MICHIGAN STATE UNIVERSITY

Human Research Protection Program
Guidance on IRB Modifications Related to COVID-19

Is the study IRB "Exempt"?

Check the MSU IRB initial correspondence letter if unsure.

NO

Is MSU the IRB of Record?

NO

Follow the External IRB requirements for submitting Modifications.

Contact the IRB of Record with any questions of whether a change requires their review.

YES

YES

Does the change affect the exempt category or criteria for exempt determination (no longer qualifies for exemption, changes exempt category)?

Consider whether the change to remote format alters the exempt criteria (e.g. identifiability, risk related to change in privacy protections); if it does, then an IRB submission is needed.

YES

MSU IRB Submission Needed

NO

Changes Do Not Need to be Submitted to the MSU IRB

If the study also involves another institution's IRB, contact that IRB to see whether changes need to be submitted.

Is the action/change being taken for public health or clinical purposes, and not for research purposes?

YES

IRB Modification Not Required

Actions taken for public health or clinical purposes, and not for research purposes, are not research procedures and therefore do not require institutional review board IRB approval before being implemented.

See Page 2 for Examples

NO

IRB Modification Required

Changes to research procedures that affects human subjects because of the research must be reviewed and approved by the IRB.

See Page 3 for Examples

Questions? Contact the MSU IRB Office
irb@msu.edu or 517-355-2180

Examples of changes related to COVID-19 that <u>do not</u> require MSU IRB review and approval

- Infection control procedures.
- Completing the MSU COVID-19 Screening Form.
- Providing the research participant with the MSU COVID-19 Information Sheet for Research Participants.
- Calling the participant before the study visit to complete the health screening.
- Wearing a face mask and any other PPE (e.g. face shield).
- Using Plexiglass or another physical barrier between the participant and researcher.
- Social distancing.
- Disinfection procedures.
- Providing hand sanitizer.
- Institutional requirement to not permit individuals with potential COVID-19 symptoms or those who don't want to wear a face mask to participate in in-person interactions to protect the participant and the researcher (unless there is special approval).
- Research team SOPs related to COVID-19 safety precautions.
- You do not need to modify the informed consent to add institutionally required COVID-19 requirements like using face mask, using Plexiglass, etc.; these are public health mitigation strategies to protect participants and researchers from COVID-19 (for example, you wouldn't describe the disinfection that occurs in a clinic before and after a visit, or that the person drawing blood will be wearing gloves, etc.).
- You typically would not need to modify the informed consent to include the risk of COVID-19 as this is a risk in everyday life (e.g. when go to grocery store).

Examples of changes related to COVID-19 that <u>do</u> require MSU IRB review and approval

- Moving in-person participant visits to a remote format.
- Using or analyzing data from the MSU COVID-19 Screening Form for research.
- Performing a COVID-19 diagnostic test on research participants as part of the research.
- Changing the research location from what has been approved by the IRB (e.g. research was going to be conducted at X facility, now it is being conducted at Y facility). *Check your IRB submission to see how you identified your research location (e.g. did you specify a room number and that location is now different?).*
- Changing a research procedure to reduce the COVID-19 risk (e.g. before the research was going to involve a two-hour long interaction, now the interaction will only be 30 minutes).
- Changing who will perform a research activity from what was approved by the IRB (e.g. before MSU research team was going to obtain consent, now an individual at the facility will obtain consent). *Check your IRB submission to see if you specified who was going to be performing any of the research procedures, recruitment, consent, etc.*
- Engaging new external collaborators (e.g. before MSU research team was going to perform the research procedure, now an external collaborator will perform the procedure). *Check your IRB submission to see which External sites are listed.*
- Modifying your informed consent to incorporate any procedure changes or if the research increases the COVID-19 risk above what a participant would experience in everyday life.
- Modifying your informed consent process (e.g. previously the informed consent was completed onsite, now the informed consent is obtained over the phone before the visit). *Consider whether a signature is needed on the consent document; minimal risk studies that involve no procedures for which written consent is normally required outside the research context can be granted a waiver of the requirement to obtain a signature by the IRB.*
- Consider whether the inclusion / exclusion criteria need to be modified (e.g. sponsor has updated inclusion/ exclusion criteria to exclude COVID-19 individuals, you want to exclude high-risk COVID-19 individuals from participating in the research).