Information for our researchers in response to COVID-19

Our primary concern is the safety of our research participants and the research team members. For general updates on research, please stay up-to-date with University announcements:

CORONAVIRUS (COVID-19) UPDATES AND RESOURCES

The following Guidance pertains to human subjects research overseen by COMIRB.

COMIRB

COMIRB remains fully operational while working remotely. We are available to answer any questions and provide assistance about your human subjects research. Contact us at COMIRB@ucdenver.edu.

Campus & Affiliate Approvals

IRB approval alone is not sufficient for research to proceed. The COVID-19 pandemic has necessitated a site approval process to ensure necessary resources are in place to support the conduct of research in compliance with University and affiliate screening, space, distancing and PPE requirements.

Review the Coronavirus Research Guidance for the latest information.

Amendments

Researchers who makes changes to their approved protocols to get studies re-started must submit amendments for COMIRB review and approval. This includes changes to recruitment methods, informed consent processes, and changes to the protocol to minimize in-person interactions with subjects.

Amendments may be submitted for COMIRB before or after reviews by University and affiliate site committees responsible for ramping up research.

University policies need not be reflected in individual research protocols. COMIRB does not need to review or approve COVID-19 policies and procedures implemented by the University, our affiliates, or specific site plans on campus approved by the University.

Changes to eliminate apparent immediate hazards to subjects

Federal regulations and COMIRB policies allow researchers to make changes to eliminate apparent immediate hazards to subjects without IRB approval. If the state, county or University implements new restrictions to mitigate a public health emergency, researchers are obligated to respond but those actions do not need to be reported to or approved by COMIRB.

Protocol deviations: 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. Researchers should document these deviations in their research records.

Protocol reactivation: As discussed above, amending the protocol to reactivate the study does require COMIRB approval.

Options for Obtaining Informed Consent:

Changes to the approved consent process require IRB review and approval. The following guidance documents discuss the use of eConsent and the process for obtaining informed consent by phone and teleconference. Contact COMIRB if you wish to discuss alternate plans for obtaining informed consent.

- Electronic Consent (eConsent): Guidance for Human Subjects Research
- Obtaining Informed Consent by Phone or Videoconference: Guidance for Human Subjects Research

Unanticipated Problems:

If a research subject acquires SARS-CoV-2 infection and is not directly related to the research, it does not require reporting to COMIRB, within 5 days or at time of continuing review. An example of when SARS-CoV-2 infection would need to be reported is if a research subject becomes infected specifically because a research team did not follow if campus policies and space plans for COVID-19.

If a research staff member acquires SARS-CoV-2 infection, that is a matter of occupational health and does not need to be reported to COMIRB. For more information see instructions on the Coronavirus webpage under Report COVID-19 Exposure & Testing.

Sponsors, External IRBs, and the FDA

This guidance applies to research overseen by COMIRB.

If sponsors issue updated protocols, or require evidence of IRB approval of changes, researchers should submit an amendment to COMIRB as usual.

Researchers must remain compliant with requirements to report adverse events to research sponsors and/or the FDA.

External IRBs will have their own requirements related to COVID-19. If your research is overseen by an external IRB, check with that IRB for their requirements.

FAQ's

The study site is requiring all research subjects be tested for SARS-CoV-2 before the study visit. Do I need COMIRB approval for this testing?

It depends. If the SARS-CoV-2 testing is charged to the subject as a clinical test, COMIRB approval is not needed. If the cost of the SARS-CoV-2 testing is covered by research funding, the testing is a research activity and should be described in the protocol and consent form, and requires COMIRB approval.

Can I move study visits to the subjects' homes?

Moving the location of a study visit from campus to a subject's home in response to COVID-19 restrictions is not advisable. COMIRB and site approval would be required before implementing such changes to make sure risks to research staff, subjects and all household members are minimized.