Fred Hutch Cancer Center

IRO News

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Latest information from the Fred Hutch Institutional Review Office

New Forms and Supplements

New IRB forms were released on February 27, designed for use along with the new Hutch IRB electronic system. During this interim period, before the system launch, you can use the new form versions to prepare submissions that will be submitted in Hutch IRB *after* the March 29 launch. These new forms will not be accepted for submissions made outside of Hutch IRB.

From the IRB Forms page, click the name of an individual form to see the versions available for download. For most forms, there are two versions available – a version to use for submissions outside of Hutch IRB and a version to use for submissions in Hutch IRB. Please take care to use the correct forms to avoid any processing delays and need for rework.

At launch, we will no longer accept the outgoing versions of the forms. Submissions in the system must be accompanied by the new forms.

In this issue:

Hold Your IRB Submissions if Not Timely

Hutch IRB launches on March 29, and there is a black-out period immediately before that, from March 23 – 28. In addition, in-flight submissions will impact migration of a study into Hutch IRB. Because of this, we ask that you carefully consider whether a Modification or New Study submission is necessary in March, or whether this submission could be held until after the launch.

Studies that still have in-flight submissions the week of March 20 will not migrate in the first data migration wave. As a result, new submissions cannot be accepted for these studies until they are fully migrated into Hutch IRB. The second data migration wave will occur 4 to 6 weeks after launch (final date TBD).

Keep in mind that for existing studies that get migrated into Hutch IRB, the first submission in the new system will require you to complete the record by attaching existing IRB-approved forms as well as IRB Supplement forms. Detailed instructions for this process will be posted to the IRB website as we approach the launch date.

Training on Hutch IRB

As was announced recently by email, there are multiple opportunities to learn to use Hutch IRB. One opportunity is an optional live Microsoft Teams training session, which you can register for here:
Fred Hutch Legacy SCCA Other Affiliation

Other opportunities are described on the Training page, including a live training environment for practice.

NOTE: Only individuals within the Cancer Consortium will have access to log in to Hutch IRB. If Fred Hutch serves as the IRB of record for sites outside the Consortium for your study, it is the Fred Hutch study team who needs to manage the sites' IRB submissions. Site forms are designed to collect the information you need to enter into the system (See New Forms article above).

Word Documents or PDFs?

Currently, IRO requests all documents submitted in PDF format. However, with the launch of Hutch IRB on March 29, we will instead ask you to submit only **Microsoft Word documents**. The only exception to the Word document requirement will be if you truly do not have access to a Word document, such as for an industry-sponsored protocol or an Investigator's Brochure.

In addition, when submitting Word documents, you will no longer have to include a tracked changes version for a Modification—because the system has a document history feature and produces a tracked changes version for the IRB to see. You would still need to include a tracked changes version for any changing document that is in PDF format.

Keep Informed about the Hutch IRB Launch

Make sure to bookmark the Hutch IRB project page and watch for all emails from IRO so that you keep apprised of the launch.

E-Consent

Clinical Research Support recently announced the launch of the Florence e-consent platform, which is open and available to all teams working within the Florence eBinder System. This platform will allow for teams to utilize a 21 CFR Part 11 compliant e-consent system for research participants. Those teams interested in pursuing Florence e-consent for their trials can reach out to eRegSupport@fredhutch.org for further information.

IRB approval is necessary to use e-consent on any individual study. Florence e-consent is now the recommended platform for any e-consent request. It also offers several advantages in terms of your IRB request:

- Florence's e-consent platform is allowable on a study that involves greater than minimal risk. (Sponsor's e-consent tools might also be allowable.)
- You do not need to request Fred Hutch Information Security Office review for Florence e-consent because it has already been fully vetted by ISO. Requests involving *other* platforms still require ISO review.

Contact IRO@fredhutch.org if you have questions about IRB submissions involving e-consent.

IACUC

Additional Approvals Necessary for Some Research

The goal of an IACUC protocol is to describe work occurring in live, vertebrate animals. Often this work includes components that require separate approvals from other committees, such as the Institutional Biosafety Committee (IBC) or Radiation Safety Committee (RSC). Coordination between the IBC, RSC, and IACUC is essential to maintaining compliance, safety, and good animal welfare. A few important points about committee approvals:

- The IBC and RSC review and approve three varieties of Memoranda of Understanding and Agreement: EMUA for etiological agents, CMUA for carcinogenic agents, and RMUA for radioactive materials.
    - EMUA, CMUA, and RMUA numbers are listed in IACUC protocols when they apply to the animal work described there-in.
    - Occasionally, required updates to an EMUA, CMUA, or RMUA are flagged during IACUC reviews.
- **EMUA, CMUA, and RMUA approvals are separate from IACUC approval.**
    - If EMUA, CMUA, or RMUA approval is pending, the associated animal work CANNOT OCCUR until those approvals are in place (even if the IACUC protocol has been approved).
- Learn more about safety committees and MUAs here: Environmental Health & Safety
- If human cells or tissue from a repository will be used, Institutional Review Board (IRB) review may also be required, which necessitates separate review and approval before the research can begin.

Our Regulatory Veterinarian Ashlee Langford (atyler@fredhutch.org) is happy to answer any questions or point you in the right direction for these additional reviews.

Contact Us

Institutional Review Office
Phone: 206.667.5900
Email: iro@fredhutch.org
Web: https://extranet.fredhutch.org/en/u/iro.html