

March 16, 2020

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

Research visits conducted in inpatient settings and COVID-19 focused research are addressed separately in the latest interim policy on human subjects-related research visits (see ucsf.edu/coronavirus).

The updated, March 16th interim UCSF policy on human subject research visits at UCSF campuses during the COVID-19 outbreak requires determination of whether or not a research visit in the ambulatory setting is urgent and medically necessary, thereby "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 make this determination. 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. NIH has released a guidance called "NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19", supporting limits on in-person study visits during the COVID-19 outbreak. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html>

- 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 in the ambulatory setting " <u>essential to the health and/or well-being</u> " of the participant, thus supportive of an in-person visits if a remote visit is not possible?	
	These visit types may in some circumstances be "essential" (Support for in-person visit will depend on study specifics)	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	<ul style="list-style-type: none"> • 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		<ul style="list-style-type: none"> • New enrollments • Follow ups
Early phase (e.g., phase I or IIa) pharmacodynamic, safety, tolerability or feasibility trial a potential drug or device or other intervention	<ul style="list-style-type: none"> • Follow ups 	<ul style="list-style-type: none"> • New enrollments
Non-randomized interventional trial of a drug, device, or other intervention requiring safety monitoring	<ul style="list-style-type: none"> • Follow ups 	<ul style="list-style-type: none"> • New enrollments
Non-randomized interventional trial of a drug, device, or other intervention not requiring safety monitoring		<ul style="list-style-type: none"> • New enrollments • Follow ups
Comparative effectiveness studies or other study types describing the natural history of disease or other clinical outcomes		<ul style="list-style-type: none"> • New enrollments • Follow ups
Non-interventional qualitative study		<ul style="list-style-type: none"> • New enrollments • Follow ups
Non-interventional study with collection of clinical data and/or biological specimens for future research		<ul style="list-style-type: none"> • New enrollments • Follow ups