



# OHSU SIREN NETWORK NEWS

Issue: May 2021

## CALENDAR

5/4 1-2pm ET Study

Coordinator Meeting – [Web Link](#)

5/13 3-4pm ET Finance

Committee Call – [Web Link](#)

5/26 12-1:30pm ET Steering

Committee Meeting – [Zoom Link](#)

5/19 1pm ET Journal Club

Link TBD

6/1 1-2pm ET Study

Coordinator Meeting – [Web Link](#)

Contact us: Jenny Cook,  
Coordinator, 503.494.1230  
[cookjen@ohsu.edu](mailto:cookjen@ohsu.edu)

[OHSU SIREN Website](#)

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

## Newsletter at a Glance

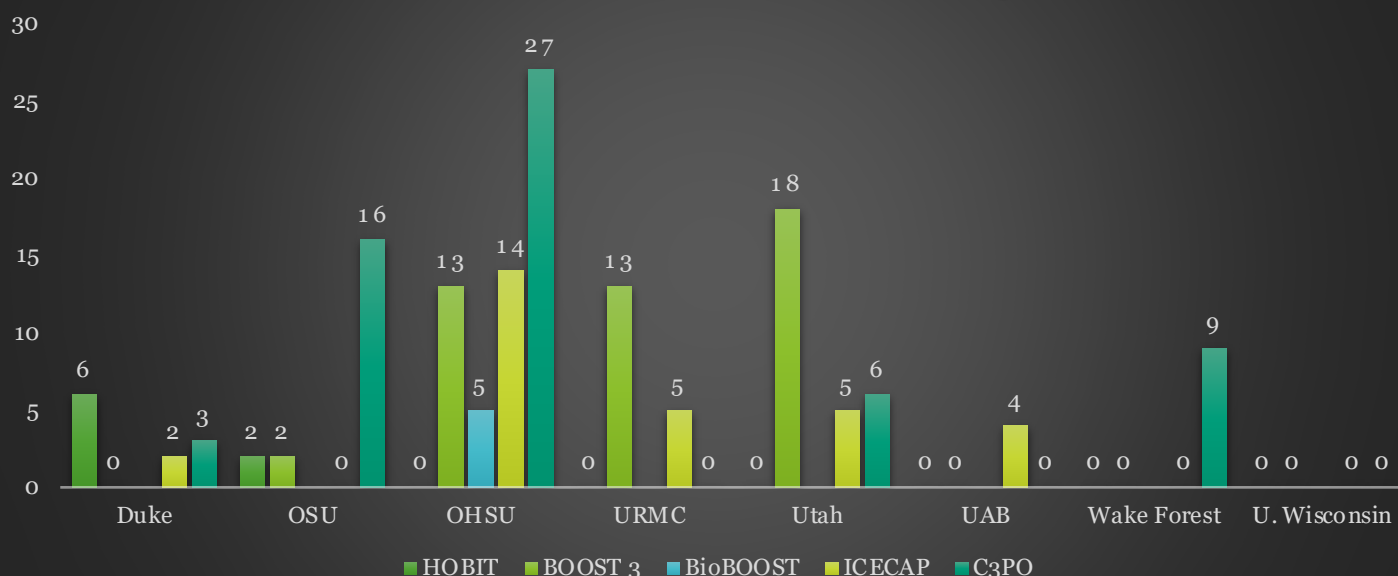
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## OHSU NETWORK PERFORMANCE AT A GLANCE

The OHSU network is the top performing network in SIREN. Fun Facts (and some to do's):

- #1 in BOOST3 Enrollments, 2<sup>nd</sup> in both HOBIT and ICECAP.
- 99.3% subject retention across all trials (1 lost to f/u)
- 95.9% CRF completion rate – 307 outstanding forms -can you complete your data today?
- #2 in regulatory document collection – 66 outstanding forms– any reg docs at your site that you can complete asap please?

## OHSU Network Enrollment (updated 4.29.21)



## CLINICAL TRIALS METHODOLOGY COURSE

We are happy to announce that the **Clinical Trials Methodology Course 2021 Webinar Series** will commence on **May 10<sup>th</sup> at 12:00p EDT**. Please feel free to share this with your colleagues - **all are welcome**. The detailed information is below. You may also **subscribe to the CTMC Google calendar** by clicking [here](#) (all the webinar dates/details are posted). Please email [ninds-ctmc-info@umich.edu](mailto:ninds-ctmc-info@umich.edu) with questions. Thank you!

***NOTE:** There is no video to view prior to or any preparation needed for this webinar.*

Session	Title	Presenter
May 10 <sup>th</sup> at 12p EDT Join the webinar at: <a href="https://umich.zoom.us/j/94619382835">https://umich.zoom.us/j/94619382835</a>	What do you want to learn? Pearls and Pitfalls when considering an early phase clinical trial	Will Meurer, MD

## SIREN FELLOWSHIP ANNOUNCEMENT

The SIREN Network has a new Fellowship program – an opportunity to provide mentorship to emerging researchers who will be the future leaders of emergency research in neurologic, heart, lung and blood conditions. Additional Information: [SIREN Fellowship webpage](#) and email questions to [Dr. Will Meurer](#).

### Expectations:

We anticipate the fellows would be embedded into the leadership teams of ongoing SIREN trials. The trial and Network PIs would work with the fellows to determine the roles and responsibilities. Each fellow would be placed on a trajectory to generate at least one peer-reviewed manuscript related to the experience. We anticipate the fellows will attend approximately 3-4 hours of weekly operational and planning calls and be involved in additional projects focused on planning, operations, and interpretation of the trials. Fellows would have additional expectations (present at SIREN journal club, and other opportunities tailored to individual goals) during the experience. Additionally, the fellows would be involved in the planning of new trials being considered by the Network. Fellows will be accepted on a rolling basis for approximately one-year terms, but multi-year experiences may be possible.

### Eligibility:

Candidates for the fellowship could be residents with protected time for research, fellows (in ACGME and non-ACGME programs), and early-career faculty with an interest in patient oriented emergency care research. Knowing that there are a variety of career pathways, there is not a specific time limit from completion of training in order to be eligible.

### Application Process:

Interested candidates should submit a biosketch with a personal statement indicating motivations and interest. Please be sure to cover what you hope to gain from this experience up front in your personal statement. SIREN leadership and the Education, Training and Collaboration Working Group will review applications and request additional information, including potential letters of support from departmental leadership / supervisor of the fellow.

[\*\*SIREN Fellowship Application Link\*\*](#)

## ICECAP NEWS & UPDATES

- Enrollment: 190 (Goal: 1800)
- **OHSU Network Enrollment: 28**
- Shout out to UAB for 3 enrollments in April!
- PREcision Care in Cardiac Arrest (PRECICECAP) contracts are in process – we are expecting this sub-study to start in the next month!
  - UAB will be participating in this sub-study
- PEDSICECAP received a good score, and the IDE has been submitted to the FDA for this sub-study

## BOOST 3 NEWS & UPDATES

- BOOST 3 enrollments: 163 (Target enrollment 1094)
- **OHSU Network Enrollment: 46**
- **Attention BOOST 3 site coordinators** – we'd like to find a time for our BOOST network study coordinators to meet and discuss best practices, challenges, creative solutions, etc. Please e-mail Jenny Cook ([cookjen@ohsu.edu](mailto:cookjen@ohsu.edu)) and let me know whom from your site should be invited to this call.
- The following FAQ is posted on the FAQs page. If you have questions please email [boost-contact@umich.edu](mailto:boost-contact@umich.edu).

### **Q: How can you do an FiO<sub>2</sub> challenge if the ventilator is already set at 100% FiO<sub>2</sub>?**

*A: Consider performing a blood gas to determine the safety of lowering the FiO<sub>2</sub> temporarily for the FiO<sub>2</sub> challenge.*

- If lowering FiO<sub>2</sub> below 100% results in lowering PbtO<sub>2</sub> by >5 mmHg, raise FiO<sub>2</sub> to 100% again. If that results in increase in PbtO<sub>2</sub> by at least 5 mmHg again, that is considered passing the FiO<sub>2</sub> challenge.
- If it is not feasible to lower the FiO<sub>2</sub>, consider doing a MAP or CO<sub>2</sub> challenge to determine if that raises the PbtO<sub>2</sub>. A MAP or CO<sub>2</sub> challenge should not be performed in subjects in the ICP-only group.
- If the second FiO<sub>2</sub> challenge again fails, further management will be determined by patient group.
- In the ICP+PbtO<sub>2</sub> (intervention) group, a non-functioning or mal-positioned PbtO<sub>2</sub> probe should be replaced within 2 hours if at all possible.
- In the ICP only (control) group, the study team will document that the PbtO<sub>2</sub> probe is unreliable but will not replace it. Do not inform the treatment team that the probe is malfunctioning in a blinded patient.
- You may check the FiO<sub>2</sub> daily in case it begins to function. This happens.

## C3PO NEWS & UPDATES

- Final Enrollment Total: **511 (61 subjects enrolled from our network)**
- Have an idea for a secondary research paper? Submit your C3PO ideas here: [https://siren.network/clinical-trials/c3po/research\\_ideas](https://siren.network/clinical-trials/c3po/research_ideas)
- On 4/27 your site should have received an e-mail with instruction on what to do with your leftover convalescent plasma. If you did not receive instruction, e-mail [c3po-contact@umich.edu](mailto:c3po-contact@umich.edu).
- **R2D2: “Recovering from SARS-CoV-2: Risk Factors Contributing to the Development of Post-Acute Sequelae of SARS-CoV-2 in Persons with Mild to Moderate COVID-19 Illness”** the follow-on project to C3PO is still awaiting a funding decision.

## HOBIT NEWS & UPDATES

- Enrollment: 57 (Goal: 200)
- **OHSU Network enrollment: 8**
- The following resources have been added to the HOBIT Trial.org toolbox under [Chamber Resources](#):
  - Monoplace Safety Technical Bulletins
    - Drip Monitor for Baxter 6201 Flo-Gard IV Pump
  - Technical Memo
    - Installation of the 60 Micron Particulate Filter for Magellan
    - Removal and Replacement of the Magellan Ventilator
- View the latest edition of the [HOBIT Newsletter](#).

## 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)

## HOBIT NEWSLETTER

Hyperbaric Oxygen in Brain Injury Treatment Trial

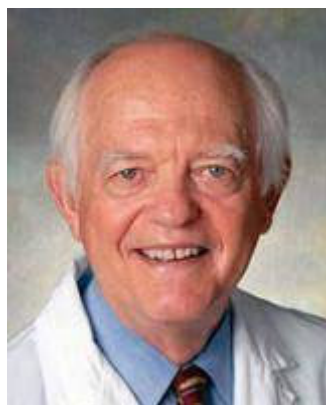
# HOBIT NEWSLETTER



April 30th, 2021

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**Dr. Gaylan Rockswold to be Keynote speaker for the “Eric P. Kindwall, MD Memorial Lecture” at the 2021 UHMS Annual Scientific Meeting**



Dr. Rockswold will present the HOBIT trial and speak on the nature of severe TBI. He will explain the role of oxygen in normal brain metabolism, versus the lack of oxygen (ischemia) in precipitating brain cell death and poor clinical outcome in severe TBI. He will discuss the potential efficacy of HBO<sub>2</sub> in the treatment of severe TBI and will also give a review of the pre-clinical and clinical data supporting the funding of the HOBIT Trial. The structure of the HOBIT Trial and progress to date will conclude the lecture.

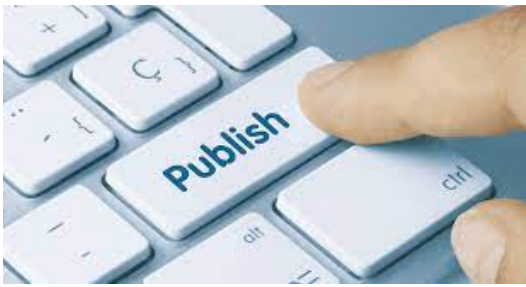
The UHMS Annual Scientific Meeting is viewed by an international audience of physicians, scientist, medical researchers, diving and aerospace experts, military researchers, and clinical hyperbaric practitioners.

We will provide a link to view Dr. Rockswold's recorded presentation sometime after the June 10th meeting.

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## ***HOBIT Publication Policy***

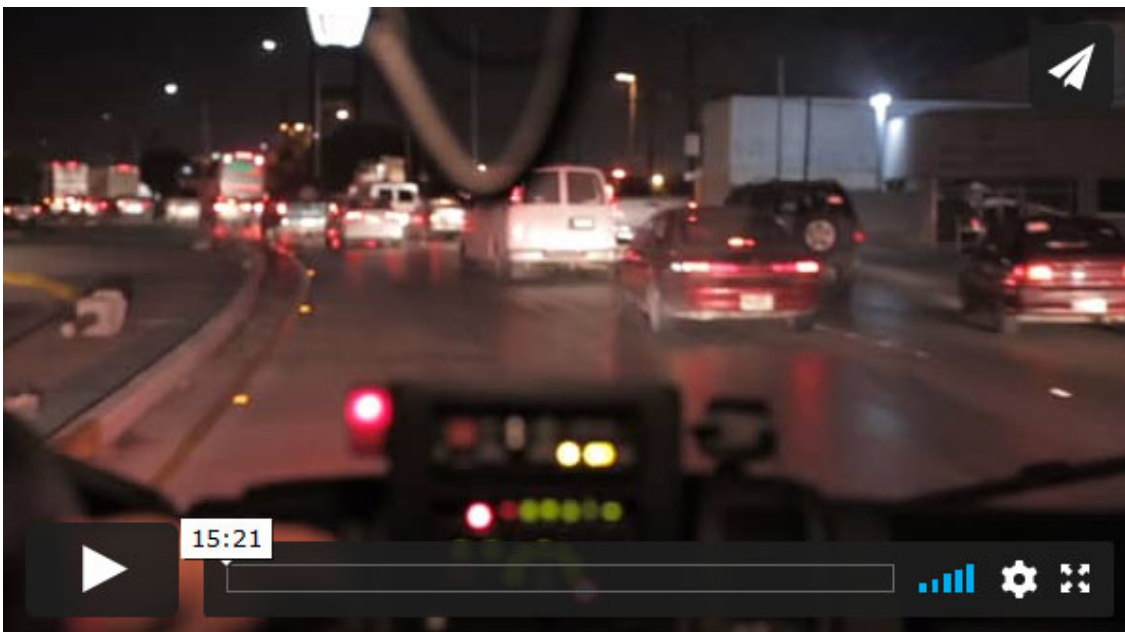
The HOBIT Publication Policy is available to review. Please click the link below.



## HOBIT Publication Policy

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## HOBIT Educational Video



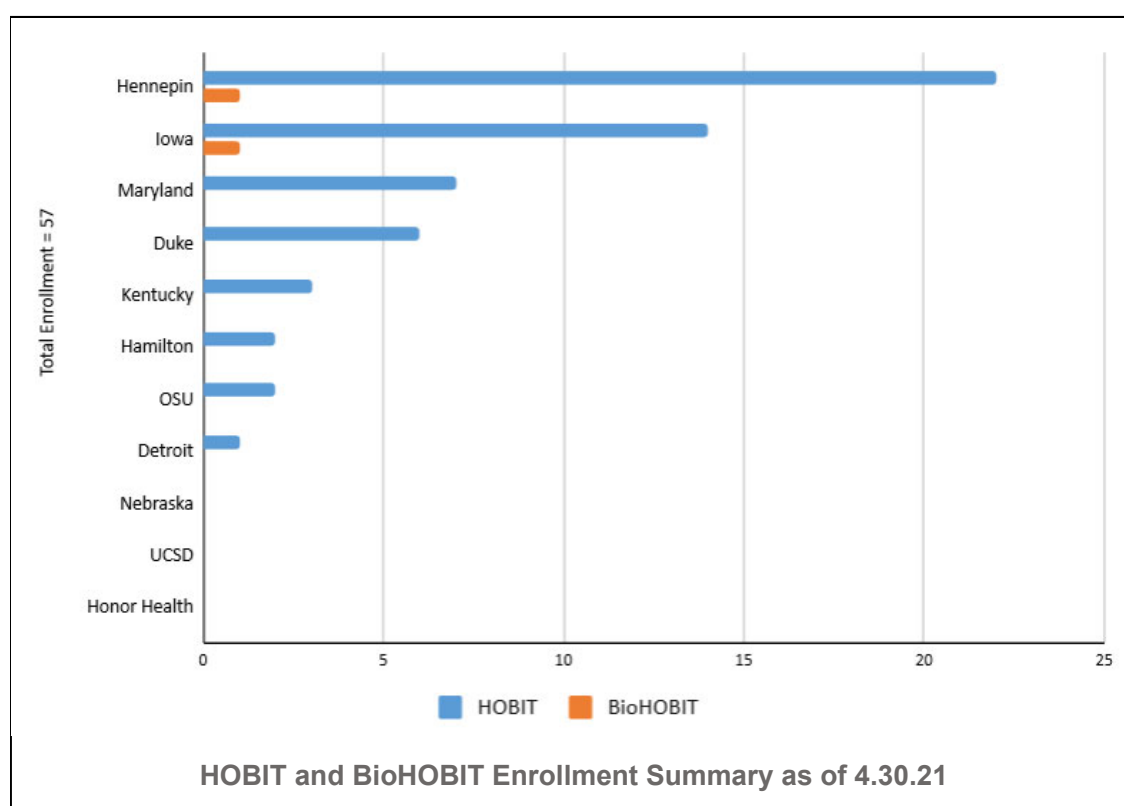
A video has been developed for the purpose of education, training and inspiring all research and clinical team members participating in HOBIT. The HOBIT Leadership Team's request is that you use this video as an opportunity to re-energize and inspire your intensivists, neurosurgeons, critical care staff, respiratory therapists, HBO technicians and all who have worked so hard on the HOBIT Trial.

Enrollment has been very slow due to COVID, but as this burden on our health care systems ease and trauma season approaches we have an opportunity to refocus our efforts on this important study.

As they are intended for research and clinical team education, the videos should not be used as participant recruitment materials. The Long Version (15 min) contains more comprehensive information about TBI and the HOBIT Study. The Short Version (7 min) is more specific to the HOBIT Study.

Video Links can be found on the HOBIT Website in the Toolbox:  
<https://siren.network/clinical-trials/hobit/toolbox#Video>

## ENROLLMENT UPDATE



## EFIC UPDATES

All sites should complete EFIC activities by July 1, 2021. Please let us know if you cannot make this deadline.



Duke University is our 1st site  
approved to enroll with EFIC

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## HOBIT TIPS

### Screening Tips

Please continue to screen potential subjects and add them to the screening log on an ongoing basis. Remember:

- Only add the primary reason for the screen failure
- Keep general comments short and concise
- "Other reasons" should be used only when the reason is not listed in WebDCU

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**HOBIT PI Hotline 24/7:** 1-833-HOBIT-PI (833-462-4874)  
**WebDCU Emergency Randomization Hotline:** 1-866-450-2016  
**HOBIT site management general questions:** [hobit-milestone@umich.edu](mailto:hobit-milestone@umich.edu)  
**Data Management Support:** Catherine Dillon [rileycp@muscc.edu](mailto:rileycp@muscc.edu)