



OHSU SIREN NETWORK NEWS

Issue: July 2020

CALENDAR

7/14 1pm ET Study

Coordinator Meeting –
Bluejeans link in e-mail

7/9 3-4pm ET – Finance

Committee Call – Bluejeans
link in e-mail

7/15 12-1pm ET Steering

Committee Meeting –
Bluejeans link in e-mail

*Journal Club is on hiatus
until Sept 2020*

8/4 1pm ET Study

Coordinator Meeting –
Bluejeans link in e-mail

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[OHSU SIREN Website](#)

Twitter: [@OHSU CPREM](#)

Newsletter at a Glance

COVID 19 SIREN Study: C3PO	1
Ongoing Trials	2
OHSU Network Performance at a glance.....	2
BOOST 3 News and updates.....	2
Action Item: EMS Survey	2
Glossary of Frequently Used Abbreviations.....	3

COVID 19 SIREN STUDY: C3PO

The Clinical Trial of COVID-19 Convalescent Plasma of Outpatients (C3PO), is rapidly moving forward. This 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 6 network sites planning to participate: Wake Forest, Duke, OSU, UPMC, Univ. Wisconsin, OHSU
- Virtual investigator meetings were held on 6/25.
- Blood bank C3PO meetings were held on 6/24

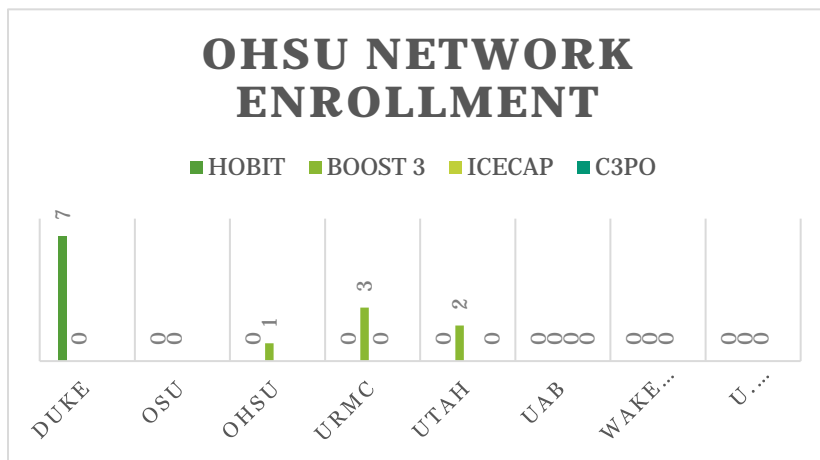
If someone on your team was unable to attend, recordings will be available at [Investigator Meetings tab](#)

- The approved protocol, ICF, and other trial preparation resources are available on the website. (<https://siren.network/clinical-trials/c3po>)
- Please seek a ceding agreement from your local IRB to Advarra, and begin working on pre-trial preparations at your site now.
- Sites need to be ready to launch in the coming weeks, so please set yourself up for success if your site is planning to participate!

ONGOING TRIALS

OHSU NETWORK PERFORMANCE AT A GLANCE

Team, we are trying out a new network enrollment chart. Please let us know if any of the information for your site is incorrect. We will be working to fine tune this graph, and welcome input on what information you would find helpful for us to display.



BOOST 3 NEWS AND UPDATES

- **BOOST 3 enrollments: 37** (Target enrollment 1094)
- **OHSU Network Enrollment: 7** – URMIC, OHSU, Utah
- **Congrats to Utah on their first BOOST 3 subject enrollment!**
- **Did you know?** The enrollment goal across the SIREN network is 5 subjects per week, which has been achieved 1 week so far. As life begins to ‘open up’ and ‘trauma season’ begins, be sure to remind your research and clinical teams to be on the lookout for eligible subjects.
- 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.
- **BioBOOST:** The sub-study BioBOOST is getting close to launching. The CCC announced in June that the participating sites, and OHSU & URMIC were selected! Kudos to Dr. Hinson who is leading this substudy, and worked diligently with the study team to include OHSU as a participating site.

HOBIT – Hyperbaric Oxygen Brain Injury Treatment Trial

- Enrollment: 42 (Goal:200)
- **OHSU Network enrollment: 7** – Duke – Keep up the outstanding trial effort!!

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

- Enrollment: 1 (Goal: 1800)
- 4 sites in the SIREN network have been released to enroll
- OHSU Network readiness calls completed: URMIC, Utah
- Pre-study preparation: UAB, Duke, OHSU, OSU
- An ICECAP slide set was posted to the ICECAP website under the [Presentations tab](#). This is a general overview of the trial and can be tailored to your site’s specific educational needs.

ACTION ITEM: EMS SURVEY

FROM THE CCC: We would like to send the SIREN EMS Working Group survey out once more and stress that this is needed from EMS systems that intend to participate in SIREN prehospital clinical trials. This information is crucial for a grant application and we need to prove that we have enough EMS systems to

conduct a trial in a timely manner. The first clinical trial being planned will compare two different OHCA treatment strategies: Stabilizing on Scene versus Early Transport to Hospital.

Your participation is voluntary and appreciated. This should only take 5 minutes to complete and the information you provide will help establish the necessary information for developing the plan for this clinical trial and formulating an NIH grant submission to fund the trial. Information collected in this survey will be shared through the SIREN EMS Working Group anonymously.

Please complete a separate survey for each EMS agency (i.e. if you have multiple EMS agencies you work with, please complete a survey for each individual agency) that you represent and let us know if you have any questions. https://pitt.co1.qualtrics.com/jfe/form/SV_e3vYVIXxAoXtNEF

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)