

Latest information from the Fred Hutch Institutional Review Office

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IRB

Reminder: Short Form Consent Process Changed January 1

Starting January 1, 2025, any use of the short form consent process now must be followed by translation of the full consent form to provide the participant with a consent form they can refer to throughout their participation in research.

Limited institutional funds have been set aside during this fiscal year to bridge the interim period when such funds may not have been included in finalized budgets.

Review the announcement and updated policy on the IRB [New Short Form Translation Requirement](#) webpage and contact IRO@fredhutch.org with questions.

IRB Document Updates

The IRO launched some document and form changes that were effective on February 3, 2025. These changes included:

1. Document Numbering

You may have noticed IRO has been changing policies and other documents to an HRP-xxx numbering system (for example, HRP-321) since the launch of Hutch IRB. The bulk of all documents are now on this new numbering system. A number of policies were recently brought into this new numbering system and had minor wording clarifications/typos corrected at the same time. All Fred Hutch IRB policies are available on the [IRB Policies and Procedures](#) webpage.

2. Children Supplement

The [Children Supplement](#) has been updated to collect specifics about the consent or notification plans for when children become adults while still on study. Investigators are asked to outline their plan for consenting or notifying the now-adult participants.

What about studies approved prior to this revised Supplement? If the IRB approved a study in the past to enroll minors who reach the age of majority without a specific consent/notification plan described in the IRB file, the IRB is assuming the consent plan already in place (for adult participants and/or parent/guardians of child participants) will be used to consent the minor participants when they reach the age of majority. If you have other plans to consent or notify the now-adult participants, you must first turn in an IRB [Modification](#) for the IRB to consider an alternative plan.

3. New Application and Modification Supplement

These have been revised to include a new question about Artificial Intelligence. See the Studies Involving Artificial Intelligence (AI) article in this newsletter.

Studies Involving Artificial Intelligence (AI)

Effective immediately for studies reviewed by the Fred Hutch IRB, IRO staff will send studies involving certain components of Artificial Intelligence (AI) for an AI Governance triage by a Fred Hutch Data Governance Specialist. Some studies may be referred for further review and consideration by the AI Governance Workgroup. When this Workgroup review is required, their approval (or any modifications they require) would be a condition of IRB approval.

A new question asking about the use of these AI components (artificial intelligence, machine learning, generative AI, or large language models) has been added to the [IRB Application forms](#) (Contact and No Contact versions) and to the [Modification Supplement](#).

For questions about the use of AI in research and the AI governance triage process, please contact dataprotection@fredhutch.org or see resources on CenterNet around [Understanding Artificial Intelligence](#) and [Artificial Intelligence Review](#).

Submitting Study Documents in a Timely Manner

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 [HRP-119 - POLICY - Modification to Ongoing Activities](#) for additional information.

WCG IRB Address Change and 1572s

For investigators that rely on WCG IRB, please note their mailing address will change in March 2025 to:

WCG IRB
5000 Centregreen Way, Suite 200
Cary, NC 27513, USA

Phone numbers and staff email addresses will remain the same.

Regarding 1572s:

- For currently approved sites or those pending approval, you DO NOT need to update your 1572s. WCG IRB will be including a “IRB Change in Address” Memo with every approval communication for approximately 3 months after the move. Keep a copy of the Memo from WCG in your regulatory folders.
- If your site is approved after the IRB’s move but you have already submitted a 1572 with the old address, or if you submit a 1572 after March 2025 but forget to use the WCG’s new address, simply keep a copy of WCG IRB’s Memo on file. You do not need to send FDA a revised 1572.

IRB Website Update

The IRB website has been recently updated. The content has been refreshed to provide additional clarification and information regarding a variety of IRB related topics, such as Hutch IRB.

The IRB website can be found on Centernet at <https://centernet.fredhutch.org/u/irb.html> or on Extranet at <https://extranet.fredhutch.org/u/irb.html>.

IACUC

Hutch IACUC System Upgrade

As we recently communicated, Hutch IACUC will be upgraded April 7, 2025. The system will be unavailable over the weekend of April 4 – April 6 while the upgrade is installed and verified.

We encourage research teams to submit any planned submissions well in advance of the upgrade date, if at all possible. As an institution, it will be helpful to have as few “in-flight” items as possible at the time of the upgrade to minimize impact. Please note the following submission due dates for the last available review dates prior to the upgrade:

Submission Type	Submission Due Date	Review Date	Information
Amendments – staff or funding changes	April 1	By April 3	-
Amendments – significant (that qualify for DMR)	March 7	March 24 DMR batch	If you will submit a significant amendment between March 7 and April 7, contact IACUC@fredhutch.org for guidance.
Amendments – significant (requiring full committee review)	February 11	March 4 committee meeting	If you will submit a significant amendment between March 7 and April 7, contact IACUC@fredhutch.org for guidance.
New Protocol Applications	February 11	March 4 committee meeting	-
Triennial Reviews	February 11	March 4 committee meeting	If you have a triennial review due prior to the upgrade, refer to email from IACUC staff on January 22.
Annual Reviews	N/A	N/A	Annual Reviews will no longer be required after the upgrade.

If you are not able to submit by these due dates, or not able to wait until after the upgrade, your submission will likely be in-flight at the time of the upgrade. Be aware, the upgrade will introduce new required questions in the protocol SmartForm, which must be answered in order to proceed with in-flight submissions (e.g. amendments, triennial reviews).

Training regarding changes to the protocol SmartForm, including new required questions, will be available March 10.

Save the Date! Biomedical Research Awareness Day on April 14

Fred Hutch’s second annual celebration of Biomedical Research Awareness Day (BRAD) will be held on April 14, 2025.

BRAD is an international outreach program through Americans for Medical Progress that seeks to increase public awareness about animal roles in biomedical research and the resulting medical advancements that benefit both humans and animals. BRAD highlights the importance of animal studies and demonstrates research organizations’ commitment to providing excellent animal care. It also builds a research advocate community and showcases biomedical research and laboratory animal care and medicine careers.

At Fred Hutch, last year’s BRAD lectures were standing room only, so a larger room will be used this year. Additional details coming soon.

IRO

Local Continuing Education Opportunity

The [Northwest Association of Biomedical Research \(NWABR\)](#) annual IRB, IBC and IACUC conference will be held March 3-5, 2025. The conference will take place at Seattle Children's Research Institute in downtown Seattle, and there is a virtual attendance option. This year's theme is "Community Connections in Research." As member organization of NWABR, Fred Hutch employees qualify for a 65% discounted rate by using the code NWABRMEMBER2025 at registration.

For more information, including the offered sessions and how to register, review the [2025 IRB, IBC & IACUC Conference Series](#) webpage.

Staff Updates

Join us in welcoming IRO's newest staff member:

Rachel Kegerreis, IRB Analyst 1

CONTACT US

INSTITUTIONAL REVIEW OFFICE

PHONE: 206.667.5900

EMAIL: IRO@FREDHUTCH.ORGWEB: [HTTPS://EXTRANET.FREDHUTCH.ORG/U/IRO.HTML](https://extranet.fredhutch.org/u/iro.html)*SUBSCRIBE OR MANAGE YOUR SUBSCRIPTION AT:**[HTTPS://LISTS.FHCRC.ORG/POSTORIUS/LISTS/IRO-NEWS.LISTS.FHCRC.ORG/](https://lists.fhcrc.org/postorius/lists/iro-news.lists.fhcrc.org/)*