CWRU Safety Plan: 
Checklist for In-person Human Subject Research Activities

Please note that a Research Laboratory or Center can develop one safety plan to cover all of their research activities. However,

- Each research activity must be listed,
- Information is required to be provided, and
- Questions answered for each one throughout this document.

Describe research activities that need to be completed in person and explain why you could not accomplish your study via remote methods.

What is the duration of contact with the participant for the activities?

Indicate where in-person research activities will take place:

- On CWRU’s campus in a laboratory or designated research space
- Off-campus in Cleveland or elsewhere in Ohio
- Off-campus outside of Ohio in the United States:
  ____________________________________________
- Off-campus outside the United States (International):
  ____________________________________________

**For U.S. studies outside of Ohio and International studies:** We need to understand the local context of your research site with respect to resuming in-person research activities. Please describe the following:

- What research activities are permitted by local authorities at your site?
- What COVID-19 protections are required to permit in person activities to go forward?
- What guidance/requirements have been issued by local authorities (Health Departments, Ministries of Health, Government authorities, local IRBs, etc.)?
- What COVID testing capacity is available?
- Upload all documents associated with your responses with this form.

What is the makeup of the research personnel that will be conducting the in-person research by role (select all that apply)?

- PI/Faculty
- Staff
- Graduate student
- Undergraduate student
- Other (please specify): __________________

Social Distancing
For each room used in the research activities, provide the square footage of the room and the number of individuals to be present in the room.

Describe any signs or floor markings that will be used to help maintain social distancing.
Face coverings
- For researchers and research participants:
  - Required to come with mask
  - Will provide masks
- What type of mask will be worn by researchers and study participants?
  - N95 mask
  - Cloth/surgical mask
  - Face Shield
  - Other _____________________
- Other PPE which will be used (e.g.; gloves, gown):

Hand washing
Please describe the plan for hand washing (e.g., research staff and participant(s) will locate a sink and wash their hands, or will use hand sanitizer, prior to initiating contact).
- If using hand sanitizer, who will provide the hand sanitizer?

Cleaning procedures
- Please describe the cleaning procedures you will use prior to initiating contact with equipment/surfaces.
  - At a minimum this should include wiping down all surfaces with sanitizing wipes prior to contact.
  - There should be ample time allotted between cleaning the equipment and surfaces and the next participant performing research activities to give the cleaning product time to dry and be effective.
  - Please indicated if the cleaning will be done by the CWRU team, facility staff, or others.

Shared Equipment
Please list any shared equipment used by other individuals outside of the research team (departmental equipment, shared between labs, etc).

Participant screening and triage methods:
Screen all study participants prior to commuting or entry into the research site for:
- Meeting the inclusion criteria of the study
  - Calling research participant
  - Emailing research participant
- Elevated temperature and COVID-19 symptoms
  - CWRU COVID Daily Health Assessment
  - COVID-19 Screening Symptoms

Requirements and Resources:
- If you have no space in your site for screening, perform screening via phone the day before or day of the research study visit.
- If in-person temperature measurement and symptom screening is proposed, conduct triage outside or upon initial entry into the research space.
IRB Protocol Criteria:
Prior to an in-person visit, the study team should be in contact with participants to determine eligibility, and begin the consent processes (review consent document). Describe your plan for this process.

In most cases, a waiver of documentation of consent should be requested in order to reduce unnecessary contact between participants and the research team. The IRB protocol may need to be updated to request this waiver and provide justification. The participant can be given the document to have, and additional information will need to be added to the confidentiality section in the event that a participant or researcher becomes infected with COVID-19 for contract tracing purposes.

Please Read & Keep as a Reference:
CWRU Best Practice Contingency Plans for In-person HSR COVID-19 Exposure-
- Plan for handling a study team member testing positive for COVID-19
- Plan for handling a study participant who tests positive or has experienced unprotected exposure to COVID-19
- When to Self-Isolate
- When to Quarantine

As PI, I certify to the following statements:
- I have discussed the In-person HSR plan and CWRU’s Best Practice Contingency Plans for COVID-19 Exposure with all members of the research team.
- I understand that this plan will be reviewed by the Office of the President and the CWRU Health and Counseling Services and I will adhere to the specifics included in the plan.
- The research team will follow prevailing guidelines regarding infection control, including not having staff come to work who have symptoms of illness, and following current CWRU guidelines if members of the team test positive for COVID-19.
- I have discussed with my research team the importance of personal safety practices of daily symptom reporting, universal face coverings, physical distancing, and handwashing and ensured training in these areas.
- Research team members and participants will wear face coverings at all times, with the exception of pre-approved locations where not feasible (e.g. eating lunch in designated break room; dedicated office for sole individual use).
- The research team will ensure that study participants undergo screening for symptoms and fever prior to entry into research space.
- The research team has developed a study work plan based on size and layout of research space for physical distancing to enable a 6-foot distance between all persons in the research environment, including both research staff and study participants.
- The research team will minimize the duration of time of in-person interaction with study participants and will continue remote research activities to the extent possible.
☐ I am providing appropriate personal protective equipment (PPE) for research team members and ensuring appropriate training per guidelines. Appropriate levels of PPE will be utilized when physical distancing is not possible due to performing research assessments.

☐ The research space has regular cleaning practices in place. The research team has developed protocols for use and cleaning of the research space, surfaces and equipment in between study participants.

☐ Once this Safety Protocol/Plan is approved by the Office of the President and the CWRU Health and Counseling Services, I will submit it with my new IRB protocol submission or submit a modification to my existing CWRU IRB protocol.

Investigator’s signature: _____________________
Dean’s signature: _____________________
Executive Director’s, Health & Counseling Services signature: _____________________
Executive Director’s, Research Compliance signature: _____________________