

# **OHSU SIREN NETWORK NEWS**

Issue: October 2023

## **CALENDAR**

10/3 1pm ET Study Coordinator Meeting – Zoom Link (Meeting ID: 959 9800 0564 Passcode: 113257)

10/4 1pm ET Monthly Didactics - Zoom Link (Meeting ID: 950 8157 4770 Passcode: 898235)

10/18 1pm Journal Club: Zoom Link (Meeting ID:927 2287 6863 Passcode:808062) (Speaker Link)

10/25 12pm ET: Steering Committee (Agenda Link) Zoom Link (Meeting ID: 976 1520 1082 Passcode: 890819)

11/1 1pm ET Monthly Didactics - Zoom Link (Meeting ID: 950 8157 4770 Passcode: 898235)

11/7 1pm ET Study Coordinator Meeting – Zoom Link (Meeting ID: 959 9800 0564 Passcode: 113257)

Contact us: Jenny Cook, Hub Project Manager, 503.494.1230 cookjen@ohsu.edu **OHSU SIREN Website** OHSU Co-PI's: Dr. Mo Daya, Dr. Bory Kea **OHSU Finanace & Contracts:** Denise Griffiths griffitd@ohsu.edu

## NEWSLETTER AT A GLANCE

Network News1	
Standard Operating Procedure (SOP) Spotlight	
BOOST 3 News & Updates 2	
ICECAP News & Updates 2	
Peds ICECAP News & Updates	
Studies in Development	
C3PO Manuscript	

## **NETWORK NEWS**

As we continue to grow and build our network, we look at new ways of communicating, sharing, and distributing information between our centers and study teams. To that end, we are in the process of developing a Microsoft Teams group. Each PI and a primary study coordinator will receive an invite from us to join the Team "PROJ.OHSU SIREN Network". There will be a way to request additional team members be added once we get the initial launch off the ground.

Quarterly team meetings - We will hold our first all-site meeting on 10/23/2023. We ask that the site SIREN PI, study PIs, and primary study coordinators all attend these meetings where we will share any updates we have and, more importantly, have a chance to hear how study operations are going at each of your sites. These calls will be an opportunity to learn from each other, offer best practices, and brainstorm solutions to any challenges our teams may face.

Upcoming team meeting schedule through 2024:

- Monday, January 22, 2024 @noon Pacific •
- Monday, April 22, 2024 @noon Pacific •
- Monday, July 22, 2024 @ noon Pacific •
- Monday, October 28, 2024 @ noon Pacific •

Steering Committee Schedule - This is the Central Coordinating Center run meeting. This group meets three months on then takes one month off.

- October 25, 2023 •
- February 28, 2024 April 24, 2024

June 26, 2024

November off •

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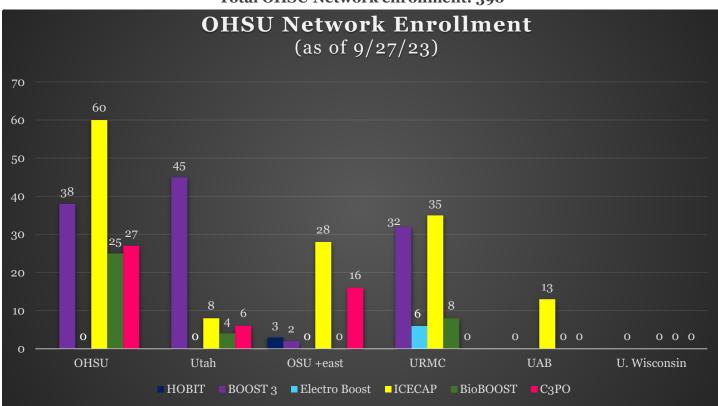
Dec. 27, 2023 May 22, 2024 •

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January 24, 2024

1 | Page



#### Total OHSU Network enrollment: 390

#### STANDARD OPERATING PROCEDURE (SOP) SPOTLIGHT

As a part of the new SIREN award notice, we will help facilitate the DCC efforts to distribute the SIREN general SOPs and training for our spoke sites.

Your site can access all SIREN SOPs at any time here: <u>https://siren.network/nett-resources/standard-operating-procedures.</u> We will also spotlight a monthly SOP in our newsletter for your review.

This month, please review the Maintenance of Essential Documents SOP

#### **BOOST 3 NEWS & UPDATES**

Brain Oxygen Optimization in Severe Traumatic Brain Injury Phase 3

- BOOST 3 enrollments: 529; 48% of target (Target enrollment: 1094)
- OHSU Network Enrollment: 120
- Bio-BOOST enrollments: 114; OHSU Network: 37
- ELECTROBOOST enrollment: 65 **OHSU Network: 6**
- Good news! The probe shortage/manufacturing issues seem to have been resolved. If you do/are experiencing any issues with acquiring probes, please let us know.

## **ICECAP NEWS & UPDATES**

Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients

- ICECAP Enrollments: 791; 44% of target (Target enrollment: 1800)
- OHSU Network Enrollment: 153

• **POST-ICECAP** (ancillary study of long-term outcomes on ICECAP-eligible subjects) – Contracts/agreements are being sent to sites. Please check with your grants office if you haven't seen this arrive at your institution.



#### • Thank you to Dr. Will Meurer

(https://www.instagram.com/goals.of.hair/) for joining the Adventist, OHSU, and Doernbecher teams for ICECAP and Pediatric ICECAP and giving incredibly insightful talks. He presented four lectures! If your team would like a copy of the recordings, please e-mail Jenny Cook to request!

#### **PEDS ICECAP NEWS & UPDATES**

Pediatric Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients

- P-ICECAP Enrollments: 96 10.67% (Goal: 900)
- OHSU Network Enrollment: 2

#### **STUDIES IN DEVELOPMENT**

- **P-ICECAP Extended** this is a longitudinal f/u study. **Update:** Application received a good score, and the grant has been sent to the council
- **ED-SED** this is the ED sedation study. **Update:** Did not receive a fundable score, but issues cited by reviewers are addressable. Plan to resubmit in Feb 2024
- **SPEED** this is the seizure prevalence on EEG in ED. **Update:** Resubmission did not score well; received summary statement and have decided to go back to the drawing board
- **KSETT** Ketamine for status seizure trial. **Update:** Resubmitting in Nov. Sites will receive a request soon for updated LOS
- **PERFECT** TNK dose in PE. **Update:** Plan to resubmit in Nov
- **VETO-Sepsis** was going to be a planning grant for etomidate v ketamine. **Update**: Per NIH, it should be submitted as a trial and not a planning grant. There is a plan for submission early next year; the investigator team will be on the steering committee call soon to present the study plan.
- **CABO** serum/clin biomarker substudy in ICECAP/PICECAP. **Update:** Did not receive a fundable score; summary statements are being reviewed. Plan to resubmit in Feb 2024
- WINDSURFER HHFO v BiPAP in resp failure. Update: Approval received to submit in Oct 2023
- 5-6 additional studies are in the development phase right now; rot ready for submission (both ancillary and primary trials)

## C3PO MANUSCRIPT

https://www.sciencedirect.com/science/article/pii/S0735675723004886

Pobee R, Cable T, Chan D, Herrick J, Durkalski-Mauldin V, Korley F, Callaway C, Del Rios M. Association of substance use with outcomes in mildly ill COVID-19 outpatients. Am J Emerg Med. 2023 Sep 20;74:27-31. doi: 10.1016/j.ajem.2023.09.017. Epub ahead of print. PMID: 37748266.

Abstract: **Background.** Smoking, alcohol use, and non-prescription drug use are associated with worsened COVID-19 outcomes in hospitalized patients. Whether there is an association between substance use and outcomes in patients with COVID-19 who visited the Emergency Department (ED) but did not require

hospitalization has not been well established. We investigated whether smoking, alcohol, and non-prescription drug use were associated with worsened COVID-19 outcomes among such patients presenting to the ED.

**Methods.** We conducted a secondary analysis of a clinical trial which sought to determine the effect of early convalescent plasma administration in patients presenting to the ED within 7 days of onset of mild COVID-19 symptoms. The study recruited 511 participants who were aged 50 years or older or had one or more risk factors for severe COVID-19. The primary outcome was disease progression within 15 days after randomization, which was defined as a composite of hospital admission for any reason, seeking emergency or urgent care, or death without hospitalization. Secondary outcomes included: no hospitalization within 30 days post-randomization, symptom worsening on the 5-category COVID-19 outpatient ordinal scale within 15 days post-randomization, and all-cause mortality. Substance use was categorized into either use or never use based on participant self-report. Logistic regression models were used to determine the association between substance use and outcomes.

**Results.** The mean age of the 511 patients enrolled was 52 years and the majority were females (274, 54%). Approximately 213 (42%) were non-Hispanic Whites, 156 (30%) Hispanics, 100 (20%) non-Hispanic Blacks, 18 (4%) non-Hispanic Asian, 8 (1%) American Indian Alaskan, and 16 (3%) unknown race. Tobacco 152 (30%) was the most common substance use reported. Alcohol use 36 (7%) and non-prescription drug use 33 (6%) were less common. Tobacco use and non-prescription drug use were associated with an increased risk for meeting the primary outcome ((tobacco: adjusted odds ratio [aOR] =2.08; 95% confidence interval [CI]: 1.37–3.15) and (drug: aOR =2.41; 95%CI: 1.17–5.00)) and increased risk for symptom worsening on the 5-category COVID-19 outpatient scale ((tobacco: aOR = 1.62; 95%CI: 1.09-2.42) and (drug: aOR = 2.32 95% CI: 1.10-4.87)) compared to non-use after adjusting for age, sex, plasma administration, and comorbidity.

**Conclusion.** Tobacco and non-prescription drug use but not alcohol use were associated with worsened COVID-19 outcomes in patients who did not require hospitalization on their initial presentation. Future studies should determine the quantity, duration, and type of drug/tobacco use that may worsen COVID-19.