Request to Conduct HSR During COVID-19

Instructions: Please utilize this form to indicate how your human subject research (HSR) activities will implement COVID-19 safety precautions. To complete this form, refer to this document which includes: 1) list of safety procedures, 2) Checklist for HSR Planning During COVID-19, and 3) the handout “Special COVID-19 Information for Research Participants.” To submit your Request for consideration, submit an IRB Protocol (for new projects) or Modification (for existing approved protocols) in Mentis and upload this completed Request Form as an attachment. **Please note that unless otherwise expressed by you, the special accommodations described in #8 - #14 below will be considered as temporary; once HSR restrictions related to the COVID-19 pandemic are lifted, it is understood that you will return to the standard procedures approved in your IRB protocol.

1. Principal Investigator:

2. IRB Protocol # and Title:

3. Is your protocol federally funded and/or FDA regulated?

4. Describe the in-person HSR activities that are essential for the research purpose and that cannot be postponed or occur in some other way.

5. What direct physical contact or close interactions will take place (please be specific)? How long will the activities last, and how many times will they take place?

6. Where will the activities take place? Will any other individuals be present or in the vicinity other than research team personnel and the subjects (for example, in a shared lab space)?

7. Describe the subject population. What is the age range of subjects? Will any be considered at higher risk for severe illness from COVID-19 according to CDC guidelines?

8. Describe how hand washing, face coverings, eye protection, and gloves will be utilized and enforced for subjects and research team personnel. If one or more of those precautions is not possible due to the nature of the study procedures, please explain. Describe the use of any additional PPE, safety measures, or engineering controls. Longer periods of close interaction or direct physical contact (>10 minutes of direct contact or close interaction) or activities with potential for high exposure may require additional personal protective equipment (PPE) or engineering controls such as face shields, physical barriers, etc.

9. Describe how social/physical distancing will be maintained and enforced (other than the occasions requiring direct physical contact/close interactions).

10. Describe how scheduling will be managed to ensure that 1) exposure/presence of research team personnel is minimized to the greatest extent possible, and 2) an appropriate amount of time will be allotted to clean and disinfect between each subject’s visit.

11. Describe your process and products for cleaning and disinfection of facilities and equipment/devices. Confirm any products used are EPA-approved for use with human coronavirus.

12. The process for symptom screening and temperature checks for subjects and research team personnel is described in the “Checklist for HSR Planning During COVID-19” referenced in this form’s instructions.
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Please confirm you will follow those procedures and utilize the screening questions in the Checklist. If you propose any alterations or additions, please describe them here.

13. The process for notifications if someone (a subject or research team personnel) identifies being exposed to or tested positive for COVID-19 is also described in the “Checklist for HSR Planning During COVID-19” referenced in this form’s instructions. Please confirm you will follow those procedures. If you propose any alterations or additions, please describe them here.

14. Describe how you will ensure all research team personnel follow the procedures and requirements described above, and how you will monitor for continued adherence.

Reminder:

The handout “Special COVID-19 Information for Research Participants” must be presented and signed by each research subject prior to participation.
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, in-person human subject research activities including close or direct physical contact 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. The following points must be communicated to subjects in advance of their visit:
   a. The use of face coverings is requested for the safety of the subjects in relation to the specific protocol procedures, and/or to reduce variability in the data collected;
   b. The research activity is completely optional/voluntary. Therefore, if they are unwilling or unable to wear a face covering they can decline or defer participation to a later date when face coverings may no longer be necessary for the study’s procedures.

2. When participants arrive for a research-related visit, the study team must acquire the subject’s signature on this form, and provide them with a copy.

Any changes or additions proposed to the content of the Information Sheet must first be authorized 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 the use of face coverings or “social distancing” which is a practice to decrease the potential for direct exposure to others who may have been exposed to COVID-19. 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.

**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, gloves or eye protection. 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 completely optional and voluntary, and you may decline or discontinue at any time without penalty.** If there are certain safety precautions or procedures you are uncomfortable with, notify the research team. 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. If you develop symptoms or test positive for COVID-19 within 14 days of this activity, please immediately notify the research team.

__________________________________________  _______________
Signature of Participant                          Date