Grand Valley State University Institutional Review Board (IRB)	
G-19: Guidance on Conducting Human Subjects Research Studies During COVID-19	
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Researchers need to critically think about how new and on-going human subjects research studies will be affected by the COVID-19 crisis. Risks to the researchers, participants, and the environment need to be adequately considered when determining if a research project should be conducted during the COVID-19 pandemic. Additionally, it is possible that the risk-to-benefit ratio of a previously approved study may now be different due to the added risks of COVID-19. This is a fluid situation and the below recommendations and subsequent IRB approvals may need to be reevaluated in the face of new guidance from the Centers for Disease Control (CDC) or if new local, state or federal guidelines are published. It is imperative that researchers continually monitor their research to determine when new information is applicable, and to proactively work with the IRB on risk minimization.

As such, all previously approved IRB studies involving in-person interactions must be re-reviewed by the IRB before the research may resume. Researchers must submit an IRB Amendment Request Form in IRBManager indicating how they will address the added risks due to COVID-19. New protocols submitted at this time must also adequately address how participant and researcher interactions will be conducted safely during the COVID-19 pandemic.

This guidance document provides information related to COVID-19 that researchers should consider when preparing study amendments and new protocol submissions.

General Guidance

- Current CDC Guidelines may be accessed here: https://www.cdc.gov/coronavirus/2019-nCoV/index.html

- Follow the latest advice from the CDC and relevant research regarding COVID-19 precautions, and ensure you are operating under the most current federal, state, and local executive orders and directives, including one-on-one and multiple people interactions.

- Minimize in-person interactions to the greatest extent possible. Any interactions that can be conducted in a remote manner should be done remotely. Note this may require additional privacy and confidentiality considerations.

- Consider the delay of all work involving contact with multiple people (e.g., any work in towns, cities and other high population density areas; visits to public locations; in-person polling of the public; group interventions or other group-based observations). If such work cannot be delayed, researchers must adequately minimize the risks by maintaining substantial physical distancing whenever possible, and practicing proper hygiene and

safety precautions utilizing available personal protective equipment (PPE). Ensure you are following the latest CDC advice and federal, state, and local directives related to the size of group gatherings. Note these directives may differ depending upon whether or not the participants and researchers are vaccinated.

- Require face masks to be worn by all participants and researchers at all times. The type of face mask utilized should align with current CDC guidelines, and be a minimum of a 2-ply cloth face covering, that fits snuggly on the face, covering both mouth and nose. Individuals must practice proper hand hygiene when placing and removing the face covering. If the research requires removal of masks for any reason (e.g. saliva collection), this must be included in the IRB submission, and additional risk mitigation steps may need to be taken.

- Consider the use of additional PPE (e.g., lab coats or gowns, gloves, eye protection, and respirators) when a sufficient distance cannot be maintained between the participant and other individuals who may be present. Note that some face coverings (such as N-95 respirators) require fit testing to be worn properly and result in additional regulations that need to be followed for their use. Contact the GVSU Director of Laboratory Safety (Jim Seufert, 616-331-8628, seufertj@gvsu.edu) if you need assistance in determining what PPE is appropriate for your research, if you are unsure of the requirements for your specific PPE, and/or if you require fit testing.

- Refrain from using PPE that is in short supply and required for clinical purposes.

- Obtain updated permission from external partners for work to be conducted in non-GVSU locations (e.g., clinics, schools, etc.). This permission must indicate that it is still allowable to conduct the research at the location during the COVID-19 pandemic, and a copy of the updated permission must be submitted to the IRB.

- Conduct in-person activities with the fewest number of people possible (both researchers and participants) physically present.

- Decontaminate any physical item that participants will come into contact with for the purposes of the research BEFORE and AFTER each participant.

- Submit an amendment to the IRB via IRBManager. For studies originally approved by the Institutional Biosafety Committee (IBC) as well as the IRB, it may be necessary for researchers to also submit an amendment to the IBC; researchers should contact the IBC for further guidance.

In-Person Interactions

The guidance below suggests items that should be addressed in the IRB application for studies involving in-person interactions. This list is not all inclusive, and not all items will necessarily apply to all studies. The IRB will consider each study on a case-by-case basis.

Study Risks:

- Identify new risks related to the potential for COVID-19 exposure
    - Consider the distance between the participant and researcher relative to the activity involved and the potential for aerosol droplet exchange. For example, the distance required may be greater for those participants engaged in physical activity compared to those who are stationary.
    - Aerosol-generating procedures and bodily fluid collection greatly increase the risk of spreading COVID-19.
- Identify how risks will be mitigated at every point in the research. This should include minimally following CDC guidelines such as, but not limited to, the use of social distancing, PPE, cleaning/disinfecting, changes in participant flow, etc.
- Consider risks to the participants, the researchers, and those related to the physical environment. Examples of questions to consider:
    - Are the participants at a higher risk of contracting COVID-19 and/or experiencing complications from COVID-19 if infected (e.g., age of population, presence of co-morbidities, etc.)?
    - Are the researchers and participants fully vaccinated for COVID-19? (I.e., have 2 weeks passed since the last required vaccine dose was received?)
    - Can procedures be developed to self-direct the participant to place electrodes, wires, and other equipment that may be necessary for the research, to decrease close contact between the participant and researcher?
    - What COVID-19 screening will be conducted for participants when they arrive at the study location?
    - If the participant notes that someone else in their home is exhibiting COVID-19 symptoms or tested positive for COVID-19, will you allow the individual to participate in the study?
    - If a participant or researcher is found to exhibit COVID-19 symptoms or later report a positive COVID-19 result, how will you inform the relevant individuals (both potential participants affected and research team members)?
    - What PPE is needed? Will participants and researchers be provided PPE or have to bring their own? How will researchers ensure the PPE brought in by participants is clean?
    - Will the researchers provide participants with the proper donning and doffing instructions for PPE? Will a separate space be devoted to donning and doffing?
    - Will PPE be reused? If so, how will it be cleaned? If not, how will it be disposed?
    - Will the researchers allow a participant to continue in the research if the participant refuses to wear the recommended PPE?
    - Who will check student researchers for proper PPE use and fitting?
    - What additional training will be provided to the research team?
    - If the participants require first aid delivery during the research, how will this be provided considering COVID-19 concerns?
    - Can “symptom-free” washout periods between participants be used?
    - Are changes to participant flow warranted (e.g., one-way traffic systems within the study location)?
    - How will items with porous surfaces be cleaned?

- How will the study site be cleaned between participants?

- Note that if in-person interactions occur with minors, children 2 years of age and older should also wear a mask. Please note that correct and consistent use of masks may be challenging for some children, such as children with certain disabilities, including cognitive, intellectual, developmental, sensory and behavioral disorders. PIs should reflect on how to address the role of minors and their ability or willingness to wear appropriate PPE.
- Identify the plans and processes to be used in the case of an illness to a research team member or a participant.

Study Benefits:

- Indicate what direct benefits, if any, participants may receive from participating in the research (i.e., is there anything related to this research that participants can only receive by being in the study?). This should highlight why in-person contact is necessary and why other mechanisms may not be feasible.
- Describe how the risk-to-benefit ratio of the study is impacted by COVID-19.
- Describe if and how the benefits outweigh the above identified risks.

Consent Process and Consent Forms:

- Update consent process and document(s) to communicate the increased risks associated with COVID-19 and methods to be used to reduce the risk of contracting COVID-19, including procedures for researchers, participants, and the physical environment.
- Provide the updated consent form to participants and reconsent any participants continuing in the study.
- Include the following statement in the consent form: "As outlined in this consent document, steps will be taken to protect against risks related to COVID-19. However, the risk of contracting an illness, including COVID-19, cannot be completely eliminated."

Review of Protocols

Please note that IRB protocols involving in-person interactions may be subject to additional review by the Institutional Biosafety Committee. As such, it is anticipated that review times may take longer than usual. The Office of Research Compliance and Integrity will coordinate this additional review; a separate submission to the IBC is therefore not required, unless the study originally received IBC approval, and the IBC protocol needs to be amended.

Research can resume only upon approval from the IRB (and possibly the IBC).