



IRO NEWS

Latest information from the Fred Hutch IRO

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2018 Common Rule Topics

The topics below apply to studies subject to the 2018 Common Rule Requirements. This means all research receiving initial approval (or *de novo* approval) on or after January 21, 2019.

Status Report Process Replaces Continuing Review for Some Expedited Research that is Not FDA-Regulated

In general, minimal risk research subject to only the 2018 Common Rule will not require annual continuing review. However, the IRB retains the authority to require continuing review for specific projects. If a study is subject to FDA regulations, continuing review must still be conducted.

A new check-in process called the Status Report has been developed for studies that do not require continuing review. IRB staff will email you annually to ask about the current status of the study. You will be asked to respond by a specified date. This helps the IRB assure study status records are maintained for institutional reporting and any external audits of IRB records. See [IRB Policy 2.28, Status Reports for IRB Files](#) for additional details.

All minimal risk research is still subject to all other IRB reporting requirements, such as reporting of noncompliance or unanticipated problems involving risks to subjects or others, and obtaining prospective IRB approval prior to implementing any changes to the research.

NOTE: Research approved before January 21, 2019 must still submit annual Continuing Review Reports for IRB review.

Requirement to Post Consent Forms on a Federal Website

Any [clinical trial](#) supported by federal funding and subject to the 2018 Common Rule must post one IRB-approved consent form on a publicly available federal website within a specific time frame. Two websites satisfy the consent form posting requirement: [ClinicalTrials.gov](#) and a docket folder



on Regulations.gov ([Docket ID: HHS-OPHS-2018-0021](#)).

The consent form must be posted after the clinical trial is closed to recruitment, and no later than 60 days after the last protocol-required study visit by any participant. If you need assistance with Clinical Trial reporting requirements, contact ctgov@fredhutch.org.

New HHS Single IRB Requirement for Cooperative Research

Under the 2018 Common Rule, [cooperative research](#) projects must now rely on a single IRB. This provision applies to “research involving more than one institution” located in the United States. The compliance date of the Cooperative Research provision is January 20, 2020. (Please note: This is a regulation that applies to all federally funded research.)

The Office of Human Research Protections (OHRP) has recently stated that all cooperative research studies subject to the 2018 Requirements of the Common Rule (initially IRB-approved on or after January 21, 2019) are required to come into compliance by January 20, 2020. This means studies already approved by local IRBs since January 21, 2019 would need to be identified and undergo a new single IRB review if the research involves more than one institution.

Based on this current interpretation by OHRP, all new federally funded, cooperative research projects being reviewed by Fred Hutch IRB need to use a single IRB **now**. Delaying would not allow sufficient time to establish the appropriate reliance agreements for compliance by January 20, 2020. Alternatively, you may request an exception from the requirement to use a single IRB from the funding agency. Please contact iro@fredhutch.org for assistance if you are planning to submit a new cooperative research project that has federal funding.

The following research is not subject to this provision:

1. Non-federally funded research; or
2. Cooperative research for which more than a single IRB’s review is required by law (e.g., Veterans Affairs or tribal law); or
3. Research for which any Federal department or agency supporting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

Watch our [Single IRB webpage](#) for additional resources and details coming soon!

Revised Short Forms

When researchers unexpectedly encounter a potential research participant who does not speak and/or read English, a short-form consent can be used with approval from the IRB. The short form is used to document that the elements of informed consent were orally presented to the research



participant by a qualified interpreter. Because the revised Common Rule added new elements of consent, Fred Hutch's translated short forms were revised to incorporate this new information.

There are now two versions of the short form available for use:

- [2018 Requirements version](#): For use in studies approved by the IRB on or after January 21, 2019.
 - [Pre-2018 Requirements version](#): For use in studies approved by the IRB before January 21, 2019.
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General Topics

Determining Whether Your Project is Research

Occasionally, the IRO receives questions about whether a project is considered research. Perhaps you are developing a website and want feedback from a user group about whether the interface makes sense. Or perhaps you are working on a case report about one or two specific individuals.

To support Fred Hutch investigators in considering this issue, the IRO recently launched a [new webpage](#) that provides examples of different types of projects that may or may not constitute research under the federal Common Rule.

Another new tool is the [Research Assessment Form](#). Non-research activities do not need IRB review, so you may use this tool to self-assess the project. However, you may still choose to submit to IRO if you want help in determining whether a project is research or if you need a written determination for any reason (such as payment of funds or submission to a journal for publication).

Investigators whose primary appointment is at another institution should contact their institution's IRB for assistance regarding specific projects.

Informed Consent Frequently Asked Questions

The IRO has created a new [FAQ](#) webpage related to Informed Consent. Topics covered include who can obtain consent and re-consent, who should sign the consent, when the consent should be signed, and more. Please check out this new resource.



Hutch IACUC Project Update

The development of the electronic system is complete, and migration of active protocols is in progress. In May, Group 1 research teams converted a set of 25 protocols from the old application form to the new Hutch IACUC protocol smartform. The partnership with Group 1 was critical to the success of the project. During this soft launch, we received valuable input and made refinements to the system. We appreciate the feedback!

This month, the Hutch IACUC team is creating “shell records” for the remaining active protocols, and the current approved protocol document will be attached to that record to allow the system workflow to be used. After go-live, the research teams with shell records will fully convert their active protocols according to a predetermined timeline.

In early July, selected individuals from research teams, Comparative Medicine, and the IACUC will perform user testing of the system. This is the last step of preparation before the system launches.

Training on the system will be offered starting in mid-July. Information on training dates will be circulated soon.

See our [project page](#) for more details and see our [transition schedule](#) for important upcoming dates.

Staff Update

The IRO would like to welcome Hillary Beehler and Aaron Puetz to the team! Hillary joined the team on March 11 as the IRO Administrative Assistant II for External IRB and Training Support. Aaron joined the team on May 1 and is the IRB Administrative Assistant II for Committee A.

CITI Training

A new Revised Common Rule course is now available through CITI. It covers the regulatory changes to 45 CFR 46, Subpart A, “Federal Policy for the Protection of Human Subjects” (the Common Rule) that became effective on January 21, 2019. Completion of this course will satisfy the Human Subjects **Refresher** Training requirement. To access CITI, click [here](#).

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