

Special Requirements for Federally-Funded or FDA-Regulated Clinical Trials

Background

Clinical Trials are subject to special requirements beyond IRB review that vary depending on funding source or regulatory-body oversight. This document summarizes these requirements.

Definitions

Federally Sponsored Clinical Trial – A research study sponsored by a federal funding agency 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 the interventions on *biomedical or behavioral health-related outcomes*.

FDA-Regulated Applicable Drug or Device Trial – includes either of the following, regardless of funding source:

Drugs and Biologics: A controlled clinical investigation, other than a Phase 1 clinical investigation, of a drug or biologic product subject to FDA regulation.

Medical Devices: A prospective clinical study of health outcomes comparing an intervention with a medical device against a control, or pediatric postmarket surveillance required by the FDA.

Special Requirements for all *Federally Sponsored* Clinical Trials

1. **Public Posting of Informed Consent Form** – one IRB-approved informed consent form that is used when enrolling subjects must be posted to a federal repository after the clinical trial is closed to enrollment, and no later than 60 days after the last study visit by any subject.
 - Only one IRB-approved version must be posted, but it must be a version that was used to enroll subjects
 - Re-posting revised or modified consent forms is NOT required.
 - Redaction of information may be permitted by the federal sponsor in some cases.

Where to post:

Two federal websites that will satisfy the consent form posting requirement have been identified:

1. www.ClinicalTrials.gov; and
2. www.Regulations.gov, Docket ID: [HHS-OPHS-2018-0021](https://www.fda.gov/oc/ohrt/2018-0021)

How to post:

[Instructions for posting on www.ClinicalTrials.gov](#)

[Instructions for posting on www.Regulations.gov](#)

2. Effective January 2020, cooperative projects (those that involve more than one institution) must rely on approval by a **single IRB** for research conducted in the United States. The revising IRB will be identified by the Federal sponsor, or proposed by the lead institution and subject to approval by the federal sponsor. The ISU IRB will more fully develop policies and procedures to meet this requirement when more guidance is available from the Office of Human Research Protections.

Special Requirements for *NIH Sponsored* Clinical Trials

Clinical Trials sponsored by the National Institutes of Health or any of its institutes, centers or offices must also meet the following requirements:

1. Clinical trials must be registered and results reported at www.ClinicalTrials.gov within specified timelines. More details can be found [here](#).
2. **Good Clinical Practice (GCP) training** is required for all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials. See the [IRB webpage](#) for more details.
3. All NIH sponsored research is automatically issued a **Certificate of Confidentiality**.¹ A CoC protects participants by preventing compelled disclosure (i.e., subpoena) and assuring identifiable information can be shared with anyone not connected to the research ONLY in the following circumstances:
 - a. If required by other Federal, State, or Local Laws, such as for reporting communicable diseases;
 - b. If the subject consents; or
 - c. For the purposes of scientific research that is compliant with human subjects protection regulations.

Important: Researchers are responsible for ensuring that anyone conducting research as a sub-awardee or that receives a copy of identifiable research data understands they are subject to these disclosure restrictions—even if they are not funded by NIH.

4. Multi-site clinical trials must utilize a **single IRB-of-record (sIRB)** for IRB review. More details about meeting the sIRB requirement can be found on the [IRB webpage](#). Note that *ISU will not serve as the sIRB of record*. Researchers may budget to us a commercial IRB (Advarra) or arrange for the IRB at a collaborating institution to serve as the sIRB for NIH-sponsored trials.

Special Requirements for FDA-Regulated Applicable Drug or Device Trials

1. Obtain FDA approval of an **Investigational Device Exemption (IDE)** or **Investigational New Drug Application (IND)**, when applicable. See [here](#) for more details about FDA requirements.
2. Clinical trials must be registered and results reported at www.ClinicalTrials.gov within specified timelines. More details can be found [here](#).

¹ Research sponsored by federal agencies other than NIH or that is FDA regulated may apply for a Certificate of Confidentiality when necessary to protect subjects' confidentiality. If granted, researchers must adhere to any disclosure restrictions required by the agency issuing the CoC.

Summary Table of Requirements

	Any Federally Sponsored Trial	NIH Sponsored Trial	FDA Applicable Clinical Trial
Publicly posting informed consent document at either: www.ClinicalTrials.gov ; or www.Regulations.gov , Docket ID: HHS-OPHS-2018-0021	X	X	
Registration and results reported at www.ClinicalTrials.gov		X	X
Good Clinical Practice training		X	
Certificate of Confidentiality disclosure restrictions	If CoC is sought & granted	X	If CoC is sought & granted
Single IRB-of-Record (sIRB)	Effective Jan. 2020	X	
FDA Approval of IND or IDE and associated FDA requirements			X

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