MEMORANDUM

To: Clinical Research Investigators and Study Personnel

From: Randolph W. Hall, Ph.D

Date: May 22, 2013

Subject: Status Report on Creation of Clinical Trials Office

I am writing to provide an update on the establishment of the new clinical trials office at USC.

**Hiring:** Hiring and interviews are well underway. As of today, six employees have accepted offers to work within the new CTO. Interviews have been conducted with the faculty search committee for four finalists for the position of director, which I expect to be filled within the next two weeks. Interviews are underway for other positions.

**Transfer of Agreements:** All sponsors have been notified of USC’s intent to transfer agreements into the university and asked, where necessary, to assign these agreements. In the next few weeks, as we receive responses from sponsors, we will begin to transfer these agreements into the university. Each agreement will be established as a new award within the Kuali Coeus (KC) system, and then a new account will be established within the Kuali Financial System (KFS), from which investigators can spend, based on HRA/CRO’s assessment of expenses and receipts to date. This process will take place in June. Once completed, investigators will have immediate access to award and account information, enhancing their ability to manage accounts.

**Software Systems:** Existing HRA/CRO software will be retained and maintained under Josh Lee, CIO for Keck Medical Center. The exception is that KC and KFS will be the systems for managing award and account information. The university is continuing to explore long-term solutions for a Clinical Trials Management System. One vendor has already visited USC, and another will visit at the end of the month. A CTMS would replace the remaining legacy systems from HRA/CRO. We are soliciting feedback on alternatives for a CTMS. In addition, over the next few weeks, we will be making minor modifications to KC and KFS to account for specific billing features of industry sponsored clinical trials.
Negotiation of New Agreements: I understand that investigators are eager to initiate new trials. The new CTO office will have a "soft launch" around the start of June, at which time it will initiate negotiations for new agreements. To expedite contracting, negotiators will be trained on parameters of acceptable terms that are consistent with USC policies and, unlike the past, contract negotiators will be given signature authority consistent with current contracts and grants processes. This should greatly reduce the need for review from other USC entities.

Residual Accounts: The building in which HRA resides is on the market for sale. Once the sale occurs, we will have an exact determination of funding for existing residual accounts. In the future, residual accounts will be created following USC policies and procedures for "unobligated balance transfer" overseen by Sponsored Projects Accounting (http://fbs.usc.edu/depts/spa/page/815/forms-page/).

Overheads: The existing 35% overhead rate will be retained, with 25% used to compensate for central costs, including IRB, budgeting, Medicare Coverage Analysis, contract negotiation, and billing, and the remaining 10% used to compensate departments or centers for their obligations. The unit that receives the 10% component will be responsible for supporting and managing accounts for the trials within its unit.

Website: A website has been established, and will continue to be enhanced, at: https://research.usc.edu/clinical-trials-at-usc/. The site has sections for investigators, patients and sponsors. An email account has been established: clinicaltrials@usc.edu.

Training: Training materials continue to be developed for a new orientation course for research coordinators and new clinical investigators. This is being developed in cooperation with CISO, CTSI, Compliance and OPRS. We are planning a first offering in September. In addition, we are developing materials to train on business processes, and will offer separate orientations on procedures for working with the CTO. This should begin in early July.

Salary Pools: Options are being developed for support of pooled positions across multiple studies. One possibility will be the creation of recharge centers, automatically billed through use of CORES software.

I know that the transition has created significant concerns for investigators. We are doing our best to get the CTO up and running. In the end, I believe that the changes will create a much more responsive and streamlined office for execution of agreements and other business processes, which will in turn enable the university to grow its clinical research program. I thank you for your patience as we move through this transition.

I would be happy to answer any questions related to the new clinical trials office at vpres@usc.edu. Questions related to existing accounts within HRA/CRO should be directed to HRA/CRO.