Keck School of Medicine of USC

THOMAS A. BUCHANAN, MD

Vice Dean for Research

Director, Southern California Clinical and Translational Science Institute

Co-director, USC Diabetes and Obesity Research Institute

Chief, Division of Endocrinology & Diabetes, Department of Medicine

Professor of Medicine, Physiology & Biophysics, Obstetrics & Gynecology

Date: January 15, 2016

To: Clinical Research Faculty & Staff

From: Tom Buchanan, Vice Dean for Research
        Ted Budge, Chief Operating Officer
        Keck School of Medicine of USC

Re: Update on the Clinical Trials Office

Happy New Year! We hope you and your family enjoyed a relaxing holiday break.

We continue to make progress on creating a more efficient, transparent and user-friendly approach to managing clinical trials at USC. We are writing to update you on three areas of progress; **the first two need immediate attention from you and your study teams**.

1. <u>Transition to OnCore (Clinical Trials Management System)</u>

   - As of April 1, 2016, all new studies will be initiated and managed in OnCore. This means that **research teams need to be trained in OnCore before the date** (see page 2 for details).

   - Initially, OnCore will generate Research Order Forms (ROFs) that you will use, as you do now, to order services from the Keck and LA County health systems. Once Keck's EHR (KeckCare) completes enhancements to allow test-by-test designation of research vs. clinical care, we will switch to using Power Plans for ordering services in KeckCare. Our target for that transition is early summer. We anticipate continuing to use paper ROFs at LA County for the foreseeable future.

   - We will continue to operate the TRUE system for trials were activated in that system before April 1, 2016. Once the last of those trials is completed, the True system will be retired.

2. <u>Backlog of Studies</u>

We have also begun to address the backlog of studies submitted to CTO but not yet activated. As a first step, we asked all PIs with pending studies to rank them by importance and viability. **If you received that email, you need to respond by Monday, January 18th or we will assume that your trials are low priority**. E-mail your response directly back to me at buchanan@usc.edu. Once we have a better handle on the volume of viable trials in the backlog, we will have a better idea of how long it will take to get the backlog down to our goal of <60 days.

3. <u>Staffing</u>

We are actively interviewing candidates for the position of Director of CTO. We aim to have a new director by March 1. Until then, Ben Holstein continues as interim director. We are also hiring several new staff members to increase capacity and streamline operations in the CTO.

We thank the research community for your help and patience as we transition the CTO into the Keck School. We look forward to your feedback as we work to provide more efficient, user-friendly and transparent services to all who conduct clinical trials at USC.

OnCore Training

All new clinical trials will be entered into and managed with OnCore starting April 1, 2016. Therefore, all research team members who are involved in study initiation and/or trial management will be required to be trained in the relevant functions of OnCore by April 1. Two types of training sessions will be offered for research team members (some people need one or the other, many people need both):

- **Pre-Award/Study Initiation Training**: Focuses on how to submit a protocol to CTO for review of contracting, budgeting and/or coverage analysis. People who currently have access to True 2 and who have job responsibilities that require use of True 2 need to complete this training.

- **Study Management/Maintenance Training**: Focuses on accurate registration and tracking of study participants. Staff members with access to True and/or Iris and responsible for notifying the post award team of new study participants, completion of study visits and/or validating research-related activities will need to complete this training.

Training sessions are currently scheduled on the dates and times below. Additional sessions will be added in March if needed. People who have already completed training as part of the pilot testing program for OnCore do not require additional training, but can these sessions if they want.

Current OnCore Training Schedule (all sessions in Soto Building II, room 2095)

PRE-AWARD/STUDY INITIATION TRAINING
- Tuesday, January 26th, 9:00 AM – 11:00 AM
- Tuesday, February 2nd, 9:00 AM – 11:00 AM
- Monday, February 8th, 2:00 PM – 4:00 PM
- Friday, March 4th, 1:00PM – 3:00PM

STUDY MANAGEMENT/MAINTENANCE TRAINING
- Friday, January 29th, 1:00 PM – 3:00 PM
- Friday, February 5th, 1:00 PM – 3:00 PM
- Tuesday, March 1st, 9:00AM -11:00AM
- Monday, March 7th, 2:00PM – 4:00PM

Register for individual training or request group training at: OnCore Training Registration

Additional Information
Submit questions about OnCore to oncoresupport@med.usc.edu or contact Amanda Schmitz directly at 323.442.4047

 Interested in utilizing OnCore before April 1st? Join our pilot users (contact Amanda Schmitz).