



IRO NEWS

Latest information from the Fred Hutch IRO

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Coronavirus-related Research

New Applications or Modifications Required Because of the Current Outbreak

The IRO is receiving inquiries regarding coronavirus research. We are also receiving questions about potential changes to existing research to accommodate the current public health situation. Please contact [Meghan Scott](#) and/or [Jennifer Kogut](#) with specific questions about such submissions. IRO will prioritize new studies related to the novel virus, as well as modifications required because of the developing public health situation.

NOTE: If you are planning to screen participants for coronavirus risk, you can do this as part of regular institutional/clinical screening. This should not require a modification to the research.

If you have a timely IRB submission directly related to the developing coronavirus situation, please do the following:

- Send the submission to IRBinbox@fredhutch.org as usual
- To help IRO triage submissions, ensure the beginning of the email subject line reads:

CORONAVIRUS-RELATED

Hutch IACUC Update

We've passed the halfway mark! Study teams have transitioned more than half of all IACUC protocols to the new electronic Hutch IACUC system. The goal is to transition all protocols by July 2020. Thank you to all the teams who have converted their protocols. We know this is a big undertaking.



Hutch IRB Up Next

Starting this spring, IRO will begin undertaking the planning, customization, and implementation of the electronic tool on the IRB side, called “Hutch IRB.”

Stay tuned for more information as we approach the project kick-off date in May 2020!

Single IRB Requirements for Federally Funded Research

As a reminder, under the 2018 Common Rule, cooperative research projects must now rely on a single IRB (sIRB). The compliance date of the Cooperative Research provision was January 20, 2020. All new federally funded research projects involving more than one domestic institution must now use a single IRB. Previously, this requirement had been limited to NIH-funded multi-site trials.

NIH-funded researchers should be aware of the need to transition existing, IRB-approved NIH studies to a single IRB at the time of competing renewal.

Re-accrediting the IRB

Fred Hutch IRB first achieved accreditation by the Association for Accreditation of Human Research Protection Programs (AAHRPP) in 2008. The re-accreditation process is conducted three years after initial accreditation and then every five years thereafter. It’s that time again, and our re-accreditation application is due in March 2020.

In light of the upcoming reaccreditation, IRO has been revisiting policies and forms to make sure we are still on track with the high standards set by the accrediting body, and to ensure our recent updates related to the revised 2018 Common Rule requirements are up to par. Recent document updates are described below.

The accreditation process involves the Center's entire Human Research Protection Program. In the fall, AAHRPP site visitors will come to Fred Hutch to interview leadership, staff, and representatives from various divisions as well as key collaborators from our Consortium partners. We look forward to welcoming the visitors and to reaffirming our commitment to human research protections.



Recent IRB Policy & Form Updates

Effective February 24, 2020, the following policy and form updates reflect clarifications that strengthen Fred Hutch's ability to meet the requirements of our accrediting body, AAHRPP. Please contact IRO if you have any questions about updated documents. For a list of all documents that changed, click [here](#).

IRB POLICIES

IRB Policy 1.11, Reporting Obligations for Principal Investigators

When relying on an external IRB, the PI must be familiar with the external IRB's policies and procedures because events must be reviewed in accordance with that IRB's policies. This relates to noncompliance, serious adverse events, unanticipated events involving risk to subjects or others, and third-party safety reports. If an external IRB determines the event rises to the level of being reported to federal authorities, they will notify the Fred Hutch IRO according to the terms in the reliance agreement.

Certain major events must be reported to the IRO, regardless of whether Fred Hutch is the IRB of record (because Fred Hutch must report these to AAHRPP within 48 hours).

“The Principal Investigator must ensure any of the following events are reported to the Institutional Review Office within 48 hours of becoming aware of the event:

- 1) *Any negative actions taken by a government oversight office, including but not limited to:*
 - *OHRP Determination Letters;*
 - *FDA Warning Letters;*
 - *FDA 483 Inspection Reports with official action indicated;*
 - *FDA restrictions placed on the investigator;*
 - *Any corresponding compliance action taken by non-US authorities*
- 2) *Any negative press coverage (including but not limited to radio, TV, newspaper, online publications) regarding the Fred Hutch Human Research Protection Program.”*

IRB Policy 2.5, Modification to Ongoing Activities

Section 5 more clearly outlines the process of modifying multi-site trials under Fred Hutch IRB review.



IRB Policy 2.14, Multi-Center Study Coordination

The policy has been substantially reworked for clarity and alignment with current practices.

New: The addition of non-Cancer Consortium sites to research can now generally be reviewed by an Expedited reviewer rather than needing full IRB review. Sites with a conflict of interest, sites enrolling a prisoner population, and international sites will still be automatically scheduled to a full IRB meeting, and an Expedited reviewer retains the authority to refer any site to the full IRB.

IRB Policy 2.12, Privacy and Confidentiality

Certificates of Confidentiality (CoC) have been automatically issued to studies with NIH funding, and now studies with CDC or FDA funding will also receive an automatic CoC. Note: This refers only to *funding* or other support, not to whether the regulatory entity has oversight over the research. For example, research subject to FDA oversight but not funded by FDA does not automatically receive a CoC.

The policy now provides additional guidance for researchers if a Certificate of Confidentiality may no longer be in effect. If the CoC will expire but research data collection is still ongoing, the investigator generally should request a continuity of the CoC protections rather than allowing the protection to expire. Researchers who do not wish to extend the Certificate will be required to notify participants that the protection is no longer available for any future data collected.

IRB Policy 2.15, Research Involving Special Populations

Adults with impaired decision-making capacity:

The policy has been strengthened to clarify the context and expectations around enrollment of this special population. Researchers should have a plan to assess and document the individual's lack of capacity to provide informed consent (e.g., post-consent interview, standardized cognitive tests, or court documentation of guardianship). Under the principle of respect for persons, assent should be ongoing to the extent possible based on the individual's capacities. Researchers should ideally obtain written assent, or at the least, plan to obtain and document verbal assent.

Please note that the IRB application forms have also been revised to more clearly collect this information.

Prisoners:

Updates include:

- The involvement of healthy donors in a transplant study will generally not meet the requirements for enrollment of a prisoner. Therefore, if a



healthy donor participant on such a trial becomes incarcerated, they should be excluded from the research until such a time as they are no longer incarcerated.

- For data/specimen studies where the dataset would not enable knowing whether a participant is a prisoner, researchers do not need to mark “prisoners” as a special population on the IRB application.

IRB Policy 2.2, Continuing Review

When changing an IRB file status to “closed to accrual, in long-term follow-up only” status, please be aware that the IRB definition of “long-term follow-up” refers to *accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care*.

IRB FORMS

New Applications

New questions regarding ethnicity have been added to help address the Center’s requirements for Cancer Center Support Grant data reporting. Please note that all NIH-funded studies that meet the [NIH definition for clinical trial](https://grants.nih.gov/policy/inclusion/women-and-minorities.htm) must address plans for the inclusion of women and minorities. See <https://grants.nih.gov/policy/inclusion/women-and-minorities.htm>. All other studies should also collect this information to the extent possible based on the study design.

The [interventional application](#) includes a prompt reminding researchers that Scientific Review Committee approval document must be included with the IRB submission.

The [specimens/data application](#) has been updated regarding enrollment of special populations. Researchers are now prompted to only mark special populations if they will have sufficient information in the datasets to know that the special population is included. Please do not mark special populations if it is only a theoretical possibility and you will not know that these populations are included.

Research Modification Form

There are a couple of new questions:

- Confirm current status of study must be indicated. It is helpful to the IRB’s decision-making to have the current status: for example, if the study is no longer open to accrual at the time of the modification, this could change the IRB’s decisions about whether the consent needs to be updated.
- Consider whether Scientific Review Committee review and approval is



required. If so, an IRB submission cannot be scheduled for IRB review without documentation of SRC's approval.

[Human Subjects Research Determination Form](#)

Instructions have been added at the beginning that researchers should contact IRO@fredhutch.org if they suspect Fred Hutch is not "engaged" in the research. See section 3 of [IRB Policy 1.14 Determining when Activities are Research or Research Involving Human Research Participants](#) and the OHRP guidance on [Engagement of Institutions in Human Subjects Research](#) for more information about non-engagement in human subjects research that already has IRB approval at another institution.

[International Research Performance Site Assessment Supplement](#)

The form has a few new questions to help the IRB consider international sites. New questions address international collaborators, languages, and export controls.

[Certificate of Confidentiality Supplement](#)

This form, to be used in conjunction with the Specimens/Data application, has been reworked for clarity, usability, and to ensure researchers consider not just NIH funding but also CDC or FDA funding. (Note: This refers only to *funding* or other support, not to whether the regulatory entity has oversight over the research. For example, research subject to FDA oversight but not funded by FDA does not automatically receive a CoC.)

Institutional Review Office Leadership Updates

Meghan Scott was named the new director of Fred Hutch's IRO in November 2019. Meghan replaced Karen Hansen, who retired after 44 years at Fred Hutch. Meghan joined Fred Hutch as the IRO Assistant Director in 2016 after more than a decade at an independent IRB.

Jennifer Kogut has been promoted to the new Assistant Director of the Fred Hutch IRO. Jennifer joined Fred Hutch in 2017 as the IRB Operations Manager after more than eight years at an independent IRB.

Together, Meghan and Jennifer will lead the Institutional Review Office, which supports the ethical and compliant review of research involving human subjects and animals.



Other Staff Updates

Promotions

- Hillary Beehler promoted to IRB Reliance Coordinator, effective February 1, 2020
- Ashlee Langford promoted to IACUC Analyst/Post-Approval Monitor, effective February 1, 2020
- Amanda Egge promoted to Senior IACUC Analyst, effective February 1, 2020

Arrivals

- Jennifer Linton – IRO Admin Assistant started February 1, 2020
- Megan Tully – Expedited Analyst starts March 9, 2020

CONTACT US

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