18.6 Public Registration of Clinical Trials

The FDA requires that certain trials be publicly registered at “clinicaltrials.gov” before any subjects are enrolled. [See PHSA; Section 13 of MMA; 21 CFR §312; 42 USC 282(i)]. The URL for the registration site is: https://register.clinicaltrials.gov/

18.6.1 Who Must Register?

The responsible party for registering applicable clinical trials is the Sponsor of the clinical trial, which means the person who initiates a clinical investigation.

- For investigator-initiated trials, the lead PI responsible for initiating, conducting and coordinating the overall clinical trial is responsible for registration;
- For Sponsor-initiated trials the Sponsor is responsibility for registration;
- For trials Sponsored or funded wholly or in part by the NIH the grantee is responsible for registration; and
- For trials associated with IND or 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.

Once a trial is registered, the responsible person also must ensure on an ongoing basis 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.

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.

18.6.2 Which Studies Must Be Registered?

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; and/or
• 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.

18.6.3 When Must the Information Be Submitted?
Information about new Protocols open for enrollment must be registered not later than 21 days after Protocol approval. [42 U.S.C. 282(j)(3)]. Supplemental information can be submitted at 30-day intervals. The FDA strongly encourages you to update information about trials that are unexpectedly closed (e.g., clinical hold) within 10 days after the closing or sooner if possible.

18.6.4 How To Register a Clinical Trial?
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 with registration.

Establish an account with the ClinicalTrials.gov. Within 2 business days, you will receive an E-mail message from ClinicalTrials.gov containing your login name and temporary password.

Once you have received your login information, register 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.

Some suggestions for completing certain items that you might not have available are:

• Unique Protocol ID: The Tulane IRB number is recommended. An IRB number can be generated by starting an application in the IRBNet system. IRB approval is not required to register a trial. The IRB number is also used in the Board Approval Number field.
• Secondary IDs: The grant number, funding agency number or other funding source number is recommended.
• Board Name (Full name of the approving human subjects review board): Tulane University Biomedical Institutional Review Board
• Board Affiliation (Official name of organizational affiliation of the approving human subjects review board): Tulane University Biomedical Institutional Review Board
• Board Contact (Contact information for the human subjects review board):
  Name: Roxanne R. Johnson, Director
  Phone: 504-988-2665
Email: rjohnson@tulane.edu
Address: 1440 Canal Street, Suite 1705, New Orleans, LA 70112

Oversight Authorities: should always include **United States: Institutional Review Board**; other oversight authorities such as the FDA may also apply depending on the clinical trial

When the template is complete, hit “Submit” for release of the content to ClinicalTrials.gov

Information should be reviewed and updated as needed every 6 months or more frequently if changes occur

**18.6.5 What Information Must Be Submitted?**

The following are examples of information to be submitted:

- **Descriptive Information**
  - Brief Title (in lay language)
  - Brief Summary (in lay language)
  - Study Design/Study Phase/Study Type
  - Condition or Disease
  - Intervention

- **Recruitment Information**
  - Study Status Information including
  - Overall Study Status (e.g., recruiting, no longer recruiting)
  - Individual Site Status
  - Eligibility Criteria/Gender/Age

- **Location and Contact Information**
  - Location of Trial
  - Contact information (includes an option to list a central contact person for all trial sites)

- **Administrative Data**
  - Unique Protocol ID Number
  - Study Sponsor
  - Verification date

**18.6.6 Who Receives the Submitted Information?**

The DHHS Secretary acting through the NIH Director receives information submitted to ClinicalTrials.gov.

**18.6.7 Who Can Access the Registered Information?**

Studies will be made available to the public through ClinicalTrials.gov within two to five days after submission by the Sponsor. Except for the IND number, serial number, and FDA center designation, all information submitted through the PRS is made available to the public.
18.6.8 Must Information Be Included About Foreign Trial Sites?

Yes, a Sponsor must include information about foreign trials when those trials are conducted under an IND submitted to FDA and the trial meets the criteria for submission to the Clinical Trials Data Bank. [42 U.S.C. 282(j)(3)]. Sponsors may voluntarily conduct a foreign trial under the IND regulations. Sponsors are not required to submit information to the Clinical Trials Data Bank when a foreign trial is not conducted under an IND.

18.6.9 Can Intermediaries Act on Behalf of a Sponsor?

Yes. For example, in some cases a Sponsor might want to contract with an information management company to serve as an intermediary in preparing data for inclusion in ClinicalTrials.gov. The information management company, when authorized by the Sponsor, could act on behalf of the Sponsor for this purpose.

18.6.10 Can Sponsors Designate Multiple Individuals to Be Data Providers?

Yes. When Sponsors register to become a PRS data provider, they will be given information, including instructions, for creating additional users for their accounts. A Sponsor can control access to the account by designating users and administrators for the account.

18.6.11 What are the NIH Requirements for ClinicalTrials.gov Registration Information in Applications and Progress Reports?

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. Investigators and Sponsors must ensure that applicable Drug, Biologic and Device trials are registered within 21 days of enrollment of the first subject and preferable before first subject enrollment. The legislation also requires applications or progress reports for any clinical trials required to be registered which are funded in whole or in part by a grant from any agency of the DHHS to contain specific information certification registration in ClinicalTrials.gov.

18.6.12 How do the FDA registration requirements affect 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, Tulane 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.”

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, Tulane 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 non-competing progress reports with budget start dates of April 1, 2008 or later (applications due on or after 2/1/08).

18.6.13 Do the FDA regulations have any 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.

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.