKER SURVEY

Dear Colleagues of the Healthcare Workforce,
We're conducting a survey regarding the healthcare workforce during the COVID-19 pandemic. The survey should take about 3-8 minutes to complete. We hope that results of this survey will provide critical information on medical response efforts. Please send this out widely as ANYONE (MDs, RNs, LVNs, NP, PAs, EMTs, home health nurse, registration, valets, transportation, etc...) that encounters patients is eligible. This study will be conducted monthly as your exposure may have changed.

Access the survey here: [COVID Workforce Study \(www.ohsu.edu/covidworkforce\)](http://www.ohsu.edu/covidworkforce) or QR Code:



Thank you,

Bory Kea, MD, MCR
Matt Hansen, MD, MCR

Oregon Health & Sciences University
Please e-mail: cprem@ohsu.edu with any questions

OHSU SIREN NETWORK TEAM CALL

So much for an in-person meeting, instead we'll go virtual! You should have received a WebEx meeting request for:

May 4, 2020 @ 9am Pacific

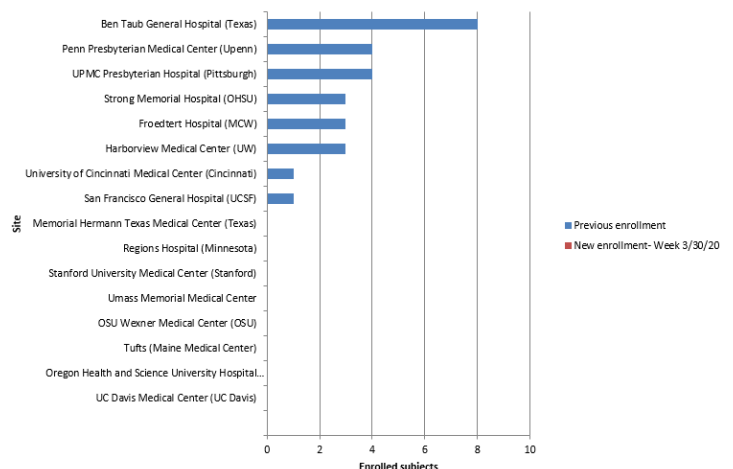
Don't see this on your calendar? E-mail [Jenny Cook](mailto:jenny.cook@ohsu.edu) to be added to the appointment. Have a new team member? Feel free to forward the info to them as well.

ONGOING TRIALS

BOOST 3 NEWS AND UPDATES

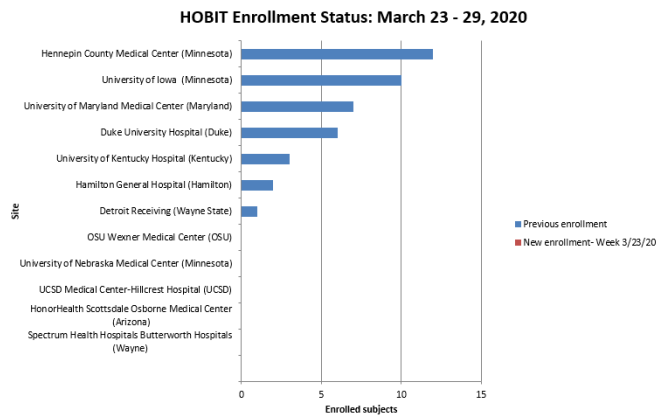
- **BOOST 3 enrollments: 27** (Target enrollment 1094)
- **OHSU Network Enrollment: 3 – URM**
- On 4/2 Anna Rodriguez sent out Moberg software updates – did you get those installed?
- The study coordinator spotlight in March was: *Helpful Hints for Interpreting and Entering Tier Interventions*, [Slide Template and Presentations](#) –check out these useful tools!

BOOST-3 Enrollment Status: March 30 - April 5, 2020



HOBIT – Hyperbaric Oxygen Brain Injury Treatment Trial

- Enrollment: 41 (Goal:200)
- **OHSU Network enrollment: 7**
- Kudos to Duke for being the 4th highest enrolling site in the HOBIT network!
- OSU and OHSU have also been released to enroll.
- EFIC – while many sites cannot enroll subjects at this time, it may be OK to continue with EFIC community and consultation and public disclosure.
- See page 3 for the suggestions on how to complete these during this time of social distancing; or visit the website: https://siren.network/clinical-trials/hobit/efic_resources



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.

- 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>

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.

THANK YOU FOR YOUR SITE SUMMARIES

Thank you again to all network sites for contributing your site summary for our annual report. We are happy to announce that we were able to submit our complete network report on time!

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

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)