Interim UCSF Policy on Human Subjects-Related Research Visits at San Francisco Campuses during COVID-19 Outbreak
Effective March 11th, 2020

Background

In the context of recent municipal and institutional statements on COVID-19 and the rapidly evolving outbreak, the UCSF Office of Research has revised its policy related to human subjects-related research visits. This policy is being implemented to protect research participants, researchers, and the larger UCSF community from risk of infection with COVID-19 as well as to ensure ongoing access to research which may provide essential support and care to participants. This policy will be revised weekly or when appropriate based on new information and circulated to the UCSF research community. It will also be available on the UCSF coronavirus microsite https://www.ucsf.edu/coronavirus.

- Please send questions and comments on this policy to research@ucsf.edu
- Please send questions and comments about coronavirus to emer.mgt@ucsf.edu

Interim Policy (Effective March 11th, 2020)

Participants

Research visits should be performed remotely (e.g., by phone, Zoom, or other means) whenever possible. See the following link for relevant guidance: https://it.ucsf.edu/services/zoom-web-conferencing.

Non-Essential Research Visits

Research visits that cannot be performed remotely and are not essential to a participant's health and/or well-being should be postponed until further notice. Currently, the determination of whether or not a research visit is "essential to the health and/or well-being" of a participant is determined by the principal investigator of the research study, the participant, and the participant's care provider, and should be informed by current public health guidance regarding the COVID-19 outbreak.

Essential Research Visits

Research visits that cannot be performed remotely and are essential to a participant's health and/or well-being may be performed in person, with the following additional guidance:

a) Participants should be provided with information regarding the current COVID-19 epidemic and how best to reduce their risk of infection. This information may be provided in multiple forms suited to the type of contact, including a website link, a telephone script and an in-person handout. If possible, this information should be shared before the research visit. See the following CDC COVID-19 link for reference and materials: https://www.cdc.gov/coronavirus/2019-ncov/index.html.
b) All research participants should be screened for fever, cough and flu-like symptoms by research staff prior to the research visit if possible, with repeat screening by research

staff at the time of an in-person visit. Those who screen positive will require triage as per site-specific protocol (e.g., for UCSF patients, a referral to UCSF's Respiratory Care Clinics; at VAMC see https://www.sanfrancisco.va.gov/covid-19.asp; as ZSFG see https://www.sfdph.org/dph/alerts/coronavirus.asp) before being cleared to participate in an in-person research visit. More information on screening and triage is available on the UCSF coronavirus microsite https://www.ucsf.edu/coronavirus.

c) Enrollment of new patients on a clinical trial or other human subject-related research should be allowed only if: 1) participation in the trial is essential to a participant's health and/or well-being, as determined as above; or 2) the enrollment and longitudinal participant management can be conducted remotely for the duration of the COVID-19 outbreak.

Research Personnel

All study personnel (faculty and staff) should receive appropriate training regarding proper research participant screening (e.g., masking protocols) and participant triage should a research participant be deemed at risk for COVID-19 infection during an in-person research visit screening. Please contact your local Environmental Health and Safety office/website for guidance.

Guidance from the IRB will be forthcoming on a master amendment to studies addressing missed visits, remote visits, study visits out of window, etc., as well as reporting of study deviations for the same.

Study Sponsors

Principal investigators or their designees are asked to contact study sponsors to notify them of this policy and make appropriate arrangements. All sponsor visits for clinical trials or other human subject-related research, whether for site qualification, site initiation, or monitoring visits, should be postponed whenever feasible. Consideration for remote monitoring should be based on study need and resource availability.

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Addendum 03/11/2020

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.

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