Clinical Trials Registration At Clinical Trials.gov

I. Purpose

To explain the types of research that must be listed on Clinical trials.gov and provide instructions and guidance.

II. Overview

On September 27, 2007 Congress enacted U.S. Public Law 110-85 (also known as H.R. 3580, or Food and Drug Administration Amendments Act of 2007). This act mandates the expansion of ClinicalTrials.gov, expands the required submission elements and establishes penalties for not listing a trial. The FDA requirements are in addition to the 2005 policy established by the International Committee of Medical Journal Editors (ICMJE) requiring the entry of clinical trials in a public registry prior to subject enrollment as a condition of consideration for publication of the trial results.

Registration is required for any research study that:

- Prospectively assigns human subjects to intervention and at least one concurrent control or comparison groups AND
- Uses a drug, biologic, or device as the intervention or control/comparison AND
- Studies the safety, efficacy or cause-and-effect relationship between an intervention and a health outcome

The registration requirement does not apply to:

- The use of FDA approved, marketed products used in the course of medical practice
- Phase I clinical investigations of drugs or biologics
- Small clinical trials to determine the feasibility of a device or clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes
- FDA required pediatric post-marketing surveillance of devices
- Purely observational studies, meaning those studies where the assignment of the intervention is not at the discretion of the investigator

Investigators and sponsors are encouraged to register all clinical trials to ensure they meet the publication requirements of the International Committee of Medical Journal Editors (ICMJE) and to promote transparency in clinical research.

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III. Registration Responsibility on ClinicalTrials.gov

The FDA regulations require the responsible party to register applicable clinical trials. The responsible party is the sponsor of the clinical trial, meaning the person who initiates a clinical investigation.

- For investigator-initiated trials, the lead principal investigator responsible for initiating, conducting and coordinating the overall clinical trial is responsible for registration
- For sponsor-initiated trials the sponsor is responsible for registration
- For trials sponsored or funded wholly or in part by the NIH the Principal Investigator is responsible for registration
- For trials associated with Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications with the FDA, the IND/IDE holder is responsible for registration
- The sponsor, grantee, contractor, or awardee may designate the principal investigator of a clinical trial as the responsible party, 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

If unclear who is responsible registering an applicable clinical trial, investigators should consult with the sponsor, funding agency, and/or other study investigators to define who the responsible party will be.

IV. Managing Trials listed on ClinicalTrials.gov

If you are the responsible party and register a study on Clinical trials.gov, you are responsible ensuring that the information is complete, accurate and updated. This includes reviewing the listing and making necessary changes every 6 months or more frequently if significant changes occur. You are also responsible for noting when enrollment ceases. All correspondence from Clinical Trials.gov will come to the e-mail address of the owner of the account the trial was registered under.
V. Additional Requirements

a) NIH Funded Studies

Competing renewal applications that include studies that are required to be registered must include as part of the Human Subjects Section of the Research Plan the following items:

- A statement that “This application includes a trial which requires registration in ClinicalTrials.gov,”
- The National Clinical Trial (NCT) number (i.e. the ClinicalTrials.gov number)
- Brief Title as listed in ClinicalTrials.gov, and
- The name of the individual or entity responsible for registering the study (responsible party) for each study being conducted under the application. (As grantee, Thomas Jefferson University designates the lead investigator of the trial as the responsible party.)

If the application does not include studies that are required to be registered the Human Subjects Section of the Research Plan should include a statement that “This application does not include a trial which requires registration in ClinicalTrials.gov.” These requirements apply to all competing applications submitted to the NIH on or after January 25, 2008.

New applications that include studies that are required to be registered must include as part of the Human Subjects Section of the Research Plan a statement that “This application includes a trial which requires registration in ClinicalTrials.gov.” The study would then need to be registered and the National Clinical Trial (NCT) number, Brief Title as listed in ClinicalTrials.gov and the individual or entity responsible for registering the study (responsible party) for each study being conducted under the application as part of the Just-In-Time (JIT) information. If a New application does not include studies that are required to be registered the Human Subjects Section of the Research Plan should include a statement that “This application does not include a trial which requires registration in ClinicalTrials.gov.”
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Non-competing progress reports that include studies that are required to be registered must include as part of the Human Subjects Section of the Progress Report the following items:

- A statement that “This application includes a trial which requires registration in ClinicalTrials.gov”
- The National Clinical Trial (NCT) number (i.e. the ClinicalTrials.gov number)
- Brief Title as listed in ClinicalTrials.gov and
- The name of the individual or entity responsible for registering the study (responsible party) for each study being conducted under the application. (As grantee, GRU designates the lead investigator of the trial as the responsible party.)

If the application does not include studies that are required to be registered the Human Subjects Section of the Research Plan should include a statement that “This application does not include a trial which requires registration in ClinicalTrials.gov.” These requirements apply to all non-competing progress reports with budget start dates of April 1, 2008 or later (applications due on or after 2/1/08).

b) FDA regulations special requirements for IND, IDE or BLA studies

Studies conducted under an IND or IDE must include in the informed consent documents and the informed consent process a statement that clinical trial information for the study has been or will be submitted for inclusion in ClinicalTrials.gov as required by FDA regulations.

A certification must accompany human drug, biological, and device product submissions made to FDA. At the time of submission of an IND, IDE or BLA application or submission of a report, amendment, supplement or resubmission, such application or submission must be accompanied by a certification that all applicable requirements related to clinical trial registration have been met. Where available, such certification must include the appropriate National Clinical Trial (NCT) numbers.

The official certification form, Form FDA 3674 entitled "Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank is available on FDA’s Web site.
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For sponsor held INDs, IDEs and BLAs the sponsor must provide the certification. For investigator held INDs, IDEs and BLAs the individual holding the IND, IDE or BLA must provide the certification.

Where can I find more information from the NIH about the requirement to register clinical trials?

The NIH has posted information on clinical trials registration at:

VI. Registration Process for ClinicalTrials.gov

Step 1: Search ClinicalTrials.gov to ensure that the trial is not already listed. NIH-sponsored clinical trials and many industry-sponsored trials have already been registered on this site. If the trial is not listed, continue

Step 2: Establish an account with the ClinicalTrials.gov Protocol Registration System (PRS) by sending an e-mail message to GRU’s PRS administrator, Angela Toole (atoole@gru.edu). The subject line should state “ClinicalTrials.gov Protocol Registration” and the body of the message should contain your name, telephone number, and email address

Within 2 business days, you will receive an e-mail message from ClinicalTrials.gov containing your login name and temporary password

Step 3: Upon receipt of your login information, proceed with registering the trial. This process will take approximately 1 hour, and it will be helpful to have the protocol, informed consent document, and IRB approval (if available) on hand. IRB approval is not required to register a trial. Note that this system offers the option to save data if you do not have time to complete the entire process. A list of all the variables you will be asked to provide can be found at http://prsinfo.clinicaltrials.gov/definitions.html and a guided tour is available at http://prsinfo.clinicaltrials.gov/title.html

- To begin the registration process, go to the ClinicalTrials.gov registration website [https://register.clinicaltrials.gov/]. Complete the login fields. In the “Organization” field, enter MCGeorgia

- The “Main Menu” page will appear. The “User Account” link provides information on changing your temporary password, and this should be done as soon as possible. This link also has a helpful “User’s Guide”

- To complete the protocol template, begin from the “Main Menu” page, go to “Protocol Record” and select “Create.” You can copy and paste information from the protocol into the data fields.

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