Guidance & Process for Reactivation of In-Person Research

Guiding Principles:

With the gradual re-opening of UNTHSC during the current COVID-19 pandemic, efforts to re-initiate in-person research activities have begun as well. In doing this, the health and safety of our researchers and research subjects continue to be a top priority. As it is the responsibility of the North Texas Regional IRB to oversee the ethical management of human subject research, plans for UNTHSC researchers to safely engage with subjects and mitigate new risks introduced by a pandemic need to be developed.

In accordance with guidance issued by the University (see the Research Recovery Plan on the HSC Coronavirus FAQ site), the gradual return to in-person human subjects researchers activities will be completed in phases. (Please note that, at this time, these phases are safety-bound, rather than time-bound). Additionally, it is important to note that the overall return to in-person research activities may change (or revert) based on CDC, institutional, state and local guidelines. *Thus, the information included in this guidance document is current until further guidance from the University (or other entities) is issued.*

Continuation of Remote Research Procedures:

When possible, researchers are encouraged to continue with remote study procedures (e.g., via Zoom, Qualtrics, and other platforms supported by the University) in order to ensure safety of the research participants and minimize potential risks. **In-person research activities should only be completed for those research activities in which in-person procedures are necessary to carry out the research.** Researchers should continue to submit modifications through IRBNet for any changes from in-person to remote procedures (where possible), to be reviewed by the North Texas Regional IRB. If you have questions regarding conducting study activities via remote procedures, please contact the North Texas Regional IRB / Office of Research Compliance.

Completion of Form & Safety Plans for Reactivation of Research Procedures:

If there is a *need* to resume in-person activities, the North Texas Regional IRB and Office of Research Compliance, in conjunction with the Office of the Vice President for Research (VPR) and department Deans, have developed a process for PIs to obtain approval for re-starting their in-person research procedures. This process includes the following:

- PIs will establish specific COVID-19 safety procedures/plans for resuming in-person human subjects research.
- To obtain approval, PIs will need to complete and submit a signed copy of the following form, "Research Recovery Plan and Safety Protocol for COVID-19".

This form will include the following fields to be completed by the PI:

- PI name, department and contact information
- Current approved studies (titles, IRB #s, and funding information)
- Description of location(s) of in-person research activities (includes safety strategies)
- Description of subject populations to be participating in in-person activities (including information about screening procedures)
- A detailed plan from the PI about how participants will be kept safe (preventive measures/PPE; special instructions/measures to be given to participants; cleaning/disinfecting plans;

information about whether or not participants will need to interact with each other; any activities in which PPE, i.e., masks, cannot be used; etc.)

- ***ADDITIONAL REQUIREMENT*:** *As indicated in the email from UNT System Chancellor, Lesa Roe, on June 25, 2020:* Face coverings (cloth face coverings, disposable masks, etc.) ***must*** be worn by all students, faculty, staff, contractors, tenants and visitors at all UNT system locations and campuses. As such, **the safety plans from investigators will need to require that, at all times when engaged with human subjects in person, both parties (investigators and study participants) will need to wear a face covering/mask**. Additionally, investigators should have face coverings/masks available to study participants, in the event the study participant shows up to the study visit without one.

The information captured on this form will allow the Office of Research Compliance / North Texas Regional IRB, and appropriate entities to effectively and appropriately evaluate a PI's safety plan, and help ensure the safety of those engaged in the research. As this form is ***not*** project-specific, the PI must include a thorough and complete description of the proposed procedures for ALL those involved in their research studies (key study personnel as well as research subjects).

Once completed (in its entirety), the PI must sign the (pdf) form. Electronic signatures (Adobe or docusign) as well as physical signatures are permissible. To submit the form, please click on the "Submit" button found on the lower right-hand corner of the form. This should allow you to submit the document directly to the North Texas Regional IRB email account. Alternatively, you may send the signed form to: NorthTexRegIRB@unthsc.edu. Please do ***not*** send it to any other email.

Additionally, please ***do not*** route the form for other signatures; once you sign and hit the "Submit" button, the Office of Research Compliance / North Texas Regional IRB will review then route the form for all appropriate signatures.

General Reminders for Completing the Form and Safety Plan:

- The PI is responsible for the ethical management of the research, including ensuring adequate safety measures and practices are in place for those involved in conducting and participating in research.
- Given these unique times, COVID-19 is part of that risk portfolio researchers now need to consider, address and mitigate. Therefore, when designing your safety plan, please consider ALL subject populations involved in your research studies. The proposed protocol should be designed with the most vulnerable populations (as defined by the Center for Disease Control and regulatory guidelines, e.g., OHRP, FDA) in mind.
- Additionally, the proposed procedures must be consistent with ALL institutional guidelines, current Centers for Disease Control & Prevention (CDC), state and local guidelines and requirements.
    - **INSTITUTIONAL UPDATE/REQUIREMENT NOTE:** *As indicated in the email from UNT System Chancellor, Lesa Roe, on June 25, 2020:* Face coverings (cloth face coverings, disposable masks, etc.) ***must*** be worn by all students, faculty, staff, contractors, tenants and visitors at all UNT system locations and campuses. As such, **the safety plans from investigators will need to require that, at all times when engaged with human subjects in person, both parties (investigators and study participants) will need to wear a face covering/mask**. Additionally, investigators should have face coverings/masks available to

study participants, in the event the study participant shows up to the study visit without one.

GENERAL NOTE/REMINDER: All Human Subjects Research protocols are subject to safety/compliance inspections (i.e., audits) at any time. Thus, investigators should ensure they are consistently adhering to the processes/procedures outlined in their approved Safety Plan (in addition to IRB-approved protocols) and institutional guidelines at all times.

Review & Approval Process:

Once submitted, the form will get routed to the appropriate entities (North Texas Regional IRB, Department Dean, Research Compliance, VPR) for review and approval. ***Please note that this form must be completed in its entirety, or will be sent back to the PI without review.*** If any questions arise during the review process, you will be contacted by the appropriate individual(s) from our offices.

Final authorization will be dependent on a variety of factors and be evaluated in accordance with the University's plan for phasing in in-person human subject research activities (as outlined in the Research Recovery Plan).

Once the final approval signature has been received, you will receive an email notification which includes the fully executed copy of the approved plan.

REMINDER: Please ensure you wait to receive the final VPR approval (fully executed copy of the form/safety plan) before beginning in-person research procedures! No in-person procedures should be started until ALL required approvals/signatures have been received (which includes the final approval signature from the VPR).

Questions?

Please feel free to reach out to the Office of Research Compliance (Tania.Ghani@unthsc.edu) or North Texas Regional IRB (Itzel.Pena@unthsc.edu) if you have questions before or while completing the form. As always, we're happy to help and committed to your research success!