August 9, 2019

HOBIT NEWS

Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminders

+NETT/SIREN Steering Committee Call

August 28th at 12pm ET

+NETT/SIREN Study Coordinator Call

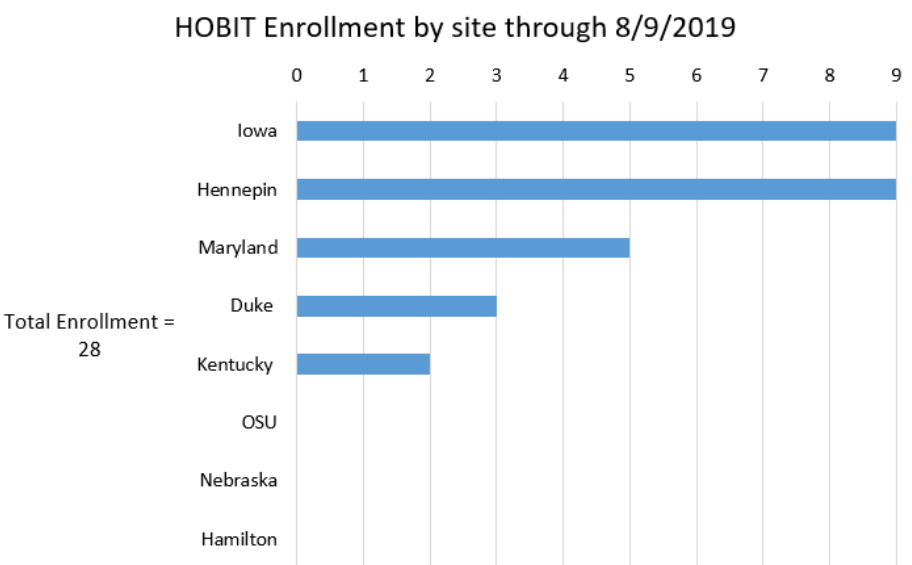
September 10th at 1pm ET

Iowa, Hennepin, and Maryland — Participant Enrolled

Great job to the teams at Iowa, Hennepin, and Maryland for recently enrolling! Way to go!

Baylor — Filming Simulation

Nice work by Baylor University Medical Center for working on their simulation video!



HOBIT Updates

MOP Updates

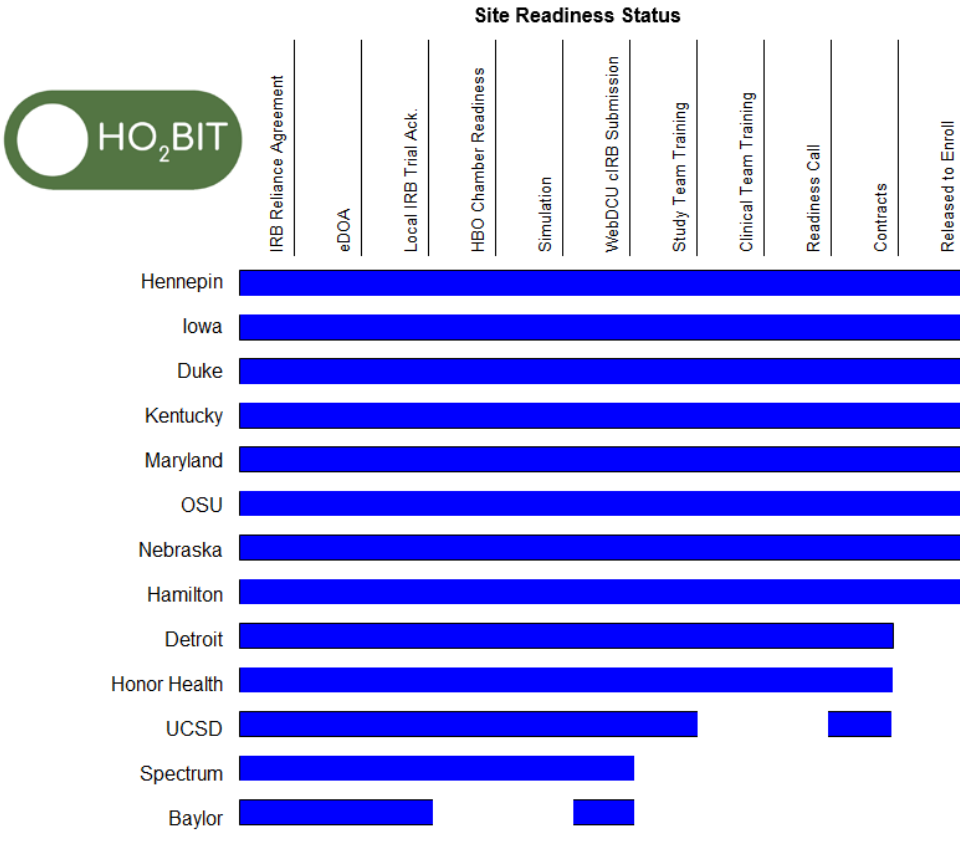
3.6.1 Conducting the GOSE Assessments

We recently updated the MOP GOSE section 3.6.1. Please see the updates outlined below:

Page 16— The PSC should be working with the GOSE assessor to help with providing participants contact information, helping arrange phone calls and in person visits, and also advising the assessor if an LAR needs to be present.

Page 16— If the blinded GOSE assessor thinks s/he may have become unblinded at any time, s/he should either contact their study coordinator or the HOBIT and/or SIREN leadership team. The other site GOSE assessor or backup should perform all the remaining GOSE assessments for that subject.

Page 16— In the rare case where the participant becomes “lost to follow up”, a representative from the site’s study team will discuss the case during the SIREN Operations Committee Call. HOBIT and SIREN personnel will provide strategies to reach subject and prevent lost to follow up.

Page 17— A minimum of 5 GOSE assessments will be recorded for each GOSE assessor. Once the GOSE assessor has submitted a minimum of five assessments, if no major errors were made on at least the last two 6 month visits, the Outcomes Committee will discuss whether the assessor needs to continue recording assessments. If no longer needs to record assessments, the assessor will be notified.

Page 17— Feedback will be given to assessors on all reviews, even if no mistakes are found. Feedback will be given via an email from Sarah or Angi. If Sarah or Angi disagrees with scoring for items, a phone call will be arranged to discuss. Following discussion and agreement between the assessor and OCM, any required changes in webDCU will be documented by a DCR.