MEMORANDUM

Office of the Vice Chancellor for Research
Office of the Vice Chancellor for Medical Sciences

ANNOUNCEMENT: DELEGATION OF CLINICAL TRIALS INDUSTRY CONTRACTING FOR THE MEDICAL SCIENCES CAMPUS

September 20, 2005

Dear Colleagues:

Clinical trials are an important component of UCLA’s research portfolio. Over several years, there have been a number of working groups that have assessed various issues related to how clinical trials research is administered, particularly during the pre-award stage. In December 2004, a Clinical Research Faculty Steering Committee was jointly appointed by us to help oversee a project to assess improvement opportunities, implement changes, and help assure that changes are responsive to the needs of faculty who are actively engaged in clinical research. Implementation of some of the recommended changes is now beginning.

Effective immediately, the administration of clinical trials industry contracting for the Medical Sciences Campus has been delegated to the David Geffen School of Medicine. A new Industry Contracting Unit is being established within the Office of Clinical Trials. This unit has authority to develop, negotiate, and sign industry contract agreements for clinical trials projects that are conducted by faculty in the Schools of Medicine, Dentistry, Nursing, and Public Health.

Helene Orescan is the new Director of the Industry Contracting Unit and reports directly to Vikki Jenkins, who serves as the Director of the Office of Clinical Trials. The Department of Medicine contracting staff is now also part of the new contracting unit headed by Ms. Orescan. By January, the new consolidated contracting unit will be moving into physical space adjacent to the Medical Center. Transferring the contracting function to the School of Medicine will involve a transition over several months. Important information that you and your staff need to know regarding clinical trials contracts is as follows:

- Only industry sponsored clinical trial contracts will be handled by the expanded Office of Clinical Trials. (This new office will NOT handle Material Transfer Agreements or other sponsored Research Agreements).
  - For the Department of Medicine, please note that the handling of Material Transfer Agreements (effective September 12, 2005) and other sponsored Research Agreements (effective October 1, 2005) will be transferred from
the DOM Contracting Office to the Office of Intellectual Property Administration (OIPA), which is now under the direction of Dr. Kathryn Atchison. For all other SOM departments and other schools, these types of agreements are already handled by either OCGA or OIPA, and that will not change.

- Campus addresses and phone numbers for both the former OCGA industry contracting and the Department of Medicine contracting office staff who now report to the SOM Office of Clinical Trials will remain unchanged for now (and until a physical move into a new office in January).

- The contracting process itself will continue as in the past until further notice regarding submission and other process changes are announced.

- Matters previously addressed to Gayle Lund or Mary Gibson regarding clinical trials contracting matters should now be addressed to Helene Orescan (Campus Address: Office of Contract and Grant Administration, 10920 Wilshire Boulevard, Suite 1200, Los Angeles, CA 90024-1406; Mail Code: 140648; Phone: Ext. 40137).

Please keep in mind that we are only at the beginning stages of implementing needed improvements, and expect that the transition to new contracting and related pre-award processes will take several months to complete. Our goals are to make the contracting process more transparent so that faculty and staff better understand how it works, what the related institutional polices are, and how to get help, as well as to optimize processing time that is within the control of the contracting unit.

A number of additional changes intended to improve the pre-award process for clinical trials and formalize research quality assurance and training programs for the Medical Sciences campus will be announced over the coming months.

If you have any questions about any clinical trials contracting matters, please contact Helene Orescan at ext. 40137 or Vikki Jenkins at ext. 48713.

Sincerely,

Roberto Peccei
Vice Chancellor for Research

Gerald Levey
Vice Chancellor for Medical Sciences
Dean, David Geffen School of Medicine