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To: USC Clinical Research Community

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Re: Clinical Trials Office

As announced previously by Dr. Randolph Hall, on January 1, 2016, the USC Clinical Trials Office will move from the USC Office of Research into the Office of the Dean in the Keck School of Medicine. We have been meeting with stakeholders at all levels to understand the operations of the CTO and to identify ways to enhance its efficiency, transparency and user experience. We are writing to give you an update about our immediate plans as we undertake this transition.

What will the new CTO do? It will oversee the pre-award (coverage analysis, budgeting and contracting) and post-award (contract management, billing and collections) processes for all industry-sponsored clinical trials and other industry-sponsored research studies that are conducted at USC and that utilize health system resources. The CTO will also conduct coverage analysis for non-industry trials/studies that use health system resources. Budgeting, contracting and post-award processes for those non-industry studies will be handled by the USC Offices of Contracts and Grants and Sponsored Projects Accounting (SPA).

Who will be in the CTO? The staff members who have been conducting pre- and post-award processes for industry trials separately in CTO and SPA will be combined into a single CTO housed on the USC Health Sciences Campus. A search is underway for a permanent director of the CTO. Interim Director Ben Holstein will continue to lead the CTO staff until a permanent director is hired. We (Buchanan and Budge) will oversee the operations of the CTO. CTO staff members and services can be accessed through the CTO website (www.clinicaltrials.med.usc.edu), which will be updated as we implement new policies, procedures and resources. The new website will be live in early January.

What changes will be made? We are working to understand fully what we can do to optimize the services provided by the CTO. Based on what we have learned so far, here is how we plan to address the following issues over the next several months:

- **Study Activation:** We are committed to reducing study activation times. We will need strong cooperation from study teams to achieve this goal. There is a considerable backlog of trials that are pending activation. We will soon contact PIs of those trials to determine which ones are still open for enrollment and which are the highest priority for activation. We plan to invest new



resources in getting the viable, especially high-priority trials activated quickly. Simultaneously, we will increase staffing within the CTO to handle new trials more expediently.

- **Trial Management**: Implementation of our new clinical trials management system, OnCore, is nearing completion. Our goal is to use OnCore for activation of backlogged and new trials no later than March 2016. OnCore training sessions for research teams will begin in January 2016. They will be announced in separate notices to the faculty and staff. Be sure that staff members involved in the submission, activation, conduct and/or administration of your clinical studies attend these training sessions so they are ready for the transition to OnCore. Consider attending the training yourself so you fully understand how OnCore can help manage your trials (we did – it was very informative). OnCore will be our trials management system going forward; we plan to maintain the True system only until trials that are already active in that system have been completed.
- **Ordering Clinical Services**: The Cerner EHR system at Keck allows the creation of templates for ordering clinical services, templates called Power Plans. We are working with the Cerner team on a process to assist research teams in developing Power Plans that they will use to order clinical services for research studies. Power Plans will contain information from the coverage analysis regarding research vs. standard-of-care procedures to facilitate research billing. Our goal is to begin using Power Plans by April 2016. Until then, we will be able to generate Research Order Forms from OnCore so that teams can order clinical services for studies entered in OnCore just as they currently do with the True system. Once the Power Plan approach is fully operational, Research Order Forms will only be used to order clinical services outside of the Keck system (e.g, at LA County Hospital).
- **Billing and Collections**: We are committed to increasing transparency for research teams regarding payment for services and collection from sponsors related to clinical trials. We will continue our dialog with the research community to determine how best to achieve this goal.

We hope you find this general overview helpful. Details for the specific components will follow. The CTO will continue to evolve as we work to understand the needs of the clinical research community and then implement and evaluate processes to create a more efficient, transparent and user-friendly CTO. We look forward to working closely with you and your research teams in this important endeavor.

