

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 125	
CHAPTER: Institutional Review Board	ISSUED:	REVISED:
POLICY: Registering Clinical Trials	PAGE 1 OF 8	

1. PURPOSE

The purpose of this policy is to comply with Clinical Trials Registration in ClinicalTrials.gov (Public Law 110-85).

2. REGISTRATION OF A CLINICAL TRIAL ON CLINICALTRIALS.GOV

- 2.1. 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.
 - 2.1.1. For investigator-initiated trials, the lead Principal Investigator is responsible for initiating, conducting, and coordinating the overall clinical trial for registration
 - 2.1.2. For sponsor-initiated trials, the sponsor is responsible for registration
 - 2.1.3. For trials sponsored or funded wholly or in part by the NIH, the grantee is responsible for registration
 - 2.1.4. 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
 - 2.1.5. For trials associated with Biologics License Applications (BLA), the person who has submitted the application is responsible for registration.
- 2.2. 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 it is unclear who is responsible for 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.

3. RESPONSIBILITIES OF THE PERSON DESIGNATED TO ENTER A CLINICAL TRIAL

- 3.1. The designated person (the Principal Investigator or designee) who is assigned to maintain the registration shall ensure that the information is complete, accurate

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 125	
CHAPTER: Institutional Review Board	ISSUED:	REVISED:
POLICY: Registering Clinical Trials	PAGE 2 OF 8	

and updated. This includes reviewing the listing and making necessary changes every six months or more frequently if significant changes occur. The site also must be updated at the time enrollment ceases.

4. HOW IS A TRIAL REGISTERED ON [CLINICALTRIALS.GOV](https://clinicaltrials.gov)? (GO HERE TO REGISTER AND READ INSTRUCTIONS)

- 4.1. Search [ClinicalTrials.gov](https://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.
- 4.2. Establish an account with the Creighton University [ClinicalTrials.gov](https://clinicaltrials.gov) administrator (IRB director). Email requests to irb@creighton.edu for access to the system. The administrator shall register the person who will be responsible for entry.
- 4.3. Within two business days, you will receive an email message from [ClinicalTrials.gov](https://clinicaltrials.gov) containing your login name and temporary password.
- 4.4. To begin the registration process, go to the [ClinicalTrials.gov registration](https://clinicaltrials.gov) web site. Complete the login fields. In the “Organization” field, enter CreightonU.
- 4.5. The “Main Menu” page will appear. The “User Account” link provides information on changing your temporary password; do this as soon as possible. This link also has a helpful “User’s Guide.”
- 4.6. After you have received your login information, register the trial. This process will take approximately one 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.
- 4.7. 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. A [list of all the variables](#) you will be asked to provide can be found on the Clinical Trials web site.
- 4.8. Some suggestions for completing certain items that you might not have available include:

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 125	
CHAPTER: Institutional Review Board	ISSUED:	REVISED:
POLICY: Registering Clinical Trials	PAGE 3 OF 8	

- 4.8.1. **Unique protocol ID:** The Creighton University IRB number is recommended. If the project has not yet been assigned a number, an IRB number can be generated by emailing the IRB at irb@creighton.edu and requesting a number. When emailing the IRB office, include the exact title of the project and the name of the Principal Investigator. IRB approval is not required to register a trial. The IRB number is also included in all correspondence from the IRB.
- 4.8.2. **Secondary IDs:** The grant number, funding agency number, or other funding source number is recommended.
- 4.8.3. **Board Name** (*Full name of the approving human subjects review board*): Creighton University Institutional Review Board
- 4.8.4. **Board Affiliation** (*Official name of organizational affiliation of the approving human subjects review board*): Creighton University.
- 4.8.5. **Board Contact** (*Contact information for the human subjects review board*):
 - 4.8.5.1.1. Name: Director of the Institutional Review Board
 - 4.8.5.1.2. Phone: 402-280-3586
 - 4.8.5.1.3. Email: irb@creighton.edu
 - 4.8.5.1.4. Address: Creighton University, Human Research Protection Program Office, 2500 California Plaza, Omaha, NE 68178
- 4.8.6. **Oversight Authorities:** should include other oversight authorities (e.g., the FDA or the OHRP) that may apply, depending on the clinical trial.
- 4.9. When the template is complete, click on “Submit.” The template will be forwarded to the University’s PRS administrator, who will review it and release the approved content to ClinicalTrials.gov.
- 4.10. Information should be reviewed and updated as needed every six months or more frequently if changes occur.
- 4.11. See the [Fact Sheet for clinicaltrials.gov](#).

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 125	
CHAPTER: Institutional Review Board	ISSUED:	REVISED:
POLICY: Registering Clinical Trials	PAGE 4 OF 8	

5. STUDIES REQUIRED BY THE FDA REGULATION TO BE REGISTERED

5.1. Registration is required for any research study that:

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

5.2. The registration requirement does not apply to:

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

5.3. Investigators and sponsors are encouraged to register applicable 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.

6. THE INTERNATIONAL COMMITTEE OF MEDICAL REQUIREMENTS FOR REGISTERING CLINICAL TRIALS

To promote transparency of the clinical trial process, the ICMJE established a policy in 2005 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. The ICMJE requires any research project that prospectively assigns human subjects to the intervention and at least

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 125	
CHAPTER: Institutional Review Board	ISSUED:	REVISED:
POLICY: Registering Clinical Trials	PAGE 5 OF 8	

one concurrent control or comparison group to study the cause and effect relationship between a medical intervention and a health outcome to be registered. Studies designed for other purposes, such as evaluation of pharmacokinetics or toxicity (i.e., phase I trials), are not required to be registered. Medical intervention is defined broadly and includes any intervention used to modify a health outcome, including drugs, surgical procedures, devices, behavioral treatments, and/or process-of-care changes.

7. 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 HR 3580, or Food and Drug Administration Amendments Act of 2007). This act mandates the expansion of <http://www.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 (or 30 days) days of enrollment of the first subject, and preferably before first subject enrollment. The legislation also requires applications or progress reports for any clinical trial that is required to be registered and that is funded in whole or in part by a grant from any agency of the Department of Health and Human Services to contain specific information on certification registration in ClinicalTrials.gov.

8. HOW THE FDA REGISTRATION REQUIREMENTS AFFECT NIH FUNDED STUDIES

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

8.1.1. A statement that reads, "This application includes a trial that requires registration in ClinicalTrials.gov;"

8.1.2. The National Clinical Trial (NCT) number (i.e., the ClinicalTrials.gov number);

8.1.3. Brief Title as listed in ClinicalTrials.gov, and

8.1.4. The name of the individual or entity responsible for registering the study (responsible party) for each study being conducted under the application. (As grantee, Creighton University designates the lead investigator of the

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 125	
CHAPTER: Institutional Review Board	ISSUED:	REVISED:
POLICY: Registering Clinical Trials	PAGE 6 OF 8	

trial as the responsible party.)

- 8.1.5. 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 reads, “This application does not include a trial that requires registration in ClinicalTrials.gov.” These requirements apply to all competing applications submitted to the NIH on or after January 25, 2008.
- 8.2. 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 reads, “This application includes a trial that requires registration in ClinicalTrials.gov.” The study would then need to be registered as follows:
 - 8.2.1. National Clinical Trial (NCT) number,
 - 8.2.2. Brief Title as listed in ClinicalTrials.gov, and
 - 8.2.3. 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.
 - 8.2.4. 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 reads, “This application does not include a trial that requires registration in ClinicalTrials.gov.”
- 8.3. 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:
 - 8.3.1. A statement that reads, “This application includes a trial that requires registration in ClinicalTrials.gov,”
 - 8.3.2. The National Clinical Trial (NCT) number (i.e., the ClinicalTrials.gov number),
 - 8.3.3. Brief Title as listed in ClinicalTrials.gov, and
 - 8.3.4. The name of the individual or entity responsible for registering the study (responsible party) for each study being conducted under the application.

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 125	
CHAPTER: Institutional Review Board	ISSUED:	REVISED:
POLICY: Registering Clinical Trials	PAGE 7 OF 8	

(As grantee, Creighton University designates the lead investigator of the trial as the responsible party.)

- 8.3.5. 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 reads, “This application does not include a trial that 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 February 1, 2008).

9. SPECIAL FDA REGULATION REQUIREMENTS FOR IND, IDE, OR BLA STUDIES

- 9.1. Studies conducted under an IND, IDE, or BLA 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.
- 9.2. A certification (as described in the following paragraph) must accompany human drug, biological, and device product submissions made to the 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. When available, such certification must include the appropriate National Clinical Trial (NCT) numbers.
- 9.3. The official certification form, [Form FDA 3674](#), entitled “Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank,” is available on the FDA’s web site.
- 9.4. For sponsor-held INDs, IDEs, and BLAs, the sponsor shall provide the certification. For investigator-held INDs, IDEs, and BLAs, the individual holding the IND, IDE, or BLA shall provide the certification. Sponsors use [Form 3674](#) to tell the agency they have complied with the regulations regarding Clinicaltrials.gov.

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 125	
CHAPTER: Institutional Review Board	ISSUED:	REVISED:
POLICY: Registering Clinical Trials	PAGE 8 OF 8	

10. ADDITIONAL INFORMATION FROM THE NIH ABOUT THE REQUIREMENT TO REGISTER CLINICAL TRIALS

The NIH has posted [information on clinical trials registration](#).

11. OTHER SOURCES OF INFORMATION ABOUT CLINICAL TRIAL REGISTRATION

- 11.1. [ClinicalTrials.gov](#)
- 11.2. [International Committee of Medical Journal Editors](#)
- 11.3. Center for Drug Evaluation and Research; U.S. Food and Drug Administration. [Guidance for Industry: Information Program on Clinical Trials for Serious or Life-threatening Diseases and Conditions](#).
- 11.4. [WHO International Clinical Trials Registry Platform \(ICTRP\)](#)
- 11.5. [National Library of Medicine ClinicalTrials.gov Questions](#)