### ****When can I restart in-person interactions?****

Governor Whitmer has issued a number of Executive Orders related to the COVID-19 pandemic. Several Executive Orders provide limitations on activities that can be conducted and provide safeguards to protect Michigan's worker's from COVID-19.

MSU had restricted most in-person interactions with participants with limited exceptions.

MSU is now in the process of resuming in-person interactions using a [Tiered approach](https://hrpp.msu.edu/COVID-19/covid-tiers.html). If the study meets the criteria within a Tier where the [Human Research Plan for a Safe Return](https://hrpp.msu.edu/COVID-19/covid-forms.html) may be submitted, the in-person interaction may occur if the Human Research Plan for a Safe Return is approved, and any other approvals have been obtained. A Human Research Plan for a Safe Return must be completed and approved before in-person interaction continue, unless the in-person interactions were permitted as basic minimum operations.

Please note that restrictions to human research will continue to be evaluated based on any new Executive Orders and the restrictions may be modified as appropriate.

Last updated: 7/28/2020

### Can remote research procedures continue?

Research procedures involving no direct in-person interactions with participants may continue (e.g. data analysis, online surveys, telephone interviews) and need to follow all Executive Orders or jurisdictional requirements.

Last updated: 7/28/2020

### What is the impact to clinical trial activity conducted in Michigan, which if discontinued, would negatively impact the patient’s care?

In Michigan, ongoing clinical trial activity, which if discontinued, would negatively impact the patient’s care may continue with already enrolled participants. To the extent possible under the circumstances, researchers and participants must adhere to social distancing measures recommended by the Centers for Disease Control and Prevention, including remaining at least six feet from one another. Researchers should follow the clinic or facility’s policies related to COVID-19, including screening prior to the study visits for COVID-19. Researchers with their unit’s leadership (e.g. Chair and Dean’s Office) will need to evaluate whether clinical trial activities are essential or whether any could be delayed without negatively impacting the patient’s care.

To initiate new enrollment, researchers should determine if a [Human Research Plan for a Safe Return](https://hrpp.msu.edu/COVID-19/covid-forms.html) may be submitted using the [Tiers](https://hrpp.msu.edu/COVID-19/covid-tiers.html). Flow diagrams have been developed to help assist researchers with this determination. Please contact ORA if unsure at ora.hrpp@msu.edu.

Last updated: 7/28/2020

### What is the impact to subject enrollment in new or ongoing clinical trials?

To initiate new enrollment, researchers should determine if a [Human Research Plan for a Safe Return](https://hrpp.msu.edu/COVID-19/covid-forms.html) may be submitted.[Flow diagrams](https://hrpp.msu.edu/COVID-19/covid-flow-diagrams.html) have been developed to help assist researchers with this determination. Please contact ORA if unsure.

Last updated: 7/28/2020

### Are there exceptions to the Tiers?

Contact ORA if the research does not meet a permitted [Tier](https://hrpp.msu.edu/COVID-19/covid-tiers.html) and there is an urgent issue (e.g. participant safety) at ora.hrpp@msu.edu.

Last updated: 7/28/2020

### If my work was permitted under research related minimum operations, are additional actions needed?

Yes. Even though these activities have been ongoing, the [Human Research Plan for a Safe Return](https://hrpp.msu.edu/COVID-19/covid-forms.html) must be completed. This assures that COVID-19 safety precautions that are applied consistently to all in-person interactions.

Last updated: 7/28/2020

### How long will the restrictions last?

The [Tier](https://hrpp.msu.edu/COVID-19/covid-tiers.html) approach permits the initiation of some research studies; MSU continues to evaluate when and how research activities may continue to resume.

7/28/2020

### Who do the restrictions apply to?

The restrictions applies to all research conducted by MSU employees or agents, regardless of the location of the research (e.g. MSU campus, international, elsewhere in the United States).

Last updated: 5/1/2020

### How do the restrictions impact collaborative research?

Sites under the oversight of their local organizations should be informed of the restrictions by the MSU PI or research team, but the organization would make an independent decision as to whether to proceed with research activities at their organization.

MSU researchers should communicate and work with their collaborators to ensure COVID-19 risks have been addressed through COVID-19 mitigation strategies appropriate to the research and location. The expectation is that collaborating organizations have COVID-19 safety protocols in place appropriate to the location and procedures being conducted.

If there are any concerns about the collaborator’s procedures, Principal Investigators should address these with the collaborators and consult with their Department Chairs and Associate Deans for Research as needed

Last updated: 7/28/2020

### What if MSU is the Single IRB for multiple institutions?

The relying institutions should be informed of the restrictions by the local collaborating PIs through communication with the MSU PI or research team and should be asked to consider the restrictions with their institution. Researchers should consider how modifications to in-person participant interactions at MSU impact the overall study. As the COVID-19 situation evolves rapidly, other sites may also be required by their institution to restrict activities as well.

Last updated: 5/1/2020

### What if an External IRB is the IRB record for my study?

The restrictions apply to all research conducted by MSU employees or agents, even if the study is under review by an External IRB. The research team should notify the External IRB and follow all External IRB requirements for any modifications or reporting that occurs from the restrictions, as well as any reporting requirements if approved to resume in-person interactions with participants.

All COVID-19 safety requirements described in the [Human Research Plan for a Safe Return](https://hrpp.msu.edu/COVID-19/covid-forms.html) must be followed, even if MSU is not the IRB record. For example, the [Coronavirus Disease (COVID-19) Research Participant Screening](https://hrpp.msu.edu/COVID-19/covid-forms.html) and the [Michigan State University COVID-19 Information Sheet for Research Participants](https://hrpp.msu.edu/COVID-19/covid-forms.html) must be used, unless otherwise approved in the Human Research Plan for a Safe Return. Check with the External IRB on whether any of the COVID-19 safety precautions require their review.

Last updated: 7/28/2020

### I am relying on an External (non-MSU) IRB for IRB review of my project. Do I need to submit a Human Research Plan for a Safe Return?

Yes. If the study involves the potential for in-person interaction with research participants conducted by MSU individuals (e.g. faculty, staff, students, agents), a Human Research Plan for a Safe Return is required, regardless of what IRB is the IRB of record. If an External IRB is the IRB of record, researchers should also check with the External IRB to see if that IRB has additional requirements.

Last updated: 9/4/2020

### If I am pausing or a restriction applies to study procedures on a project reviewed by an External IRB of Record, must I notify that IRB?

Yes, as soon as feasible, for their awareness. The IRB of Record may require review/approval prior to resumption of study procedures.

Last updated: 3/26/2020

### Which research procedures may continue?

Studies that do not involve in-person (face-to-face) interactions with participants (e.g. data analysis, online surveys, telephone interviews), so long as those procedures are done in compliance with any State or local restrictions.

Other studies may be permitted to continue based on the [Tiers](https://hrpp.msu.edu/COVID-19/covid-tiers.html) and approval of a [Human Research Plan for a Safe Return](https://hrpp.msu.edu/COVID-19/covid-forms.html), and any other needed approvals (e.g. facility, university).

Last updated: 7/28/2020

### ****Is a Human Research Plan for a Safe Return required if I am asking participants to interact with others, even if no MSU individual will interact with the subjects (e.g. photovoice)?****

Yes. If there is no potential for in-person interactions with MSU individuals, a [Human Research Plan for a Safe Return](https://hrpp.msu.edu/COVID-19/covid-forms.html) is still required if MSU researchers ask participants to perform tasks outside their home that the participants would not have otherwise performed and there is potential for in-person interactions with others (e.g. photovoice, recording their observations of a particular activity). However, if such research procedures are also occurring through another institution as part of a collaborative research study, that institution’s approval of COVID-19 safety precautions may be accepted. Contact [Judy McMillan](https://hrpp.msu.edu/contacts/directory.html) with questions.

Last updated: 9/29/2020

### What if I am performing a clinical trial in Michigan that is in follow-up only with no active drug?

Ongoing clinical trial activity, which if discontinued, would negatively impact the patient’s care may continue with already enrolled participants. Researchers, working with the study sponsors, should determine if in-person visits are necessary to fully assure the safety of trial participants (for example to carry out procedures necessary to assess safety or the safe use of the investigational product appropriately). Such decisions will depend on specific circumstances of the study, and whether alternative processes to an in-person visit are possible under the circumstances.

A [Human Research Plan for a Safe Return](https://hrpp.msu.edu/COVID-19/covid-forms.html) must still be submitted.

Last updated: 7/28/2020

### Can I continue a Phase I clinical trial?

It depends on the study and whether discontinuing the clinical trial activity would negatively impact the patient’s care. If the subject is already enrolled and the patient’s care would be negatively impacted if the clinical trial activity were discontinued, the clinical trial activities may continue. If the subject is already enrolled and the patient’s care would not be negatively impacted if the clinical trial activity were discontinued, the in-person clinical trial activity should not continue until a [Human Research Plan for a Safe Return](https://hrpp.msu.edu/COVID-19/covid-forms.html) can be submitted based on the [Tiers](https://hrpp.msu.edu/COVID-19/covid-tiers.html) and is approved.

New enrollment in clinical trials may be permitted; view the [Tiers](https://hrpp.msu.edu/COVID-19/covid-tiers.html) to see whether a [Human Research Plan for a Safe Return](https://hrpp.msu.edu/COVID-19/covid-forms.html) may be submitted to restart new enrollment.

Last updated: 7/28/2020

### What type of study is considered to provide the potential for direct therapeutic benefit to study participants?

Studies that involve the administration of drugs or monitoring of devices that provide the potential for direct therapeutic benefit (drug or device) to at least one group of study participants may continue. For the purpose of the MSU pause, it is assumed that trials with investigational treatments, including drugs and devices, provide the potential for therapeutic benefit (drug or device) and should continue.

A [Human Research Plan for a Safe Return](https://hrpp.msu.edu/COVID-19/covid-forms.html) must still be submitted.

Last updated: 7/28/2020

### What if my study doesn't clearly offer direct benefit to subjects but I am concerned about subject safety by stopping the study?

Send an email to ora.hrpp@msu.edu to discuss the safety concern to participants if they can't continue the in-person interaction and why alternatives to the in-person interaction with participants isn’t possible.

Last updated: 3/26/2020

### Should in-person participant interactions in social or behavioral and observational studies be paused?

View the [Tiers](https://hrpp.msu.edu/COVID-19/covid-tiers.html) to determine whether the in-person interaction falls within a Tier that permits the restart of in-person interactions with the submission and approval of the Human Research Plan for a Safe Return.

Last updated: 7/28/2020

### May we continue already approved data collection that occurs by telephone or online?

Yes.

Last updated: 3/16/2020

### May we conduct home visits to collect data for studies conducted in Michigan?

Yes, it if falls within a permitted [Tier](https://hrpp.msu.edu/COVID-19/covid-tiers.html) and a [Human Research Plan for a Safe Return](https://hrpp.msu.edu/COVID-19/covid-forms.html) is approved.

Last updated: 7/28/2020

### Can I go to a participant’s home in Michigan and pick up something for research from their porch, there will be no interaction?

Yes, it if falls within a permitted [Tier](https://hrpp.msu.edu/COVID-19/covid-tiers.html) and a [Human Research Plan for a Safe Return](https://hrpp.msu.edu/COVID-19/covid-forms.html) is approved.

Last updated: 7/28/2020

### Do I need a Human Research Plan for a Safe Return to post recruitment flyers?

A Human Research Plan for a Safe Return is required when there is potential for an in-person interaction with research participants by MSU individuals (e.g. faculty, staff, students, agents). A plan would not be required if the only activity was posting recruitment flyers, with no potential interaction with research participants. However, safeguards must still be in place to protect you or members of the research team from COVID-19 when performing such activities as part of the research study.

* Check with your department on whether the activity is permitted, or whether additional approvals are needed.
* Please note that researchers who are undergraduate students or visiting scholars may only participate if they are essential to the conduct of the study and are paid. You would need to obtain specific approval from the department, college, or university to permit the individual to take part in the activity.
* Follow MSU travel requirements. Check with the MSU Office of International Health and Safety for requirements: <https://oihs.isp.msu.edu/>
* Assure that that the location permits entry into the facility to post recruitment flyers. The location may also have requirements to enter the location.
* Other COVID-19 safety measures must also be taken, such as:
  + Complete COVID-19 training. Visit the EHS COVID-19 Resources webpage for links to the COVID-19 training courses: <https://ehs.msu.edu/covid-19/index.html>
  + Complete the required online MSU Health Screening Form.
  + Wear a face mask that covers the nose and mouth.
  + Limit interactions with others.
  + Social distance and maintain a six foot distance from others.
  + Wash your hands or use hand sanitizer frequently.

Last updated: 9/8/2020

### My thesis or dissertation project required in-person participant interaction. What can I do?

Please work with your advisor to determine if the project can be modified to include a procedure that does not include in-person participant interaction, or whether the activity may fall within a permitted Tier. If the activity falls within a permitted Tier, please work with your advisor to determine whether the Human Research Plan for a Safe Return can be submitted for approval.  Please see the [IRB information](https://hrpp.msu.edu/COVID-19/index.html) related to what modifications need to be submitted for review. If the project cannot be modified, please work with your advisor.

Last updated: 7/28/2020

### Can we submit a new study for IRB review that involves a drug or device?

Yes, however, IRBs will triage the review of new submissions based on applicability to the current COVID-19 circumstances, applicable resources, and risk/benefit to the potential subjects. The IRB plans to continue to review new studies that involve in-person participant interactions, even if the study cannot be initiated until after the restrictions are lifted. We do not want to delay this review, as this would create a backlog of IRB submissions that could delay study start-up once the restrictions are lifted.

Last updated: 3/26/2020

### Is the IRB still reviewing continuing review (renewal) submissions?

Yes. The continuing review (renewal) submissions are still undergoing review. If you have difficulty completing the continuing review submission because you are unable to access subject information in your office or lab, for example, please provide a detailed explanation within the continuing review submission.

Last updated: 3/31/2020

### What if I would like to conduct research related to COVID-19?

Studies related to COVID-19, particularly if they have a timeline for deployment that could address the crisis, are permitted to proceed under the restrictions for human subjects research. Investigators should work with the IRB to modify or submit the studies as appropriate. A Human Research Plan for a Safe Return must also be approved.

Last updated: 7/28/2020

### Must the IRB approve modifications to the study protocol before implementing changes?

It depends on whether the study is exempt or non-exempt, and whether MSU is the IRB of record. Please view the Guidance on IRB Modifications Related to COVID-19 for information and examples of when modifications are required.

Last updated: 7/28/2020

### Does COVID-19 screening require a modification to my protocol?

For research approved by the MSU IRB, no, COVID-19 screening procedures do not need to be reported as a modification to the protocol even if done during clinical study visits unless the sponsor or researcher is incorporating the data collected as part of a new research objective or will be using or analyzing the data for research. 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.

For research relying on an External IRB (MSU IRB is not the IRB of record), please check and follow the External IRB’s requirements.

Last updated: 7/28/2020

### I am modifying my study to collect data remotely, and I can’t obtain a signed consent. What do I need to do for non-exempt studies?

Investigators would need to submit the informed consent script with their modification or new application submission for IRB review. The IRB may waive the requirement for the investigator to obtain a signed informed consent for some or all subjects in several circumstances. One of those circumstances relevant to COVID-19 and conducting research remotely is a waiver may be granted when the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Investigators should also keep a log documenting the oral consent process throughout the duration of the study and maintain such records. The IRB may require the investigator to provide subjects with a written statement regarding the research.

### What do I do if a change is necessary to eliminate an apparent immediate hazard to participants for a non-exempt study?

For research approved by the MSU IRB, if a change in protocol is made to eliminate an apparent immediate hazard to participants, it must be reported immediately thereafter. Please submit a “Report of New Information” through Click, explaining why the change was necessary to ensure the participant’s welfare and please include COVID-19 in the RNI title. Please contact the HRPP with any questions.

For research relying on an External IRB (MSU IRB is not the IRB of record), please check and follow the External IRB’s requirements for changes necessary to eliminate an apparent immediate hazard.

Last updated: 3/16/2020

### Changes in non-exempt studies may be made without IRB approval when the change is necessary to eliminate an apparent immediate hazard to subjects. What is an apparent immediate hazard?

An apparent immediate hazard is a hazard that could place the subject’s life or well-being at risk, and the change must be made immediately to prevent the subject from being exposed to the hazard (e.g. there is not time to obtain IRB approval for the change). In such situations, however, investigators must report the change in protocol to the IRB immediately thereafter through a Report of New Information in the Click system. Within the report, the investigator should document why the change was necessary to ensure the subject’s welfare.

If your study is reviewed by an External IRB, contact the External IRB for any questions on what is considered to be an apparent immediate hazard.

Last updated: 3/31/2020

### How do I let the IRB know that the modification is related to COVID-19?

The HRPP staff and the MSU IRB will be prioritizing modifications related to COVID-19. To help with this process, when summarizing the modification in the Click Modification submission, please indicate that the change is related to COVID-19. You may also email (irb@msu.edu) to let us know so we can prioritize the submission.

Last updated: 3/16/2020

### Do we need approval from the IRB for communications to study subjects explaining the restriction in activities?

For research approved by the MSU IRB or determined exempt by MSU, no, it is not necessary to submit a modification. However, if the study is sponsored, please check with the study sponsor for any requirements.

For research relying on an External IRB (MSU IRB is not the IRB of record), check with the External IRB.

Last updated: 3/26/2020

### I am conducting FDA-regulated research for which I am the sponsor of an IND or IDE. Do I need to notify the FDA if the restrictions apply to my study?

Yes. The FDA will need to be notified as soon as feasible. Contact the HRPP Compliance office via email at ora.hrl@msu.edu for specific guidance and information on the notification process.

Last updated: 3/26/2020

### Should I notify the industry sponsor if my research activities are restricted on my clinical trial?

If the study activities need to be restricted, the sponsor will need to be notified as soon as feasible. Utilize the standard process for informing sponsors of changes to the research.

Last updated: 3/26/2020

### Where do I find more information about the impact of COVID-19 to sponsored research projects?

Please visit the MSU Office of Sponsored Programs Administration [webpage](https://osp.msu.edu/PL/Portal/1736/COVID19InformationfromSPAOSPCGA) related to COVID-19 for the latest information.

Last updated: 3/16/2020

### What should I do if I want to use telehealth as part of my clinical trial because of COVID-19?

The Office for Civil Rights at the U.S. Department of Health and Human Services has issued a notification of enforcement discretion for telehealth remote communications during COVID-19 nationwide public health emergency. Researchers who are covered health care providers should work with the covered entity if telehealth is necessary to provide both standard of care and research to patients.

Last updated: 3/31/2020

### Will the restrictions or change to the method of data collection be considered a protocol violation?

A protocol deviation/violation (deviation) is any change, divergence, or departure from the study design or procedures of a research protocol that has not been approved by the IRB, such as failure to perform a required lab test, or the study visit is conducted outside the required time frame. Deviations need to be reported even if it was outside of the researchers’ control (e.g. participant is in self-isolation or sick, hospital does not have resources to perform the test). Report the deviation to the IRB through a “Report of New Information” through Click and please include COVID-19 in the RNI title. Deviations that may affect participant’s rights, safety, or well-being and/or affect the participant’s willingness to participate in the study should be reported within 72 hours. See HRPP Manual Section 9-8, Protocol Deviations or Violations for more information.

Last updated: 3/26/2020

### What are some considerations for communicating with study sponsors?

* Contact study sponsors/industry for study-specific information on how to continue the study or pause the research, or to discuss MSU restrictions
* Obtain sponsor guidance for study conduct, including:
  + Changes in reporting requirements
  + Sample storage and shipping
  + Drug shortages or delays in shipping
  + Facility restrictions or requirements
  + Alternative safety assessments due to delays
  + Delayed or missed participant contacts/visits
  + Changing the study procedures with appropriate IRB approval

Last updated: 7/28/2020

### Where can I find answers about how to manage my human subjects research protocols and changes amid the COVID-19 situation?

Please refer to the MSU [HRPP COVID webpage](https://hrpp.msu.edu/COVID-19/index.html), which will be updated with additional information amid the COVID-19 situation. The FAQs will also be updated as the situation evolves.

Last updated: 3/16/2020

### How is the IRB and the IRB office impacted by COVID-19?

Convened IRB meetings will continue but will be conducted remotely. Expedited reviews will continue remotely as well. The IRB staff plan to work their standard hours but will be working offsite. However, they will be responding to all phone calls and emails. If you have a question do not hesitate to call or email the HRPP office or the IRB Coordinator.

Last updated: 3/16/2020

### How is the Compliance office impacted by COVID-19?

The HRPP office is working remotely. During this time the Compliance office will only conduct site visits in-person when there is a risk to subjects. Scheduling for routine site visits have been placed on hold unless they can be conducted without an in-person visit, but the Compliance Office will begin remote monitoring soon. TEACH visits will not be conducted in-person. Compliance reviews will continue, and any submissions related to COVID-19 will be prioritized.

Last updated: 7/28/2020