



IRO NEWS

Latest information from the Fred Hutch IRO

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Certificates of Confidentiality

Effective October 1, 2017, a federal Certificate of Confidentiality will now automatically be issued to almost all NIH-funded research that involves human subjects. The [NIH policy](#) is retroactive and applies to all NIH-funded studies ongoing or initiated on or after December 13, 2016.

Certificates of Confidentiality generally require researchers to refuse to disclose names or other identifying characteristics of research participants in response to legal demands.

PRACTICAL IMPACTS:

- New IRB applications have been revised to ask whether the research is covered by a Certificate of Confidentiality.
- A new [Certificate of Confidentiality Supplement](#) will need to accompany Specimen/Data applications, and modifications adding/removing NIH funding or using specimens from a new source.
- Standard Certificate of Confidentiality language is available in the Fred Hutch [model consent templates](#).
- Two new tools are available on the IRB website:
 - [Certificate of Confidentiality guidance](#)
 - [A decision tree](#) to assist NIH-funded researchers to decide whether the study is covered automatically by a Certificate of Confidentiality

IMPORTANT TO REMEMBER:

- Information the Certificate covers is permanently protected.
 - Primary researchers sharing covered information with secondary researchers must inform them of the Certificate, and secondary researchers are also responsible for abiding by it.
- Coverage of automatically issued Certificates is tied to NIH funding; if NIH funding ends, any new data are not protected unless you apply for “continuity of protection” with the NIH.
- For studies that require informed consent, investigators must inform research participants of the protections and limits to the protections provided by a Certificate.
- Studies with current NIH funding that submit Modifications or Continuing Reviews will be asked to update the consent form to include Certificate language, when applicable.



Qualifications for Obtaining Consent

The Fred Hutch IRB has finalized guidelines for its expectations regarding qualifications of individuals responsible for obtaining informed consent from research participants. The guidelines illustrate the different levels of qualifications depending on the study's level of risk. With appropriate justification, the IRB may allow other qualified individuals to obtain consent on a case-by-case basis. This guidance is intended to assist research teams in preparing their IRB applications, and promote greater consistency when applying these standards across committees.

See the guidelines in Appendix A of [IRB Policy 2.11 Informed Consent](#).

NIH Definition of “Clinical Trial”

Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

The NIH definition of a clinical trial changed in 2015 to more broadly encompass research the agency supports. This year the NIH implemented a policy that requires all clinical trials to [register and report](#) to www.clinicaltrials.gov. In recent months, the NIH has provided [updated information](#) to assist researchers in identifying whether a study is considered a clinical trial. If you have questions or need additional information, contact ctgov@fredhutch.org.

The Fred Hutch IRB has updated its Informed Consent policy, Interventional IRB application, and Model Consent Form templates to help ensure that NIH-funded clinical trials include the required consent form language stating that the trial is registered on clinicaltrials.gov.

Single IRB

As a reminder, competing NIH grant applications (new, renewal, revision, or resubmission) with a receipt date on or after January 25, 2018 must include a plan for which IRB will be the single IRB (sIRB) of record for multi-site trials. See the IRO's [Single IRB and IRB Reliance Agreements](#) page for information about single IRB review and establishing the reliance agreements that need to be in place between institutions and sIRBs before your research is submitted. Please plan ahead and contact the IRO with any questions!



Common Rule Update

On October 7, 2017, the Trump administration [published a proposal](#) to delay the general implementation date of the revised Common Rule by one year. There has been no update since.

As a reminder, these regulatory changes would only impact **new** federally funded studies approved by the Fred Hutch IRB on or after January 19, 2018. If you already have an approved IRB study, the regulations you follow will not change.

Additionally, FDA-regulated research that does not receive federal funds will continue under the present FDA regulations.

However, in anticipation of a possible delay, Fred Hutch IRO and OGC are re-evaluating the implementation date of our revised policies and forms for the new Common Rule requirements. For an overview of what these changes would entail, please see the IRO's [August newsletter](#).

IRB Forms & Policies

We have updated several IRB documents based on the changes discussed in this newsletter. For a summary of the documents that changed, please visit: <https://extranet.fredhutch.org/en/u/iro/updates/11-20-17.html>.

The newest versions of the submission forms must be used by February 20, 2018.

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