

Registration of Clinical Trials

Background

In September 2005, the International Committee of Medical Journal Editors (ICMJE) announced a new requirement specifying that certain categories of clinical trials be registered in a public registry. The role of the new registration requirement is best described by the ICMJE (http://www.icmje.org/update_may05.html), as follows:

To thank the thousands of participants who have placed themselves at risk by volunteering for clinical trials. They deserve to know that the information that accrues from their altruism is part of the public record, where it is available to guide decisions about patient care, and deserve to know that decisions about their care rest on all of the evidence, not just the trials that authors decided to report and that journal editors decided to publish.

Another goal of the registry is to allow investigators to make available information to a broad array of potential subjects and for patients to find potential research enrollment opportunities. In September 2007 Public Law 110-85 amended the Public Health Service Act to expand the scope of clinical trials that must be registered in ClinicalTrials.gov. It also increases the number of registration fields that must be completed, requires certain results information to be included and sets penalties for noncompliance.

Frequently Asked Questions (FAQ)

Should my research protocol be registered?

Registration is required for trials that meet the FDAAA 801 definition of an ‘Applicable Clinical Trial’ and were either initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007. Trials that were ongoing as of September 27, 2007 and reach the Completion Date before December 26, 2007, are excluded. “Applicable Clinical Trials” include the following:

- 1. Trials of Drugs and Biologics:** Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation;
- 2. Trials of Devices:** Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric postmarket surveillance required by the FDA.

‘Applicable Clinical Trials’ usually include interventional studies of FDA-regulated drugs, biological products, or devices that meet the following conditions:

- The trial has one or more locations in the United States.
- The trial is conducted under an FDA investigational new drug application or investigational device exemption.
- The trial involves a drug, biologic, or device that is manufactured in the United States or its territories and is exported for research.

NOTE: NIH encourages registration of ALL trials whether required under the law or not.

Furthermore, the ICMJE member journals require prospective registration of clinically directive trials for all trials that began enrollment on or after July 1, 2008. The ICMJE uses WHO's definition of clinical trials:

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.

When must my protocol be registered?

The ICMJE requires that registration occur before the first patient is enrolled. The FDA allows registration up until 21 days after enrollment of the first participant.

Who is responsible for registering my research protocol?

The entity responsible for registering is the 'Responsible Party'. The statute defines the Responsible Party as:

1. the sponsor of the clinical trial (as defined in 21 CFR 50.3) **OR**
2. the principal investigator (PI) of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, provided that the PI is responsible for conducting the 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 FDAAA's requirements for the submission of clinical trial information.

Complete definitions on the meaning of 'Responsible Party' and 'Sponsor' can be found at <http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf>

Note: The PI is responsible for ensuring that all registration requirements are met, regardless of whether the PI is the one registering the trial.

How do I determine if I am the responsible party?

Investigators are encouraged to consult with the Einstein IRB to determine if they are the "responsible party" for registering a trial. It is your responsibility to determine if you are obligated to register any of your clinical trials.

1. If you are the Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) holder, you may be the "sponsor" as that term is defined in the FDA regulations found at 21 C.F.R. 50.3. For studies that are conducted under an IND or IDE, the "sponsor" is identified in the course of filing the IND (commonly called the "IND holder" or the "part 812 sponsor") **OR**

2. You may not be the sponsor, but if you are the Principal Investigator you may have been delegated registration duties by the sponsor provided the other conditions for access and control over information are met **OR**
3. For extramural trials, where there is no IND or IDE holder, NIH would not be the responsible party. The funding recipient may be a “responsible party” as that term is defined in the Act, depending on the unique circumstances of the trial.

How Do I Register my Clinical Research Protocol?

In order to register, you will need to have a ClinicalTrials.gov account from the institution responsible for the research/payroll of the PI. The contacts for requesting an account are the following:

- **Montefiore Researchers:** Joshua.Massei@einstein.yu.edu
- **PAGNY/HHC Researchers:** Caron.Davis@nychhc.org
- **YU/Einstein Researchers:** Sathya.Chandrasekar@einstein.yu.edu

1. Send an email requesting a clinical trials account the appropriate contact from the list above. Please include your:
 1. Name;
 2. Telephone number;
 3. E-mail address;
 4. Einstein IRB number;
2. You will receive an e-mail from the ClinicalTrials.gov website with your log-in information.
3. Log on to: <https://register.clinicaltrials.gov>. (In the “Organization” field, type the organization name and registration info. “Einstein” or “Montefiore MC”.
4. Go to "User Account," and change your temporary password.
5. On the Main Menu page, under "Protocol Records" hit "Create" and complete the study description template. Required fields are marked with a red asterisk (*). There are explicit instructions on the website to guide you in the completion of each field. For the following fields please note:
 1. Unique Protocol ID = the study’s Einstein IRB number.
 2. Board Affiliation: Albert Einstein College of Medicine of Yeshiva University
 3. Board Contact: 718-430-2237, irb@einstein.yu.edu, Belfer Bldg #1002; 1300 Morris Park Avenue; Bronx, NY 10461
 4. Oversight Authorities: Add "United States: IRB" and "United States: Department of Health and Human Services". "If this is not an FDA-regulated protocol, remove "United States: Food and Drug Administration."
 5. Sponsor will automatically populate with the institution’s name (e.g. "Albert Einstein College of Medicine of Yeshiva University"). This is generally correct.

What does the "Record Status" mean?

Record Status	Description
In Progress	User is creating (or modifying) the record.
Completed	User has finished - record is ready for review.
Approved	Administrator has reviewed record and has made any necessary changes.
Released	Administrator has released the record to ClinicalTrials.gov. Please allow a few days for the posting to appear on the ClinicalTrials.gov site.
Once you have fully completed the necessary fields your record will be routed to the Einstein/Montefiore/HHC administrator for review. Subsequent to review the administrator will approve and release the record for posting.	

Results of which studies need to be published on clinicaltrials.gov?

Results submission is required for 'Applicable Clinical Trials' that were required to be registered under *FDAA 801* and that study drugs, biologics, and devices that are approved, licensed, or cleared by FDA.

When do I need to submit results?

In general, results of an Applicable Clinical Trial of a drug, biologic, or device that is approved, licensed, or cleared by FDA must be submitted by the Responsible Party no later than 12 months after the 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, whether the clinical trial concluded according to the pre-specified protocol or was terminated).