Title: ClinicalTrials.gov Registration and Results Reporting

Effective Date: TBD  Last Revision: 3/23/2017
Area of Oversight: Human Subjects Protection Program (HSPP)

I. PURPOSE
The purpose of this policy is to outline the process for registering, results reporting, and managing of Investigator-initiated interventional clinical trials through ClinicalTrials.gov.

II. ACCOUNTABILITY
It is the responsibility of the Principal Investigator to ensure ClinicalTrials.gov registration and results reporting are completed and trial information is updated on the ClinicalTrials.gov website as required.

III. 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.

Applicable Clinical Trial (ACT): This Food and Drug Administration Amendment Act of 2007 (FDAAA) definition of clinical trials includes interventional studies (with one or more arms) of FDA-regulated drugs, biological products, or devices.

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.

Clinical Trial (ICMJE): As defined by the International Committee of Medical Journal Editors (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.

ClinicalTrials.gov: A registry and results database of publicly and privately supported clinical studies of human participants conducted nationally and/or internationally that serves as the mechanism for fulfilling registration and results reporting requirements of FDAAA.

Food and Drug Administration Amendment Act of 2007 (FDAAA), Section 801: A federal statute, enacted September 27, 2007 that requires registration of an Applicable Clinical Trial (ACT) that is initiated after September 27, 2007 or ongoing as of December 26, 2007.

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

International Committee of Medical Journal Editors (ICMJE): A group of general medical journal editors. They are the authors of The Uniform Requirements for Manuscripts Submitted to Biomedical Journals.

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.

**Qualifying Trial:** A Center for Medicare and Medicaid Services (CMS) designation for clinical trials that qualify for coverage as specified in the “Medicare National Coverage Determination (NCD) Manual,” Section 310.1. The purpose of the trial must be the evaluation of an item/service that falls within a Medicare benefit category (e.g., physicians’ services, durable medical equipment, diagnostic test). The trial must have therapeutic intent and must enroll patients with diagnosed disease not only healthy volunteers.

**Responsible Party (RP):** Rutgers University defines “Responsible Party” as the Principal Investigator 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 has the ability to meet all of the requirements under this policy.

**National Clinical Trial (NCT) Number (NCT Number/NCT #):** A unique identifier that has been assigned to a study that has been successfully registered on ClinicalTrials.gov.

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

**IV. POLICY STATEMENT**
Rutgers University complies with FDAAA, NIH, CMS, and ICMJE clinical trial registration and reporting requirements.

The Principal Investigator of an Investigator-initiated, interventional clinical trial that meets FDAAA, NIH, CMS, ClinicalTrials.gov registration and reporting requirements is responsible for posting the requisite information on Rutgers University’s organizational account on ClinicalTrials.gov.

The Principal Investigator of all interventional clinical studies that would like to be considered for publication within an ICMJE journal must register the clinical trials in a public trials registry.

Registration and results reporting must occur within the timeframe set by FDAAA, NIH, CMS and/or ICMJE, as applicable with whichever timeframe is earliest.

**A. POLICY**

a. **Registration**

Registration and results reporting of clinical trials is REQUIRED if your study is:

1. FDA regulated clinical trials (other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation).

2. National Institutes of Health funded Clinical Trials (fully or partially funded)

3. Principal Investigators of clinical trials who plan to publish in an International
Committee of Medical Journal Editors (ICMJE) member journal.

Note: The ICMJE clinical trial registration policy requires public, prospective registration in an acceptable public registry or in the World Health Organization (WHO) International Clinical Trials Portal. It is important to understand that ICMJE requires Principal Investigators to adhere to the registration guidelines of the chosen registry. However, by the conditions set forth by FDAAA 801, registration of a clinical trial on ClinicalTrials.gov requires the posting of summary results data.

4. Center for Medicare and Medicaid Services (CMS): Qualifying clinical trials who seek reimbursement for items and services from the Center for Medicare and Medicaid Services.

Note: The National Clinical Trial (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 (NCD) Manual," Section 310.1

b. Registration/Record Updates
i. For Applicable Clinical Trials, Rutgers University Principal Investigators are ultimately responsible for:
   • ensuring that clinical trials are registered in ClinicalTrials.gov in a timely manner
   • reviewing the content of the clinical trial information posted on ClinicalTrials.gov
   • reviewing the clinical trial record for any inconsistencies and/or errors
   • reviewing the clinical trial record as required to verify that updating is taking place as required

ii. It is the responsibility of the Principal Investigator to register the trial in accordance with the following timelines:
   • FDAAA requires that the RP (or designee) for an ACT must submit required clinical trial information through the PRS no later than 21 days after enrollment of the first participant.
     ➢ https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa
   • The 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. These studies should be registered no later than 21 days after enrollment of the first participant.
   • ICMJE requires trial registry at or before first patient enrollment as a condition for publication
     ➢ http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/

iii. Principal Investigator Responsibilities for Updating ClinicalTrial.gov Records
   • Registration information must be updated no less than once every 6 months.
   • If recruitment status for the study changes (e.g., recruitment suspended), the registration must be updated within 30 days.
   • If the trial is complete (whether concluded or terminated prior to conclusion), registration must be updated within 30 days.

C. Results Reporting
   Aggregate results reporting, including reporting of adverse events, are required if the trial meets one of the following requirements:
   • The trial meets the definition of an Applicable Clinical Trial specified in FDAAA. Reporting aggregate results and adverse events on ClinicalTrials.gov must occur within 12 months of the Primary (endpoint) Completion Date; or
• The trial is NIH-supported, in whole or in part, are required for results submission no later than one year after the trial’s Primary Completion Date; or
• A study registered on Rutgers University’s organizational account and is identified as a probable ACT/non-probable ACT based on its study information on ClinicalTrials.gov.

d. Transfer of Principal Investigator Responsibilities
During the course of a clinical trial, the Principal Investigator may relocate to another institution or otherwise be unavailable to fulfill Principal Investigator responsibilities. Before leaving the University, the Principal Investigator is responsible for working with the Department or Division Chief to ensure an orderly transition of their responsibilities to the new Principal Investigator at Rutgers University or to initiate transfer of the ClinicalTrials.gov account/record(s) and Principal Investigator responsibilities to the departing Principal Investigator’s new institution.

If a clinical trial remains at Rutgers University and there are continuing ClinicalTrials.gov reporting obligations without a named PI, then the Department or Division Chief is responsible for assuming the obligations or appointing a PI to serve and meet any remaining reporting obligations.

e. Compliance with this Policy
Rutgers University requires compliance with ClinicalTrials.gov requirements for registration and results reporting.

If the Principal Investigator does not comply with this policy, the HSPP 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 results reporting.
V. REFERENCES

- FDAAA 801: [https://clinicaltrials.gov/ct2/manage-recs/fdaaa](https://clinicaltrials.gov/ct2/manage-recs/fdaaa)
- ClinicalTrials.gov website: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
- Center for Medicare and Medicaid Services (CMS):