



To: Research Personnel (Faculty Investigators, Coordinators, and Administrators)

**From: Harry B. Greenberg, M.D.
Senior Associate Dean for Research**

Re: The Stanford Clinical Trials Web Site: <http://clinicaltrials.stanford.edu>

I am happy to announce that the long awaited Stanford clinical trials website is finally ready for general use. Effective November 9, 2007, the Stanford School of Medicine will require registration of all clinical trials conducted at Stanford and affiliated facilities in a single, comprehensive and publicly accessible database, the Stanford Clinical Trials Web Site - <http://clinicaltrials.stanford.edu>. The Web Site, developed and hosted by the School's Office of Information Resources and Technology (IRT), will be used to gather descriptive information about our trials for publication on other Stanford websites and automatic uploading to the NIH-operated site, clinicaltrials.gov. This will greatly enhance the visibility of our trials online and will assist in meeting the pre-publication requirements of the International Committee of Medical Journal Editors (ICMJE – please see below).

clinicaltrials.stanford.edu will provide:

- Appropriate, real-time descriptive information about all clinical trials conducted at Stanford, serving as a convenient central resource for investigators, research personnel, administrators, sponsors, study subjects, and the general public.
- Automatic electronic transmission of appropriate trials to clinicaltrials.gov. This will include all trials where Stanford is the lead sponsor.
- Pertinent CMS, FDA and other government agency updates for our clinical research faculty and staff.

Why is this needed?

Ever increasingly the web is used by patients and referring physicians as the primary mechanism to learn about clinical trials. To date, finding comprehensive information about studies at Stanford has been extremely difficult. By providing a single, easy to use website with information about all trials at Stanford, this system will provide a means for the public to more easily discover our studies.

In addition, in 2005, the International Committee of Medical Journal Editors (ICMJE) initiated a policy requiring investigators to deposit information about trial design into an accepted clinical trials registry before the onset of patient enrollment. This policy aimed to ensure that information about the existence and design of clinically directive trials

was publicly available. Response to the policy has been overwhelming with over 40,000 trials registered by April, 2007 and with more than 200 new trial registrations now occurring each week. But as clinicaltrials.gov has grown, its utility as a means of disseminating information about clinical trials being conducted at Stanford has waned; thus the need for a comprehensive, Stanford-specific clinical trials database.

Which studies must be registered?

In accordance with the policies of the ICMJE, Stanford requires registration of 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. 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. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration.

Those who are uncertain whether their trial meets this definition should err on the side of registration. After November 9, investigators must be able to affirm that a qualifying trial has been registered *prior to enrolling any patients*. In addition, failure to register qualifying trials prior to patient enrollment makes that study ineligible for publication in an ICJME journal (*eg.*, *Annals Internal Med*, *the Lancet*, *JAMA*, *NEJM*, and many others).

ALL new clinical trials meeting the ICMJE definition above, including Phase I trials, must be registered. As preparation for the public launch on November 9, SPCTRM and IRT have pre-loaded into clinicaltrials.stanford.edu all Stanford trials that currently exist on clinicaltrials.gov, so there will be no need to re-register those studies. However, between October 18 and November 9, investigators and coordinators whose trials are not cancer studies should login to clinicaltrials.stanford.edu to verify the accuracy of the information and provide any missing data. Detailed instructions will be provided at the October 18, 2007 workshop (see below) and are available from SPCTRM. [Please note that the Cancer Clinical Trials Office will continue to perform all website-related tasks for all cancer studies.]

What this means for you:

- The ability to simultaneously publish trials in a centralized directory available from the School's homepage and on any Departmental/Divisional School of Medicine web site.
- Added recruitment value for potential research participants and investigators.
- One-stop entry for both clinicaltrials.stanford.edu and clinicaltrials.gov
- Greater visibility for both internal and external viewing of clinical research being conducted at Stanford

How to Learn More:

Attend one of the two Training Presentations that will be held on the following dates:

- **Friday, October 12, 2007, 12-1:30pm in CC2103-2105:**
This program is only for those with cancer studies.
- **Thursday, October 18, 2007, 12-1:30pm in the Clark Center Auditorium:**
This program is for investigators, coordinators and administrators whose studies do not involve cancer research.

Who Can Help?

The SPCTRM office will be the primary administrator to facilitate this process. Please contact Linda Walker at 498-7425 or linda.walker@stanford.edu with any questions about trials that do not involve cancer research.

The Cancer Clinical Trials Office (CCTO) is providing registration services for all cancer trials. For questions or assistance on cancer study registration, contact Ellen DiNucci, CCTO Recruitment Specialist at 725-2839 or edinucci@stanford.edu.