

Policy Title: **Clinical Trials Registration and Results Reporting**
Responsible Office: Office of Academic Affairs
Originally Issued: July 2, 2018
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I. POLICY STATEMENT

This policy is established primarily in response to requirements of the Food and Drug Administration (FDA) and National Institute of Health (NIH) to register and report results of certain clinical trials (defined in section III) on **ClinicalTrials.gov**. The policy also responds to the requirements of the International Committee of Medical Journal Editors (ICMJE) and The Centers for Medicare & Medicaid Services (CMS) for registration of clinical trials on ClinicalTrials.gov.

ClinicalTrials.gov is a publicly-accessible registry established by federal mandate to facilitate public access to information on clinical trials. The registry increases transparency of, and improves public awareness around, clinical trials.

Montefiore Medical Center and Albert Einstein College of Medicine require registration and results reporting on ClinicalTrials.gov in order to:

- 1) Ensure compliance with FDA mandated regulations
- 2) Maintain eligibility and good standing with NIH and other funding agencies
- 3) Preserve researchers' ability to successfully meet ICMJE publication standards
- 4) Meet CMS billing criteria for routine costs associated with clinical trials

II. SCOPE

This policy applies to all employees, researchers, research coordinators, faculty, staff, students, and other individuals involved in research under the jurisdiction of, or using property belonging to, Montefiore and/or Einstein. This policy attempts to convey relevant information regarding requirements for registration and results reporting on ClinicalTrials.gov. However, the **Responsible Party** (defined in section IV) is responsible for independently knowing the requirements and ensuring compliance with all applicable federal regulations, funding agency policies, publication standards, and billing criteria. As required by law, the Responsible Party must ensure qualifying studies are registered and the required information is submitted accurately, completely, and on time.

III. THE POLICY

Montefiore and Einstein require submission of all clinical trials that fall under any of the following categories:

- A. **Trials classified as Applicable Clinical Trials (ACTs) by FDA regulation** (FDAAA 801 and the Final Rule) require registration and results reporting. ACTs must meet all of the following criteria:
1. The trial is an interventional clinical trial,
 2. The intervention is a product (drug, biologic or device) regulated by the FDA and,
 3. The trial is not a Phase 1 nor a small device feasibility study. (Phase 1 trials evaluate the safety, side effects, optimum dose and formulation method of the drug, with no health-related outcome measure. Feasibility trials evaluate device prototypes and have no health-related outcome measures.)
- B. **NIH-funded clinical trials, whether funded in whole or in part**, require registration and results reporting if the proposal was received by NIH on or after January 18, 2017. NIH follows the same requirements and timetables for registration and results reporting as the FDA. NIH broadly defines clinical trials to include any intervention (not just FDA-regulated products) and any phase (including phase 0, phase 1, and pilot studies) with any behavioral or biomedical health-related outcomes. Grant application for NIH funding must include the institutions' [NIH Dissemination Plan](#).
- C. **Clinical trials intended for publication in ICMJE-affiliated journals** must be registered before the first subject is enrolled. The ICMJE broadly defines clinical trials to include any intervention, any phase, and any health-related outcome including pharmacokinetic measures and adverse events. The ICMJE requires the following data elements with initial registration submission:
- 1) Official Title of the study (must match protocol title)
 - 2) Overall Study Officials (i.e. Study PI, Study Director, Study Chair)
 - 3) The *Plan to Share IPD** data element indicates whether or not there is a plan in place to share *de-identified* IPD (Individual Participant Data) with colleagues external to the research team. (*NOTE: this is an optional field as of July 2, 2018. It is anticipated to become a required field beginning January 2019.)
- The ICMJE does not require nor discourage results reporting. As with all applicable regulations and policies, it is incumbent upon the Responsible Party to stay informed of relevant ICMJE publication standards and requirements.
- D. **Clinical trials involving routine Medicare-billable charges** must be registered on ClinicalTrials.gov prior to submission of a claim in order to receive payment. The Centers for Medicare & Medicaid Services (CMS) created this policy in response to a federal mandate to authorize Medicare payments for certain costs associated with participation in clinical trials.
- E. For all external funding and sponsorship, the Principal Investigator is required to review all award letters to ascertain if registration on ClinicalTrials.gov is required.

- F. Studies that do not generally require registration on ClinicalTrials.gov include expanded access studies, observational studies, and Patient Registries (unless PCORI-funded).

IV. THE RESPONSIBLE PARTY

In this document, the terms Principal Investigator and Responsible Party are synonymous.

Montefiore and Einstein designate the main Principal Investigator (PI) as the Responsible Party (RP) for registering and results reporting on ClinicalTrials.gov provided the Principal Investigator meets all of the following criteria:

- 1) The PI is responsible for conducting the trial,
- 2) The PI has access to and control over the data from the trial,
- 3) The PI has the right to publish the results of the trial and,
- 4) The PI is able to meet all of the requirements for submitting and updating clinical trial information.

In general, Montefiore and Einstein designate the Principal Investigator as the Responsible Party for the following trials:

1. Trials in which the Principal Investigator holds the IND/IDE
2. Trials initiated by the Principal Investigator (i.e. the Principal Investigator designed the trial and wrote the protocol)
3. NIH-sponsored trials in which Montefiore or Einstein is the grantee institution
4. Trials sponsored by a foundation, cooperative or group of investigators for which the Principal Investigator accepts the role of the Responsible Party
5. Trials, initiated by private industry, for which the Principal Investigator accepts the role of the Responsible Party in an explicit agreement:
 - a. If possible, the Principal Investigator should request a userID on the industry's ClinicalTrials.gov account and create the study record under the industry's Organization Name
 - b. For commercial-sponsored trials in which the Montefiore/Einstein investigator is just a co-principal investigator, the co-PI should confirm with the sponsor that the study is registered on ClinicalTrials.gov

Records for trials in which the Principal Investigator holds the IND/IDE must list the Responsible Party as the "sponsor-investigator"; this will make the PI the sponsor by default. Records registered under Montefiore or Einstein must list the Principal Investigator as the Responsible Party and the institution as the sponsor.

In the event the Responsible Party intends to transition away from the institution, s/he must contact the IRB and the PRS administrator to facilitate the transfer of the study record to another Principal Investigator at the institution or to the Responsible Party's new institution.

V. REGISTERING A TRIAL

Montefiore and Einstein require the Principal Investigator to register ACTs and NIH-funded trials prior to IRB (Institutional Research Board) approval. To preserve the ability to publish and to meet billing criteria, the Principal Investigator is strongly encouraged to register clinical trials that are neither ACTs nor NIH-funded.

The Protocol Registration and Results Reporting System (PRS) is the data entry portal to ClinicalTrials.gov. To obtain a PRS account, email clinicaltrials.gov@einstein.yu.edu.

Elements of successful registrations include the following:

- * Most of the required registration information is extracted from the protocol.
- * Descriptive text is concise and free of errors
- * Abbreviations are spelled out on the first entry
- * No personal pronouns are used
- * **Outcome measures** contain the name of the specific measure with a description of the metric/scale used to measure it and the time point(s) at which the measurement is assessed. A tutorial on outcome measures is available [here](#)

Data entry can be performed by the study coordinator or the Responsible Party. Once all the required registration information is entered, the Responsible Party must review the record and then release it to PRS review. If the record is returned for correction, the Responsible Party must correct and re-release the record by the indicated deadline.

After the study record passes PRS review, the study is posted on ClinicalTrials.gov and the National Clinical Trials number (NCT#) is emailed to the Responsible Party. The Responsible Party must notify the IRB of the NCT# through a revision of the IRB application.

VI. REQUIREMENTS FOR UPDATING REGISTRATION INFORMATION

The regulations mandate timely updates to the study record after it is registered. The Responsible Party must ensure updates are submitted on time. The table below depicts the more frequently performed updates and their deadlines. A more detailed timetable is found [here](#).

Data Element	Deadline for Updating
Study Start Date	Update the field within 30 calendar days of the enrollment of the first participant
Overall Recruitment Status	Update the field within 30 calendar days of a change in overall recruitment status (enrolling, active but not enrolling, suspended, terminated, etc.)

Human Subjects Protection Status	Update the field within 30 days of a change to the IRB application status (pending, approved, etc.) **Update the study record within 30 days of approved IRB amendments (i.e., change in main Principal Investigator, change in study site(s), change in study contact, etc.)
Primary Completion Date; Study Completion Date	Update the fields within 30 calendar days of the actual completion date. (Completion dates refer to collection of data, <u>not</u> analysis of data.)
Record Verification Date	Update the field any time the record is edited. Update at least once every six months if no other changes are made to the record
Errors and PRS Reviews Comment	Records containing errors or flagged for correction by the PRS staff must be corrected promptly

VII. REQUIREMENTS FOR POSTING RESULTS SUMMARY DATA

The Responsible Party is required to submit summary results data to ClinicalTrials.gov for ACTs and NIH-funded trials within **twelve (12) months of the trial's completion dates**, regardless of whether the clinical trial was completed as planned or terminated earlier. No qualitative, descriptive, or preferential summary of the results should be submitted. Prior to the results due date, the Responsible Party can request an extension to the results submission deadline for “good cause”.

All results information must be aggregated, summary level data; not data for the individual participants. For studies where the participant level data can be easily determined, as in studies with only 1 participant, contact the PRS administration at clinicaltrials.gov@einstein.yu.edu prior to submitting results data.

VIII. REQUIREMENTS FOR UPLOADING DOCUMENTS

For trials with primary completion dates on or after January 18, 2017, the protocol and statistical analysis plan must be uploaded to ClinicalTrials.gov. The protocol should be clear, concise and written in English. It should clearly delineate the primary and secondary outcome measures. Personal identifiable information, trade secrets, and confidential information should be redacted from all documents prior to uploading, unless such information is required by the regulation. *It is best practice to load the protocol with the results data, rather than earlier so that only the final version is submitted.*

Informed Consent Forms - starting January 21, 2019, clinical trials supported by federal funding must post the informed consent document after the trials is closed to recruitment and no later than 60 days after the last study visit by any subject, as required by the protocol. NOTE: the timeframe for uploading the informed consent forms is NOT the same as the timeframe for uploading the protocol and statistical analysis plan.

The Informed Consent Forms for ACTs and NIH-funded clinical trials must include the following ClinicalTrials.gov **disclosure statement**:

“A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

IX. CONTACT INFORMATION

Contact the PRS Administrator at clinicaltrials.gov@einstein.yu.edu or call 718-430-2643 with questions or to report any errors.

LINKS

ClinicalTrials.gov

[PRS Data Entry Website](#)

[FDAAA 801](#)

[The Final Rule \(42 CFR part II\)](#)

[CMS \(Centers for Medicare & Medicaid Services\)](#)

[Checklist to determine if trial is an Applicable Clinical Trials \(ACT\)](#)

[ClinicalTrials.gov Updating Deadlines](#)

[ICMJE \(International Committee of Medical Journal Editors\)](#)

[Informed Consent Disclosure Statement](#)

[IRB web page](#)

[NIH Dissemination Plan](#)

[NIH Definition of Clinical Trials](#)

Video: [Tutorial on Outcome Measures](#)

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This policy is subject to change at any time. In the event of any apparent or implied discrepancy between this policy and the requirements of any of the referenced agencies (FDA, NIH, ICMJE, or CMS), the agency's guidance unequivocally supersedes this policy. Please report any discrepancy between this policy and any other internal document/policy to clinicaltrials.gov@einstein.yu.edu.

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