FAQ's – Resuming Human Subject Research with an In-Person Component

1. **When can I resume in-person interactions/interventions with research participants?**

   An interim policy was issued to allow continuation of human subjects research activities with an in-person component on May 30, 2020.

2. **How long will this new interim policy last?**

   There is no definitive end date for this interim policy. This interim policy will remain active until the Department of Health and Human Services (DHHS) declare an end to the pandemic. The Office of Research Compliance will communicate any changes in a timely manner to allow investigators plan accordingly.

3. **What do I need to do to continue with in-person study-related activities?**

   Investigators are required to submit a Risk Mitigation Plan that details how in-person human subject's research will be resumed during the COVID-19 pandemic. This plan must describe in detail the measures that will be implemented to reduce risk to research participants. Once approved it must be distributed to the research personnel.

4. **How can I submit my Risk Mitigation Plan?**

   A Risk Mitigation Plan questionnaire will be available to all researchers that want to restart their projects. This questionnaire should be submitted to the IRB as an Amendment to your approved application in Tick@Lab. Details on how to submit the Risk Mitigation Plan can be found on the guide found here.

5. **How long will it take the IRB to approve the Risk Mitigation Plan?**

   UTRGV has constituted an Emergency IRB Panel to review and approve Risk Mitigation Plans in an expedited manner. This panel will meet as often as necessary and outside scheduled monthly meetings to accomplish this task.

6. **Do new projects need to have a Risk Mitigation Plan?**

   Yes, even though it is not required to use the questionnaire, a mitigation plan should be described under the Project Information tab on the Tick@lab application. The plan will be taken into consideration by the IRB when evaluating the risk to the subject vs. the benefit of the study.

7. **What if my project was originally approved with the in-person component, and later amended to conduct research activities through other means, can I go back to in-person activities?**

   Yes; however, you must submit a request for an Amendment describing that you want to revert to in-person interactions along with the Risk Mitigation Plan.

8. What if my pending project has an in-person component?

- The IRB Coordinators will be reaching out to you to provide you an opportunity to attach the Risk Mitigation Plan to your pending application
- If you decide not to include a Risk Mitigation Plan, the IRB will approve the study without it. However, you will not be able to engage in in-person activities until a Risk Mitigation Plan is approved via an amendment to your study.

9. After the IRB approves the Risk Mitigation Plan, what other measures should I consider for minimizing exposure during in-person interactions?

Please follow UTRGV and Centers for Disease Control and Prevention (CDC) Guidelines on COVID-19.

10. What can be considered as risk mitigating activities and/or screening questions?

Please refer to the list of potential risk mitigating measures.

11. My research is conducted in person in a medical setting. Do I need to submit a Risk Mitigation Plan?

Yes, despite the guidelines and procedures established on the location, the mitigation plan is specific for the research study and applicable to the research team and research participants. Also, the Risk Mitigation Plan is to be maintained with the research records and it should be made available upon request to the IRB, compliance officers, and/or sponsors (if applicable).

12. What if my project was approved by an external IRB?

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 Control and Prevention's (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.

13. What if I do not feel comfortable resuming the study-related procedures? Am I obligated to continue?

No, if research participants are not harmed with the pause. You can resume your research activities when you feel ready to continue.

14. Can I also submit other study amendments along with the Risk Mitigation Plan?

Yes, they can be submitted simultaneously using the same guidance.

15. Will I need to provide face masks to study personnel and subjects?

Yes; please visit the UTRGV Environmental Health, Safety & Risk Management webpage for guidelines on how to request disposable face masks and sanitizing materials.