June 7, 2019

HOBIT NEWS

Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminders

+Virtual Investigator Meeting

June 11th 11:00am-12:30pm ET

June 13th 3:00pm-4:30pm ET

+GOSE Quarterly Meeting

June 12th 12:00pm ET

+NETT/SIREN Steering Committee Call

June 26th at 12pm ET

Hennepin — 2 Participants Enrolled

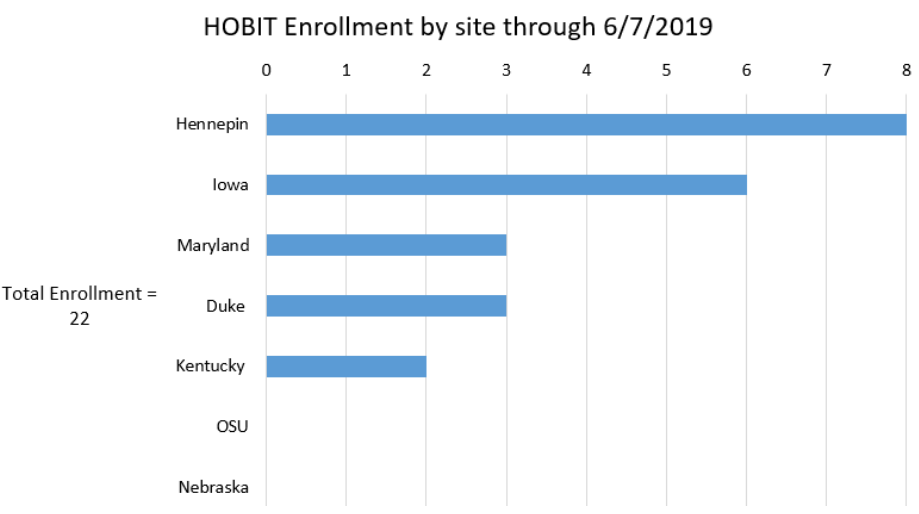
Great job to HCMC on recently enrolled 2 participants!

HonorHealth—Simulation Video Filmed

Nice work by HonorHealth Scottsdale Osborn Medical Center on recently filming their simulation video!

UCSD—HBO Chamber Readiness

Great job to UCSD Medical Center—Hillcrest Hospital on competing the HBO readiness checklist!



HOBIT Updates

MOP Updates

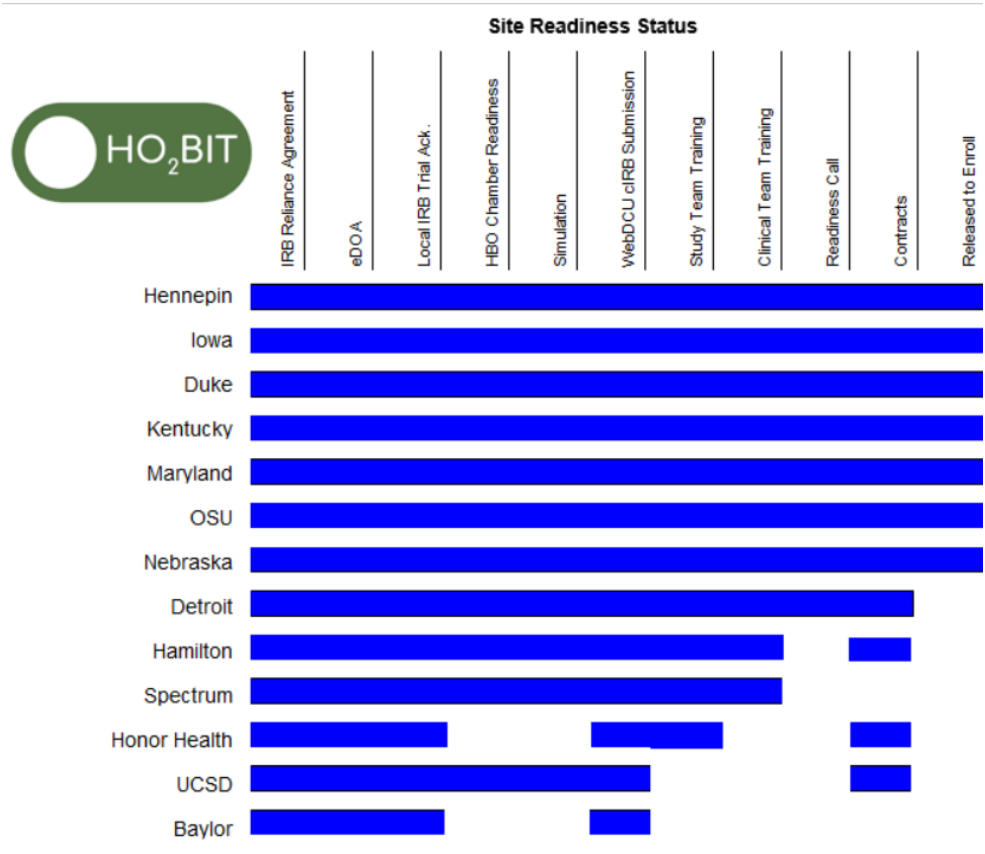
Update to section 3.6.1 page 16 (new language added)

To ensure that GOSE assessments are performed uniformly across study sites, each blinded assessor should audio or video record their GOSE assessments. These assessments should all be recorded until notified otherwise by the HOBIT outcomes team. The recording will be used to assess how well the GOSE assessor performs, therefore the focus of the recording should be the assessor and not the subject. Also, specifically for the 180 day assessment, the blinded Outcome Central Monitor (OCM) will review, double score, and check data entry of all materials. Feedback will be given on all reviews, even if no mistakes are found. Feedback will be given via an email if the OCM agrees with the original scoring. If the OCM disagrees with any of the scoring for any items, a phone call will be arranged between the OCM and the GOSE assessor who conducted that interview to discuss the differences. This will be documented by a DCR within WebDCU. No GOSE score documented in WebDCU will be changed by the OCM.

FAQ

A new FAQ has been added to the HOBIT website:

Q: Which GCS should be used to determine eligibility for HOBIT?
A: The GCS used to determine eligibility is not necessarily the initial GCS or the lowest GCS but the most RELIABLE GCS. The GCS exam should be performed after resuscitation, off sedatives and paralytics and closest to the time of enrollment. This is because patients frequently improve or deteriorate neurologically during the first hours following injury. Alcohol and recreational drugs may suppress neurological function, resulting in a low GCS which may improve quickly. Therefore it is particularly important especially in patients with an initial GCS of 7 and 8 to obtain a repeat GCS close to enrollment. Do not hesitate to call the PI hotline if you have questions regarding eligibility.

Monthly Monitoring Log

We want to remind study teams to conduct monthly follow-up phone calls with enrolled subjects/LAR during their time of enrollment for the first 6 months post-randomization. These calls are essential to maintaining contact with subjects/LAR and decreasing the likelihood of "loss to follow-up" at the 6-month visit. A log of all calls is documented in the Monthly Follow-up Log in WebDCU under the **Study Progress** tab. More instructions are available in the MOP on page 17 section 3.6.1.