



Reminders

+NETT/SIREN Steering Committee Call

March 25th at 12pm ET

+NETT/SIREN Study Coordinator Call

April 7th at 1pm ET

Participant Enrolled—Duke

Great job to Duke University Hospital on recently enrolling a participant!

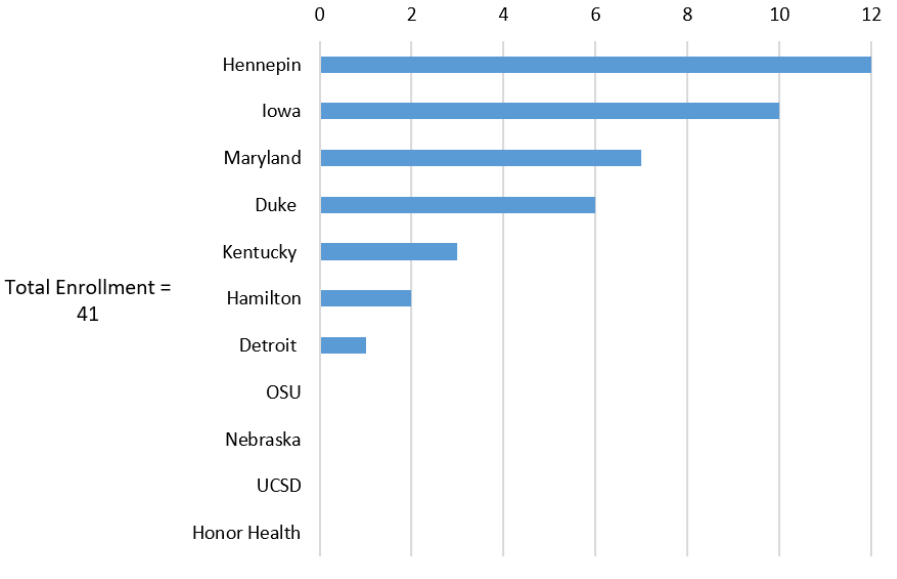
EFIC Milestone 1 Complete—Detroit

Thank you to Detroit Receiving Hospital on completing the tasks of Milestone 1!

Local Context Form Complete—UCSD

Good work done by UCSD on completing the Local Context Form in WebDCU!

HOBIT Enrollment by site through 3/6/2020



HOBIT Updates

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 Milestone 1 should be completed by **March 20**. 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.

New FAQ

The FAQ below was posted to the [FAQs](#) page under Consent.

Q: The timestamp on the e-consent does not reflect my time zone. What should I do?

A: A generic [note to file](#) is now available that reflects clarification on the time zone reflected on the e-consent PDF and the solution moving forward.

EFIC Readiness - Milestone 1

