



Georgetown University Medical Center

Georgetown University Medical Center Registration of Clinical Trials

Dear User (PI):

Georgetown University has adopted the National Library of Medicine's Clinical Trials Protocol Registration System (PRS) to enter clinical trial records into ClinicalTrials.gov. The program provides patients, family members, and members of the public current information about clinical research studies. To create new records and to modify existing records, you will need to use PRS. Georgetown's Office of Regulatory Affairs will create an account under your name so that you can enter into the PRS. Soon after this enrollment, you will receive an automated e-mail from ClinicalTrials.gov providing you with login information to enter study specific information.

The Principal Investigator is responsible for ensuring that registration requirements are met. Even though some sponsors will do the actual registration work for the PI's, it is still the PI's responsibility to ensure that the registration has been accomplished.

Below you will find the most frequently asked questions of ClinicalTrials.gov. Please read through the material. A reference guide for the PRS can be found at <http://prsinfo.clinicaltrials.gov>. A short step-by-step process on how to apply for your ClinicalTrials.gov login will follow the FAQ section below.

CLINICAL TRIALS REGISTRATION FREQUENTLY ASKED QUESTIONS (FAQs)

What is the requirement?

The International Committee of Medical Journal Editors (ICMJE) announced that in order for clinical trial results to be considered for publication in journals that adhere to ICMJE standards, all clinical trials that start recruiting on or after July 1, 2005, must be registered with a public registry before the enrollment of the first patient. Details of this requirement are described on their website: http://www.icmje.org/clin_trialup.htm

The ICMJE re-evaluated its original policy in 2007 and published an editorial entitled "[*Clinical Trial Registration: Looking Back and Moving Ahead.*](#)" This editorial presents a revised "clinical trial" definition and describes registries currently acceptable to the

ICMJE.

What is the purpose of this requirement?

As described on the ICMJE Website, the Committee's purpose is "*to promote the public good by ensuring that everyone can find key information about every clinical trial whose principal aim is to shape medical decision-making,*" and to foster conditions in which decisions about care "*rest on all of the evidence, not just the trials that authors decided to report and that journal editors decided to publish.*"

How is "clinical trial" defined?

The 2005 (initial) ICMJE "clinical trial" definition has been changed.

2005 definition: "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. The trial must have at least one prospectively assigned concurrent control or comparison group in order to trigger the requirement for registration."

2007 definition: "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 2005 definition specifically *excluded* preliminary trials designed to study pharmacokinetics or major unknown toxicity (phase 1 trials). The 2007 definition now includes phase 1 trials.

The ICMJE will start to implement the expanded definition for all trials that begin enrollment on or after July 1, 2008. The ICMJE will not strictly impose this expanded definition until the stated date. *However, trials that meet the expanded definition CAN be registered before the stated date, and the ICMJE encourages investigators to do so, noting that such action is consistent with their goal of "full transparency with respect to performance and reporting of clinical trials."*

The ICMJE advises that those who are uncertain whether their trial meets the ICMJE definition should register if they wish to seek publication in an ICMJE journal.

Do the terms "health-related interventions" and "health outcomes" suggest that this requirement applies only to biomedical clinical trials?

No. According to the ICMJE, "health-related" interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical

procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Does the registration requirement apply only to industry-sponsored clinical trials?

No. It does not matter who the sponsor is or whether there is an external sponsor.

Are there any exceptions?

Yes. Observational studies in which the assignment of the medical intervention is not at the discretion of the investigator are not required to register.

Where / what are the clinical trial registries?

In its editorials (2005 and 2007), the ICMJE describes the characteristics of an acceptable clinical trial registry and the required minimal data for each trial. One of the registries that meets the ICMJE descriptive criteria is ClinicalTrials.gov, a service of the NIH, developed by the National Library of Medicine. More information about the Protocol Registration System (PRS) is available at <http://clinicaltrials.gov/>.

Who does the registration?

The Principal Investigator is responsible for ensuring that registration requirements are met. Even though some sponsors will do the actual registration work for the PIs, it is still the PI's responsibility to ensure that the registration has been accomplished. Before enrolling subjects, every PI should ask the trial's sponsor, "Is this clinical trial fully registered?"

- NIH-sponsored trials should be registered by the Institute that is funding the research.
- Industry-sponsored trials (industry-written protocol) should be registered by the sponsor.
- Investigator-initiated trials (for which industry has supplied drug or grant funds) should be registered by the PI.
- Trials for which PIs hold their own INDs or IDEs should be registered by the PI.
- 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.

How is Georgetown University involved?

Georgetown University is registered as an institution at ClinicalTrials.gov. In addition, ClinicalTrials.gov asks each institution to identify a PRS administrator. At Georgetown, the administrator is Patricia L. Mazar in the Office of Regulatory Affairs.

How to register your trials?

Investigators at Georgetown University who are responsible for registering a qualified clinical trial should take the following steps.

1. Search www.clinicaltrials.gov to ensure that the trial is not already listed. Many NIH- sponsored clinical trials and industry-sponsored trials have already been registered on this site. If the trial is not listed, continue through this process.
2. Establish an account with the ClinicalTrials.gov Protocol Registration System (PRS) by sending an e-mail message to the University's PRS administrator, Patricia Mazar @ mazarp@georgetown.edu. The subject line should state "Protocol Registration" and the body of the message should contain your name, telephone number, and e-mail address.
3. Within 24-48 hours, you will receive an e-mail message from ClinicalTrials.gov containing your login name, temporary password, and login instructions.
4. Once you have received your login information and instructions, register the trial. This process will take approximately 1 hour, and it will be helpful to have the protocol, informed consent document, and IRB approval on hand. (Note that this system offers the option to save data if you do not have time to complete the entire process.)
5. To begin the registration process, go to the ClinicalTrials.gov registration website (<https://register.clinicaltrials.gov/>). Complete the login fields. In the "Organization" field, enter "**Georgetown_University_MC**".

6. The “Main Menu” page will appear. The “User Account” link provides information on changing your temporary password, and this should be done as soon as possible. This link also has a helpful “User’s Guide.” To complete the protocol template, return to the “Main Menu” page, go to “Protocol Record” and select “Create.” The information that you will be required to enter will be variations of the following.

➤ **Unique trial number**

(Use the Georgetown University IRB number that was assigned to the trial)

- **Trial registration date**
- **Funding source**
- **Primary sponsor**
- **Secondary sponsor (s)**
- **Responsible contact person**
- **Research contact person**
- **Title of the study**
- **Official scientific title of the study**
- **Research ethics review**
- **Medical condition studied**
- **Intervention(s)**
- **Key eligibility criteria**
- **Study design**
- **Anticipated trial start date**
- **Target sample size**
- **Recruitment status**
- **Primary outcome**
- **Key secondary outcomes**