APPLICATION NUMBER:
(Office Use Only)

Daemen University IRB – Human Subjects Research
Safety Plan for In-Person Research
During Covid-19 Pandemic

INSTRUCTIONS

The purpose of this form is to ensure that appropriate safety procedures are in place before conducting any in-person, face-to-face research with human subjects. This form needs to be submitted, reviewed, and approved by Daemen's Institutional Review Board - Human Subjects Research (IRB) *before any in-person, face-to-face human subjects research can begin*.

To request approval to conduct in-person, face-to-face research procedures with human subjects, please submit this form, and *append it to the appropriate application for review* (i.e., an application for exempt or expedited/full review for new research protocols, or a modification application to resume previously approved research protocols) *as a Single MSWord file to the IRB Chair at irb@daemen.edu*. Please copy (cc) all associate investigators and use Daemen University e-mail addresses (where applicable). For student projects, faculty supervisors must submit on behalf of the student researcher(s).

Before submitting, it is important to make sure that the research protocol and safety procedures are appropriate for the current designated research stage (e.g., red, orange, yellow, green). See IRB Standards for Conducting In-Person Research.

I. PARTICIPANTS:

1. **Does the study specifically target or would expect to include a majority of participants that have been identified as being at increased risk for severe illness?**

☐ Yes ☒ No

If 'Yes', which of the following apply?

☐ Older age individuals Indicate age range

☐ Underlying health conditions* Describe conditions

*Examples include, chronic kidney disease, COPD, immunocompromised state, obesity, serious heart conditions, sickle cell disease, type II diabetes. This list is likely to change with new and evolving research. Please see CDC website for current conditions.

If 'Yes', please justify the use of participants with increased risk:

II. SCREENING:

1. **Describe the *participant* screening procedures that will be utilized (e.g., upon entering the research site):**

Upon arrival, but before any study or consenting procedures take place, participants will be asked the questions below related to Covid-19 screening. If they indicate "yes" to any of the questions, it will be explained that they cannot participate at this time and will be offered an opportunity to reschedule if they wish. If all responses are "no", then the study procedures will begin.

Please indicate if you have had any of the following within the last 10 days:

- Close or proximate contact (within 6 feet) with anyone who tested positive for COVID-19 or anyone who has or had symptoms of COVID-19.
- Experienced any COVID-19 related symptoms such as the following (you may answer "No" to this question if you have had a negative COVID-19 test within 10 days after the onset of symptoms):
  - Fever (above 100.4 degrees F)
  - Chills
  - Dry cough
  - Unexplained shortness of breath
  - Unexplained muscle pain
  - Loss of taste or smell
  - Diarrhea
  - Vomiting

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2. **Describe the *researcher* screening procedures that will be utilized:**

Before researchers arrive at the study site for the day, they will engage in a self-screening using the same questions from above. If the answer to any of the questions is "yes", the researcher will not conduct any in-person study procedures (another researcher will fill in or participants will be contacted to reschedule if they wish). If the answer to all the questions is "no" the researchers will proceed according to the research protocol.

III. PARTICIPANT CONTACT:

1. **How many participants will be present during a single study session?** **Up to 4**

2. **How many researchers will be present during a single study session?** **1**

3. **Describe the level of researcher-participant contact and distancing procedures throughout the study:**

Participants will be seated at computers that are at least 6 feet apart. The researchers will need to come into close proximity to participants (within 6 feet) several times throughout the study (e.g., to distribute and collect the various study materials). However, this will be limited to only a few seconds at a time. Otherwise, the researcher will sit at least 6 feet away from participants for the duration of the study.

IV. FACE COVERINGS AND PPE:

1. **Describe the procedures for ensuring that face masks will be worn by both participants and researchers:**

All recruitment materials will mention that face masks will be required for participation. There will be a box of extra masks at the study site in case either researcher or participant forget their mask.

2. **Describe any additional PPE that will be used if necessary:**

No additional PPE will be used.

V. HYGIENE AND CLEANING:

1. **Describe the cleaning procedures* that will occur to maintain proper cleanliness standards during each research session and before/after each participant (e.g., handwashing, wiping down any equipment used, etc.):**

*If the research is taking place at a specific facility or institution, it is okay to simply indicate that the cleaning procedures/policies of that institution/facility will be followed.

In addition to normal Daemen cleaning procedures utilized by cleaning personnel, the computer keyboard, mouse, and pens will be wiped down with antibacterial wipes between uses. Hand sanitize will also be available for participants and researchers at the study site.

VI. COMMUNICATION:

1. **Describe how consent procedures will ensure that participants are properly notified of risk:**

Under the "Risks" section of the consent, it will state the following: "Although no greater than minimal, because the research study is conducted in-person, there is the risk of exposure to and resulting symptoms of Covid-19."

2. **Describe how participants will be made aware of safety procedures before their arrival (e.g., that they must wear a mask, etc.)**

All recruitment materials will mention that face masks will be required for participation. There will be a box of extra masks at the study site in case either researcher or participant forget their mask.

3. **Describe the communication plan in place for researchers and participants to communicate information related to a potential or confirmed case (including notification to local and state health departments and contact tracing efforts, if applicable):**

Daemen protocols will be followed.

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VII. CERTIFICATION

This form must be signed (either by typing in your name or inserting an electronic signature) and appended to the appropriate application for review.

The signatures below indicate that both the researcher(s) and the faculty supervisor (if student researchers are involved) will operate in accordance with the details in this safety plan and all professional, federal, state, local, and Daemen University regulations and guidelines for the protection of human subjects during the COVID-19 pandemic.

Principal Investigator: _____ Date: _____

Faculty Supervisor: _____ Date: _____

Associate Investigator: _____ Date: _____

Associate Investigator: _____ Date: _____

Associate Investigator: _____ Date: _____