FRED HUTCH
Institutional Review Office

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IRO NEWS

Latest information from the Fred Hutch IRO

In this issue:

Revisions to the Common Rule Officially Delayed until January 21, 2019

On June 18, 2018, Health and Human Services (HHS) officially delayed the implementation of revisions to the "Federal Policy for the Protection of Human Subjects" (also known as the Common Rule) until January 21, 2019.

To support compliance with these updated regulations, the IRO has revised IRB policies, templates, and forms that will be released in phases beginning later this year. IRO staff will provide further communications, resources, and in-person training opportunities in the months to come.

These regulatory changes will only impact **new** federally funded studies approved by the Fred Hutch IRB on or after January 21, 2019.

All studies approved prior to January 21, 2019, will not be subject to this regulatory change. FDA-regulated research that does not receive federal funds will continue under the present FDA regulations. For an additional overview, please refer to our recent newsletters available here.

The "Final Rule" allows the option to implement three provisions this July; however, Fred Hutch as an institution has made the decision not to proceed with their early implementation.

If you have any questions about this upcoming change, please reach out to our office at IRO@fredhutch.org. To view the revised regulations directly, visit https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html.

Annual Renewal of Non-USDA and Non-DOD Funded Research Protocols has been Eliminated

On February 6, 2018, the Institutional Animal Care and Use Committee (IACUC) eliminated the annual renewal requirement for protocols that both do not receive funding from the Department of Defense (DOD) and that only involve non-USDA regulated species (i.e. mice, rats, and fish).

Annual Renewal Required	Annual Renewal Not Required
• Protocols with USDA-regulated species • Protocols that receive DOD funding	• Protocols that receive no DOD funds and that use non-USDA regulated species

For USDA regulated species and/or DOD funded research, the IACUC will continue to review protocols at least annually. For both USDA and non-USDA regulated protocols, the IACUC will continue to conduct a *de novo* protocol review at least once every three years.

Changes to Designated Member Review (DMR) Eligibility

The IACUC has implemented changes to the DMR eligibility criteria. The following protocol modifications are no longer eligible for DMR and will require convened meeting review:

- Addition of a new species
- New major surgical procedures
- Changes to or addition of Pain Category E procedures

Updated IACUC Protocol Form

On May 29, 2018, a revised version of the IACUC Protocol Form was released. The revised version of the protocol from will be required for all new and 3-Year *de novo* submission as of August 29, 2018. A summary of the protocol form changes can be found here.

Hutch IACUC

Software solution on the horizon to support IACUC review

We are excited to share news about Hutch IACUC, a single web-based system for submitting, reviewing, approving, and storing animal research protocols. In the near future, Hutch IACUC will join Hutch Grants in the research administration suite adopted by Fred Hutch. The IACUC solution will modernize the IACUC office, allow for greater transparency into protocol status, improve review process efficiency, and aid in regulatory compliance.

The implementation project for Hutch IACUC kicked off in early May. The IRO, along with individuals in Center IT, Comparative Medicine, the research divisions, and IACUC committee members, is working with the product vendor (Huron) to identify areas where the product will benefit from changes to best fit Fred Hutch's research environment. Development will begin this summer. The goal is to launch in early 2019. Stay tuned for more updates!

Personnel Updates

It is with great excitement that our IRB Operations Manager, Caroline Davis, has announced she is expecting a new member of her family this August. After eight years in the IRO, she'll be taking some time off work to spend time with her family. Caroline has been an integral member of the IRO, having held five positions in the office including IRO Admin Assistant, IACUC Admin II, IRB Admin Assistant II, and IRB Expedited Analyst. We wish her and her family all the best and will miss seeing her smiling face every day.

The IRO would like to welcome Jennifer Kogut to the team! Jennifer joined the IRO on June 1st and will be taking over the IRB Operations Manager role. She joins us from Quorum Review IRB, where she most recently held the position of Regulatory Editor & Analyst. She brings a wealth of knowledge and experience and the IRO is excited to have her join us.

In addition the IRO has seen some changes to the administrative assistant and analyst teams. Check out our contacts page for details.

Contact Us

Institutional Review Office
Phone: 206.667.5900
Email: IRO@FREDHUTCH.ORG
Web: HTTPS://EXTRANET.FREDHUTCH.ORG/EN/U/IRO.HTML