

ClinicalTrials.gov Protocol Registration

SHOULD I REGISTER MY CLINICAL TRIAL IN THE CLINICALTRIALS.GOV SYSTEM?

This checklist should help to determine if you are responsible for registering your clinical trial in the ClinicalTrials.gov system using the Protocol Registration System (PRS).

☐ 1. This is an “applicable clinical trial.” (***Federal law requires registration of applicable clinical trials. However, many medical journals and funding agencies, including NIH, require or recommend registration.***)

Applicable Device Clinical Trials

- Clinical study of health outcomes with an FDA approved Investigational New Device (IDE) against a control in human subjects. (Device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act.) *Feasibility studies or tests of prototype devices where the primary outcome relates to feasibility and not to health outcomes are excluded.*
- Pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act

Applicable Drug Clinical Trials

- A controlled clinical investigation, other than a phase I trial, of drugs or biological products subject to Food and Drug Administration (FDA) regulation.

☐ 2. I am the sponsor or responsible party for this clinical trial.

- Sponsor-a person who initiates a clinical investigation (IND or IDE holder).
- Responsible party – the principal investigator if so designated by a sponsor, grantee, contractor, or awardee. *The investigator must be responsible for conducting the trial and have access to and control over the data with the right to publish the results. If unsure, contact your funding agency to determine the responsible party.*

☐ 3. This trial is ongoing as of December 26, 2007 or any date thereafter.

- An ongoing trial has one or more patients enrolled and the final subject has not been examined or received an intervention for the purposes of final data collection.

☐ 4. I have checked ClinicalTrials.gov and my study is not registered.

If items 1-4 are true, you must register your clinical trial in the ClinicalTrials.gov system.

DEADLINES FOR REGISTRATION:

The FDAAA and the NIH requirements dictate that the clinical trial must be registered in ClinicalTrials.gov within 21 days after the first patient is enrolled.

ClinicalTrials.gov Protocol Registration

Clinical trials are registered with ClinicalTrials.gov via a web based data entry system. Multi-site trials and multi-sponsor trials are susceptible to duplicate registration, so care must be taken in how trials are registered. For multi-sponsor trials, the lead sponsor is responsible for registration. It is critical that investigators and sponsors work together to ensure that a trial is registered only once.

ACCOUNT APPLICATION PROCESS

USC has an organizational account with the ClinicalTrials.gov Protocol Registration System (PRS). To request an individual account to enter protocol information, use the following steps. Information may be entered by the investigator or a designated assistant, such as the study coordinator.

Web site the Protocol Registration System information: <http://prsinfo.clinicaltrials.gov/>

On this page, click the link for “Apply for an individual account. Under the section titled “Obtaining a PRS Account,” click the [Administrator Contact Request Form](#) link.

This link will send you to a page where you may agree to the terms and conditions of system use and enter the information required for account setup.

Our organization is listed as: University of South Carolina. The requestor information is the name of the individual who will be using the account. Complete the requestor information and click the “Submit Request” Button at the bottom of the page. This information is sent to all system administrators. One of them will set up an account and contact you with further information.

PRS Administrator Contact Request Form

OMB No: 0925-0586

Expiration Date: 08/31/2015

[Burden Statement](#)

Each entity submitting data to ClinicalTrials.gov must adhere to the following terms and conditions, which are intended to ensure the accuracy, currency, and validity of the data:

- Only data for studies that are in conformance with applicable human subjects or ethics review regulations (or equivalent) and applicable regulations of the national (or regional) health authority (or equivalent) may be submitted.
- Notice of changes in recruitment status must be provided as soon as possible, but no later than 30 days after such changes. All other submitted data must be reviewed, verified, and updated as necessary and no less than every 12 months.
- The submitting organization, or individual designated as the [Responsible Party](#), is responsible for the completeness and accuracy of the data submitted to ClinicalTrials.gov.
- Study data must be submitted in English.
- Multiple groups within a single entity (e.g., company, university, government agency) must share a single Protocol Registration and Results System (PRS) organization account.
- Previous versions of study data will be available to the public, although the default view will be the most recent version.

(Acceptance Required)

☐ Accept

☒ Do Not Accept

If your organization is already registered with ClinicalTrials.gov, provide the following information to request contact with your organization's PRS Administrator.

* **Organization:** Please enter the name exactly as it appears on the [list of organizations with a PRS account](#).
University of South Carolina

Requestor Information

* **Name:**

* **Department or Group:**

* **Phone:** Please enter a valid phone number, including area code.

* **Email:**

Questions about this form and the PRS may be sent to register@ClinicalTrials.gov.

ClinicalTrials.gov Protocol Registration

You may request accounts for investigators and assistants. Keep in mind that only the individual who created the record (the owner) has access to it. You may grant access to other account owners as needed. Each protocol record may be previewed and printed for checking and distribution. System administrators may also change ownership of the protocol if necessary.

ACCESSING THE PROTOCOL REGISTRATION SYSTEM

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](https://register.clinicaltrials.gov/) Protocol Registration and Results System (PRS).

OMB NO. 0925-0599
EXPIRATION DATE: 09/31/2015
[Burden Statement](#)

Organization:
One-word organization name assigned by PRS (sent via email when account was created)
Username:
Password: [Forgot password](#)

Login

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.
[Send email to ClinicalTrials.gov PRS Administration](#)

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

The URL for the PRS login is: <https://register.clinicaltrials.gov/>

Our Organization name for the login is: USouthCarolina

Once you are in the system, follow the directions to complete the protocol information.