

Review of In-Person Research with Human Subjects When TU Occupancy is Limited

The following guidelines should assist with the preparation and review of applications for research involving human subjects during periods when COVID-19 restrictions are in place. It is important to recognize that each study is unique. Therefore, there may be instances where flexibility is required when applying this guidance. Further, PIs will need to adapt to changing restrictions that may be in place, such as shutting down work if stay-at-home orders are introduced or adopting less stringent social distancing requirements if restrictions are loosened.

Requirements

- 1) To minimize risk to human subjects, all research should be conducted remotely whenever possible.
- 2) Approval Process for Human Subjects Research that Requires In-Person Interaction
 - a) Protocol Preparation/Amendment
 - i) PIs must obtain approval to Conduct in-Person Human Subjects Research from their Department Chair, College Dean, and the Provost using the Return to Research Planning Form (RTRF). If the research is being conducted off-campus, the PI must adhere to all TU requirements for approval of this work. PIs who are not affiliated with TU must obtain approval to visit the campus. The Office of Sponsored Programs & Research will advise an unaffiliated PI on this process.
 - ii) PIs must submit a new application or amend an existing application prior to conducting in-person research. A review may be initiated, but final approval of the study will not be provided until the IRB receives the approved RTRF.
 - iii) PIs must outline a consent process to be used until COVID restrictions are lifted. In order to minimize contact with individuals who may be COVID positive or ultimately decide not to participate in a study, PIs must obtain consent remotely prior to gathering data from any human subjects research participant until TU returns to 100% occupancy. Consent will need to be repeated when participants arrive at the study site.
 - iv) If PIs cannot transition consent to a remote process, a justification for this must be included in the protocol/amendment.
 - v) The consent process will include a University-developed document that outlines risks specific to participating in research when COVID-19 restrictions are in place. This document must be used while TU remains at less than full occupancy.
 - vi) Projects should adhere to TU social distancing standards for the location where the research will be conducted. PIs must refer to procedures outlined in the RTRF.
 - vii) If the research project does not adhere to TU social distancing standards, the PI must outline the procedures and the protections that will be utilized during the time period when social distancing restrictions are in place. In such cases, the researcher must clearly explain the risk/benefit ratio of the research to be conducted and in particular make the case that the risk of in-person contact is justified by the potential benefits of the research.
 - viii) Participants must be provided appointment times for the conduct of the research. PIs must require participants to complete and return the Screening Questionnaire to the PI on the day prior to their scheduled appointment on campus. PIs must review the form to ensure it is appropriate for the participant to come to campus. The form must be repeated in person as the first activity of their on-campus visit. This form must be included with your

amendment or new application materials and be approved by the IRB before screening can commence.

ix) Research that will not occur on the TU campus must adhere to the following additional requirements:

- (1) In the event that PIs plan to conduct the research off campus (e.g. schools, community partner locations, etc.), they must obtain site approval from the organization/facility where the research will be conducted. Documentation that site approval has been obtained must be provided with the application/amendment.
- (2) PIs must adhere to the minimum standards that these organizations require for conducting research when COVID-19 restrictions are in place. The site requirements (maximum room occupancy, face mask requirements, etc.) should be attached to the application.
- (3) If the organization's requirements are less stringent than Towson University's, the PI must explain how the welfare of participants will be upheld in the off-campus environment.
- (4) The consent process must include a statement of risk specific to off-campus work alerting participants that TU does not have oversight of the location and does not oversee the site's cleaning, access and space use. The consent form should include a link or documentation on the site's procedures related to COVID-19.

b) Protocol Review

- i) For ongoing projects, when (iii) and (vi) above apply, the project may qualify for accelerated approval.
- ii) For all other projects, the IRB will review the project through its standard procedures. The IRB may assign two reviewers to these projects.
- iii) The IRB may choose to defer approval of projects that offer high risk to participants in the pandemic environment if the project offers no benefits to participants until the risk to the participants is mitigated.