



# OHSU SIREN NETWORK NEWS

Issue: January 2020

## CALENDAR

1/15 1-2pm ET Journal Club

<https://bluejeans.com/7342322138>

1/29 Steering Committee In Person Meeting – Florida

1/30-1/31 ICECAP Investigator Meeting - Florida

2/4 1pm ET SIREN Study Coordinator – Bluejeans conference link in e-mail

2/13 3pm ET Finance Committee meeting

For working group meeting times visit:

[SIREN CCC Events Calendar](#)

Contact us: Jenny Cook, Coordinator, 503.494.1230

[cookjen@ohsu.edu](mailto:cookjen@ohsu.edu)

[OHSU SIREN Website](#)

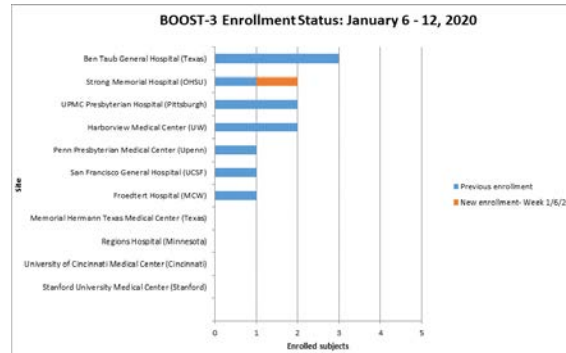
Follow our research team on

Twitter: [@OHSU\\_CPREM](#)

## ONGOING TRIALS

### BOOST 3 NEWS AND UPDATES

- **BOOST 3 enrollments: 12** (Target enrollment 1094)



- **OHSU Network Enrollment: 2 – URM** (Great work team URM)

- **BOOST Data Freeze – First DSMB data freeze** occurred on 1/10/20

- **CarePath Update – BOOST 3 sites** should have received an e-mail on 12/27 with the link to

update the CarePath Software. If you have not yet downloaded this, please do so in the near future.

- **Link 2** (CNS Reader/CarePath):

<http://go.moberg.com/CNSReader-BOOST-App-PC-Z.00.29>  
MD5: 3f9faedbd4da55cc4c8adc3a07784a31

### HOBIT – Hyperbaric Oxygen Brain Injury Treatment Trial

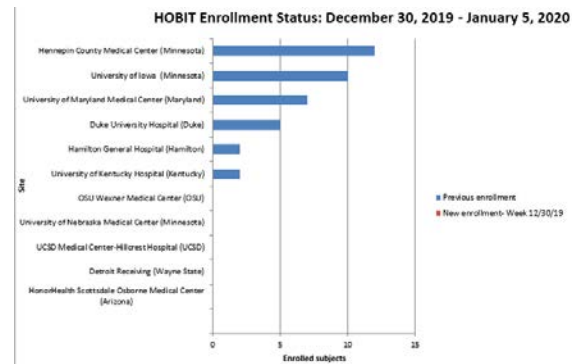
- Enrollment: 38 (Goal:200)

- 10 Active sites

- New subject handout approved – Visit the website to download.

<https://siren.network/clinical-trials/hobit/toolbox#IRB>

- EFIC – Exception from Informed Consent has been



approved for HOBIT!

- **In order for your site to enroll patients under EFIC, you must seek individual cIRB approval.**

- To get started, please review the EFIC start-up activities and tasks outlined in the [HOBIT Milestone Document](#).
- The cIRB approved [EFIC plan](#) is available in the [EFIC Resources](#) tab of HOBITtrial.org

- **Use protocol version 5 until your site is approved for the EFIC process.**

- MOP Section Update – 3 Exception from Informed Consent– be sure to review!

- Have additional questions? Contact Natalie Fisher @ [brownnat@med.umich.edu](mailto:brownnat@med.umich.edu)

## OHSU SIREN QUARTERLY MEETING

Thank you to all our sites who were able to join – it was great to have strong representation from across our network. We discussed trial progress at sites, preparations for the upcoming ICECAP trial. We have a couple of sites who were not ‘selected’ to be part of the initial rollout of ICECAP. The OHSU leadership team is looking into the reasons why the number of sites being allowed into ICECAP initially is being limited. Once we have more information we will share that with everyone.

Other items discussed:

- cIRB population ‘issues’ – the cIRB is being very meticulous in site community consultation efforts and ensuring that populations you list in your local context information have indeed been reached in the consultation process. Be sure to review what you have provided to the cIRB, and confirm you are reaching the appropriate groups, as this will help keep you from being delayed in the cIRB process.
- UAB has a ED based cardiac arrest service and has offered their expertise (as needed) for our network in ICECAP. If you would like to talk with their site more, please let Jenny know and we may arrange a group discussion after the investigator meeting if there is interest from sites.

Tentatively we are planning to hold our next Quarterly meeting at SAEM, and will provide a conference call method for those who are not able/planning to attend that conference.

## JOURNAL CLUB

1/15/2020 – Below are the articles that will be discussed – join if you are able:

To join the Meeting:

<https://bluejeans.com/7342322138>

To join via Room System:

Video Conferencing System: bjn.vc -or-199.48.152.152

**D. Mark Courtney, MD, MSc will present:** Kearon C, de Wit K, Parpia S, Schulman S, Afilalo M, Hirsch A, et al. Diagnosis of Pulmonary Embolism with D-Dimer Adjusted to Clinical Probability. NEJM 2019;381:2125-34.



**Jaideep Kapur, MB, BS, PhD will present:** Kapur J, Elm J, Chamberlain JM, Barsan W, Cloyd J, Lowenstein D, et al. Randomized Trial of Three Anticonvulsant Medications for Status Epilepticus. NEJM 2019;381:2103-13.



## UPCOMING TRIALS

### **ICECAP = The Influence of Cooling duration on Efficacy in Cardiac Arrest Patients**

Brief summary: ICECAP study will enroll comatose adult survivors of out of hospital cardiac arrest that have already been rapidly cooled using a definitive temperature control method to a target of 32-34°C. Enrolled subjects will be randomized to different cooling durations using an adaptive design. Those with and without initial shockable rhythms will be studied as distinct populations (maximum of 1800 subjects over four years). ICECAP will determine if identifying an optimal duration of cooling can improve outcomes, and if development of a duration response curve can substantiate efficacy in a wider patient population.

- Investigators meeting planned for 1/30-1/31 –Please double check the hotel reservation list for your site to confirm everything is correct!
- MOP and CRF's are in development and not ready to be circulated. Stay tuned.
- Webinar planned for 12/19 to discuss more trial logistics
- FINANCIAL:
  - There will be 5,000 in startup funds for the first 50 sites to enroll. If you have any spokes, or additional sites you want to bring on that are not in the current list, it is likely they will not receive startup funds.
  - Per subject payment will be \$10,000 inclusive of indirect's.
- Preparation activities
  - Please check with your EMS agency partners about what cardiac arrest data you are able to obtain regularly.
  - Goals of care conversations will need to be performed as part of the enrollment process. This is an important point to discuss with your trial team, and providers who will be involved in patient care.
- OHSU Network sites participating in ICECAP – UAB, OSU, OHSU, URM, Utah, Duke, Wake Forest

## GLOSSARY OF FREQUENTLY USED ABBREVIATIONS

CCC = Central Coordinating Center (i.e. University of Michigan)

EFIC= Exception from informed consent

CC = Community Consultation

PD = Public Disclosure

cIRB = Central IRB (in this case Advarra)