**Basic Requirements for Risk Mitigation Standard Operating Procedures (SOP)**

Researchers who plan to resume in-person research activities with human participants should develop plans that outline the additional procedures that have been implemented to prevent the transmission of COVID-19. All research staff should be familiar with and trained on the new procedures outlined in these plans.

This list below outlines the basic requirements to be included in the plan. Additional areas might need to be addressed based on the type of research procedures and where it is being conducted. As you develop your plans, walk through the process (recruitment, consent, research procedures) from the time you reach out to a participant to ask them to participate through the end of the research activities and the participant has left the facility. Please keep in mind this information is subject to change based on new information and guidance that is released.

The risk mitigation SOP will be reviewed according to the reasonable person standard and adherence to the requirements listed below. The IRB and HRPP will not require revisions to SOPs that are reasonable and adherent.

Please consider the following when developing your risk mitigation SOP:

* General Procedures:
	+ Streamline study procedures to reduce time and minimize exposure.
	+ Wear masks or other facial covering.
	+ Provide adequate space for physical distancing of at least 6 feet to reduce proximity is possible based on previously approved research procedures intended to reduce risks..
	+ Instruct staff and participants to remain home if they feel ill, have had any symptoms of COVID-19 in the past 14 days, or have been in contact with someone who tested positive for COVID-19 or has symptoms.
	+ Persons with a fever are not allowed in laboratories.
	+ Post signs to remind staff to stay home if they feel ill, have symptoms, or have been exposed.
	+ Consider daily check-in/symptom attestation for students and staff.
	+ Notify local public health authorities and perform enhanced cleaning and disinfection if someone tests positive within 14 days of being on-site.
	+ Provide a way for participants to wash their hands when they enter the research site (sink with soap and water or hand sanitizing station).
	+ Instruct students/staff to wash their hands or use hand sanitizer once in the lab before and after interacting with each participant.
	+ Remind students/staff and participants to avoid touching their faces during study procedures.
	+ Provide masks for any study participant who arrives to participate and does not have a mask.
	+ Properly sanitize common/shared space between each use.
	+ Develop a schedule and task list so you can track and monitor who will be on-site and who is responsible for specific disinfection tasks.
	+ Avoid- drop-in visitors by posting a sign with instructions on what to do upon arrival.
	+ Document a plan for receiving deliveries.
* Plans for Physical Distancing:
	+ Minimize the number of individuals (research staff and participants) that will be on-site at one time taking into consideration previously approved safety precautions.
	+ Post signs to remind participants about physical distancing.
	+ Consider contacting participants in advance to ask screening questions related to symptoms or exposure to COVID-19.
	+ Provide participants with instructions they need to follow when they arrive at the research site.
	+ Maintain physical distancing (at least 6 feet) for as much of the study visit as possible. If the study involves forceful exhalations (such as during exercise), additional distance will be needed.
	+ Require cloth masks or face shields for both participants and study staff when the study procedures make if difficult or impossible to maintain a distance of at least 6 feet between research staff and participants.
	+ Maintain physical distance of at least 6 feet between research participants at all times.
	+ For studies involving groups of participants, develop a plan to maintain at least 6 feet of space between participants and stay within state or local requirements on size of group gatherings.
	+ Consider asking participants to wait in their car until the study team is ready for them and provide contact information to the participant to allow them to contact the team when they arrive.
	+ Consider your lab’s ventilation and airflow as part of your plan. If there is poor airflow, greater distancing (more than 6 feet) might be required.
* Plans to Require and Supply Personnel Protective Equipment (PPE)
	+ Review the university guidance for procuring PPE <https://www.procurement.vt.edu/AcquisitionPPE.html>
	+ Pause research activities if adequate PPE and disinfecting supplies cannot be obtained.
	+ Based on your research design and environment, develop a plan for PPE that offers the most protection for your staff and participants.
	+ Require masks or face covering if unable to maintain at least 6 feet of space between people. Encourage everyone to wear face masks when 6 feet of space can be achieved.
	+ Require that both participants and staff wear an N95 mask when physical contact is required for study procedures.
	+ Require staff to wear nitrile gloves for the duration of any participant contact.
* Plans for Disinfecting Equipment and Surfaces
	+ Obtain supplies for cleaning and disinfecting daily and in between participants.
	+ Evaluate the laboratory and study procedures for commonly touched surfaces. Disinfect between participants using products listed on the EPA website (<https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>). Include all high-touch areas and objects, including door knobs, arm rests, keyboards, and computer touch screens.
	+ Disinfect medical and other study equipment that will be used by multiple participants after each participant according to manufacturer instructions.
	+ Ask participants to bring their own pen, or provide each participant with a pen that they can use during their visit and take with them when they leave.
	+ Clean and disinfect areas that are restricted to staff only as well.
	+ Perform enhanced cleaning and disinfection in the event of possible exposure.

Revisit your plan after it has been implemented and make adjustments as needed. Minor adjustments will not need further IRB or HRPP review. Below are additional resources from CDC. Keep in mind that your study location is also a workplace for your employees, and guidance directed towards workspaces is relevant. You can also contact Environmental Health and Safety (EHS) at VT-EHS@vt.edu or 540-231-3600.

<https://www.cdc.gov/coronavirus/2019-ncov/downloads/community/workplace-decision-tree.pdf>

<https://www.cdc.gov/coronavirus/2019-ncov/community/pdf/ReOpening_America_Cleaning_Disinfection_Decision_Tool.pdf>

<https://www.cdc.gov/coronavirus/2019-ncov/community/pdf/Reopening_America_Guidance.pdf>

<https://www.cdc.gov/coronavirus/2019-ncov/downloads/guidance-administrators-college-higher-education.pdf>