

COVID-19 / Coronavirus Considerations for Human Subjects Research

Please note that the below FAQs have been developed in response to the University of North Texas Health Science Center (UNTHSC) guidance that has been recently released in regard to COVID-19. In addition to the North Texas Regional (NTR) IRB guidance provided below, investigators from other institutions (e.g., JPS, UNT-Dallas, Cooks, etc.) should also appropriately follow guidance from their institution (in regard to COVID-19 precautions).

Please reach out to the NTR IRB office if you have specific questions regarding any of the information below.

What do I need to know about conducting human subject research that is currently approved by the North Texas Regional (NTR) IRB?

As referenced in the guidance issued by the UNTHSC Vice President for Research on March 17, 2020:

- **All research activities involving in-person interaction with human research participants/subjects (recruitment, interventions, follow-up visits, etc.) are put on hold until further notice.**
- **Exception:** Ongoing research activities where suspending interventions presents a clear and immediate risk to subjects (such as might occur in clinical trials, or studies involving therapeutic test articles or procedures, which are essential to participants' health and well-being) may continue ONLY if research personnel conduct such activities and interactions employing appropriate pathogen protection equipment and procedures to protect both researchers and subjects.

In addition, the following is general guidance about research activity:

- All researchers should consider the impact of their research activity on the health and safety of colleagues (staff, students, and faculty) as well as any human research participants.
- UNTHSC Deans are developing contingency plans and guidance for research within their schools/colleges. UNTHSC investigators should consult with their appropriate Dean on these plans.
- Individual investigators should develop their own contingency and research continuity plans, especially for essential critical activities that require ongoing personnel attention.
- The idea is to minimize social interactions and manage essential experiments (experiments that would create significant financial and data-stream losses if discontinued).
- Principal investigators must also develop a plan to "step-down" activities in their labs, with the expectation that operations will remain in a reduced state for six to eight weeks.
- Investigators should also develop contingency/continuity plans for a possible institution-wide closure of campus and laboratory facilities in the event that happens at some point.

Click [here](#) for more information about CDC Guidance related to COVID-19. Click [here](#) for UNTHSC-specific updates related to COVID-19.

Will the Office of Research Compliance (including the North Texas Regional IRB) continue normal operations?

The Office of Research Compliance (including North Texas Regional IRB) will remain available and can be reached via email (NorthTexRegIRB@unthsc.edu) or if you're working with a specific staff member, use the appropriate [contact information](#). **A note / reminder that the Office of Research Compliance is moving to 550 Bailey Avenue and delays in response / review may occur between March 18th and March 23rd, 2020.**

How will COVID-19 affect NTR IRB meeting dates and submission deadlines?

If needed, the NTR IRB will meet remotely (e.g., via teleconference) to ensure continuing oversight and programmatic activities. At this time, submission deadlines and meeting dates will continue to take place as stated in the [IRB Review Schedule](#).

What should I communicate to the NTR IRB about changes to study procedures?

As research teams develop individual contingency plans, ensure that these plans are consistent with the IRB approved protocol synopsis. If modifications are needed, please submit these modifications to the NTR IRB (via IRBNet) prior to implementation.

***PLEASE NOTE: Changes to study procedures which are needed to eliminate apparent immediate hazards to research participants, including those to reduce potential exposure to COVID-19 or to continue to provide medically necessary study care to participants who have been placed in isolation, do not need prior approval by the IRB. These changes can be implemented immediately. However, please notify the NTR IRB of these changes as soon as possible. The notification should be submitted within IRBNet within 10 business days (preferably though as soon as possible).**

However, for long-term, more permanent planned modifications to study procedures, please proceed to submit an amendment to the protocol (via IRBNet). (For example, researchers need to modify recruitment strategy from in-person to online). Indicate in your submission (preferably in the message box that appears right before you submit the package to the NTR IRB) that this is an update in response to COVID-19 so that the NTR IRB can prioritize reviewing these submissions accordingly. Researchers need to describe the proposed changes and modify any/all relevant study documents as appropriate/needed. Further, researchers can include the below statement (or something similar to this) within the protocol as part of the rationale for the changes:

“Due to health concerns related to COVID-19, and following government and institutional guidance/directive, we (researchers) plan to implement measures and procedures to address these concerns, ensure subject safety and minimize risk to subject. Once public health concerns regarding COVID19 have lessened/lifted, and as institutional policy permits, researchers will resume previously NTR IRB approved (in-person) study procedures.”

The amendment must receive NTR IRB review and approval prior to implementation.

Please note that if you need to change your consent procedures to waive the requirement for a signature so that consent can be done remotely, please submit a protocol modification requesting a waiver of documentation of consent. The modification should also include an appropriate consent script/letter/statement (which includes all of the required elements of informed consent). This request can only be made for studies involving no greater than

minimal risk (usually considered Exempt or Expedited category of research) and which meet the criteria for qualifying for a waiver of documentation of consent. Waiver of documentation of consent criteria can be found [here](#).

What should I do if I need to access my research data remotely?

Verify that your IRB-approved study protocol allows the option for research data to be stored electronically / accessed remotely. Based on institutional and regulatory guidance, investigators/researchers should not store research data on a personal device. Research data should be stored on an appropriate device issued and secured by the researcher's institution (provided the protocol synopsis allows for this type of data storage). Researchers can also explore the use of password protected / secure-based online servers.

If you discover that your data storage plan does not allow for remote access and you anticipate needing to access the data remotely, please submit a protocol modification to the NTR IRB (via IRBNet) prior to implementation. Researchers should continue to incorporate as much data security into data access contingency plans as circumstances permit. Please include the following information within the protocol synopsis when describing the contingency plan:

- The type of data that will be accessed / stored remotely (i.e. identified or de-identified data, will the data include PHI?)
- *How the data will be stored / accessed
 - For example:
 - Cloud-based storage such as Lab Archives or Dropbox Business
 - Password-protected Excel sheets
 - Encrypted hard drives with appropriate security measures
 - **If data is identifiable or involves PHI, HIPAA compliant data storage procedures must be in place and described as part of the contingency plan**
- Insert a statement in the protocol synopsis that states something similar to the following:
 - "Once COVID-19 restrictions have been lifted, data storage procedures will revert back to their original IRB-approved state."
- Ensure the protocol synopsis is consistent with the contingency plan as far as who has access to the data, and that only appropriate key study personnel are accessing private and/or sensitive data

**Data security procedures / measures are project specific. The study risk level and types of information being stored or accessed should be taken into consideration when determining data security measures for these contingency plans.*

Indicate in your submission (preferably in the message box that appears right before you submit the package to the IRB) that this is an update in response to COVID-19 so the NTR IRB can prioritize reviewing these items accordingly.

What do I do if my Continuing Review is due?

Please submit Continuing Review documents according to the deadlines indicated in approval letters from the NTR IRB. As NTR IRB staff will work remotely if needed, these items will continue to be processed. This also includes setting up our committee meetings to be carried out remotely if needed. Therefore, if your Continuing Review documents are not submitted by the deadline, the IRB may not have time to conduct an effective and timely review. As your result, your study may be subject to Suspension / Administrative Hold.

How should I proceed with a Sponsored Clinical Trial?

In situations such as COVID-19, sponsors will often issue guidance. Please follow the sponsor's guidance and keep the IRB informed of the sponsor's decisions regarding how to proceed with the study during this time.

Is there guidance from other sources that I can refer to for additional information regarding how COVID-19 might affect my research?

NIH has issued some guidance regarding human subjects studies and clinical trials affected by COVID-19 as well as some flexibilities that may be available to applicants/recipients of federal financial assistance:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html>

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-086.html>

The following video from Dr. Mike Lauer, NIH Deputy Director for Extramural Research may also provide some helpful guidance during this time:

<https://www.youtube.com/watch?v=jLmBi5wvifk&feature=youtu.be>

General information from the CDC regarding COVID-19 and how you can protect yourselves as well as your research participants can be found here:

<https://www.cdc.gov/coronavirus/2019-ncov/about/>

Please note that we will update guidance on this page as new information regarding COVID-19 becomes available.