



OHSU SIREN NETWORK NEWS

Issue: January 2023

CALENDAR

1/10 1pm ET Study Coordinator Meeting – [Zoom Link \(Meeting ID: 989 9320 6584 Passcode: 361919\)](#)

1/12 3-4pm ET Finance Committee Call – [Web Link](#)

1/18 1pm ET Journal Club – [Click Here](#)

1/25th – 26th: In Person Steering Committee [Details on page 2](#)

Contact us: Jenny Cook, Hub Project Manager, 503.494.1230 cookjen@ohsu.edu [OHSU SIREN Website](#) Twitter: [@OHSU CPREM](#)

NEWSLETTER AT A GLANCE

Network News & Updates	1
SIREN Steering Committee Meeting & Retreat	2
HOBIT News & Updates	3
BOOST 3 News & Updates	3
ICECAP News & Updates	3
Peds ICECAP & Updates	3
New Study Alert: Wind surfer	4
CTMC Series Presentation links	5
Glossary of Frequently Used Abbreviations	5

From our team to yours this festive time of year



We wanted to take just a moment to say thank you to each and every person who has contributed to our network since we started this journey back in 2017. The journey has been unexpected, full of challenges no one could have ever anticipated, and yet, we have all persevered – because each of you has stepped up and continued to believe in our mission, our team, and the science! We are all responsible for creating one of the strongest hubs within SIREN, having grown something truly exceptional despite all that has challenged us along the way. From the bottom of our hearts, thank you for all your hard work and a very happy New Years to all!

NETWORK NEWS & UPDATES

We are still waiting for the official Notice of Award from the NIH (now expected 1/15), and have been told to anticipate a 2/1/23 start date. Stay tuned! Once this happens, our network will decrease in size since we will bid farewell to Duke and Wake Forest (they are moving over to the new Duke hub).

We did receive drafted milestones for the first year for your review:

1. Randomize at least 5 new participants
2. Facilitate the DCC efforts to distribute SIREN General SOPs and Training
3. Facilitate the CCC efforts to train hubs and spokes in new protocol implementation
4. Identify a Junior Faculty that will participate in the research activities of the network

We are actively searching for additional sites that could join our network. If you know a colleague at an unaffiliated site who may be interested in joining us, please let us know!

SIREN STEERING COMMITTEE MEETING & RETREAT

The SIREN Steering Committee Meeting and Retreat meeting is being held on January 25th through 26th, in Clearwater, FL.

From the CCC: We are in the process of solidifying the agenda for the meeting, yet attendees should plan to **arrive the afternoon/evening of January 24th and leave the venue around 1 PM on January 26th.** The Tampa airport (TPA) is typically a 30–40-minute drive from the venue.

Please note that we are not covering or reimbursing expenses related to your travel

We are holding 2-3 rooms per Award Hub at the preferred rate of \$279 + \$25 resort fee/night at the venue noted below based on availability. **Please coordinate with your colleagues regarding who should attend this meeting.**

HILTON CLEARWATER BEACH RESORT & SPA

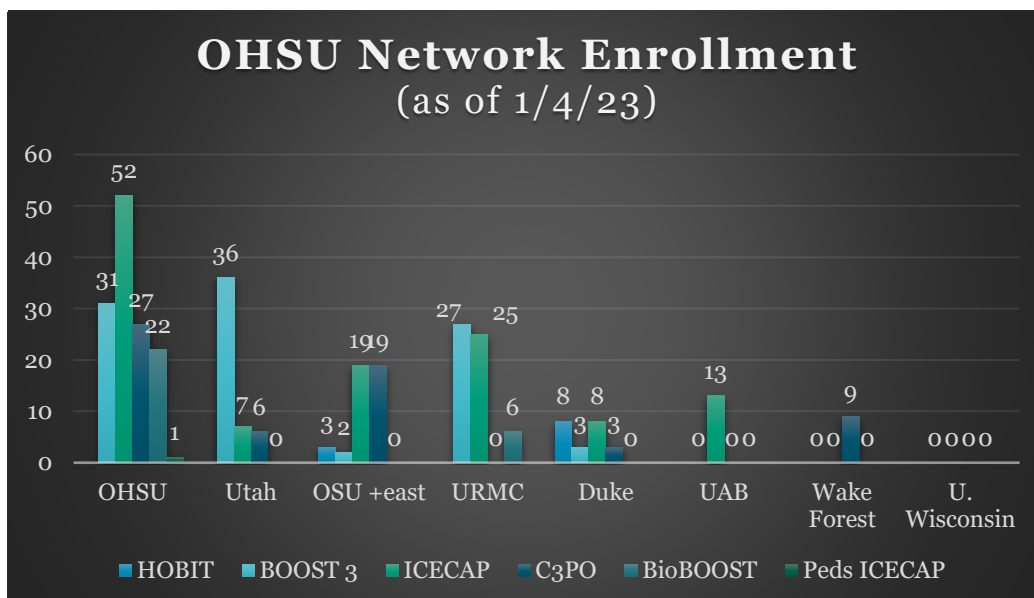
400 Mandalay Ave Clearwater FL 33767

[hiltonclearwaterbeach.hilton.com](https://www.hiltonclearwaterbeach.hilton.com)

The link to reserve rooms at the venue is https://umich.qualtrics.com/jfe/form/SV_djrLnpLRF3l7bLM

The SIREN leadership is expecting the Hub PI's and a coordinator and/or program manager to attend. Unfortunately, there are no travel funds and room availability is limited. These dates were chosen to overlap with the NAEMSP annual meeting.

Total OHSU Network enrollment: 320



BOOST 3 NEWS & UPDATES

- BOOST 3 enrollments: 438 (Target enrollment 1094)
- **OHSU Network Enrollment: 99**
- A recording of the investigator meeting is now available on the BOOST3 [website](#).
- Big shout out to our URMC-Strong Memorial & OHSU. We have enrolled 5 BOOST3 subjects since our last newsletter! Strong work team!
- Bio-BOOST enrollments: 83; **OHSU Network: 28.**
- ELECTROBOOST enrollment: 20 **OHSU Network: 0**
 - OHSU's Electro-BOOST team is hoping to finish training and start enrollment in January

HOBIT NEWS & UPDATES

- Enrollment: 93 (Goal:200)
- **OHSU Network enrollment: 11**
- BioHOBIT Enrollment: 24

ICECAP NEWS & UPDATES

- ICECAP Enrollments: 621 (Goal: 1800)
- **OHSU Network Enrollment: 126**
- Our HUB has enrolled 3 ICECAP subjects since our last newsletter

PEDS ICECAP & UPDATES

- P-ICECAP Enrollments: 28 (Goal: 900)
- **OHSU Network Enrollment: 1**
- There was a great group discussion about screen fails with Moni and Carol last week. If you were unable to attend, here is the link for the recording: https://umich.zoom.us/rec/share/_gIzm-8JkWkoD8VQf6LZoTFxx4cRiPQg28t89rDfGevBraurFEOb1adJAZOBYn4.r2J9A9eevWAH3QTV
- CCC office hours are Mondays from 3-4 EST, and Carol and/or Moni will be available.
 - The link is: <https://umich.zoom.us/j/96979875686> Passcode: 758039
- P-ICECAP Steering Committee meetings are held the week of the month. Here is the link: <https://umich.zoom.us/j/95238964868?pwd=QjNHUjZvM2RCOU5LYkxTYWhEc2E3QT09>

Meeting ID: 952 3896 4868

Passcode: 259968

One tap mobile

+13126266799,,95238964868# US (Chicago)

+16468769923,,95238964868# US (New York)

- If you have a question for the CCC, it is best to email this address: picecap-contact@umich.edu . This goes to multiple people and will get you the quickest and most accurate answer.

NEW STUDY ALERT: WIND SURFER

SIREN WINDSURFER Trial

WIN Ratio Analysis to Determine a Strategy of Non-Invasive Support for Respiratory Failure in the Emergency Department

To indicate your interest in participating in the SIREN WINDSURFER trial, please complete these tasks no later than **Tuesday, January 10, 2023**:

- 1) Complete the site survey using the Qualtrics link or QR code:
https://uarizona.co1.qualtrics.com/jfe/form/SV_82ny5Wj04WNpDeK



- 2) Edit, sign and return the site letter of support via the Qualtrics link.

Completion of this survey will likely require input from respiratory therapy managers, medical directors and SIREN hub/spoke staff. Paper responses are also acceptable – send to Jarrod Mosier, MD (jmosier@arizona.edu).

For more information or questions, please contact Jarrod Mosier, MD (jmosier@arizona.edu) or Mark Tidswell, MD (Mark.Tidswell@baystatehealth.org), or Henry Wang, MD, MS (henry.wang@osumc.edu),

Q. What is WINDSURFER?

A. WINDSURFER is a national clinical trial to determine the optimal noninvasive respiratory support strategy for emergency department patients presenting with undifferentiated acute hypoxemic respiratory failure. WINDSURFER will enroll patients using Exception from Informed Consent (EFIC) and will randomize 500 patients to either a noninvasive positive pressure ventilation strategy (using either continuous positive airway pressure or bilevel positive airway pressure) or a high flow nasal oxygen strategy (using a high-flow nasal cannula system). The trial will compare the strategies using a hierarchical composite outcome (major adverse pulmonary events) which includes death, mechanical ventilation days, and noninvasive respiratory support hours.

Q. What is the funding for WINDSURFER?

A. We are preparing a grant application for submission to NIH/NHLBI in early 2023, with the goal of starting the trial in 2024.

Q. How many sites will be included in WINDSURFER?

A. We expect to include 10 sites in the trial. The final sites will be selected just prior to project initiation. They will consider factors such as experience with critical care research, experience with EFIC, enrollment capacity, regional location, and patient diversity.

Q. Who will lead the trial?

A. The Principal Investigators will be Jarrod Mosier, MD (MPI – University of Arizona), Mark Tidswell, MD (MPI – Baystate Medical Center), and Henry Wang, MD, MS (corresponding MPI – The Ohio State

University). The lead statistician is Lai Wei, PhD (DCC MPI - The Ohio State University). The University of Michigan SIREN Clinical Coordinating Center (William Meurer, PI) and the Medical University of South Carolina SIREN Data Coordinating Center (Valerie Durkalski, DCC corresponding MPI) will coordinate execution of the trial.

Q. What is the definition of a WINDSURFER Enrolling Site

A. An enrolling site will consist of a defined SIREN spoke or hub hospital. You may propose more than 1 hospital, but the start-up and close-out payments will be fixed by site.

Q. What are important considerations for WINDSURFER site selection?

- Candidate emergency departments (ED) should have experience with both NIPPV and HFNO for treating respiratory failure. EDs should have both technologies immediately available for clinical use in the Emergency Department.
- Sites should have a history of collaboration between the ED and ICU teams in executing clinical trials.
- Sites should have adequate patient volume with acute hypoxemic respiratory failure to enroll 1-2 patients per month over 5 years.
- Sites should have an adequate research infrastructure to support enrollment of 1-2 patients per month over 5 years.
- Sites should have prior Exception From Informed Consent experience.
Sites should have support from SIREN hub, ED, ICU, and hospital medicine leadership.

CTMC SERIES PRESENTATION LINKS

- The Clinical Trials Methodology Course has announced the 2022 FALL webinar series schedule.
Please note that the schedule has been updated since it was last sent out in spring
- Thank you to all who could attend the most recent webinar on the 28th of October that focused on **Optimizing Clinical Trial Design in Rare Disease**. If you missed out on this presentation, there is a link listed below to the YouTube channel and here is the link to the course webinar page:
<https://siren.network/training/ctmc/ctmc-webinars>
- Need to catch up on the last webinar? Find the presentation here:
<https://www.youtube.com/watch?v=O6IoiLXVa44>
- Webinar schedule & other past recordings: <https://siren.network/training/ctmc/ctmc-webinars>

GLOSSARY OF FREQUENTLY USED ABBREVIATIONS

- CCC = Central Coordinating Center (i.e., University of Michigan)
- DCC – Data Coordinating Center (i.e., Medical University of South Carolina)
- EFIC= Exception from informed consent
- CC = Community Consultation
- PD = Public Disclosure
- cIRB = Central IRB (in this case Advarra)