

Addressing Questions Related to Changes to Human Subjects Research Made in Response to COVID-19

We understand that some changes to ongoing human research may be expected in response to the current COVID-19 epidemic. Our priority is to ensure the safety and welfare of our research subjects. Federal regulations allow for investigators to implement protocol changes where necessary to eliminate apparent immediate hazards to human subjects prior to IRB review and approval (21 CFR 56.108(a)(4)).

The following are situations in which the **IRB does not need to be notified**:

- Implementation of clinical screening procedures at healthcare facilities for all patient related visits including research visits.
- These procedures are not considered part of “IRB approved procedures” for individual protocols and would not require IRB reporting.
- An exception to this would be situations in which the investigator incorporates the data collected under these clinical procedures into their individual protocol (i.e. adding a research objective of analyzing the results of the clinical screening procedures based on subject demographics). Investigators are encouraged to contact the IRB prior to collecting and analyzing the data collected from COVID-19 clinical screening as part of their current IRB approved protocol. An IRB approved amendment would be required to prior to implementing these changes.

The following are situations in which the **IRB should be notified prior to implementing the change**:

- Except in the case of eliminating an immediate risk, investigators must submit a protocol amendment to the IRB prior to implementation of any changes to the protocol. Investigators are encouraged to contact the IRB prior to implementing broad plans to modify study visit schedules or conducting additional safety screening measures for all subjects. The IRB will prioritize amendments associated with the COVID-19 situation and will be able to quickly act to the review and approve these requests.
- In some cases, protocol changes may involve the investigator temporarily stopping subject recruitment or placing a temporary hold on all study procedures. Submission of a formal IRB amendment in these cases will not be required. These changes can be communicated to the IRB by sending an email to IRBMail@uthscsa.edu and including: the protocol number, PI Name, and date voluntary halt was initiated.

The following are situations in which the **IRB should be notified after the change has been implemented**:

- Research related visits being cancelled or modified to allow social distancing by decreasing the number of protocol-mandated in-person study visits at healthcare facilities (i.e. replacing face-to-face visits with home visits or telemedicine, allowing blood draws at remote or commercial laboratories).
- Investigational products/medications may be directly mailed to research participants who have been placed in isolation or quarantine because of suspected or known exposures.
- Conducting additional safety screening implemented by the investigator prior to in-person visits occurring to prevent research team member exposure to this highly communicable disease.
- The above measures may be implemented prior to IRB review and approval when necessary to eliminate apparent immediate hazards to the human subjects. 21 CFR 56.108(a)(4). Eliminating immediate hazards may include actions to reduce potential exposure to COVID-19, or to continue to provide medically necessary study care and medications to participants.
- Any protocol changes to eliminate an immediate hazard to subjects or others without ample time to receive prior IRB approval must be reported to the IRB within 7 days of being implemented as a prompt report (UPIRSO) using the [Prompt Report Form](#). Investigators are encouraged to contact the IRB for questions related to this reporting requirement.

Remember reporting to the IRB is independent of any reporting requirements which may be required by the investigators to the funding agency or sponsor for a protocol.

If you have any questions about UHealth SA IRB policy on changes to research or the acceleration of review for COVID-19 research, please reach out to the IRB at 210-567-8250, or email us: IRB@UTHSCSA.edu.