



OHSU SIREN NETWORK NEWS

Issue: March 2021

CALENDAR

3/2 1-2pm ET Study

Coordinator Meeting – [Web Link](#)

3/11 3-4pm ET Finance

Committee Call – [Web Link](#)

3/24 12-1:30pm ET Steering
Committee Meeting – [Zoom Link](#)

*Journal Club is on hiatus for
the month of March*

4/6 1-2pm ET Study

Coordinator Meeting – [Web Link](#)

Contact us: Jenny Cook,
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cookjen@ohsu.edu

[OHSU SIREN Website](#)

Twitter: [@OHSU_CPREM](#)

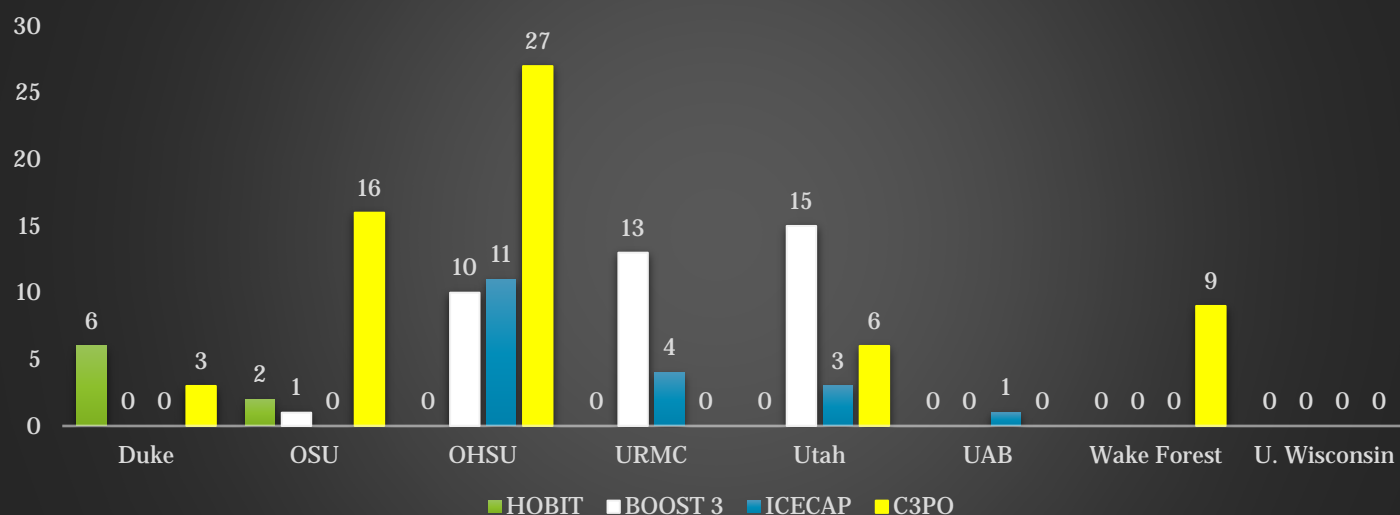
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OHSU NETWORK PERFORMANCE AT A GLANCE

The OHSU network continues to be the top performing network in SIREN. Great work to all our sites! This month we want to recognize the University of Utah who enrolled 7 patients across the 3 studies in February! We also want to recognize University of Alabama who enrolled their first patient in ICECAP. Finally, we also want to recognize Ohio State University for their first enrollment in Boost3. Outstanding work!

OHSU Network Enrollment



COMPETITIVE GRANT RENEWAL FOR SIREN COMING IN '21

Later this year, the NIH announcement and details surrounding the SIREN network competitive renewal process is expected to be released around June. We are now expecting the competitive renewal to be due in fall (October). Given the success of the network we have built to date, we are hopeful that each of our current sites will chose to continue to partner with us. However, we understand that you may also wish to apply as a separate award Hub network. As we learn more about this next funding cycle, please keep us informed about your plans, and we will keep you updated on our Hub renewal application. The SIREN network is hoping to expand from 11 to 14 Hubs and have requested funds to help train future researchers for the network.

C3PO NEWS & UPDATES

- Final Enrollment Total: **511**
- ***Study enrollment was suspended 2/25/21.*** The DSMB met for their 2nd interim analysis and recommended stopping the trial for futility of detecting a difference in the primary outcome.
- ***Please review the [C3PO Press release on page 4.](#)***
- **OHSU Network Enrollment: 61** (Our 4 sites accounted for 12% of total enrolled subjects!)
- Have an idea for a secondary research paper? Submit your C3PO ideas here: https://siren.network/clinical-trials/c3po/research_ideas
- Long COVID study – OHSU PI Bory Kea is exploring a study to follow subjects with persistent COVID symptoms. We plan to query sites for interest in the near future – stay tuned!
- The NIH released an ROA “Post-Acute Sequelae of SARS-CoV-2 Infection Initiative: SARS-CoV-2 Recovery Cohort Studies” <https://covid19.nih.gov/sites/default/files/2021-02/PASC-ROA-OTA-Recovery-Cohort-Studies.pdf>

BOOST 3 NEWS & UPDATES

- BOOST 3 enrollments: 137 (Target enrollment 1094)
- **OHSU Network Enrollment: 39** (28% of total enrolled subjects)
- Congratulations to OSU on their 1st BOOST3 enrollment!
- Kudos to Utah who has moved into 2nd place in enrollments, and URMU who is the 3rd highest enrolling site!
- BioBOOST:
 - OHSU has enrolled 2 subjects in BioBOOST – great work to the study team for getting the first enrollment in BioBOOST and working through the glitches in the system that needed to be ironed out!

HOBIT NEWS & UPDATES

- Enrollment: 55 (Goal:200)
- **OHSU Network enrollment: 8** (15% of total enrolled subjects)
- A new Technical Memo is now available on the HOBIT website under [Toolbox > Chamber Resources> Technical Memo.](#)
 - COVID-19 Infection Prevention and Control Considerations for the HOBIT Trial
- The HOBIT promotional video was posted to the [Toolbox > Video](#). It's also posted to the homepage.

ICECAP NEWS & UPDATES

- Enrollment: 150 (Goal: 1800)
- **OHSU Network Enrollment: 19** (13% of total enrolled subjects)
 - **Congrats UAB on their first ICECAP enrollment!**
- Did you miss the ICECAP investigator meeting? View it now! [Investigator Meetings](#)
- Also, the following presentations were posted under the [Presentations](#) link:
 - ICECAP Presentation at U Wash Emergency Medicine Grand Rounds (3-10-20)
 - Short Overview on Adaptive Design (4-10-19)
- There are a number of sub studies being developed with ICECAP:
 - P-ICECAP is a Pediatric ICECAP study that has been submitted for review. No additional updates yet, but we will send you a summary once we have one. This study is also a duration of cooling study and plans to use the SIREN and PECARN networks to enroll.
- PRECICECAP (Precision Care in Cardiac Arrest)
 - Funding has been released for this study from the NIH.
 - Initially 10 sites have been selected to participate. Kudos to UAB who will be participating in this substudy!
 - If you're interested in reviewing the introductory webinar, you can view it here: <https://siren.network/clinical-trials/icecap/precicecap>

STUDIES IN DEVELOPMENT

SPEED – Seizure Prevalence by Electroencephalography in the Emergency Department Trial

This trial was submitted for funding consideration in the Feb cycle. Thank you to all sites that submitted LOS and survey data to support this grant application.

EPIC2 - Excellence in Prehospital Injury Care Traumatic Brain Injury trial

Thank you to those of you who submitted survey data expressing your interest in this trial! We expect to hear more from the EPIC2 team as they prepare to submit this grant for consideration for the June funding cycle.

KESETT – Ketamine in Established Status Epilepticus Treatment Trial follow up trial

This study presented their trial design to the PECARN network in the last week of February. Details and budget are still being finalized. Survey data from sites may still be requested. We will keep you posted.

KETOSIS - Ketogenic Emergency Treatment of Status epilepticus In SIREN

This grant is being resubmitted next week for funding consideration. Again, thank you to sites who also submitted new LOS for this grant resubmission. We will keep you posted as we learn more.

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)

C3PO PRESS RELEASE INFORMATION

From: Callaway, Clifton <callawaycw@upmc.edu>

Sent: Tuesday, March 2, 2021 11:52 AM

Cc: Johnson, Lenora (NIH/NHLBI) [E]; Sampson, Mark (NIH/NHLBI) [E]

Subject: [EXTERNAL] C3PO - Press Release from NIH

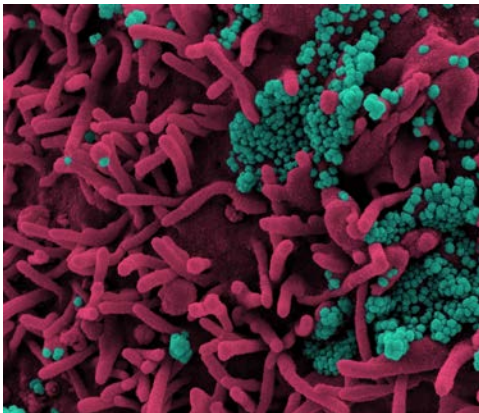
Dear C3PO teams:

Stopping a big trial attracts public attention. There have already been a few inquiries from media, and our stopping enrollment has appeared in some blogs. It is best not to talk much about the trial at this time because we still have many patients who are completing follow-up and because the final data are not locked yet. Here are a few guidelines:

- Below is the **press release from NIH** that you can use
- If you have media attention, or talk to anyone in media, **please notify Lenora Johnson and Mark Sampson** (copied) at NIH.
- Feel free to **refer media inquiries** to Lenora Johnson and Mark Sampson and to this press release (this is best course)
- Be respectful of patients who are still in follow-up. I would hate for them to read on the news that this trial is over, which might make them think that their contribution does not matter: they still matter a lot. We are asking IRB to approve a **letter to participants** who are still in follow-up in order to emphasize this point.

Congratulations again on your excellent work that is already getting A LOT of attention!

<https://www.nih.gov/news-events/news-releases/nih-halts-trial-covid-19-convalescent-plasma-emergency-department-patients-mild-symptoms>



[NIH halts trial of COVID-19 convalescent plasma in emergency department patients with mild symptoms | National Institutes of Health \(NIH\)](https://www.nih.gov/news-events/news-releases/nih-halts-trial-covid-19-convalescent-plasma-emergency-department-patients-mild-symptoms)

The National Institutes of Health has halted a clinical trial evaluating the safety and effectiveness of COVID-19 convalescent plasma in treating emergency department patients who developed mild to moderate symptoms of COVID-19, the disease caused by the coronavirus SARS-CoV-2. An independent data ...

www.nih.gov