



IRO NEWS

Latest information from the Fred Hutch IRO

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Revised IRB Policy 2.5, Modifications to On-going Activities

Effective September 30, 2019, the IRB Modification Policy has been revised to describe the IRB's expectations regarding the submission of changes in study documentation (e.g., revised protocol, updated Investigator's Brochure, etc.). The below expectations apply once a study has been fully approved by the IRB:

- Investigators should submit revised study documentation to the IRO within 30 days of receipt of the new information from the Sponsor (even if the study status is "closed to accrual").
- For studies in "open to accrual" status, if revised study documentation will not be submitted within 45 days, the PI should submit a

Research Modification to change the study status to "Temporarily Closed to Accrual."

- For changes that could represent an increase in risk to participants, the investigator should report this information as soon as possible.

Additional tips about IRB Modifications:

➔ **TIP:** Don't submit a Modification if you don't need to.

Occasionally the IRB receives Modification forms that are unnecessary. You do not need to submit an IRB modification to:

- Change the status of the study. You can just update it at your next Continuing Review Report (CRR).
 - ◇ EXCEPTION: If you are temporarily closing to accrual (or re-opening to accrual), this must be submitted as a Modification.
- Remove funding from the file. Just email IRBinbox@fredhutch.org as an FYI (we will update our database), and then omit the funding from your Funding Source Supplement at your next CRR.
- Change study staff.
 - ◇ EXCEPTION: Change in PI must be submitted as a Modification
 - ◇ EXCEPTION: If the changing staff were listed on your protocol or consent, etc., you need to submit a Modification to update those documents.



→ **TIP:** Remember to consider whether your IRB Modification needs Scientific Review Committee review before submitting to the IRB. When SRC review is necessary, the IRB no longer accepts a Modification without documentation of SRC's approval. Review the Clinical Research Support SRC Modification Form to confirm whether your Modification requires SRC approval: <https://www.cancerconsortium.org/en/support/forms/renewing-modifying-studies.html>

Secondary Research: Criteria for Exempt Category 4 Have Expanded

Fred Hutch researchers who envision [secondary research projects](#) should be aware of a recent expansion to the federal criteria for Exempt category 4.

You may recall that an [Exempt](#) determination by the IRB means that a study is considered to be human subjects research, but that it is not subject to the requirements of the Common Rule because the risks to subjects are low. Study methods must fit into one or more categories to receive an Exempt determination. For Exempt category 4, this generally means that although the researcher is accessing identifiable info/data, the researcher is recording the information in such a manner that the identity of the participants cannot readily be ascertained either directly or through linked identifiers; the researcher does not contact the participants; and the researcher will not re-identify subjects.

Two recent changes that expand the Exempt secondary research category include:

- Under the old rule, Exempt category 4 required that all study data or specimens be existing or “on the shelf” at the time of the IRB submission. Now, effective January 2019, the Exempt category was expanded to encompass the secondary research uses of identifiable private information or biospecimens **even if** the information or biospecimens are not yet in existence at the time of the IRB submission. This means an activity might qualify for an Exempt determination whether the data or specimens are retrospectively or prospectively obtained from another research study or from clinical care.
- Under prior Washington state law, access to UW medical records automatically precluded an Exempt determination. However, a recent change in Washington state allows access to UW medical records to qualify for an Exempt determination, if all other criteria are met. (Note that access to other types of Washington state records still precludes an Exempt determination. See [RCW Chapter 42.48](#) for more information.)

Thanks to these updates, numerous research projects at Fred Hutch may now qualify for an Exempt determination, instead of having to submit as a minimal risk application. This means fewer application questions to answer.



In addition, the Exempt determination is a “one and done” determination that does not require annual check-ins.

Please reach out to IRO@fredhutch.org if you have questions about the Exempt categories.

Good Clinical Practice (GCP) Training and Human Subjects Training Requirements

Effective January 1, 2017, the IRB Training Policy was revised to require GCP training *and* human subjects training every 3 years, consistent with NIH policy. As a reminder, GCP training no longer counts towards the human subjects refresher training requirement. For a list of accepted human subjects refresher training courses, click [here](#). For additional information regarding GCP training courses and requirements, click [here](#).

Revised IRB Fee Schedule and IRB Fee Waiver Requests

Effective September 1, 2019, the [IRB Fee Schedule](#) has been updated to include scenarios that may qualify for a waiver of Fred Hutch IRB fees. All requests for IRB Fee waivers will be considered on a case-by-case basis and must be submitted to Elizabeth Boyd, VP of Research Administration & Faculty Affairs using the [Waiver of IRB Fee Request Form](#).

NIH Genomic Summary Results Update

In November 2018, the NIH issued an update to its Genomic Data Sharing policy: The NIH has moved genomic summary results (GSR) from controlled access to unrestricted access. NIH defines GSR as aggregate data, “the output of analyses of genomic data across many individuals included within a specific study’s dataset.” This may be aggregate data sets uploaded by researchers, or the NIH may create their own aggregate sets from uploaded data.



The IRO had reached out this spring to all researchers for whom the Fred Hutch IRB had previously made a genomic data sharing determination to trigger an assessment about this issue. The update meant that any GSR were being automatically made available to researchers via unrestricted access, unless the submitter determined and documented (with a confirmation by the IRB) that GSR should not be made publicly available due to the sensitivity of the data.

For brand-new genomic data sharing plans, you will be asked to consider not only individual-level genomic data (as you have historically been asked to consider) but also to consider whether GSR/aggregate data should be retained in controlled access. In general, the only time such protective measures are necessary is if heightened privacy risks exist for some study populations—such as those from isolated geographic regions or those with rare or stigmatized traits.

Please note that the Fred Hutch Genomic Data Sharing Supplement has not yet been updated to address this new question, so our staff may be reaching out to you via email about this issue as needed.

Hutch IACUC Update

Hutch IACUC went live on July 31, 2019. In the weeks following launch, the Hutch IACUC team has received feedback and has been working hard to mitigate system issues. We thank you for your patience as we work towards steady state.

Visit our [support page](#) for more information, including system guidance and learning resources. If you encounter any problems, please don't hesitate to contact us! You can email iacuc@fredhutch.org for process questions or help using the system. You can also email our new support inbox if you need technical assistance: iro-support@fredhutch.org.

A big thank you to Comparative Medicine, Center IT, our research team champions, and the IACUC members. Their help with design, testing, and implementation of Hutch IACUC was instrumental! Also thank you very much to the Group 1 research teams who input their protocols early. Not only did that help us get a jump on conversion into the system, but they helped us identify problems to be fixed prior to go-live. Thank you!



Staff Updates

Karen Hansen's Retirement

As many of you know, Karen Hansen, Director of the Institutional Review Office is retiring December 6, 2019. The IRO staff will work closely with Karen to provide continuous and sustaining support for our researchers, staff and collaborators.

A celebration of Karen's 44 years of service to Fred Hutch is planned for November 8, 2019 from 3:30 pm to 5:00 pm in the Sze Suites.

Other IRO Staff Updates

Departures

- Sonja de Moya – Committee A IRB Analyst departed in August 2019
- Mark Thornquist – Committee C IRB Chair retired from the IRB as of July 31, 2019

Arrivals

- Elisa Butler – Committee A IRB Analyst started September 16, 2019

Promotions

- Shannon Wood promoted to Admin Coordinator II as of September 1, 2019.

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