

Revised Interim UCSF Policy on Human Subjects-Related Research Visits at San Francisco Campuses during COVID-19 Outbreak. Effective on March 16th, 2020

In the context of the rapidly evolving COVID-19 outbreak, the UCSF Office of Research has revised UCSF's policy on human subjects-related research visits at its San Francisco campuses. This policy is being implemented to conform to the San Francisco City and County Department of Public Health Order of the Health Officer and other public health measures undertaken by UCSF Leadership and the City and County of San Francisco. Its goal is to protect patients, research participants, staff, and the UCSF community from risk of infection with COVID-19, to protect UCSF's critical healthcare capacity and resources, and to preserve access to important life-saving clinical research studies.

The policy on human subjects-related research visits at UCSF's San Francisco campuses will continue to be revised when appropriate based on new information circulated to the UCSF research community. It will also be available on the UCSF coronavirus microsite 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.

Human Subjects-Related Research Visits Performed in Inpatient Settings

All human subjects-related research visits performed in inpatient settings at UCSF Health, Zuckerberg San Francisco General, or the San Francisco Veterans Administration are to be postponed unless directly related to COVID-19 or approved as "essential". An essential research visit conducted in the inpatient setting is defined as a visit providing life-saving patient care that cannot be postponed.

"Essential" Visit Approval Process

Principal investigators should submit a declaration of essential study visit to research@ucsf.edu. Declarations should include a brief study synopsis, inpatient location of visit, IRB approval number, and a statement of how the research visit is providing life-saving patient care. Declarations also require assurance of compliance with institution-specific health and safety training for research staff in infection control and proper handling of biospecimens (if relevant) in the acute care setting. For selected situations, declarations may address multiple in-person visits that are part of research protocols delivering important lifesaving patient care that cannot be postponed.

All declarations will be reviewed and approved within 24-48 hours.

Human Subjects-Related Research Visits Performed in Ambulatory Settings

Research teams should follow the following steps in determining whether to conduct human subjects-related research visits in ambulatory settings:

Step 1: Research visits planned for ambulatory settings should be performed remotely whenever possible. Options for remote visits include phone and Zoom (or other web-conferencing services). See the following link for guidance on Zoom: <https://it.ucsf.edu/services/zoom-web-conferencing>.

Step 2: Research visits planned for the ambulatory setting that cannot be performed remotely and are not essential to a participant's health and/or well-being should be postponed. A research visit in the ambulatory setting should only be determined to be "essential" if it is urgent and medically necessary to a participant's health and/or well-being (see further guidance on determination of essential visits in the ambulatory setting at ucsf.edu/coronavirus). This determination is made by the principal investigator of the research study, the participant, when possible the participant's care provider and should be informed by current public health considerations and directives regarding the COVID-19 outbreak.

Step 3: Research visits planned for the ambulatory setting that cannot be performed remotely and are urgent and medically necessary to a participant's health and/or well-being (i.e., "essential") may be performed in person, with the following additional requirements.

- a) All 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 (see [ucsf.edu/coronavirus](https://www.ucsf.edu/coronavirus), research guidance tab for more information).

Human Subjects-Related Research Visits: Additional Requirements

All research study personnel (faculty and staff) must comply with guidance regarding research participant screening for COVID-19 and research participant triage should a research participant be deemed at risk for COVID-19 infection during an in-person research visit screening. Please see [ucsf.edu/coronavirus](https://www.ucsf.edu/coronavirus) for guidance.

Principal investigators or their designee should contact study sponsors to notify them of this policy and make appropriate arrangements. UCSF is not contacting sponsors centrally at this time. An open letter to research sponsors and collaborating institutions is posted on the [ucsf.edu/coronavirus](https://www.ucsf.edu/coronavirus) microsite.

All sponsor visits for human subject-related research should be performed remotely or postponed. Any in-person monitor visits deemed essential to the health and/or well-being of the participants will require pre-approval. Please contact research@ucsf.edu for approval requests.

Revised Interim UCSF Policy on Human Subjects-Related Research Visits Algorithm

