



IRO NEWS

Latest information from the Fred Hutch IRO

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Revised Common Rule Effective on Monday

The federal regulations for the protection of human subjects known as the Common Rule have been revised, with a compliance date of **January 21, 2019**. The regulatory changes will only impact **new** federally funded studies that receive initial review by the Fred Hutch IRB on or after that date.

The IRO has prepared numerous revised policies and forms that will affect all submissions:

Some **forms** were pre-released in November.

Prior versions are no longer accepted for these forms:

- Application for Review Observational Research
- Application for Review Human Specimens or Data Research
- Participating Site Application
- Exempt Checklist
- Waiver of Consent Supplement

Revised policies, consent templates, and some additional form updates will be live on our website on Monday. To view the version and date changes, click [here](#).

FAQs:

Will the regulation changes affect my existing approved studies?

No. Studies that received IRB approval before January 21, 2019, will continue under the prior Common Rule requirements. Fred Hutch does not currently plan to transition existing studies to the revised regulations.

What if my study is “in-flight”?

Disapproved Studies: If your study was disapproved by the IRB before January 21, you must re-submit on the new versions of the forms (in addition to addressing the IRB requirements as outlined in your IRB result letter).

Studies Approved with Minor Modifications: Studies that were approved with minor modifications before January 21 are considered approved under the “Pre-2018 Requirements” of the Common Rule. You do not need to resubmit on the new versions of the forms. You only need to address the IRB requirements outlined in the IRB result letter.

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What if my study is FDA-regulated?

FDA regulations have not changed. If you are submitting new research that is also federally funded, the revised regulations impact you.

What if the IRB requests a *de novo* new application?

For older studies, the IRB occasionally requests a *de novo* new application submission, to ensure compliance with current regulations and policies. If your *de novo* application will be reviewed by the IRB after January 21, the research must switch to the “2018 Requirements” of the revised Common Rule.

What do “Pre-2018 Requirements” and “2018 Requirements” mean?

The initial effective date of the revised Common Rule was in 2018. Therefore, even though final compliance date is January 2019, the regulations refer to “Pre-2018 Requirements” and “2018 Requirements.” Fred Hutch has adopted this terminology for consistency with published regulations and guidance.

If you have any questions about these changes, please reach out to our office at iro@fredhutch.org. To view the revised 2018 Requirements directly, visit <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>.

2018 Common Rule Training

If you missed the 2018 Common Rule trainings in December and January but would like to learn more, please contact us at iro@fredhutch.org. We want to hear from you to help decide if more training times are needed.

Removal of Division Director Signature Requirement

The requirement to provide sign-off from a Division Director or designee has been eliminated with the newest IRB Applications for Review, dated 01/21/2019.

The Division Director sign-off previously confirmed 1) the proposed research study had scientific merit and 2) the PI was qualified to conduct the research. After careful analysis by the institution, it was determined that there continue to be mechanisms in place to ensure both requirements are met. Removal of the signature requirement will help streamline the IRB submission process and reduce the administrative burden to both the research teams and Division Directors.

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PI Qualifications: Fred Hutch employees with a faculty appointment of Member, Associate Member, or Assistant Member at Fred Hutch may serve as Principal Investigators. Division Directors are asked to evaluate one-off requests for Fred Hutch employees, or Affiliate Investigators, without a faculty appointment at Fred Hutch to serve as Principal Investigator. The IRO will facilitate this review process with the Division Directors.

UW Minimal Risk Oncology Studies

Effective January 1, investigators whose primary appointment is at the University of Washington will submit all [minimal risk](#) oncology research to the UW IRB for review (except when there are other IRB reliance arrangements in place, such as for industry-sponsored research reviewed by WIRB or Advarra). Previously, UW investigators conducting minimal risk oncology research would send applications to Fred Hutch (Cancer Consortium) IRB for review.

UW investigators will continue to submit greater-than-minimal risk oncology research to Fred Hutch IRB.

Investigators whose primary appointment is at Fred Hutch will continue sending applications to Fred Hutch IRB as normal.

IACUC Form Change

The IACUC Protocol Form was updated to Version 4.00, effective May 29, 2018. Please ensure that all submissions are made on the most current version of the form. Older versions of the form will no longer be accepted.

Hutch IACUC Project Update

The Hutch IACUC electronic submissions system project is nearing the end of the design phase, after which development of the system will start. The project team has identified the Group 1 protocols targeted for migration into the system prior to launch this summer. Training will be provided on how to use the new system. Over the course of FY2020, research teams in Group 2 and beyond with approved protocols will be asked to switch over to the new system. Visit the [project webpage](#) for information.



Staff Update

The following are staffing updates since our last newsletter:

The IRO would like to welcome Valerie Dossing (Expedited Analyst), Sean Evans (Admin Assistant II), Christina Ironside (IRO Assistant – Training), Kim Lawler (Admin Assistant I), Erin Loadvine (Admin Assistant II), Holly Sanders (Admin Assistant II), and Wonsun Shin (Admin Assistant II) to the team.

Additionally, please join us in congratulating Van Nguyen who was promoted from Admin Assistant II to Expedited Analyst and Tara Bauman who was promoted from Expedited Analyst to IRB Analyst (Committee D).

To reach us, visit our [IRO Contact Information page](#).

CONTACT US

INSTITUTIONAL REVIEW OFFICE

PHONE: 206.667.5900

EMAIL: IRO@FREDHUTCH.ORG

WEB: <HTTPS://EXTRANET.FREDHUTCH.ORG/EN/U/IRO.HTML>

