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IRO News

Fred Hutch Cancer Center

Latest information from the Fred Hutch Institutional Review Office

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IRB

Reconsenting Guidance

After participants initially agree to join a study, an important part of the ongoing informed consent process is sharing any new information that may affect their willingness to continue to participate. For significant changes to the research procedures, risks, potential benefits, or available alternatives, re-consent is typically required.

When submitting a Modification, the investigator must indicate whether re-consent will be obtained and outline the plan to provide updated information to participants. As part of this plan the PI may request, and the IRB may allow, other members of the research team to conduct the re-consent discussion that may differ from the individuals allowed to obtain the *initial* consent. The type of information that needs to be communicated to participants will dictate the qualifications of the individuals allowed to re-consent participants. For example, the PI might propose that an MD or APP discuss with the participant new drug risks or new alternative medical treatments that become available. On the other hand, the non-medical staff might re-consent participants if a research modification adds another study visit to the planned schedule, or if an additional research test is planned for already obtained biospecimens.

For additional information, please refer to IRB Policy 2.11 Informed Consent. For consortium members, Clinical Research Support recently published guidance on Recommendations for Timely Reconsent of Study Participants.

Prospective Protocol Deviations Are Not Allowed

As a reminder, the Fred Hutch IRB does not recognize prospective protocol deviations. If an investigator wants to alter an aspect of how the protocol is conducted, including the inclusion/exclusion criteria as approved by the IRB, this requires an IRB Modification first to request that the IRB consider the change. This allows the IRB to conduct its necessary risk/benefit assessment of the change, thereby protecting participants.

The only allowed exception to obtaining IRB approval first would be when a change is necessary to eliminate apparent immediate hazards to an existing, enrolled participant. In such a case, the IRB reviews the change via a Reportable New Information submission to determine that it was consistent with ensuring the enrolled research participants' continued welfare. If the change will be necessary on a go-forward basis, a Modification should also be submitted.

Consent Forms and Institutional Name Citation

For all consent documents, the first use of the institution's name should always cite the full legal name: Fred Hutchinson Cancer Center. Thereafter, variations of the shortened name such as Fred Hutch or Fred Hutch Cancer Center can be used.

Hutch IRB Training

To learn more about Hutch IRB, the electronic IRB submission system, several training modules are available on the Hutch IRB Training webpage. Training modules are regularly updated and added to this webpage.

The "Creating and Submitting a New Study" module was updated at the end of July.

For additional Hutch IRB Support, office hours are also available on Wednesday mornings from 10-11 am. Contact IRO@fredhutch.org.

IACUC

AAALAC Reaccreditation

The Fred Hutch animal care and use program is currently undergoing reaccreditation with AAALAC International. Site visitors were on campus this week assessing animal facilities and IACUC protocols. Congratulations to all involved in the animal care and use program for going above and beyond: The site visitors had no findings and no suggestions!

Fred Hutch was first accredited by AAALAC International in 1979, and the reaccreditation process occurs every three years.

AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. Meeting AAALAC's standards means that Fred Hutch goes above and beyond the federal regulatory requirements in ensuring the wellbeing and importance of animals in research.

Animal Use Medical Screening is Now an Annual Requirement

Participation in the EH&S Animal Use Medical Screening Program is required for personnel who:

- directly care for or use animals, their tissues, fluids, or housing materials.
- work in spaces where animals are present (example: you work in a shared lab space where another study team is working with animals).
- enter the vivarium in their role but do not care for or use animals (example: facilities, engineering).

Please be aware that EH&S has recently made some changes to the Animal Use Medical Screening Program, including requiring completion of the Animal Use Medical Screening form **annually** (previously required every three years).

To ensure you are in compliance, please visit the Enterprise Health (EHS) Employee Portal via MyApps and complete any pending questionnaires that have been assigned to you. For questions, please reach out to Occupational Health at ohn@fredhutch.org.

Hutch IACUC Upgrade Project

Our Hutch IACUC upgrade project is well underway, and we are aiming for a launch date of early 2025. We will send additional specifics to the Hutch IACUC user community in the coming weeks.

Please note that there will be a brief downtime associated with this upgrade. We are working to minimize disruptions, and we will send advanced notice of the planned outage so that users can prepare accordingly.

Training videos and additional resources will be available prior to the upgrade to introduce new features and changes to the system.

This upgrade will bring our electronic IACUC protocol system up to the latest supported release version, ensuring a more stable and secure platform while allowing Fred Hutch to benefit from new features, product enhancements, and fixes. It will also integrate Hutch IACUC to Comparative Medicine's Cayuse system, streamlining processes between the two platforms.

IRO

Correction to IRO Newsletter Volume 59: Reporting of Third-Party Safety Events to the IRB

In Volume 59 (February 2024) of the IRO Newsletter, it was stated that "all events meeting the definition of an Unanticipated Problem Involving Risk to Subjects or Others" need to be reported within 10 business days of receipt of the information. The timeframe noted was incorrect, and these events should be reported within 10 calendar days. Reporting within 10 calendar days aligns with IRB Policy 1.11 Reporting Obligations for PI.

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