FRED HUTCH
Institutional Review Office

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IRO NEWS

Latest information from the Fred Hutch Institutional Review Office

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How Will the New 'Fred Hutchinson Cancer Center' Impact the IRB/ IACUC Processes?

Fred Hutchinson Cancer Research Center (Fred Hutch) plans to merge with its longtime clinical affiliate, Seattle Cancer Care Alliance (SCCA) to form the new Fred Hutchinson Cancer Center (FHCC), effective April 1, 2022.

The IRO has received several questions asking about any anticipated impacts to approved IRB and IACUC studies if the proposed FHCC merger moves forward. Answers to the most frequently asked questions have been added to the OSR FHCC Transition Management FAQ in a new IRO section. Additionally, study teams can submit any merger-related questions for the IRO using a button on OSR's transition management page. Below you can find the most current FAQs related to IRO activities:

- **Will approved consent forms and other participant-facing study materials need to be revised to reference the institution's new name by April 1?**

  No. Approved study materials do not need to be immediately updated. These materials can be revised at the time of the next Modification or Continuing Review after the merger closes. The IRO will release revised consent form templates and forms to reflect the new legal name.

- **Will there be any changes to the human or animal subject assurance numbers?**

  No. The IRO has confirmed with both the Office for Human Research Protections (OHRP) and the Office of Laboratory Animal Welfare (OLAW) that the federalwide assurance (FWA) number and OLAW assurance number will remain the same.

- **Will reliance agreements need to be updated to reflect the new legal name?**

  Generally, no. The IRO is working with the Office of General Counsel to notify all organizations with existing reliance agreements of the legal name change.

- **Will a new Funding Verification and Activation Form (FVAF) be required for existing awards novating to FHCC?**

  No. An FVAF will not be required solely due to the funding novation process.

Continued...

- **Does the IRO need to be notified about changes to the project IDs associated with an approved IRB File?**

  Revisions to the project ID(s), and any other administrative updates, can be reported with the study's next Continuing Review Report on the *Funding Source Supplement*. A separate Modification is not required if there are no changes to the scope of work. For studies not required to submit Continuing Review Reports, please incorporate these administrative updates into a future Modification.

- **Does the IRO need to be notified about changes to the project IDs associated with an approved IACUC protocol?**

  Revisions to the project ID(s), and any other administrative updates, can be updated at the time of the protocol's next Amendment or Triennial review in Hutch IACUC. A separate Amendment is not necessary if there are no changes to the scope of work.

- **Is there any impact to Department of Defense (DOD) awards that have IRB or IACUC approvals from HRPO or ACURO, respectively?**

  The IRO will notify HRPO and ACURO about the change in legal name on behalf of all Fred Hutch investigators with active DOD awards. No additional action should be required by the study teams.

Submit Study Documents on Time

The IRB has seen noncompliance events lately that involve study teams not submitting updated study documents to the IRB in a timely manner. When an investigator receives updated study documentation from the sponsor (e.g., revised protocol, updated Investigator Brochure), these should be assessed by the PI right away and submitted to IRO within 30 to 45 days of receipt of the new information, even if the study is closed to accrual. Refer to IRB Policy 2.5: Modifications to On-Going Activities for additional information.

Protocols Using Total Body Irradiation

There is a new question 8.8 on the *Application for Review: Interventional Research* that asks whether the study uses Total Body Irradiation (TBI) procedures. If the answer is yes, the investigator needs to first send the protocol to the University of Washington Radiation Oncology department to confirm the TBI plan is appropriate. (UW Radiation Oncology contact information is provided under question 8.8.) This new ancillary review is required even if the study is using standard-of-care TBI procedures. This ancillary review is separate from the radiation safety review.

When Biospecimens or Data Remain

In order to close a study with the Fred Hutch IRB, all remaining biospecimens must first be either destroyed or transferred to another IRB file, to the sponsor, or to a designated third party as required by protocol or contract. Additionally, a study cannot be closed until there is a plan to destroy or archive identifiable data according to institutional policies and procedures. For Fred Hutch investigators, General Counsel maintains a set of Record Retention Guides here.

If your group holds biospecimens without current IRB oversight, please consult with the IRO at IRO@fredhutch.org.

Reminder: IRB/IACUC Approvals Necessary Before Release of Funds

For grant-funded work, please work on your IRB or IACUC submissions once you receive notice of a fundable score on the grant. This is to allow sufficient time to obtain IRB/IACUC approvals. Once the grant is received, Office of Sponsored Research cannot activate the funding until all necessary IRB/IACUC approvals are in place.

Hutch IRB Project Continues

The Hutch IRB project, which involves customization and implementation of an end-to-end electronic IRB submission system, is in full swing! The new system will tentatively launch in fall 2022. For details about the project and periodic updates please visit our project webpage.

Staff Updates

Welcome to our Newest Arrivals!

Rose Cabrito, CIP, IRB Operations Manager

Allie Criado, IRO Administrative Assistant II

Paul Gilmartin, IRB Reliance Coordinator

Congrats to Our Staff for These Promotions

Valerie Dossing, CIP, promoted to IRB Committee Analyst (from Expedited Analyst)

Christina Ironside, BS, promoted to IRO Training Administrator (from IACUC Assistant/Training Specialist)

Ashlee Langford, DVM, promoted to Regulatory Veterinarian (from IACUC Analyst) – *new position is 50% shared with Comparative Medicine*

Jennifer Linton promoted to IACUC Analyst (from IRO Administrative Assistant II)

Aaron Puetz promoted to IRB Expedited Analyst (from IRB Admin Assistant II)

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