



TO: UNT RESEARCHERS

FROM: INSTITUTIONAL REVIEW BOARD

SUBJECT: RESPONSIBILITY OF RESEARCHERS DURING THE CHANGE IN UNIVERSITY OPERATIONS

DATE: MARCH 16, 2020

UNT Researchers,

The purpose of this message is to address expectations of the UNT IRB with regard to protection of participants (and researchers) during the conduct of human subjects research.

The IRB expects that investigators and their research staff will act to protect the rights and welfare of participants involved in UNT research involving human subjects. Measures to eliminate immediate hazards to research staff may also be warranted.

➤ **CHANGES TO ONGOING STUDIES:**

At times, it may become apparent to the researcher that acting in the best interest of a research participant will cause a deviation from an IRB approved protocol. Normally, changes may not be implemented prior to IRB review and approval. An exception is when changes are necessary to eliminate apparent immediate hazards to study participants (permitted under both OHRP and FDA regulations). The cause may be emergent (e.g. like present concerns involving potential spread of a disease) or non-emergent (a chance occurrence). Potential issues that may be encountered in emergent situations include but are not limited to:

- Insufficient staff to safely/effectively conduct research
- Research location becomes unsafe for the participants
- Necessity to cancel non-essential study visits
- Conducting phone visits in lieu of in-person visits
- Conducting safety screenings prior to in-person visits occurring
- Other changes as deemed appropriate to eliminate immediate hazards to

participants because of the risk of exposure to this highly communicable disease.

Regardless of the cause, the IRB expectation is the same: **Always act (using your best judgement) to avoid unnecessary harms to research participants and staff.** In some cases, changes may include temporarily stopping subject recruitment or placing a temporary hold on all study procedures. Such holds should be communicated to the funding agency or sponsor (if any) as needed.

➤ **TAKE ACTION:**

In the event that doing so causes (or will cause) a deviation from your approved protocol, the following actions are recommended:

1. If you reasonably expect that deviation from a protocol will become necessary and have time to submit an amendment to the IRB to address the anticipated deviation, please do so. The IRB office will do their best to expedite review of amendments intended to minimize (or decrease) risks to subjects.
2. If you anticipate a deviation from your protocol but do not have time to submit an amendment, consider at least informing the IRB (phone or e-mail) that you anticipate you will need to deviate from your protocol. The IRB can provide guidance and document that notification was made in advance of the deviation and a reporting form can be submitted later (as soon as is practicable).
3. If a deviation is required to avoid harming a participant and there is insufficient time to either submit an amendment or inform the IRB via other means, the expectation of the IRB is that you will report the deviation as soon as is practicable.
4. If you reasonably expect that the deviation is likely to repeat, the IRB office will work with you to determine the best approach (including potentially amending your protocol) to address these potential exceptions.
5. Deviations from a protocol that are made, in good faith, solely for the purpose of protecting research participants or others will rarely be considered non-compliance (e.g. only if the above guidance is not followed), these deviations will be classified as exceptions and the IRB office will work with you to determine any future actions required to address the exception/deviation.

➤ **IMPACT OF UNIVERSITY CLOSURE:**

The UNT IRB staff are all capable of working remotely. We are also experienced with holding Committee meetings via teleconference. The University of North Texas closure should not significantly impact our ability to review research studies, modifications, and renewals.

➤ **ADDITIONAL QUESTIONS:**

If you have additional questions, please contact our staff leadership at untirb@unt.edu.