University of California
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Human Research Protection Program

Institutional Review Board (IRB)
Quality Improvement Unit (QIU)
Gamete, Embryo and Stem Cell Research Committee (GESCR)

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RE: IRB Reporting Requirements for Protocol Deviations during the COVID-19 Public Health Emergency

Dear Principal Investigator,

This letter may be shared with research sponsors to describe the types of protocol deviations made in response to the ongoing COVID-19 pandemic that do not require prior UCSF Institutional Review Board (IRB) approval. This is an update ***that contains important modifications to the initial*** May 8, 2020 memorandum.

If done for the purposes of adhering to the UCSF Office of Research Guidance for Onsite Clinical Research Activities and eliminating apparent immediate hazards to the participant, changes which do not increase risks to participants, 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 then notify the IRB at the time of the next necessary modification or continuing review submission.

Examples not requiring prior IRB approval:

- 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.

Federal Regulations permit changes to the approved protocol if the changes are necessary to immediately eliminate or reduce an apparent hazard to the safety of research participants or others. Such changes may be initiated without prior IRB approval. A report must be submitted to the IRB/HRPP within 10 working days of initiation on a protocol violation/incident report form.

[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).

Modifications that **require prior IRB approval** include any changes that may increase risks to subjects, such as (but not limited to) the following:

- Changes to eligibility criteria
- Omitting critical safety labs/procedures/visits, or performing them significantly out-of-window
- Changing from signed to verbal consent
- Changes not related to the Office of Research Guidance

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