March 15, 2019

HOBIT NEWS

Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminders:

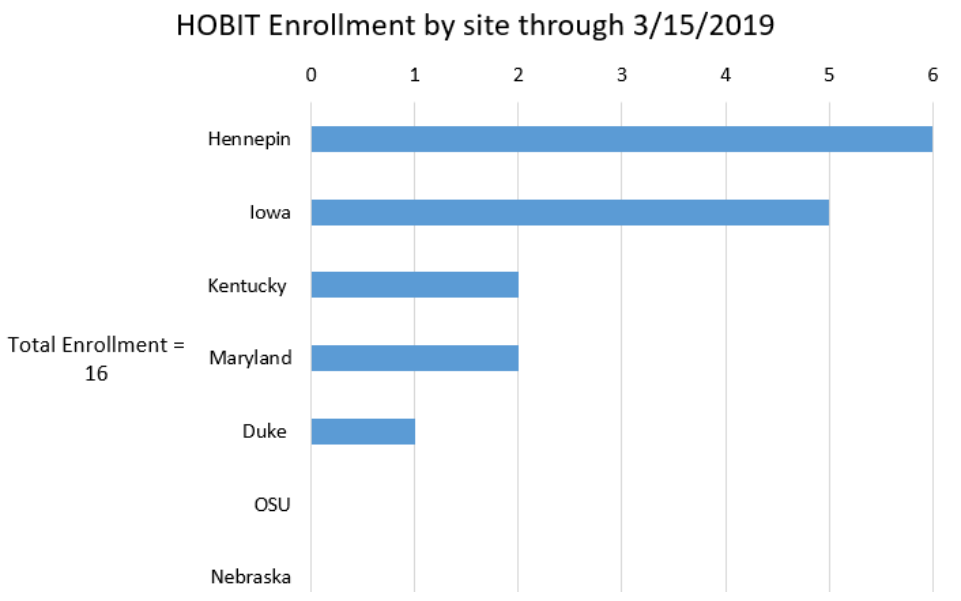
+The next NETT/ SIREN Steering Committee Call is March 27th at 12pm ET

Hamilton—Contract Complete

Thank you to Hamilton Health Sciences on completing their contract!

Hennepin, Iowa, & Kentucky—GOSE Assessments Complete

Great job to Hennepin, Iowa, and Kentucky for recently completing GOSE assessments!



HOBIT Updates

Enrollment Suspension Lifted

The cIRB has lifted the enrollment suspension and sites can resume enrolling subjects. This was in response to the report of an incident that took place at one of our monoplace sites during routine device maintenance of the Ohmeda battery pack. No subjects were involved. We have created a Monoplace Safety Technical Bulletin and this is available in the HOBIT Toolbox under Chamber Resources: **Charging Ohmeda Batteries**

cIRB Continuing Review

We have submitted the Continuing Review with Advarra. We hope to have the approval letter by next week.

MOP Updates

Please see **Section 6: Safety Monitoring Plan** for recent updates.

In Section 7: Site Reporting Requirements for SAEs, we've updated the laboratory abnormality reporting requirements. "Laboratory abnormalities need to be reported only when they are (a) clinically significant, and (b) represent a unique adverse episode (are not part of another already reportable event), and (c) result in a specific therapeutic response. As with any other AEs, laboratory abnormalities are only serious when potentially life threatening or meeting other criteria for seriousness."

In Section 7.1 Guidelines for reporting SAEs, we've included an SAE template that combines CPP,ICP, & MAP and updated guidelines for combining groups of event reflecting identical underlying pathophysiology. "Combining groups of events reflecting identical underlying pathophysiology: For example, if a patient has an elevated ICP and a decreased MAP/CPP all due to cerebral edema, you can report cerebral edema and mention elevated ICP and decreased MAP/CPP in the cerebral edema SAE. Other examples would be large cerebral contusion or venous sinus thrombosis. We encourage reporting related SAEs as one SAE instead of splitting them in to their component parts (for example, report pneumonia instead of reporting fever, infiltrates on chest x-ray and hypoxia separately).

TEMPLATE FOR COMBINED CPP/ICP/MAP
The subject is a {age, gender} who suffered his/her TBI on {date} and was admitted on {date}. S/He underwent {any cranial surgeries} on {date}. Subject was randomized into the {treatment arm} on {date} and completed {number} treatments on {date}.
The subject had {number} episodes of decreased CPP.
Episode #1 {needs to be < 60 on at least 2 consecutive readings, 30 minutes apart} CPP readings were {number} on {date, time}, {number} on {date, time} – continue readings for that episode.
Also give ICP reading and MAP reading for each of those time points.
{State treatment given, or state no intervention needed, resolved spontaneously}
If another episode than:
Episode #2 (needs to be < 60 on at least 2 consecutive readings, 30 minutes apart) CPP readings were {number} on {date, time}, {number} on {date, time} – continue readings for that episode.
Also give ICP reading and MAP reading for each of those time points.
{State treatment given, or state no intervention needed, resolved spontaneously}
Continue to list all episodes of cerebral hypoperfusion in that way.

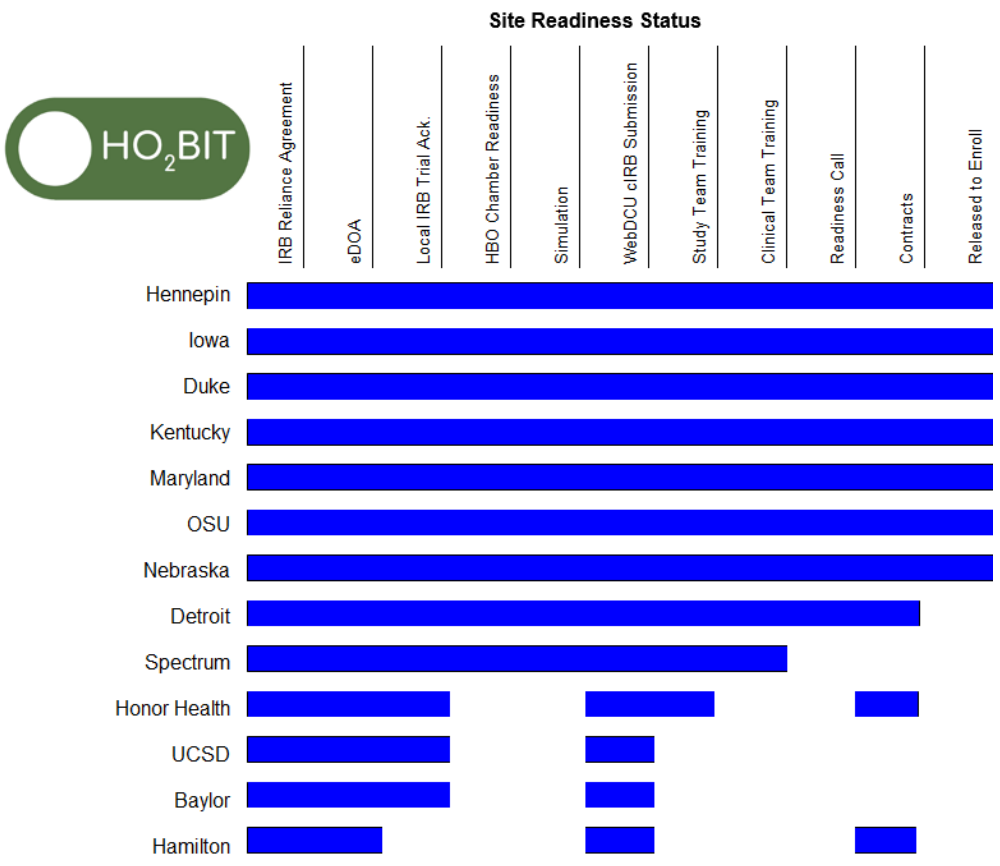
If any episode was close to or during hyperoxia treatment or during transport to/from the HBO chamber state and also state if it's felt to be unlikely secondary to dive such as it started prior to treatment. State if the patient remained neurologically stable or not during these episodes."

FiO2 Challenge

Reminder** If brain tissue partial pressure is being monitored, an FiO2 challenge procedure is required to be done daily as described in Section 3.7.3 of the MOP. This should be documented in the eMR and will be verified by the site monitor. Please discuss with your site team how this will be accomplished and who will be responsible.

GOSE

We are asking all site to please keep sending in recorded GOSE assessments until notified. It's extremely important to obtain verbal consent from the patient or LAR when conducting these assessments. Please be sure to obtain verbal consent on the recording itself. If we do not hear verbal consent, we will not be able to use the video or audio. Make sure that your assessors are recording verbal consent prior to the assessment.

Dive Logs

We are making slight modifications to the Chamber Logs. Once these are updated, we'll make these available on the HOBIT website toolbox. It's important that all sites are completing these for all patients to document that we are treating them safely.