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IRO News

Fred Hutch Cancer Center

Latest information from the Fred Hutch Institutional Review Office

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Training Updates & CITI Course Changes

A revision to IRB Policy 2.20 Training was published September 18, 2023. The revised policy clarifies when human subjects protection (HSP) and Good Clinical Practice (GCP) training are applicable to Fred Hutch *clinic* staff. These changes do not impact the applicability of training for *research* staff.

Additionally, for staff who complete training through the CITI online platform, you may notice that some training course titles have changed. Course titles were renamed for greater clarity; however, the content of each course remains unchanged. The below chart shows the old and new course names.

Old Course Title	New Course Title	Who should take this course?
Biomedical Research *Basic Course*	Human Subjects Protection (HSP) *Basic Course*	For staff primarily involved in **treatment intervention trials** (e.g., drug, biologic, or device), who have **NOT** previously completed an institutionally approved course in HSP
Biomedical Research *Refresher Course*	Human Subjects Protection (HSP) *Refresher Course*	For staff primarily involved in **treatment intervention trials** (e.g., drug, biologic, or device), who **HAVE** previously completed an institutionally approved course in HSP
Social Behavioral Research *Basic Course*	Social Behavioral Human Subjects Protection (HSP) *Basic Course*	For staff primarily involved in **non-treatment** intervention trials (e.g., observational), who have **NOT** previously completed an institutionally approved course in HSP
Social Behavioral Research *Refresher Course*	Social Behavioral Human Subjects Protection (HSP) *Refresher Course*	For staff primarily involved in **non-treatment** intervention trials (e.g., observational), who **HAVE** previously completed an institutionally approved course in HSP
Investigators, Staff and Students *Basic Course*	Working with the IACUC *Basic Course*	For staff working with vertebrate animals or animal tissue; a PI of an IACUC file or PI of a grant involving animals

IRB

IB Updates: New Requirement

When submitting an updated Investigator's Brochure (IB) for IRB review, please include a copy of the **cover letter or email** from the sponsor/CRO. This helps the IRB confirm the sponsor has also assessed the updated risks.

The Modification Supplement is being updated to remind you of this new requirement and will be available soon. IRO staff will begin asking for this additional documentation if not provided in the submission.

Continuing Review (CR) Reminders

Studies that require continuing review should turn in their CR submission at least **45 days prior to the expiration date**. This allows time for IRO staff to screen your submission and ensure it is review ready for the IRB. Plan well in advance to help avoid expiration or a last-minute rush.

Additional tips for your continuing review submissions:

- If you plan to turn in a substantive Modification, we discourage you from combining it with the CR submission because there is no way to separate them later. If the IRB has concerns with the Modification, the entire combined submission would be delayed. Minor changes can be combined with the CR (including "complete the record" for your first submission in Hutch IRB), but otherwise please plan to submit a separate, stand-alone Modification.
- The CR submission requires a CR Supplement to be attached, and questions must also be answered within the system SmartForm. Ensure the responses in the system do not contradict answers you provide on the Supplement.
- If there are sites outside the Cancer Consortium under our IRB's purview, those sites each need to complete their own site-specific CR Supplement – Participating Site form, and this must be included with the lead file CR submission. (See additional article on IRB Submissions for pSites later in this newsletter.) Ensure that responses related to enrollment do not contradict answers provided for the lead file CR and that the study-wide numbers add up.

Modification Supplement

When submitting a Modification in Hutch IRB, research teams must also generally attach a Modification Supplement. This form provides additional information to assist the IRB with performing their review. Please pay particular attention to question 2. This question assists IRO staff in appropriately routing a modification for review and helps the IRB better assess the changes to the research. Selecting "None of the above" is rarely the correct option. Please assess this question carefully to avoid unnecessary delays in the review process.

2. Does this modification involve changes to any of the following aspects of the research? *(Check all that apply.)*
   - ☐ Research Design and/or Resources
   - ☐ Participant Selection or Recruitment/Approach Process
   - ☐ Consent Process and/or Compensation
   - ☐ Methods for Documenting Consent
   - ☐ Potential Willingness of Research Participants to Continue to Take Part in This Study
   - ☐ Monitoring of the Data being collected
   - ☐ Privacy of Research Participants and/or Confidentiality of Research Participants' Data
   - ☐ Funding (Update the Funding page in Hutch IRB)
   - ☐ None of the above

Hutch IRB Tips

Hutch IRB launched just over six months ago! A huge **thank you** to study teams for working through this transition period with us. Below are some additional tips that may enhance your use of the system.

What documents go where?

We have developed a new resource guiding you on where to attach documents in Hutch IRB, available here.

System of Record

Hutch IRB is a system of record. Anything entered into Hutch IRB (including but not limited to study information, uploaded files, and comments) becomes part of the permanent study record. Please be thoughtful about what you add to Hutch IRB.

Helptext!

For additional tips and information when completing a submission in Hutch IRB, utilize Helptext by clicking on the ? symbols. Helptext has been updated since launch with information specific to our system. Any feedback on how Helptext can be made clearer is welcome.

Hutch IRB Tips (continued)

Is it multi-center or a single site study?

The involvement of two or more Cancer Consortium institutions makes a study "multi-site" in Hutch IRB. A "single-site" study is one where all research activities occur at only one single institution (for example, research where only Fred Hutch is involved).

Local Research Locations

A question in Hutch IRB requests a list of each Cancer Consortium location (site) where research activities will be conducted and directly overseen by the local investigator. For non-exempt human subjects research, this question is intended to capture all Cancer Consortium locations that are "engaged" in the research (according to the 2008 OHRP Guidance on engagement of institutions).

A few additional notes about local research locations:

- If Fred Hutch's only involvement in the research is to serve as the prime awardee of a federal grant, we are still considered engaged per OHRP and must be listed as a location.
- If no research activities are being conducted at any Cancer Consortium locations, select *No Research Location.* However, we recommend you consult with IRO@fredhutch.org before selecting this option because this situation is rare.
- A Modification is required to add an additional Cancer Consortium location or to close a particular Cancer Consortium site's involvement with the study.

IRB Submissions for Participating Sites (pSites)

When Fred Hutch has been selected as the single IRB, the local Fred Hutch/ Cancer Consortium study team is responsible for making IRB submissions on behalf of the participating sites outside the Cancer Consortium (who do not have access to the system). Additionally, there are site-specific application forms that must be completed. Generally, these forms are completed by the site investigator and their team, with help from the Fred Hutch coordinating center team.

- Participating Site Supplement: This form is completed and included in a new pSite submission within Hutch IRB. A reliance agreement must be in place before the site submission can be reviewed. In addition, the Fred Hutch IRB approves the lead file with the protocol and template consents before reviewing any pSite submissions.
- Modification Supplement – Participating Site: This is the site-specific version of the standard (study-level) Modification Supplement. A site-specific Mod is submitted via the site workspace in Hutch IRB. Note: The system does not allow pSite mods to be combined with a continuing review submission.
- Continuing Review Supplement – Participating Site: Each pSite outside the Cancer Consortium must complete its own continuing review (CR) Supplement specific to the activities that have taken place at that pSite during the review period. This form is uploaded on the Sites tab that is part of the continuing review workspace in Hutch IRB. The Fred Hutch study team prepares a **single** CR submission in Hutch IRB that encompasses: (1) the lead file CR Supplement and (2) any site-specific CR Supplements for each pSite under our purview. These are reviewed by the IRB as a single packet. Because of this, it is crucial to work with any pSites well in advance of the study's expiration to avoid issues. The entire packet is due to IRO **45 days** before the study expiration date.
- Closure – Participating Site: When a pSite has closed out its work on the study, the site investigator completes the closure form. The Fred Hutch study team uploads it via a Comment on the site workspace in Hutch IRB, making sure to select "IRB Coordinator" as the recipient so our staff receives a notification.

Again, remember that only employees within the Cancer Consortium have access to Hutch IRB for security reasons, so it is the responsibility of the Fred Hutch study team to coordinate and facilitate the pSite's IRB submissions for the life of the pSite on the study. It is also the responsibility of the Fred Hutch study team to provide IRB-approved documents to the pSite for their use in conducting the research.

IRO offers an online training specific to managing pSites, available here:

Online training: Creating and Managing a Participating Site

Fred Hutch Legacy SCCA

Please contact IRO@fredhutch.org with any questions about managing pSite submissions.

IACUC

IACUC Protocol Non-Compliance Prevention

The IACUC administrative team recently contacted research team members who are listed as animal handlers on IACUC protocols, but who have never logged into the Hutch IACUC system. Hutch IACUC is the online platform for IACUC protocol management at Fred Hutch and is the only location where research team members should access the current, approved version of their IACUC protocol. Research team members who are listed on an IACUC protocol are required to read the protocol and understand the procedures they are assigned to perform. A clear understanding of what is written in the IACUC-approved protocol is critical to preventing non-compliances when performing research involving vertebrate animals.

Research team members who are already listed on an IACUC protocol, but unable to access Hutch IACUC via MyApps, should submit a Study Staff Role Request Form.

For questions, please contact iacuc@fredhutch.org.

Contact Us

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