Human Subjects Research Guidance

Under Current COVID-19 Restrictions

The following guidance is designed to assist MSU researchers engaged in human subjects research during this unprecedented period of disruptions due to COVID-19.

Face-to-face human subject research that does not provide potential for direct benefit to the subjects should be paused, until the COVID-19 restrictions are lifted. Where possible, in-person interactions for all studies, regardless of benefit, should be modified to employ remote interactions in order to limit the risk of exposure. As the current restrictions are phased out, the IRB will work with you to make sure that your protocols are ready for re-activation or modification.

Studies that provide no direct benefit to subjects may be allowed to continue only if study interactions can be conducted using remote platforms.

- If study interactions are interviews, simple study follow-up visits or focus groups, consider interactions via phone or videoconference.

- If your study requires signed informed consent, consider whether you can modify study procedures by requesting a waiver of documentation of consent from the IRB so that consent may be obtained without requiring a signature. It is well to note that in order to approve a waiver, the study must present no more than minimal risk of harm to participants and involve no procedures for which written consent is normally required in a non-research context.

- If study is sponsored, contact sponsors to inquire about the acceptability of modifying protocol to permit remote interactions.

For those studies that provide direct benefit to participants and necessarily require face-to-face interactions, and cannot be paused, it is well to consider strategies that can be undertaken to minimize risk of exposure during face-to-face encounters. Some specific considerations include:

- Implementing participant screening to minimize exposure to risk, especially for participants who fall in a high-risk category, such as:
  - 65 years of age or older
  - Underlying health conditions including heart disease, lung disease, and diabetes
  - Compromised immune system
  - Pregnant

A possible screening question, depending on the study population, nature of the interaction, and location of the study interaction, is suggested below:
Have you had close contact with a person who is being evaluated for possible COVID-19?
Close contact is defined by the CDC as:
(a) being within approximately 6 feet of a COVID-19 case for a prolonged period of time. Close contact can occur while caring for, living with, visiting, or sharing a health care waiting area or room with a COVID-19 case; or
(b) having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed or sneezed on).

- Ensuring that hand sanitizer and hand washing facilities are readily available, and encouraging regular use.
- Establishing rigorous disinfecting protocols for any equipment, manipulatives, or other study equipment that will be used with multiple participants.
- Maintaining appropriate social distancing.

If you have questions on modifying your study protocol under the current COVID-19 restrictions, please contact irb.research@morgan.edu.