

IRB Guidance – Special Considerations for Human Subjects Research During the COVID-19 Pandemic

Due to the Coronavirus Disease 2019 (COVID-19) national emergency and pandemic, research activities involving human participants are subject to additional requirements in order to protect human research participants and researchers. In March 2020, Iowa State University enacted restrictions prohibiting face-to-face research activities. Beginning July 15, 2020, Iowa State is implemented a phased approach to safely resume research that requires face-to-face interactions with research participants. **This phased return is a fluid process that will be determined by the current COVID-19 situation.** Researchers should continually monitor ISU guidance for conducting human subjects research until further notice.

This document provides current guidance on *IRB review and approval* during the COVID-19 pandemic. For clarity, it also references Iowa State’s institutional requirements (COVID-19 risk mitigation, screening, etc.) that do not require IRB approval. Details about Iowa State’s institutional requirements can be found [here](#).

IRB Approval Requirements

IRB review and approval requirements have not changed. Prospective IRB approval or determination of exemption is required before human subjects research begins and before any changes to approved research are initiated. IRB applications must describe all study plans, including any remote procedures.



A guiding COVID-19 risk-mitigation principle is minimizing face-to-face contact. Therefore, research should be designed to use remote processes whenever possible throughout the research (e.g., recruitment, informed consent, screening and data collection, compensation, etc.). Face-to-face interactions must be limited to only those procedures that cannot reasonably be performed remotely. See [here](#) for IRB guidance on remote human subjects research.

Additional Institutional (Non-IRB) Requirements

Risk Mitigation Plans

Approval of a COVID-19 Risk Mitigation Plan is required for research that involves face-to-face interactions. Risk Mitigation Plans are reviewed/approved by the Department or College of the Principal Investigator/Supervising Investigator. Researchers are responsible for ensuring congruence between applicable elements in Risk Mitigation Plans and IRB applications. Guidance and templates for risk-mitigation plans are available [here](#).

COVID-19 Risk Mitigation Plans DO NOT require IRB review, and should not be submitted with IRB applications.

COVID-19 Screening

Research participants and research staff must be screened for COVID-19 symptoms and exposure. Screening information can be found [here](#).

COVID-19 screening procedures DO NOT require IRB approval, and need not be described in IRB applications.

Notification to Participants

Participants must be informed about ISU's COVID-19 risk mitigation procedures using the [most current version](#) of the prepared *COVID-19 Research Participant Information Sheet*. This document also describes expectations of participants (e.g., social distancing, face coverings, handwashing/sanitizing, etc.).

IRB approval is NOT required for this notification process.

Documented Permission from Off-Campus Sites

Research teams must obtain documented permission from off-campus sites prior to any face-to-face visits at that site. Permission must come from an individual authorized to grant permission on behalf of the setting. It may be documented via email, letter, or similar. Verbal permission is acceptable if the researcher documents the time/date of the verbal permission and from whom it was obtained. After receiving verbal permission, the researcher should follow up with the site in writing to document the permission. Documentation must be retained in study records.

Documented permission is NOT required when the research takes place in public outdoor settings, such as parks, public plazas, or similar settings. However, researchers must follow any applicable Iowa State policies and those of the location.

Documentation of off-campus site permission need NOT be submitted with IRB applications.

Frequently Asked Questions

What human subjects research is permitted during the pandemic?

Research that can be performed remotely is permitted (after IRB approval or determination of exemption is granted).

Face-to-face research is permitted if it meets ALL criteria associated with ISU's current phase of allowable research. See [here](#) for information about the phased approach and current phase. Researchers must carefully consider whether their research meets all phase criteria. If not, research may be re-designed to satisfy all criteria or it must be postponed until a future phase.

Are there any changes to the IRB review process?

No. IRB review of submitted applications continues as usual. The IRB will not assess whether research falls within the current phase of allowable research. Instead, research will be approved with the condition that only activities in the current phase may proceed. This allows proactive submission and approval of future projects.

I need to modify my currently approved research for remote implementation. Is IRB approval required for this type of change?

Exempt Research: If your research is exempt, IRB review is required before implementing certain types of changes. See IRB guidance [Modifications to Exempt Research](#) for details. Researchers should carefully review their IRB protocols in conjunction with this guidance.

Non-exempt Research: IRB approval is required before implementing any changes to the approved protocol, unless the change is necessary to eliminate apparent immediate hazards to participants.

When modifying an existing protocol, consider all aspects of the study. For example, changes to remote implementation may affect previously-approved consent processes, plans to distribute compensation, privacy and confidentiality protections, how surveys/questionnaires are administered, etc. The application should be modified throughout to reflect all processes that will be administered remotely.

Can informed consent be obtained remotely? What about participant signatures?

Informed consent should be an interactive, ongoing process between the researcher and participant that communicates information about the study in an understandable way to facilitate a participants' voluntary choice of whether to participate. Remote methods that facilitate communication, comprehension, and voluntariness, and DO NOT present privacy risks are acceptable. For example, consent information could be:

- sent to participants via email followed by a phone or video call for discussion.
- shared as an introductory page of an online survey, and participants click "I agree" to proceed.
- discussed at the beginning of a videoconference interview, where consent text is shared via the screen and reviewed.

Signed consent (via handwritten or authenticated electronic signature) is NOT required for most minimal risk studies. Verbal or online consent is acceptable.

If signed consent is required (e.g., for FDA-regulated studies), participants may send scanned copies of hand-signed documents.

For research with children, researchers need a method of verifying parent consent is in place for each child. Signed documents facilitate verification, but other record-keeping methods are acceptable.

IMPORTANT: *For non-exempt studies, plans to obtain informed consent (remote or in person) must be described in your IRB application and approved by the IRB. Changes from in-person to remote consent processes require IRB approval prior to implementation.*

Can study personnel work remotely on human subjects research projects?

Yes, but privacy and confidentiality of research subjects must be protected. Investigators should develop protocols and train study personnel on methods of protecting privacy and confidentiality during remote work. Advance preparation, such as removing identifiers from data sets and establishing CyBox folders to permit remote access is also advised. [Click here for additional guidance and information](#) on privacy and confidentiality considerations for working remotely with human subjects research.

What if I need to cancel or reschedule study visits (e.g., if a researcher or participant is ill, etc.)?

If a study visit needs to be canceled, participants should be informed of the reason and that they will be contacted again when the visit can be rescheduled. **These messages to subjects do not require prior ISU IRB approval.** Visit cancellations related to COVID-19 do not need to be reported to the IRB, unless the cancellation places participants at risk (very rare).

How should I respond if a research participant reports a positive COVID-19 test after participating in my research?

Research participants who are also Iowa State employees or students must report a positive test result occurring within 10 days of a study visit to Iowa State using the [Iowa State University Positive COVID-19 Reporting Form for Campus](#). Contact tracing will be handled in accordance with Iowa State's established processes.

Reporting and contact tracing for research participants are not Iowa State employees or students but who test positive is handled by the appropriate public health agency.