

Clinical Trial Requirements

Research involving clinical trials must comply with additional regulatory requirements. The purpose of this guidance document is to provide an overview of important regulatory requirements for clinical trials for guidance and consideration only.

Clinical Trial Definition:

A prospective, biomedical, or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, biologics, treatments, devices, or new ways of using known drugs, biologics, treatments, or devices). Behavioral interventions are intended to prevent or treat an acute or chronic disease or condition. A Clinical trial involves evaluating effects of an intervention on biomedical or behavioral human health outcomes per NIH. This definition is not intended to be inclusive of all clinical research activities.

Principal Investigators (PIs) are responsible for making the determination if their study meets the definition of a clinical trial. Information is posted at: <https://grants.nih.gov/ct-decision/index.htm> which outlines requirements for registration of the trial. The ASU IRB will review the study to see if it should be reviewed by the ASU IRB or if review by an external IRB is required. This is done on a study by study basis.

ASU Investigator must comply with Clinical Trials Registration and Reporting requirements if:

- The ASU Investigator is the Principal Investigator (PI) for the clinical trial AND
- The study is investigator-initiated (If the trial is an industry trial, the industry sponsor is required to register the clinical trial.)

Principal Investigator Responsibilities for Investigator-initiated Clinical Trials:¹

1. Register the clinical trial within 21 days (if sponsor is FDA or NIH) before the first subject is enrolled;
2. Designate the Responsible Party in the PRS as either ASU as the sponsor, or the PI him/herself if there is an FDA IND/IDE (generally the PI);

¹ Note. Adapted from "Clinical Trials Registration & Reporting," by the University of California, San Francisco Office of the Executive Vice Chancellor and Provost. Copyright 2022 by The Regents of the University of California. Reprinted with permission. <https://policies.ucsf.edu/policy/100-36>

3. Update ClinicalTrials.gov records at least once every 12 months (Recruitment Status and Primary Completion Date). It is recommended that the Record Verification Date be updated at least every 6 months, even if there were no changes to the record, for studies that are not yet completed. ([ClinicalTrials.gov guide to updating registration information](#))
4. Close-out any studies before departing from ASU, including ensuring that studies are properly closed or transferred to another investigator via the Office of Research Integrity & Assurance; and
5. Submit summary results to ClinicalTrials.gov no later than 1 year after the Primary Completion Date (ACTs only).

The Office of Research Integrity & Assurance (ORIA) is responsible for general oversight of ClinicalTrials.gov registration and enforcement of this policy. Please contact ORIA at asuirb@asu.edu if you need help with your PRS account.

Training Requirements:

Per [NIH policy](#), all investigators responsible for the conduct, oversight, or management of NIH-funded clinical trials are required to complete Good Clinical Practice (GCP) training. At ASU, researchers conducting clinical trials are required to complete GCP training irrespective of the funding source.

Complete the Good Clinical Practice training below which corresponds to the research being conducted through CITI at www.citiprogram.org: **GCP – Social and Behavioral Research Best Practices for Clinical Research**

- **GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)**
- **GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)**
- ASU can also accept other trainings accepted by the NIH:
https://ocr.od.nih.gov/clinical_research_training.html Please contact asuirb@asu.edu for information.

All individuals engaged in research at ASU need to be listed as a study team member on the ASU IRB submission in the ERA IRB module and need to complete CITI human subjects research training, in addition to the GCP training. For information on how to create an account in CITI and register for training, visit <https://researchintegrity.asu.edu/human-subjects/training>.

You may complete either of the below courses-

- **IRB - Biomedical Research (Group 1)** - Complete this training if your research includes medical procedures, athletic procedures, or studies health outcomes.
- **IRB - Social & Behavioral Research (Group 2)** - Complete this training if your research involves social and behavior techniques such as interviews or surveys.

Summary of ClinicalTrials.gov Registration Requirements per Agency:²

Required by:	Types of studies:	When to register by:
FDA Food and Drug Administration	Registration is required for studies that meet the definition of an “applicable clinical trial” (ACT) and either were initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007. FDA definition of an ACT	No later than 21 days after enrollment of the first participant
NIH National Institutes of Health	Regardless of study phase or type of intervention, all NIH-funded clinical trials are expected to register and submit results information to Clinicaltrials.gov, as per the “NIH Policy on Dissemination of NIH-Funded Clinical Trial Information” for competing applications and contract proposals submitted on or after January 18, 2017. NIH definition of a clinical trial	No later than 21 days after enrollment of the first participant
ICMJE International Committee of Medical Journal Editors	For studies that plan to publish within medical journals, ICMJE requires registration of clinical trials. ICMJE definition of a clinical trial	At or before the time of first participant enrollment

Studies that fall under multiple registration requirements only need to be registered in ClinicalTrials.gov once. It is important to keep in mind that different agencies and sponsors have different registration and reporting requirements for clinical trials studies. For resources on key US policies, please visit <https://clinicaltrials.gov/ct2/manage-recs/resources#KeyUSPolicies>.

² Note. Adapted from “Clinical Trial Requirements,” by Northwestern University Institutional Review Board Office. Copyright 2022 by Northwestern University. Reprinted with permission. <https://irb.northwestern.edu/resources-guidance/policies-guidance/clinical-trial-requirements.html>

Important: Even if your investigator-initiated clinical trial does not meet the NIH or FDA clinical trials registration requirements, you are strongly advised to read and consider registering your trial to comply with the following additional requirements:

- [International Committee of Medical Journal Editors \(ICMJE\)](#) for publications purposes
- [Center for Medicare & Medicaid](#) for research billing claims for qualifying clinical trials
- Research funders now requiring registration and results reporting

Important Considerations:

Local Review, Affiliation Agreements, and Multi-site Research Studies

Because ASU is not a medical institution, clinical trials conducted by ASU investigators are typically multi-site studies where the collaborating institution is a medical institution or clinic. When possible, ASU will defer review to the participating site's Institutional Review Board (IRB) and will rely on their review and approval.

The ASU IRB may enter into affiliation agreements with other institutions based on recommendation and approval from the ASU Institutional Official. The institutions may cover single protocols or enter into general agreements for reciprocity between institutions. Finalized agreements are recorded in the applicable study record.

When another IRB is designated as the IRB of record, then the ASU IRB will rely on the review, approval, and continuing oversight by the responsible IRB. ASU requires that a local contextual review form and copy of all the approved documents by external/non-ASU IRB be submitted through the ERA IRB module to the ASU IRB for local contextual review (see <https://researchintegrity.asu.edu/human-subjects/forms>).

Revised Common Rule ([45 CFR Part 46](#)) and Posting of Clinical Trial Consent Forms

The revised Common Rule ([45 CFR 46.116\(h\)](#)) that took effect on January 21, 2019 requires that any clinical trial conducted/supported by an agency that have signed onto the Common Rule must have one IRB-approved consent form posted to a publicly accessible federal website during a certain time frame (after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol). These publicly available accessible federal websites are identified as ClinicalTrials.gov and Regulations.gov.

For instructions on posting the consent forms, please refer to the link below.

<https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html>

Contact

If you have questions regarding clinical trials, please contact the Office of Research Integrity & Assurance at asuirb@asu.edu

Resources

1. ASU Office of Research Integrity & Assurance: <https://researchintegrity.asu.edu/human-subjects>
2. ASU ERA Module: <https://era.oked.asu.edu/>
3. FDA Clinical Trials Guidance Documents: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-trials-guidance-documents>
4. NIH Clinical Trials Decision Tool: <https://grants.nih.gov/ct-decision/index.htm>
5. ClinicalTrials.gov Key US Policies: <https://clinicaltrials.gov/ct2/manage-recs/resources#KeyUSPolicies>
6. Guideline for Good Clinical Practice: https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf