February 8, 2019

HOBIT NEWS

Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminders:

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

Nebraska—Released to Enrolled

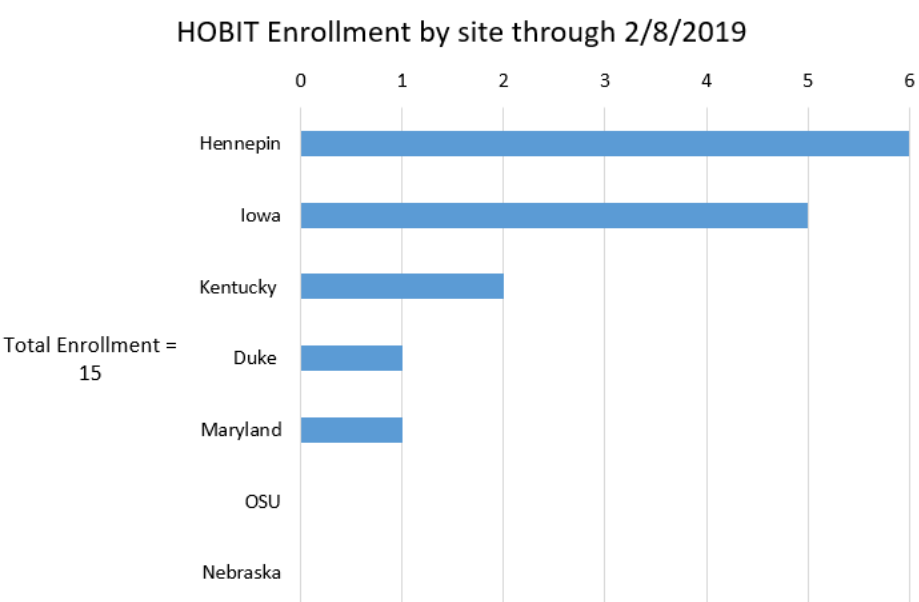
Congrats to the University of Nebraska Medical Center on being released to enroll!

Spectrum—Simulation Video Submitted

Great job to Spectrum Health on submitting their simulation video!

Iowa—Recent Enrollment

Great work by the University of Iowa HOBIT team on their recent enrollment!



HOBIT Updates

Protocol V4 and Consent Update

Protocol Version 4 and the revised consent form have been approved by the cIRB, Advarra. Protocol Version 4 is now available on the HOBIT website, under the Protocol tab. A summary of changes from version 3 to 4 can be found on page 48.

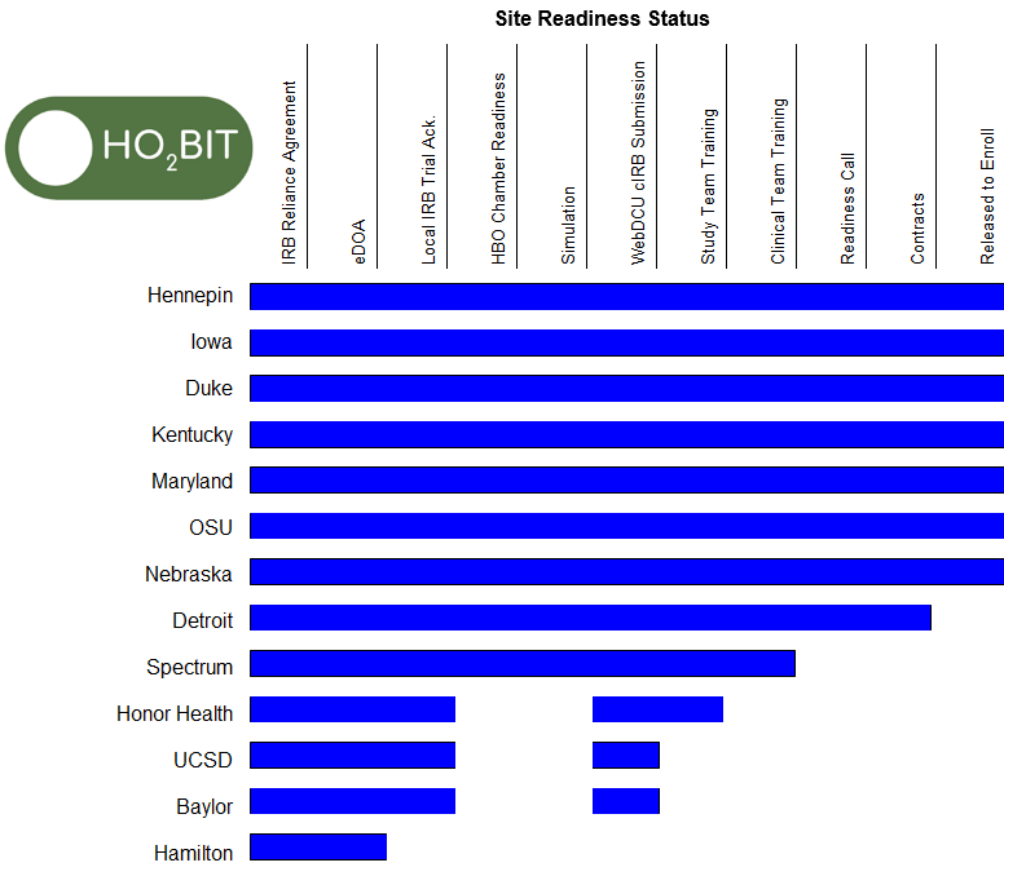
The approval letter from the cIRB is in the toolbox, as well as the consent template and consent tracked changes. All site's newly approved consent forms have been uploaded to WebDCU and are available for use. Please discard any old paper versions you might have printed out and let your team know about the new consent form. We've also updated the e.consent links with the new consent form. You will continue to use the e.consent links we've provided to your site. Please note the addition of the HBO handout as a hyperlink within the consent form. You can easily access the handout while conducting in person consent and LARs can access the link while they are remote.

MOP Update

Please see section 3.7.3: **Procedure for FiO2 Challenge,** as it has recently been updated. We previously stated that the FiO2 challenge should done before each dive but this is now updated to: once a day.

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. Please continue to send in videos. 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.

Calendar Reminder for GOSE

The study calendar is now functioning within the HOBIT database. Sites can use this to help keep track of GOSE assessment due dates by checking the calendar, which is located under the Study Progress tab in WebDCU.