Dear Researchers,

The purpose of this guidance is to describe how researchers may request to proceed with in-person human subjects research during the COVID-19 University reopening. We must ensure that appropriate safety precautions are in place before commencing with in-person human subjects research. Safety precautions related to COVID-19 are distinct from the ethical review of human subjects research performed by the IRB. Permission to proceed with IRB submission (Step 1) must be completed in addition to IRB approval (Step 2) for your human subjects research study.

It is important to remember that human subjects are volunteers and you may not always be aware of those in higher-risk groups. The IRB will continue to consider the risk: benefit ratio for all human subjects research studies. When activities are conducted in person, additional precautions may be required to protect both the research participants and the study team.

Permission to perform in-person human subjects research activities will be assessed on a case-by-case basis. Permissions may change based on the current county/city/state/federal situation. You are responsible for monitoring your emails and this website. Additionally, you must comply with all IRB guidelines and mandates when performing human subjects research.

GENERAL CONSIDERATIONS:

➢ Remote Research vs. In-Person Research
  o All human subjects research that can be conducted remotely (via phone, Zoom, etc.) should continue to be conducted remotely.
  o If you are performing remote human subjects research only, and your study does not contain any in-person interaction, then please skip Step 1 and only complete Step 2 below. For studies that contain only remote research procedures, approval
can be directly obtained from the IRB via Cayuse.

Guidance for All Researchers

- CDC guidelines should be followed. Please read the CDC guidelines to stay up to date on the ways in which you should protect yourself and others. This includes, but may not be limited, to the following:
  - Knowing and understanding how COVID-19 spreads
    - The best way to prevent illness is to avoid being exposed to this virus
    - The virus is spread mainly from person-to-person
      - Between people who are in close contact (within 6 feet) of one another
      - Through respiratory droplets when an infected person talks, coughs, or sneezes
      - These respiratory droplets can land on people who are nearby or be inhaled into the lungs, causing infection
      - Some studies have suggested that COVID-19 may be spread by people not showing symptoms
    - There is currently no vaccine to prevent COVID-19 disease
  - Wash your hands often with soap and water for at least 20 seconds
    - It’s especially important to wash:
      - Before eating or preparing food
      - Before touching your face
      - After using the restroom
      - After leaving a public place
      - After blowing your nose, coughing, or sneezing
      - After handling your cloth face covering
      - After changing a diaper
      - After caring for someone sick
      - After touching animals or pets
    - If soap and water are not readily available, use a hand sanitizer that contains at least 60% alcohol
    - Cover all surfaces of your hands and rub them together until they feel dry
  - Avoid touching your eyes, nose, and mouth with unwashed hands
  - Social Distance
    - Avoid contact with people who do not live in your household or those known to be sick
    - Remember that people without symptoms may be able to spread COVID-19
    - Put 6 feet of distance between you and other people
  - Masks Must Be Worn
    - Masks must be worn by faculty, staff, students, and any person who will be working within 6 feet of others
    - Everyone should wear a mask in settings when other people, who don’t live in your household, are around
    - Masks should not be used for children under 2 years old, anyone who is unconscious, incapacitated, or cannot remove the mask themselves without
assistance

- Masks are not substitutes for social distancing. You should continue to keep 6 feet of distance between yourself and others.
- Research participants may be required to wear masks during human subjects research activities.

○ Cover Coughs and Sneezes
  - Always cover your nose and mouth with a tissue when you cough or sneeze and throw the tissue away immediately.
  - Use the inside of your elbow if a tissue is not available
  - Do not spit
  - Wash your hands immediately after you cough or sneeze, following the guidance for washing your hands noted above.

○ Clean and Disinfect Surfaces
  - Clean and disinfect frequently touched surfaces daily
  - This includes, but is not limited to, doorknobs, tablets, phones, light switches, countertops, handles, desks, keyboards, and faucets
  - If surfaces are dirty, clean them using detergent or soap and water prior to disinfecting

➢ Self-Health Checks
  - DO NOT PERFORM RESEARCH ACTIVITIES WHILE FEELING SICK!
  - Be alert for presentation of symptoms.
  - Symptoms include cough, shortness of breath, fever, chills, headache, muscle and body aches, fatigue, new loss of taste or smell, sore throat, congestion or runny nose, nausea, vomiting, and diarrhea. This list does not include all possible symptoms. Please check the CDC website to find an updated list.
  - Follow University guidance and CDC guidance if symptoms develop.

➢ Contact Tracing
  - You should document which individuals had contact with human subjects participants for contact tracing purposes.
  - This information may need to be accessed later if a positive case is noted
  - You should maintain this information in the confidential research file to protect the study information
  - Your plan to document this information should be noted in your IRB application

➢ Reporting Requirements
  - There are currently no state or county reporting requirements for reporting if research participants self-disclose that they have had a confirmed case of COVID-19. However, if a research participant self-discloses that they have a confirmed case of COVID-19, please contact untirb@unt.edu for further instruction.
  - If you have an IRB approved human subjects research study that requires an FDA-approved COVID-19 test to be performed for research purposes, all positive and negative cases must be reported to local and state health authorities. This language must be placed within the consent forms to notify the participants of this mandatory reporting.
Travel Restrictions
- Travel to perform human subjects research is not permissible at this time

Study Location
- Research performed outside of UNT Campus will be evaluated on a case-by-case basis. All researchers must comply with UNT guidance as well as the external policies associated with the research study location.

Ramp Down
- Permission to perform in-person human subjects research activities may change based on the current county/city/state/federal situation. You are responsible for monitoring your emails and this website. Additionally, you must comply with all IRB guidelines and mandates when performing human subjects research.
- The IRB will notify you of the requirement for immediate cessation of in-person research activities if research is deemed to be too risky or if required by University, local, state, or federal mandate.
- When completing Step 1 below, you will be required to provide a plan explaining how you will safely stop all research activities and notify participants, if necessary.

TAKE ACTION:

STEP 1: Obtaining Permission to Proceed with IRB Submission
1. Before submitting a request to conduct in-person human subjects research, researchers must ensure proper safety precautions will be taken per institutional guidelines. If you are performing remote human subjects research only and your study does not involve any in-person interaction, you can skip Step 1 (Obtaining Permission to Proceed with IRB Submission) and go directly to Step 2 (IRB Approval).
2. Please submit the Permission to Proceed with IRB Submission form. These requests must contain the following information:
   - The rationale for in-person research to resume given the potential risks of COVID-19. Simply indicating there will be marginal gains in productivity will not be sufficient and compelling. Rationales are expected to bring together multiple concerns (e.g., closing of age window to collect longitudinal data, lack of alternatives to collect data remotely, funder lack of willingness to extend deadlines).
   - The procedures for mitigating risk related to COVID-19, including social distancing practices, symptomatic pre-screening, use/availability of PPE (e.g., masks, face coverings, etc.), disinfecting protocols, study staffing needs, study location requirements, etc.
3. Upon submission, the Research Integrity and Compliance (RIC) staff will review for completeness and send the information to the IRB Chair, or designee member of the Board with specific expertise, for review.
4. The IRB Chair, or designee, will review the form submitted and make a determination if in-person research can proceed.
5. Once reviewed by the IRB Chair, the RIC Office will send the researcher a formal letter regarding their study’s determination.
6. If permission was granted to proceed with your IRB submission, the researcher
will follow the next steps to obtain IRB approval. Human subjects research cannot proceed until IRB approval is obtained under Step 2.

**STEP 2: IRB Approval**

If permission has been granted to proceed with IRB submission, the researcher will then submit for IRB review and approval via Cayuse, attaching correspondence as provided by the RIC Team. If you are performing remote research only, and your study does not have any in-person interaction, no permission is needed under Step 1.

- **Modifications:** To continue with an IRB approved study that was on hold due to COVID-19, submit a modification through IRB Cayuse, attaching the correspondence provided by RIC staff under Step 1. Attachments should be placed in Section 3 of your IRB submission, under study location noted in the picture below. All sections of your IRB application should be edited to reflect modifications needed to comply with institutional guidelines regarding COVID-19 and in-person research activities.

- **New Studies:** For new studies, start a new IRB application through IRB Cayuse. Please attach the correspondence provided by RIC staff, under Step 1. Attachments should be placed in Section 3 of your IRB submission, under study location noted in the picture below.

**STEP 3: Post Approval**

- Once the IRB has approved the project, the research may proceed.
- If a modification is needed after the study is active, you may also need to modify your “Permission to Proceed with IRB Submission” form. Contact untirb@unt.edu if you have any questions.
WORKFLOW:

1. Researcher submits "Permission to Proceed with IRB Submission" form.
2. Research Integrity and Compliance reviews the form for completeness and sends to the IRB Chair, or designee for review.
3. The IRB Chair, or designee, reviews the form and makes determination.
4. Researcher will receive correspondence from the IRB staff regarding determination.
5. If approved, Researcher submits for IRB approval. Once IRB approval is obtained, in-person research activities can proceed.

If Review Not Needed:
6. Researcher submits request to modify "Permission to Proceed with IRB Submission" form.

If Review Needed:
7. Research Integrity and Compliance staff determine if the project changes require review from the IRB Chair.
8. Researcher sends email to oric@unt.edu explaining the changes that will be made to the project.
9. Researcher would like to make a modification to the project.