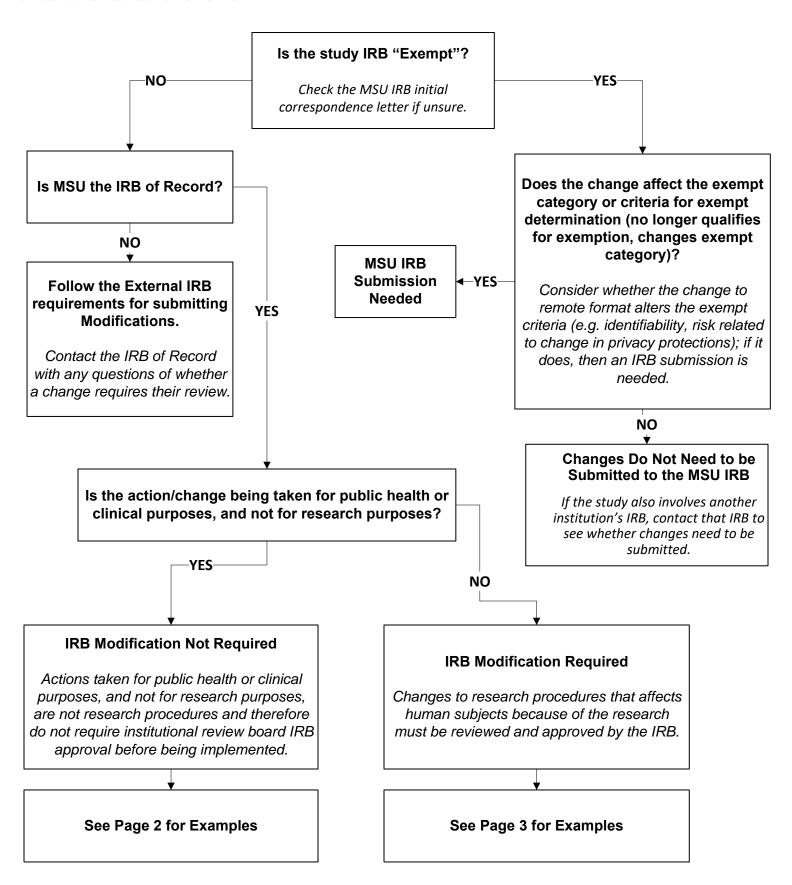


Human Research Protection Program Guidance on IRB Modifications Related to COVID-19



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

Examples of changes related to COVID-19 that do not 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 do 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).