Clinical Research Operations Update

June 2018

We understand that one of our top areas for improvement continues to be 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. This is the second monthly update to report on our progress in these efforts.

External IRB Use
In December 2017, we temporarily expanded the criteria for studies that can use an external IRB (e.g., WIRB) to include Phase II and foundation-funded studies. This expansion was originally in effect through June 30, 2018 and was implemented to help address turnaround times. Based on feedback from investigators, the expanded criteria will remain in effect through December 31, 2018. In addition, federally funded studies are also eligible.

The following types of studies can rely on a commercial IRB:

- Clinical trial phases II***,** III, or IV
- Expedited/minimal risk studies [**Note**: These have always been able to rely on external IRBs, but were never explicitly listed in the criteria.]
- Industry-funded, foundation-funded*****, federally-funded**

***** temporarily added 12/1/17 to 6/30/18, extending through 12/31/2018
** temporarily added from 6/2018 to 12/31/18

Single IRB Use for NIH Multi-Site Studies:
Effective January 25, 2018, NIH requires that all sites participating in multi-site studies will use a single Institutional Review Board (sIRB). At this time, UCSF can serve as the sIRB for select studies on a case-by-case basis. To request consideration for UCSF to be the sIRB for your study, follow the instructions on the IRB website's new sIRB section. Please contact the SingleIRB@ucsf.edu 60 to 90 days prior to grant submission date to discuss which IRB can review your study.

Human Research Protection Program (HRPP) Office Staffing
We have been actively recruiting to fill multiple vacancies in staff and leadership positions. In order to address approval times while we continue to fill positions, we have enlisted the services of an IRB consultant firm. The consultants are working with our staff to screen and review new submissions.

Common Rule: Delay of Compliance Date
On June 18, 2018, the Department of Health and Human Services announced that the changes in the Common Rule will be delayed for another 6 months, until January 21, 2019. The IRB is

working to update our application forms, website and procedures in preparation for the implementation of the Final Rule. Additional announcements will be forthcoming as the date approaches.

We continue to be 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 July, this clinical research update will be included in a broader Office of Research newsletter. 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 of Research, UCSF