UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

Registration of Clinical Trials in a Public Registry for Publication

A. GENERAL INFORMATION

Background: As many of you know, the International Committee of Medical Journal Editors (ICMJE) that represents major journals such as the New England Journal of Medicine and the Journal of the American Medical Association, now requires that clinical trials be registered in a publicly accessible trials' registry as a condition of consideration for publication.

Purpose: Registration of clinical trials in a public registry is intended to enhance public access to information about clinical trials, and to increase dissemination of both negative and positive results.

Publication of research results in major journals plays a significant role in the dissemination of information and advancement of scientific discovery, and failure to register a trial may result in a publisher's rejection of important scientific papers. Therefore, everyone with an interest in publishing papers about a trial has an interest in ensuring that the trial is registered in accordance with the ICMJE policy.

Definition: It is important to understand if this registry requirement applies to your trial. Clinical trials are defined by ICMJE as:

1) "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."
2) Medical intervention is defined as any intervention used to modify a health outcome. This is inclusive of clinical trials involving of drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, etc.
3) Among the trials that meet this definition, ICMJE wants to ensure public access to all "clinically directive" trials, trials that test a clinical hypothesis about health outcomes (e.g., "Is drug X as effective as drug Y in treating heart failure?") as well as trials whose primary purpose is to affect clinical practice (phase 3 trials).

ICMJE has excluded trials from the registration requirement if their primary goal is to assess major unknown toxicity or determine pharmacokinetics (phase 1 trials).

B. WHEN SHOULD THE REGISTRY BE COMPLETED

In general, the funding entity (if the trial is fully sponsored) will take the lead in registering trials. If your trial meets the above definition, the policy already applies to trials that began enrolling subjects after July 1, 2005. The September 13 deadline applies to trials that began enrolling subjects before July 1, 2005. Per ICMJE guidelines:

1) As of September 13, 2005, if your study began enrollment before July 1, 2005, then you or the sponsor must register your trial **before** submission to a journal.
2) If your study began on or after July 1, 2005, then you (or the responsible funding entity) must register before enrolling your first participant.

3) If your study began on or after July 1, 2005 **and** you have already enrolled your first participant then you (or responsible funding entity) should register as soon as possible because you have missed the ICMJE's registration deadline.

C. WHO SHOULD COMPLETE THE REGISTRY

1) Principal Investigators should ensure registration of **investigator-initiated** trials regardless of fund source, including company funded, **unfunded studies** (such as gifts, departmental funds), and those funded by non-profit organizations that meet the above criteria (see A, Definition).

2) While **clinical trial sponsors,** such as **NIH, and other federal agencies may register trials they are sponsoring**, and while some campuses are considering requiring industry sponsors of **industry-initiated** trials to assume responsibility for clinical trial registration, **the PIs involved in the study should verify that the registration requirements have been met**. As stated above, in general, the funding entity (if the trial is fully sponsored) will take the lead in registering trials. However, it is best if lead PIs on clinical trials coordinate with sponsors and study coordinators to verify registration.

D. HOW DO I COMPLETE THE REGISTRY

If the trial is not registered by a sponsor, UCSD investigators must establish individual accounts in order to register their trials at http://www.clinicaltrials.gov/. (Note: Investigators who have established individual accounts report that they received an email confirmation within 10 minutes.) Directions for registration and how to establish an individual account are available at: http://prsinfo.clinicaltrials.gov/gettingIndivAccount.html.

Please note that the answer to Question #6 is "No."

E. FOR FURTHER INFORMATION

1) ICMJE's Frequently Asked Questions, see: http://www.icmje.org/faq.pdf.

2) Please refer to http://prsinfo.clinicaltrials.gov for information about how to register a trial in ClinicalTrials.gov.

3) To assist investigators in complying with ICMJE requirements, the UC Office of the President (UCOP) has prepared a brief fact sheet. This can be accessed at the following url: http://www.ucop.edu/research/documents/RegistrationofClinicalTrials-InformationforResearchers.doc.

4) UCs are currently reviewing the ICMJE registration requirement and will be distributing information as it becomes available. In the interim, information will be posted on the following websites:

   a) Office of Contract and Grant Administration, http://ocga.ucsd.edu.
   b) Clinical Trials Administrative Services and Research Compliance, http://health.ucsd.edu/compliance/index.html.
   c) Human Research Protections Program, http://irb.ucsd.edu.