Texas Christian University Guidance for Human Subjects-Related Research during the COVID-19 and the Phase III return to campus/research plan

Effective August 19, 2020

While the entire TCU community continues to navigate the uncertainty of COVID-19, the Office of the Associate Provost for Research and Dean of Graduate Studies is also working to ensure that TCU research administration remains available to serve faculty, staff, and the research community. Our goal is to enable TCU faculty, staff, and researchers to continue their work while keeping the health and safety of employees, students and the public as our top priority. To that end, faculty and students are expected to follow all necessary precautions and use their best judgment to keep research participants and research team members healthy and safe in accordance with [Tarrant County](https://www.tarrantcounty.com/en/public-health/disease-control---prevention/coronaviruas.html) and [CDC](https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html) guidelines.

In efforts to align with TCU’s Phase III plans, direct in-person research and lab spaces will be allowed to resume on August 17, 2020 in accordance with the guidelines outlined below. **Please note that this may change at any time due to the evolving nature of this pandemic**. Per TCU’s Return to Campus Plan, research spaces and lab spaces will operate at reduced capacities. TCU Facilities will provide and install signage with appropriate guidance for physical distancing.

**Guidelines for Resuming In-person Research On Campus**

* **All on-campus research participants must be TCU faculty, students, or staff.** Research participants who are not TCU students, faculty, or staff may not come on campus to participate in research. Instead, these researchers should continue to utilize remote efforts (e.g., online surveys, Zoom, phone, etc.) to conduct their research.
* Schedule participants so there is no congregating in research settings.
* Before researchers or participants enter research or lab spaces, a mechanism for pre-screening should be put in place. Researchers should instruct participants to notify the research team, before their scheduled study visit, if they have a fever or symptoms of COVID-19. They should then be allowed to reschedule or cancel their study visit.
* Examples of pre-sceening/risk assessment for participant visits could include:
1. Have you traveled within the last 14 days to a location designated by the CDC to be an at-risk area for novel Coronavirus, COVID-19?
2. Have you or members of your household been diagnosed with COVID-19 or asked to self-quarantine due to potential exposure to the novel Coronavirus, COVID-19?
* Participants’ temperatures should be checked using a noncontact thermometer before entering the research or lab space. After a research participant is screened and reports having no symptoms and no fever is detected, they should be directed to a waiting area for participants without symptoms, if available. All participants should wear a face mask/ shield and maintain a safe distance (at least 6 feet) from each other whenever possible.
* Disinfect all equipment that will be in contact with the subject and all contact surfaces after each subject exits and wash your hands.
* All researchers and participants should maintain physical distance (6 ft) from each other
* MUST wear a face mask/shield (**not optional**).
* If a researcher must be within 6 feet of a participant, they should use appropriate PPE, including an N95 or higher-level respirator (or face mask/shield if a respirator is not available), gloves, and eye protection.
* If any member of the research team has a fever or feels they are experiencing symptoms of COVID-19, they should not report to the lab but remove themselves from the lab immediately and follow [TCU guidelines](https://healthcenter.tcu.edu/).
* Review  [CDC guidance for Where You Live, Work, Learn, Pray, and Play](https://www.cdc.gov/coronavirus/2019-ncov/community/index.html)
* **All new applicable protocol submissions and amendments should include a pre-screening plan for minimizing transmission before and during research procedures. Please see revised protocol review request template on the** [**Office of Research Compliance website**](https://research.tcu.edu/research-compliance/irb/irb-forms-templates/)**.**

**Guidelines for Off-Campus Research**

TCU faculty, undergraduate, and graduate student researchers will not be permitted to travel off-campus, nor will off-campus visitors be allowed on campus for research purposes without written approval from your Dean and the Vice Chancellor as outlined below. See TCU’s policy (<https://www.tcu.edu/coronavirus/travel.php>).

The Vice Chancellor must approve all exceptions to this travel suspension. Begin this process by submitting your research protocol to TCU’s IRB (irbsubmit@tcu.edu). Once you received IRB’s pending approval, complete one of the appropriate forms listed below that will be available on our website and can also be provided by your Dean. Submit the completed form to your Dean. If your Dean approves, your request will then be sent to the Vice Chancellor for review/approval. If your Dean does not agree that your research off campus is necessary or provides a direct benefit to participants, you will not be able to conduct your study until restrictions on off-campus research have been lifted.

Submit one of the following forms after obtaining IRB’s pending approval, as appropriate for your study:

* Internship Research for Clinicals for credit
* Off-Campus Acitivity Approval form
* On Campus Activity approval form

\*Please note the IRB will only review protocols that involve off campus travel to the point of approval and will be in a “pending” state until we receive final approval from the Vice Chancellor or until these restrictions are lifted. The IRB and its approval of research is superseded by Univeristy guidelines and the Vice Chancellor’s approval.

 If you are permitted to conduct your research off-campus at any local businesses, health facilities, schools, or prisons, you are expected to adhere to that establishments COVID-19 guidelines and instructions. This means if they will not allow any research to take place, then you are subject to the protocols they have in place, regardless of IRB approval. If they do allow research to take place, a letter of support of the research will still be required to be included with your protocol submission.

For research that was reviewed to the point of approval during the on-campus shutdown, the Office of Research will re-evaluate your study. If your study is taking place off-campus we will alert you to the above mentioned off-campus guidelines you now fall under. If your study is taking place on-campus and includes in-person interactions you will receive your approval letter and documents, however you will be expected to submit an amendment to follow the above mentioned on-campus guidelines.Please keep in mind any changes you need to make related to COVID-19 or otherwise, should be submitted via an amendment/modification request. Consent forms should be updated to include language about how the study will minimize the risk as it relates to COVID-19(please see revised consent documents on our [website](https://research.tcu.edu/research-compliance/irb/irb-forms-templates/)). Please explain in the risk section of the consent when and why social distancing can or cannot be maintained. Research participants should be re-consented if already enrolled prior to restrictions that were put in place back in March 2020, with updated risk related to COVID-19 if applicable to your research.

Research teams should also ensure that, currently enrolled participants can withdraw their participation at any time due to any changes to their risk and any changes to research procedures. If modifications were approved for your study to switch from in-person to online, we encourage you to continue this methodology. However, if you would like to change back to in-person contact, the IRB will review as long as necessary precautions are described in the protocol and consent documents.

Other consideration for researchers who are involved with collaborative or multi-site research, should consult with sponsors, lead investigators, and coordinating centers to avoid potential negative study impacts due to variabilities in site approach, following the requirements of the IRB of record. For grant-funded research, consulting with the grantor regarding modifications to the research plan, grant timelines, and reporting requirements may be necessary.

The TCU IRB will continue to function as usual and is here to assist and support our excellent research community as best we can and continue to help our researchers navigate conducting research during these times. If you have any questions, please feel free to contact us at IRBsubmit@tcu.edu. We are grateful and appreciative of the patience and flexibility you all have demonstrated over the past few months.