

Texas Christian University Guidance for Human Subjects-Related Research during the  
COVID-19 Outbreak  
Effective March 17<sup>th</sup>, 2020

Due to the rapidly evolving situation with the COVID-19 and in the interest of keeping public health and safety as our top priority we are placing the following restrictions on human subject research effective immediately. This is being implemented to protect research participants, researchers, and the larger TCU community from risk of infection with COVID-19 as well as to ensure ongoing access to research which may provide essential support and care to participants. The restrictions will be in place until further notice, and we will reevaluate when in-person human subject research can safely resume.

1. Any in-person participant interaction must immediately pause. Research procedures involving no direct in-person interactions with participants may continue (e.g. data analysis, online surveys, telephone interviews). This applies to both exempt and non-exempt research studies.
2. During this pause, researchers should consider whether it is feasible to modify their in-person participant research procedures to use alternative methods to gather study data (e.g. telephone, online). Investigators with protocols currently approved for in-person participant interaction can submit amendments to transition to alternative (i.e., remote) methods by submitting an [amendment modification request form](#) to [IRBsubmit@tcu.edu](mailto:IRBsubmit@tcu.edu). Please make sure the study protocol and consent forms are updated appropriately.
3. Research visits that cannot be performed remotely and are not essential to a participant's health and/or well-being should be postponed until further notice.
4. Enrollment of new participants in human subject-related research should be allowed only if: 1) participation in the trial is essential to a participant's health and/or well-being (must be cleared by TCU IRB in order to continue with restrictions); or 2) the enrollment and longitudinal participant management can be conducted remotely for the duration of the COVID-19 outbreak.
5. All new protocols submitted to the IRB for review that do not require direct in-person interactions with participants will be reviewed according to our normal processes. Those new protocols that require in-person interactions will be reviewed and feedback provided; however, no protocols requiring in-person interactions will be approved at this time.
6. Continuing reviews of human-subject research will still occur during this time.