

Towson University
Procedures for Return to Campus for In-Person Human Subjects Research

Overview of return to research for human subjects research

This document outlines the procedures to be followed to return to in-person research with human subjects. It focuses on the environmental accommodations as well as research staff training and behavior that must be in place and documented during periods when Towson University (TU) is at less than 100% occupancy. A separate document covers considerations for working with human participants that will be helpful to Principal Investigators (PIs) who are preparing applications or amendments for IRB approval.

A primary question that should guide research with human subjects when TU is not at full occupancy is: Must this study be done in person?

While there may be some instances wherein research requires in-person contact, these situations should be minimized to the extent possible. A two-step process will be required for such research to be approved. First, it must be approved by the PI's Department Chair, College Dean, and the Provost. Then an amendment or new application must be approved by the Institutional Review Board (IRB). In such cases, taking measures to ensure the protection of human subjects and research staff is critical to approval for in-person research to take place.

Covered research may qualify for IRB review through its accelerated, standard, or full Board review process. Some of this work may include brief and, in rare cases, prolonged periods of time in close physical proximity to others. Examples include:

- Research involving the use of equipment
- Research involving clinical/practical assessment
- Interviews or focus groups that can only be conducted in person

Note: PI's will be expected to provide a compelling justification that the research must be carried out now and that the potential risk associated with close contact is outweighed by the potential benefit to participants.

Step 1 Preparedness (includes review and approval of PI plans by the Department Chair, College Dean and Provost. It articulates preparatory steps prior to reentry of personnel into lab for research purposes). This step is a prerequisite for IRB approval.

- 1) Faculty PIs and Faculty Sponsors (who oversee student projects) must complete the Return to Research Planning Form (RTRF) to Conduct in-Person Human Subjects Research. This form requests information on the project to be conducted and steps that PIs will take to minimize health risks from COVID-19 among research staff and participants. The form is also used to request Personal Protective Equipment.
 - a. The completed form should be submitted to the Department Chair who, upon approval, will send it to the College Dean who, upon approval, will forward it to the Provost for final review and approval. The approved form must be submitted to the IRB as part of an application for all new studies and amendments to existing projects that involve in-person interaction with human subjects. Once the RTRF is approved, the PI can begin training personnel for work with human subjects, however, no interaction with human subjects may occur until the IRB also grants approval. The IRB may begin to review a project but will not grant final approval until documentation is received demonstrating approval by the Chair, Dean and Provost of the Return to Research plans.

- 2) PIs must document that all research personnel have watched the following training prior to participating in research activities (* required; others recommended):
 - a. *CITI Training including COVID-19 modules
<https://www.towson.edu/academics/research/sponsored/comply/irb/training.html>
 - b. Handwashing
(2:00): https://www.youtube.com/watch?time_continue=4&v=d914EnpU4Fo&feature=emb_title
 - c. Donning (4:15): <https://www.youtube.com/watch?v=H4jQUBAIBrI>
 - d. Doffing (3:26): <https://www.youtube.com/watch?v=PQxOc13DxvQ>

Step 2: Preparing for In-Person Research to Begin

- 1) The PI must adhere to CDC, State, Local, and TU guidance adapting the measures outlined in the RTRF as such requirements change in response to improving or deteriorating conditions.
- 2) All lab personnel must adhere to TU testing and daily monitoring requirements.
- 3) If the research will be conducted off-campus and students are involved, all students must complete a statement of risk form prior to any off-campus work.
- 4) The PI must ensure that all personnel are trained to implement the procedures elaborated in the RTRF including but not limited to maintaining the research lab, adhering to social distancing and PPE requirements, both in the lab and in common spaces, screening of all participants, and cleaning of the lab space after interaction with each participant and at the end of the day.

Step 3: Beginning In-Person Research after IRB approval has been obtained

- 1) The PI should coordinate with the Chair, Dean, or staff, as appropriate, to ensure that lab space is scheduled to minimize overlap. Participants must be given appointments to limit the number of people gathering outside the building. The PI should inform participants that they should expect to line up at the exterior of the building. If the participants are visitors, they should expect to be escorted to the research site at the designated time.
- 2) Researchers should do a dry run of the procedures prior to participant arrival to ensure that the new procedures work smoothly.
- 3) All human subjects must complete the Screening Questionnaire and Consent forms/ waiver documents remotely. These must be completed and submitted to the research team at least 24 hours prior to the subject's arrival on campus. Upon arrival, in person consent must be obtained, however, this can be obtained verbally.
- 5) Faculty and student researchers must arrive at least 15 minutes prior to the start of the lab to ensure that they are not entering at the same time as the participants.
- 6) Face coverings or masks that **cover the nose and mouth** will be worn by faculty, students and participants at all times except when eating unless the approved IRB protocol modifies this requirement.
- 7) When participants arrive on campus, they must be screened again. This screening must be signed by the research staff member and be maintained on file (see attached form).

General Requirements for Lab Personnel

The following information will be helpful in planning for maintaining a safe environment for participants and personnel.

- 1) Follow and adhere to all State, local, University and CDC guidelines. Adapt measures according to changing conditions and guidelines.

- 2) If symptoms are present or there is a positive exposure, the person will be sent home and will need to contact their medical care provider; TU policies must be followed before the individual may return to campus. Immediately inform the Dean and the IRB who will advise on actions to be taken.

Environment

- 1) Researchers will supply their own face coverings which the wearer will be responsible for cleaning daily. <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-to-wash-cloth-face-coverings.html>.
- 2) Researchers must ensure that they provide sufficient PPE for participants. A supply should be available for any individuals who may have forgotten theirs.
- 3) Face coverings will be required at all times except during consumption of food/drink (see below for instructions on breaks). <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-to-make-cloth-face-covering.html>
- 4) Labs must be cleaned regularly including after individual contact with surfaces and thoroughly at the end of the day using approved chemicals and observing appropriate kill times. If researchers are using multi-user labs or other spaces, cleaning must be coordinated to ensure that the surfaces have been cleaned and sanitized according to University standards between contact with each individual. Students will not have 24/7 access to the labs during this time.
- 5) The rooms will be limited to the density outlined in the Reoccupancy Planning Form and approved protocol, whichever is less. Densities may only be modified if the University changes density requirements.
- 6) When walking in the hallways, maintain physical distancing.
- 7) Obey all directional signs in the building.
- 8) If linens are used, the PI must adhere to College requirements for cleaning.
- 9) Hand sanitizer and/or hand washing stations will be widely available. Personnel must utilize hand sanitizer regularly, including after breaks, use of the bathrooms, contact with any individual, and contact with any surface used by an individual.
- 10) Student researchers will remain in their assigned room except for bathroom breaks and lunch, which will be staggered by room. Interactions with participants should be kept to a minimum so that no lunch or bathroom break is required.
- 11) Research staff should familiarize themselves with CDC guidance: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>

Breaks

- 1) If the schedule requires a lunch break, personnel will remain in their assigned room or other designated space. It may be necessary to stagger such breaks to maintain social distance requirements. Personnel must position themselves six feet apart before removing masks for eating and drinking and remain six feet apart until replacing their mask.
- 2) Microwaves and refrigerators will not be available. Researchers should consider this when packing lunch.
- 3) Students and faculty who choose to exit the building for lunch will be asked to keep their mask on until exiting the building, although it is recommended to keep it on when walking outside the building as well.
- 4) There will be no snacks or beverages allowed in the lab. Proper hand hygiene should be used upon return to the lab.
- 5) Project personnel should refrain from taking bathroom breaks during lab by using the restroom prior to lab. Participant interaction should be scheduled to ensure that interactions are kept to a minimum so that bathroom breaks are not needed.

- a. If anyone must use the restroom during the lab, they should communicate with the lead researcher prior to exiting.
- b. Use of restrooms should be limited based on size to ensure at least 6 feet distance between individuals. Individuals should wash their hands thoroughly with warm water and soap for at least 20 seconds afterward to reduce the potential transmission of the virus. Capacity of each restroom will be clearly marked and posted with signage.
- c. During lunch, rooms will be assigned staggered bathroom breaks.

Supplies

- 1) Faculty and students will supply their own face coverings, which the wearer will be responsible for cleaning daily. <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-to-wash-cloth-face-coverings.html>.
- 2) [Participants must be instructed to wear a face mask when on campus. They will be supplied with any additional PPE that is necessary to the study.](#)
- 3) TU will supply gloves and gowns. These will be hospital patient gowns. If you wish to wear a long-sleeve shirt under the gown that is permissible.
- 4) Equipment will be cleaned and issued to each group to use during the labs. Each group will clean their equipment between each use and after each use. At the end of the block, all equipment will be cleaned.
- 5) Equipment will be limited. To prevent contact printers may not be available and bringing laptops to research spaces may be restricted.

Cleaning:

- 1) All tables and work spaces will be cleaned with paper towels and a bleach solution according to University and CDC guidelines (see link below) before and after labs begin as well as after contact with each individual participant or researcher.
- 2) <https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html>
- 3) Equipment will be cleaned with a disinfectant wipe such as Clorox or Lysol, or with alcohol wipes as appropriate.