December 14, 2018

HOBIT NEWS

Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminder:

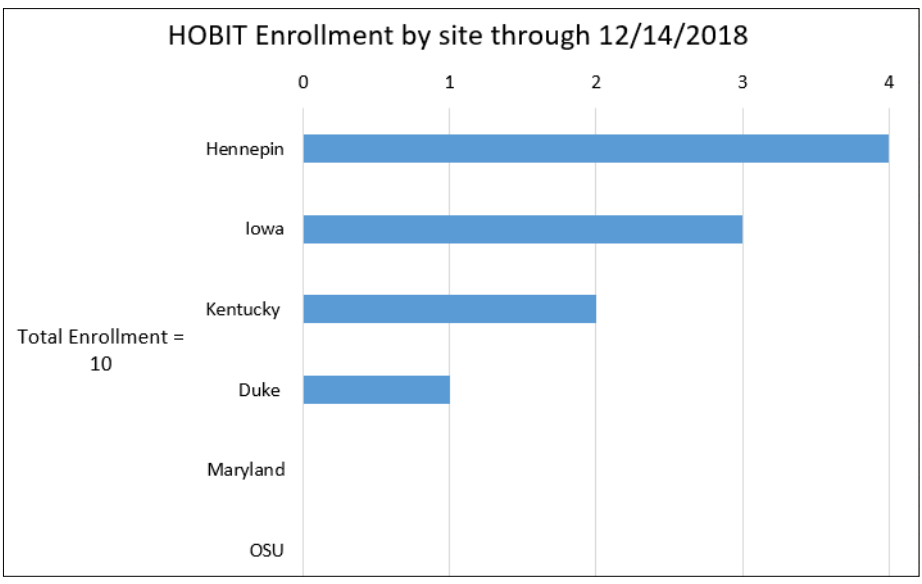
+The next NETT/ SIREN Steering Committee call is Dec 19 at 12pm EST

Kentucky—Participant Enrolled

Congrats to Kentucky on enrolling their 2nd participant!

Detroit and Nebraska—Readiness Calls Scheduled

Great job to Detroit and Nebraska on scheduling readiness calls!



HOBIT Updates

GOSE Assessments

To ensure that GOSE assessments are performed uniformly across study sites, each blinded assessor should audio or video record their first 2 GOSE assessments and upload them via the HOBIT website (hobittrial.org) under "Video Upload". The recordings should include both the assessor's questions and the subject/representatives responses. Please obtain verbal permission from the subject/LAR prior to performing the audio/video recording. **If video recording, only the GOSE assessor should be in view, not the subject or family member.** When uploading audio/video to HOBIT website, include the following in the "File Description" line: The subject number (no patient identifiers), the Assessor name, date/time/location, and which assessment (30 day, 3 month, or 6 month).

To video record using the HOBIT Ipad, follow these instructions:

Enable video camera by selecting: "Settings" -> "General" -> "Restrictions" -> enter Ipad passcode -> turn camera on by selecting "Camera" (make sure the button is green). Videos can be directly uploaded to the HOBIT website from the Ipads.

If there are any questions regarding how to perform the GOSE examination please contact Natalie Fisher (email: brownnat@med.umich.edu).

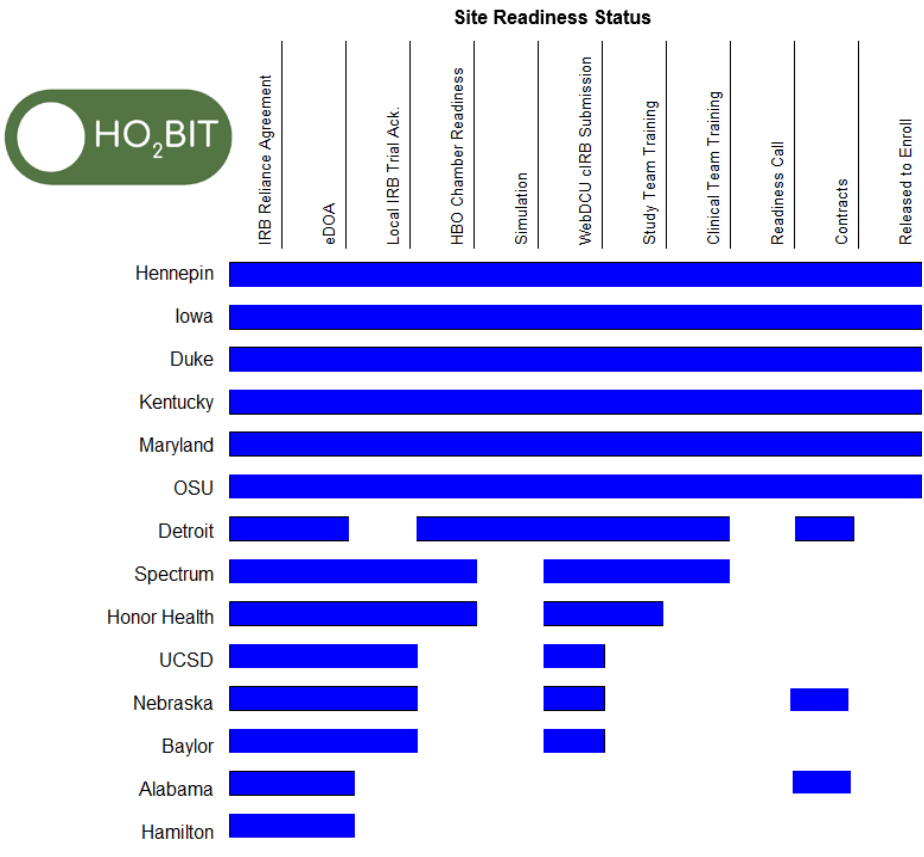
Reporting (S)AEs

A quick reminder about AEs - The AE form is used from enrollment through subject's End of Study. Serious adverse events occurring at any time between enrollment and subject's end of study are to be reported. Non-serious adverse events are only reported when occurring during the first 24 hours after enrollment. All serious AEs must be data entered and submitted in WebDCU TM within 24 hours of first knowledge of the event. It's important to note that the site PI will need to review and sign off on these forms. You can refer the CRF guidelines on more detailed information on reporting AEs.

Screening Logs

We'd like to remind site about the importance of completing Screening Logs during the trial. This is crucially important, especially at this beginning phase of the study, to collect data on those considered for enrollment but not randomized. This will provide insights into how we can best optimize subject enrollment. This log will allow a better understanding of the population considered, the population enrolled, and the reasons for ineligibility. It will also be helpful if we need to apply for EFIC in the future, should we fail to reach enrollment targets.

The Screening Log should be entered into WebDCU monthly, by the 10th day of the following month. If you need more information on completing the screening log—please refer to the HOBIT CRF Competition Guidelines in WebDCU.

New Resource—Technical Safety Bulletin and Technical Memo

Attached to this email, you will find: HOBIT Technical Safety Bulletin No.4 "Removing Oxygen Sample Flow Indicator" & HOBIT Technical Memo No.1 "Servicing the Witt Oxygen Blender (monoplace)". Please be sure to review these documents. They will be available in the HOBITTRIAL.org toolbox soon. If you have any question or concerns, contact Bill Gossett: bill.gossett@hcmed.org.