UTA Human Subject Research (HSR) Phased Ramp-Up: Permitted Activities

Restarting of any in-person human subject research (HSR) study will be based on the ability to abide by current COVID-19 restrictions in place (described below) and the risk for exposure or transmission as it relates to the interaction, interventional activity, or procedure necessary to conduct the study.

INSTRUCTIONS:

1. Ensure your research activities are permitted as described in the table below.
2. If changes need to be made to your research protocol, submit a Modification for IRB approval.
3. Consult the Checklist (pages 2 - 4) and ensure your lab and activities can meet all requirements.
4. Ensure all subjects sign and receive a copy of the informational handout, "Special COVID-19 Information for Research Participants" (pages 5 - 8).
5. Ensure that all students and research personnel are trained and familiar with special precautions and lab procedures.

Risk Category	HSR Person-to-Person Study Activities Allowed	Status	Notifications and Approval	Additional HSR COVID-19 Requirements
Unrestricted – (No Risk)	• Studies conducted via phone, virtual, electronic, or online methods • Analysis of data collected prior to pause of an active study • Secondary use of data (retrospective) **Example Activities:** Online surveys, virtual interviews	Currently unrestricted	IRB approval needed only if protocol requires modifications to conduct research under COVID-19 restrictions.	N/A
Phase 1 – (Low Risk)	• In-person interaction, observational or interventional activities, and procedures that can maintain social distancing[2] and avoid all direct physical contact, either on UTA campus, or at an IRB-approved off-site/off-campus setting • Activities or procedures must be completed in a single brief visit (maximum of 2 hours total) • Subject population is limited to healthy adults age 18 - 65, and not at higher risk for severe illness from COVID-19[2] ***No procedures or activities involving direct physical contact with participant (including to instrument them for a test) is allowed at this level.***	Permitted to begin June 15, 2020	*Notification* of plans to initiate must be provided to (1) your Associate Dean of Research (or Dean in absence of ADR) for college-level/resource considerations and (2) to the IRB via email for tracking purposes only. IRB *approval* will be needed if protocol requires modifications to conduct research under COVID-19 restrictions. For off-site/off-campus settings, *approval* of the site/location is required.	• Social distancing[1] • Face coverings[4] (EH&S Request Form) • Hand hygiene and respiratory etiquette • Research team and participant screening including temperature checks (see Checklist) • Increased disinfecting procedures[3] • Contact tracing (see Checklist) • Use of handout "Special COVID-19 Information for Research Participants" • Contingency plans • Off-site activities must apply these standards at a minimum, plus comply with state and institutional policies of the site/location
Future phases and requirements will be announced at a later date.				

[1]Social distancing, as defined by the CDC, must also correspond to any applicable institutional, state, or local restrictions in place.
[2]Further information regarding people at higher risk for severe illness from COVID-19 can be found in detail on the CDC website.
[3]For a list of disinfecting options and guidance refer to List N: Disinfectants for Use Against SARS-CoV-2 (COVID-19) and https://www.cdc.gov/coronavirus/2019-ncov/community/clean-disinfect/index.html.
[4]Refer to UTA's Face Covering Policy

CHECKLIST: HSR Ramp-Up Additional COVID-19 Requirements

All researchers planning to initiate in-person research activities with human subjects must plan for and address each item in this Checklist. This Checklist is intended to implement *minimum* precautions for mitigating exposure and transmission while conducting research. There may be additional requirements at the college or department level, or building-specific requirements. Researchers should also consider whether any of the additional procedures listed below could significantly impact the subject's safety or comfort level in the particular study, or impact the study's research results (for example, by introducing unwanted variables). The decision to proceed should be after careful consideration and notification to the appropriate Associate Dean of Research (or Dean for colleges that do not have an ADR).

☐ **PLANNING AND RESPONSIBILITIES**

Follow any active UTA Guidelines for reporting of symptoms, COVID-19 exposure, or illness. To further reduce the risk to participants, a more thorough procedure must be developed and communicated to all research team members. Procedures should include:

- What must be reported and to whom
- Plans for handling temporary pause/closure of HSR study and lab space impacted by exposure
- How long impacted person(s) must self-quarantine or be symptom free before being permitted to conduct HSR activities
- Team member designated to send notification to the UTA IRB to report potential exposure to research participant
- Process to follow if a participant contacts any team member and reports symptoms or exposure within 14 days of research activity
- Plans for spacing/scheduling subject visits to allow enough time for appropriate cleaning and disinfection between subject visits and participant screening (limit the visit to the minimum amount of time needed and consider splitting long visits into multiple, shorter visits)
- Plans for acquiring appropriate amount of PPE for team members and participants
- Plans for lab access and limiting room occupancy (see "Lab Safety" section)

☐ **RESEARCH TEAM MEMBER SCREENING**

Establish process to perform daily health screenings for research team members, including symptom checks and taking temperatures before arriving to campus. Team members should take their own temperature immediately prior to coming to campus and document (either individually or within the lab) that their temperature is less than 100.4° F (38.0° C).

☐ **PARTICIPANT SCREENING AND NOTIFICATIONS**

The following screening information should be collected from any new or returning participants via phone, email, or other virtual method within 24 hours of the participant's planned study-related visit or interaction and immediately before in-person interaction. Researchers are not required to submit an IRB Modification to add the screening to their study procedures, unless changes or additions are proposed to the *content* of the screening questions below.

1. Confirm that the participant is not a person at higher risk for severe illness from COVID-19. Refer to the CDC website for a complete list.
2. Questions relating to COVID-19 exposure, symptoms, and travel.
   - Have you been diagnosed with COVID-19?
     - If yes, when were you diagnosed?
     - Have you had a negative test? When?

- Have you been tested for COVID-19 antibodies? When?

- Have you experienced any of the following symptoms (even if they were mild) in the past 14 days?
  - Cough
  - Shortness of breath or difficulty breathing
  - Fever
  - Chills
  - Muscle pain
  - Sore throat
  - New loss of taste or smell
- Have you been in close contact with any person experiencing symptoms or confirmed case of COVID-19?
- Have you traveled the last two weeks? If so, to what locations? (Refer to UTA's Travel Guidance for restrictions.)

Participants that report any symptoms of COVID-19 or possible exposure within the last 14 days are not permitted to participate in HSR research at this time, and should be referred to their primary care physician.

In addition to the screening questions above, the following notifications/discussion should take place with participants *prior to* their visit:

1. Review the information from the "Special COVID-19 Information for Research Participants" handout with the participant.
2. Inform the participant that guests are discouraged, but a maximum of one *adult* guest may accompany them to the visit if necessary.
3. Inform the participant that their (and guest's) temperature will be taken when they arrive for the study visit using a contactless thermometer.
4. Instruct the participant (and guest) to bring and wear their own face covering (refer to UTA's Face Covering Policy). If they do not have their own, one must be provided to them upon their arrival to campus. Masks can be obtained through EH&S: EH&S Request Form.

When the participant arrives for the study visit:

1. Confirm the subject (and guest) are wearing face coverings or provide one to them.
2. Take the participant's (and guest's) temperature using a contactless forehead thermometer. For guidance, refer to CDC's FAQ under Reducing the Spread of COVID-19 in the Workplace: "Should we be screening employees for COVID-19 symptoms (such as temperature checks? What is the best way to do that?" Participants should be rescheduled if they or their guest have/has a temperature higher than 100.4° F (38.0° C). When temperatures are confirmed as acceptable, social distancing should continue to be maintained for the remainder of the visit.
3. Repeat the health screening questions above while maintaining social distancing.
4. Obtain participant's signature on the COVID-19 informational handout and provide a copy.
5. Keep a log/documentation of participant's name, guest's name (if any), date of visit, participant/guest temperature readings, and which member(s) of the research team were present during the visit.

☐ **SOCIAL DISTANCING PLANS**

Create social distancing plans according to CDC guidelines that can be maintained by research team members and participants throughout the in-person interaction or visit. Be sure to think about shared laboratory spaces and limiting researchers in small spaces at one time in the plans.

☐ **FACE COVERINGS AND GLOVES**

Prior to restarting, procure all necessary face coverings and gloves for research team members and participants in accordance with UTA's Face Covering Protocol. Researchers are responsible for reviewing and complying with CDC's guidance for appropriate use and removal of face coverings and gloves. Researchers are responsible for providing instruction of proper use to participants.

☐ **DISINFECTING AND CLEANING**

Adhere to UTA's guidelines for Lab Safety (click Lab Safety on this page for drop-down content) and post this flyer in the laboratory. Where possible, labs should also adhere to CDC and EPA recommendations: List N: Disinfectants for Use Against SARS-CoV-2 (COVID-19) and https://www.cdc.gov/coronavirus/2019-ncov/community/clean-disinfect/index.html. Appropriate cleaning and disinfection must take place *between each subject* that visits campus.

☐ **CONTACT TRACING FOR COVID-19**

Develop a system to closely document laboratory activities to quickly identify any person impacted by a report of illness or exposure. Remember that any documentation accessible or visible to non-research team members must maintain participant confidentiality. At minimum, documentation should include participant's name, guest's name (if any), date of visit, participant/guest temperature readings, and which member(s) of the research team were present during the visit. Report any potential exposure or personal diagnosis of COVID-19 in accordance with UTA's procedures (see "Report Close Contact Form"). Communication and notifications to individuals regarding potential exposure will be coordinated with the local public health agency. If a research participant is potentially exposed to COVID-19, the incident must also be reported to the IRB.

☐ **IMPLEMENT USE OF "SPECIAL COVID-19 INFORMATION FOR RESEARCH PARTICIPANTS"**

Provide this special Information Sheet to all human subjects participating in face-to-face interactions or activities. Obtain subject's signature on the form and provide them with a copy.

☐ **CONTINGENCY PLANS**

Given the uncertainty and evolving nature of the COVID-19 pandemic, it remains important for every research team to have a plan in place for additional closures, increased restrictions, or illness of essential team members/PI.

RESOURCES:

- UTA Coronavirus Information: https://www.uta.edu/announcements/coronavirus
- CDC Coronavirus Information: https://www.cdc.gov/coronavirus/2019-nCoV/index.html
- EPA Coronavirus Information: https://www.epa.gov/coronavirus

HANDOUT AND INSTRUCTIONS:

SPECIAL COVID-19 INFORMATION FOR RESEARCH PARTICIPANTS

INSTITUTIONAL REVIEW BOARD (IRB) STATEMENT:
Special COVID-19 Information for Research Participants

Until further notice, human subject studies that involve in-person interactions with participants must administer the "Special COVID-19 Information for Research Participants" Information Sheet in addition to the protocol's approved informed consent process/document. Researchers must provide each participant being seen with the Information Sheet as follows:

1. Research teams must contact each participant before their scheduled research visit to provide the information about COVID-19 risks. The information can be emailed or presented verbally to subjects by phone or other virtual method.
2. When participants arrive for a research-related visit, the study team must acquire the subject's signature on the form, and provide them with a copy.

Researchers are not required to submit an IRB Modification to add the Information Sheet to their study procedures. However, any changes or additions proposed to the *content* of the Information Sheet must be submitted as a Modification request for approval by the IRB.

INFORMATION SHEET:
Important Information about COVID-19 and Research Participation

At the University of Texas at Arlington, our primary responsibility related to research is to protect the safety of our research participants.

COVID-19 refers to the Coronavirus that is being spread from person to person across our communities. We are providing you with important information about COVID-19 and the ways your study participation might change because of COVID-19 related risk.

If you are considering joining a study at this time or are currently enrolled in a study, it is important that you consider the following information to determine if study participation is right for you at this time.

How is COVID-19 spread? COVID-19 is a respiratory virus spread by respiratory droplets, mainly from person-to-person. This can happen between people who are in close contact with one another (less than 6 feet). It is also possible that a person can get COVID-19 by touching a surface or object (such as a doorknob or counter surface) that has the virus on it, then touching their mouth, nose or eyes.

Can COVID-19 be prevented? Current ways to minimize the risk of exposure to COVID-19 include "social distancing" which is a practice to decrease the potential for direct exposure to others who may have been exposed to COVID-19, for example by avoiding large gatherings or refraining from shaking hands with others. It is important to understand that since study participation may include increased travel outside of your home and increased exposure to others within a clinical care environment or research site, it may increase your exposure to COVID-19. At this time there is no vaccination to prevent COVID-19 infection.

What are the risks of COVID-19? For most people, the new coronavirus causes only mild or moderate symptoms, such as fever and cough. For some, especially older adults and people with existing health problems, it can cause more severe illness, including pneumonia. While we are still learning about this virus, the information we have right now suggests that about 3 of 100 people who are infected might die from the virus.

Who is most at risk? The Centers for Disease Control and Prevention (CDC) warns that older adults and people of any age who have serious underlying medical conditions might be at higher risk for severe illness from COVID-19. The following settings or conditions specifically may place you at high-risk:

- Age 65 years and older
- Live in a nursing home or long-term care facility
- People of all ages with underlying medical conditions, particularly if not well controlled, including:
  - Chronic lung disease or moderate to severe asthma
  - Serious heart conditions
  - Immunocompromised

    - Many conditions can cause a person to be immunocompromised, including cancer treatment, smoking, bone marrow or organ transplantation, immune deficiencies, poorly controlled HIV or AIDS, and prolonged use of corticosteroids and other immune weakening medications
- Severe obesity (body mass index [BMI] of 40 or higher)
- Diabetes
- People with chronic kidney disease undergoing dialysis
- People with liver disease

How could your participation in this research change as a result of COVID-19? There are several ways we try to minimize your risk. If possible, we limit the number of times you have to come to a clinical care or research site. We ask every research participant if they have the symptoms of COVID-19 or have been in close contact with anyone who has or had COVID-19. It may be a requirement to check your temperature or we may ask you to wear personal protective equipment (PPE) such as a mask or gloves. During your research visits, we try to reduce the time you are exposed to other people as much as possible. There may be last minute changes to how research procedures are performed (such as a change from an in-person visit to a telephone call) or cancellations of research tests or procedures to ensure your safety. It is even possible that your research procedures will be put on hold or stopped because of COVID-19.

The information related to risks of COVID-19 changes every day. The University is actively monitoring these risks and deciding how these risks should change our research. If you have questions or concerns about COVID-19 and your participation in research, please talk to the research team.

Your participation in the research remains voluntary, and you may discontinue at any time without penalty. If there are certain safety precautions or procedures you are uncomfortable with, notify the research team. Certain accommodations may be possible, but it is also possible that we choose to delay your research participation until a later time when the precautions are no longer necessary, or withdraw you from the study.

_____ _____

Signature of Participant Date