

ClinicalTrials.gov Protocol Registration

Should I Register My Clinical Trial in the ClinicalTrials.gov System?

Federal law requires that all “applicable clinical trials” should be registered. However, many medical journals require registration as a condition for publication. Phase I trials are exempt from registration by both entities.

Definitions for “applicable clinical trials”:

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

Drug Clinical Trials

- A controlled clinical investigation, other than a phase I trial, of an FDA approved Investigational New Drug (IND). (Drug subject to section 505 or 351 of the Federal Food, Drug, and Cosmetic Act.)

To avoid duplicate registration and to ensure that the appropriate organization or investigator provides the information for each trial, please consider the following questions and take the suggested steps.

1. Has the trial already been registered with ClinicalTrials.gov?

- Yes: Stop
 No: Continue

2. Are you 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.*
- No: Please ask the sponsor (IND/IDE holder) to register the trial.
 Yes: Continue

If unsure, contact your funding agency to determine the responsible party. ORSP will be happy to assist you in making this determination.

3. Is the study funded by the National Institutes of Health (NIH)?

- Yes: Send an email to register@clinicaltrials.gov including the trial title, grant number and NIH institute or center.
 No: You must register you clinical trial in the ClinicalTrials.gov system.

Deadlines for registration

- Federal requirement – no later than 21 days after the first patient is enrolled.
- Journal publication requirement – before the onset of enrollment.

ClinicalTrials.gov - Protocol Registration System

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

MUSC 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.

Send an email to ORSP@musc.edu and type "Request ClinicalTrials.gov account" in the subject line. Put your name and NetID (This will be your user name for the system.) in the subject of the email. You will be contacted when your account is activated.

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 preview and print it for checking and distribution. System administrators may also change ownership of the protocol but only the owner has access.

Once you have your account information, follow the instructions below to access the protocol registration system.

Accessing the Protocol Registration System

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

Our Organization name for the login is: **MUSouthCarolina**

Login

Welcome to the [ClinicalTrials.gov](https://register.clinicaltrials.gov/) Protocol Registration System (PRS). OME NO: 0910-0459
EXPIRATION DATE: 11/30/2007
[Burden Statement](#)

Organization:

User Name:

Password: [Forgot password](#)

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