Fred Hutch Cancer Center

Institutional Review Board

"Completing the Record" for Migrated EXTERNAL IRB Studies

Explanation

If you had an External IRB study in an "approved" state prior to the launch of Hutch IRB, **only the study data** migrated into Hutch IRB, **the study documents did not migrate**. To provide these documents and "complete the record" in Hutch IRB, sites must review the SmartForm data for accuracy and attach some documents. This is done when you report Continuing Review to the IRO.

Please read this document carefully and follow the steps outlined below.

IMPORTANT REMINDERS

- To access Hutch IRB, you and the PI must first complete your Hutch IRB System Access training.
- **To make submissions in Hutch IRB, you must be added as a study team member and designated as a Proxy by the PI**. See the instruction sheet, "Adding Study Team Members and PI Proxies on Migrated Studies in Hutch IRB." Note that these are administrative modifications which IRO staff can approve.

Overview

At the first report of a Continuing Review approval in the Hutch IRB system, the study team must complete all the following three activities:

1. Run the **Report Continuing Review Data** activity and fill out the form.

2. **Create a Site Modification** to update the local site record and any local site-related documents.
3. **Update Study Details** to update the study level record and any study/protocol level documents.

Instructions

You may choose to use this document as a checklist.

☐ Step 1: Report Continuing Review Data

NOTE: You must be a Proxy to access the Report Continuing Review activity, otherwise only your PI will have this ability.

- ☐ Find the migrated study in the External IRB tab and open it. In the study workspace, click the **Report Continuing Review Data** activity link on the left side, under the big blue buttons.
- ☐ Complete the SmartForm questions.
- ☐ Questions 1 and 2 refer to local enrollment totals.
- ☐ Question 3, check all item that were TRUE for the last approval period. Any unchecked items require an explanation.
- ☐ Question 4, attach the following:
  - An explanation of any items left unchecked in question 3 **OR** a copy of the continuing review report submitted to the external IRB.
  - A copy of the external IRB's reapproval letter showing the new approval period. **Be sure it reflects approval for the Fred Hutch site or clarify why not.**
- ☐ Click OK to save and exit. The continuing review data has been submitted.

☐ Step 2: Gather Copies of Study Documents.

TIP: Unlike for internal reviewed files, you may submit PDF copies showing the external IRB's approval stamps.

- ☐ Existing, current study documents approved by the external IRB:
  - ✓ Protocol
  - ✓ Local site consent forms
  - ✓ Local site consent scripts
  - ✓ Study consent form (only if there is no local consent form)

  (Note: this was what you were asked to provide in the legacy process for External Continuing Reviews if these documents have been updated during the year.)

  You do NOT need to gather the following:
  - × IBs or Package Inserts
  - × HIPAA authorization forms
  - × Recruitment materials
  - × Past IRB Forms or Supplements

☐ Step 3: Create Site Modification in Hutch IRB.

- ☐ Find the migrated study in the External IRB tab and open it. In the study workspace, click the big blue "**Create Site Modification**" button. Select Modification/Update for the purpose of the submission, then select the type of modification you are creating.
- ☐ For the Scope, select **both** "Study team and research location information" **and** "Other parts of the site".
- ☐ In Question 1, indicate the current study status.
- ☐ In Question 2, summarize the modifications, write: "Completing the record on a migrated study."

  If there are new versions of any documents since the last continuing review, also describe which documents are new or updated.
- ☐ In Question 3, a Modification Supplement is NOT required for External IRB studies.
- ☐ Click **Continue** and the local site SmartForm pages are unlocked to be modified. Review all data fields in the SmartForms:

- ☐ Confirm all migrated data is accurate and complete.
- ☐ Additional Local Funding Sources page: Add any local funding associated with this study. You do not need to attach any funding source documents (i.e., grants or contracts) unless you are a Fred Hutch investigator and are adding a **new** funding source to this file.
- ☐ Local Study Team Members page: Add anyone who needs to view, edit, or be designated as a PI Proxy, including the Primary Contact person.
- ☐ Local Site Documents: Attach the current IRB approved consent forms used by the local cancer-consortium site. You do not need to attach recruitment materials.

☐ Step 4: Click Submit

Only the PI or a designated PI Proxy for the study may take this action.

(See instruction sheet "Adding Study Team Members and PI Proxies on Migrated Studies in Hutch IRB")

☐ Step 5: Update Study Details in Hutch IRB.

- ☐ Find the migrated study on the External IRB tab and open it. In the study workspace, click the big blue "**Update Study Details**" button.
- ☐ On page 1, in the "Summarize the updates" field, write: "Completing the record on a migrated study." If there are new versions of any documents since the last continuing review, also describe which documents are new or updated.
- ☐ 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. Update this to a shortened title because this is what shows in all workspaces.
    - Do not put the RG number here.
  - ☐ Review the Description: This field is migrating in the description from the study's original "aims" when you first submitted the study to the IRO. Revise as needed for accuracy with the current study description.
  - ☐ Complete any blank data fields.
  - ☐ 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.
  - ☐ Study Funding Sources page: This page captures funding that applies to the entire study. For external studies, you will generally leave this page blank and complete the Local Funding Sources page instead (when you complete the Site Modification)
  - ☐ Drug and Device pages: Confirm the data is accurate. You do not need to attach a Drug or Device Supplement, IBs, or package inserts. List the study drug/s and all other drugs involved in the study.
  - ☐ Study-Related Documents: This page is intended to capture protocol-level documents, such as a Sponsor's model consent template. You can leave this page blank unless there is no local consent form.
- ☐ Click **Finish** when you are done editing the SmartForm. This is all you need to do to submit. **DO NOT click "finalize updates".**
- ☐ The External Update is in the "Updating Study" state and will show as an EXTUPDATE in the History tab.
- ☐ You are done with this step. Next, the IRO will finalize the updates.

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