

Clark University IRB Policy on Human Subjects Research Under COVID-19 Risk

March 16, 2020

This memo provides an important update regarding allowable human subjects research at Clark University during the current COVID-19 pandemic.

According to federal guidelines and precedent grounded in the Belmont Report and CFR §46, IRBs must reevaluate research protocols *if events are identified that represent unanticipated problems involving risk to subjects or others*. None of the research protocols previously approved by the IRB anticipated risks related to COVID-19 transmission, relative to those expected in the absence of research participation.

Amidst the uncertainty of the pandemic in the US and elsewhere, the IRB cannot rule out the possibility that any research-induced, in-person contact between people (researchers and/or subjects) could increase the expected probability and magnitude of harm from the virus. Because the virus can be transmitted by asymptomatic carriers, any additional in-person contact increases the risk of potential infection. Due to the lack of testing in the US and elsewhere, this risk is currently uncertain.

Temporary Pause for In-Person Human Subjects Research

Due to this new and unforeseen risk, **the IRB is temporarily suspending (or pausing) all human subjects research at Clark University involving additional in-person interactions involving research subjects or others**. With regard to this suspension, “additional in-person interactions” implies that **participating in the research will cause people to come into additional personal contact with other people**—including researchers, subjects or others.

This pause applies to all research conducted under Clark IRB approval that fits the above description, regardless of location (i.e., on- or off-campus). This includes multi-institutional (collaborative) research projects operating under Clark IRB approval. That is, if the project fits the above description and is operating under the oversight of Clark’s IRB, it is subject to this temporary suspension of activities. If you are in doubt as to whether this suspension applies to your project, please assume that it **does** apply unless instructed otherwise by the IRB.

This decision has been made in coordination with the Clark administration, and with full recognition of the disruptive impact that this will have on many of us conducting research at Clark. We emphasize that—to the knowledge of the IRB—no unanticipated problems related to COVID-19 have occurred already within Clark University human subjects research. This research pause is designed to prevent these unanticipated events from taking place.

Research subject to this suspension includes but is not limited to activities such as in-person interviews or surveys (not conducted remotely), focus groups, experiments requiring subjects to be present in person, and all other activities with in-person contact between researchers and subjects. This applies regardless of how “close” these additional in-person interactions might be (e.g., six feet apart).

This suspension **does not apply** to many categories of research, including:

1. Interactions conducted remotely such as via Skype, Zoom or telephone, that cause no additional in-person contact involving subjects.
2. Surveys or data collection conducted online, via telephone/mail, or using other remote methods.
3. Circumstances wherein the researchers and subjects will already be in identical degrees of in-person contact regardless of the research taking place. (An example would be in-school classroom observations during regular classroom activities, where observations are conducted by a teacher who would be present in the classroom regardless of whether the research takes place.) **For this exception to apply, researchers must submit a request to the IRB as explained below.**
4. Data analysis from human subjects interactions that have already taken place—and hence require no further in-person contact.
5. Other types of human subjects research that can be conducted without in-person contact.

To enable researchers to submit waiver applications involving certain research categories (see below) and top ramp down research activities, we are **delaying the implementation of this suspension until March 20 (11:59pm).**

For researchers conducting in-person research that they believe to fall under exception #3 above (i.e., in-person research that will not cause *additional* in-person contact), you **MUST** submit a formal request if you wish this research to continue during the pause. Submit these requests, along with clear explanation and justification (and the original IRB protocol number), to humansubjects@clarku.edu. **No in-person (i.e., face-to-face) research of any type is allowed during the pause without explicit prior approval of the IRB.** We will process these requests as soon as possible.

Waiver Conditions and Requests

Researchers may **request a waiver of this suspension in particular circumstances**, which will be reviewed by the IRB on a case-by-case basis. There is no specific form that must be completed. Submit these requests via email, along with clear explanation and justification, to humansubjects@clarku.edu. All requests must include the original IRB protocol number and previously approved proposal (as an attachment).

Cases in which waivers might be granted include:

1. Research for which the researchers can demonstrate clearly that the benefits of continued on-person interactions outweigh the risk due to COVID-19. Except in rare cases, these waivers will not apply to most types of social and behavioral research conducted at Clark.
2. Research for which the researchers can demonstrate, beyond a reasonable doubt, that the proposed in-person interactions will not increase the probability and magnitude of harm from COVID-19. (The IRB cannot currently envision cases where this would apply at Clark, but is leaving this option open to address unforeseen circumstances.)
3. Other research for which the researcher can present a clear and compelling reason why in-person interactions need to occur or continue as part of the project. (The IRB cannot

currently envision cases where this would apply at Clark, but is leaving this option open to address unforeseen circumstances.)

Modification Requests for Ongoing Research

For research that is subject to this temporary suspension, **the IRB encourages researchers to request a formal modification of their research protocols so that research can continue via remote means.** Submit these modification requests via email, along with clear explanation and justification, to humansubjects@clarku.edu. All requests must include the original IRB protocol. Attached your previously approved proposal with “tracked changes” (preferred) or highlights to identify the modifications to your original protocol that are requested in order to allow research to continue during the suspension. For example, interviews or even focus groups can potentially be held via remote platforms such as Skype or Zoom. The IRB will review and approve these modification requests as soon as possible to enable research to continue.

As mentioned above, human subjects research that involves only remote data collection, e.g., via internet or telephone, does not require modification and can continue as originally approved by the IRB. If you have questions about whether your research is subject to this mandated pause, please contact IRB Chair, Robert Johnston, rjohnston@clarku.edu.

Lifting the Suspension

The IRB will lift this suspension as soon as conditions demonstrate that in-person research interactions will not place subjects or others at significantly increased risk due to COVID-19. We understand that this will be difficult for many of us at Clark, and regret any disruption that this may cause. The IRB may issue updates to this policy as conditions dictate or to address questions as they arise.

Questions

Please address any questions regarding this policy to the IRB Chair, Robert Johnston, rjohnston@clarku.edu.

We realize that questions may arise concerning this policy. If in doubt, your affirmative duty as a researcher at Clark is to protect the rights and safety of your research subjects.