University of California
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Human Research Protection Program

Institutional Review Board (IRB)
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RE: IRB Reporting Requirements for Protocol Deviations During the COVID-19 Public Health Emergency

Dear Principal Investigator,

This memo may be shared with research sponsors to describe the types of protocol deviations made in response to COVID-19 that do not require prior UCSF Institutional Review Board (IRB) approval.

If done for the purpose of adhering to the Revised Interim UCSF Policy on Human Subjects-Related Research Visits at San Francisco Campuses during COVID-19 Outbreak and eliminating apparent immediate hazards to the subject, changes such as (but not limited to) the examples below do not need to be approved by the UCSF IRB prior to implementation.[1] You should implement the change, log it in the study record, and update the IRB as follows:

If changes do not increase risks to subjects, notify the IRB at the time of the next necessary modification or continuing review. Examples:

- Incorporating screening questions to identify potential exposure to COVID-19.
- Adding links to reputable websites for information about COVID-19 (UCSF, CDC, etc.) to the study website.
- Postponing or cancelling non-essential study visits/procedures that do not impact participant safety.
- Changing visits that are not essential to the health and/or well-being of participants from in-person visits to remote/virtual visits.
- Moving from in-person to remote procedures for obtaining written consent and HIPAA authorization. Note: If your study has a requirement for signed consent, you must still collect signatures remotely.
- Pausing/suspending recruitment and enrollment.

If changes may increase risks to subjects, notify the IRB by submitting a Protocol Violation/Incident Report form within 10 business days of implementing the changes. Please note that the IRB recognizes that delayed reporting may occur during the COVID-19 outbreak. Examples:

- Elimination of safety-related procedures that can no longer be conducted because an in-person visit cannot occur, such as critical safety labs or a scan to monitor disease progression.
- Changing the timing or location of visits/procedures determined to be essential to the health and/or well-being of the participant, such as a significantly out of window safety lab, as determined by the PI.

Note: Modifications that **require prior IRB approval** include changes to eligibility criteria, changing from signed to verbal consent, and changes not related to the Interim Policy per standard IRB policy.

Please visit the IRB COVID-19 FAQ's & Resources page for more guidance about IRB submissions during this public health emergency.

Sincerely,

Edward Kuczynski, MA
Director, Human Research Protection Program

[1] 45 CFR 46.108 (a)(3)(iii) and 21 CFR 56.108(a)(4); FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency; OHRP Guidance on COVID-19 (April 8, 2020).