Carnegie Mellon University

Pandemic Safety and Preparedness Guidelines for On-Site Human Subject Research

Version 2.0 (11/20/2020)

Note: For the purposes of these guidelines, "research participants" include those who are the subjects of research studies ***and anyone who accompanies them on-site, such as parents and caregivers.***

Environment Health and Safety Procedures and Quick Facts:

Consistent with the university minimum requirements for members of the CMU community and other visitors, the following guidelines should be followed during the administration of on-site human subject studies in CMU facilities[1]*:*

1. On-site human subject research studies must be part of an approved pandemic safety and preparedness plan for on-site research, as outlined on the COVID-19 researcher resources web page.

2. At the time a subject session is scheduled and on the day of a visit, research participants, should be administered screening questions to identify any of the following:

    a. COVID-19 related symptoms

    b. Exposure to COVID-19 via close contact with others diagnosed with COVID-19

    c. Travel outside of the Commonwealth of PA in the last 14 days.

    Participants who do not "pass" the screening process will not be able to participate in studies until certain conditions are met. Specific questions and procedures are outlined in a separate document entitled: *COVID-19 Screening Process and Questions for Participants in On-site Research Studies.*

3. Research participants must adhere to any temperature checks required upon entry to a facility. (Note that temperature checks may only be mandated by the university as a result of specific circumstances and cannot be a "local" rule of a lab, department or college.)

4. Research participants should wear a cloth face covering whenever possible. Self-supplied face coverings are acceptable. Researchers should ensure that disposable face coverings are available for distribution to research participants who are not wearing a self-supplied face covering upon arrival for their visit.

5. Researchers and research participants must adhere to physical distancing protocols wherever possible. Personal protective equipment (PPE) for researchers performing

[1] "CMU facilities" includes mobile testing centers owned/controlled by CMU. However, studies performed at other sites not controlled by CMU are subject to local requirements on administering human subject studies.

human subject assessments where social distancing requirements are not feasible should consist of a minimum of safety glasses or a face shield in addition to the required facial covering. 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 in addition to the face covering and eye protection.

6. All relevant surfaces and touch points should be cleaned and disinfected prior to and after each study.

7. Special consideration must be given to studies that involve aerosol-producing research procedures (e.g. those expected to result in a cough or sneeze, talking loudly, singing, and exercise and physical therapies), including but not limited to the use of N95 respirators by the researchers (note that N95 respirators are not appropriate or necessary for research participants unless part of the IRB-approved study)[2], installing protective barriers and shields between the researcher and research participant, taking steps to improving the ventilation in the facility where the study will be administered and/or relocating the study to another location with improved ventilation.

8. Prior to the administration of screening questions and preferably at the time of scheduling, research participants should be provided a human subject participant informational flyer, which advises of the screening process, its potential outcomes, their requirements while on-site (i.e. mask wearing, etc.), the inherent risks of COVID-19 and the risk mitigation activities that are relevant to their visit (i.e. cleaning and disinfecting protocols, etc.)

CMU Institutional Review Board (IRB) Quick Facts:

1. You do not need CMU IRB approval in order to contact participants to determine COVID-19 exposure or symptoms as this activity is not a research procedure. However, as described above, you must implement procedures in order to identify participants whose visits should be postponed, modified, or delayed due to COVID-19.

2. If resuming research procedures on campus requires you to alter your **research protocol** (beyond the required university prescreen) consult the IRB (irb-review@andrew.cmu.edu) to see if a modification submission is needed. Similarly, **research informed consents** do not need to be modified to address the potential risks of COVID-19 exposure in connection with traveling to participate and/or participating in a study at CMU (assuming the study is not related to COVID-19 exposure). Consents may, however, need to be modified to be consistent with any research protocol related changes.

[2] CMU researchers using an N95 mask must be registered in the CMU Respiratory protection management program and be fit-tested for the respirator. Contact safety@andrew.cmu.edu for more details. Non-CMU researchers should be fit tested for respirators by their home institution.