

# Extended: Actions for Human Subject Research during COVID-19 Outbreak

## Notice to Researchers

The University of Texas Rio Grande Valley has extended the Interim Policy on Human Subjects Research based on the rapidly evolving circumstances regarding COVID-19, and the University's focus on social distancing and the health and well-being of the community. **The Interim Policy has been extended to May 30, 2020.** At that time, UTRGV will reevaluate this decision on an ongoing basis, while sharing additional updates or modifications as more information becomes available.

1. Except as noted on number 3 below, any research procedures that involve in-person interactions/interventions with participants must be immediately paused. Research procedures involving no direct in-person interaction/intervention with participants may continue (e.g. data analysis, online surveys, telephone interviews). This applies to both exempt and non-exempt research studies.
2. During this pause, Investigators should consider whether it is feasible to modify their in-person research procedures to use alternative methods for data gathering (e.g. telephone, online, Zoom, Skype, or other means). If alternative methods to in-person participation are feasible and desired, Investigators should submit a modification/amendment to the study and secure IRB approval prior to the implementation of changes. Keep in mind that it is possible for the Office of Research Compliance and the IRB to experience a high volume of requests during this time.

If the study cannot be conducted without the in-person participant interaction/intervention, then new participant enrollment and any ongoing in-person participant interactions/interventions must be immediately paused.

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 participants 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 cases, the Principal 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 as soon as it is feasible.

3. Exception to the in-person interaction/intervention pause:
  1. Projects in which a pause of the in-person interaction/intervention will have the potential for direct harm to participants. These studies may continue subject to the following: any in-person participant interactions/interventions must be minimized and alternatives for in-person data collection should be considered if feasible. Investigators should consider their ability to continue with the research based on current and future staffing resources, facility restrictions, and any other factors specific to the study. Investigators should also consider the rapidly evolving environment and plan for research continuity, such as planning for facility restrictions or closures, illness or absence of research team, drug or device shortage, or lack of required personal protective equipment. New participants should not be enrolled without prior permission from the IRB.
  2. Projects actively studying influenza and COVID-19 in collaboration with the CDC or the NIH.

3. Projects where the in-person interaction/intervention with participants is conducted by international partners or by UTRGV researchers in another country in compliance with governmental and UTRGV's COVID-19 restrictions. Investigators must consult with the country's local IRB/ethics board regarding the continuation of the research. If the local IRB determines that it is safe for the work to continue, then the project may proceed. Principal Investigators must provide documentation of this determination to the UTRGV IRB via [irb@utrgv.edu](mailto:irb@utrgv.edu) prior to the continuation of the research. Modified procedures to eliminate or minimize the need for in-person contact are recommended and the investigator must continue to monitor the changing COVID-19 situation.
4. Investigators and their research personnel should work with their study sponsors and others to evaluate impacted studies and develop a plan appropriate to their research procedures, including financial considerations. For questions on how to contact a study sponsor and other considerations related to sponsored projects, please email the [Office of Sponsored Programs](#).

A list of [Frequently Asked Questions \(FAQs\)](#) [is] posted on the IRB webpage. If there are other questions or you need assistance, please email the [Office of Research Compliance](#).

Thank you for your continued support and assistance in protecting human subjects research and research personnel.

Parwinder S. Grewal, Ph.D.  
Executive Vice President  
Research, Graduate Studies, and New Program Development