January 11, 2019

HOBIT NEWS

Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminders:

+The next NETT/ SIREN Steering Committee Call is January 23 at 12pm ET

+WebDCU Database Freeze. Enter all data by January 18.

Maryland—1st Participant Enrolled

Congrats to Maryland on enrolling their 1st participant!

Iowa and Hennepin—Participants Enrolled

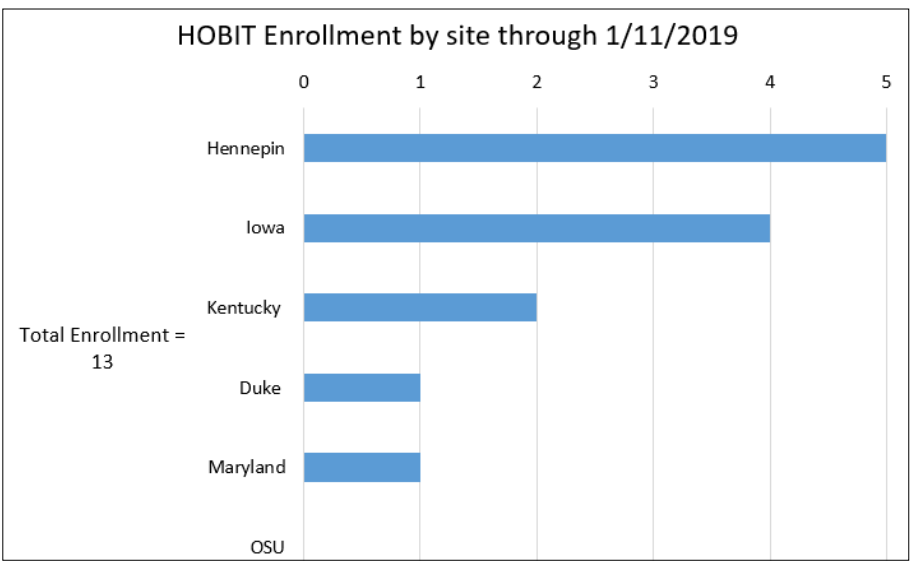
Great job to both Iowa and HCMC on enrolling 1 participant each!

Detroit and Nebraska—Readiness Calls Held

Thanks to Detroit and Nebraska on all their hard work in preparing for their readiness calls!

Iowa—HBO Certified

Kudos to Dr. Nick Mohr (PI) & Dr. Archit Sharma (Co-I) for certifying in HBO, due to unforeseen staffing issues.



HOBIT Updates

WebDCU Database Freeze—Enter All Data by January 18

The DCC statistical team will need to prepare reports for an upcoming DSMB meeting, resulting in a database freeze ahead of time.

Please address open queries, missing CRFs/data and rule violations by the end of Friday, January 18th. Additionally, ensure that screen failures up to January 18th have been input into WebDCU. Considering the specificity and size of this patient population, screen failures are integral to determine eligibility revisions as well as EFIC determination.

Thank you in advance for the assistance in providing the DSMB with the most accurate reflection of the HOBIT study. Keep up the diligence to enter data promptly and please continue to send us questions or ask for help when necessary.

eConsent Checklist

There have been some recent instances of eConsents being completed without containing local site contact information. We have provided a few verification steps below to help avoid this error from occurring in the future. Please add these steps to your consenting process:

1. Confirm the eConsent form is in fact your site's consent form, each time it is used. Local site contact information will appear on the first page (as it does on your paper version).

2. Confirm again on the confirmation page before the eConsent is submitted, that the consent form filled out reflects your site's consent form.

3. Wait to receive the email confirmation and attachment of the completed eConsent before enrolling the patient. The email can be instant or may take up to 10 minutes to be received. If you do not have time to wait, call the HOBIT Hotline to confirm the correct consent has been completed and received.

If the eConsent does not contain your current local site contact information, please make sure the email link is not broken. Your site name should appear at the end of the URL. Alternatively, use the IRB approved paper version of your site consent form and/or contact the HOBIT team at the CCC at hobit-milestone@umich.edu. This checklist is available on the HOBIT toolbox, under "e-Consent".

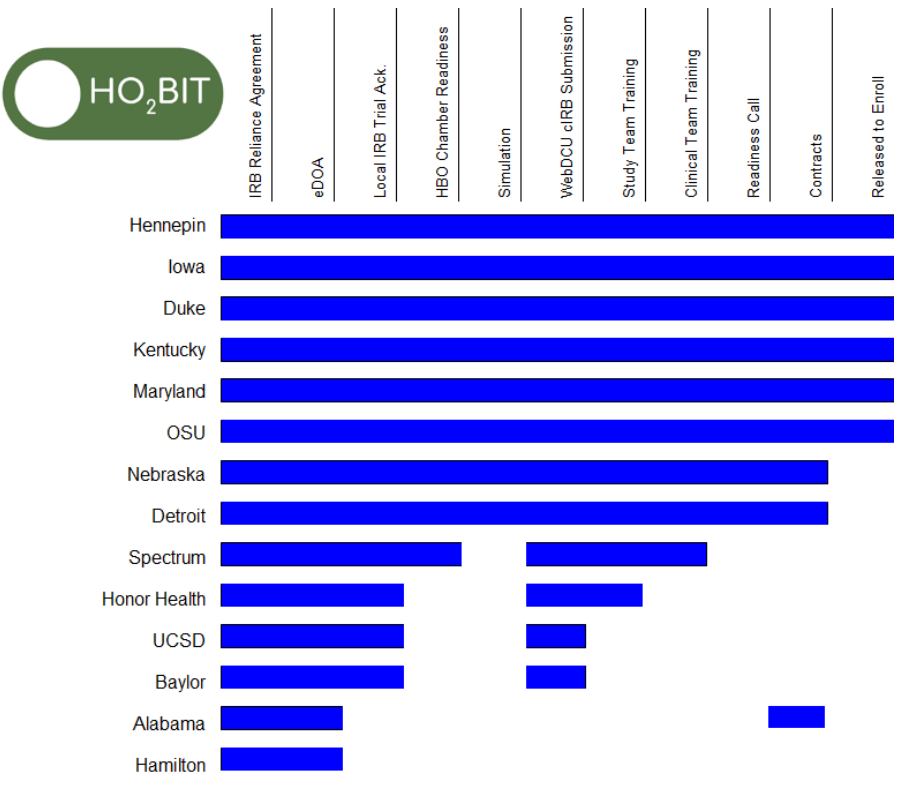
Updated Dive Logs—Version 3

A revision has been made to the dive logs and is now available in the HOBIT toolbox, under, "Chamber Resources". Instructions for completing this form are on page 2 of the log. Please note:

1. Only use the latest revision of this form from the HOBIT website toolbox.

2. Only use this HOBIT form for recording the HOBIT treatment data and upload this form to WebDCU.

3. If possible, for consistency, please have only one individual complete this form.

FAQs

Please check out newly added FAQs on the HOBIT website, under FAQs.