



OHSU SIREN NETWORK NEWS

Issue: Aug/Sept 2020

CALENDAR

9/10 3-4pm ET – Finance
Committee Call – Bluejeans
link in e-mail

9/16 12-1pm ET Steering
Committee Meeting –
Bluejeans link in e-mail

9/16 1-2pm ET Journal Club
– Bluejeans link in e-mail

10/5 10am PT – OHSU
QUARTERLY SIREN
NETWORK CALL

10/6 1-2pm ET Study
Coordinator Meeting –
Bluejeans link in e-mail

Contact us: Jenny Cook,
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[OHSU SIREN Website](#)

Twitter: [@OHSU CPREM](#)

Newsletter at a Glance

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OHSU SIREN NETWORK UPDATES

With all the uncertainty, chaos, and upheaval we have all faced in 2020, one thing is certain: 2020 is a year for the record books. First and foremost we want to thank each and every site for the extraordinary effort they have put in to keep moving the needle on these important research endeavors despite the challenges we have all faced: working through modified operations, financial impacts of COVID on our research teams and enterprises, limits on how, when, and under what circumstances we conduct research, shortages of PPE, and concerns about keeping ourselves and our colleagues safe through it all. So THANK YOU. Thank you for persevering, thank you for working tirelessly to bring up the SIREN trials your team is participating in – BOOST 3, ICECAP, and now C3PO. Thank you to our HOBIT partner sites who have been exploring the new world of

EFIC in a virtual environment (have any hints or tricks to share??) We see, recognize and honor your accomplishments.

OHSU SIREN NETWORK QUARTERLY MEETING

Date: October 5, 2020 @10am Pacific

We strongly encourage the site PI, and lead SIREN coordinator from your site to join these calls. Any additional team members who would like to join are welcome. An agenda will be sent out in the week prior to the call. Check your inbox for the calendar invite!

COVID 19 SIREN STUDY: C3PO

The Clinical Trial of COVID-19 Convalescent Plasma of Outpatients (C3PO), is a multi-center randomized, single blind, two arm, placebo controlled phase III trial with blinded outcome assessment to establish the

safety and efficacy of a single dose of convalescent plasma (CP) for preventing the progression from mild to severe COVID-19 illness. This is an ED based study that focuses on patients well enough to be discharged home after treatment. The primary endpoint is return to ED or hospitalization within 15 days. Sample size goal: 600

- OHSU has 5 network sites planning to participate: Wake Forest, Duke, OSU, URMC, OHSU
- OSU and OHSU have both been released to enroll
- All site enrollment: 14
- Review the [NIH letter of support](#) – this letter is intended to help inform leadership of the trial, and need to prioritize this research.
- The CCC is also providing assistance to sites in need of rapid COVID testing by providing the Abbott ID Now platform (machine and reagents) to sites.
- Documents and tools are available for repurposing and reuse at your local site. Check out the study coordinator guide, EPIC and Cerner order set builds, and posters/handout available [here](#)

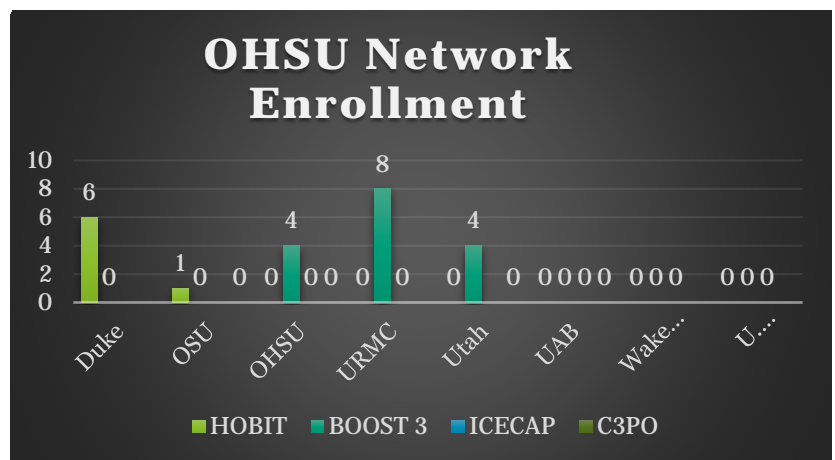
ONGOING TRIALS

OHSU NETWORK PERFORMANCE AT A GLANCE

Great work keeping our enrollment numbers strong across trials. To date we have collectively enrolled 23 subjects in SIREN network trials!

BOOST 3 NEWS AND UPDATES

- **BOOST 3 enrollments: 66** (Target enrollment 1094)
- **OHSU Network Enrollment: 16** – URMC, OHSU, Utah
- 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:** The sub-study BioBOOST training dates have been postponed. New save the dates should be coming in the near future. BioBOOST is also recruiting additional sites and so please complete the [survey link](#) from the CCC.
- **Electro-BOOST:** Don't forget to [fill out your survey](#) if your site is planning to participate



HOBIT – Hyperbaric Oxygen Brain Injury Treatment Trial

- Enrollment: 46 (Goal:200)
- **OHSU Network enrollment: 7**
- Congrats to OSU who recently enrolled their first HOBIT subject and to DUKE for their stellar enrollment to data!

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

- Enrollment: 17 (Goal: 1800)
- URMC & Utah have been released to enroll
- OHSU expects to start enrollment in mid Sept.

KUDOS TO UTAH FOR ENROLLING IN 2 SIREN TRIALS LAST WEEK!!!

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)

BOOST 3 SCREEN FAIL INTERNAL TRACKING LOG EXAMPLE

WebDCU Screenfail #	Name	MRN	Screening date & Initials	Time and Date of Injury	TBI? (Yes or No)	ICP and/or PBO2 Placed within 6 hours of TOA and 12 hours of TOI? (Yes or No)
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ICU Admission? (Yes or No)	Screen Failed Patients (Yes to TBI, ICU Admit, & ICP/PbO2 placed) (Yes or No) Emailed BOOST3 Team?	Reason for Screenfail	Meets Preliminary Inclusion and no Exclusion Email to BOOST3 team sent? <i>Place Patient on Trauma List</i>	Notes
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