May 26, 2017

Deans, Directors, Department Chairs and Administrative Officers

Re: Updated Guidance on ClinicalTrial.Gov Registration and Reporting Requirements

This guidance is issued to remind the campus clinical research community of the longstanding requirements to register and report results of clinical trials on the Federal database, www.ClinicalTrials.gov. It supplants campus guidance distributed in 2008.

Several changes to relevant federal regulations took effect in January 2017. They are:

The Final Rule for Clinical Trial Registration and Results Information Submission (42 CFR Part 11) went into effect on January 18, 2017. The Final Rule clarifies and expands the requirements of the Food and Drug Administration Amendments Act of 2007, Section 801 (FDAAA 801) registration and reporting requirements. Studies subject to the registration and results submission requirements described in FDAAA 801 are known as Applicable Clinical Trials (ACTS). See: https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission

National Institutes of Health Policy on the Dissemination of NIH-Funded Clinical Trial Information (NOT-OD-16-149) went into effect on January 17, 2017. It requires registering and submitting results information to ClinicalTrials.gov for all studies funded wholly or in part by the NIH regardless of study phase, type of intervention, or whether they are subject to FDAAA Section 801. See: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html

Additionally, the International Committee of Medical Journal Editors (ICMJE) requires prospective registration in ClinicalTrials.gov as a precondition of consideration for publication of research results generated by a Clinical Trial in their journals (http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html).

Under the FDA regulations and NIH policy, the entity or individual responsible for registering a clinical investigation and submitting Clinical Trial information to ClinicalTrials.gov is known as the Responsible Party.
UCLA has established two institutional accounts in the Protocol Registration and Results System (PRS) for ClinicalTrials.gov to support UCLA investigators who serve as the Responsible Party on a clinical trial:

*For cancer studies:* The Office of Regulatory Compliance, Jonsson Comprehensive Cancer Center: jccorc@mednet.ucla.edu. The process of registering trials and results reporting is managed by the JCCC in collaboration and consultation with the investigator, using investigator-supplied information and documentation. Investigators do not need to maintain individual user accounts for cancer studies.

*For all non-cancer studies.* The Office of Regulatory Affairs, Clinical and Translational Science Institute (CTSI): ctsiora@mednet.ucla.edu. Each Investigator receives a user account under the “UCaliforniaLA” organization name to be able to log in to register and maintain their own studies. CTSI staff can view and edit all records in the organizational account and can provide guidance on registration and results-reporting requirements and the Protocol Registration System (PRS) data entry process. Study support staff and co-investigators may be given access to view and edit a study record, but only the Responsible Party can release the record to ClinicalTrials.gov.

Complying with the regulations is mandatory. We urge all investigators to avail themselves of the support provided by the CTSI and JCCC to make reporting and registration easier, and to reduce the risk of monetary penalties that can be imposed by the FDA and/or the NIH for failure to comply.

For additional information see: [http://researchgo.ucla.edu/clinicaltrialsgov](http://researchgo.ucla.edu/clinicaltrialsgov).

Sincerely,

Ann Karagozian, Ph.D.     John Mazziotta, M.D., Ph.D.
Interim Vice Chancellor for Research     Vice Chancellor UCLA Health Sciences

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1 The Responsible Party is defined under the federal regulations as the holder of an Investigational New Drug Application (IND) or an Investigational Device Exemption (IDE); or the PI if so designated by the study sponsor or award recipient.

- For most *industry-initiated* Clinical Trials, the industry sponsor is the Responsible Party. The UCLA PI is advised to check with the industry sponsor to verify registration of the Clinical Trial.

- For *PI-initiated* Clinical Trials, the PI will likely be the Responsible Party. For non-cancer Clinical Trial the PI is designated as the Responsible Party. As noted above, the Jonsson Comprehensive Cancer Center acts as the Responsible Party for UCLA PI initiated cancer Clinical Trials.

- The lead institution or cooperative group will be the Responsible Party for most *multi-site and collaborative group* Clinical Trials. The UCLA PI is advised to check with the study chair or coordinating site to verify registration of the Clinical Trial.