HOBIT Newsletter - May 19, 2023

Hyperbaric Oxygen in Brain Injury Treatment Trial

SIREN Steering Committee Meeting
May 24 @ 12pm ET

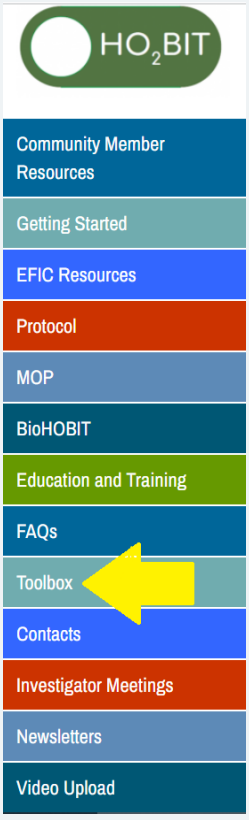
SIREN Study Coordinator Call
June 6 @ 1pm ET

HOBIT CQIP
June 12 @ 1pm ET

Congratulations to our recent enrolling site!

Hennepin County Medical Center

Reminder of HOBIT Resources



The HOBITTRIAL.org toolbox offers a multitude of resources for sites! Take a look and explore!

[Informed Consent Process Overview Video]

[Rationale for the Potential Efficacy of HBO2 in Severe TBI]

[Simulation Example Videos]

[Education/Training Video for Clinical and Study Teams]

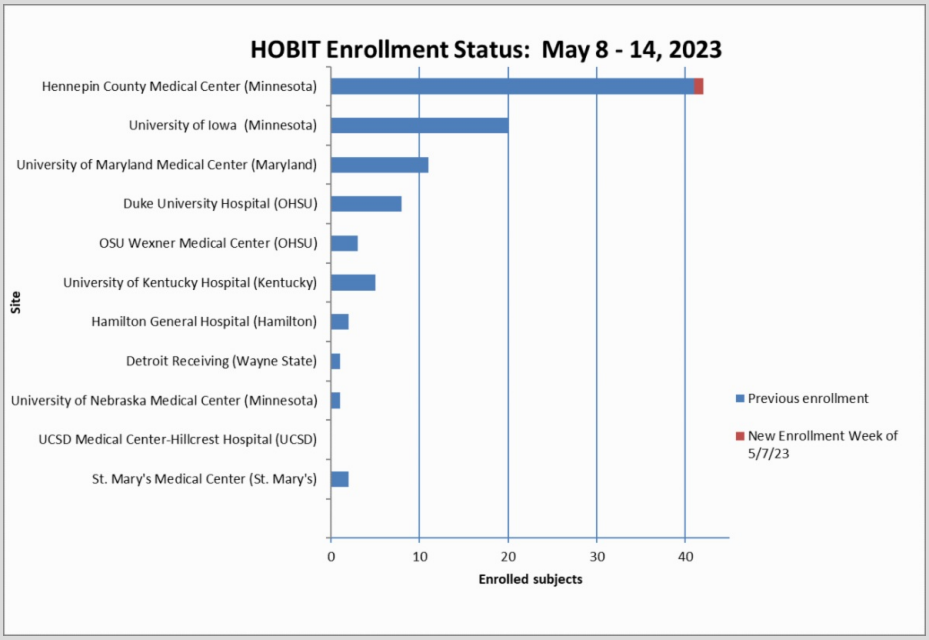
[Subject Enrollment Checklist]

[Clinical Standardization Guidelines]

[Chamber and Subject Log (Dive Log) Version 8]

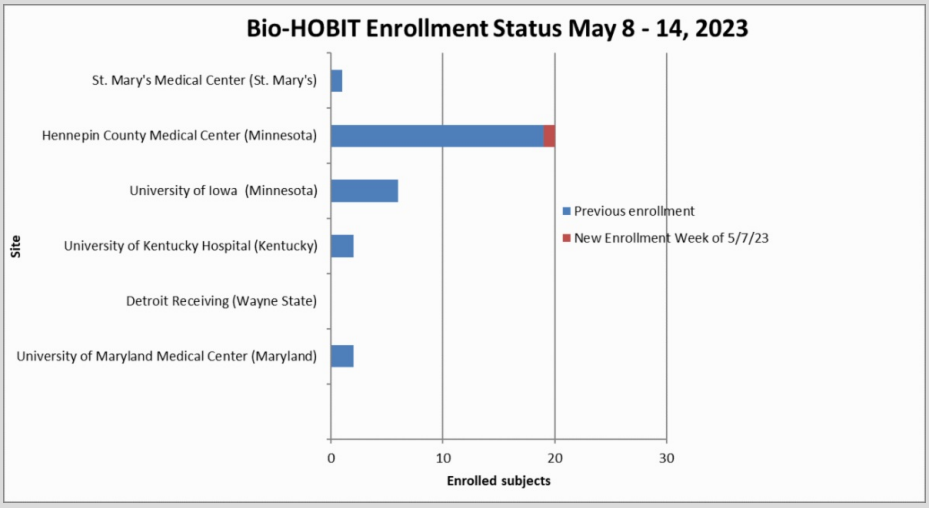
[CRF Completion Guidelines]

Enrollment Updates



HOBIT Enrollments: 95

9 sites released to enroll



BioHOBIT Enrollments: 31

6 sites released to enroll

Reminder! Enrolling Without ICP Monitor

We are aware that occasionally there are subjects who meet the criteria for enrollment in HOBIT however, the neurosurgery team is unwilling to place an ICP monitor because they deem it unwarranted clinically. Going forward, we will consider the enrollment of such subjects on a case-by-case basis. If you think you are going to miss a potential subject because the neurosurgery team does not think that ICP monitoring is warranted clinically, please call the PI HOTLINE (833-HOBIT-PI (833-462-4874)) to discuss further.

Let us know if you have questions!

Important EFIC Reminders!

- If no LAR is found within 6 hours of patient ED arrival, the patient can be

enrolled under EFIC.
- No EFIC prior to 6 hours!
- ICL CRF (Form 211) - Document steps taken to identify the patient and find the LAR:
    - The first attempt on the log should always capture what is known about the patient ID and family status at time of arrival.
    - Subsequent hourly attempts in the first six hours prior to an EFIC enrollment, should be captured on the CRF and use available resources (social work, waiting room, treating team, patient bedside, etc.) until randomization.
    - For an EFIC enrollment, the attempt logged minutes prior to randomization should reflect what is known about family/LAR status at that time.
    - Finally, ongoing attempts should be captured no less than daily (as appropriate) until a consent determination is made by an LAR or the participant.
    - The ICL-CRF should be started as soon as possible and should be saved and submitted on a rolling basis as new information is added until a final consent outcome has been reached.
- A consent determination should be obtained within 24hrs. Except in rare circumstances.
- For subjects who expire before LAR consent is obtained, the HOBIT Deceased Notification Letter (located in the appendix of the EFIC plan) should be sent.
- Similarly to the process for loss to follow-ups, when a consent determination of “obtained” or “refusal” is not obtained by six months. The study team will be asked to present the case to HOBIT Leadership and the best final consent outcome code will be discussed.

Important resources: HOBIT MOP, Section 5, AND CRF Completion Guidelines, Form 211.

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