IRB Update: In-Person Research Pause

UPDATE (May 24, 2021): Subject to public health and vaccination data, the IRB anticipates that the current pause on in-person due to Covid-19 risk will be lifted as of June 1, 2021 for most research involving human subjects conducted in the United States. The pause will be lifted for all domestic in-person research involving individual subjects. In-person research activity involving human subjects outside the United States remains paused. Furthermore, studies that include research subject group activities (e.g., focus groups) in indoor settings remain paused until further notice. For research activity that remains paused, researchers may continue to apply for waivers of the pause following the IRB policy statement issued on August 5, 2020 (see [https://www.clarku.edu/offices/sponsored-programs-and-research/irb-human-subjects/](https://www.clarku.edu/offices/sponsored-programs-and-research/irb-human-subjects/)).

Researchers must comply with all other restrictions imposed by the Clark Reopening Committee (CRC). For example, because Clark University does not currently allow external visitors on the campus grounds, it is not permissible to conduct human subjects research that requires outside visitors to the campus. Due to this university restriction on outside visitors to campus, on-campus human subjects research with external participants (i.e., those not already permitted to be on campus as Clark faculty/student/staff/etc.) remains de facto paused until this university policy is changed.

Additional Information
All permitted in-person research interactions are expected follow relevant health and safety protocols applicable to the setting (e.g., social distancing, masking), consistent with Clark University, CDC, state/site guidelines. Where multiple sets of health and safety protocols are applicable, the most restrictive guidelines apply. This is required to ensure that all research interactions are minimal risk for the study site (i.e., no more than the risk encountered by subjects in the course of their regular day-to-day activities).

If complying with these guidelines will require changes in your approved study procedures, then an amendment must be filed with the IRB for approval prior to the commencement of in-person research activities. If relevant to your study, consent forms must also be updated to describe procedures that will be applied to comply with applicable health and safety guidelines. If there are questions about how this requirement applies to your study, please contact the IRB.

If your originally approved IRB protocol allowed in-person interactions but you have since amended it for solely remote (not in-person) implementation, it may be necessary to “reverse” this amendment to proceed with in-person interactions. To do so, submit an amendment request indicating that you wish to revert to the previously approved in-person research methods. As described above, the amendment should include any relevant information on COVID-safety procedures (e.g., social distancing; vaccination by researchers and/or subjects) used to comply

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1 As an example, mask-wearing by the researcher prior to the study would typically not represent a change in a research procedure in the absence of other protocol changes, as mask-wearing is currently common and recommended in day-to-day life and would be unlikely to influence other dimensions of the study. However, requiring subject to complete a Covid-19 health screening or be vaccinated prior to participation would represent a material change, if these were not already part of your approved protocol. Please contact the IRB for further guidance. If in doubt, an amendment request should be filed with the IRB.
with University, CDC, and state/site guidelines. These amendment requests may be submitted at any time and will be approved conditional on the anticipated lifting of the in-person research pause in August. An amendment is not necessary if your current protocol already allows for the use of either in-person or remote interactions, and no other changes are required.

Any questions regarding this policy should be directed to the IRB (humansubjects@clarku.edu) or Robert Johnston, the IRB Chair (rjohnston@clarku.edu).