# Frequently Asked Questions

1. ***What are examples of studies that must be paused?***

Some examples of studies that must be paused are:

- In-person interactions/Focus Groups
- Visits with participants or in-person meetings regardless of the location
- Public observations of participants within close quarters (not following social distance as recommended by the CDC)

2. ***Are the UTRGV Office of Research Compliance (ORC) and IRB operating as usual?***

The ORC and IRB are fully functional and operating as usual. We expect this to continue even if the UTRGV suspends operations for contagion control purposes. Most ORC staff are working remotely, and all IRB meetings are being held remotely via Zoom. All ORC email addresses continue to be monitored with the same or greater frequency. As always, the staff at ORC is available to answer your questions via email (best). There may be a possibility that phone calls are not answered immediately and instead re-directed to ORC staff email addresses. Please leave a message with clear contact information. This will allow the staff to receive your message in their email inbox and respond back to you.

3. ***Can I continue to interact with my research participants?***

In-person research interactions/interventions should be postponed during this time unless the interaction/intervention is essential to the health and well-being of the participant (medical related studies that include treatment to participants). Research interactions/interventions for both essential and non-essential studies should be performed remotely (e.g., by phone, Skype, Zoom, mail delivery of study medications, or other means) whenever possible. Non-essential studies that require in-person interactions/interventions should be postponed until further notice.

4. ***What studies can continue during the pause?***

Approved studies or research procedures that do not involve any in-person interaction/intervention with participants, for example:

- Web surveys
- Telephone
- Audio-video Conferencing
- Mail surveys
- Self-collection of Biospecimens by the Subject (e.g., a cheek swab or spit kit) mailed to the lab
- Data analysis, either secondary use projects or data analysis activities on other projects

5. ***Can I modify in-person participant interactions/interventions to be conducted remotely?***

Yes, however you will need to submit a request for modification/amendment to the IRB prior to implementing the change, unless such change is necessary to eliminate apparent immediate hazards to the subjects as described in federal regulations. Please refer to *What changes require an amendment? Below* for details.

Amend your study to convert in-person data collection or other procedure to a remote method (web surveys, telephone, audio/video conferencing, mail surveys, self-collection of biospecimens by the subjects). Include "COVID" in the amendment description to alert the IRB staff to the need for priority review. However, please note that due to the volume of requests it may not be possible for the IRB to approve the modifications within the targeted turnaround time.

In the Amendment Tab, describe the need for the change in terms of minimizing risk under the COVID-19 emergency. Edit the IRB application in Tick@Lab to reflect the proposed changes in the Project Information, Inform Consent, and Recruitment tabs, including any changes to the method for obtaining informed consent or documents. Consider whether the proposed change may impact potential risks to the participants, particularly for projects that collect sensitive and identifiable information, such as the introduction of additional informational risks from video recording an interview, or privacy risks of interviewing a teenager at home rather than at a clinic. Remember that you must use data collection and management tools that are approved by the institution and appropriate for the level of sensitivity of your data, such as Qualtrics, Zoom and Skype.

6. ***Can new participants be enrolled?***

New participant enrollment and any ongoing in-person participant interactions/interventions must pause, unless it satisfies the criteria on number 4 of the Interim Policy.

7. ***What about effects on study enrollment goals?***

Studies may not be able to meet their participant enrollment goals because of COVID-19-related issues. This should be described in a study's Continuing Review application, unless your study is exempt from the Continuing Review requirement. Please refer to the approval or determination letter for your study to confirm whether you are required to submit a Continuation Review. The IRB will be mindful of the circumstances when conducting its review.

8. ***What is the effect of the current situations on studies that have been submitted to the IRB, but not yet approved?***

The IRB will continue to review and approve submissions. For studies that are approvable but involve in-person interactions/interventions with study subjects and do not have the potential for direct benefit to participants (as determined by the IRB), the IRB will approve the study but explicitly note that enrollment cannot start until the pause in the in-person research activities is lifted by the Institution.

9. ***What types of additional disruptions to research may occur in the future?***

The Investigator of studies that are not paused should anticipate staffing shortages due to research personnel being unable to work in person because of quarantine, isolation, care of children due to school closings, travel restrictions, etc. Additional disruptions could involve being unable to obtain study drugs or protective personal equipment or limits on the availability of UTRGV services and space.

10. ***How do participants need to be notified of in-person interaction/intervention cancellations or changes?***

When a study in-person interactions/interventions need to be cancelled or changed to a phone call or on-line encounter, the subject should be told the reason and that they will be contacted again when the visit can be rescheduled. This notice to the subject does not require IRB approval.

***11. What changes require an Amendment?***

Amendment requests are NOT REQUIRED if you are halting, rescheduling, or delaying study enrollment/procedures, UNLESS those actions are at the request of the funding agency, study sponsor, or data & safety monitoring group.

Amendment requests are REQUIRED, and IRB approval must be obtained before you change study procedures (including consenting processes) for new or existing participants.

An investigator may implement changes to approved research prior to obtaining IRB approval if such changes are necessary to eliminate apparent immediate hazards to the subjects as provided for in federal regulations (45 CFR 46.108(a)(3)(iii) under the 2018 Rule and 45 CFR 46.103(b)(4)(iii) under the pre-2018 Rule). In such events, the investigator must promptly notify the IRB via the IRB Protocol Deviation/Possible Non-Compliance Report Form and submit the corresponding modification/amendment via Tick@Lab.

***12. Will submissions to the IRB of COVID-19 research be prioritized?***

Yes, COVID-19 and other research studies applications will be prioritized as follows:

1. Any new studies regarding COVID 19 (and Quality Improvement determinations on COVID-19)
2. Continuation Reviews for ongoing studies, not involving face-to-face interactions to avoid their expiration.
3. Amendments to ongoing studies that need to change interaction procedures based on COVID-19 precautions.
4. Amendments to COVID-19 research.
5. New studies, Continuation Reviews and other Amendments not involving face-to-face interactions
6. New studies, Continuation Reviews and other Amendments involving face-to-face interactions.

***13. What should I do if my study is sponsored?***

You should work with your research team and study sponsor to evaluate impacted studies and develop a plan appropriate to their research procedures, including financial considerations. Please email the Office of Sponsored Programs for more information about how to contact your sponsor and considerations related to your funded project.