

Office of Clinical Trials Research,
Office of Sponsored Programs' Pre-Award Service Office
and Research Protections Office
University of Vermont/Fletcher Allen Health Care

CLINICAL TRIALS REGISTRATION
INFORMATION

Clinical Trials Registration

Effective July 1, 2005, the International Committee of Medical Journal Editors (ICJME) adopted a new policy that requires that a clinical trial* must be registered in a public registry in order to be considered for publication. (ICJME journals include JAMA, NEJM, The Lancet, National Library of Medicine and others.) The goal of trial registration is to foster a comprehensive, publicly available database of clinical trials, so everyone can find key information about every clinical trial whose principle aim is to shape medical decision making. Details of this requirement are described at the **International Committee of Medical Journal Editors** Web site (http://www.icmje.org/clin_trialup.htm)

The Federal Drug Administration Act of 1997 also requires that submission of “information to the data bank about a clinical trial conducted under an investigational new drug (IND) application if it is for a drug to treat a serious or life-threatening disease or condition and it is a trial to test effectiveness (42 U.S.C. 282(j)(3)(A)).” This requirement initially applied to all trials for drugs to treat serious or life-threatening disease or condition regardless of whether they are intended for publication in one of the journals represented by the ICMJE. As required by Public Law 110-85, Title VIII, on September 27, 2007 a U.S. law was enacted that expands the types of clinical trials that must be registered in ClinicalTrials.gov, increases the number of data elements that must be submitted, and will also requires submission of results data in the near future. These trials must be registered at www.clinicaltrials.gov as detailed below in How to Register a Clinical Trial. Further information about this requirement is available at <http://clinicaltrials.gov/>.

How is “clinical trial” defined?

ICJME website defines 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.”

- Trials must have at least 1 prospectively assigned concurrent control or comparison group to trigger the requirement for registration.
- Includes studies on drugs, devices, surgical procedures, behavioral treatments, and process-of-care changes.
 - Includes ‘clinically directive’ trials - that test a hypothesis about health outcomes.
 - Includes all Phase III trials; does not include Phase I trials. (Trials in between these two extremes are considered on a case-by-case basis.)
 - If in doubt, register. (An author will need a sound rationale for not registering a trial.)

Which trials must be registered and when?

- ICJME Requirement:
Clinical trials, as defined above, must be registered in a public registry at or before the onset of patient enrollment.
- FDA Requirement:
The following trials must be registered at ClinicalTrials.gov:
 - Trials of Drugs and Biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation
 - Trials of Devices: Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric postmarket surveillance

In general, the applicable clinical trial must submit required information by the later of 12/26/2007 or 21 days after the first patient is enrolled.

Exceptions: (a) data for trials “ongoing” as of 9/27/2007 that do not involve a “serious or life threatening disease or condition” must be submitted by 9/27/2008;
(b) trials that involve a “serious or life threatening disease or condition”, are initiated before 9/27/07, and have a “completion date” prior to 12/26/2007 are not subject to the new requirements, although they may be subject to other laws.

See the following FDA guidance for additional information:

<http://prsinfo.clinicaltrials.gov/s801-fact-sheet.pdf>

Who is responsible for registering clinical trials?

- FDA requirement,
 1. The sponsor of the clinical trial **OR**
 2. The principal investigator (PI) of such clinical trial **if so designated** by a sponsor, grantee, contractor, or awardee, so long as the PI is responsible for conducting the trial and has sufficient data rights”(For further detail, see the Guidance on New Law (Public Law 110-85) Enacted to Expand the Scope of ClinicalTrials.gov: Registration at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-014.html>)
- In general, the following guidelines apply:
 - Investigator-initiated trials at UVM/FAHC - Usually the principal investigator is responsible for registering the trial, unless otherwise specified in a contract or agreement.
 - Multi-site or multi-sponsored trials - The sponsor is responsible for registering the trial. In order to avoid duplicate registrations, this should be done by the lead sponsor, or the sponsor with primary responsibility for starting and conducting the trial, or the IND/IDE holder.)

How to register

The following web site is a link to the ClinicalTrials.com Protocol Registry System, a registry sponsored by the U. S. National Library of Medicine which meets the criteria established by the ICMJE: <http://prsinfo.clinicaltrials.gov>. The site includes a guided tour, definitions and frequently asked questions, and a list of the data elements needed for registration.

- To include a trial on this registry you will need to apply for an individual account (instructions are provided below).
- If you have questions about the registry or have trouble with the registration process, you may contact register@clinicaltrials.gov.

Instructions for Individual Account Application

Note: It may be helpful to have this in front of you while you register.

- On the Clinical Trials.gov Protocol Registration System (PRS) home page (<http://prsinfo.clinicaltrials.gov/>), scroll down to the “Account Application Process” section and select “**Apply for an individual account**”.
- This opens the “Getting a PRS Individual Account” page, which asks six questions before starting the account application process.
- For question 6, “Is your organization already registered with the PRS?” the answer is “no” and select “Apply for a PRS account”.
- This opens the “Individual Account Application” page. First, you will need to read and either accept or not accept the terms and conditions for submitting data to ClinicalTrials.gov. Once you accept these terms and conditions, you will need to complete the appropriate fields in the application.
- 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 Fletcher Allen Health Care 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/FAHC, 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, Sponsored Programs, University of Vermont, 245 South Park, Suite 900, Colchester, VT 05446.*
- 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.

Instructions to Register a Clinical Trial

Note: It may be helpful to have this in front of you while you register.

- To register a clinical trial, login to the PRS web site (<https://register.clinicaltrials.gov/>) for the registration process. This will then take you to the Main Menu page which provides you with several options, including “Change password” under “User Account”.
- Under “Help” you can receive detailed instructions by selecting “User’s Guide” or definitions of the different fields by selecting “Data Element Definitions”.
- To register a trial select “Create” under “Protocol Records”.
- One section of the registration form asks for information regarding human subjects review. The following are suggested entries for these fields.
 - For Board Approval Number - *List the CHRMS OR CHRBS Protocol number assigned to your research)*
 - For Board Name – *List the appropriate UVM IRBs # CHRMS = IRB #1, CHRBS = IRB #3*
 - For Board Affiliation – *University of Vermont*
 - For Board Chair – *Include appropriate IRB Chair Name (check under contacts on the IRB website for the name of the current IRB Chair - <http://www.uvm.edu/~irb/?Page=contacts.html>)*
 - Phone *802-656-5040*
 - Email - irb@uvm.edu
 - Address - *Research Protections Office, Sponsored Programs, University of Vermont, 245 South Park, Suite 900, Colchester, VT 05446*
 - Oversight Authorities – *List United States Food and Drug Administration as the oversight authority if the research involves an investigational drug, device or biologic. Otherwise, list the appropriate Institutional Review Board as the oversight authority.*

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.

Who do I call if I have questions?

If you have questions, contact: Kimberly Luebbers at 656-8990 / Kimberly.Luebbers@uvm.edu