

Towson University Return to Research Task Force Planning Form Required to Conduct In-Person Human Subjects Research

*This form must be approved by your Department Chair, submitted to your Dean, and approved by the Provost before applications and amendments to conduct in-person human subjects research can be approved by the IRB. The form requires that Principal Investigators (PIs) consider the welfare of participants, personal contact, physical space, and the ability to maintain personal and environmental safety precautions necessary while TU remains at less than 100% occupancy. It also will be used to ensure that adequate PPE and other equipment is available for the in-person research that faculty are conducting on- and off-campus. **Faculty members must submit the form for student projects they are sponsoring. Faculty members will be responsible for ensuring that student projects adhere to all required guidelines.***

Faculty/PI Information

Name (Last, First)	
Department	
Email Address	
If this form is being submitted for a student project, indicate the student and whether the project is for a course, thesis, or other requirement.	

Project Information (attach additional detail if needed)

Brief Description of Work including a description of the in-person interaction with the human subjects	
Brief description of participant pool and maximum number of participants who will be present at a given time. If the work will not be conducted at TU, describe location.	
Explain why the work cannot be done remotely	

Laboratory Information (or off-campus site information)

Building(s)	
Lab room numbers with approximate square footage	
Common research labs to be used with approximate square footage	
Maximum number of individuals who will be present in the lab at any given time	

Laboratory Personnel who will be involved in in-person activities for the project

PIs must adhere to TU occupancy requirements at all times. They may adapt their projects to increased occupancy in accordance with modified TU requirements. If decreased occupancy is required, PIs must adhere to these requirements.

Name (Last, First)	Employee/ Student ID	Position/Appt Type	Email Address	Completed COVID-19 training?	Completed COVID-19 Testing?
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>

Laboratory preparation and planning for in-person human subjects research.

PIs must outline their plans to ensure that appropriate steps are taken to protect research staff and human participants. The following items should be outlined in an attached narrative as appropriate to their projects:

- How will lab personnel and research participants be scheduled to ensure appropriate social distancing and capacity? In addition to considering the research lab, PIs should consider whether the research space is shared with others on campus and use of common facilities. How will this be coordinated and planned to ensure appropriate social distancing is maintained?
- Is the study limited to individuals who already would be on campus? If not, have you obtained approval to have visitors come to campus? If so, please document. If not, please provide a rationale for allowing visitors on campus. Further, how will participants be escorted to the study environment? Are you allowing sufficient time when scheduling participants to clean the research space between participants?
- Is the study being conducted off-campus? If so will students be involved? If so, all students must complete the Statement of Risk form prior to participating in any off-campus research activities.

- If current social distancing guidelines (6 ft.) and TU personnel density requirements cannot be met, provide a rationale as to why this is not feasible. Explain the measures that will be taken to protect the research staff and participants in such cases.
- Using the table on p. 4 indicate PPE that will be needed for research personnel and participants. (The Dean will forward a request to Campus Safety/Facilities based upon the needs listed in the table below).
- Are there other factors in your project that need to be considered? For example, are you using any procedures that might increase the risk of airborne disease transmission/COVID-19 such as contact with body secretions, increased respiratory output, etc? Are you working with individuals who have any of the high risk factors for covid, either on campus or off? If so, what precautions are being taken?
- Describe social distancing plans in equipment rooms and other spaces that require shared use. Include the facilities/spaces shared by groups outside your lab which may need centralized scheduling system to be coordinated by department or college. Have you communicated with colleagues and your chair to coordinate these activities?
- Describe plans to monitor activities. This should include maintaining records of:
 - daily lab activities.
 - a daily log of who enters and exits the lab.
 - documentation of health of lab personnel.
 - documentation of cleaning performed.
 - documentation of participant health status.
 - documentation of any actual or suspected cases of COVID-19 among research staff and participants (with the exception of participants in a study of COVID-19 patients approved through this process). (In such instances, the Dean and the IRB should be notified immediately). If any lab personnel member is experiencing any COVID-19 symptoms, s/he may not come to campus and all University guidelines must be followed.
- Other factors to consider:
 - How are safety protocols communicated to research staff and participants?
 - Are required procedures (daily self monitoring) being followed by all personnel?
 - What plans are in place for cleaning and disinfecting the research space between interactions with participants and at the end of the day?
 - If you are working with vulnerable populations, what additional measures might be needed to protect them?
 - Is there a plan in place to shut down on short notice if necessary?

PPE Supples

Indicate below the PPE you will need to initiate in-person human subjects research. Deans will coordinate PPE acquisition via Campus Safety.

Gloves	
Masks	
Protective eye-wear	
Face shields	
Gowns	
Aprons	
Other needs	

I agree to follow the applicable local, State, and federal directives regarding required safety measures during the COVID-19 pandemic, and institutional policies and guidelines when conducting the research being described on these pages. If this has been submitted for a student project I am sponsoring I understand that I am responsible for ensuring that the student adheres to these requirements. I understand that I the IRB must approve an amendment to the existing protocol or a new application for human subjects research prior to commencing work with any human subjects.

Signed by:

Principal Investigator

Department Chair(s) approval and date _____

Dean approval and date _____

Provost approval and date _____