March 11, 2020

Guidance to Researchers Regarding Determination of "Essential to the health and/or well-being" for human subject research visits during the COVID-19 outbreak.

The interim UCSF policy on human subject research visits at UCSF's San Francisco campuses during the COVID-19 outbreak requires determination of whether or not a research visit is "essential to the health and/or well-being of a participant." **The following examples are provided as a guide to help principal investigators, participants, and participant care providers determine suitability of in-person research visits. These determinations and the balance of potential benefits and harms will vary by study objectives, target patient population, and may change as the COVID-19 outbreak evolves.** The following examples are not intended to be comprehensive of all study types.

- Please send questions about this guidance or UCSF's interim policy to research@ucsf.edu.
- Please send questions about coronavirus to emer.mgt@ucsf.edu.

For these study designs:	**Is the specific research visit "essential to the health and/or well-being" of the participant, thus supporting in-person visits?**		
	These visit types are LIKELY "essential" (supports an in-person visit)	**These visit types may or may not be "essential" (Support for in-person visit will depend on specifics of the study)**	**These visit types are LIKELY not "essential" (does not support an in-person visit)**
Randomized controlled efficacy trial (e.g., phase IIb or III) of a potential drug or device or other intervention	• New enrollments • Follow ups		
Post-approval trial (e.g., phase IV) of a therapeutic drug, device, or other intervention to assess tolerability and/or long-term benefit	• Follow ups	• New enrollments	
Early phase (e.g., phase I or IIa) pharmacodynamic, safety, tolerability or feasibility trial a potential drug or device or other intervention	• Follow ups	• New enrollments	
Non-randomized interventional trial of a drug, device, or other intervention requiring safety monitoring	• Follow ups	• New enrollments	
Non-randomized interventional trial of a drug, device, or other intervention not requiring safety monitoring		• New enrollments • Follow ups	
Comparative effectiveness studies or other study types describing the natural history of disease or other clinical outcomes		• Follow ups	• New enrollments
Non-interventional qualitative study			• New enrollments • Follow ups
Non-interventional study with collection of clinical data and/or biological specimens for future research			• New enrollments • Follow ups