

Other Developments

Clinical Trial Consent Requirements

The following exact statement must be included in the informed consent documents of **applicable clinical trials**: “A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

FDA has issued **[guidance related to this new informed consent element](#)**.

See: <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf>

Single IRB-of-Record (sIRB)

National Institutes of Health sIRB policy went into effect January 25, 2018 for: NIH grant applications (new, renewal, revision, resubmission) received *on or after 1/25/18* and NIH contract solicitations issued *on or after 1/25/18*. NIH-funded multi-site studies involving non-exempt human subjects research will be required to utilize an sIRB for the review of human research. The **[NIH policy](#)** applies to: domestic NIH-sponsored multi-site studies (same protocol implemented at the sites). Only the IRB review functions will be handled centrally; related local functions (e.g., ancillary committee review, training completion verification) rest with the individual participating institutions. The conduct and reporting of the research remain the study team's responsibility.

Will FSU act as the sIRB?

The FSU IRB will evaluate on a case-by-case basis whether they can effectively serve as the sIRB for a proposed multi-site project. The main evaluation criteria are:

- Whether the FSU PI holds the funding grant
- sIRB designation by cooperative institutions and/or sponsor
- Required IRB review expertise

NIH Clinical Trial Policies

The NIH has issued several other policies and guidance designed to "enhance the accountability and transparency of clinical research." For an overview of the changes, **[view the NIH Clinical Trials Requirements presentation](#)**. NIH defines a clinical trial as 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; see <https://grants.nih.gov/policy/clinical-trials/definition.htm>

To help you identify whether your NIH-funded research would be considered a clinical trial under this definition and, therefore, subject to all the related policies (e.g., NIH

sIRB, ClinicalTrials.gov registration and reporting, etc.), the NIH offers the following resources:

- [FAQs and case studies](#)
- [NIH Deputy Director's blog](#)
- [NIH Clinical Trials Policy website](#)
- Video: [Overview of New NIH Policies on Human Subjects Research](#)

Effective October 1, 2017, all NIH funded research meeting certain criteria, that was commenced or ongoing on or after December 13, 2016, is deemed to be issued a **Certificate of Confidentiality** ("COC") pursuant to a new NIH policy. Therefore, researchers no longer have to proactively apply to the NIH for a COC. Please note that this change may require an update/addendum to the COC consent form section.

NIH Policy for GCP (Good Clinical Practice)

Good Clinical Practice training requirements became effective on January 1, 2017. This Policy applies to NIH-funded investigators and clinical trial site staff who are responsible for the conduct, management and oversight of NIH-funded clinical trials. FSU requires CITI GCP training for investigators on FDA regulated clinical trials. The new NIH policy now requires GCP training for personnel or students that meet the **NIH definition of clinical trial** for NIH funded research. GCP training must be refreshed every three years while the research is actively funded.

Links:

NIH single IRB requirements/policy and FAQs:

- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-076.html>
- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>
- <https://osp.od.nih.gov/clinical-research/irb-review/>

NIH notice of changes to NIH Policy for Issuing Certificates of Confidentiality (COC):

- <https://grants.nih.gov/node/1280>

Good Clinical Practice Training Requirement changes:

- <https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm>

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Other News for Researchers

Federal Policy for the Protection of Human Subjects

Final revisions to the Federal Policy for the Protection of Human Subjects (a.k.a. the "Common Rule") were issued by signatory federal agencies on January 18, 2017;

changes generally were effective **January 19, 2018**. The Common Rule is a set of federal regulations that apply to human research conducted at FSU.

Select Key Changes:

- **Continuing Review** – No longer required for most minimal risk research, including studies where the only remaining activity is the analysis of identifiable data/biospecimens or activity to obtain follow-up clinical data.
- **Exemptions** – New categories and clarification of existing categories. Four categories may require "limited IRB review" (similar to an expedited review process).
- **Informed Consent** – A new "Key Elements" section and a rearrangement of content is designed to facilitate a potential subject's decision to participate or not.
- **Single IRB-of-Record (sIRB)** – IRB oversight for most federally-funded cooperative research projects conducted in the U.S.

NOTE: The new regulations do not impact studies approved prior to January 19, 2018 and that do not transition to the new rules. Related link: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>

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