



IRO NEWS

Latest information from the Fred Hutch Institutional Review Office

In this issue:

- IRB Submission Deadlines Are Changing
- Recent IRB Policy & Form Updates
- USDA Inspection
- AAALAC Site Visits Completed
- Staff Updates

IRB Submission Deadlines Are Changing

Plan ahead!

Effective September 1, IRB meeting submission deadlines will fall one business day earlier.

Previously, the submission deadline was Mondays at 5 p.m., and the new deadline is **Fridays at 5 p.m.**

In addition, because there is no IRB meeting on the 5th Wednesdays of a month, the deadline before an IRB meeting that falls *after* a 5th Wednesday will move **three** business days earlier (Wednesdays at 5 p.m. instead of Monday at 5 p.m.).

As always, rush items will be considered on a case-by-case basis.

The table below shows updated meeting deadlines for September and October 2021:

Submission Deadline	IRB Meeting
September 3	September 22
September 15*	October 6
September 24	October 13
October 1	October 20
October 8	October 27
October 15	November 3
October 22	November 10
October 29	November 17

*Shifted due to 5th Wednesday

See the full schedule here: <https://extranet.fredhutch.org/en/u/irb/meeting-schedule.html>



Recent IRB Policy & Form Updates

Effective August 9, 2021, the following policy and form updates address activities that increased during the pandemic, in addition to addressing requests from researchers, IRB members, and IRO staff. Please contact IRO@fredhutch.org if you have any questions about updated documents.

We have highlighted the major changes below. For a list of all documents that changed, click [here](#).

Protocol Document Now Required

Moving forward, all new studies will require a research protocol document for IRB review (not just a copy of the grant). The only exception will be Not Human Subjects requests.

A research protocol should generally address the following elements: Study summary, background/significance, objectives, endpoints, study procedures, study timelines, subject population and inclusion/exclusion criteria, statistics and rationale for number of subjects, risks and benefits, recruitment methods, the proposed consent process, data management and confidentiality, use of data and specimens, and provisions to monitor data and protect privacy.

Clinical Research Support offers protocol templates for transplant and solid tumor research, available on the [Clinical Research Resources Website](#) (CRRW). There are other template protocol resources available as well, such as the NIH: <https://grants.nih.gov/policy/clinical-trials/protocol-template.htm>.

Non-Native English Speakers

Short Form

We now have a new [tip sheet](#) to support researchers using the short form process to consent non-native English speakers.

HIPAA Authorizations

Historically when consenting non-native English speakers, researchers have asked the participant to sign the English HIPAA authorization form.

However, it's generally inappropriate for individuals to be asked to sign a document they cannot read. For new study submissions, please follow the below process for HIPAA if the study may enroll non-English speakers using the short form process. This process only applies to new studies moving forward.

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1. Researcher requests a HIPAA Alteration (a waiver of the HIPAA signature) from the IRB. (The [HIPAA Supplement and Waiver of Authorization](#) form has been updated to address this specific kind of request.)
2. When the HIPAA authorization is presented to the non-English speaking participant, the HIPAA document is orally interpreted for the participant.
3. A **verbal** HIPAA authorization (permission) is obtained from the participant.
4. The verbal authorization is documented in the research record.

This process allows HIPAA authorization to be obtained when required, but without someone being asked to sign a form they cannot read.

Consent Templates

The Fred Hutch [model consent form templates](#) have been updated. Researchers should always use the latest version as the basis for study-specific consent forms.

One important update involves template language for future **research uses of biospecimens or information**, in order to meet federal regulations around this topic. For new consent forms, researchers should always include one of three options about future research:

1. Biospecimens and tissue will not be used for future research (even if made anonymous) – only use this option if you and the sponsor can guarantee no future research will ever occur with the data or specimens (not even retrospective reviews). If you include this consent option, ensure mechanisms and a timeline are in place to destroy/discard all tissue and identifiable data at the end of the study.
2. Future research may be done, but only on de-identified materials. Ensure you plan mechanisms and a timeline to fully de-identify materials.
3. Future research will be done, including on identifiable data or specimens. This consent template language provides the participant the opportunity to say yes or no to the future research. Generally this is the preferred option when future research is planned or possible. Offering participants a choice is especially important if the study holds the prospect for direct benefit to the participant. Mandating agreement to storage and sharing materials for future research may be considered coercive if the participant does not want to agree to sharing of data and biospecimens but feels compelled to agree anyway in order to join a possibly beneficial clinical trial. Ensure you have mechanisms in place to document and track participants' choices so the tissue and information from anyone who says "No" can be appropriately destroyed or discarded at the end of the study.

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Informed Consent Policy

[IRB Policy 2.11 Informed Consent](#) has now been updated to reflect an increase in the use of **remote** and **electronic** consenting plans. If you are submitting a request for this kind of flexibility in consenting, please review the policy carefully to ensure your request will meet regulatory and institutional expectations.

We have also clarified expectations **for site-specific consent forms when Fred Hutch IRB is the single IRB**. Sites are asked to track any site-specific language into the model consent form the IRB has already approved. Sites are expected to limit their edits, relying as much as possible upon the model form's language. Fred Hutch typically will only allow site-specific changes in limited sections, such as name, contact info, injury language, privacy language, and updates to the signature blocks, or changes required to address state law requirements.

IRB Forms

Many of the [IRB forms](#) have been updated to clarify wording and instructions. Again, please ensure you are using the latest version of a form for your submission. We allow a grace period of 90 days, and after that a submission will be returned if not using the current version.

For all IRB applications except the new applications, there is now a new box for a **designee** to check if they are signing on behalf of the Principal Investigator. The designee is asked to attest the PI is aware of the submission and has given the designee permission to submit on their behalf. You must save documentation of the PI's permission to submit the form (you do not need to submit that documentation to the IRO).

USDA Inspection

The USDA came on campus June 30, 2021, for an unannounced inspection of the IACUC. Not only were there no findings, but the inspector said she was impressed with the documentation, including minutes and the new Hutch IACUC system-based protocols.



AAALAC Site Visits Completed

Following our [AAALAC](#) site visit in July, the site visitors recognized the program as exemplary and recommended Fred Hutch's Animal Care and Use Program for full continued accreditation. There were no findings, although three suggestions were made for improvement. We should hear the final decision from the AAALAC Council about our reaccreditation before the end of the year.

The site visitors recognized the strong teamwork between Comparative Medicine, the IACUC, Environmental Health and Safety and Occupational Health, Facilities and Engineering, IRO staff, leadership, and the research labs here as instrumental in the success of our program. Kudos were also offered for the excellent IACUC committee, a well-managed and documented husbandry and veterinary care program, and the high level of institutional commitment to the program.

Staff Updates

New Arrivals

Emily Michelbrink, CIP, is the newest IRB Analyst in the IRO. Welcome, Emily!

Departures

Hillary Beehler, IRB Reliance Coordinator

Elisa Butler, IRB Analyst for Committee A

Now Hiring

[IRB Analyst](#)

[IRB Reliance Coordinator](#)

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