Reset Form

Research Recovery Plan and Safety Protocol for COVID-19

With the gradual re-opening of the University, efforts to re-initiate in-person research activities have begun as well. As it is the responsibility of the North Texas Regional Institutional Review Board (NTR IRB) to oversee the ethical management of human subject research, a plan to safely engage with subjects and mitigate new risks introduced by a pandemic, needs to be developed.

As part of the process for re-activating (in-person) research activities, each principal investigator (PI) must establish specific COVID-19 safety procedures for in-person human subject research using the below form. The information captured on this form will allow the Office of Research Compliance / North Texas Regional IRB and appropriate officials to effectively and appropriately evaluate a PI's safety plan, and help ensure the safety of those engaged in the research. Because 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). Therefore, when designing your safety plan, please consider ALL subject populations (including the most vulnerable) involved in your research studies.

It is important to note though that when and where possible, researchers are still 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. ***This form/safety plan should only be used, or completed for those research activities in which only in-person procedures are necessary to carry out the research.*** *If you have questions regarding conducting study activities via remote procedures, please contact the North Texas Regional IRB / Office of Research Compliance.*

FORM INSTRUCTIONS: All fields are required. Please complete the entire form below and hit "Submit". Please do NOT obtain the other signatures on this form. The Office of Research Compliance will route for the appropriate signatures. You may also submit the form to NorthTexRegIRB@unthsc.edu. The Office of Research Compliance, North Texas Regional Institutional Review Board (including designated IRB reviewers), and the appropriate entities listed on this form will review the safety plan, and follow-up with the PI in the event there are any questions or additional clarification is needed. Follow-up will be done through this office. The safety plan will receive final approval by the Vice-President of Research. Notification of the approval will be sent directly to the PI from the Office of Research Compliance.

SAFETY PLAN for Reactivation of In-Person Human Subjects Research		
Principal Investigator (PI)		
Department / Institute		
PI email and phone number		
IRB Numbers associated with PI		
Study titles associated with PI		
Sponsored project(s) (include agency and award number) – include any sponsor related deadlines (include sponsor)		

A. Location(s) of in-person research activity		
Location Description of Research Activities		
☐ On campus (include buildings and room numbers) ☐ Off campus (describe locations and precautionary measures for off-site research activities)		
Location Safety Strategies		
Describe your plan for maintaining social distancing among individuals in the space, including safe entrance, waiting and exit, and safe exchange of items.		
Describe the plan for limiting or monitoring the amount of personnel in the research space. For example: 1) How many individuals (including research personnel and subjects) may be in the research space at one time, including an estimate of square footage per individual simultaneously in the space? 2) If there is a need of proximity (closer than 6 feet between individuals in the space), please indicate the reason, how long this will be for and any special precautionary measures that will be in place (e.g., wear facial covering / mask).		
B. Participants and Research Activities		
Participant Description		
To what degree is your population COVID-19 vulnerable (i.e. over the age 65, underlying health conditions, etc.)?		

Will researchers be screening participants? If so, describe procedures including how and when?		
Participant Safety Plan		
Describe the protocol for preventive measures for participants (i.e. masks, hand sanitizer prior to entry and on departure, barriers or partitions, cleaning floors, etc.) including who will provide items such as masks and who will track adherence to written safety protocol.		
Do researchers plan to convey to research participants any special instructions or measures related to safety (e.g. handouts, etc.)? If so, please describe. **(NOTE: Please consult with the IRB regarding what documents require review and approval prior to implementation).**		
Indicate whether participants will need to interact with each other and any precautionary measures to minimize exposure risk.		
Describe any research related activity(ies) that cannot be done while wearing personal protective equipment, or a face mask covering, and steps that will be taken to minimize the potential for viral spread (e.g., screening beforehand, etc.)		

Describe general cleaning/disinfecting plan for any research instrumentation/object that will come in contact with the research subject / volunteer and/or research personnel, or be shared between subjects and research personnel. This includes a description of the frequency in which instruments/devices/objects are disinfected (or if disposable items will be used).		

C. Study Team Safety Plan – Checklist

☐ Research team received appropriate training on this safety plan and institutional guidelines related to COVID-19.

☐ Appropriate Personal Protective Equipment (PPE) have been provided to research personnel, and will be used while interacting with human subjects and working in the research space.

☐ There are steps and procedures in place to clean and disinfect general research areas and high touch surfaces.

CERTIFICATION AND SIGNATURES

I (the Principal Investigator) agree to adhere to this safety plan and am responsible for the safety management of the research.

PI Signature _____ Date _____

Director, NTR IRB Signature _____ Date _____

Dean Signature _____ Date _____

Director, Research Compliance _____ Date _____

Vice-President of Research Signature _____ Date _____

Submit Form