

September 12, 2008

Deans, Directors, Department Chairs and Administrative Officers

Re: Guidance on the expansion of Clinical Trial Registration Requirements

This updated guidance is being issued to alert you of important changes to the Federal requirements for reporting clinical trials on the www.ClinicalTrials.gov database. Effective **September 27, 2008**, completion of the “Basic Results Reporting Requirements” section will be a legal requirement. In addition, certain previously optional data elements in the registration process will now become mandatory for all “Applicable Clinical Trials”¹.

As of September 27, 2008, the “Responsible Party”² is required to report the results of “Applicable Clinical Trials” for FDA approved/cleared medical products within 12 months of the estimated or actual trial “Completion Date”, whichever date is earlier. The “Completion Date” is when the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol, or was terminated.

Deadlines for submissions can be delayed if it can be certified that a new use for drugs/devices is being sought. If a delay is appropriate, then the results must be posted within 30 days of the FDA’s approval/clearance or non-approval/clearance action. Results must also be posted if the application for new use is withdrawn and not resubmitted within 210 days.

The “Responsible Party” for reporting results for *PI-initiated* clinical trials is the PI. The “Responsible Party” for reporting results of *sponsor-initiated* clinical trials is the sponsor or the sponsor’s designated PI.

The Basic Results Reporting Requirements statutorily required include:

1. Demographic & Baseline Characteristics:
 - Tables of values, overall and for each arm
 - Number of subjects started, completed
2. Primary and Secondary Outcomes:

- Table of values for each primary & secondary outcome measure, by arm
- Scientifically appropriate tests of statistical significance
- 3. Point of Contact:
 - Point of Contact needed for scientific information
- 4. Certain Agreements:
 - Restrictions on PI to discuss or publish results after trial completion date

For additional and detailed information of the ClinicalTrials.gov basic results registration system and requirements, it is **highly recommended** that you view the WEBINAR (runtime 25 minutes) available on the ClinicalTrials.gov website: <http://prsinfo.clinicaltrials.gov/fdaaa.html>. For more information on the collection of basic results visit the “mockup information page” on the same website. For further questions, please contact Marcia Malmel in the Office of Clinical Trials at mmalmel@mednet.ucla.edu or 310-794-8766.

Sincerely,

Roberto Peccei
Vice Chancellor for Research

Alan G. Robinson
Executive Associate Dean
David Geffen School of Medicine

¹An “applicable clinical” trial is defined as:

- Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase I investigations, of projects subject to FDA regulation; and
- Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric post market surveillance.

² “Responsible Party” is defined as the holder of an Investigational New Drug Application (IND) or an Investigational Device Exemption (IDE); or the Principal Investigator if so designated by the study sponsor.