UTPB Institutional Review Board

**Risk Mitigation Plan[[1]](#footnote-1)**

Researchers wishing to conduct in person research during the COVID-19 pandemic should consider the general recommendations below and then complete the questions that follow. Please attach this document to your IRB application. All studies that implement data collection or recruitment procedures that require face-to-face interaction require full board approval.

General Recommendations

1. All persons should wear face masks, and maintain physical distancing of 6 feet or more. Provide floor or seat markings where appropriate to indicate distance. When physical distancing isn’t possible use face shield (in addition to masks) or barriers between people.
2. Frequently wash hands or use alcohol-based hand sanitizer.
3. Investigators should disinfect all surfaces, equipment, and other materials (e.g., pens) in shared spaces touched by researchers or between each interaction (if participants are seen in the same room in succession).
4. Reduce the number of personnel or researchers present in the same room (or place) at the same time to the minimum necessary.
5. Study personnel and research participants should be screened prior to the scheduled in-person interaction by verbally confirming that they have not experienced COVID-19 symptoms or have not been diagnosed within the past fourteen days, and have not been in close contact with a person who is lab-confirmed to have COVID-19. Researchers may take participants’ temperature using a contactless gauge prior to the interaction. Inform participants of the safety protocol prior to their scheduled interaction.
6. Maintain logs of in person interactions and contact information.
7. Engage in healthy hygiene behaviors during the interaction.
8. If meeting at a specific location, provide instructions for participants about how to approach the site to avoid people gathering.
9. Modify lab or location layouts to ensure physical distancing.
10. Modify exclusion criteria to exclude participants [who need extra precautions or are at higher risk for severe illness.](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html)
11. Consider whether face-to-face activities can be postponed or substituted by other means.

In addition to the general recommendations, the full IRB committee will consider time sensitive and career advancing research activities in their consideration of benefits. This includes

* Graduate students completing master’s theses, tenure and tenure-track faculty, and undergraduate research conducted with the aim of publication
* Researchers with grant or other funding deadlines

**Mitigation Plan for Face-To-Face Human Subjects Research**

Researchers will be required to complete the form below detailing how they propose to minimize risk for research requiring face-to-face procedures. Please attach this form to your IRB application or update form for existing research.

1. Please justify the benefits of your study in light of the increased risk to research participants during this pandemic.
2. Explain why the study visits cannot be postponed or completed remotely until restrictions are lifted.
3. Describe the potential harm to subject or value of data lost if face-to-face visits are to cease or be delayed until restrictions are lifted.
4. Describe how you will incorporate additional COVID-19 screening procedures for research participants or study personnel. Detail how these procedures will be completed prior to recruitment and enrollment of research particpants.
5. Explain how you will regularly communicate with the research team, sponsor, study sites, and research participants to ensure safety and compliance.
6. Please explain how you will adhere to physical distancing guidelines and how you will provide personal protective equipment (PPE) and handwashing supplies to your research personnel and research participants.
7. Describe procedures for daily decontamination of lab, clinic, or research-space including the cleaning of all work benches, door handles & lock keypads, keyboards/mice/desks for shared equipment computers, telephones, printer, cameras, microscopes, control panels, etc.
8. If applicable, please describe the plan to implement a staff rotation that maintains restricted use of the research facility to a limited number of persons at any given time. Describe how you will handle a reduction in study staff if needed.
9. If applicable, please explain if it is necessary to enroll persons at higher risk of severe illness from COVID-19 or whether these individuals should be excluded from the research at this time.
10. Explain what will happen if you become aware of a research staff member or research participant that has developed COVID-19 (e.g., rescheduling visits, study withdrawal, etc.) and describe how you will notify others that may have been exposed because of their participation.

1. This document was adapted from the form used by the IRB at UT Rio Grande Valley. [↑](#footnote-ref-1)