FRED HUTCH
Institutional Review Office

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IRO NEWS

Latest information from the Fred Hutch IRO

In this issue:

Long-Term Remote Work Updates

IRO Goes Virtual

To meet pandemic physical distancing requirements, the IRO has mostly been working remotely since March 4, 2020. Currently we can have a portion of staff in the office as needed. Our IACUC team processes were already fully electronic thanks to the recent Hutch IACUC electronic system implementation, so the switch to remote work for this team was seamless. For the IRB side, we normally function as a paper-based office because of FDA Part 11 compliance requirements. Under social distancing limitations, IRO rapidly created and implemented a remote IRB process within one day. It took a couple more weeks to iron out the wrinkles.

The IRB and IACUC Committee meetings are running virtually on normal schedules, using Microsoft Teams functionality.

New IRB Submission Requirement: PDFs

Effective immediately, the IRO now requires **all IRB submissions to include PDF documents** instead of other document formats. This is required to support efficiency during the remote work period.

Reminder: Steps Required Before IRB Submission

Before submitting to the Fred Hutch IRB, please ensure the following steps are complete:

1. **OnCore entry** – Study teams now submit a REDCap Intake form to initiate the creation of a new protocol record in OnCore. This entry is required for all human subjects research protocols. For OnCore-related questions, please contact the CTMS Program Office at CTMS_Office@fredhutch.org.

2. **Scientific Review Committee (SRC) review** – Documentation of SRC approval must be included with your IRB submission materials for new

interventional cancer-related studies and for applicable modifications.

3. **University of Washington Zipline authorization** – For investigators whose primary appointments are at UW, documentation of UW Zipline authorization to rely on the Fred Hutch IRB must be included.

Failure to complete these steps in advance of submitting to the IRB will result in delays in IRB review.

Consent in the Age of COVID? Electronic Consent and Remote Consent Possibilities

In recent months there has been a tremendous uptick in Modifications for studies requesting flexibility in the process for obtaining informed consent from a research participant. Historically, waivers and alternative methods of obtaining consent are only approvable by an IRB in specific situations, and usually only for minimal risk studies. In the age of COVID, the IRB has been making an exception to allow remote consenting even on some greater-than-minimal-risk studies, given the goal to slow the spread of this serious virus and limit the amount of personal exposure to not only participants, but also study staff.

As such, the IRB has come up with FAQs to address possible modified consent practices. Researchers wishing to modify their consent process are strongly encouraged to make sure all requested changes in their process follow these standards in order to gain IRB approval. Be aware all requests are reviewed on a case-by-case basis. Feel free to contact the IRB office at IRO@fredhutch.org if you have questions about these FAQs.

Institutional Review Office (IRO) Coronavirus (COVID-19) Frequently Asked Questions:

Can I switch to electronic consent (eConsent)?

"If the study is greater than minimal risk, Fred Hutch IRB is not approving eConsent plans at this time because further assessment is required. You can request a remote (video/phone) consent process but must still obtain a signed consent form from the participant."

Can I switch to remote consenting?

"Yes, the IRB will generally allow remote video or phone consenting in the context of the pandemic. You must still obtain a signed consent back from the participant. See IRB Policy 2.11."

To see more details, and to view other COVID-19 FAQs related to the IRB, go to: https://extranet.fredhutch.org/en/u/irb/special-topics/covid-19-faq.html

Enrollment of Diverse Populations in Research

Part of the ethical framework the IRB upholds is the principle of *justice*, which includes looking at the population of research participants bearing the risks of research, and who among the wider societal population benefits from the research. The IRB is paying close attention to researchers' plans to recruit from among diverse populations. This is especially crucial for investigations on diseases that disproportionately affect specific populations[1] —such as breast cancer and prostate cancer, both of which have higher incidences and poorer outcomes for African Americans[2]. Research results cannot fully be considered generalizable if the research does not include groups most greatly affected.

The Office of Community Outreach and Engagement (OCOE) can help Cancer Consortium investigators in better understanding how to engage diverse populations with the goal of broadening research participation. To start the consultation process, fill out a REDCap form here https://redcap.link/ocoe_rrr and OCOE will be in touch.

[1] https://www.cancerconsortium.org/en/about/news/ocoe-2019-communityhealthneedsassessment.html

[2] https://cancerprogressreport.aacr.org/disparities/

Updated Not Human Subjects (NHS) Sources List

The IRO maintains a list of sources of data and specimens that will automatically qualify as NHS research. These means that if your research involves de-identified human data or specimens obtained *exclusively* from the providers on the list, your research is "presumptively" considered Not Human Subjects research, and no additional paperwork is required to be submitted to the IRO.

The list has just been updated to include two new sources: WiCell, a provider of stem cells, and Stemcell Technologies, a commercial provider of primary and cultured cells. We have also removed two prior sources from the list, Astarte Biologics and Asterand. Please contact IRO@fredhutch.org with questions about NHS determinations.

IRB Reaccreditation Update

Fred Hutch IRB first achieved accreditation by the Association for Accreditation of Human Research Protection Programs (AAHRPP) in 2008. The reaccreditation process is conducted three years after initial accreditation, and every five years thereafter.

AAHRPP will be conducting the reaccreditation site visit remotely on **November 5 and 6**. As part of the process, the AAHRPP site visitors will be interviewing leadership, staff, representatives from various divisions, and key collaborators from our Consortium partners, as well as reviewing IRB records.

In preparation for the site visit, the IRO is working in collaboration with personnel across the Hutch to gather requested documents. All individuals who were selected for interviews by the AAHRPP site visitors have been notified.

Hutch IRB Project Paused

As noted in a town hall meeting this summer, Fred Hutch paused multiple projects to conserve capital during these uncertain economic times. In support of this effort, the electronic IRB system project is on hold. The timeframe for when this project will resume is unknown at this time; however, we will provide updates as we learn more.

Hutch IACUC Conversion Status

Study teams have transitioned more than 83% of all IACUC protocols to the new electronic IACUC system, with additional converted protocols currently in the review process. The IACUC team is available through Microsoft Teams to provide training and individual sessions to help groups convert their protocols. If you are interested in a training session, please contact Christina Ironside. Thank you to all the research teams who have put in the effort to convert their studies into the Hutch IACUC protocol format.

Staff Updates

Introducing Our New IRB Operations Manager

The IRO office would like to welcome Chris Weir, CIP, as the new IRB Operations Manager as of July, 2020. Before joining the Hutch, Chris spent the last 15 years with Benaroya Research Institute (BRI) at Virginia Mason Medical Center supporting all aspects of the research protections mission (i.e., IRB, IACUC, IBC). As well, he continues as an active member of the Virginia Mason (VM) Bioethics Committee that evaluates difficult ethical issues surrounding the treatment and care of VM patients. Prior to BRI, he spent several years at an independent IRB, Quorum Review, supporting researchers and sponsors in approving multi-center FDA-regulated trials nationwide. After graduating at the UW in Speech Communication he spent several years working and travelling throughout Japan, Taiwan, and Southeast Asia as a teacher and recruiter. As a cancer survivor himself, he looks forward to supporting the research mission at Fred Hutch through the protection of human subjects for many years to come.

Contact Us

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