

## **Deans, Directors, Department Chairs and Administrative Officers**

This is a reminder that registration is now required on ClinicalTrials.gov (a publicly available data base) for virtually all clinical trials/studies. This memo outlines the requirements and available resources to assist investigators.

As amended in September 2007, the Drug Modernization Act (DFAMA) of 1997 requires registration in ClinicalTrials.gov, of what are termed “Applicable Clinical Trials,” *regardless of the source of funding* for these studies. These include:

- **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.

Registration is also required by the International Committee of Medical Journal Editors (ICMJE). However, the ICMJE requirements are more stringent. These requirements apply to:

- Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects of health outcomes. *NB: Unlike the DFAMA requirement above, this includes Phase I studies.*

Registration is to be completed by the “Responsible Party” defined under the federal regulations 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 or award recipient.

- *For Industry supported studies:*
  - Most industry-initiated clinical trials will be registered by the industry sponsor. PIs are encouraged however, to check with the industry sponsor to verify registration of the clinical trial.
  - For PI-initiated studies for which there is industry funding, the PI has the primary responsibility for the registration and most industry sponsors will not register the trial. *NB: For PI-initiated studies, registration of the trial will be required after IRB approval, but prior to execution of the contract.*
- *For federally or non-profit-supported clinical studies:*

- Consistent with federal regulations, the IND holder is responsible for registering the study. PIs are encouraged however to check with the federal sponsor about the registration of the clinical trial.
- When there is no IND or IDE holder, the award recipient is responsible for registering the study. *N.B.: At UCLA the PI is responsible for registering these studies.*

Timing of the registration requirements varies:

- “Applicable Clinical Trials” that involve a serious or life-threatening disease or condition which were initiated after September 27, 2007, or trials that were initiated prior to September 27, 2007, but were ongoing as of December 26, 2007, were required to have been registered by December 26, 2007, or 21 days after the first subject is enrolled.
- “Applicable Clinical Trials” that do not involve a serious of life threatening disease or condition must be registered by September 27, 2008.
- IRB approval must be received before a clinical trial can be registered.

Failure to comply with the federal regulations may result in penalties. Failure to comply with the ICMJE requirements may preclude publication in member journals. NIH encourages registration of all clinical trials/studies whether required under the law or not. We also recommend that all clinical trials/studies be registered.

Competing (new and renewal) applications submitted to the NIH on or after January 25, 2008 must include certification of registration and provide basic registration information. NIH applications requesting support for a new clinical study should explain that it will require registration in [ClinicalTrials.gov](http://ClinicalTrials.gov). NIH progress reports submitted on or after April 1, 2008 should also provide certification of registration and basic registration information. Failure to comply with these requirements may result in the withholding of award funds.

Clinical trials can be registered at: [www.clinicaltrials.gov](http://www.clinicaltrials.gov). For help in registering a clinical trial (*regardless of the sponsor*), please contact Marcia Malmet in the UCLA Office of Clinical Trials at [mmalmet@mednet.ucla.edu](mailto:mmalmet@mednet.ucla.edu) or 310-794-8766.

See the NIH Notice on “[Clinical Trials Registration in ClinicalTrials.gov](#)” and the UC Letter Information Memo 08-04 “[Registration of Clinical Trials–new Federal legislation and expanded ICMJE Requirements.](#)”

We will provide updates as additional information and clarification becomes available.

Sincerely,

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