



October 21, 2022

**Great job to our recent enrollers!**

**University of Maryland Medical Center  
Hennepin County Medical Center**

## UPCOMING MEETINGS



**SIREN Steering Committee**

Wednesday, October 26, 2022 12:00pm ET

**CQIP Meeting**

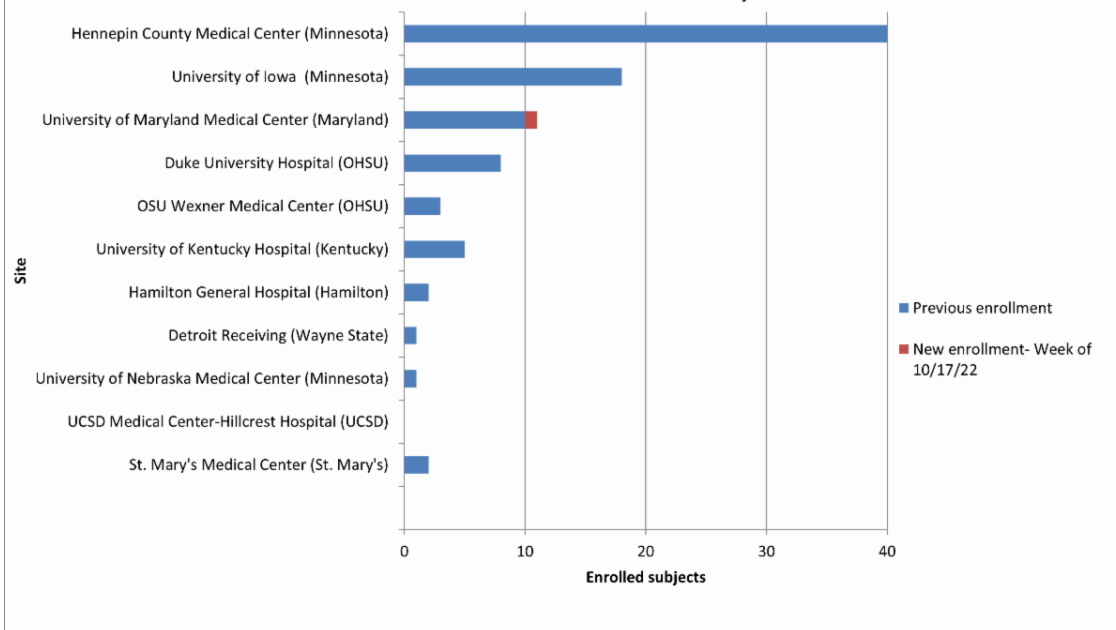
Monday, November 14, 2022 1:00pm ET

## ENROLLMENT

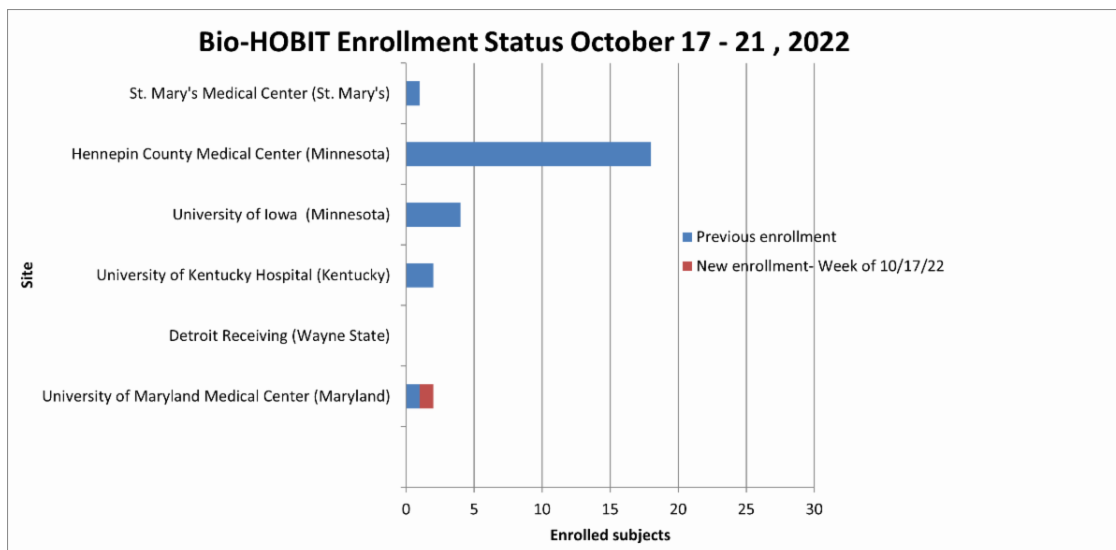
**HOBIT: 91 BioHOBIT: 27**

**\*\* Aim to enroll every HOBIT subject in BioHOBIT \*\***

### HOBIT Enrollment Status: October 17 - 21, 2022



### Bio-HOBIT Enrollment Status October 17 - 21, 2022



**Please continue to screen diligently and enter screen failures in WebDCU**

## UPDATES & RESOURCES

### Protocol Version 7

We recently amended the protocol to clarify that exacerbation of intracranial hypertension has always been an anticipated risk of participation in the trial. We anticipated that it could be caused by the stimulation inherent in transport to and from treatments in the chamber, by hypercarbia related to manual ventilation during transport or changes in mechanical ventilation during dives, or perhaps directly from treatment. We originally described these risks in the consent form and the protocol as risks of transportation to the chamber and as decreased cerebral perfusion pressure (the manifestation of intracranial hypertension). To avoid confusion and be even more inclusive in our language, we have now also explicitly included the term 'intracranial hypertension' to the list of expected adverse events in the protocol. This clarification of terminology only adds another way to describe the previously anticipated risks, and does not represent any new, incremental, or change in risks of

participation in the trial.

Please see the protocol changes outlined below:

Section of Change	Version 6	Version 7	Rationale
Title Page	Version Number 6 November 8th 2019	Version Number 7 October 10th 2022	
Header	HOBIT Protocol Version 6	HOBIT Protocol Version 7	
Signature Page	6, dated November 8th, 2019	7, dated October 10th, 2022	
Table of Contents			
1.3			Data Collection Schedule updated to reflect current CRF schedule
9.4		Intracranial hypertension (ICP > 22 mmHg) This is defined as intracranial pressure > 22 mmHg. This AE is not specific to HBO therapy. It is an expected sequela of GCS 3-8 TBI. However, it is also possible that HBO therapy including the transportation of patients from the ICU to the HBO chamber may result in an increase in intracranial pressure.	We have now listed intracranial hypertension as an expected adverse event. This is not a new expected adverse event. We have always considered intracranial pressure an expected adverse event. However, it was inadvertently omitted from the early versions of the protocol. Our consent form did indicate that there may be complications related to transport to the hyperbaric chamber, however, we did not explicitly state that intracranial hypertension was one of the expected complications. We are revising the protocol and consent form to make this statement explicit.

## New Informed Consent Forms

The HOBIT Informed Consent Form now includes the statement “Elevated intracranial pressure during HBOT or during transportation to the chamber (may occur in 2 - 10 out of 100 persons)” in the section **What are the possible risks and discomforts?**

The English and Spanish Informed Consent Forms and corresponding Advarra Approval Letters are now available in WebDCU. Please use these versions going forward and remove any old versions you may have printed.

To access these documents go to: HOBIT – Regulatory Document -Site Reg Doc Status – click on your site.

In addition, site specific eConsent links (English only) are updated and reflect the recent change. eConsent links are ready to use.

---

HOBIT Trial Contacts: [hobit-milestone@umich.edu](mailto:hobit-milestone@umich.edu) | [hobittrial.org](http://hobittrial.org)  
**Emergency** 24-Hour Study Hotline: 1-833-HOBIT-PI (833-462-4874)

HOBIT | 24 Frank Lloyd Wright Dr, Ann Arbor, MI 48105

[Unsubscribe brownnat@med.umich.edu](mailto:brownnat@med.umich.edu)

[Update Profile](#) | [Constant Contact Data Notice](#)

Sent by brownnat@med.umich.edu powered by



Try email marketing for free today!