Clinical Research Operations Update

May 2018

As one of the leading research institutions in the U.S. and arguably the world, we are committed to not only maintaining but improving UCSF’s position and world-class reputation. We understand that one of our top areas for improvement is the time it takes for investigators to initiate clinical trials, and as such, this is an active area of focus for us, along with more general improvements and streamlining of our clinical research operations. To keep everyone informed of such efforts, we will begin sending monthly updates to report on our progress.

Industry-Sponsored Clinical Trials: Process Improvement Workshop
Invited researchers and research support unit heads will be meeting for a series of workshops in May and June to identify ways to improve the process in which industry-sponsored clinical trials are implemented. Goals are to reduce the time it takes to complete the steps needed to initiate such trials and explore potential efficiencies in the process.

Clinical Research Task Force
In addition to the process improvement workshops, Lindsey Criswell, UCSF Vice Chancellor for Research (VCR) is forming a task force composed of researchers and research support unit heads to address clinical research operations on an ongoing basis. Participants will provide their various perspectives on all aspects of clinical research processes and how those functions are administratively supported.

Industry Contracts Division
The Office of Sponsored Research leadership is working in tandem with the formal process improvement efforts to improve contract review, negotiation and execution turnaround time, as well as develop an escalation protocol for agreements with prolonged or protracted negotiations.

IRB Turnaround Time Reduction
Consultants are being used by the HRPP office to assist permanent staff in screening new submissions in order to reduce approval times.

Track More with OnCore
May 7th was the go-live date for the Office of Clinical Research’s (OCR) initiative to use a single clinical trials management system, OnCore, for all subject enrollment and study visit tracking for UCSF clinical trials that bill through APeX. This initiative bolsters our compliance efforts by providing a centralized system of record for patients who are enrolled in UCSF clinical trials, supports accurate and compliant billing practices for those individuals, and enables UCSF to be audit-ready with OnCore’s ability to generate automatic reports across all clinical trials. For more information, visit the OCR website.
We are committed to communicating regularly with you on all of these important issues. Please feel free to share this update with others in your unit. In the meantime, you may contact us through the Office of Research email at: research@ucsf.edu

Sincerely,

Lindsey A Criswell, MD, MPH, DSc
Professor of Medicine and Orofacial Sciences
Jean S Engleman Distinguished Professor of Rheumatology
Vice Chancellor for Research, UCSF

Brian Smith, JD, MBA
Interim Chief Ethics & Compliance Officer
Associate Vice Chancellor,
Research Infrastructure & Operations