

COVID-19—Face-to-Face Human Subjects Research Restrictions (COVID-19 HSR Restrictions, March 20, 2020)

In response to the constantly evolving global pandemic of the Coronavirus Disease 2019 (COVID-19) and in consideration of the health and safety of our students, faculty, and staff, we want to do our part to slow the spread of COVID-19 and protect our community. Therefore, consistent with UT Tyler, Centers for Disease Control and Prevention and Texas Department of State Health Services guidelines, effective immediately, **human subjects research activities involving face-to-face interactions with human subjects must be paused until further notice.** The only exceptions are for (a) studies where there is the potential for direct benefit for the participant; (b) instances where canceling or postponing research activities would increase the risk to the subject's safety or well-being, and (c) cases involving emergency use/compassionate use and Humanitarian Use Devices (HUDs).

From a regulatory perspective, these precautionary measures are considered a temporary pause in human subjects research activities.

Ongoing Human Subjects Research Activities that Involve Face-to-Face Interactions

Face-to-face interactions with human research subjects must be halted promptly. This directive applies to domestic and international human subjects research. The following exceptions apply:

- The research holds the potential for direct benefit to the subject/patient (e.g., investigational drug, devices or surgical procedure) and the interaction is required to deliver that potential direct benefit.
- Collection of safety data (based on clinical judgment of the importance of the visit to detect potential adverse events)
- The PI determines that an in-person visit is vital to the subject's safety and/or well-being.

All Socio-Behavioral and Education (SBER) research activities involving face-to-face interactions with human subjects, approved by The University of Texas at Tyler IRB, must be halted immediately. Exceptions can be made on a case by case basis.

Ongoing Human Subjects Research Activities that Do Not Involve Face-To-Face Human Interactions

Research activities that do not involve face-to-face interactions with human research subjects may continue. This includes non-direct benefit studies that can be managed remotely/virtually as long as that process is part of your IRB-approved protocol. For IRB-approved studies that do not currently include remote/virtual participation (face to face), researchers may submit modifications to their IRB protocols to include this flexibility where appropriate.

New Enrollment into Existing Human Subjects Research with Face-to-Face Human Interactions

New enrollment for studies involving face-to-face human subjects research must stop immediately unless enrollment provides the potential for direct benefit; that is, benefits that are not available through standard of care.

Pending IRB Application Submissions for Human Subjects Research

Pending IRB applications will continue to be reviewed and approved as usual. Similarly, for studies involving face-to-face human interactions that fall under the above restrictions, the IRB review and approval process will be conducted as usual. However, approval letters for these applications will explicitly note that subject enrollment will not be permitted to start until the above restrictions are lifted. Considering the fluid and evolving nature of the COVID-19 pandemic, the review and processing of IRB applications is likely to take longer than normal.

New IRB Application Submissions for Human Subjects Research

An exception to the human subjects research restrictions can be requested by contacting the Office of Research and Scholarship at research@uttyler.edu. Exceptions may be granted for studies involving emergency use/compassionate use and Humanitarian Use Devices (HUDs) and new studies if they do not involve face-to-face interactions with humans.

Notification of Research Sponsors, Funders, and Other Oversight Bodies

If the study needs to be paused, please notify any sponsors and funding agencies based on guidance provided in your award notice, agreement or contract. You may also be required to notify the Food and Drug Administration (FDA) under certain circumstances; for example, if the PI is the sponsor of the Investigational New Drug (IND) or Drug Exemption (IDE). When notifying sponsors and funding agencies, please be sure to copy the Office of Research & Scholarship via e-mail at research@uttyler.edu.

Research Approved by a Non-UT Tyler IRB

Consult the reviewing IRB for guidance on (a) whether COVID-19 screening requires prior IRB approval, (b) whether/how to report the restrictions on face-to-face study procedures, and (c) whether/how to modify an approved study to allow remote procedures.

For questions related to the above-listed restrictions on human subjects research, Contact:

- Dr. David Pearson, IRB Chair & Associate Professor of Pharmacy, via e-mail dpearson@uttyler.edu or phone (903) 566-6109; or
- Mrs. Tamela Kimbro, Research Compliance Coordinator, via e-mail tkimbro@uttyler.edu or phone (903) 566-6317

Thank you for your understanding as we work to respond to the COVID-19 circumstances.

Kouider Mokhtari, Ph.D.

Interim Associate Provost for Research