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# IRO News

Fred Hutch Cancer Center

**Latest information from the Fred Hutch Institutional Review Office**

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# IRB

## "Complete the Record" is Required on Migrated Studies

The end of March marks the one-year anniversary of the launch of the IRB electronic system, Hutch IRB. A big thank you to investigators and study teams for collaborating with us throughout this transition period!

At launch, we were only able to migrate *data* on existing studies into Hutch IRB. This means that all migrated studies must have a "complete the record" Modification to add current documents. Studies migrated into Hutch IRB that have not yet completed the record are **required to submit a Modification by March 29, 2024**.

For studies reviewed by the Fred Hutch IRB, instructions to complete the record are available here.

For external studies relying on an external IRB, you should complete the administrative record in Hutch IRB when you are informing the IRO of the next continuing review having been reviewed and approved by the external IRB. If no continuing reviews are required on the study, you must also complete the record by March 29 if you have not yet done so. Instructions for these studies are available here.

Please contact iro@fredhutch.org right away if you have questions about this requirement so that we may assist you. You may also contact IRO Training Administrator, Christina Ironside, at cironsid@fredhutch.org for 1:1 assistance with completing the record. We also have weekly office hours (see Hutch IRB and Hutch IACUC Office Hours article).

## Reporting of Third-Party Safety Events to the IRB

Sponsors routinely route safety reports to investigators who are conducting clinical trials using an investigational product. Such reports may be variously called IND, third-party, or external safety reports, MedWatch reports, or SUSARs. Safety reports must be assessed in a timely way to consider whether changes to the research are necessary and/or the criteria for IRB reporting has been met.

Reporting to the IRB promptly is required for all events meeting the definition of an Unanticipated Problem Involving Risk to Subjects or Others. When the Fred Hutch IRB is reviewing the study, this means reporting such events within 10 business days of receipt of the information (see *IRB Policy 1.11 Reporting Obligations for PI*). As a reminder, the Fred Hutch definition of an Unanticipated Problem Involving Risk to Subjects or Others includes three distinct parts:

- Unexpected,
- Related or possibly related to the research, AND
- Serious or suggests the research places the participants or others at a greater risk of physical or psychological harm than was previously known or recognized

If in doubt about whether all three criteria of this definition are met, it is best to report to the IRB.

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## Reporting of Third-Party Safety Events to the IRB (continued)

To help determine whether a harm was “unexpected,” the IRB generally considers whether the risks were originally outlined in the consent. If the risk was already conveyed to participants, it is not unexpected - unless there is an increase in the severity, frequency, or nature of the risk now being seen in the research.

When submitting third-party safety reports for IRB review by the Fred Hutch IRB, use the Reportable New Information pathway in Hutch IRB. Find the relevant study and click the big blue **Report New Information** button. Respond to the SmartForm questions in Hutch IRB. You must also complete an RNI Supplement and attach it to the SmartForm.

# Ancillary Review Matrix

In addition to IRB review, additional regulatory or institutional reviews may be required for the research taking place at a Cancer Consortium institution. These are called “ancillary” reviews because they are additional requirements beyond IRB review.

To help determine which ancillary reviews are required for your study, please refer to the Ancillary Review Matrix for assistance. This document outlines whether an ancillary review is required prior to submission to the IRB, can be done concurrent with IRB review, or is simply required before a study can be opened to accrual. You can also find relevant contact information for each ancillary review group.

# Hutch IRB Document Management

### Naming Documents

Consider how you want your documents to appear on your approval letter when naming them in Hutch IRB. Please be descriptive and clear - for example "Protocol Version 3" instead of just "Protocol". If the sponsor or other parties have expectations about how documents are to be listed on the approval letter, please name them accordingly.

To rename existing documents in Hutch IRB, use the **Update** button found next to the document to be renamed.

### Updating Existing Documents

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. Please do not delete the existing version and then re-add because we lose the version history that way.

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

### Submitting Documents

Submit clean Word versions of all documents whenever possible. If you do not have a version in Microsoft Word (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.

Please note: Hutch IRB is unable to accept Adobe PDF Portfolios. Single PDFs and Word documents should be submitted instead of a Portfolio.

# Hutch IRB and Hutch IACUC Office Hours

Do you need help creating or managing Hutch IRB or Hutch IACUC Submissions? Office hours are available to support study teams on Wednesday mornings from 10:00 AM – 11:00 AM.

For 1:1 assistance, contact iro@fredhutch.org for Hutch IRB submissions or iacuc@fredhutch.org for Hutch IACUC submissions. You may also contact IRO Training Administrator Christina Ironside directly at cironsid@fredhutch.org.

## Need a Translator?

Collaborative Data Services (CDS) is a fee for service CCSG-funded Shared Resource at the Fred Hutch. CDS Translation, Interviewing and Interpretation Services offer the following services in Spanish:

- Translation of study materials (consent forms, questionnaires, etc.)
- Bilingual Research Interviewing
- Interpretation
- Transcription
- We also can link researchers to external validated vendors to support the other top 5 languages in WA
- Other services

| Internal Rate/Hr. | Cancer Consortium Rate/Hr. | External Rate/Hr. |
|---|---|---|
| $45 | $62.10 | $90 |

For more information, please contact Angela Carvajal at acarvaja@fredhutch.org or extension x7357; or Jude Warner at vjwarner@fredhutch.org or extension x1492.

# IACUC

## Hutch IACUC Upgrade

The IRO has kicked off a project that will involve upgrading our current Hutch IACUC software to the latest version. Hutch IACUC is more than two major versions behind the Huron IACUC product and is therefore no longer on an officially supported release version. This increases our risk for software failure or issues. Upgrading allows Fred Hutch to benefit from product enhancements and fixes and to stay current on a supported version. Part of this project will also involve establishing an integration between Hutch IACUC and Comparative Medicine's Cayuse system.

The upgrade is expected to occur this calendar year, but no official launch date has been established. We will share more information as the timeline is finalized.

We expect limited impacts to research teams, but training will be developed to highlight any new features or changes.

## Culture of Caring: Caring for the People who Care for Animals

A shout-out to all the people who care tirelessly for animals in research. From the Comparative Medicine and animal husbandry staff, to EH&S, to the research labs and PIs - Fred Hutch is actively building a culture of caring. The IRO has been working with these groups to help further these efforts.

Professionals working with research animals want to help both people and animals. They care deeply for both the research animals and advancing science, but their work can come with many challenges. There are resources that may help with these unique challenges and stressors. Visit the 3R's Collaborative website or reach out to Stephen King or Jourdan Cruz for support with these topics:

- 3R's Collaborative Compassion Fatigue Resiliency resources: https://www.na3rsc.org/compassion-fatigue/
- Stephen King, 206-606-1099 sdking@fredhutch.org
- Jourdan Cruz, 206-247-9377 jscruz@fredhutch.org

Additional support options include the Employee Assistance Program (EAP) and Peer-to-Peer support:

- EAP: https://centernet.fredhutch.org/cn/u/benefits/eap.html
- Peer to Peer: https://faculty.uwmedicine.org/p2p/ (Although housed within UW Faculty Affairs, this service is available for Fred Hutch employees as well and one does not need to be a faculty member)

## Local Continuing Education Opportunity

Fred Hutch is a member institution of the Northwest Association of Biomedical Research (NWABR). If research teams have continuing education budget available, NWABR's IACUC Conference is a great training opportunity offered in February. This year's theme is "At the Leading Edge of Research." NWABR member organizations qualify for a 47% discounted rate by using the code NWABRMEMBER at registration.

Read additional information at the NWABR website: 2024 IBC, Security, and IACUC Conferences | NWABR.ORG.

## IRO Staff Updates

***Welcome to our newest arrivals!***

Emily Berrios, IRB Analyst 1

Austin Mansell, IRB Analyst 2

Lauren Santos, IRO Business Analyst

***Congratulations on this promotion!***

Jason Major, promoted to Senior Business Analyst

**Contact Us**

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