Procedure for In Person Human Subject Research during the COVID-19 Pandemic

This procedure for in person human subject research is in addition to the TU Institutional Review Board Policies and Procedures. While the IRB assures safety for research participants, the aim of this procedure is to provide additional steps to assure a safe environment for the TU community and research participants during the COVID-19 pandemic.

In order to limit the transmission of the virus that causes COVID-19, any research that can be conducted remotely should be done remotely. Human subject research that cannot be conducted remotely needs both the typical IRB review for the safety of human participants and an additional review of a COVID-19 plan to reduce possible transmission of the virus. This plan should be devised to limit the time the participant is in the building and limit the time the participant interacts with researchers. The COVID-19 plan should minimally include the following elements.

1) Justification for research and why it must be performed in person
2) Number of researchers and participants needed
3) Identification of rooms and labs used as research space
4) Identification of restrooms, sinks for washing hands, and waiting areas (must be able to provide six-foot social distancing) if needed
5) Path used for movement of participants to and from the research space
6) Can six-foot social distancing be maintained? If not, will the researcher and participant be closer than six feet for greater than fifteen minutes? If due to the nature of the research, there will be periods greater than fifteen minutes that six-foot social distancing can’t be maintained, then the researcher and participant must wear surgical masks or higher grade PPE. While not required, the use of goggles or face shields should also be considered if there will be periods greater than fifteen minutes that social distancing can’t be maintained.
7) Requirements of participants (are any items transferred to or from the participants)
8) Planned time between participants (should be at least 30 minutes)
9) Cleaning and sanitization plans for surfaces, instruments, research materials

The COVID-19 plan should be routed in the following order with approval necessary at each step.

1) IRB whether a modification or new proposal for review of COVID-19 safety procedures.
2) Department Chair
3) Dean
4) Vice Provost for Research

The following are requirements for human subject research during the COVID-19 pandemic. Items 5 through 8 are only necessary for participants that are visitors to campus.

1) Student researchers must explicitly have been granted access to campus for research by Vice Provost for Research.
2) Researchers and participants must wear face masks at all times and six-foot social distancing should be practiced throughout the interaction between researchers and participants if at all possible.

3) Facilities and equipment must be thoroughly cleaned and disinfected before and after interaction with the participant. Researchers should also wash their hands with soap and water for 20 seconds at the nearest sink or have applied an alcohol-based hand sanitizer that contains at least sixty percent alcohol before and after interaction with the participant and cleaning.

4) A log should be maintained by the Principal Investigator or the PI’s designate that includes the time that the participant (and driver, if necessary) was involved in research, rooms they visited, and researchers present (this information should specify if the researcher and participant were less than six feet apart for more than 15 minutes). The log will only be disclosed if it is necessary to perform contact tracing and will only be provided to those authorized by the university to perform contact tracing.

5) Potential participants that are visitors to campus should be informed of the requirements expected on campus and that their name and contact information will be stored in case they need to be contacted if the university needs to conduct contact tracing. They should also be informed that anyone driving the participant to campus must provide contact information, remain outside the building and maintain six-foot social distancing, preferably staying in the vehicle if conditions allow. The participant must also fill out a questionnaire and receive approval before being allowed on campus. Participants must also sign a statement acknowledging inherit risks. A copy of this statement should be provided in advance to limit the time necessary for the participant to review on site. If the research requires the participant to fill out forms or waivers, this should be handled online as much as possible.

6) Participants that are visitors to campus should arrive on campus at a set time and location, and a researcher wearing appropriate PPE should meet them outside the building. These participants must be able to attest that their responses to the questionnaire have not changed. Their temperature should be checked and must be less than 100.4 F, and they should be provided a face mask if they are not wearing a mask.

7) The researcher should escort the participant to the research space along the predetermined path. The researcher should perform actions such as opening doors for the participant to limit the contact of the participant with surfaces while still maintaining six-foot social distancing as much as possible. The participant should wash their hands with soap and water for 20 seconds at the sink specified in the plan or apply an alcohol-based hand sanitizer that contains at least sixty percent alcohol.

8) After completing the activities with the participant, the researcher should escort the participant out of the building along the predetermined path as described in Step 7, if appropriate.

The requirements for performing research on human subjects at another facility must follow the requirements above in addition to any requirements of the other facility.