



<b>Policy Name: Clinical Trials Registration Policy and Procedures</b>			
Approved			Date: 11/01/08
Effective Date: <b>02/20/09</b>	Page 1 of 3	Section: HRPP 4.12	Policy Number: N/A
Replaces Policy: N/A			Dated: N/A

**I. POLICY**

**A. Introduction**

The FDA and the International Committee of Medical Journal Editors (ICMJE) each have their own registration requirements. While some of the requirements overlap, there are also significant differences. In order to comply with new laws and preserve the ability to publish in ICMJE journals **both** sets of requirements must be met.

**B. FDA Clinical Trials Registration**

In September 2007, the FDA Amendment Act expanded the ClinicalTrials.gov requirements previously established in the 1997 FDA Modernization Act (FDAMA) requiring registration of trials testing drugs for life threatening diseases and conditions. This new FDA policy:

1. Expands the types of trials that must be registered to all clinical trials for drugs, devices, and biologics with the exception of Phase I drug trials and small device feasibility studies.
2. Increases the data elements that must be included in the registration.
3. Results of trials must be registered within 3 years of the completion of the primary aim of the study. The process for registration of results is in development

**C. ICMJE Clinical Trials Registration**

Effective July 1, 2008, the ICMJE revised its policy of June, 2005. The new policy requires the registration of all clinical trials including Phase I and pharmaco-kinetic trials. ICMJE defines clinical trials as:

1. Any human research project that prospectively assigns human subjects to an intervention or comparison group to study the relationship between a medical intervention and a health outcome.

2. ICMJE Signatories: New England Journal of Medicine, Journal of the American Medical Association, Annals of Internal Medicine, The Lancet, The Medical Journal of Australia, The New Zealand Medical Journal, Norwegian Medical Journal, Canadian Medical Association Journal, Croatian Medical Journal, Dutch Journal of Medicine, Journal of the Danish Medical Association

## II. PROCEDURES

### A. Updating Registrations:

Once a trial is registered, both the FDA and the ICMJE require that registrations be updated as follows:

1. FDA updating requirements:
  - a) Information must be updated at least every 12 months
  - b) Additionally, the registry must be updated within 30 days of any changes in recruitment status or completion of study.
2. ICMJE requires updating study information every six months.

### B. Who is responsible for registration?

#### 1. For FDA Registration

The sponsor of the drug or device clinical trial, as defined/identified under the FDA regulations, is responsible for registering the trial. This could be either the company or the investigator.

If the sponsor is the company, the company at its discretion, can delegate the principal investigator as the “responsible party.” This may only be done when “the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements” for submitting information under the law

#### 2. For ICMJE Registration

While anyone involved in the clinical trial could register the trial, in practice this responsibility usually falls with the individual submitting the publication to the ICMJE journal, which is usually the Principal Investigator.

### C. Deadline for Registration

Compliance with the ICMJE is only required if publication in one of the relevant journals is planned. In contrast, compliance with the FDA regulations is required for relevant trials. If there is any possibility of submission to an ICMJE journal for publication, ensure compliance with both registration requirements.

#### D. Registering a Study

The Medical University of South Carolina has established an online Information Sheet detailing the instructions for clinical trials registration. The following Account Application Process must be used for registration. The University 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:

1. Send an email to [ORSP@musc.edu](mailto:ORSP@musc.edu) and type "Request ClinicalTrials.gov account" in the subject line.
2. Enter 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.
3. 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.
4. Once the account is established you may login in to the registration system using this URL for the PRS login <https://register.clinicaltrials.gov/>. Our Organization name for the login is: **MUSouthCarolina**
5. Once you are in the system, follow the directions to complete the protocol information. In addition, if a member of the primary review team cannot adequately evaluate the scientific merit and scholarly validity of an assigned protocol, (s)he will notify the Chair to discuss the use of another member of the IRB or whether it is necessary to obtain a consultant to assist in the review or request that the investigator provide additional information and/or be present for IRB discussion.

### III. REFERENCES

- A. [MUSC ClinicalTrials.gov Protocol Registration](#)