Information for our researchers in response to COVID-19

Our primary concern is the safety of our research participants and the research team members. We understand that the COVID-19 outbreak will affect the continuity and integrity of many research studies. We hope the following guidance is helpful in protecting our participants and staff and minimizing adverse impacts for research.

Please review the [CU Anschutz Medical Campus web page for the Latest Coronavirus Updates and Resources](https://anschutz.cu.edu/coronavirus/).

Changes to eliminate apparent immediate hazards to subjects

Federal regulations allow researchers to make changes to research to eliminate apparent immediate hazards to subjects without IRB approval. COMIRB policies are consistent with this, as are most other IRBs.

Examples of changes to eliminate immediate hazards to subjects in response to COVID-19 include, but are not limited to, cancelling non-essential study visits, conducting phone visits in lieu of in-person visits, conducting additional screening of current and potential research subjects prior to in-person visits, and temporarily suspending enrollment.

Also, any new screening procedures or other policies implemented by the campus or any of our affiliate health care systems to in response to COVID-19 are not policies or procedures that require IRB approval and do not require COMIRB approval.

**Deviations from the Protocol:** If researchers deviate from their approved protocol to eliminate apparent immediate hazards to subjects, that does not require COMIRB approval and does not fall under COMIRB 5-day reporting requirements assuming the deviations are considered temporary and are relatively minor. Deviations that are necessary to comply with new policies issued by the University, our affiliate health systems or public health directives also do not require COMIRB approval and do not fall under COMIRB 5-day reporting requirements.

Researchers should document these deviations and submit a single summary report to COMIRB at time of Continuing Review. For research that does not require Continuing Review, submit the summary report with a UAP submission at a reasonable point in the future (e.g., around the anniversary date of your approval or after university operations return to normal).

If deviations from the protocol are necessary which might result in potential new risks to subjects, these would need to be reported to COMIRB within 5 days. Examples include
interruption of study drug prescriptions, or cancellations of study visits critical for subject safety.

Changes to the Protocol: If researchers change their protocol (e.g., to make deviations permanent) to eliminate apparent immediate hazards to subjects, they can do so without prior IRB approval but should report the protocol change to COMIRB within 5 days and submit an amendment for review and approval of the revised protocol. COMIRB will review and approve those amendments quickly but since prior approval is not required, researchers are not out of compliance in the interim.

Limitations:

The conduct of research must otherwise remain in compliance with human subjects regulations, COMIRB policies and the terms of COMIRB’s approval. The following are some examples where prior IRB approval should be obtained.

Informed Consent: If signed consent is required for research participation, changing to verbal consent would not be an acceptable deviation or protocol change without IRB approval. If circumstances make obtaining signed consent impractical, researchers should consider slowing or suspending enrollment. Contact COMIRB if you wish to discuss whether conducting a consent process over the phone is feasible. COMIRB approval would be required before implementing the new consent procedure.

Visit Locations: Carefully consider any changes before implementing them. For example, moving study visits from a clinic to the subject’s home in the current environment would need to involve new screening procedures for the subjects, the household members, and for your research staff. Such a change may also require additional staff training and protective gear, which is in very short supply at this time. Moving study visits from clinical locations to campus non-clinical locations is not advisable. Contact COMIRB if you wish to discuss whether some study procedures could be moved to new locations. COMIRB approval would be required before implementing these changes to make sure risks are minimized.

External IRB: If your research is under the purview of an external IRB, there may be some slight differences in IRB policies but these would not impede a researcher’s responsibility to make immediate changes eliminate apparent immediate hazards to subjects.

New Data and New Objectives: If researchers wish to collect additional data for their studies or add research objectives to approved research in response to COVID-19, an amendment should be submitted to COMIRB for prior approval.
Requirements from Sponsors: If sponsors issue updated protocols, or require evidence of IRB approval of changes, researchers should submit an amendment to COMIRB as usual.

Unanticipated Problems:

Considering the broad public awareness of COVID-19, COMIRB would not consider the infection of a research subject or research staff member to be an unexpected event which required reporting to the IRB within 5 days. Researchers must remain compliant with other requirements to report adverse events to research sponsors and/or the FDA.

Contact COMIRB:

Contact us at COMIRB@ucdenver.edu for any questions or assistance. COMIRB remains operational while working remotely. We will be conducting IRB meetings virtually and reviewing research as usual. We are readily available to answer any questions, to consult, and to provide assistance. We are happy to set up conference calls and/or virtual meetings.