November 18, 2019

HOBIT NEWS

Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminders

+EFIC Virtual IM

November 22nd at 10am ET & 2pm ET

+NETT/SIREN Steering Committee Call

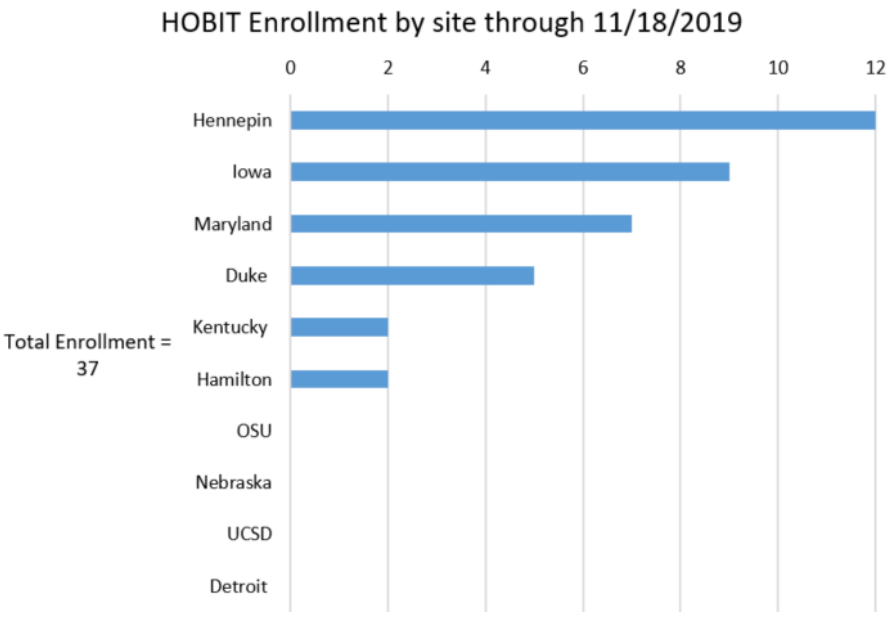
November 27th at 12pm ET

+NETT/SIREN Study Coordinator Call

December 3rd at 1pm ET

Kentucky, Duke, Detroit, Iowa & Maryland — Screening Logs Complete

Thanks to University of Kentucky, Duke University Hospital, Detroit Receiving Hospital, University of Iowa Hospitals & Clinics, & University of Maryland Medical Center for recently completing screening logs in WebDCU!



HOBIT Updates

EFIC Virtual Investigator Meeting

Reminder! The HOBIT EFIC Virtual Investigators Meeting will be held on **Friday, November 22nd from 10:00am – 12:00pm ET**; and on **Friday, November 22nd from 2:00pm – 4:00pm ET**.

The FDA has recently approved HOBIT to enroll subjects under EFIC. This will be an interactive opportunity to learn about HOBIT EFIC requirements, protocol updates, and facilitate discussion among study teams.

Please reach out to Natalie Fisher (brownnat@med.umich.edu) if you have registered but have not received an invitation to the meeting.

MOP Updates

New Section Added

8.4: Prompt Reporting Events (including of Protocol Deviations, Unanticipated Problems, and Noncompliance)

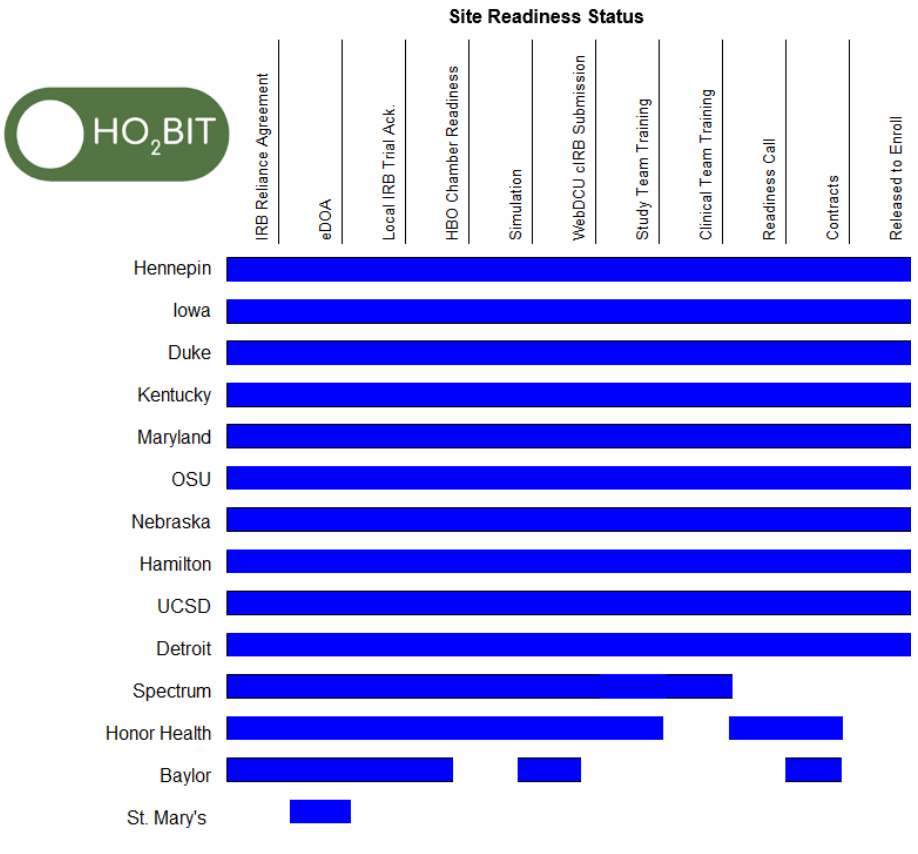
Notification of a protocol deviation, unanticipated problem, or noncompliance must be entered into WebDCU promptly but no later than 2 weeks (10 business days) from the time of identification. Sites must report all protocol deviations, unanticipated problems, or noncompliance via the Issues table, located under the central IRB tile in the WebDCU study specific database. Once an event is captured, the HOBIT executive team will review. If the event meets Advarra's reporting criteria, the HOBIT site manager at the CCC will promptly report it to Advarra on the sites' behalf.
* see section 8.4 for more information.

13.2: CRF Completion Guideline

New language Added:

Death, surgery, intubation, etc. are not adverse events. They are outcomes of adverse events. When a subject dies, has surgery, is intubated, etc. please enter the reason for the death, surgery, intubation, etc. in the response to Q01. If the subject dies after being withdrawn from life support and placed on comfort care secondary to their neurological injury, that should be reported in one of 2 ways. 1) If they were deteriorating neurologically, the AE should be reported as "neurological deterioration." In the vast majority of cases, the death should be reported this way. 2) In the unusual circumstance that the subject remained neurologically stable or improved, the SAE may be reported as "withdrawn from life support." The GCS at the time of enrollment and the one closest to withdrawal from life support should be included in the SAE narrative.

Resources

Chamber and Subject Log V5
An updated version of the Chamber and Subject Log is now available in the HOBIT website Toolbox, under Chamber Resources & Simulation. Please use this version going forward.

Certified Letter to LAR
The cIRB has approved a certified letter template that can be mailed to LARs that have become lost to follow up. Please use this template, as provided. The letter template can be found in the HOBIT website Toolbox, under: IRB—ER—cIRB Issued Documents.