OHSU SIREN NETWORK NEWS

CALENDAR

2/7 1pm ET Study Coordinator Meeting – Zoom Link (Meeting ID: 989 9320 6584 Passcode: 361919)

2/9 3-4pm ET Finance Committee Call – Web Link

2/15 1pm ET Journal Club –Click Here

2/22 12pm ET : Steering Committee
Zoom Link (Meeting ID:979 0254 5896 Passcode: 838488)

3/7 1pm ET Study Coordinator Meeting – Zoom Link (Meeting ID: 989 9320 6584 Passcode: 361919)

Contact us:
Jenny Cook, Hub Project Manager, 503.494.1230
cookjen@ohsu.edu
OHSU SIREN Website
Twitter: @OHSU_CPREM
Co-PI's: Mo Daya, Bory Kea
OHSU Lead Study Coordinator: Keeley McConnell
OHSU Finanace Manager: Denise Griffiths

NEWSLETTER AT A GLANCE

NETWORK NEWS & UPDATES

We have some great news this month! We have received the official Notice of Award from the NIH for years 6-10 of our OHSU SIREN Network. The new award starts on February 1st, 2023, and will run for 5 years until 01/31/2028. The SIREN Award Hub network grew, adding four new hubs to the network this funding cycle. Yale, UC Davis, Duke, and Hopkins are new, and 8 hubs were renewed: University of Chicago, Pittsburgh, OHSU, Temple, University of Washington, VCU, University of Minnesota, Wayne State, and UCLA.
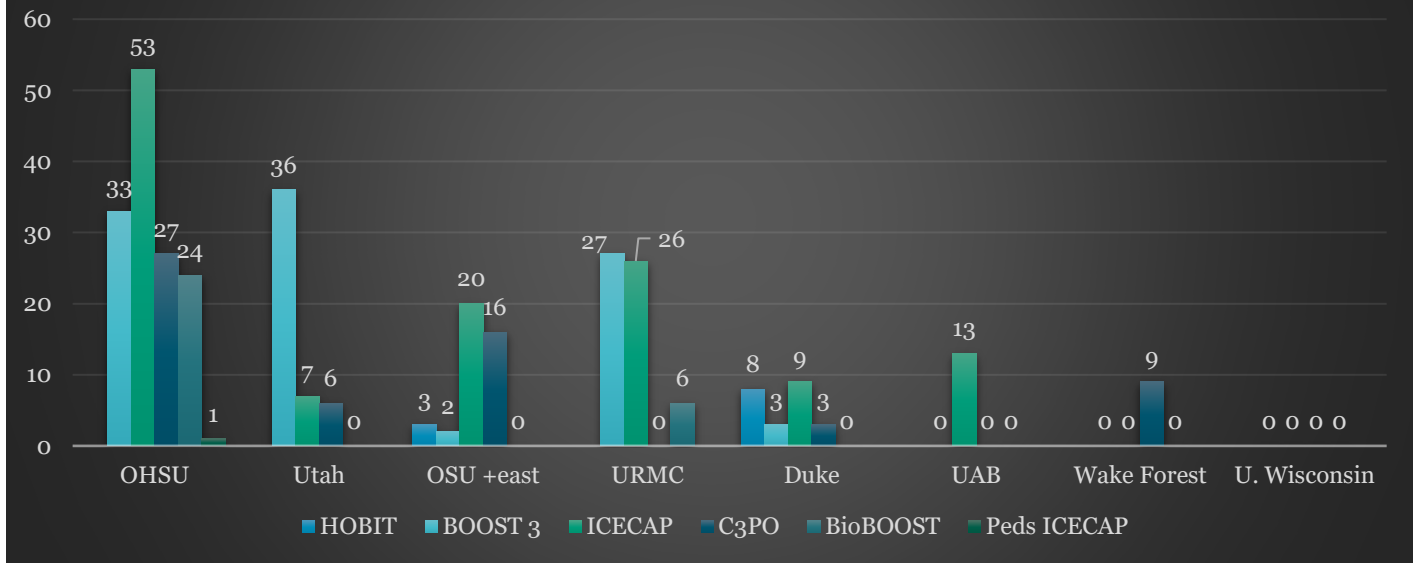
Wake Forest has joined Duke's hub. Our network now consists of

1) OHSU (award hub)
   a) OHSU-Adventist (spoke)
   b) OHSU-Doernbecher Children's(spoke)
2) The Ohio State University (Hub)
   a) OSU-East (spoke of OSU)
3) University of Alabama – Birmingham (spoke)
4) University of Rochester Medical Center – Strong Memorial (spoke)
5) University of Utah (hub)
6) University of Wisconsin (spoke)

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!

Total OHSU Network enrollment: 332

OHSU Network Enrollment
(as of 01/30/2023)

Legend: HOBIT, BOOST 3, ICECAP, C3PO, BioBOOST, Peds ICECAP

- OHSU: 33, 53, 27, 24, 1
- Utah: 36, 7, 6, 0
- OSU +east: 3, 2, 20, 16, 0
- URMC: 27, 26, 0, 6
- Duke: 8, 3, 9, 3, 0
- UAB: 13, 0, 0, 0
- Wake Forest: 0, 0, 9, 0
- U. Wisconsin: 0, 0, 0, 0

Important Reminder: The SIREN award is co-funded by the National Institute of Neurological Disorders and Stroke (NINDS) and National Heart, Lung and Blood Institute (NHLBI). All publications, posters, oral presentations at scientific meetings, seminars, and any other forum in which results of this co-funded research are presented must include a formal acknowledgment of the NINDS/NHLBI support, citing the NINDS grant number as identified on this award document. Our OHSU Network Award # is: U24NS100657

MILESTONES AND TRAINING FELLOWSHIP UPDATE

A. **Milestones for year 6:**

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

B. **Training Fellowship:** The application process for HONE-IT, the OHSU Hub training program, is being finalized, and details will be distributed this month. Thank you for your patience, and we are excited to launch this program very soon.

SOP SPOTLIGHT

As a part of the new SIREN award notice, we 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. We will also be spotlighting a monthly SOP in our newsletter for your review.

As we head into our new award year, we want to highlight the **Responsibilities of the Site Investigators** SOP for your review. This SOP aims to describe the roles and responsibilities of SIREN site investigators.

SIREN SOP General Responsibilities of Investigators:

The site investigator assumes **full responsibility** for the conduct of the study at her site, including:

a.   Protecting the rights and safety of research participants.

b.   Protecting the health information and confidentiality of research participants.

c.   Ensuring that the investigation is conducted according to local and federal guidelines and regulations.

d.   Obtaining informed consent from each research participant or their legally authorized representative, or complying with all requirements for waiver or exception from informed consent.

e.   Providing all information necessary for ER-CIRB initial and continuing review of the study.

f.   Maintain adequate and appropriate study documentation, including source documents, institutional regulatory communications, and adverse experience reports.

g.   Communicating with SIREN CCC and DCC and engaging in network activities in a prompt conscientious manner.

This SOP also details the investigator's responsibilities for delegation of authority, maintaining site records, IRB interactions, and other specific responsibilities regarding finance management, spoke management, and ensuring that the management of necessary credentials and trainings are completed to participate in an NIH trial.

Please take a few minutes to review the SOP at this following link: **Responsibilities of the Investigator**

BOOST 3 NEWS & UPDATES

- BOOST 3 enrollments: 446 (Target enrollment 1094)
- **OHSU Network Enrollment: 101**
- **FEBRUARY DATA LOCK:** A DSMB meeting is scheduled at the end of the month to review the progress and data of the trial. To prepare for this meeting, the DCC requests that all subject data be up-to-date in WebDCU by **February 24th, 2023.**
- **The DCC asks that all sites pay extra attention to upcoming automated WebDCU emails. For sites that are having a more difficult time with data entry due to institutional operation issues (insufficient staff, etc.) Zeke and Sara will reach out with separate correspondence in the upcoming week.**
- Our HUB has enrolled **4** BOOST3 subjects since our last newsletter! Please continue your diligent patient screening.
- 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 February

ICECAP NEWS & UPDATES

- ICECAP Enrollments: 648 (Goal: 1800)
- **OHSU Network Enrollment: 130**
- Our HUB has enrolled **7** ICECAP subjects since our last newsletter!!! Way to go teams! It has been a busy start to the new year.
- Please be mindful of items that require your attention under the 'Alerts' tab over the next few weeks, as the DCC is preparing the next data transfer for the Data and Safety Monitoring Board (DSMB) meeting. The DCC will reach out to sites individually with outstanding data entry toward the end of this month.

PEDS ICECAP & UPDATES

- P-ICECAP Enrollments: 35 (Goal: 900)
- **OHSU Network Enrollment: 1**
- Please be mindful of items that require your attention under the 'Alerts' tab over the next few weeks, as the DCC is preparing the next data transfer for the Data and Safety Monitoring Board (DSMB) meeting. The DCC will reach out to sites individually with outstanding data entry toward the end of this month.
- There are new training and education materials on the P-ICECAP website. You can find video training for E-Consent, Randomization, and Reporting SAE's.
- 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 on the third Thursday 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.