April 12, 2019

HOBIT NEWS

Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminders

+NETT/SIREN Steering Committee Call

April 24th at 12pm ET

+Virtual Investigator Meeting

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

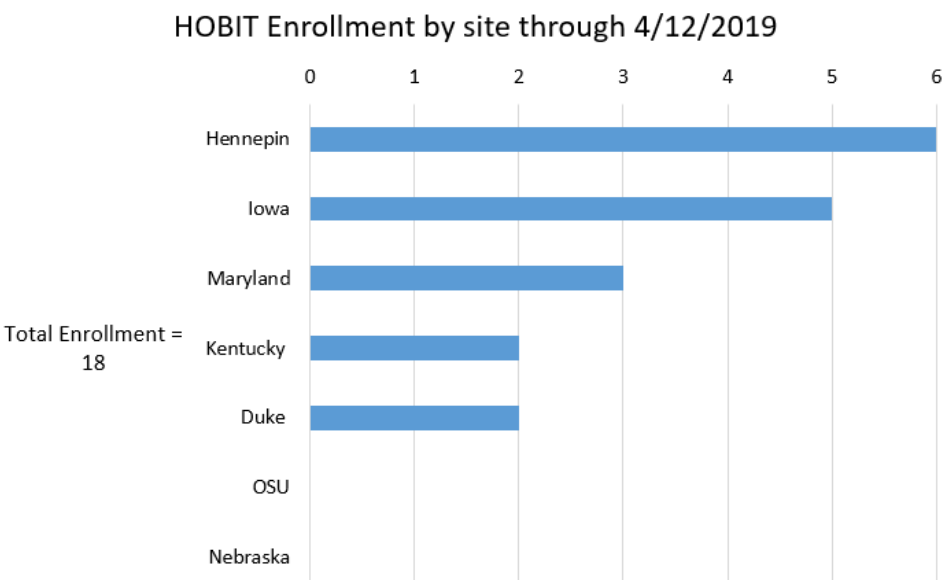
June 13th 3:00pm-4:30pm ET

UCSD—Simulation Submitted

Great job to UCSD Medical Center—Hillcrest Hospital on submitting their simulation video!

Maryland & Iowa—GOSE Assessments Complete

Great job to Maryland and Iowa for recently completing GOSE assessments!



HOBIT Updates

Protocol Version 5 Available on HOBIT Website

HOBIT Protocol Version 5 is now available on the HOBIT website, under Protocol tab. A summary of protocol changes can be found on page 48.

Protocol Version 5 Approval Letter Available in WebDCU

Site specific approval letters are available in WebDCU, under "Site IRB Approval".

cIRB Approved GOSE Video Recording Script

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 be recorded until notified otherwise by the HOBIT outcomes team. Please obtain verbal permission from the subject/LAR prior to beginning the audio/video recording. We recommend that prior to the start of the recording, the GOSE assessor uses the cIRB approved GOSE Video Recording Script, available in the HOBIT website Toolbox. Please see updates to the MOP Section 3.6.1, Page 16 for more information.

Virtual Investigator Meeting

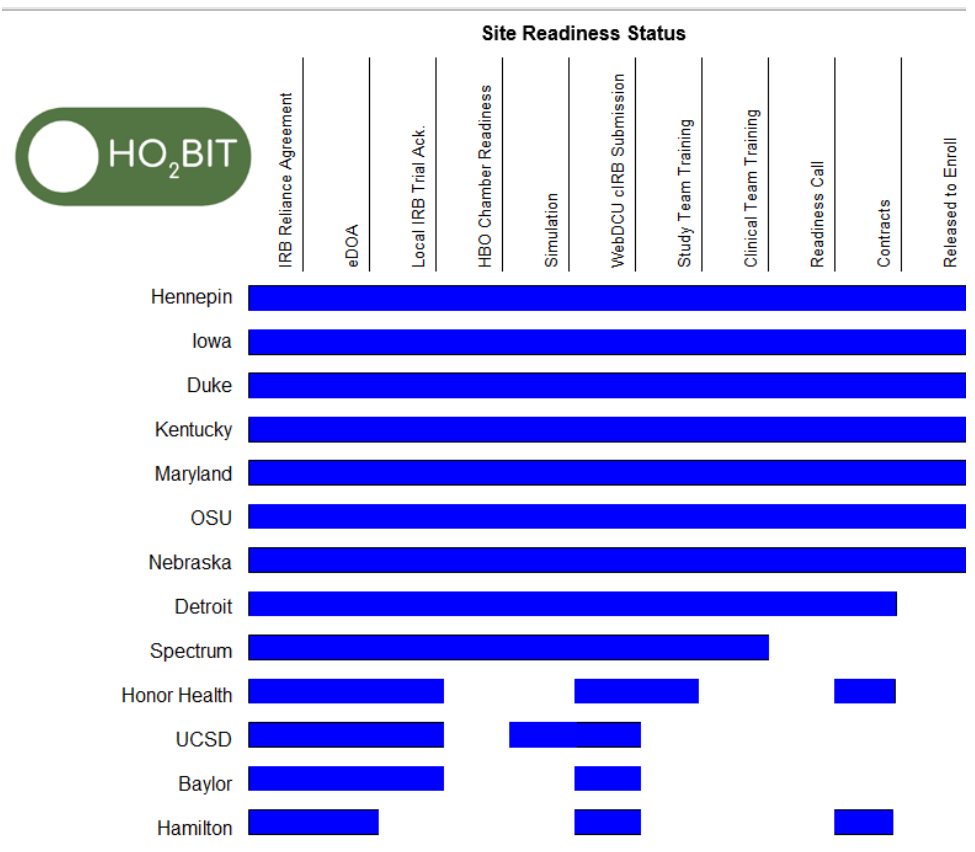
Please save the date for the HOBIT 2019 Virtual Investigators Meeting which will be held on June 11th from 11:00am – 12:30pm; and on June 13th from 3:00pm – 4:30pm. This will be an interactive opportunity to review important HOBIT topics and facilitate discussion among study teams. Emphasis will be on protocol adherence, screening, and ongoing training of clinical staff. We are offering two different meeting times to accommodate schedules. However, you are only expected to attend one of the meetings. The PI and Primary Study Coordinator from each site are required to attend at one of the meetings. Others are welcome to attend as well. Please register for the meeting via the link :Bit.ly/HOBITmeeting2019

FAQs

The following FAQs were posted to the FAQs page under Screening and Inclusion/ Exclusion:

Q: Which GCS should be used to determine eligibility for HOBIT? (New 4-3-19)
A: The GCS used to determine eligibility is not necessarily the initial GCS or the lowest GCS but the most RELIABLE GCS. This should be obtained after patient is hemodynamically stable and is off sedatives and paralytics. A patient's GCS may change over time. If a patient presents with GCS>8 but deteriorates neurologically over time and has a GCS<8 due to worsening TBI, that patient may be enrolled if they meet other study eligibility criteria. We would like to avoid enrolling subjects whose low GCS is primarily from a non-TBI cause and that is why we ask that those with etoh level >200 mg/dl should have at least a Marshall head CT score>1. However, if for example you have a patient with a GCS of 8, an elevated alcohol level and small subdural hemorrhage (Marshal head CT score>1) you should consider repeating the GCS at the closest point prior to randomization to see if GCS has improved and the patient is no longer eligible for HOBIT. Do not hesitate to call the PI hotline if you have questions regarding eligibility.

Q: If a potential subject is intubated, which GCS should be used to determine eligibility for HOBIT?
A: Since the verbal component of GCS cannot be calculated reliably in intubated patients, you should use the motor score component of the GCS. Potential subjects are eligible for HOBIT if the most reliable motor score (obtained after patient has been stabilized and is off sedatives and paralytics) is 5 or less.

CT Imaging Repository

The image repository is close to being ready to accept CT scans. While we work to finish the final touches, we just want to ask that all sites make sure their eDOA is up to date for the CT scan responsibility delegation. Whoever will be responsible for transferring the CT scans to the imaging repository should be assigned this role. This will be important since we'll be creating user names and passwords for the system.