

UTRGV Reiterates Pause on Research Procedures with Human Subjects; Pause to Apply to Studies Approved to Continue under Risk Mitigations Plans

UTRGV is reiterating the pause on all research procedures with human participants, with limited exceptions as indicated below. This policy applies to studies (Exempt, Expedited, Full Board, Reliance) where UTRGV is the lead institution conducting research or where UTRGV IRB provides oversight.

Exceptions to the Pause:

1. Studies in which the research procedures do not involve direct in-person interaction/intervention with participants (e.g., data analysis, online surveys, telephone interviews).
2. Studies in which the pause to the in-person interaction/intervention will have the potential for direct harm to participants. These studies may continue provided the in-person contact is minimized and alternatives for in-person data collection have been 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.
3. Projects actively studying influenza and COVID-19.
4. 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 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.

What's new? Research procedures of studies that were approved to continue under Risk Mitigation Plans, as per the previous interim policy (published on June 1st, 2020), are now to be paused immediately. No new Risk Mitigation Plans will be approved until further notice.

This decision is in response to the alarming number of active coronavirus cases in our community and State and the fact that hospitals have reached full capacity in the Rio Grande Valley. We apologize for the multiple communications on this matter. This is a fluid situation and our priority continues to be the safety of individuals who participate in our research studies as well as our students, employees, and the community we serve.

For questions please contact the Office of Research Compliance at researchcompliance@utrgv.edu.

For your convenience, below is a summary of the Interim Policies that have been published related to Human Subjects Research (in chronological order) during the pandemic.

Interim Policies on Human Subjects Research during the COVID-19 Outbreak

March 21, 2020:

UTRGV Announces Actions for Human Subjects Research during COVID-19 Outbreak. This Interim Policy paused all research procedures with human participants, with limited exceptions, through April 15, 2020.

April 15, 2020:

UTRGV Extends the Interim Policy on Actions for Human Subjects Research during COVID-19 Outbreak. UTRGV extended the pause on research procedures through May 30, 2020.

May 30, 2020 (Published on June 1, 2020):

UTRGV Announces New Interim Policy for the Continuation of Human Subjects Research with In-Person Component through the COVID-19 Outbreak. This new Interim Policy allowed for the continuation of studies with in-person interventions/interactions that were paused under the March 21, 2020 policy, provided IRB approved a Risk Mitigation Plan.

August 12, 2020:

UTRGV Reiterates Pause on Research Procedures with Human Subjects; Pause to Apply to Studies Approved to Continue under Risk Mitigations Plans. This Policy restated the pause of all research procedures with human participants, with limited exceptions, until further notice. The pause will also apply to projects that were approved to continue by the IRB under Risk Mitigation Plans in accordance to the previous interim policy.