

Guidelines for Human Subject Research Restart: FAQs and Case Examples

1. Research participants should be screened for COVID-19 related symptoms, exposure to close contacts with COVID-19 related symptoms or positive diagnosis of COVID-19, and travel of concern at the time the visit is scheduled and on the day of the visit. An example of a symptom screening tool for research participants is available here (<https://www.ehs.pitt.edu/sites/default/files/ResearchParticipantCOVID19ScreeningQs.pdf>).
 - a. While temperature screening is not currently required as part of COVID-19 screening for University personnel, individual departments may choose to ask personnel to self-monitor their temperature at home. Researchers are strongly encouraged to ask research participants to take their own temperature at home and report their temperature as part of the COVID-19 screening process.
2. Research participants should wear a face covering whenever possible. Self-supplied face coverings are acceptable. Researchers should ensure that disposable face masks or surgical masks are available for distribution to research participants who are not wearing a self-supplied face covering upon arrival for their visit.
3. Personal protective equipment for researchers performing human subject assessments where social distancing requirements are not feasible should consist of a minimum of a surgical mask and safety glasses or a face shield. A cloth face covering is not sufficient for these tasks. If gloves and/or laboratory coats are routinely required for the research procedure, these PPE requirements should not be altered. In most cases, if the use of gloves and laboratory coats are not currently required for the researcher, it is not necessary to add these PPE items to the surgical mask and eye protection.
 - a. Hand washing and keeping hands away from face should continue to be emphasized.
 - b. Gloves should be worn to protect skin from chemical disinfectants used to decontaminate surfaces and equipment between research participants and at the end of the day.
4. Face coverings (e.g. self-provided cloth face coverings or surgical mask) used by researchers in cases where social distancing can be maintained during interaction with participants are not PPE and may be used and reused for as long as possible. Face coverings that become soiled or visibly contaminated should be laundered or replaced.
 - a. Surgical masks required for researchers unable to maintain social distancing while performing human subject assessments that do not produce aerosols may be used and reused unless they become damaged or visibly contaminated.
 - i. Personnel should view online educational resources describing how to safely put on and take off surgical mask (<https://www.ehs.pitt.edu/online-covid-19-educational-resources>). After removing surgical mask it should be placed in a bag for storage and reuse and individual must immediately wash hands.

5. Aerosol-producing research procedures (e.g. those expected to result in a cough or sneeze, talking loudly, singing, and exercise and physical therapies) where participants cannot comfortably wear a face covering should be carefully evaluated.
 - a. If the aerosol-producing procedure requires researchers to be in close proximity to the participant, consideration should be given to relocating the procedure to an appropriate healthcare facility with the availability of respiratory protection and proper ventilation. Respirators and other work practice requirements for healthcare personnel performing aerosol-generating procedures should be followed in the site of relocation.
 - b. If clinical space is unavailable, the feasibility of increasing airflow in the study room and/or adding barriers between participant and research personnel should be considered.
 - c. In cases where relocation or room modification is not feasible, researchers should consider postponing such procedures.
 - d. If the study is deemed to be essential and the procedure has been specifically approved by the school/department, research personnel with close contact to a research participant that is not able to wear a face covering should wear a properly fit-tested N95 respirator. N95 respirators are not appropriate or necessary for research participants (unless part of the IRB-approved study)
 - i. These research personnel must enroll in the University's Respiratory Protection Program (<https://www.ehs.pitt.edu/lab-safety/respiratory-protection>). Upon completion of medical evaluation with Employee Health Services, personnel must contact the Department of Environmental Health and Safety at 412-624-9505 to make arrangements for fit testing and training.
 - ii. Researchers should ensure that N95 respirators can be obtained for fit-tested personnel prior to scheduling participant visits. Per CDC and PA Department of Health guidance, N95 respirators are designated for priority use by healthcare personnel, and it is currently difficult to procure N95 respirators for research use. If relocation or procedure alteration cannot be achieved, or if sufficient supplies of N95 respirators can't be obtained, aerosol-generating research procedures must be postponed until appropriate PPE is available.
6. The process for individual investigators to obtain approval to restart research is available in the "Governance and Process" section of the Research Restart website: <https://www.svcresearch.pitt.edu/pitt-researchers/research-restart>. Investigators should ensure that all requirements for health, safety, and social distancing can be met before allowing some, or all, research personnel and students to resume research activities.