

CUNY HRPP Guidance: Definitions and Requirements for Clinical Research, Clinical Trials and Clinical Investigations

CLINICAL RESEARCH

Clinical Research is a broad category of research, which encompasses clinical trials and clinical investigations, amongst other types of research. The term, *clinical research*, is defined by the National Institutes of Health (NIH) as *research with human subjects that is:*

1) *Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies;*

2) *Epidemiological and behavioral studies;*

3) *Outcomes research and health services research;*

Studies falling under 45 CFR 46.101(a) or exempted under §46.104 are not considered clinical research by this definition.¹

Descriptions of a number of different types of clinical research are provided by the [Food and Drug Administration \(FDA\)](#).

All clinical research in which CUNY is engaged, including clinical trials and clinical investigations, must comply with all applicable [CUNY HRPP policies and procedures](#).

CLINICAL TRIALS and CLINICAL INVESTIGATIONS

Clinical Trials are defined differently by NIH and FDA, and researchers must understand this difference to ensure compliance with the requirements of each of the oversight agencies.

The **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 outcomes².*

It is important to note, however, that FDA regulations consistently refer to **clinical investigation** and not clinical trials. The FDA defines a clinical investigation broadly as:

¹ [NIH Glossary of Terms & Acronyms – Clinical Research](#)

² [NIH Office of Science Policy – Definition of Clinical Trial. \(See also NIH Glossary of Terms & Acronyms – Clinical Trial\)](#)

*“any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under the Federal Food, Drug and Cosmetic Act (the Act) or is not subject to requirements for prior submission to the FDA under the Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit...The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous.”*³

With respect to the use of **drugs**, the FDA defines a clinical investigation as *any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.*⁴

With respect to the use of **devices**, the FDA defines a clinical investigation as *a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.*⁵

A. Requirements for NIH-funded Clinical Trials

This section highlights certain requirements that are specific to NIH-funded clinical trials and is not all inclusive. Researchers must comply with all applicable requirements outlined in [CUNY HRPP Policies and Procedures](#) as well as any additional sponsor requirements, regardless of whether they are mentioned in this brief section.

1. **Training Requirements:** All NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials, as defined by the NIH, are required to be trained in **Good Clinical Practice (GCP)**.

At CUNY, the responsibility to identify and provide GCP training resides with each campus’ administration. CUNY researchers who are involved in designing, conducting, overseeing or managing clinical trials, as defined by the NIH, must contact their campus based [Research Integrity Officer \(RIO\)](#) to ensure compliance.

2. **IRB Review Requirements:** All research sites participating in multi-site studies, which involve non-exempt human subjects research funded by the NIH, are required to use a **single Institutional Review Board (IRB)** to conduct the ethical review required for the protection of human subjects. This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research. It does not apply to career development, research training or fellowship awards.

Details regarding CUNY’s implementation of this policy are included in *CUNY HRPP Policy: Multisite Research*.

³ [21 CFR 50.3\(25\)\(c\)](#); [21 CFR 56.102\(23\)\(c\)](#)

⁴ [21 CFR 312.3\(b\)](#)

⁵ [21 CFR 812.3\(g\)](#)

3. **Registry and Reporting Requirements:** All NIH-funded awardees and investigators conducting clinical trials, as defined by the NIH, are required to register and report results of their trial in clinicaltrials.gov registry.

At CUNY, the responsibility to manage and administer the clinicaltrials.gov registry resides with each campus' administration. CUNY campuses set up their respective account at clinicaltrials.gov. Each campus must select one Administrator who consistently submits studies on behalf of the campus, and advises the researchers to go through that Administrator, rather than having multiple individuals submit on behalf of the same campus. The Official Representative identified in each campus' registration should be CUNY's Executive Vice Chancellor and University Provost, and the regulatory authority should be the CUNY University Integrated IRBs.

4. **Posting of Clinical Trial Consent Form:** For each clinical trial, as defined by the NIH, that is conducted or supported by a Federal department or agency, a copy of the IRB-approved informed consent form used to enroll subjects must be posted on a publicly available Federal website established as a repository for such informed consent forms. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal website, such Federal department or agency may permit or require redactions to the information posted.

B. Requirements for FDA-Regulated Clinical Investigations

This section highlights certain requirements that are specific to FDA-regulated clinical investigations and is not all inclusive. Researchers must comply with all applicable requirements outlined in [CUNY HRPP Policies and Procedures](#) as well as any additional sponsor requirements, regardless of whether they are mentioned in this brief section.

1. **Registry and Reporting Requirements:** All clinical trials that meet the [FDAAA 801](#) definition of an *applicable clinical trial* and that were either initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007 are required to register and report results of their trials in clinicaltrials.gov registry. *Applicable Clinical Trials* include the following:
 - **Trials of drugs and biologics:** Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation;
 - **Trials of devices:** 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies; and 2) pediatric post-market surveillance of devices required by FDA.

Applicable Clinical Trials generally **include** interventional studies (with one or more arms) of FDA-regulated drugs, biological products, or devices that meet one of the following conditions:

- The trial has one or more sites in the United States;
- The trial is conducted under an FDA investigational new drug application or investigational device exemption;
- The trial involves a drug, biologic, or device that is manufactured in the United States or its territories and is exported for research;
- Pediatric post-market surveillance of devices.

At CUNY, the responsibility to manage and administer the clinicaltrials.gov registry resides with each campus' administration. CUNY campuses set up their respective account at clinical trials.gov. Each campus must select one Administrator who consistently submits studies on behalf of the campus, and advises the researchers to go through that Administrator, rather than having multiple individuals submit on behalf of the same campus. The Official Representative identified in each campus' registration should be CUNY's Executive Vice Chancellor and University Provost, and the regulatory authority should be the CUNY University Integrated IRBs.

2. **Informed Consent Requirement:** All informed consent documents for *applicable clinical trials* must include the following statement: "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time."⁶

⁶ [21 CFR 50.25](#)