

Guidance on ClinicalTrials.gov Registration

[ClinicalTrials.gov](https://clinicaltrials.gov), a service of the National Institutes of Health, was developed by the National Library of Medicine (NLM) in collaboration with the Food and Drug Administration (FDA). Its purpose is to “link patients to medical research” by providing information to the general public on federally and privately supported clinical research for a range of diseases and conditions. Trial registration is therefore established to promote the public good by ensuring that the existence and design of clinically directive trials are publicly available.

Requirements

International Committee of Medical Journal Editors: Investigators or sponsors must register clinical trials in the Protocol Registration System (PRS) of ClinicalTrials.gov to comply with the [International Committee of Medical Journal Editors \(ICMJE\) Initiative](#), which requires prior entry of clinical trials in a public registry as a condition for publication.

Food and Drug Administration: [Section 801 The Food and Drug Administration \(FDA\) Amendments Act of 2007](#) requires registration of “[applicable clinical trials](#)” involving drugs, biologics, or devices that are subject to FDA regulations. In most cases, the sponsor of the trial will be the “[responsible party](#)” for registering the trial. However, in some cases, as outlined below, FDAAA allows the sponsor to delegate all registration and reporting responsibilities to the principal investigator (PI).

National Institutes of Health: [National Institutes of Health \(NIH\) policy](#) requires registration at ClinicalTrials.gov for all clinical trials funded wholly or partially by NIH. 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. This includes trials that do not involve any FDA-regulated products such as trials involving only behavioral interventions.

Informed Consent and Data Sharing: Regulations require the trial consent form(s) to include the following statement: “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. ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. You can search this Web site at any time.”

The ClinicalTrials.gov registration must include a data sharing statement.

Clinical trials conducted or supported by a federal department or agency must post one IRB-approved consent form on a website specified by the US federal government. If a PI is responsible for registering the clinical trial (see below), they are also responsible for posting one copy (any approved version) of the consent form. The consent form must be posted on the website after the clinical trial is closed to recruitment, but no later than 60 days after the last study visit by any participant, as required by the protocol.

The supporting federal agency or department has the authority to determine if an exception to the consent form posting requirement is appropriate, or if certain information about the trial should not be made publicly available. If the federal agency or department determines that certain information should not be made publicly available, redactions may be permitted or a full exception granted. The investigator cannot make this determination.

Responsible Party: Typically, the sponsor is the responsible party. The sponsor may also

designate the investigator as the responsible party when the following criteria are met.

When the trial is investigator-initiated at UGA, the PI will be designated as the “responsible party” for registering a clinical trial at ClinicalTrials.gov when:

- The trial is investigator-initiated, and the investigator is responsible for conducting the trial,
- The investigator has access to and control over the data from the clinical trial,
- The investigator has the right to publish the results of the clinical trial, and
- The investigator has the ability to meet all of the requirements for submitting and updating clinical trial information as specified in 42 CFR Part 11.

If a PI is responsible for registration, he/she may designate an individual (PRS User) to register the trial(s) and complete registration information. However, the PI is ultimately responsible for ensuring that the information entered is accurate and for releasing the protocol record for PRS posting. The clinical trial registration must be kept up to date should any changes to the protocol take place. Specifically, notice of recruiting status changes must be made immediately, and all submitted data must be reviewed, verified, and updated on a periodic basis (typically, every six months).

Multi-site trials should be coordinated among the sites and registered by the “lead sponsor” so that ClinicalTrials.gov does not receive multiple registrations for the same trial.

The Registration Process

Step 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, proceed with the registration. You will need an active user account to access the system.

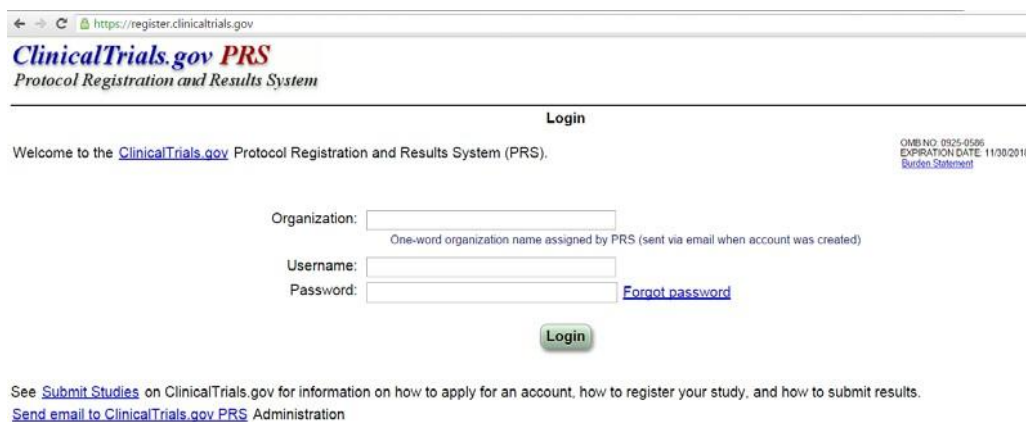
Step 2: To create an account with the ClinicalTrials.gov Protocol Registration System (PRS), send an e-mail message to UGA's PRS Administrator, Kimberly Schmitz, at schmitzk@uga.edu. On the subject line, indicate "ClinicalTrials.gov Protocol Registration" and the body of the message should contain your name, telephone number, and email address.

Within 2 business days, you should receive an e-mail message from ClinicalTrials.gov containing your login name and temporary password.

Step 3: Upon receipt of your login information, you may proceed with registering the trial. Use the list of helpful definitions available at <http://prsinfo.clinicaltrials.gov/definitions.html> for reference.

To begin the registration process, go to <https://register.clinicaltrials.gov/>.

Complete the login fields. In the "Organization" field (see diagram below), enter UGeorgia.



The screenshot shows the login page for the ClinicalTrials.gov Protocol Registration and Results System (PRS). The browser address bar displays <https://register.clinicaltrials.gov>. The page header includes the ClinicalTrials.gov PRS logo and the text "Protocol Registration and Results System". Below the header, the word "Login" is centered. A welcome message states: "Welcome to the [ClinicalTrials.gov](https://clinicaltrials.gov) Protocol Registration and Results System (PRS).". In the top right corner, there is a small box containing the text: "OMB NO. 0925-0506", "EXPIRATION DATE: 11/30/2018", and "System Statement". The login form consists of three input fields: "Organization:" with a text box below it containing the instruction "One-word organization name assigned by PRS (sent via email when account was created)"; "Username:" with a text box; and "Password:" with a text box and a "Forgot password" link. A green "Login" button is positioned below the password field. At the bottom of the page, there is a footer with the text: "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." and "[Send email to ClinicalTrials.gov PRS Administration](#)".

The “Main Menu” page will appear. Go to the “Accounts” tab to change your temporary password immediately. There is also a “Help” tab with a very useful Quick Start Guide.

A study is registered in the ClinicalTrials.gov system by creating a protocol record. Select “New Record” on the Home page (either from Quick Links or the Records menu) and fill in a series of data entry pages.

Tips: You can copy and paste information from your IRB protocol into the data fields; in fact, this is highly recommended to ensure consistency of data entry. Data is saved as each page is filled in, so that you can "Quit" at any time, saving the record for later completion using the "Modify a record" instructions provided below.

Additional Resources (links):

[User's Guide](#)

[NIH Clinical Trial Requirements for Grants and Contracts](#)

[Guidance: Is My Project a Clinical Trial, Basic Experimental Study Involving Humans \(BESH\), or an Observational Study Involving Humans?](#)