



# IRO NEWS

Latest information from the Fred Hutch IRO

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## Changes to the Common Rule

The Federal Policy for the Protection of Human Subjects, known as the Common Rule, is a set of regulations adopted by 16 Federal Departments and Agencies, including the Department of Health and Human Services (45 CFR 46). Those departments and agencies have published a new version of the Common Rule.

### *When does it take effect?*

The revised Common Rule was published on the last day of the Obama administration. Most provisions of the new rule are set to go into effect on January 19, 2018. However, on January 20, 2017, the Trump administration mandated review of federal rules that had not reached their implementation date. The revised Common Rule is subject to this review. At this time, the fate of the revised Common Rule (and the date compliance is required) is uncertain. Nevertheless, in order to ensure that operational changes are made consistent with the revised Common Rule, the IRB community is moving ahead with the assumption that the revised Common Rule will take effect on January 19, 2018. The current effective date of the revised Common Rule provision requiring a single IRB review is January 20, 2020.

### *What is Changing?*

The “2018 Requirements” are sweeping updates to the Common Rule, and are the first major changes in decades. The IRO is in the process of revising all IRB policies, templates, and forms to be in compliance. IRO staff will provide further communications, resources, and training opportunities in the coming months. In the meantime, we would like to highlight a few of the many changes to the Common Rule requirements.

*At Fred Hutch, we apply the Common Rule to all research involving human subjects.*

- Expanded requirements for consent forms intended to aid potential participants’ understanding of the research. There is a new requirement for “key information” to be provided upfront in the consent form to serve as a concise summary. Additionally, there are **new basic and additional elements of consent**, which must be incorporated.
- Updated definitions around human specimens and data.
- Changes to specific requirements surrounding **Continuing Review** for minimal risk research.



- Revisions to the IRB Exemption categories and a new requirement for “limited IRB review” for certain types of exemptions.
- New requirement for a single IRB (sIRB) of record for multi-site research projects (NIH policy change for sIRB will be effective first, on January 25, 2018).

IRO staff and OGC are working on a plan to efficiently implement this change.

If you have questions about how these upcoming changes will affect you and your study team, please feel free to reach out to our office directly. We would be happy to assist you in navigating this new regulatory landscape.

For more information or to read the Common Rule in its entirety, please visit: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>.

**Q.** *What about my study I had approved last year? Do I need to update anything?*

**A.** *No. If your study was approved by Fred Hutch IRB prior to January 19, 2018, your requirements are not changing. Your research will remain under the “Pre-2018 Requirements.”*

**Q.** *What if I have a study already approved, but I’m asked to complete a de novo review?*

**A.** *If the IRB requires a de novo review of your study, you will be asked to submit all study documents on the current IRB forms and to comply with the current regulations. That would mean your application would need to comply with the 2018 Requirements of the Common Rule.*

**Important note:** The FDA’s regulations are not changing at this time. If your IRB study is FDA-regulated, you must still follow those separate requirements.

## FDA Guidance on Waiver or Alteration of Informed Consent

The FDA released guidance on July 24, 2017 for immediate implementation regarding waivers or alterations of informed consent. The full document is posted [here](#). The FDA guidance harmonizes with the HHS regulations and will now allow waivers or alterations of informed consent when the IRB finds that the following criteria are met:

- The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The clinical investigation could not practicably be carried out without the waiver or alteration; and



- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

We have updated several IRB documents to reflect this guidance. Click here for a summary of the documents that changed:

<https://extranet.fredhutch.org/en/u/iro/updates/8-28-17.html>.

## Reminders

### *IRB Forms*

IRB forms underwent changes in July. All forms with a July 3, 2017 version date must be used when submitting to the IRB beginning September 1, 2017.

### *Veterinarian Pre-Review Turnaround Times*

Comparative Medicine (CM) veterinarians are available to help pre-review IACUC protocols (prior to submission to the IACUC) to make sure that anesthesia, analgesia, procedures, and clinical care are covered appropriately. For protocols involving USDA-regulated species (e.g. canines, hamsters, and guinea pigs), vet pre-review is required for new applications, 3-year *de novo* reviews, and protocol revisions. Additionally, veterinarian pre-review is required for all protocol revisions (regardless of species) in order to be considered for DMR. The standard pre-review turnaround times (from veterinarians) will be:

- 3 Business days for DMR items
- 5 Business days new/3-year *de novo* reviews

Please note that complex and lengthy protocols may require additional time.

Contact Comparative Medicine (CM) at 667-4558 or [cm@fredhutch.org](mailto:cm@fredhutch.org) to arrange for a veterinarian pre-review before submitting to the IACUC. Please make sure that protocols are submitted for pre-review early enough so that you do not miss the IACUC submission deadlines.

#### CONTACT US

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