

Human Research Protection Program ClinicalTrials.gov Policy

SCOPE

This policy applies to all investigators conducting clinical trials as defined by the Food and Drug Administration (FDA), International Committee of Medical Journal Editors (ICMJE), the National Institutes of Health (NIH), or submitting qualified research billing claims to the Centers for Medicare and Medicaid Services (CMS).

This policy is overseen and managed by the Human Research Protection Program (HRPP) and Human Research Compliance.

POLICY STATEMENT

Weill Cornell Medicine (WCM) is committed to fostering compliance with requirements concerning the public availability of clinical trial data on ClinicalTrials.gov. Thus, WCM requires registration and result posting for clinical trials, as defined below. This policy is intended to provide an organizational framework around and support to investigators responsible for complying with regulation, grantor requirements and/or publication standards regarding registration and reporting.

REASON FOR POLICY

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

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 NIH and CMS obliges grantees to follow registration and reporting requirements to qualify for funding. Further, ICMJE established similar standards that investigators must follow if they wish to publish in [participating journals](#).

DEFINITIONS

Clinical Trial definitions:

- 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.; or

- (b) the trial is conducted under an FDA investigational new drug application (IND) or investigational device exemption (IDE); or
- (c) 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:

- (a) Applicable Clinical Drug Trial: A controlled clinical investigation, other than a Phase I clinical investigation, of a drug or biological product subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of the Public Health Service Act, where 'clinical investigation' has the meaning given in 21 CFR 312.3 (or any successor regulation) and 'Phase I' has the meaning given in 21 CFR 312.21 (or any successor regulation); and
- (b) 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. 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); and a pediatric postmarket surveillance of a device as required under section 522 of the Federal Food, Drug, and Cosmetic Act.

ClinicalTrials.gov 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.

ClinicalTrials.gov is a public registry developed by the National Library of Medicine (NLM) as part of a mandate from the Food and Drug Administration Modernization Act (FDAMA) and further enhanced to include a results database as part of a mandate from FDAAA.

Primary Completion Date is defined as the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome measure.

Enrollment is typically defined as placing a consenting human research subject into a clinical trial.

National Clinical Trial Number (NCT) is an eight-digit number initiated that is assigned to identify the record and is issued when the record registration is publically posted on ClinicalTrials.gov.

Protocol Registration and Results System (PRS) is the internal system where data entry is completed prior to the public posting of the record on ClinicalTrials.gov. Each sponsoring entity has an assigned PRS organizational account.

Responsible Party is identified as the entity or individual who is responsible for registering a clinical trial and submitting clinical trial data to ClinicalTrials.gov.

Principal Investigator (PI) is identified as the responsible leader of a team of investigators (and research team) who has the ultimate responsibility for the conduct of the research. The Principal Investigator is delegated the Responsible Party role and assumes the associated responsibilities on a WCM investigator-initiated clinical trial.

PROCEDURE

REGISTRATION

To facilitate timely and compliant registration and data posting on the ClinicalTrials.gov database, the Human Research Compliance office serves as the WCM Protocol Registration System (PRS) administrator (hereafter referred to as **WCM ClinicalTrials.gov Administrator**). The WCM ClinicalTrials.gov Administrator shall work closely with investigators and staff to ensure that information is posted according to the applicable regulations.

Principal Investigators are responsible for:

- registering and maintaining clinical trials, as defined in the aforementioned **DEFINITIONS**, through WCM's account,
- reviewing the content of the information uploaded to the registry to verify completeness and accuracy, and
- ensuring all data entry activities occur within required time frames.

Registration must occur prior to enrollment of the first subject. Registration of studies can be initiated, even if IRB approval has not been obtained.

REQUIREMENTS FOR POSTING

Before the WCM ClinicalTrials.gov Administrator approves and releases a record for posting on ClinicalTrials.gov, the following data elements must be in place:

1. The IRB number must be used as the record's "Unique Protocol ID".
2. If NIH funded, the "Secondary ID" must include the NIH Grant #.
3. The "Responsible Party" in the "Sponsor/Collaborators" section must be listed as "Sponsor".
4. Sponsor must be Weill Cornell Medicine of Cornell University
5. The PI or designee must be the record owner. The PI must formally provide the name of their designee to the WCM clinicaltrials.gov administrator.
6. All notes, warnings, and errors in the record need to be cleared to the best of the submitter's ability.
7. The "Oversight" Section of ClinicalTrials.gov will contain accurate information pertaining to:
 - Board Status (i.e, request not yet submitted; submitted, pending)
 - Board Name (Weill Cornell Medicine Institutional Review Board)
 - Board Affiliation (Weill Cornell Medicine)
 - Board Contact
 - Business Phone (646-962-8200)
 - Business e-mail (irb@med.cornell.edu)
 - Address of IRB [(1300 York Avenue, Box 89 New York, NY 10065)]

8. In the “Contacts/Locations” section of ClinicalTrials.gov, “Overall Study Officials” must indicate the name of the WCM Principal Investigator in their role as Study Principal Investigator.

USER ACCESS

All users of the WCMC institutional account must have a valid WCM email address, unless they are an investigator who has left the institution but still needs to correct a record.

UPDATING RECORDS

Principal Investigators are responsible for updating clinical trial records 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 12 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*.

RESULTS POSTING

Principal investigators are responsible for reporting results of clinical trials *within 12 months of the Primary Completion Date*, unless the study does not qualify as a clinical trial under FDAAA or NIH, in which case results reporting is voluntary. If a Principal Investigator volunteers to post results, all elements required under the FDAAA or NIH are required, including posting the protocol and statistical analysis plan according to WCM’s Standard Operating Procedures (SOP).

RESPONSIBILITIES OF INVESTIGATORS LEAVING THE INSTITUTION

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 PI must work to ensure an orderly transition of his/her responsibilities, either to a new PI or work to initiate transfer of the record(s) and PI responsibilities to the new institution, in accordance with WCM’s SOP.

LANGUAGE IN THE CONSENT FORM

By federal regulation, ACTs must include the following language in the consent form. The language cannot be altered in any way.

"A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US

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."

NONCOMPLIANCE WITH FEDERAL REGULATION

Failure to comply with this policy may lead to criminal proceedings and civil penalties, loss of Health and Human Services (HHS) or NIH funding; inability to publish in ICMJE journals, and/or having noncompliant records identified on ClinicalTrials.gov. At the institutional level, IRB approval for any study under a given Principal Investigator may be withheld for noncompliance.

DISSEMINATION PLAN

Investigators submitting NIH FORM E must utilize the following template dissemination plan language in their application:

The WCM Clinicaltrials.gov Administrator will facilitate the Principal Investigator's dissemination of study results through ClinicalTrials.gov registration and reporting.

- *X (insert your name or PI designee) will be responsible for handling ClinicalTrials.gov requirements for this project according to the WCM ClinicalTrials.gov SOP. (insert your name or PI designee) will register the trial prior to enrolling the first subject. Once a record is established, (insert your name or PI designee) will confirm accuracy of record content; resolve problems; and maintain records including content update and modifications. (insert your name or PI designee) will also be responsible for results reporting and Adverse Events reporting at the conclusion of the project.*
- *Add specifics related to this trial.*

REFERENCES

45CFR46: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>

FDAAA 801: <https://clinicaltrials.gov/ct2/manage-recs/FDAAA>

Clinical Trials Registration and Results Information Submission (Final Rule; 42CFR11):
<https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission>

ICMJE FAQ <http://icmje.org/about-icmje/faqs/>

CMS Medicare Clinical Trial Policies
<https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html?redirect=/ClinicalTrialsPolicies>