January 24, 2020

HOBIT NEWS

Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminders

+NETT/SIREN Study Coordinator Call

February 4th at 1pm ET

+NETT/SIREN Steering Committee Call

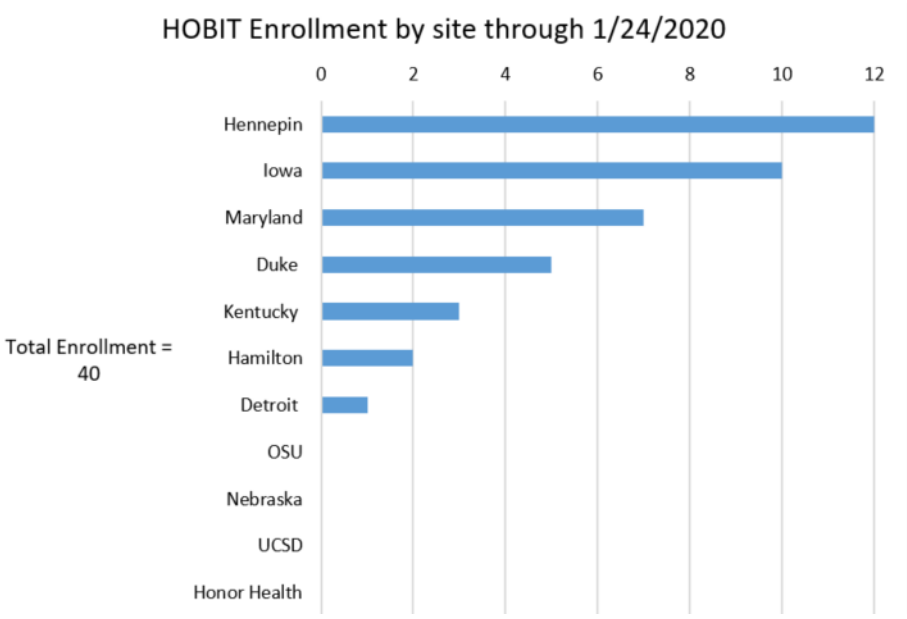
February 26th at 12pm ET

Participant Enrolled—Detroit

Congrats to Detroit Receiving Hospital for recently enrolling their 1st participant!

Participant Enrolled—Kentucky

Great job to the University of Kentucky Hospital on recently enrolling!



HOBIT Updates

EFIC Updates

Sites may start the process of obtaining EFIC approval. Sites cannot enroll under EFIC currently. Until your site has obtained cIRB approval to enroll subjects using EFIC, you must continue to use **Protocol V5** and obtain informed consent from an LAR using the current informed consent form.

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. The EFIC plan includes an overview of the EFIC regulations, the rationale for conducting HOBIT under 21 CFR 50.24, how the investigators plan to fulfill the requirements of the regulations, and how the results would be summarized and submitted to the cIRB.

The EFIC plan also includes a list of the menu options for community consultation (CC) and public disclosure (PD) activities. The Appendix lists all materials that have been cIRB approved to use to conduct CC and PD events. ***Any material that is used, must be sponsor and cIRB approved.***

NBH—Reminder!

For subjects randomized to the HBO + NBH or NBH only groups, an order set and/or other checks should be in place for the NBH treatment. This will allow tracking of the start and stop times of NBH treatment.

HOBIT HOTLINE—Call Anytime!

We want to encourage all sites to call the HOBIT hotline anytime you have questions about an eligible patient. The line is always open, 24/7.

1-833-HOBIT-PI (833-462-4874)