Fred Hutch Cancer Center

Institutional Review Board

"Completing the Record" on Migrated Participating Sites (pSites) in Hutch IRB

Explanation

If a lead file had a Participating Site (psite) in an "approved" state prior to the launch of Hutch IRB in March 2023, the site was migrated into Hutch IRB. Only limited data was migrated (the site location, title, and site PI). Therefore, a "complete the record" modification should be submitted in Hutch IRB to complete the SmartForm Basic Site Information page and to attach currently approved documents.

Please read this document carefully to ensure a smooth process of completing the record.

Tip: Only Cancer Consortium employees can obtain access to Hutch IRB, so the local study team must work with the external pSite to make the submission.

Instructions

This document can be used as a checklist.

☐ Step 1: Gather copies of all site-specific documents

TIP: All documents must be clean, without IRB stamps, and in **Microsoft Word** format if possible.

☐ Existing, IRB- Approved site-specific documents that are still in use:

- ✓ Site-specific consent forms
- ✓ Site-specific scripts
- ✓ Site-specific participating-facing materials, such as advertisements and questionnaires

☐ Existing, IRB-approved Supplement forms, as applicable to the site:

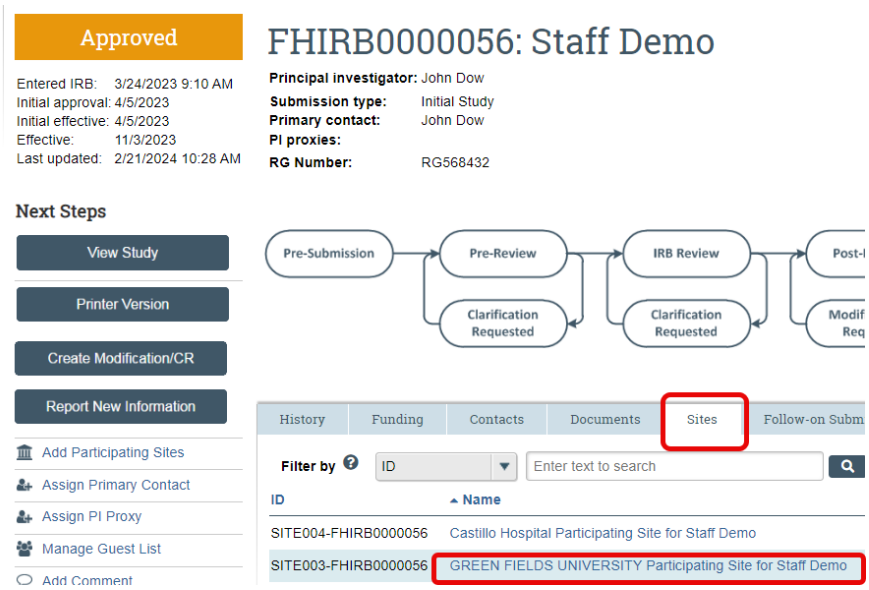
- ✓ Site-specific HIPAA Supplement and Waiver of Authorization
- ✓ Site-specific Waiver of Consent Supplement

You do not need to gather any of the following:

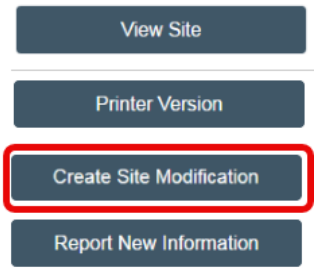
- × Any of the materials approved in the lead file
- × Original Participating Site application form
- × Site-specific Funding Source Supplement

☐ Step 2: Create a pSite Modification in Hutch IRB

☐ Navigate to the study workspace (lead file) and find the site by clicking on the **Sites** subtab, then clicking on the name of the site.



☐ On the site workspace, click the big blue **Create Site Modification** button.



☐ Complete the Modification Information page, indicating in question 2 (Summarize the modifications) that the mod is to complete the site's record. If documents need to be updated with the same mod, also describe those changes.

☐ In question 3, if there are no changes being made to the documents, an attachment here is not required. However, if you do need to update documents as part of this modification, you must also attach *HRP-886 Modification Supplement - Participating Site*.

☐ Click **Continue** and the site SmartForms are unlocked to be modified.

☐ On the Basic Site Information page: Verify the site PI name and email are accurate:

Step 1: On the Basic Site Information page: For "Local principal investigator", click the three dots to search for and open the investigator's record (it opens in a slide-in screen).

Step 2: In the "Select Person" slide-in, verify that both the spelling of the site PI's name and the included email address are accurate.

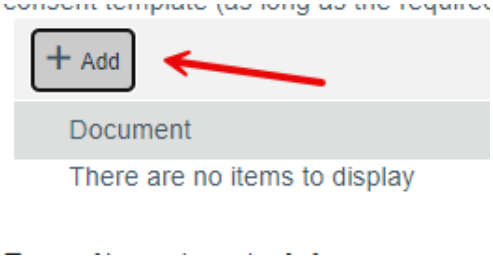
Step 3: If errors are discovered for the site PI's information, email IRO@fredhutch.org to request this be corrected in the Person record.

Click **Cancel** to exit the slide-in screen.

- ☐ Back on the Basic Site Information page, answer question 3 about conflicts of interest.
- ☐ Question 4: Remove the placeholder language, providing an accurate answer. This should match what was listed on the site's original application form.
- ☐ Add any site-specific funding. If the funding is supporting the study as a whole, it does not need to be duplicated on the site SmartForm page.
- ☐ Attach the documents gathered in Step 1.

☐ If the site is making **ANY CHANGES** to **Word documents** at the same time as completing the record:

Step 1: Click + ADD button to add the **currently approved** document version.



Step 2: Next, click the **Update** button to add a clean copy of the newly edited version on top of that:

TIP: There is no need to attach tracked changes version of Word documents when following the instructions above by using the Update function, as the system creates a tracked changes version in the background.

For PDF copies only, a tracked changes version must still be attached. However, it is important to still stack the clean version on top of the PDF copy, just like for the Word documents above.

☐ Step 3: Click Submit

Only the PI or a designated PI Proxy for the lead study may take this action. (See other instructions sheet, "Adding Study Team Members and PI Proxies on Migrated Studies in Hutch IRB.")

Questions? Contact IRO@fredhutch.org for assistance with this process.