University of North Alabama
Institutional Review Board for Research Involving Human Subjects

**Research Protocol Form**

**Section I**

1. **Project Summary:**
Please provide a brief, descriptive summary (500 words or less) that includes the following: 1) previous relevant research findings to support this research proposal, 2) a concise statement of the purpose of this research 3) a brief description of the methodology, 4) expected and/or possible outcomes, and 5) a statement about the potential significance of this research project.

2. **Research Goals:**
How will the results of this project be used (e.g. Presentation/Publication/Thesis)?

3. **Research Personnel:**
Please list all key personnel involved in this research and the specific roles and responsibilities for each.

4. **Location of Research:**
List all locations where data collection will take place. Be specific (include building names, room numbers, etc.). If data will be collected face to face, or if the physical presence of participants is required, please answer the following questions.

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. Is the location/room well ventilated and are there ways to improve ventilation?
7. What is the length of time needed for the research activities that require face to face interaction?
8. Will the participant be at the research site for purposes other than human research?
9. Will the researcher be at the research site for purposes other than human research?
10. Are the research activities similar to non-research activities the participant may engage in?

K. Describe the precautions that will be put in place to minimize the risk of COVID-19 for participants. Include copies of any documents such as screening instruments, scripts, etc.

**5. Face to Face Participation**If participants will have a physical presence and/or engage in face to face research, please answer the following questions. If all data collection can be conducted with **no** face to face participation, please skip this section and move on to Section II.

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

**Section II**

1. **Participants:**
Describe in detail 1) the participant population you have chosen for this project, 2) the minimum and maximum number of participants needed for analysis, and 3) how you plan to recruit participants. Include your recruitment script here.

4) 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*)?
3. Will your study involve high risk procedures (*examples include: administering oral or nasal swabs; procedures involving potential for increased respiratory secretions, such as VO2 max measurements*)?
4. **Group Assignment and Compensation:**
Please describe in detail 1) how participants will be selected for groups (if applicable) and 2) what if any compensation will individuals receive for their participation.

**Section III**

1. **Project Design and Methods:**
Describe in detail how you address the aims of this study (NOTE: Use language that would be understandable to a layperson.).

a. Briefly describe the study design.

b. List all instruments used in the data collection. *Please include a copy of all data collection instruments as* ***Appendix A or Appendix A1, A2…, etc., for multiple instruments****.*

c. Please describe any potential psychological or physiological risks and or discomforts that participants may experience as a result of their involvement in this study. These may include concerns related to Covid-19.

d. Please describe how those risks and or discomforts (if any) will be minimized.

**Section IV**

1. Will data be collected as anonymous or confidential?

a. If data will be confidential, explain how participant data will be coded or linked to identifying information.

b. Please describe 1) where and how the data will be stored and 2) who will have access to the data.

c. How long will the data be stored/secured? Will the data be secured on a UNA password-protected server? Will the data be secured on a biometric or password-protected external hard drive or computer? How will it be disposed of when the study is complete?

**Section V**

**Informed Consent:**
Prepare and submit as **Appendix B** informed consent document(s) using the UNA template(s) provided on the UNA Human Subjects Research webpage.