**CSU COVID-19 Safety Plan for Research with Human Participants**

***(All sections must be completed)***

This document is used to describe measures being taken by CSU investigators to prevent the transmission and spread of COVID-19 during face-to-face research with human participants. Prior to restarting face-to-face data collection with human participants, investigators must have approval from the Research with Human Participants COVID-19 Review Panel (RHPCRP) as well as their College Dean (or designee) and Department Chair (or School Director). These approvals must then be submitted to the IRB for final approval to proceed with face-to-face research with human participants.

*Failure to comply with approved plans may result in suspension of face-to-face research with human participants.*

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| **Research Contact: Faculty member/PI responsible for implementing plan and ensuring communication of the procedures to all members of the research team** | |
| **Name** |  |
| **Department** |  |
| **Phone** |  |
| **Email** |  |
| **Study Title** |  |
| **What space(s) is this plan covering?** |  |
| **How will this information be communicated to the research team?** |  |

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| **Please provide an overview of your research methodology that involves face-to-face human interaction.** |
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*For the topics below, please provide a detailed description of the following measures taken to minimize the risk of transmission and spread of COVID-19 among your research personnel and participants.*

**Research Space Management**

Each research laboratory/room should have a shared electronic schedule (i.e. Google Calendar, Google Docs., etc.) that is accessible to all researchers using the space. Researchers will need to post the times of their research activities on the schedule, and coordinate scheduling to ensure the ability to maintain physical distancing.

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| **Describe the location and areas in which people will be present as part of your research, as well as how schedules will be managed to reduce personnel density. This includes data collection sites, as well as areas for data analysis. Please be sure to include information pertaining to the following:**   * **The size of the space, as well as if it is a shared or single space** * **For shared spaces, a description of how space utilization will be coordinated to prevent overlap between research teams** * **The number of people that will be in the area/space at any one time, and how that number minimizes personnel density to allow for physical distancing of at least six feet** * **A description of work schedule management, including how work schedules will be adjusted to minimize personnel density to allow for general physical distancing of at least six feet** |
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**COVID-19 Screening**

Prior to every visit to campus, all individuals involved in research with human participants must complete the CSU COVID-19 Self-Assessment. Research participants must be screened by phone or email within 24 hours of coming to the CSU campus. No one may come to the CSU campus or participate in in-person research if they, or any members of their household are experiencing the symptoms outlined on the checklist. For every visit to campus, research participants must also complete the COVID-19 Screening Questionnaire immediately upon arrival to campus. Only participants who answer “No” to all questions may be allowed to participate in face-to-face research that day. Decisions about in-person visits for people at higher risk should be especially cautious.

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| **Prior to coming to campus, all research personnel and participants must be screened for COVID-19 symptoms and exposure. Describe how screening will be done, including who will be responsible for the screening, and when the screening will be completed.** |
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**Consenting**

All researchers must add a COVID-19 statement to their informed consent/assent. It is imperative that all human research participants demonstrate clear and complete understanding of this statement.

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| **Please describe who will be conducting the informed consent/assent procedure, and how they will ensure that the participant has full understanding of the risks involved as well as the conditions for participation?** |
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**Personal Protective Equipment**

*Please note - these are the minimum recommendations. A researcher may choose to use advanced PPE under any circumstances, particularly when working with higher risk individuals.*

* If the research involves interaction with the participant and can maintain a minimum of 6 feet of physical distance, or is within 6 feet, but with an effective barrier (e.g., glass or plexiglass barrier, cubicle) the following PPE should be worn:
  + Research Personnel – Cloth face covering
  + Participant – Cloth face covering
* If the research involves interaction with the participant within 6 feet without an effective barrier, the following PPE should be worn:
  + Research Personnel – Surgical mask and face shield
  + Participant – Cloth face covering
* In the event that wearing a mask would lead to potential interference with the research protocol, such as during heavy physical exertion, or in studies performing observations of facial expressions/body language, etc., a minimum of 6 feet must be maintained between the investigator and any other research participants, as the study permits, and the following PPE should be worn:
  + Research Personnel – Surgical mask and face shield
  + Participant – None during testing phase; cloth mask when able
* If investigators absolutely must come closer than 6 ft to the research participant while they are performing heavy physical exertion as part of the testing protocols, the following PPE should be worn:
  + Research Personnel - Surgical mask, disposable lab coat\*, face shield, goggles, and gloves\*\*.
  + Participant - None during testing phase; cloth mask when able

\*One may use a reusable cloth lab coat, but it must be washed with bleach between uses with different research participants.

\*\* Gloves are generally not recommended in typical public interactions. Instead, frequent handwashing and/or hand-sanitizing is recommended. However, it will be left to the discretion of the researchers whether or not they choose to wear gloves. Please be aware that if a researcher chooses to wear gloves, they should discard old gloves and put on a new pair of gloves frequently (i.e., after each subject, after transiting from one area to another, etc.), and that their hands should be thoroughly sanitized between changing gloves. Here are the recommendations of the CDC on wearing gloves: <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/gloves.html>

To request masks (cloth, surgical, or N95) or face shields, research supervisors/primary investigators should contact Dave Diggins at [d.diggins@csuohio.edu](mailto:d.diggins@csuohio.edu) (EHS) or Brandon Dugan at [b.c.dugan@csuohio.edu](mailto:b.c.dugan@csuohio.edu) (FAST). Please provide the name, CSU ID#, and PPE needs for each member of the research team. Researchers will be responsible for any additional PPE, including goggles, gloves, and gowns/lab coats. Departments should bill the following account for COVID-related supplies cleaning and PPE supplies obtained through FAST or EHS:  xxxx-0010-3482-50

For proper donning and doffing of PPE, please see the following website: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html>

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| **Describe all PPE requirements that will be observed during research activities, and provide reasoning for proposed PPE requirements. Please be sure to address the following:**   * **Standard PPE requirements when physical distancing is able to be maintained** * **Describe any situations in which individuals will need to be in close proximity to perform research-related activity, and what measures will be employed to minimize contact time and transmission risk. Include a description of any partitions, barriers, or other methods to physically separate people.** * **Describe any work that cannot be done while wearing PPE (for either research personnel or participants) and measures that will be taken to minimize the potential for COVID-19 transmission.** |
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**Cleaning and Disinfecting Guidelines**

Any piece of equipment or physical item that research participants make physical contact with should be disinfected before and after each participant. Ensure that your research personnel and participants have access to all necessary supplies, including paper towels, waste baskets, cleaners and disinfectants, and hand sanitizer that contains at least 60% alcohol. Clean and disinfect all surfaces that may have been contacted by participants using EPA approved disinfectants. For a list of these products and instructions on their proper use, please see the following website: <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-covid-19>

Recommended disinfectants as deemed appropriate by the CDC will be used after each in-person session.  These solutions include but are not limited to:

* Alcohol solutions with at least 70% alcohol
* Lysol/Clorox all-purpose cleaner or disinfecting wipes
* Bleach solutions diluted (1/3 cup bleach per 1-gallon water) - Solution must sit for a minimum of 1 minute on surface.

Most surfaces and objects will only need routine cleaning.  Frequently touched surfaces will need disinfecting.  All objects to be disinfected should be cleaned with soap and water first and then disinfected to further reduce the risk of germs on surfaces and objects.

Frequently touched surfaces have been identified but not limited to the following:

* All tables, doorknobs, light switches, countertops, handles, desks, phones and keyboards.  (Electronics should only be disinfected with alcohol ONLY)

Proper hand-washing and/or hand-sanitizing techniques must be followed by both investigators and research participants before and after testing, and during testing if physical contact is made. Please see the following website regarding hand hygiene: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/hand-hygiene.html>

For cleaning and disinfection supplies, as well as hand sanitizer please contact FAST at (216) 687-2500

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| **Describe all cleaning and disinfecting protocols for all research equipment, procedure areas, analysis areas, PPE, and hand hygiene. For equipment that cannot be properly cleaned with an EPA-registered cleaning product, describe what methods will be used to prevent transmission.** |
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**Dealing with COVID-19 positive cases**

In the event that research personnel or a participant becomes infected with COVID-19, researchers should contact CSU Health and Wellness services immediately, seek medical care as necessary and quarantine until they have been cleared to return to campus by CSU Health and Wellness. Personnel or research participants who were in close contact with the infected individual (close contact = spent >15 minutes within 6 feet of the person) should be notified and should self-quarantine for a minimum of 14 days and follow any additional guidance from CSU Health and Wellness. Research will need to be suspended until researchers have been cleared to return to campus.

A log of each day’s participants should be recorded and maintained in a secure location. These must be kept for 3 weeks and then securely destroyed. In the case of anonymous research, the research data should be collected anonymously. However, participants should be notified that anonymity cannot be assured due to the pandemic and contact tracing procedures. A statement reflecting this will need to be included in the updated informed consent.

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| **Describe measures that will be taken to minimize the spread of COVID-19 in the event that a member of the research team or a participant test positive for the virus.** |
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**Updating Protocols**

Please be aware that the COVID-19 pandemic presents a fluid situation that can change rapidly. All protocols will be subject to change in accordance with federal, state, local and university recommendations and requirements.

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| **Specify who will be responsible for monitoring CDC, state, and university requirements related to COVID-19, updating this plan as necessary, and communicating any procedural changes to personnel.** |
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**Other**

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| **Please provide any other steps or considerations relevant to your research. This includes a statement from the PI regarding any student workers (see below in “Personnel Sign-Off”).** |
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**Personnel Sign-Off**

All research personnel, including faculty and students who are included on the IRB for this protocol, must be documented below. Student workers who are assisting with data collection but are not on the IRB for this protocol should complete the CITI COVID-19 Back to Campus training and be familiarized with this safety plan. PI’s need to make a statement above in the “Other” section verifying this, if applicable.

By signing below, I acknowledge that I have read, understand, and agree to comply with the Cleveland State University COVID-19 Safety Plan, and all procedures described above.

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| **Printed Name** | **Signature** | **Date** |
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Department Chair/School Director: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_

*(Signature)*

College Dean or designee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_

*(Signature)*

Please submit this completed form to the Research with Human Participants COVID-19 Review Panel at: [RHPCRP@csuohio.edu](mailto:RHPCRP@csuohio.edu)