MEMORANDUM

To: All Faculty

From: Randolph W. Hall, Ph.D.

Date: March 19, 2013

Subject: Creation of New Clinical Trials Office at USC

Clinical trials are an essential component of research and clinical care within academic medical centers. Until the present, USC has relied on its subsidiary, Health Research Association/Clinical Research Organization (HRA/CRO), for contracting and billing on industry sponsored clinical trials. On March 13, the board of directors of HRA/CRO voted to dissolve HRA/CRO as a corporation, with a wind down period over the next few months. Today, I would like to announce the creation of a new Clinical Trials Office (CTO) within the university, which will ramp up over this same period.

The CTO will be responsible for budgeting, contracting, business development and Medicare coverage analysis (reporting to the Executive Director of Contracts and Grants), and will be supported by a unit devoted to clinical trial billing to sponsors (reporting to the director of Sponsor Projects Accounting, SPA, which is already responsible for other types of sponsor billing). The CTO will serve both government sponsored and industry sponsored trials, and will aim to grow the volume of clinical trials and patient participation through efficient customer service, as well as promote USC as a center for innovative patient care.

An internal CTO offers several advantages for investigators and for patients through a stronger focus on reducing time to agreement and enrolling more patients on competitive trials:

- Template intellectual property terms that reflect industry practice for industry sponsored clinical trials will be instituted to reduce the time to agreement.
- The organization will be streamlined by focusing entirely on delivering services for clinical trials, instead of ancillary activities that result from operating as a separate corporation.
- Staff can support all types of clinical trials regardless of sponsor, aiming to expedite enrollment of patients on both private and government sponsored trials.
- Clinical trials administration will be better integrated with research support services from the Office of Research and the Clinical and Translational Science Institute. Toward that end, we will initiate this September a new 8-hour course for research coordinators and new clinical investigators providing a comprehensive introduction to clinical research at USC.
• Clinical trials will be integrated with the university accounting systems, meaning that investigators will have the same ability to manage funding as they would on an ordinary research account. The proposal submission and approval process will also be standardized to be consistent with other types of research proposals, and will utilize computer systems being developed to support research within the university.

• Legal review will be streamlined, to be consistent with other types of research agreements within the university. This means that the Office of the General Counsel will be consulted for exceptional terms, but will not be a standard direct part of the contract negotiation.

In addition, the new organization aims to provide several value added services, including business development to initiate strategic relationships with sponsors of trials, and value added support for budgeting and protocol development. I also look forward to working with the Keck Medical Center and LA County/USC Hospital as partners to implement programs that promote USC to patients as a site for the latest and most innovative care, making patients and their doctors aware of the range of clinical trials taking place at USC.

The creation of the CTO will not change the overhead rate for industry sponsored clinical trials, and the division of overhead between central administration and the individual units that conduct research. We will also work with our sponsors to ensure an orderly transition of funded agreements and research accounts into the university.

As a first step toward the creation of the CTO, job positions have been posted, and recruitment has begun for a Director of the CTO, along with a set of support positions. A job description can be found at: https://research.usc.edu/clinical-trials-at-usc/ (also at jobs.usc.edu, requisition 017944). The search for the CTO Director will be guided by a faculty search committee, including Drs. Thomas Buchanan, Anthony El-Khoueiry, Mark Lew, Linda Sher, and Darcy Spicer as members. The search committee will advise Jeri Muniz, Executive Director of Contracts and Grants, and myself as we search for a leader who is experienced in clinical trials budgeting and contracting, and also has outstanding leadership skills. Nominations for this position are encouraged. Current HRA/CRO employees are eligible to apply for the open positions, and I expect that some of the employees will be rehired through a competitive selection process.

Clinical trials sponsors will also be notified of the transition, and informed of the university’s intention to strengthen and streamline its support for clinical trials, with no discontinuity in the support that we currently provide.

The transition to an internal CTO is a necessary move to achieve excellence in clinical trials, but not a move without risk. A successful transition will be my first priority over this period, but I do ask for patience. To facilitate the transition, HRA/CRO will remain under its current leadership during the transition period. The decision reflects the advice of numerous individuals throughout the university, including a faculty advisory committee, as well as a review of practices at other academic medical centers.

To conclude, I would like to thank the many talented people who have served the HRA/CRO organization over the years, and who will continue to serve the university over this transition period. HRA/CRO has served the university well for more than 65 years, and deserves our thanks and appreciation.