



Reminders

+NETT/SIREN Steering Committee Call

February 26th at 12pm ET

+NETT/SIREN Study Coordinator Call

March 3rd at 1pm ET

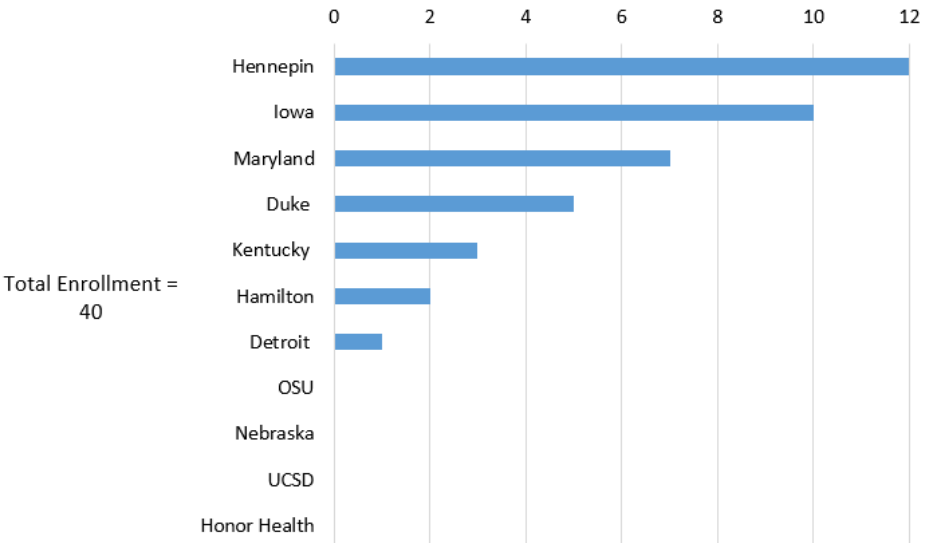
EFIC Local IRB Notification Letter

Thank you to Duke, Honor Health, Maryland for submitting the EFIC Local IRB Notification Letter!

EFIC eDOA Updated

Thank you to Kentucky for updating the eDOA to include EFIC responsibilities for team members!

HOBIT Enrollment by site through 2/7/2020



HOBIT Updates

MOP Update—Section 4.10.2 Page 29

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.

Call the hotline with any questions!

EFIC Updates

Sites may start the process of obtaining EFIC approval. Sites cannot enroll under EFIC currently. Until your site has obtained cIRB approval to enroll subjects using EFIC, you must continue to use **Protocol V5** and obtain informed consent from an LAR using the current informed consent form.

To get started, please review the EFIC start-up activities and tasks outlined in the [HOBIT Milestone Document](#).

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.**

Local Context Form

[Instructions on completing the Local Context 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.

NBH—Reminder!

For subjects randomized to the HBO + NBH or NBH only groups, an order set and/or other checks should be in place for the NBH treatment. This will allow tracking of the start and stop times of NBH treatment.

EFIC Readiness - Milestone 1

