Fred Hutch Cancer Center

Institutional Review Board

"Completing the Record" on Migrated Studies in Hutch IRB

Explanation

If you had a study in an "approved" state prior to the launch of Hutch IRB, your study data will be migrated into Hutch IRB. Only data is migrating, so you must "complete the record" in Hutch IRB by attaching documents on your first submission. Please read this document carefully to ensure a smooth process of completing the record on your migrated study.

- **Updated 6/5/23: It is recommended you submit a Modification to complete the record on a migrated study before you need to turn in a true Modification or Continuing Review.**
- If you have a timely **Modification** and you haven't already completed the record, one single Mod submission can be used to complete the record.
- If a **Continuing Review** is due and you haven't already completed the record, the study team should **add a Modification** to the submission to complete the migrated study record. It is recommended you select a combined MODCR submission type. (The CR and MOD to complete the record should be reviewed by the IRB together.)
- To add a new Participating Site on a migrated study when you haven't yet completed the record: The study team first must submit a Modification to complete the migrated **study** record. The pSite can only be reviewed after the migrated study record is completed in Hutch IRB.
- If the first submission in the new system is a **Reportable New Information (RNI)** submission, although not required it is strongly recommended that the study team **add a Modification** to complete the migrated study record for the related study if at all possible. (The RNI and MOD should be reviewed by the IRB together.)

NOTE: To make submissions on a study as a study team member, you and the PI must first have completed your Hutch IRB System Access training.

Then, you must also have been added as a study team member and designated by the PI to submit. You may want to do this right at launch. See the other instructions sheet, "Adding Study Team Members and PI Proxies on Migrated Studies in Hutch IRB." Those are administrative modifications that IRO staff can approve.

Instructions

You may choose to use this document as a checklist.

☐ Step 1: Gather copies of all study documents.

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

☐ Existing, IRB-approved study documents that are still in use:

- ✓ Protocol
- ✓ Consent forms
- ✓ Consent scripts
- ✓ Drug/device documentation such as IBs, package inserts, and device manuals
- ✓ Participant-facing materials such as advertisements and questionnaires
- ✓ Repository Access Confidentiality Pledge template

(This is what you would do in the legacy process for Continuing Reviews.)

You do <u>not</u> need to gather the following:

- ✗ HIPAA authorization forms

☐ Existing, IRB-approved Supplement forms, as applicable to your study:

- ✓ Children Supplement
- ✓ HIPAA Supplement and Waiver of Authorization
- ✓ Multi-Center Supplement
- ✓ Prisoner Certification Checklist for Investigator
- ✓ Repository, Registry or Databank Supplement
- ✓ Waiver of Consent Supplement

You do <u>not</u> need to gather any of the following Supplements:

- ✗ Original IRB application or Participating Site applications
- ✗ Department of Defense Supplement
- ✗ Expedited or Exempt Checklists
- ✗ Funding Source Supplement
- ✗ Genomic Data Sharing Supplement
- ✗ International Supplement
- ✗ Transfer Supplement

☐ Step 2: Prepare any changes to the study (if applicable).

Only if you are making a true Mod submission (not <u>just</u> completing the record):

☐ Complete *HRP-252 – FORM – Modification Supplement*.

☐ Edit any study documents as needed.

☐ If making a true Mod, remember to update any remaining references from FHCRC or SCCA to Fred Hutchinson Cancer Center or Fred Hutch (do not use “FHCC”).

☐ Step 3: Create a Modification in Hutch IRB.

- ☐ Find the migrated study and open it. In the study workspace, click the big blue "Create Modification/CR" button.
- ☐ Select either "Modification / Update" or "Modification and Continuing Review" (the latter if you are also submitting a CR).
- ☐ Once you select your option there, the "Modification Scope" question appears. You **must** select **Other parts of the study**. (If you are also updating the study team members, you can select that option in addition.)

  TIP: For a quick tutorial on creating a Modification, view this Online Video.

- ☐ In Question 2, Summarize the Modifications, write: "Completing the record on a migrated study." If additional changes are part of the Modification, also describe those changes, including any updates to the institution's name.
- ☐ In Question 3, Attach only the Modification Supplement: Attach *HRP-252 – FORM – Modification Supplement* **only if** you are making additional changes beyond completing the record. This Supplement is not required if the Mod's only purpose is to complete the record. Do not attach any study documents here.
- ☐ Click Continue and the study SmartForms are unlocked to be modified. Review all data fields in the SmartForms:
  - ☐ Confirm all migrated data is accurate and complete.
  - ☐ Update the Short Title: The full title is migrating into this field. You should update this to a shortened title because this is what shows in all workspaces. If you have a sponsor protocol number, include the protocol number at the beginning of the short title. For example, "ABC-1234: The ZERO Study." (Do not put the RG number there.)
  - ☐ Review the Description: This field is migrating in the description from the study's original "aims" when you first submitted the study to the IRB. Revise as needed for accuracy with the current study description.
  - ☐ Complete any blank data fields.
  - ☐ Local Study Team Members page: Add anyone who needs to view, edit, or be designated as a PI Proxy.
- ☐ Attach the documents you gathered in Step 1.
  - ☐ Attach the Protocol document on the "Basic Study Information" page. If your study does not have a protocol or at least a synopsis, attach a placeholder document. The IRB will assess whether they will require a protocol for this study moving forward as this is the current standard.
  - ☐ Any Drug or Device documentation must be attached on the Drug or Devices pages.
  - ☐ All other documents are attached to the Study/Local Site Documents pages.

TIP: For a single-site study, attach all documents in the appropriate categories on the Local Site Documents page.
For a multi-site study, attach study documents and templates on the Study Documents page, and attach local site-specific documents, used at the Cancer Consortium, on the Local Site Documents page.

☐ If making ANY CHANGES to **Word documents**:

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: You should **not** attach tracked changes versions of Word documents, because if you properly use the Add and Update functions, the system creates a tracked changes version in the background.

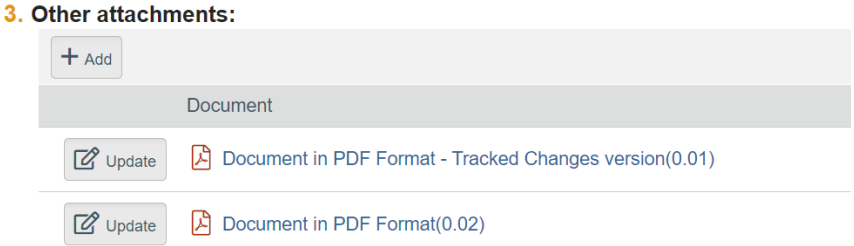
If you have PDF copies only, you must still attach tracked changes versions.

☐ If making ANY CHANGES to a document that you only have as a **PDF**:

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.

Step 3: Last, click **+ ADD** to add a tracked changes PDF of the document.



☐ Step 4: 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.”)

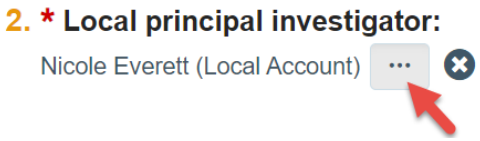
☐ Step 5: Participating Site files (if applicable).

- ☐ In the study workspace, click the Sites tab to view all pSites that migrated into Hutch IRB. Click the site "Name" to open the pSite workspace.
- ☐ You must prepare a **separate** Modification submission for each pSite to complete its record. Follow this checklist for each pSite; however, do not attach study-wide documents to the pSite Mod. Only attach site-specific documents.

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

- ☐ Verify the site PI contact information is accurate:

  Step 1: On the Basic Site Information page: For "Local principal investigator", click the three dots to open the investigator's Person record.



  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.

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