Volume 56 | May 2023

IRO News

Fred Hutch Cancer Center

Latest information from the Fred Hutch Institutional Review Office

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IRB

Protocol Document Required for All Human Research

Moving forward, all studies reviewed by the Fred Hutch IRB will require a protocol document or synopsis to describe the research.

For human research studies that do not currently have a protocol document or synopsis on file with the IRO: At the time of your next submission (Continuing Review or Modification), the IRB will give you a maximum of 6 months to prepare and submit the document via Modification. You are welcome to submit it proactively ahead of that request.

As background, a protocol document has been required by the IRB for all **new** studies for the past few years. However, some older studies were approved by the IRB without a protocol document or synopsis, which makes it challenging for the IRB to assess changes to the research over time. With the new Hutch IRB electronic system in place, the IRB now requires these older studies to come into alignment with the expectation of a single protocol document or synopsis representing the current research. (The only remaining exception will be Not Human Research activities, where the aims section from a grant may still suffice.)

Protocol templates for clinical trials are maintained by Clinical Research Support on the Clinical Research Resources Website (CRRW).

For non-clinical studies, there is no template available currently, but please note there is no minimum length for a protocol document (some protocols are only one or two pages). **The following elements should be addressed in the protocol as relevant to the research:**

- Study summary
- Background/significance and rationale
- Objectives
- Endpoints
- Subject population and inclusion/exclusion criteria and rationale for number of subjects
- Subject selection
- Consent process and methods
- Study procedures (and how these fit in the course of clinical procedures, if applicable)
- The type of biospecimens (e.g., whole blood, tumor tissue, etc.) that are included in the research
- The types of participant information records (including the specific data elements) that are included in the research
- The planned uses of biospecimens and participant information
- Risks and benefits
- Study timelines
- Statistical methods
- Data management and confidentiality
- Provisions to monitor data
- Provisions to protect participant privacy

Please contact IRO@fredhutch.org if you have questions about this requirement.

Hutch IRB Updates

Final Data Migration to Hutch IRB (Wave 3)

The IRO is preparing for the third and final data migration wave to Hutch IRB on June 12. If your study has not yet migrated, we ask that you help us resolve any pending submissions for that study as soon as possible. Studies must be in a fully approved state (with no pending submissions) no later than Friday, June 9 in order to migrate. If you anticipate you will not be able to resolve any pending items before this date, please consult with us at IRO@fredhutch.org.

Migrated Studies in Hutch IRB

If you haven't done so already, please be aware that you will need to take several actions on any study that was migrated into Hutch IRB:

- Only the PI and Primary Contact will have access to a migrated study in the system (assuming they completed their System Access training). If you wish to update who can view, edit, or submit on your studies, please access the written instructions available here.
- Only data has migrated, not documents. You will need to "complete the record" by adding approved documents. Instructions are available here.
    - UPDATE: Previously, we recommended you complete the record at the same time as your first submission in Hutch IRB on a migrated study. **Based on your feedback, we now instead recommend that you turn in a separate Modification to complete the record**, if time allows prior to your first real submission.
- For migrated studies relying on an External IRB, you "complete the record" at the time you are informing the IRO of the next continuing review having been completed with the IRB of record. Instructions are available here.

New Studies in Hutch IRB

You will still need to complete an IRB Application form when submitting a new study in Hutch IRB. The current IRB applications are broken down into three categories:

Application version	Use
IRB Application (Contact)	Use this form if you will interact with subjects, such as for an interventional study or a study with blood draws, a web-based survey, telephone interview, focus groups, etc.
IRB Application (No Contact)	Use this form only if the research consists solely of obtaining and using data or specimens from some source other than the participants (for example, it is a medical records review project or a study on leftover biospecimens).
Not Human Research Determination form	Complete this form to request a determination of Not Human Research. For more information, see this page.

IRB Supplements in Hutch IRB

After a new study is approved, any follow-on submissions require the completion of the SmartForm in Hutch IRB *and* an additional IRB submission form, referred to as an "IRB Supplement." The IRB Supplement provides additional information that is important to the IRB's assessment of the submission. Links to the most common supplements are below (you may be prompted to submit additional IRB Supplements, depending on the submission):

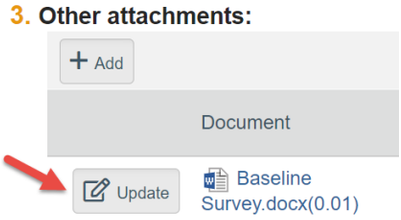
- Modification Supplement – required for all modification submissions **except**:
  - Studies overseen by an external IRB.
  - Administrative modifications to update study staff.
  - Modifications only to complete the record on a migrated study.
- Continuing Review Supplement – required for all continuing review submissions **except**:
  - Studies without a requirement for periodic continuing review that are requesting closure.
  - Studies overseen by an external IRB.
  - Exempt and Not Human Subject activities requesting closure.
- Continuing Review Supplement - Participating Site – required for sites outside the cancer consortium that are relying on the Fred Hutch IRB. This form must be collected from each participating site and submitted at the same time as the continuing review for the overall study.
- Participating Site Supplement – required for new sites outside the cancer consortium that will rely on the Fred Hutch IRB.
- RNI Supplement – required when Reporting New Information, such as a noncompliance event or an unanticipated problem involving risks to subjects or others

Change in IRB Approval Stamp Process

With the launch of Hutch IRB, study teams no longer need to resubmit copies of IRB approved documents with a continuing review submission. This is because the IRB approved documents are already saved to the study record in Hutch IRB. As a result, the IRB will no longer "restamp" already approved documents during the continuing review process. The IRB Approval date on the document will reflect the original approval date of the document and will only be updated if the document is later modified.

Hutch IRB Submission Reminders

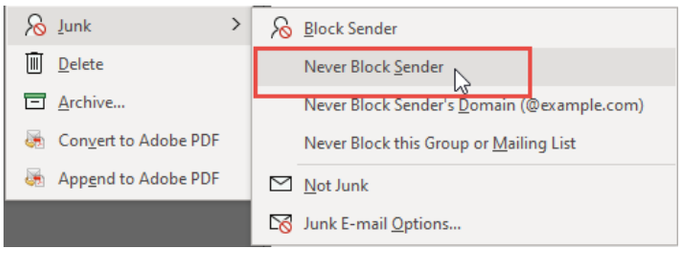
- Submit **clean Word** versions of all documents whenever possible.
- If you do not have a Word version of a document (e.g., the Sponsor's protocol), you may submit a PDF document; however, a tracked changes document will be required when the document is revised in the future.
- To update an existing version of a document (Word or PDF) in the system, use the **Update** button to add a **clean** copy of the newly edited version on top of the existing document. This creates a version history of the document in the system.



- For revised PDF documents, you will also click the **+Add** button to add a tracked changes PDF of the document.

Hutch IRB System Notifications

Hutch IRB sends a number of system-generated notifications as items move through the workflow. These notifications are important and will let you know when action is required in the system. Please double check your junk mail folder to ensure messages are being delivered. If you locate a message in your junk folder, right-click on the Hutch IRB message that is in your junk folder and click Junk > Never Block Sender.



Additional Resources to Support Your Use of Hutch IRB

- As a reminder, IRB policies, forms, and templates have been updated to support the new processes in Hutch IRB. Please ensure you are accessing the most up to date documents to avoid delays in submissions.
  - IRB Policies
  - IRB Forms
  - Consent Form Templates
- Access the training page to find links to online training modules. We will continue to add more modules in the future, including how to manage your non-Cancer Consortium participating sites and external studies.
- Hutch IRB is a production environment and is the system of record for all approved studies that reside in it. Please do not "practice" in Hutch IRB. We have a training environment for you to explore functionality and improve your understanding of the Hutch IRB system.
- **Office hours continue to be offered to support study teams with Hutch IRB:** Wednesday mornings, 10:00 AM - 11:00 AM (except holiday weeks).
- For Hutch IRB support questions (e.g., system access, technical issues, etc.), please email: IRO-Support@fredhutch.org.
- For Hutch IRB submission-related questions or to request 1:1 training or coaching on the system, please email IRO@fredhutch.org.

IACUC

IACUC Basic Training Refresher Requirements

If IACUC training applies to your current job role, you must take Basic IACUC Training upon hire (or relevant role change). In addition, please be aware that a Basic IACUC training **refresher** is required **every five years**.

There are several options to complete your required Basic IACUC **refresher** training. You only need to complete one of the following:

- Live training offered by Fred Hutch IRO (90 minutes)
  - In-person with hybrid option
  - Register via Hutch Learning
- Online CITI module (2 hours)
  - Instructions to register available here.
- Transfer of credit from another institution
- Attendance at a conference on animal welfare issues, such as the annual IACUC conference hosted by Northwest Association for Biomedical Research (NWABR)

Additional details are available on the IACUC Training page. Contact IRO@fredhutch.org with any questions.

Contact Us

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Email: iro@fredhutch.org
Web: https://extranet.fredhutch.org/en/u/iro.html