



# OHSU SIREN NETWORK NEWS

Issue: April 24

## CALENDAR

4/17 1pm Journal Club:

[Zoom Link \(Meeting ID:9272287 6863 Passcode:808062\)](#)  
[\(Speaker Link\)](#)

4/17 Journal Club – [Zoom Link](#)

4/24 12-2p ET: Steering Committee Meeting – [Zoom](#)

5/1 1pm: ET Monthly SIREN Fellow Didactics – [Zoom Link](#)  
 (Meeting ID: 950 8157 4770 Passcode: 898235)

5/7 1pm ET: Study Coordinator Meeting – [Zoom Link](#)

5/15 Journal Club – [Zoom Link](#)

5/22 12-2p ET: Steering Committee Meeting – [Zoom](#)

Working groups and other SIREN meetings can be found [here](#)

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[Teams: OHSU SIREN Network Home Page](#)

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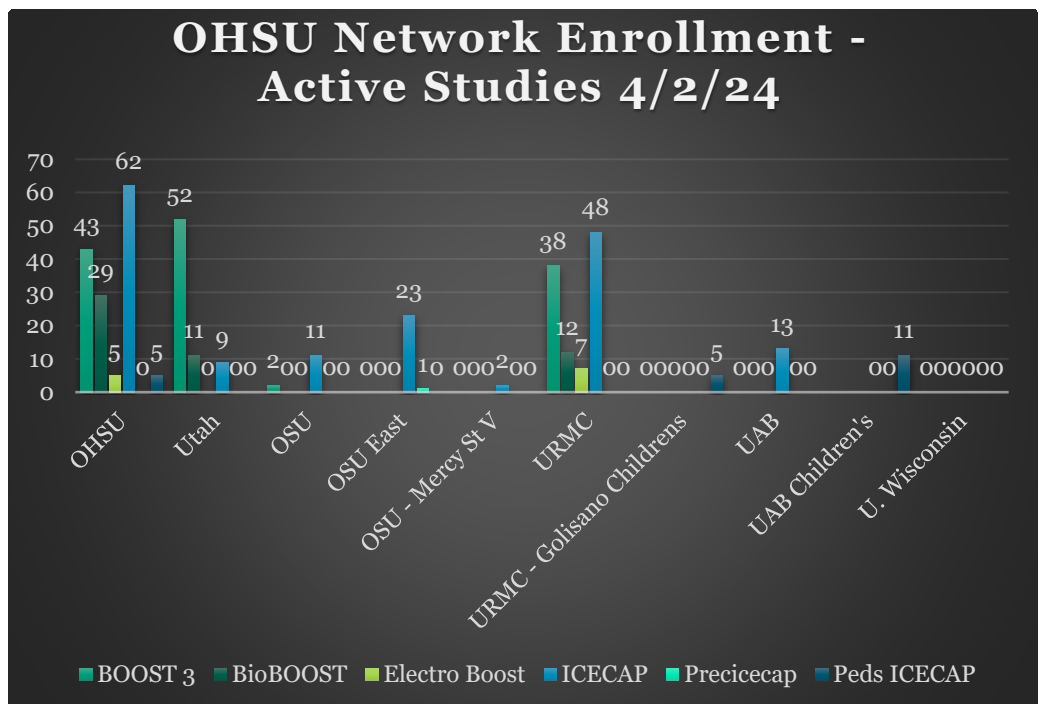
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## NETWORK NEWS

Will you be attending SAEM this year? Please contact Jenny Cook [cookjen@ohsu.edu](mailto:cookjen@ohsu.edu) to let us know. We are planning to have an OHSU Hub network gathering with those of you who will be in Phoenix.

<b>Current Network Total enrollment (Primary + sub studies)</b>	<b>441</b>	<b>Current Network Primary study enrollment</b>	<b>377</b>
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## 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: <https://siren.network/nett-resources/standard-operating-procedures>.

- This month, please review the [DSMB CIRB Joint Operating Procedure](#) SOP

## BOOST 3 NEWS & UPDATES

### *Brain Oxygen Optimization in Severe Traumatic Brain Injury Phase 3*

- BOOST 3 enrollments: 599; 55% of target (Target: 1094)
- **OHSU Network Enrollment: 135**
- Thank you to our recent network enroller! – URMC
- There are ongoing shortages of the Integra Licox PtO monitoring probes. If your sites have an issue, let us know so that we can facilitate conversations with the CCC and other Hubs.
- Bio-BOOST enrollments: 137; **OHSU Network: 52**
- ELECTROBOOST enrollment: 86 **OHSU Network: 12**

## ICECAP NEWS & UPDATES

### *Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients*

- ICECAP Enrollments: 905; 50% of target (Target: 1800) **We're over halfway there!**
- **OHSU Network Enrollment: 168**
- We did not have any enrollments in this study this month. Fingers crossed that we can get some enrollments in April!

## POST-ICECAP NEWS

### *Patterns Of Survivors' Recovery Trajectory in the ICECAP Trial*



Please visit the POST ICECAP study page for the latest documents and study updates. Site Readiness Checklist, just in time training, the Protocol, and other documents are all now available on the site. <https://siren.network/clinical-trials/icecap/post-icecap>

You can also view your progress in WebDCU: POST-ICECAP→Site Management→Readiness

Report

**POST-ICECAP Virtual Investigator Meeting on:** Wednesday, April 24<sup>th</sup> from 12:30pm-1:30pm ET

Agenda: [POST-ICECAP Virtual Investigator Meeting](#)

Join Zoom Meeting <https://umich.zoom.us/j/91526915120?pwd=NXpxVmRvWllFUzJzQUJBSFdzSlFFdxo9>  
Meeting ID: 915 2691 5120 Passcode: 234512

## PEDS ICECAP NEWS & UPDATES

### *Pediatric Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients*

- P-ICECAP Enrollments: 156; 17.33% (Target: 900)
- **OHSU Network Enrollment: 21**
- Thank you to our recent network enrollers! – Children's of Alabama, and Golisano Children's (URMC)
- **We are very excited that they have now opened all additional arms of cooling from 0 to 96 hours of cooling.**

For participants 151 or higher you will receive treatment arms of 0 additional hours of cooling\* (controlled normothermia) OR 33 C for 12, 18, 24, 36, 48, 60, 72, 84 or 96 hours. All duration arms of  $\geq 12$  hours are operationalized as you have done with 24, 48, and 72 hours arms.

\*Note after randomizing in WebDCU – if the treatment group assigned is 0, this means “controlled normothermia.”

For 0 hours of cooling (normothermia set at 36.8C), the start time of the 120 hour intervention is determined differently than the 33 C arms. Briefly, the start time is the time the device is set with an intent to achieve normothermia (usually this means time device is set to a target of 36 or greater). **Please review the CSG, the MOP and the attached slides for more detailed descriptions.**

CSG: [https://docs.google.com/document/d/1FvS31974znd7fyh\\_2A-G7KWjGldvp8KfU-VRcj2u3xA/edit](https://docs.google.com/document/d/1FvS31974znd7fyh_2A-G7KWjGldvp8KfU-VRcj2u3xA/edit) Pages C9-10

MOP: <https://siren.network/picecap/mop> Pages 24-25

**When enrolling your first participant to 0 additional hours of cooling (controlled normothermia), please call the hotline so that we can help you determine the “start time of intervention.”**

Thank you for all your hard work. P-ICECAP Leadership

- The in-person P-ICECAP investigator meeting will be May 1-2 in Clearwater, FL at the Sheraton Sand Key Resort; 1160 Gulf Blvd; Clearwater Beach, FL 33767.
  - There will be no virtual attendance option this year.
  - You should be registered and have received the confirmation. Please reach out to Valerie if you have any questions/issues with your reservation. [vwillis@med.umich.edu](mailto:vwillis@med.umich.edu)

## STUDIES IN DEVELOPMENT

- WINDSURFER and PERFECT studies received NF score after initial review. The CCC and study PI’s are waiting to review the formal feedback from the NIH.
- CABO has been resubmitted.
- At the March SC

### Studies in Development

ED-SED	less sedation after intubation	to resubmit, NET November	Callaway
KESETT	Ketamine/Seizure trial	Being reviewed in APR - no date	Silbergleit
PERFECT	TNK dose in pulmonary embolism	Resubmit NF score (42) pending summary pages	Callaway
WINDSURFER	HHFO v BIPAP in resp failure	Initial NF score (47) pending summary pages	Meurer
CABO	serum/clin biomarker substudy	both ICECAP ancillary, Submitted March 22	Korley
P-ICECAP EEG	EEG substudy (P-ICECAP ancillary)	Initial NF score, planning to resubmit in a year	Meurer
ICE-MOCCA	effect of cooling on gut microbiome	P-ICECAP ancillary, staff consultation	Meurer
RACE-CAP	impact of cooling quality	ICECAP ancillary, awaiting permission	Silbergleit
ART-BOOST	Robotic TCD monitoring	collecting pilot data	Merck
TARGET-TXA	TEG guided TXA in TBI	under development	Meurer
PS-ECMO	practice patterns in ED ECPR	under development	Mosier
Occiguide	regional block for migraine	initial call, provided feedback	Meurer

Hub-PI meeting, a preliminary discussion was held about a potential clinical trial related to use of the occipital nerve blocks for migraine headaches in the ED. The study would entail the use of a device called the Occiguide (<https://www.occiguide.com>) and is being led by Dr Benjamin W. Friedman, a neurologist who has published extensively on the acute management of migraine headaches in the ED.

- Friedman BW, Irizarry E, Williams A, Solorzano C, Zias E, Robbins MS, Harrilal MA, Del Valle M, Bijur PE, Gallagher EJ. A Randomized, Double-Dummy, Emergency Department-Based Study of Greater Occipital Nerve Block With Bupivacaine vs Intravenous Metoclopramide for Treatment of Migraine. *Headache*. 2020;60:2380-2388.
- Friedman BW, Mohamed S, Robbins MS, Irizarry E, Tarsia V, Pearlman S, John Gallagher E. A Randomized, Sham-Controlled Trial of Bilateral Greater Occipital Nerve Blocks With Bupivacaine for Acute Migraine Patients Refractory to Standard Emergency Department Treatment With Metoclopramide. *Headache*. 2018;58:1427-1434.