



OHSU SIREN NETWORK NEWS

Issue: October 2020

CALENDAR

10/8 1-2pm ET – HSP

Working Group call–
Bluejeans link in e-mail

10/21 12-1pm ET Steering
Committee Meeting –
Bluejeans link in e-mail

10/21 1-2pm ET Journal Club
– Bluejeans link in e-mail

11/3 1-2pm ET Study
Coordinator Meeting –
Bluejeans link in e-mail

11/2 3-4pm ET Finance
Committee Call – 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

Journal Club Spotlight.....	1
OHSU SIREN Network Quarterly meeting.....	1
Next Quarterly call - Save the Date	2
OHSU Network Performance at a glance.....	2
C3PO News & Updates	3
BOOST 3 News & updates	3
HOBIT News & Updates.....	4
ICECAP News & Updates	4
Glossary of Frequently Used Abbreviations.....	4

JOURNAL CLUB SPOTLIGHT

Have you tried out Journal Club yet? Join in this month to discuss these excellent articles.



Dr. James Menegazzi will present: Grunau B, Kime N, Leroux B, Rea T, Van Belle G, Menegazzi J, et al. **Association of Intra-arrest Transport vs. Continued On-Scene Resuscitation With Survival to Hospital Discharge Among Patients With Out-of-Hospital Cardiac Arrest.** JAMA. 2020;324(11):1058-1067.

Dr. Emily Gilmore will present: Rossetti AO, Schindler K, Sutter R, Ruegg S, Zubler F, Novy J, et al. **Continuous vs Routine Electroencephalogram in Critically Ill Adults with Altered Consciousness and No Recent Seizure, A**



Multicenter Randomized Clinical Trial. JAMA Neurol.

Doi:10.1001/jamaneurol.2020.2264. Published online July 27, 2020.



Dr. Emily Gilmore will also present the Editorial to the above article: Gilmore EJ. **Continuous Electroencephalogram- Necessity or Luxury?** JAMA Neurol. Published online July 27, 2020.

OHSU SIREN NETWORK QUARTERLY MEETING

Date: October 5, 2020 @10am Pacific

Thank you to those colleagues who were able to join us. We understand at least 1 person had trouble connecting – please let us know if you experienced any difficulties joining the WebEx.

Notes from the call

SIREN renewal will be in 2022 and so applications due fall of 2021

CCC and DCC will likely automatically renew

Hubs will likely have to compete again, SIREN currently has 11 hubs and is trying to increase this number

SIREN has rolled out 4 trials which is what it was expected to achieve in the first 5-year funding cycle

SIREN has also secured funding for several ancillary studies

BOOST3 – up and running at URM, Utah, OHSU, OSU and soon Duke

ICECAP – up and running at URM, Utah, and OHSU, others planning to start are UAB, Duke, OSU

HOBIT – up and running at OSU and Duke

C3PO – up and running at Wake, OSU and OHSU. Enrollment has been challenging. Working on strategies to overcome barriers.

Want to catch up? Watch the recording of the call

<https://ohsu.webex.com/recording/service/sites/ohsu/recording/playback/de5184988d854b19a070f0c3c301d271> Passcode: DraKyaQ4

Next Quarterly call - Save the Date

The next quarterly Network meeting will be:

January 20, 2021 @ 10am Pacific

Join Meeting: <https://ohsu.webex.com/ohsu/j.php?MTID=m7732652b2237b1126a7b5ed9358230f5>

Meeting password: mP4z9wmPDJ8

Phone (audio only):

1-206-207-1700 US

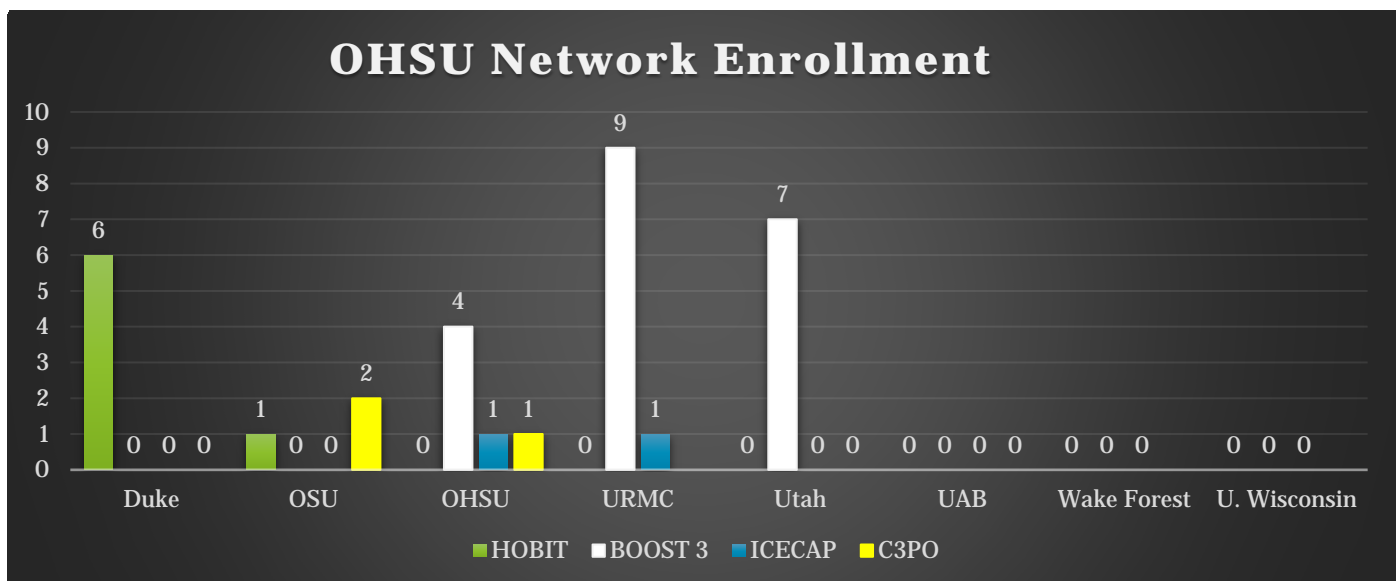
1-503-907-9144 Portland, OR

Meeting number (access code): 120 440 1808

Additional call-in numbers: <https://ohsu.webex.com/ohsu/globalcallin.php>

OHSU NETWORK PERFORMANCE AT A GLANCE

Great work keeping our enrollment numbers strong across trials. To date we have collectively enrolled 32 subjects in SIREN network trials! **Our network had 9 enrollments in the month of September!**



C3PO NEWS & UPDATES

- C3PO enrollments: 39 (Target enrollment 600)
- **OHSU Network Enrollment: 3** OSU (2), OHSU(1)
- Screen Failure & enrollment challenges
 - C3PO has been more challenging to enroll in than anticipated, and this seems to be occurring across all sites. Below is some feedback from Dr. Callaway, one of the C3PO MPI's. Please consider the barriers and feedback below and review your site practices for ways to mitigate these and other barriers you may be experiencing. Locally at OHSU we have seen a surprising number of subjects refuse to even receive a rapid test for COVID, and also a number decline study participation due to "ED fatigue" - i.e. having been in the ED for a long time, and not interested in stay just to receive the research intervention.

This past week (9/28-10/4), you have enrolled about 1 subject per day. Our goal is to triple or quadruple that rate. The fastest enrolling sites randomizing 2-3 patients / week: that seems to be coming from steady screening and consistently offering the trial to all patients going home. If we can all get to that rate, this trial will be finished soon!

Your documentation of Screen Failures is helping to improve the trial. Today, you have reported on over 260 patients who were not enrolled in the trial. Most were not eligible, but over 100 patients were eligible.

We only offered the trial to 50% of those eligible patients, with the most common reason being that they presented outside of hours when the study team was available. Please try to screen and offer enrollment as many hours as possible. Working with your pharmacy and blood bank or being on call from outside the hospital may capture more of these patients. "You miss 100% of the shots you do not take."

Among the other 50% of Screen Failures who were offered the trial, 48 patients declined to participate (i.e. more than agreed to be in the trial). If at all possible, let's try to ask patients who decline why they are declining (afraid of blood products, do not like research, feel to overwhelmed, etc.), and put this as a comment in the "Other Reasons" text box on the Screen Failure log. If a lot of patients have similar reservations, we can try to develop education or solutions to their concerns.

Thanks for doing the hard work! COVID-19 is a bad disease, and it is really important for use to develop a treatment that can prevent mild illness from becoming severe.

Best,

Clifton W. Callaway, MD, PhD

Professor and Executive Vice-Chair Emergency Medicine

Ronald D. Stewart Chair of Emergency Medicine Research

BOOST 3 NEWS & UPDATES

- BOOST 3 enrollments: 77 (Target enrollment 1094)
- **OHSU Network Enrollment: 20** – URM (9), Utah (7) OHSU (4), – **Kudos** URM and Utah who are in the top 5 enrolling sites for this trial to date!!!

- **Congrats to Duke University for completing Pre-study EFIC, and their readiness call!**
Their site expects to be released to start enrolling in BOOST 3 sometime in October
- Do you have a process for regularly reviewing screen failure logs? We suggest a regular weekly review so any potential misses can be promptly discussed and an action plan created for any missed enrollments. Page 3 contains a sample of the format we use for tracking these.
- **BioBOOST:** Investigator meetings are 10/8 @ 7am Pacific OR 10/12 @ Noon Pacific. **If you site is participating in BioBOOST your PI and SC MUST ATTEND one of these sessions.** Access information is the same for both calls (see below)
 - Conference Line: 888-240-2560
 - Access Code: 734 232 2137
 - If connecting via computer audio: <https://bluejeans.com/7342322137>

HOBIT NEWS & UPDATES

- Enrollment: 48 (Goal:200)
- **OHSU Network enrollment: 7**
- Sites continue to work towards approval to run the study under EFIC, as lack of LAR identification has impeded enrollment in this study at a number of sites.

ICECAP NEWS & UPDATES

- Enrollment: 37 (Goal: 1800)
- **OHSU Network Enrollment: 2** - OHSU and URMC have both enrolled 1 subject each.
- UAB, Utah, Duke and OSU are also participating in ICECAP and expect to be enrolling in the near future! Wake Forest is also hoping to join ICECAP and has restarted talks with their site to initiate this trial.
- Some challenges have already been noted in identifying the LAR, and in cooling the subject within the 4 hour window. Please send us your feedback as you start working on this trial so we can share lessons learned with other sites, and help us all grow a best practices list for our partner sites. Ancillary study related to neuroprognostication has been funded (PRECICECAP) by the NIH. Another ancillary study related to biomarkers has been submitted for funding consideration. Kudos to Dr. Kurz at UAB for helping lead that submission.

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)