**COVID-19 Considerations for Human Research**

The intent of this document is to assist investigators with identifying and addressing the risk and precautions related to their research arising from the emergence of COVID-19. **Although other questions may arise during protocol review, investigators should consider the following when developing and preparing protocol applications and requests to modify existing protocols.** Locations where the information should be included in protocol applications or modification requests are included below. **Please refer to the** [**IRB COVID-19 Precautions**](https://cws.auburn.edu/ovpr/pm/irb-covid19-precautions) **for additional information.** Resources will be updated as new information becomes available.

**COVID-19 RISK**

1. **Identify aspects of the project that could be high risk in relation to COVID-19.**

*Include in Protocol Application Question 12a and Modification Form Question 4*

1. Will your study involve high risk participants (*examples include: older adults or those with serious underlying medical conditions*)?
2. Will your study involve high risk populations (*examples include: those residing in prisons or long-term care facilities*)?

*Include in Protocol Application Question 13b and Modification Form Question 4*

1. Will your study involve high risk procedures (*examples include: administering oral or nasal swabs; procedures involving potential for increased respiratory secretions, such as exercise or VO2 max measurements*)?
2. **Describe the setting where face to face interaction or physical presence of the participant will occur.**

*Include in Protocol Application Question 11 and Modification Form Question 4 & 5*

1. Will research take place on campus or off campus?
2. What is the name and location of the facility (building, address, etc.) were research activities will take place?
3. What is the name or number of the location/room within the facility where research activities will take place?

*Include in Protocol Application Question 13b and Modification Form Question 4 and 5*

1. What is the size of the location/room where the research activities will take place?
2. How will the location/room be configured during research activities?
3. Who will be in the location/room with the participant?
4. What is the minimum distance that can be maintained between a participant and the researcher and a participant and others that may be present?
5. Will an effective barrier (type – window, plexiglass, curtain? dimensions?) be used if a minimum of 6 feet separation is not maintained at all times between all persons present?
6. What is the length of time needed for the research activities that require face to face interaction?
7. [What building and room ventilation factors](https://cws.auburn.edu/shared/files?id=159&filename=COVID-19%20Ventilation%20Guidance%20for%20Human%20Subjects%20Research.pdf) have been considered based on the risk factors of the proposed project?
8. **Explain how the research activities relate to other activities that may be occurring at the site at the time the research is taking place. If there is no relationship, include that participants and/or researchers will come to the research site only for the purposes of participation or the conduct of research.**

*Include in Protocol Application Question 8 and Modification Form Question 4 & 5*

1. Will the participant be at the research site for purposes other than human research?
2. Will the researcher be at the research site for purposes other than human research?
3. Are the research activities similar to non-research activities the participant may engage in?

**COVID-19 PRECAUTIONS**

1. **Describe the precautions that will be put in place to address the risk of COVID-19. Include copies of any documents such as screening instruments, scripts, consent documents, etc.** *Include in Protocol Application Question 15 and Modification Form Question 5d*

**General Precautions:**

1. If research activities will take place off campus, does the facility/location have requirements for addressing COVID-19?
2. Is there a location where researcher and participants may wash their hands?
3. Will hand sanitizer be available for researchers and participants?
4. Has COVID-19 risks and precautions been included in consent documents?
5. Will researchers self-quarantine (refrain from contact with others for a period of time) prior to or during the time-period they are physically interacting with participants?

**Screening and Rescreening:**

1. Will you use a screening process for participants and research personnel?
2. When and how will screening be addressed?
3. Will you use a rescreening process for participants and research personnel?
4. When and how will rescreening be addressed?
5. What criteria would cause a researcher to fail the screening/rescreening?
6. What criteria would cause a potential participant to fail the screening/rescreening?
7. What will happen if a researcher fails the screening/rescreening?
8. What will happen if a participant fails the screening?

**Personal Protective Equipment (PPE):**

1. What PPE will be worn by the researcher?
2. What PPE will be provided and worn by the participant?
3. Will researchers and participants be trained in donning and doffing PPE?
4. Who will conduct the PPE training?
5. How often will researchers change PPE?
6. How will PPE be disposed of or disinfected?

**Surface Decontamination:**

1. Will the participant make contact with physical items while present for research activities?
2. How will the items be decontaminated before and after each participant?