November 30, 2018

HOBIT NEWS

Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminder:

+The next NETT/ SIREN Study Coordinator call is Dec 4th at 1pm EST

Kentucky—Participant Enrolled

Congrats to Kentucky on enrolling their 1st participant!

Duke—Participant Enrolled

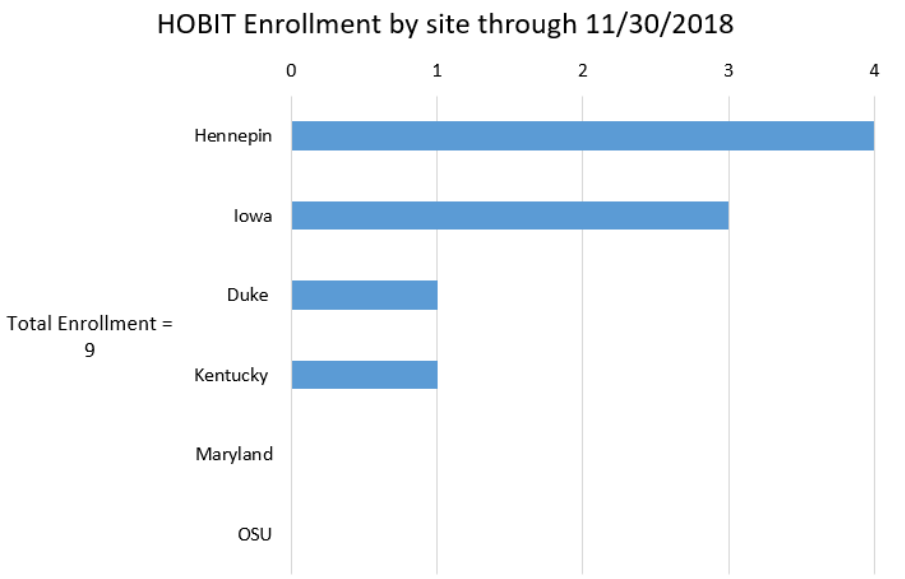
Great job to Duke on enrolling their 1st participant!

Iowa—Participant Enrolled

Congrats to Iowa on enrolling their 3rd participant!

OSU—Open to Enrollment

Thank to you OSU for all your hard work in preparation for HOBIT!



HOBIT Updates

HOBIT Retraining Requirements

HOBIT refresher training will be mandated for site that do not enroll a subject in the trial for 6 consecutive months. Retraining will include:

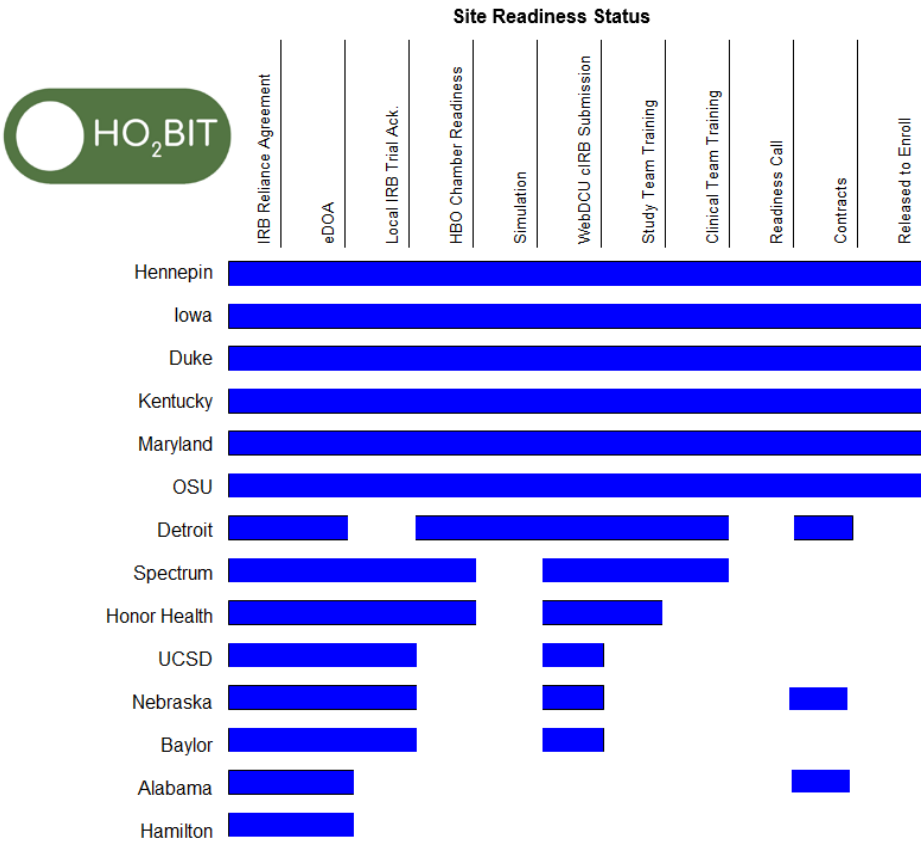
- Clinical team training
- All study team members active on the eDOA will review:
  - The protocol training video or slides
  - Review of Data Training video or slides by team member as appropriate to their role
- Blinded GOSE assessors must review the GOSE training and example videos

After the above are completed, the PI attestation will be uploaded into the HOBIT Database to document re-training. For more details regarding retraining requirements, please refer to the MOP & the SIREN SOP for Hub Performance Assessment.

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—Interventions for High ICP and Low Brain Tissue PO2

A new handy cheat-sheet is now available to use for interventions for high ICP and low brain tissue P02. The algorithm was taken from the Clinical Standardization Guidelines and these handouts can be posted on the monitors during the study treatments. This cheat-sheet is posted in the Toolbox under Clinical Resources. Thanks to Eric from Hennepin for the great idea!