

University of Rochester	CTSI		
	Office of Clinical Research		Effective Date: October 24, 2019
	Public Disclosure of Clinical-Trial Information (ClinicalTrials.gov)		Policy 001
			Version: 2.0

POLICY

1. Purpose

1.1. Describe the institutional requirements for public disclosure of clinical trial information (registration and results) to ensure compliance with federal regulations, laws and policy.

2. Scope

This policy applies to all clinical trials conducted at the University of Rochester, as defined by the policy references below.

3. Definitions

3.1. *NIH 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.” “An intervention is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.”

3.2. *Applicable Clinical Trial (ACT)* – category of trials that are subject to both registration and result reporting requirements under 42 CFR Part 11.

3.2.1. *Drug and Biologic trials* – “a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug or biologic subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of the Public Health Service Act.”

3.2.2. *Device trials* – “a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes).”

3.3. International Committee of Medical Journal Editors definition of a clinical trial- “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.”

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- 3.4. ClinicalTrials.gov - a searchable, public registry and results database of clinical studies.
- 3.5. *Controlled* - a clinical trial with one or more arms and pre-specified outcome measure(s).
- 3.6. [Protocol Registration and Results System \(PRS\)](#) - The system used to enter clinical trial information on ClinicalTrials.gov.
- 3.7. *Primary Completion Date* - date that the final subject was examined or received an intervention for the purpose of final collection of data for the primary outcome measure, whether the clinical trial concluded according to the pre-specified protocol or was terminated.
- 3.7.1. In the case of clinical trials with more than one primary outcome measure with different completion dates, this term refers to the date upon which data collection is completed for all of the primary outcomes.
- 3.8. *Responsible Party (RP)* - the entity or individual responsible for the clinical trial and for submission of clinical trial information.
- 3.9. *Study Completion Date* - Final date on which data was or is expected to be collected.

4. References

- 4.1. [Section 113 Food and Drug Administration Modernization Act \(FDAMA\) of 1997 \(US Public Law 105-115\)](#) requires registration in a public database of any clinical trial conducted under an investigational new drug (IND) application if it is for a drug to treat a serious or life-threatening disease or condition and it is a trial to test effectiveness.
- 4.2. [Section 801 Food and Drug Administration Amendments Act \(FDAAA\) of 2007 \(US Public Law 110-85\)](#) requires registration and results reporting of all 'applicable clinical trials' (ACTs) of drugs, biologics, and devices.
- 4.3. [Clinical Trials Registration and Results Information Submission \(42 CFR Part 11\)](#) (effective January 18, 2017)
- 4.4. [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](#) (effective January 18, 2017)

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- 4.5. [International Committee of Medical Journal Editors \(ICMJE\)](#)
- 4.6. [Centers for Medicare and Medicaid Services \(CMS\) billing requirements](#)
- 4.7. Guideline for Posting on ClinicalTrials.gov

5. Responsibilities

- 5.1. Investigators are responsible for compliance with all regulations related to public disclosure of clinical trial information. Failure to comply with this policy can lead to any of the following:
 - 5.1.1. Financial penalties
 - 5.1.2. Withholding of federal grant money or requirement to pay money back
 - 5.1.3. Inability to publish study results
 - 5.1.4. Institutional administrative suspension of research
- 5.2. Investigators are responsible for ensuring clinical trials are registered prior to enrollment of the first subject.
- 5.3. Investigators are responsible for utilizing www.ClinicalTrials.gov when registering clinical trials and posting required research results when the study is complete.
 - 5.3.1. For sponsored research, the trial posting must comply with the terms of the contract.
 - 5.3.2. For ACTs with funding from any agency of the Department of Health and Human Services, the University of Rochester must certify that registration and results reporting requirements are met, regardless of whether or not they are the responsible party.
 - 5.3.3. For ACTs and NIH-funded clinical trials, summary results for the primary outcome measure(s) must be entered within 12 months of the study's "Primary Completion Date" as defined by 42 CFR Part 11. Results for secondary outcome measures must be entered one year after the date on which the final subject is examined or receives an intervention for the purposes of final collection of data for that secondary outcome measure.
- 5.4. Investigators are responsible for ensuring information in ClinicalTrials.gov is current and accurate when a study is registered under the University of Rochester account.
- 5.5. Investigators are responsible for notifying the CTSI, if they will be leaving the institution and have a study on ClinicalTrials.gov.
- 5.6. Department Administrators are responsible for approving user profiles for individuals within their department.

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5.7. When the RSRB is the Reviewing IRB, the RSRB is responsible for ensuring clinical trials are registered (obtain the NCT#) prior to approving the research.

6. Requirements

6.1. The University of Rochester’s institutional account, URochester, must be used when registering a clinical trial.

6.2. For clinical trials registered under the University of Rochester institutional account, there are specific data entry requirements. The data entry requirements are outlined in the *Guideline for Posting on ClinicalTrials.gov*.

6.3. When an external entity (e.g., pharmaceutical company, cooperative group, non-profit) initiates a clinical trial, but a UR investigator is designated as the RP, the external entity’s PRS organizational account must be used for registration and subsequent management of trial data.

6.4. It is the expectation that only UR faculty and staff will manage trial information under the UR Organizational account, but if it is necessary for non-UR personnel to maintain information they will be provided with a URochester username that will allow such non-UR personnel access to CT.gov but to no other UR IT systems.

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Appendices:

None

Revision History:

2.0 Added the CTSI's clinicaltrials.gov webpage address to the footer.

Supersedes Date:

October 9, 2018