January 25, 2019

HOBIT NEWS

Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminders:

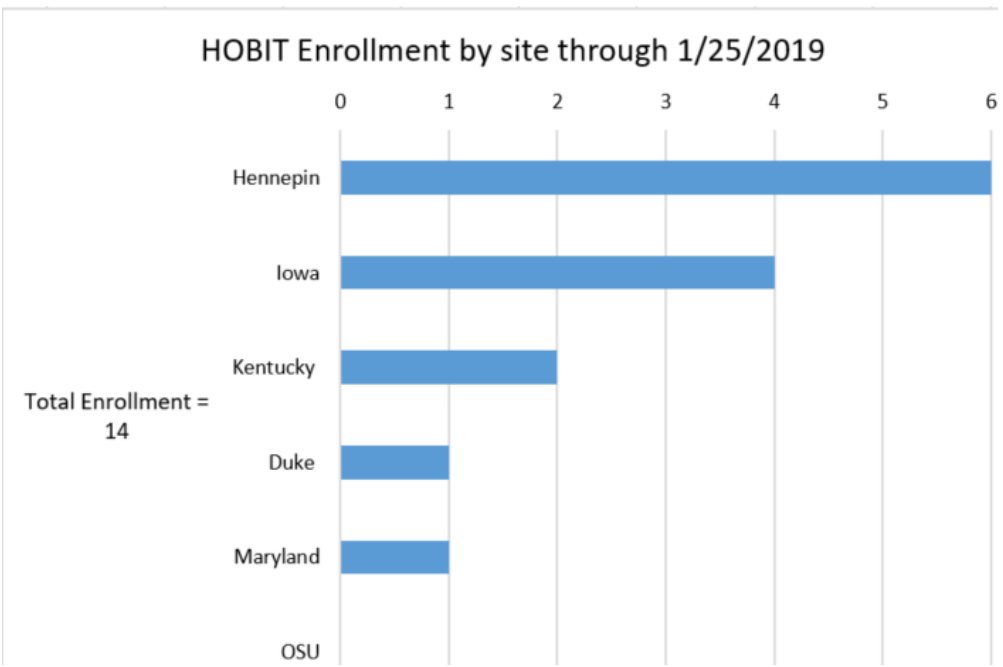
+The next NETT/ SIREN Study Coordinator Call is February 5th at 1pm ET

Hennepin—6th Participant Enrolled

Congrats to Hennepin on enrolling their 6th participant!

Duke, Hennepin, Iowa, Kentucky—Up to Date on Screen Failure Report

Great job to Duke, Hennepin, Iowa, & Kentucky on entering subjects into the screening report!



HOBIT Updates

MOP Updates

Section 3.3: Correction of sentence to remove "enrollment". Now reads "Time of study treatment initiation is defined as the time that study treatment (hyperbaric oxygen or normobaric hyperoxia) has begun. The time of initiation of study treatment is defined as

- the time the hyperbaric oxygen chamber door is closed, for subjects randomized to HBO treatment;
- the time normobaric hyperoxia is started, for subjects randomized to normobaric hyperoxia only; and
- the time of randomization allocation, for subjects randomized to "no hyperoxia treatment"

Section 3.6.1: Modification of number of videos to record for GOSE assessments. Now reads "To ensure that GOSE assessments are performed uniformly across study sites, each blinded assessor should audio or video record their GOSE assessments. Record assessments until notified by HOBIT outcomes team.

CRF Completion Guidelines

Updated CRF Completion Guidelines are now available in the WebDCU Toolbox.

Screen Failure Report

A reminder to enter screened patients into the Screen Failure Report in WebDCU each month. This is very important, especially at this beginning phase of the trial to collect data on those considered for enrollment but not randomized. The Screen Failure Report for the previous month should be entered into WebDCU, by the 10th day of the following month. The DCC has recently updated the format of the screening logs and instructions can be found in the CRF Completion Guidelines.

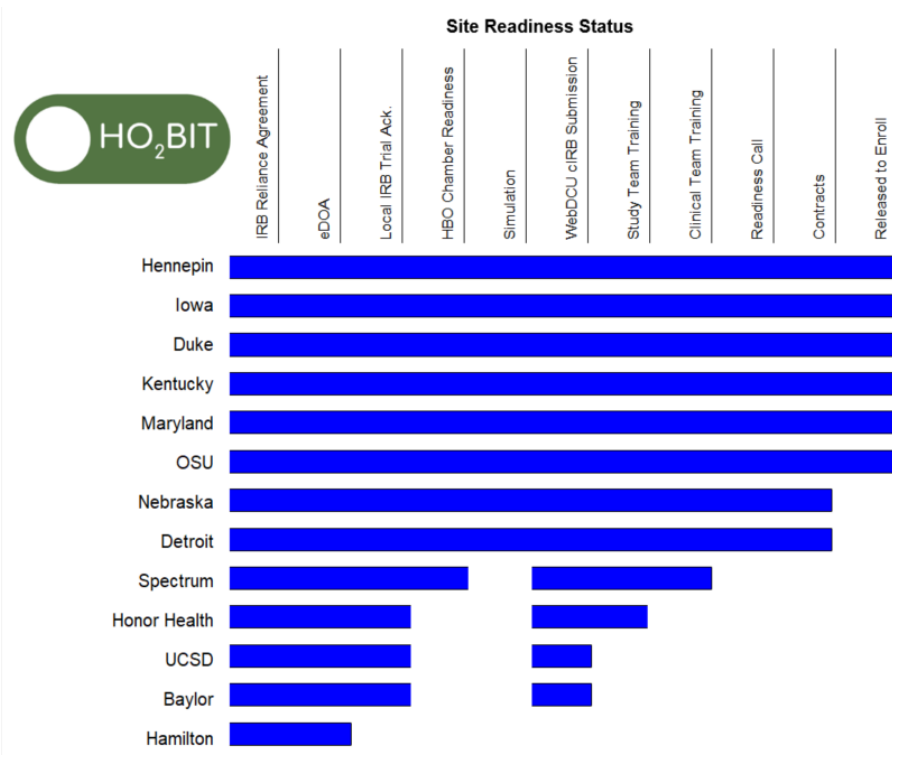
Updated Dive Logs—Version 3

A revision has been made to the dive logs and is now available in the HOBIT toolbox, under, "Chamber Resources". Instructions for completing this form are on page 2 of the log. Please note:

1. Only use the latest revision of this form from the HOBIT website toolbox.

2. Only use this HOBIT form for recording the HOBIT treatment data and upload this form to WebDCU.

3. If possible, for consistency, please have only one individual complete this form.

GOSE videos for Quality Assurance

To ensure that GOSE assessments are performed uniformly across study sites, each blinded assessor should audio or video record their GOSE assessments until notified by the HOBIT outcomes team. This is a slight change in our original requirement to only record 2 videos for each assessor. Because the GOSE is such a difficult interview to get exactly right in the beginning, we want to see more 90 day and 180 day interviews. Our reviewers, Angi or Sarah, will reach out with feedback to your assessors and whether or not they should continue to send in recordings. Please see MOP section 3.6.1 for more information.