INTERIM POLICY FOR THE CONTINUATION OF HUMAN SUBJECTS RESEARCH WITH IN-PERSON COMPONENT THROUGH THE COVID-19 OUTBREAK

On March 21, 2020, UTRGV issued an interim policy to temporarily pause all research procedures with human participants involving in-person interactions/interventions under IRB oversight (with limited exception) in response to the public emergency resulting from the COVID-19 outbreak. The interim policy was extended through May 30, 2020.

Today, UTRGV is issuing a new interim policy to support the continuation of human subjects’ studies that were paused as a result of the previous policy. This new interim policy, which will be implemented immediately, is intended to remain in effect for the duration of the public health emergency related to COVID-19 as declared by the Secretary of Health and Human Services (HHS).

UTRGV recognizes that the current public health emergency has affected the conduct of the research involving human subjects and impacted the risk/benefit analysis for participants of studies with research procedures requiring an in-person interaction/intervention.

Consistent with FDA and OHRP guidance and recommendations, UTRGV supports the continuation of human subjects’ research by minimizing risks and ensuring the safety of research participants. This policy applies to approved studies regardless of their level of review (Exempt, Expedited, Full Board) and where UTRGV’s IRB is responsible for providing oversight to the research. Investigators wishing to continue their paused studies must comply with the following conditions:

• Develop a risk mitigation plan specific to the study that describes the measures that will be implemented to reduce the risk of COVID-19 exposure through the in-person procedures.
• Mitigation plans will be submitted for the consideration and approval by an Emergency IRB specifically impaneled to evaluate human subjects’ studies in an expeditious manner during emergency situations. This panel will evaluate risk mitigation plans with the assistance of consultants, as deemed necessary. This Emergency IRB will meet as often as needed to ensure prompt determinations on the adequacy of the mitigating measures proposed. For information on how to submit the risk mitigations plans to the Emergency IRB panel, please refer to this document.
• Obtain approval of the study risk mitigation plan by the Emergency IRB prior to resuming the in-person interaction/intervention activities.

For collaborative studies in which the UTRGV IRB is relying on another entity’s IRB for oversight of the research, investigators must:

• Request a statement from the overseeing IRB certifying that risk mitigating measures have been implemented consistent with Centers for Disease Controls’ (CDC) recommendations and state/local government restrictions
• Submit the statements to irb@utrgv.edu and wait for acknowledgement by the IRB prior to resuming in-person study activities.

For a list of recommended risk mitigating measures and Frequently Asked Questions, please refer to the IRB webpage. For questions about PPE or sanitizing supplies and procedures for on-campus research, please email the Office of Environmental Health, Safety & Risk Management. For other questions or assistance, please email the Office of Research Compliance.
Thank you for your continued support in protecting human subjects and advancing UTRGV research during these unprecedented times.

Division of Research, Graduate Studies & New Program Development