



## Guidelines for Registering in the ClinicalTrials.gov Registry

[What Is ClinicalTrials.gov?](#)

[Do I Need to Register My Clinical Trial?](#)

[What Is the Definition of a Clinical Trial for Registration Purposes?](#)

[Who is Responsible for Registering the Trial?](#)

[How is a Trial Registered?](#)

[When Are Registration Updates Required?](#)

[Do Adverse Events Need to Be Posted?](#)

[Do Basic Trial Results Need to be Posted?](#)

[What Are the Consequences of Not Registering a Trial?](#)

[What Is the Specific Wording Required in the UVM/UVM Medical Center](#)

[Consent Form?](#)

[Whom Do I Contact with Questions?](#)

[References and Regulations](#)

### What Is ClinicalTrials.gov?

- [ClinicalTrials.gov](#) is a publicly available registry and [results database](#) of federally and privately supported clinical trials conducted in the United States and around the world.
- The purpose of ClinicalTrials.gov is to disclose to the public key information about clinical trials that are currently available or that have been conducted.
- ClinicalTrials.gov captures significant summary protocol information before and during the trial as well as and summary results and adverse event information of a completed trial.
- Federal laws and regulations as well as editors of prominent medical journals require registration of a clinical trial, as described below.
- The Web site is maintained by the National Library of Medicine and the National Institutes of Health.

### Do I Need to Register My Clinical Trial?

Yes, if, as described below, your clinical trial

- meets the definition of clinical trial and
- you meet the requirements of the responsible person for registering the trial.

### What Is the Definition of a Clinical Trial for Registration Purposes?

Three similar definitions of a “clinical trial” are provided below. If your study meets any one of these definitions, the trial should be registered.

***The FDA (Food and Drug Administration) requires registration for “[applicable clinical trials](#)” defined as follows:***

- For any trials of drugs and biologics: controlled clinical investigations, other than Phase I investigations, of a product subject to FDA regulation.

- For trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance.

**The ICMJE (International Committee of Medical Journal Editors) definition of a clinical trial includes:**

- 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 NIH defines a clinical trial as**

- A [research study](#) in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

## Who is Responsible for Registering the Trial?

By law, the “responsible party” must register a clinical trial. The responsible party is defined as:

- The **sponsor** of the clinical trial  
OR
- The **principal investigator** (PI) of the clinical trial if so designated by a sponsor, grantee, contractor, or awardee. For **investigator-initiated** clinical trials, the PI must register the trial since the PI is responsible for conducting the trial, has access to and control over the data, has the right to publish the results of the trial, and has all of the information necessary to complete the registration.
- For **investigator-initiated clinical trials**, whether or not there is industry funding or, in fact, if there is no funding, the PI is considered the sponsor and is responsible for registering the clinical trial.
- For those studies that involve an application for **an Investigational New Drug (IND) or Investigational Device Exemption (IDE)**, the responsible party may be someone other than the PI. If the PI receives NIH or other government funding for a trial, particularly those that do not include an IND or IDE application, the PI is the responsible party. To ensure that any extramurally funded trial is properly registered, the PI should contact the sponsor for clarification.
- For **clinical trials that are being performed at multiple institutions**, the lead sponsor should take responsibility for registering the trial. If the PI is not the lead sponsor, he or she should work with the other investigators and sponsors to ensure that the trial is registered only once for the entire project.

## When and How Does a UVM/ UVM Medical Center PI Register a Trial?

**When do I register my clinical trial?**

You must register a trial before any subjects are enrolled. **The FDA requires you to register no later than 21 days after the first subject is enrolled; however, the ICMJE requires registration before the first subject is enrolled.** To avoid publication restrictions imposed by the ICMJE, register your trial before enrolling the first subject. You may expect each registration to take approximately 1 to 2 hours.

## What are the Steps for Registering?

Clinical trials are registered on [ClinicalTrials.gov](http://ClinicalTrials.gov) via a web-based data entry system called the Protocol Registration System (PRS). As a PRS user you are responsible for ensuring that the information you provide on your trial is correct, complete, readily understood by the public, and updated in a timely manner.

- 1. Obtain an Individual User Account:** Go to <http://prsinfo.clinicaltrials.gov/> to apply for an **individual account**. Question 6 asks if your organization is already registered with the PRS (Protocol Registration System). The answer to this question is “No” as UVM/UVM Medical Center is neither registered as an organization nor does UVM/ UVM Medical Center have a PRS administrator. The UVM/UVM Medical Center PI is the responsible official for initial registration and for keeping the listing updated. You must be listed as the contact person as you will receive all correspondence in this regard.
- 2. Login to PRS:** Once your account has been created go to <https://register.clinicaltrials.gov/>. The following information is provided to assist you in completion of the application:
  - Under Sponsor information, the Organization Name is University of Vermont and/or The University of Vermont Medical Center and the Official.
  - Representative is the PI for this trial.
  - Under the Investigator Information, for the field: “Affiliation (if not the sponsor),” do not enter anything in this field (this assumes the investigator is affiliated with UVM/UVM Medical Center, which is the sponsor for this purpose) and for “Funding Organization,” list funding source, if there is one.
  - Under Regulatory Information, for “Regulatory Authority,” list United States Food and Drug Administration as the regulatory authority if the research involves an investigational drug, device or biologic. Otherwise, list the appropriate UVM Institutional Review Board as the regulatory authority - CHRMS = UVM IRB #1, CHRBS = UVM IRB #3.
  - For “Regulatory Authority Address,” if FDA is listed as the regulatory authority, use the following address: 5600 Fishers Lane, Rockville, MD 20857. If a UVM IRB is listed as the regulatory authority, use the following address: Research Protections Office, 213 Waterman Bldg, 85 South Prospect St, Burlington, VT 05405 When finished select “Submit Application” at the bottom of the application page.
  - Within approximately 24 hours you will receive an email from ClinicalTrials.gov Registration which gives you a user name and password and instructs you to login and change your password as soon as possible. The email will also provide the PRS web site address for the registration process.
- 3. Create a Protocol Record:** A trial is registered in the system by creating a “protocol record.” Click on the **Create** link under **Protocol Records** on the Main Menu and fill in a series of data entry screens. Clicking on the various fields will allow you to access instructions for that field. If you still have questions, <mailto:register@clinicaltrials.gov>
- 4. Review the Protocol Record:** After filing in the last data entry screen, the **Edit Protocol** screen will appear. Review the information for accuracy and completely and address any ERRORS, ALERTS, WARNINGS, or NOTES in the protocol record. If you fail to do so, you cannot complete the registration process.
- 5. Mark the Protocol Record as Complete:** If you fail to mark your record as complete, it will not be approved and released for publication and your trial will not be properly registered.
- 6. Keep your Protocol Record Up-To-Date:** An affirmative verification or update of the data in the protocol records that have not been closed or terminated is required every six months. Failing to login to the PRS and confirm or update your record(s) every six months, regardless of whether there has been a change to the trial or not, may result in a loss of funding and/or the inability to publish the results of a trial in an ICMJE associated journal.

**IMPORTANT NOTE:** You will receive a reminder e-mail notification from [clinicaltrials.gov](http://clinicaltrials.gov) once every six months to update your study information.

#### 7. **Suggestions for Completing Certain Items:**

- Using an electronic version of your protocol materials allows you to copy and paste information into the requested data fields.
- **Source Information:** It will be helpful to have the protocol, the informed consent document, the IRB application and the IRB approval letter on hand.
- **Unique protocol ID:** Use a combination of letters and numbers
- **IND/IDE Number:** If an IND or IDE is involved, you will need to enter the serial number. Refer to the IND/IDE letter from the FDA
- **Record Verification Date:** The date of the most recent IRB approval. This date alerts the public as to whether the information is being kept current, particularly with reference to recruiting status and contact information.
- **Study Start Date:** Use date enrollment began--not date of IRB approval.
- **Last Follow-up Date:** Actual date that the last subject was examined or treated or anticipated date when expected last follow-up will occur.

#### 8. **Helpful Hints:**

- **Smart forms.** The PRS data entry forms are “smart”. This means that some fields will appear (or not) depending upon your answers to other questions.
- **Optional elements.** A symbol indicates whether each data element is optional or required.
- **Special characters, formatting tips.** See the [PRS User's Guide](#) for formatting and special character information. For example: ≤ or ±
- **One or multiple sessions.** You do not need to complete the registration in one sitting.
- **Downloading a copy of the record.** Section 5.1 of the [PRS User's Guide](#) describes how to download a RTF file of your record. This can then be imported into Microsoft Word (or another word processing program) – which is very useful for editing and sharing a record with co-workers.
- **HIGHLY RECOMMENDED: Review what you have entered before you submit the record.** Section 5.1 of the [PRS User's Guide](#) describes several different ways to check your record. The [PRS Protocol Review Criteria](#) document is also useful.

### When Are Registration Updates Required?

Updates **within 30 days** are required for:

- Individual site status and overall recruitment status data elements
- Primary completion date data element

Other changes or updates to the record must be made at last every **12 months**.

### Do Adverse Events Need to be Posted?

As of September 27, 2009 posting of adverse events is mandatory. Adverse Event posting is required for trials of FDA-approved drugs and biologics. The following *must* be reported:

- Serious adverse events and
- Other (non-serious) adverse events that exceed a frequency threshold of five percent in any arm of the trial

**IMPORTANT NOTE:** These reporting requirements are different from the UVM/UVM Medical Center reporting requirements. Reference [Policies & Procedures](#) for details.

## Do Basic Trial Results Need to be Posted?

1. As of September 2008, posting basic study results is required within **12 months** after primary endpoint completion date.

- Basic results posting is required for trials of FDA-approved drugs and devices.
- Exceptions:
  - **Trials involving FDA-regulated products and whose results will be used very soon for seeking FDA approval, licensure, or clearance** can request a delay for up to two additional years. *This will rarely apply to anything except industry-initiated trials.*
  - **Secondary outcome measures or additional adverse event information that is not collected by the primary completion date:** Though the primary measures must still be reported by the one year deadline, these additional measures may be reported as follows:
    - *Secondary outcomes:* One year after the date on which the final subject is examined or receives an intervention for the purposes of final collection of data for the secondary outcome measure
    - *Adverse events:* One year after the date of data collection for the additional adverse event information
  - **Extensions for good cause:** The PI may request an extension of the deadline, prior to the date on which the results reporting would otherwise be due.
  - **Waiver of results reporting** for privacy or national security reasons

2. What Must Be Reported?

- Results are reported by completing four topic-specific modules.
- Almost all information must be entered in tabular format.
- Results cannot be reported by uploading publications.
- The PRS system provides numerous helpful documents and templates for each of the four results modules. The templates are especially useful, because they assist researchers in identifying and organizing the information needed by the PRS system.

3. General Documents and Links

- [PRS Help: Results Modules](#). For each of the four modules, this PRS document provides a description, resources, data elements, examples, and data entry tips.
- [PRS Results Data Element Definitions](#). This PRS documents provides definitions for each of the results data elements, and indicates whether each element is optional.
- [PRS Review Criteria for Results](#) describes the criteria used by the PRS system to assess completeness and consistency of results.

## What are the Consequences of Not Registering a Trial?

There are penalties for responsible parties who fail to register clinical trials, keep the information up to date, or submit false or misleading information.

- Civil monetary penalties are allowed under FDA regulations.
- For federally-funded trials, the penalties could include withholding or recovery of grant funds.
- The inability to publish the results of a trial in an ICMJE associated journal.

## What is the Specific Wording Required in the UVM/ UVM Medical Center Consent Form?

In the UVM/UVM Medical Center consent form in the section “What About Confidentiality” include the following wording:

### *“Clinical Trials Registration*

*A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”*

## Does the registration posting need review by the IRB or the Research Protections Office?

**No.** While it is true that ClinicalTrials.gov was initially established as a place where potential subjects and others could obtain information about clinical trials, the primary intent of registration is to ensure that research results can be published in scientific journals. Registration is performed by completing a template, and there is little, if any, room for creativity. The IRB does not review the postings.

## Whom Do I Contact with Questions?

If you have questions, contact 656-9404 [Research.Navigators@med.uvm.edu](mailto:Research.Navigators@med.uvm.edu)

## References and Regulations

Clinical Trials.gov

- [ClinicalTrials.gov registry](#)
- [Clinical Trials.gov Protocol Registration System](#)
- [Clinical Trials.gov Fact Sheet](#)

Food and Drug Administration

- [Food and Drug Administration Amendments Act \(FDAAA\) of 2007](#)
- [Food and Drug Administration Modernization Act \(FDAMA\) of 1997](#)
- [FDAAA Public Law 110-85, Title VIII, Section 801](#)

International Committee of Medical Journal Editors [website](#)

- [ICMJE Initiative](#)

National Institutes of Health

- [NIH Guide Notice NOT-OD-08-014](#)
- [NIH Guide Notice NOT-OD-10-007](#)