

SUNY Upstate Medical University

Policy for Registering Clinical Trials

In support of the idea that researchers and the public at large should have access to relevant information about ongoing clinical trials involving human subjects, SUNY Upstate Medical University expects that all clinical research studies conducted at Upstate or by Upstate faculty be registered through ClinicalTrials.gov. This expectation ensures that research data generated by Upstate faculty will be eligible for publication and trial information will be made available to the public at large.

Procedures:

Clinical trials are registered with ClinicalTrials.gov via a web based data entry system called the **Protocol Registration System (PRS)**. Multi-institutional and/or multi-sponsor clinical trials should only be registered once. This is usually done by the lead sponsor (for sponsor initiated studies) or lead PI (for PI initiated trials). The Upstate PI should confirm that the trial has been (or will be) registered.

To Register a Trial:

1. Call or e-mail Jennifer Rudes or Gerri Paparella to obtain a user login name and user password.
 - a. Jennifer Rudes - 464 5476 or rudesj@upstate.edu
 - b. Gerri Paparella - 464-4824 or paparelg@upstae.edu
2. Log in to ClinicalTrials.gov with your login name and password and input trial information.
3. Update information on the web site if study information/status changes.

From the International Committee of Medical Journal Editors (ICMJE) Initiative:

“The International Committee of Medical Journal Editors (ICJME) has established a requirement that all clinical trials be entered in a public registry before the onset of patient enrollment, as a condition of consideration for publication.

ClinicalTrials.gov provides a vehicle which allows organizations and individuals to provide the data requested by ICMJE, which has adopted the World Health Organization (WHO) minimal registration data set.

The purpose of a clinical trials registry 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. We will do what we can to help reach this goal. We urge all parties to register new and ongoing clinical trials.”

In addition to being required for publication, the FDA (Section 113 of the FDA Modernization Act) mandates registration with ClinicalTrials.gov of investigational new drug (IND) efficacy trials for serious diseases or conditions; and the NIH supports providing information to increase public awareness and access to clinical trials sponsored federally and by industry and foundations.