February 22, 2019

HOBIT NEWS

Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminders:

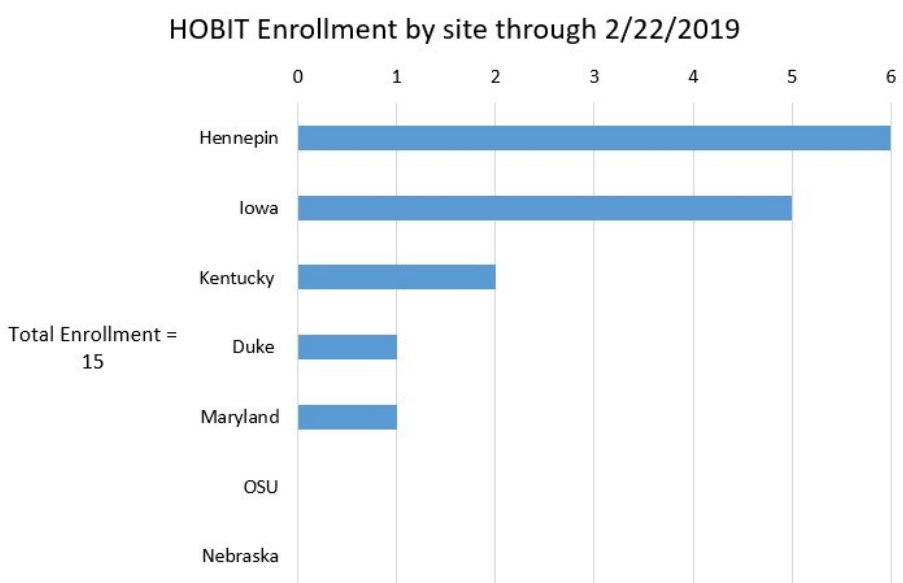
+The next NETT/ SIREN Steering Committee Call is February 27th at 12pm ET

Hennepin & Kentucky—GOSE Videos Submitted for QA

Thank you to HCMC & Kentucky for recently submitting GOSE assessor videos for QA!

Hennepin, Duke, Iowa, OSU, & Kentucky—Screening Logs Entered in February

Great job to all sites for entering screening logs this month!



HOBIT Updates

MOP Updates

Please see section 3.10.2 **Preparation of the Severe TBI Subject for HBO2** for recent update:

As discussed above, the lung is particularly susceptible to damage by hyperoxia because of the large surface area exposed to O2 in the lungs. Subjects with severe TBI are prone to the development of atelectasis and ventilator-acquired pneumonia. It is frequently difficult to distinguish the relative impact of an initial lung contusion and/or aspiration from the possible toxicity of HBO2 therapy. Based on our past experience, no subject will undergo HBO2 therapy if the P/F ratio is < 200. If the subject improves to the point that the P/F ratio is > 220 within the first 5 days after randomization, treatments will be resumed. If the P/F ratio falls again to < 200 and two consecutive HBO2 treatments are canceled, all further treatments will be permanently terminated. Likewise, if PEEP requirements are > 10 cm of water, HBO2 treatments are temporarily discontinued. If requirements become < 8 cm of water during the first 5 days after randomization, HBO2 treatments are resumed. However, if PEEP requirements again increase to > 10 cm of water on two consecutive occasions, all further treatments will be permanently terminated. Daily chest radiography is performed, and if there are changes suggesting O2 toxicity, treatment is temporarily discontinued until the chest x-ray improves or it is greater than 5 days after randomization

CRF Guideline Updates

New updates are in "green". Please see these forms for more information.

Form 172: Surgical and Procedural Interventions

Enter all surgical and procedural interventions from injury through Day 6 or Hospital Discharge, whichever comes first. Select the appropriate code(s) that correspond with surgical/procedural intervention(s).

Codes should be included ONLY when a surgical or procedural intervention is present.

EXAMPLE 1: A brain tissue oxygen monitor is initially placed and recorded on F172. There are mechanical issues with the monitor or the twist drill hole into which it was placed, requiring removal, assessment and reinsertion. The monitor is replaced into the same twist drill hole. This would not be considered a surgical/procedural intervention and would not be recorded.

EXAMPLE 2: A brain tissue oxygen monitor is initially placed and recorded on F172. There are mechanical issues with the monitor or the twist drill hole into which it was placed, requiring removal, assessment and reinsertion. The monitor is unable to be replaced into the same twist drill hole and a new hole must be drilled. Even if the same monitor is reused, this would be considered a surgical/procedural intervention and would be recorded.

Form 275: Study Therapy

This form should be completed for each treatment dive or treatment dive attempt. This form will not be posted for subjects randomized to the control group.

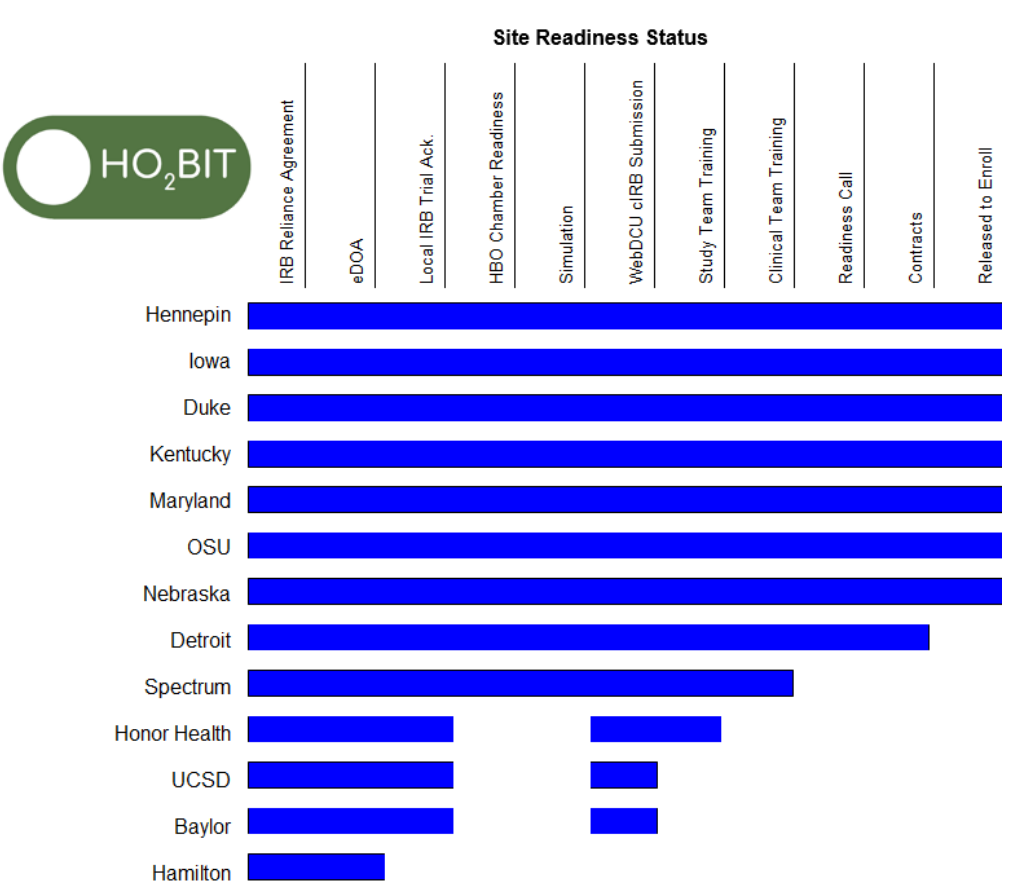
For subjects where dives are permanently discontinued, there should still be a total of 10 forms posted. Reasons for not initiating subsequent dives should be the causal event for treatment discontinuation.

EXAMPLE: The subject is only at the Day 2 visit with one successful dive on Day 1 and two instances of PF ratio less than or equal to 200 on Day 2. Treatments are permanently terminated as instructed in the MOP.

ACTION: Continue uploading study therapy forms as would have been scheduled prior to discontinuation. Indicate the reason for not initiating subsequent dives - in this case, PF ratio less than or equal to 200. Provide general comments that treatment has been permanently terminated, along with any other pertinent information.

Form 501: Hourly Monitoring

Cerebral perfusion pressure

CPP will be monitored daily during the first 6 days of enrollment. The clinical team will be trained to record hourly CPP values on ICU flowcharts at the start of each clock hour (for example 9 am to 9:59 am, or from 10 am to 10:59 am). During episodes of brain tissue hypoperfusion (CPP<60 mmHg), CPP should be recorded every 15 minutes on the ICU flowsheets. CPPs may be calculated from ICP and MAP measurements. Using the ICU flowsheet as the source document, the study team will document whether the CPP during any given clock hour was <60 mmHg (episode of brain tissue hypoperfusion) in WebDCU.

CPP should be calculated from ICP and MAP values taken close to the same time point whenever possible. For instances where ICP and MAP values are taken at separate times within the hour, CPP should still be calculated and recorded from these values.