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, on its website (http://www.icmje.org/clin_trialup.htm), 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, which was enacted, amending 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 submitted, requires certain results information to be included and sets penalties for noncompliance.

Frequently Asked Questions (FAQ)

Should my research protocol be registered?

Only "applicable clinical trials" should be registered. Those who are uncertain whether their trial meets either definition should err on the side of registration. Under the statute, these trials generally include:

1. Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation;

   and

2. Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance.

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

Furthermore, in June 2007 ICMJE accepted 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.

The ICMJE member journals will start to implement the expanded definition of clinically directive trials for all trials that begin enrollment on or after July 1, 2008.
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 C.F.R. 50.3),
   or
2. the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee (provided that “the principal investigator 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 requirements” for submitting information under the law.) See PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(1)(A)(ix)).

**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 CCI 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?

**NOTE:** The research protocol must be CCI approved prior to registering.

**MMC Researchers:** Contact Victor Hatcher, Ph.D., Associate Dean for Continuing Medical Education, at vhatcher@montefiore.org

**NYMA/HHC Researchers:** Contact Nancy Moynihan, at Nancy.Moynihan@nychhc.org.

**YU/AECOM Researchers:** AECOM has an institutional account with ClinicalTrials.gov.
Investigators who wish to register their protocols must first obtain an institutional sub-account. To obtain your AECOM institutional sub-account:

1. Send an email to David Wallach at david.wallach@einstein.yu.edu. Please include your:
   1. Name;
   2. Telephone number;
   3. E-mail address;
   4. CCI number;
   5. A sentence requesting an AECOM sub-account for registering a clinical trial.

2. You will receive an e-mail from the ClinicalTrials.gov website with a your log-in information.

3. Log on to: https://register.clinicaltrials.gov. (In the “Organization” field, type in “albert_einstein”.)

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 CCI number.
   2. Board Affiliation: Albert Einstein College of Medicine of Yeshiva University
   3. Board Contact: 718-430-2237, david.wallach@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: "Albert Einstein College of Medicine of Yeshiva University" will automatically appear. This is generally correct.

6. If a delegate of the PI is the one completing the template, send the draft template to the PI for review and approval. Please have the PI e-mail David Wallach (david.wallach@einstein.yu.edu) this approval.

What does the "Record Status" mean?

<table>
<thead>
<tr>
<th>Record Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Progress</td>
<td>User is creating (or modifying) the record.</td>
</tr>
<tr>
<td>Completed</td>
<td>User has finished - record is ready for review.</td>
</tr>
<tr>
<td>Approved</td>
<td>Administrator has reviewed record and has made any necessary changes.</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td>Released</td>
<td>Administrator has released the record to ClinicalTrials.gov.</td>
</tr>
<tr>
<td></td>
<td>Please allow a few days for the posting to appear on the ClinicalTrials.gov site.</td>
</tr>
</tbody>
</table>

Once you have fully completed the necessary fields your record will be electronically sent to the AECOM administrator for review. Subsequent to review the administrator will approve and release the record for posting.