FRED HUTCH
Institutional Review Office

Volume 53 | May 2022

IRO NEWS

Latest information from the Fred Hutch Institutional Review Office

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FHCC Engagement in Research Reviewed by an External IRB: Institutional Authorization is Required

Whenever Fred Hutchinson Cancer Center (FHCC) is engaged in human subjects research, even if you are submitting to an external IRB, it is necessary to first obtain institutional authorization. While this is not a new process, the recent merger of Fred Hutch and SCCA has resulted in additional scenarios where FHCC is now considered engaged. The IRO is actively analyzing this process to determine if any steps below can be further streamlined.

What steps are involved for the IRO to authorize use of an external IRB to cover FHCC engagement?

Here are the steps involved for this administrative process:

1. If you haven't already, email IRO@fredhutch.org to discuss a reliance agreement.
    - Exceptions: Skip this step if requesting to rely on University of Washington, Seattle Children's, Advarra, or WCG IRB, or if you otherwise know a broad (multi-study) agreement is in place with the External IRB.
2. Complete a draft of the application form required by the external IRB, but do not submit it to the external IRB yet.
3. Complete the IRO External IRB Cover Sheet. Submit the form along the requested attachments to IRBinbox@fredhutch.org. (Note this form is currently being streamlined and a new version will be released soon.)

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What is the IRO looking at in this authorization process?

The primary issues that may hold up the authorization process are:

1. Does the application to the external IRB clearly reflect Fred Hutch's engagement? If this is missing, our institution's engagement would not have IRB coverage.

What is engagement?

"Engagement" is a regulatory term used to describe certain types of involvement in human subjects research. Generally, FHCC is considered engaged when its employees for the purposes of the research project:

- Intervene or interact with participants for the research
- Have access to identifiable private information about the subjects of the research
- Obtain informed consent of human subjects for the research

Additional details and examples are provided in the OHRP guidance on Engagement of Institutions in Human Subjects Research (2008).

2. Consent checks:

a. Does the consent form reflect that Fred Hutch will have access to identifiable data?

b. If FHCC employees are involved in *consenting*, does the consent form header list Fred Hutchinson Cancer Center?

c. If a Fred Hutch investigator is the *lead PI*, does the consent list the name, affiliation and phone number of the FH PI?

3. Are applicable ancillary reviews complete and is approval documentation attached?

4. If the study involves a contract between Fred Hutch and an industry sponsor, is the final contract consistent with the consent form injury section? The Office of General Counsel (OGC) assists with this check. (Note: this step does not apply to non-Fred Hutch contracts.)

The IRB of record remains responsible to check the consent for regulatory required elements, understandability, or accuracy against the protocol. The IRO administrative checks do not duplicate IRB review. The approach is outlined in the existing Fred Hutch IRB Policy 2.14, *Multi-Center Study Coordination – IRB Review and Oversight*.

What is the timeframe and outcome of the authorization process?

With a clean submission, the IRO targets a 2-3 day turnaround time. More time is added for OGC review if the research involves a Fred Hutch contract.

Once the IRO confirms all Fred Hutch institutional requirements have been met, you will be issued an IRO Endorsement form to authorize your

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submission to an external IRB. Include the IRO Endorsement form when you submit your final application form to the external IRB.

Once the external IRB approves your application, send a copy of the IRB approval letter and all final, approved documents to IRBinbox@fredhutch.org.

Why does FHCC need to track its engagement?

When an institution is engaged in non-exempt human subjects research, the institution must:

1. Provide assurance that it will comply with the regulations (federalwide assurance), including ensuring that all research at the institution has IRB coverage.
2. Certify to federal funding agencies that the research has been reviewed and approved by an IRB.
3. If the IRB of record is an external IRB (not the Fred Hutch IRB), the institution must document the reliance arrangement and outline the IRB's oversight and the responsibilities each institution will undertake to ensure compliance.

The first point makes it essential for the IRO to track the research and ensure FHCC's engagement is known to the external IRB, and that our institutional requirements are in place.

Fees

The Fred Hutch IRO charges a one-time administrative fee of $1500 to help cover the costs of maintaining these compliance records. This fee applies to industry-sponsored studies where Fred Hutch is engaged but is not the IRB of record. For UW contacts, there will be a 6-month grace period to allow research teams to incorporate this fee in their budgets. UW contracts finalized between April 1 – October 31, 2022, will have this one-time fee waived.

Take it Seriously: When Reporting Events to the Fred Hutch IRB

When an error, adverse event, or unexpected event occurs on a study reviewed by the Fred Hutch IRB, the PI is responsible for assessing whether the event meets the reporting criteria as described in IRB Policy 1.11, *Reporting Obligations for Principal Investigators*.

Once the PI determines an event meets the IRB's reporting criteria, the following are essential:

1. Report to the IRB within **10 calendar days** of the PI or study staff becoming aware of the event.
2. Carefully consider what actions are necessary both to **correct** the event and to **prevent** it from recurring in the future.
3. Complete the Expedited Reporting form with care and double-check your

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work. For example, ask a colleague to review it for clarity, accuracy, and completeness.

In describing the event for the IRB, keep in mind that events reviewed by the full committee must be understandable to both unaffiliated and non-scientist members. With this in mind, when completing the Reporting form:

- Describe the event concisely, yet as completely as possible. The IRB frequently requests additional information when the description is unclear or assumes background knowledge or expertise.
- Define all highly technical terms or processes, as well as all acronyms on first use.
- Address the true root cause of the event and include that information.
- If applicable, outline what additional information you are still collecting about the event and when you expect to receive that information.

It should be noted that the IRB places the utmost importance on the corrective and preventive action (CAPA) plan. Consider the corrective actions required to address the current event; and then separately outline what actions are necessary to prevent the event in the future. This requires an understanding of the root cause—so if you are still working to uncover the true root cause, explain that.

Taking into account these essentials will help support the IRB's understanding of the event so it can be assessed appropriately.

Staff Updates

Welcome to Our Newest Arrivals!

Christy Callahan, IRB Reliance Project Coordinator

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