UNIVERSITY OF CALIFORNIA, LOS ANGELES

UCLA

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OFFICE OF THE CHANCELLOR
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LOS ANGELES, CALIFORNIA 90095-1405

September 27, 2012

DA 251.18

ASSOCIATE VICE CHANCELLOR, MEDICAL SCIENCES AND CHIEF MEDICAL OFFICER
J. THOMAS ROSENTHAL
DIRECTOR HELENE ORESCAN, CLINICAL TRIALS ADMINISTRATION OFFICE
ASSISTANT DIRECTOR, CLINICAL TRIALS ADMINISTRATION OFFICE
CLINICAL TRIAL CONTRACT OFFICERS

Delegation of Authority – Execution of Clinical Trial Contract Agreements with Industry Sponsors and Subcontract Agreements with Non-Profit Organizations

References: (a) UC DA 2569 (To Solicit and Accept or Execute Certain Extramural Grants and Contracts) to Chancellors, dated April 19, 2012;

(b) University of California Contract and Grant Manual;

(c) UC Operating Guidance Memo 95-05 (Requirements for Administration of Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects), issued February 15, 1995;

(d) UC Operating Guidance Memo 96-03 (University Patent Policy Interim Guidelines for Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects), issued January 31, 1996;

(e) UCLA Clinical Trials Definition Memo, September 2006.

Supersedes: UCLA DA 251.17 (Execution of Clinical Trial Contract Agreements with Industry Sponsors and Subcontract Agreements with Non-Profit Organizations) to Associate Vice Chancellor and CMO Rosenthal, et al., dated 6/19/2012.

Effective as of the date, above, I hereby delegate to you, in your respective areas of responsibility, the authority to execute contract agreements with industry sponsors for the conduct of clinical trials, in accordance with University policy and guidelines, and as specified below:

To Execute Clinical Trial Contract Agreements with Industry Sponsors with Annual Direct Costs Not Exceeding:	
Associate Vice Chancellor, Medical Sciences and Chief Medical Officer	$5,000,000
Director, Clinical Trials Administration Office	$2,000,000
Assistant Director, Clinical Trials Administration Office	$500,000
Clinical Trial Contract Officers	$500,000

At UCLA, a clinical trial is defined as the controlled, clinical testing in human subjects of investigational new drugs, devices, treatments, or diagnostics, or comparisons of approved drugs, devices, treatments, or diagnostics, to assess their safety, efficacy, benefits, costs, adverse reactions, and/or outcomes. Such studies may be conducted under an industry-developed protocol or an investigator-developed protocol. Financial support for a clinical trial must be provided by a for-profit entity.

You are also authorized to execute subcontracts awarded to The Regents that are conducted at UCLA, from other non-profit organizations (usually other educational institutions) that enter into clinical trial agreements with a for-profit sponsor. The same dollar limits by position in the table, above, shall apply to any such subcontracts.

This delegation is being reissued due to an organization change and unit name change, and there are no other substantive changes to the delegation being superseded. This authority may not be further redelegated.

Gene D. Block
Chancellor

cc: Executive Vice Chancellor & Provost
Vice Chancellor for Research
Manager, Administrative Policies & Delegations