



OHSU SIREN NETWORK NEWS

Issue: Jan/Feb 2022

CALENDAR

2/1 1 pm ET Study

Coordinator Meeting –

[Zoom Link \(Meeting ID:](#)

[931 9105 3000](#)

[Passcode: 175158\)](#)

2/10 3-4pm ET Finance

Committee Call – [Web](#)

[Link](#)

2/23 12-1:30pm ET

Steering Committee

Meeting – [Zoom Link](#)

[\(Meeting ID: 933 6447](#)

[5099 Passcode: 521223\)](#)

3/1 1pm ET Study

Coordinator Meeting

[Zoom Link](#); Meeting ID:

919 3380 5008

Passcode: 172195

Contact us: Jenny Cook,

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[OHSU SIREN Website](#)

Twitter:

[@OHSU_CPREM](#)

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THE SIREN RENEWAL RFA

Thank you, team, for your help in pulling together letters of support, data, and supporting documents for our network renewal application. Fingers crossed, we will be renewed. We will keep you updated as we receive additional information during the review process.

We want to highlight a couple of items from the grant:

1. The proposed "HONE-IT" program for early-stage investigators.

SIREN Hub—

OHSU NETWORK EMERGENCY INTENSIVE TRAINING (HONE-IT)

The purpose of HONE-IT is to train the next generation of multidisciplinary physician-scientists in emergency care research, focusing on clinical trials methodology and experiential learning through SIREN. We have designed the program to function either as a stand-alone career development program or interface with existing research training programs (e.g., fellowships and other career development awards).

The **career development aims** are: 1) a training experience built on the core elements of didactic education in research methods, a mentored research experience, and academic faculty development; 2) multidisciplinary mentoring; and 3) incorporation of scholars into SIREN network activities, trials, and work groups.

To maximize training opportunities and impact, we will select two physician-scientist scholars per year (a total of 10 scholars over the 5-year SIREN grant cycle), with a target of ≥ 1 scholar per site across the 8 sites. Training duration will be two years per scholar, with a research budget of \$25,000 per scholar to be spent over 2 years.

Because the program does not cover scholar FTE, the primary department is expected to provide at least 50% protected time for research and training through departmental funding or other training awards.

Eligible scholars include fellows and faculty at the Clinical Instructor or Assistant Professor level from any discipline involved in emergency or acute care. The Hub will provide the core administrative services, integration of scholars into the SIREN network, inter-site training opportunities, additional mentorship,

oversight, and opportunities for collaboration. Each scholar will remain at their home site, with primary mentorship provided at their home site. Additional mentors can be external. **To have a scholar, the site must actively participate in a SIREN trial and integrate the scholar into trial activities at their site.**

Dr. Craig Newgard will direct the program, and Jenny Cook will serve as the program administrator. We will create a Training Advisory Council (TAC) of Dr. Newgard and one member from each of the 7 spoke sites to recruit potential scholars, guide scholar selection, review and critique of scholar research proposals, monitor scholar progress, assess mentoring, evaluate the program, and assist with challenges and barriers. The TAC will meet every 6 months by video conference and use a rigorous evaluation process to assess scholars and the program.

If our Hub is renewed, we will provide more info on the application process for the program at that time.

2. Case Report Completion timeliness and accuracy

Trial	Funding Source	Number of Active Sites Affiliated with Hub ¹	Total Enrollment at Hub and affiliated Sites	Total Enrollment (from all clinical sites)	Relative Enrollment Ranking	Participant Retention N(%) ²	Participants with Eligibility Deviations N(%)	Data Accuracy (Data Entry Error Rate) % ³	Data timeliness (On-time CRF submission) % ⁴
BOOST	NINDS	5	63	274	1.0/11	60 (95.2)	3 (4.8)	0.6	60.6
C3PO	NHLBI	6	61	511	5.0/10	60 (98.4)	0 (0.0)	0.3	81.2
HOBIT	NINDS	1	9	74	2.5/7	9 (100.0)	1 (11.1)	0.3	65.5
ICECAP	NHLBI	7	70	365	1.0/11	70 (100.0)	6 (8.6)	1.3	69.3

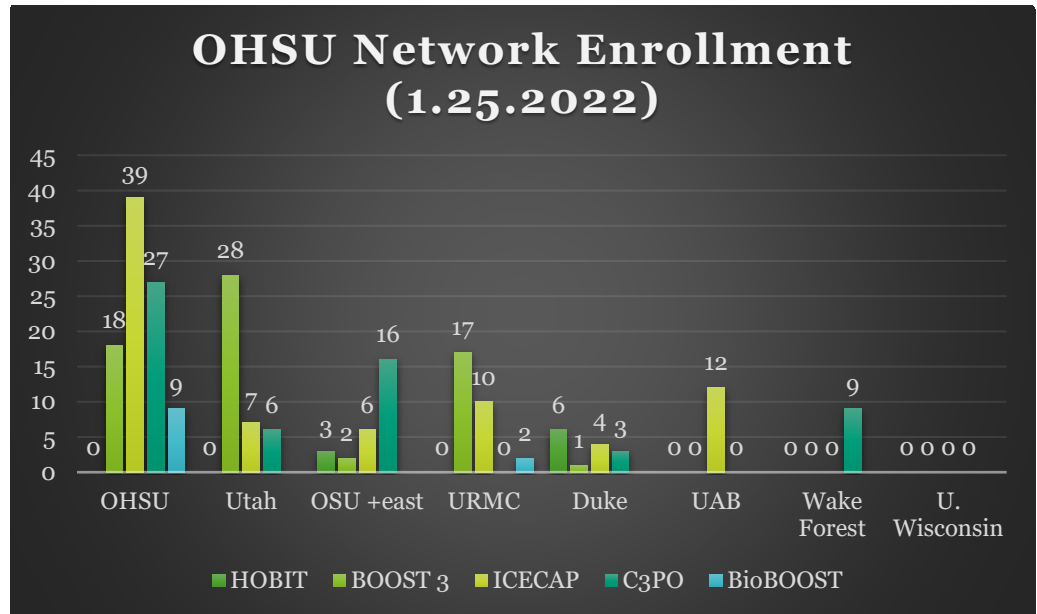
Highlighted above are the currently active trials. Overall, we have performed consistently in all trials; however, our data timeliness is still not on target. While we know some delays in case report form completion are unavoidable due to data not being available in time and staffing shortages and other barriers that have been present over the last 2 years, there is room for improvement in the timeliness of our submissions. **Our goal is to improve our data timeliness over the next year with an aim to reach 80% in all active trials.** In the CRF completion guidelines for each trial, a submission timeline is available. Please make sure your **coordinators and PI's** are aware of this completion timeline and are meeting the expected standards in most cases. Alerts will also pop up in WebDCU once a form is officially overdue as long as the visit has been populated in the subjects' CRF binder.

We will be scheduling study-specific calls for all of our sites participating in that trial to join in and discuss challenges, best practices, barriers, and solutions, so we can all continue to be successful and meet our goal of improving our data timeliness!

NETWORK NEWS & UPDATES

Total OHSU Network enrollment: 217

- Did you know that as of 1/25/2022 – our network has enrolled 17% of the subjects in all SIREN network trials? We have also enrolled more subjects than the 4 lowest enrolling SIREN networks combined. We also have enrolled 67 more subjects in the primary trials that then network in 2nd place right now. GREAT WORK!



CTMC WEBINAR

For those of you who could not attend last Friday's CTMC 2022 Informational webinar, please find the slides and recording at <https://siren.network/training/ctmc>

Please do not hesitate to reach out should you have any questions about the Clinical Trials Methodology Course. Contact: Courtney Miller coraymon@med.umich.edu

CTMC ENROLLMENT INFORMATION

We are pleased to announce that the NINDS Clinical Trials Methodology Course (CTMC) is accepting applications for the 2022 cohort. **The overarching goal of the CTMC is to help investigators develop scientifically rigorous yet practical clinical trial protocols.** Our focus is on investigators who have not previously designed their own prospective, interventional clinical trials.

Course: There is a combination of distance learning activities and a **REQUIRED** residential course, along with small group mentorship from experienced clinical trialists and biostatisticians. The residential part of the course will be held **July 18 – 21, 2022, in Iowa City, IA.** Funding for travel (within the US) and accommodations will be provided for participants.

Who Should Apply? Qualified applicants from clinical disciplines focused on neurological disease or injury (including but not limited to pediatric and rare diseases), along with biostatisticians working on projects with clinical neuroscience researchers, should apply. **All preliminary trial ideas are encouraged, but it is REQUIRED that protocols be focused on the clinical neurosciences.** Trainees should have content area mentors to assist them with the science and implementation of their project. A small number of projects may qualify for additional work using clinical trial simulation.

Application: [2022 CTMC Application Instructions](#)

[2022 Advanced Track Application Instructions](#) (open **only** to 2021 cohort)

DEADLINE: The application submission deadline is February 28, 2022, at midnight Pacific Time. Application forms and additional details are available on the course website:

<https://siren.network/training/ctmc>. Early applications may be considered for early acceptance.

Have Questions? Please contact NINDS-CTMC-Info@umich.edu or [William Meurer, MD, MS](#)

HOBIT NEWS & UPDATES

- Enrollment: 74 (Goal:200)
- **OHSU Network enrollment: 9**

BOOST 3 NEWS & UPDATES

- BOOST 3 enrollments: 284 (Target enrollment 1094)
- **OHSU Network Enrollment: 66.**
- Bio-BOOST enrollments:32 ; **OHSU Network: 9.**
- ELECTROBOOST has started! There have been 3 subjects enrolled between the 2 sites currently open.

ICECAP NEWS & UPDATES

- Enrollment: 397 (Goal: 1800)
- **OHSU Network Enrollment: 78**
- Potential IN-PERSON investigator/coordinator meeting in early May for ICECAP
- Do you tweet? Be sure to follow Dr. Will Meurer, ICECAP PI @goalsofhair
- **Save the date, more details to follow:**
 - ICECAP Investigator meeting: 5/9-5/10; New Orleans (Pre-SAEM)
 - PedsICECAP Investigator meeting: May 4-6; Clearwater, FL

C3PO NEWS & UPDATES

- Have an idea for a secondary research paper? Submit your C3PO ideas here: https://siren.network/clinical-trials/c3po/research_ideas
- If you would like to join a writing group for a trial idea already on the website, contact the lead author to request to be added to the team (list available through the link above).

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)