February 21, 2020

HOBIT NEWS

Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminders

+NETT/SIREN Steering Committee Call

February 26th at 12pm ET

+NETT/SIREN Study Coordinator Call

March 3rd at 1pm ET

+GOSE Quarterly Meeting

March 11th at 1pm ET

Local IRB EFIC Notification Letter

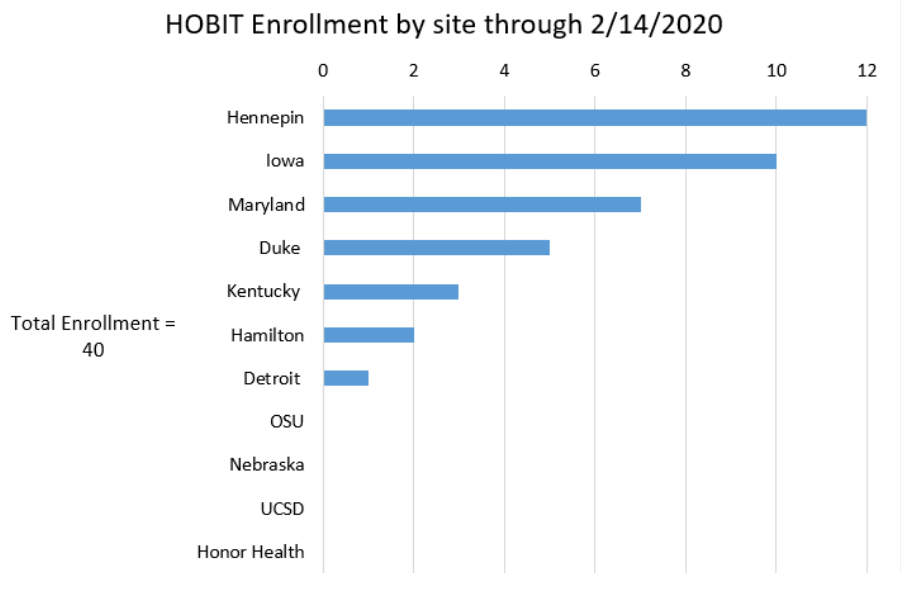
Thank you to UCSD & Spectrum for submitting the Local IRB EFIC Notification Letter!

Local Context Form Submitted

Thank you to Kentucky, Hennepin, Maryland, and Honor Health for submitting the Local Context Form!

Screening Logs Entered

Great job to Kentucky, Hennepin, Iowa, UCSD, Detroit, & Duke for recently entering Screening Log into WebDCU!



HOBIT Updates

Continuing Review Approval

Advarra has recently approved HOBIT's Continuing Review from 18 Feb 2020 to 18 Feb 2021. Site specific approval letters are available in WebDCU.

EFIC Updates

EFIC Milestone Document

To get started on your EFIC process, please review the EFIC start-up activities and tasks outlined in the HOBIT Milestone Document. *Please note that the payment module for completion of Milestone 1 has recently changed to $20,000.

EFIC Plan

The cIRB approved EFIC plan is available in the EFIC Resources tab of HOBITtrial.org. The EFIC plan includes an overview of the EFIC regulations, the rationale for conducting HOBIT under 21 CFR 50.24, how the investigators plan to fulfill the requirements of the regulations, and how the results would be summarized and submitted to the cIRB.

The EFIC plan also includes a list of the menu options for community consultation (CC) and public disclosure (PD) activities. The Appendix lists all materials that have been cIRB approved to use to conduct CC and PD events. ***Any material that is used, must be sponsor and cIRB approved.***

Completing the Local Context Form & CC Form

Instructions on completing the Local Context Form & CC Form can be found on the HOBIT website, EFIC Resources tab. This form outlines the demographics that make up your community that will guide who you will target for your CC & PD events. Please review this document for helpful information.

EFIC Office Hours

Deneil Harney (SIREN Human Subjects Protection Specialist) has sent out calendar invites to participate in EFIC Office Hours. This block of time is reserved to help answer any questions sites might have related to EFIC plan development, WebDCU documentation of EFIC events, or any general EFIC questions. Please reach out to Natalie Fisher (brownnat@umich.edu) if you would like these invitations pushed to your calendar.

MOP Update

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Based on our past experience, subjects should not undergo HBO2 therapy if the P/F ratio is < 200. If the subject improves to the point that the P/F ratio is > 200 at any time during the first 5 days after randomization, treatments may be resumed. Subsequently, treatments may be continued if the P/F ratio remains above 200. Similarly, if PEEP requirements are > 10 cm of water, HBO2 treatments are temporarily discontinued. If requirements become < 10 cm of water at any time during the first 5 days after randomization, HBO2 treatments may be resumed.

SAE FAQ

Q: If a subject has both Pulmonary Dysfunction (defined as PaO2/FiO2 ≤ 200 or requiring PEEP > 10 cm of water to maintain a PaO2/FiO2 ratio of > 200) and pneumonia (or ARDS), should these events be reported as separate SAEs?

A: No, combining groups of events reflecting the same underlying pathophysiology is important. For instance, report the diagnosis such pneumonia or ARDS as the SAE not the symptoms or signs such as pulmonary dysfunction, cough, chest pain, fever, and/or infiltrates on chest x-ray separately. However, if the pulmonary dysfunction occurs with no other concurrent related diagnosis, it should be reported as a separate SAE.

A pneumonia SAE template can be found in the HOBIT Safety Monitoring Plan in the MOP, as well as in the FAQ page on hobittrial.org.