

OFFICE OF RESEARCH REGULATORY AFFAIRS POLICY

Policy Name:	Clinical Trials Registration and Results Reporting
Approval Authority:	Institutional Official
Originally Issued:	June 1, 2017
Adopted:	June 1, 2017
Amended:	February 25, 2019
Amended Approved:	March 19, 2019
Responsible Executive:	Associate Vice President, Office of Research Regulatory Affairs
Responsible Office:	Office of Research Regulatory Affairs
Contact:	Human Subjects Protection Program https://orra.rutgers.edu/hssp (973) 972-1149

1. **Policy Statement**

The University requires registration and results reporting of certain clinical trials (as defined in Section 5 below) at ClinicalTrials.gov, a publicly-accessible registry, to promote responsible dissemination of information about clinical trials to the public, ensure compliance with pertinent Federal and State law and funding agency requirements, and to meet professional publication standards.

2. **Reason for the Policy**

Title VIII of the Food and Drug Administration Amendment Act of 2007 (**FDAAA**) established legal requirements for sponsors and designated principal investigators responsible for certain clinical trials to register and report results information to ClinicalTrials.gov. To comply with FDAAA, the National Institutes of Health (**NIH**) and the Center for Medicare and Medicaid Services (**CMS**) obliges grantees to follow registration and reporting requirements to qualify for funding. Further, the International Committee of Medical Journal Editors (**ICMJE**) established similar standards investigators must follow if they wish to publish in participating journals. This policy is intended to provide an organizational framework around and support to University investigators responsible for complying with regulation, grantor requirements and/or publication standards regarding registration and reporting.

3. **Who Should Read this Policy**

This policy applies to all faculty, staff and other employees, students, or other individuals conducting clinical trials requiring registration and results reporting on University premises, using University property or facilities, and University Institutional Review Board (IRB) authorization.

4. **Related Documents**

5. **The Policy**

It is the policy of the University that the following new or ongoing clinical trials shall be registered at <http://www.clinicaltrials.gov>:

- (A) Applicable clinical trials defined by Title VIII of the Food and Drug Administration Amendment Act of 2007 (**FDAAA**);
- (B) Clinical trials funded, either in whole or in part, by the National Institutes of Health (**NIH**);
- (C) Qualifying clinical trials which will render claims for items and services to the Center for Medicare and Medicaid Services (**CMS**);
- (D) Clinical trials that meet the clinical trial definition of the International Committee of Medical Journal Editors (**ICMJE**) and, the results of which, the investigator plans to publish in a member journal. **[NOTE: ICMJE accepts registration at registries other than ClinicalTrials.gov to meet their publication requirements. Rutgers University allows this flexibility in the selection of a registry only for trials that do not qualify at A, B or C above.]**

ACCOUNTABILITY

It is the responsibility of the Principal Investigator to ensure registration and results reporting are completed and updated, and in the timeframes required, by **FDAAA**, **NIH**, **CMS** and/or **ICMJE**.

It is the Principal Investigator's responsibility to upload the required documents per the Final Rule for Clinical Trials Registration and Results Information Submission and the 2018 Common Rule.

DEFINITIONS

Aggregate Results: Data collected from individual-level records that have been combined for statistical or analytical purposes and that are maintained in a form that does not permit the identification of individuals.

Clinical Trial:

- **Applicable Clinical Trial, or ACT (FDAAA):** includes interventional studies (with one or more arms) of FDA-regulated drugs, biological products or devices that meet one of the following conditions: (a) the trial has one or more sites in the U.S.; (b) the trial is conducted under an FDA investigational new drug application (IND) or investigational device exemption (IDE); or the trial involves a drug, biologic or device that is manufactured in the U.S. or its territories and is exported for research. There are two types of FDAAA-defined applicable clinical trials which must be registered and results reported:
 - **Applicable Clinical Drug Trial:** A controlled clinical investigation, other than a Phase I clinical investigation, of a drug or biological product subject to FDA regulation; and
 - **Applicable Clinical Device Trial:** A controlled trial with health outcomes of devices subject to FDA regulation, other than small feasibility studies or pediatric post-market surveillance required by FDA.

Registration is required for applicable clinical trials (ACT) initiated after September 27, 2007 or ongoing as of December 26, 2007.

- **Clinical Trial (NIH):** 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.
 - NIH requires registration and results reporting for all NIH-supported clinical trials, regardless of study phase, type of intervention, or whether or not they are subject to FDAAA.

- **Qualifying Trial (CMS):** The activity must be a clinical trial that qualifies for coverage (as specified in CMS Section 310.1 of the Medicare National Coverage Determination Manual) and the purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' services, durable medical equipment, diagnostic test, etc.). The trial must have therapeutic intent and must enroll patients with diagnosed disease, not only healthy volunteers.
- **Clinical Trial (ICMJE):** A clinical trial is a research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes—includes drugs, biologics, devices, surgical procedures, and behavioral treatments (see The Uniform Requirements for Manuscripts Submitted to Biomedical Journals). This definition includes Phase I studies.

Final Rule: Effective on January 18, 2017, the [Final Rule for Clinical Trials Registration and Results Information Submission](#) details the requirements for submitting registration and summary results information, including adverse event information, for specified clinical trials of drug products (including biological products) and device products and for pediatric postmarket surveillances of a device product to ClinicalTrials.gov (42 CFR Part 11).

Grantee: Recipient institution of a grant or cooperative agreement from a federal agency.

Primary (endpoint) Completion Date: The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome. This applies whether the clinical trial concluded according to the pre-specified protocol or was terminated.

Principal Investigator (PI): The individual who is responsible and accountable for conducting the clinical trial.

- **Responsible Party (FDAAA):** **FDAAA** defines the responsible party as the person who is responsible for conducting a clinical trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial and must meet all of the requirements under this regulation. **The University deems the terms Principal Investigator and Responsible Party to be synonymous for purposes of this policy.**

Protocol Registration System (PRS): The PRS is a web-based data entry system used by ClinicalTrials.gov for investigators to register a clinical study or submit results information for a registered study. Investigators must have a PRS account to register study information on ClinicalTrials.gov.

- **National Clinical Trial (NCT) Number:** The NCT# is a unique identifier assigned by ClinicalTrials.gov to a study that has been successfully registered at its site. The NCT number must be included on claims for items and services provided in clinical trials that are qualified for coverage as specified in the Medicare National Coverage Determination Manual, Section 310.1.

2018 Common Rule: The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies issued final revisions to the Federal Policy for the Protection of Human Subjects, the Common Rule. Effective July 19, 2018.

REGISTRATION

Principal Investigators are responsible to register clinical trials at a publicly-accessible registry, review the content of the information uploaded to the registry to verify completeness and accuracy, and ensure all data-entry activities occur within required time frames, as follows:

- **FDAAA:** The Principal Investigator must register and input required clinical trial information through the Protocol Registration System (PRS) at the ClinicalTrials.gov website **no later**

than 21 days after enrollment of the first participant
(<https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa>).

- **NIH:** The Principal Investigator must register and input required clinical trial information at the ClinicalTrials.gov website **no later than 21 days after enrollment of the first participant** (<https://www.nih.gov/news-events/summary-hhs-nih-initiatives-enhance-availability-clinical-trial-information>).
- **CMS:** The Principal Investigator must register and input required clinical trial information and obtain an NCT# at the ClinicalTrials.gov website **before submitting claims for such services to CMS**.
- **ICMJE:** The Principal Investigator must register with an ICMJE qualified publicly-accessible registry **at or before the first patient is enrolled in the study** as a condition for publication in a participating journal (<http://www.icmje.org/about-icmje/faqs/clinical-trials-registration>).

Studies registered on ClinicalTrials.gov must be registered through the Rutgers University's organization account at the website.

The University will assign an IRB Protocol Number at the time the IRB application is created in the eIRB system. The Principal Investigator should initiate study registration once the IRB Protocol Number is assigned.

Investigator guidance on how to register a clinical trial in the ClinicalTrials.gov Protocol Registration System is found at <https://orra.rutgers.edu/investigator-responsibilities-ct>

UPDATING RECORDS

Principal Investigators are responsible to update clinical trial records registered at a publicly-accessible registry, review the record for accuracy and verify that data-entry occurs within the required time frames, as follows:

FDAAA, NIH, CMS and ICMJE require the following:

- Registration information must be updated **no less than once every six months**;
- Recruitment/enrollment status changes (such as suspending recruitment or enrollment closed) must be input **within 30 days of any change**;
- Trial closure (regardless of the reason for closure—completion, low enrollment, etc.) must be input **within 30 days of trial closure**.

For studies registered in ClinicalTrials.gov, the National Clinical Trial Number (NCT#) assigned by ClinicalTrials.gov must appear on all Continuing Reviews and Study Closure Reports submitted to the University's IRB. For studies registered elsewhere, the registration number assigned by that registry must appear. Failure to provide the applicable registration number will cause delays in the IRB review and approval process.

RESULTS REPORTING

Principal investigators are responsible to report results of clinical trials registered at a publicly-accessible registry, review the record for accuracy and ensure data-entry occurs within required time frames, as follows:

- **FDAAA:** Aggregate results and adverse event reporting on ClinicalTrials.gov must occur **within 12 months of the Primary (endpoint) Completion Date**;
- **NIH:** Aggregate results and adverse event reporting on ClinicalTrials.gov must occur **within 12 months of the Primary (endpoint) Completion Date**;

- **CMS:** If the study qualifies as a clinical trial under FDAAA or NIH, results and event reporting must occur **within 12 months of the Primary (endpoint) Completion Date**. If the study does not qualify as a clinical trial under FDAAA or NIH, **results reporting is voluntary**.
- **ICMJE:** If the study qualifies as a clinical trial under FDAAA or NIH, results and event reporting must occur **within 12 months of the Primary (endpoint) Completion Date**. If the study does not qualify as a clinical trial under FDAAA or NIH, **results reporting is voluntary**.

If a clinical trial is subject to registration requirements by more than one entity—FDAAA, NIH, CMS or ICMJE--it need only be registered once at ClinicalTrials.gov. Registration and results reporting must occur within the timeframe set by the applicable entities, whichever is sooner.

Detailed instructions for submission of study results are found on the ClinicalTrials.gov website at <https://clinicaltrials.gov/ct2/manage-recs/how-report>.

OTHER CLINICALTRIALS.GOV SITE RESPONSIBILITIES

Principal Investigators are responsible for the following:

As mandated per the 2018 Common Rule:

- Posting (uploading) one IRB-approved informed consent form used to recruit study participants on a publicly available Federal website after recruitment closes, and no later than 60 days after the last study visit, if applicable.

As required per the Final Rule:

- Uploading the IRB-approved protocol and statistical analysis plan in a timely manner to ClinicalTrials.gov.
- Responding to registry reviewer requests for information or changes, as applicable, in a timely fashion.

TRANSFER OF PRINCIPAL INVESTIGATOR (PI) RESPONSIBILITIES

During the course of a clinical trial, the PI may relocate to another institution or otherwise be unavailable to fulfill his/her role responsibilities as PI. Before leaving the University, the PI must work with the Department or Division Chief to ensure an orderly transition of his/her responsibilities to the new PI at the University or to initiate transfer of the registry account/record(s) and PI responsibilities to the new institution.

If a clinical trial remains at the University and there are continuing registry reporting obligations without a named PI, then the Department or Division Chief must personally assume or appoint a PI to serve and assume any remaining reporting obligations.

COMPLIANCE WITH THIS POLICY

The University requires compliance with clinical trials registration and results reporting. If a PI fails to comply with this policy, the Human Subjects Protection Office will notify the applicable department chair(s) and research dean(s). Failure to comply will result in notification to the IRB of record noting regulatory noncompliance in research registration and/or results reporting.

REFERENCES

- FDAAA 801: <https://clinicaltrials.gov/ct2/manage-recs/FDAAA>
- Clinical Trials Registration and Results Information Submission (Final Rule): <https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission>
- Final Rule (42 CFR Part 11) Information: <https://prsinfo.clinicaltrials.gov/>

All policies are subject to amendment. Please refer to the Rutgers University Policy Library website (policies.rutgers.edu) for the official, most recent version.

- NIH Elaboration Document of Responsible and Applicable Clinical Trial:
<https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf>
- NIH Policy & Compliance ClinicalTrials.gov and FDAAA: FAQs
https://grants.nih.gov/ClinicalTrials_fdaaa/faq.htm
- ClinicalTrials.gov website: www.clinicaltrials.gov
- 2018 Common Rule: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>
- 2018 Common Rule – Clinical Trial Informed Consent Form Posting:
<https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html>
- ICMJE FAQ: <http://icmje.org/about-icmje/faqs/>
- CMS Medicare Clinical Trial Policies
<https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html?redirect=/ClinicalTrialsPolicies>
- Center for Medicare and Medicaid Services (CMS):
 - <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1344.pdf>
 - https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_part14.pdf