

ClinicalTrials.gov Registration Requirement

The recently enacted [U.S. Public Law 110-85](#) (Food and Drug Administration Amendments Act of 2007), Title VIII- Section 801 now has mandates that effect the NIH-maintained data bank of all clinical trials which qualify for registration at [ClinicalTrials.gov](#). Previously, the data bank only required registration of trials of drugs for serious or life-threatening diseases, and those which were to be considered for publication by the International Committee of Medical Journal Editors ([ICMJE](#)).

Clinicaltrials.gov delegates logons and initial review of clinical trials to a designated administrator at each University. Studies that meet the FDA definition of a clinical trial must be registered. In addition, studies that meet the ICMJE definition must be registered if the investigator wishes to eventually publish.

Steps for registering your clinical trial through USA:

1. Contact Protocol Registration System (PRS) Administrator: Dusty Layton, dlayton@usouthal.edu, 460-6625
2. Request account setup for PRS users, provide user ID, full user name and email address
3. Receive by return email from ClinicalTrials.gov a login name and a temporary password
4. Access the PRS website here: <http://register.clinicaltrials.gov>
5. Browse the Main Menu page. Follow the instructions for changing the temporary password. Refer to the "User's Guide" for additional information.
6. **On "register.clinicaltrials.gov":**
 - Complete the Log In fields. In the "Organization" field, enter "**USouthAlabama**". Enter your username and password you received from ClinicalTrials.gov via email.
 - On the Main Menu page, under Protocol Record, hit "Create" to begin creating your record.
 - There are 12 components to the online registration process. They are in the following sequence: Title, Oversight, Sponsor, Summary, Status, Design, Interventions, Conditions, Eligibility, Locations, Citations and Links.
 - Each component has its own separate page that links to the next page in the sequence. You are given the option on each page to either "continue" or "quit".
 - One each page, on the left hand side are links that lead to pop-up menus that give specific definitions of each section of required information for further clarification.
7. Submit the completed registration. The registration will be reviewed and approved by the PRS administrator, then released to the ClinicalTrials.gov databank. Records are made available to the public through the ClinicalTrials.gov web site within 2 to 5 days of release, following system validation and quality assurance review. New records may take up to 30 days to appear in the databank.

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Who is responsible for registering trials on ClinicalTrials.gov?

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, so long as 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 under this subsection for the submission of clinical trial information.” See [PL 110-85](#), Section 801(a), (adding new 42 U.S.C. 282(j)(1)(A)(ix)).

Since responsibility for registering trials lies with the lead sponsor of the clinical study, most “industry sponsored” trials will be registered by the sponsor, which can be a pharmaceutical company or CRO. Local sponsor-investigator studies (also known as “investigator initiated studies”), or those who hold an IND or IDE that meet the eligibility criteria, will all need to be registered by the investigator prior to study enrollment, where applicable. If the sponsor of a clinical trial is someone other than the PI, investigators should personally check the registry to ensure that all of the required registration elements are included.

NOTE: Per the Act, sponsors must now also include study results in the registry. The results submissions should include lay language summaries of subject demographics and characteristics, primary and secondary outcomes, and disclosures of any privacy agreements. Timelines for this information are set forth (see related links below).

Which clinical investigations or trials must be registered?

Trials that must be registered under the Act are called “applicable clinical trials.” Under the statute, these trials generally include:

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

**The FDA defines a clinical investigation as any experiment in which a drug is administered or dispensed to, or used, involving one or more human subjects. An experiment is any use of a drug except for the use of a marketed drug in the course of medical practice. Purely observational studies are exempt from registration requirements.*

ICMJE guidelines define a clinical trial as, “Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome.”

An intervention is any action or ministrations that produces an effect or that is intended to alter the course of a pathologic condition or disease process.

How will an investigator know if their trial should be registered?

Investigators should review the statutory definition of applicable clinical trial to identify if any of their trials must be registered to comply with the law. NIH encourages registration of ALL trials whether required under the law or not, and ICMJE advises that those who are uncertain whether their trial meets the ICMJE definition of eligible trials should err on the side of registering if they wish to seek publication in an ICMJE journal.

Registration Transition Period

Trials initiated after 9/27/2007 or trials that are ongoing as of 12/26/2007 must be registered in full by the later of 12/26/2007 or 21 days after the first patient is enrolled.

Trials that were “ongoing” as of as of 9/27/2007 and do not involve a “serious or life threatening disease or condition,” must be registered by **9/27/2008**.

As of 9/27/2008, results from all clinical trials studying drugs, biologics and devices not yet initially approved or cleared by the FDA must be submitted no later than 30 days after FDA approval or clearance.

Notice to NIH Applicants and Grantees

NIH Grant Applications and Progress Reports now require certification that clinicaltrials.gov requirements have been met. The following info must be included in Grant Applications and Progress Reports to Provide Certification:

For competing applications (new and renewal) that include applicable clinical trials:

the NCT number/s, Brief Title/s (as defined by ClinicalTrials.gov, see <http://prsinfo.clinicaltrials.gov/s801-new-requirements.pdf>), and the identity of the responsible party (or parties) must be provided in the Human Subjects Section of the Research Plan. If a new applicable clinical trial is proposed, the human subjects section of the research plan should include a statement that the application includes a trial which requires registration in ClinicalTrials.gov. The signature on the application of the Authorized Organizational Representative will now also assure compliance for the registration of any such trial.

When submitting a non-competing progress report that includes applicable trial/s:

NCT number/s, Brief Title/s (as defined by ClinicalTrials.gov, see <http://prsinfo.clinicaltrials.gov/s801-new-requirements.pdf>), and the identity of the responsible party (or parties) are to be included in the Human Subjects section of the progress report.

The registration requirement goes into effect as follows:

Competing applications: All applications submitted to the NIH on or after January 25, 2008, which incorporate an applicable clinical trial in their proposed project, are required to provide the information as detailed above.

Non-competing progress reports: All progress reports for grants which include an applicable clinical trial with budget start dates of **April 1, 2008** or later are required to provide the information as detailed above.

Please visit this site for more information: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-023.html>

What are the penalties for failing to register?

- According to the ICMJE:

Unregistered trials will not be considered for publication in journals that adhere to ICMJE standards. This penalty has not changed over time.

- According to the FDA/NIH (Food and Drug Amendments Act of 2007):

The FDA has the authority to enforce compliance to these clinical trial registry requirements put forth by the Act. If a sponsor fails to register any trial which meets the eligibility criteria, fails to submit trial results, or submits false data or information, the NIH will post a notice describing the infractions on the registry data bank.

Penalties may include civil monetary penalties up to \$10,000 fine for failing to submit or for submitting fraudulent information to ClinicalTrials.gov. After notification of noncompliance, the fine may go up to \$10,000 per day until resolved. For federally funded grants, penalties may include the withholding or recovery of grant funds.

Related Links

Register a trial: <http://prsinfo.clinicaltrials.gov>

[Registering Clinical Trials with ClinicalTrials.gov](#) - FDA pamphlet

[U.S. Public Law 110-85](#) (Sep 2007)

[FDA Amendments Act of 2007](#) (Sep 2007)

[NIH Guidance on New Law](#) (Nov 2007)

[PRS](#) and U.S. Public Law 110-85

[ICMJE registration policy](#)

NIH [FAQs](#) on clinical trial registrations