

GUIDANCE FOR HUMAN-SUBJECTS RESEARCH DURING THE COVID-19 PANDEMIC

UPDATED OCTOBER 8, 2020

NOTE: The Institutional Review Board (IRB) office and Iowa State IRB have been operating and will continue to function as usual. IRB staff can work remotely and the IRB@iastate.edu email account is monitored on an ongoing basis. IRB meetings are continuing as scheduled. If changes occur, the [IRB website](#) will be updated.

This document provides the most current guidance on human-subjects research and will be updated as situations around the COVID-19 pandemic evolve.

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 Iowa State's current phase of allowable research. See "**Can I interact with research subjects?**" below 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 redesigned to satisfy all criteria or it must be postponed until a future phase.

Can I interact with research subjects?

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. Only research which could be performed remotely was allowed.

Beginning July 15, 2020, Iowa State 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.** The Office of Vice President for Research will notify the research community of significant changes (new requirements, new phases, reverting to previous phase, etc.). Researchers should prioritize the

health and safety of human subjects, research staff, and individuals present at off-campus/community sites when deciding how to conduct research. Researchers should continually monitor ISU guidance for conducting human subjects research until further notice.

Phase 1.A Allowable Face-to-Face Research – Effective October 8, 2020

During Phase 1.A, face-to-face research is allowable if it satisfies all of the following criteria:

1. Research is conducted in:
 - Iowa State facilities, **OR**
 - Off-campus/community settings when both of the following conditions are met:
 - i. The *research space* in the off-campus/community setting maintains compliance with Iowa State’s COVID-19 risk mitigation standards for cleaning, face coverings, physical distancing; and
 - ii. The research team obtains **documented permission** to conduct research from the off-campus/community setting prior to any face-to-face visits. 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.

Research space is defined as the specific physical area in which face-to-face research activities between researchers and participants occurs.

2. Must comply with all Iowa State COVID-19 related policies that are based on federal and public health initiatives (e.g. physical distancing, face coverings, cleaning/disinfection, etc.). Must also comply with the COVID-19-related policies/guidelines of the off-campus (formal or informal) setting. If the policies of the off-campus setting differ from Iowa State policies, the research must comply with the stricter of the two.
3. Face-to-face procedures are minimized and limited to those **NECESSARY** to carry out the study. Any research procedures that can be performed using online or remote research methods must use online or remote methods. Where remote or online procedures are not an option (e.g. unreliable or biased data using remote methods; technical inabilities prevent remote data collection) or the nature of research questions restricts data

collection only to face-to-face methods, then research will be allowed based upon the risk of exposure and strategies to minimize risk.

4. The number of persons in the research space at one time is limited to that which permits physical distancing of at least 6 feet between individuals.
5. **ALL** research methods and procedures used must present low risk of COVID-19 exposure to both researchers and participants. Low risk means that there is:
 - No direct physical contact and appropriate risk mitigation measures are applied (physical distancing, face coverings, etc.); or
 - Brief physical contact (e.g. for application of devices or collection of biospecimens) and appropriate risk mitigation measures are applied (e.g. face coverings, disinfection between visits, new PPE for each visit, etc.). “Brief” refers to physical contact of less than 15 minutes with any single participant during the course of a visit.
6. The research must not:
 - Involve procedures that are intended to or likely to increase respiratory rate due to physical exertion when face coverings cannot be worn (due to increased risk of aerosolized transmission).
 - Specifically recruit individuals who are considered at-risk for serious COVID-19-related illness in accordance with current [CDC guidance](#).
7. A Risk Mitigation Plan covering the research is approved by the lead PI’s department chair or unit director. Guidance and templates for drafting risk mitigation plans applicable to on-campus and off-campus sites are available below.
8. The lead Principal Investigator (and Supervising Investigator) must agree to be responsible for:
 - Establishing and maintaining all initial lab and research readiness preparations and ongoing risk mitigation procedures;
 - Assuring off-campus/community setting(s) can accommodate Iowa State’s COVID-19 risk-mitigation standards;
 - Assuring documented permission from the off-campus setting is granted before the research begins in the setting; and
 - The adequate training, monitoring and supervision of any and all research assistants and their strict adherence to Iowa State COVID-19 safety protocols and approved Risk Mitigation Plan.

Below is a list of resources you will need to plan and implement face-to-face research activities:

[COVID-19 Researcher Checklist \(Updated 10.8.20\)](#)

[COVID-19 **On-Campus** Research Risk Mitigation Plan Guidance \(Updated 10.8.20\)](#)

[COVID-19 **On-Campus** Research Risk Mitigation Plan Template \(Updated 10.8.20\)](#)

[COVID-19 **Off-Campus** Research Risk Mitigation Plan Guidance \(**New** 10.8.20\)](#)

[COVID-19 **Off-Campus** Research Risk Mitigation Plan Template \(**New** 10.8.20\)](#)

[IRB Guidance – Special Considerations During COVID-19 \(Updated 10.8.20\)](#)

[COVID-19 Research Participant Information Sheet \(Updated 10.8.20\)](#)

[COVID-19 Off-Campus Research Site Information \(**New** 10.8.20\)](#)

[COVID-19 Research Staff Screening Questions \(Updated 10.8.20\)](#)

[COVID-19 Participant Screening Questions and Expectations \(Updated 10.8.20\)](#)

[Research Space Visitor Tracking Template \(Updated 10.8.20\)](#)

Have IRB approval requirements changed?

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.

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.

Researchers should review [IRB Guidance – Special Considerations During COVID-19](#) for more information.

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 to ensure 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 Iowa State 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?

All Iowa State employees or students, whether research staff or research participant, must report to Iowa State using the [Iowa State University Positive COVID-19 Reporting Form for Campus](#) if they test positive for COVID-19 within 10 days of a study visit. 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 will be handled by the appropriate public health agency.

What are the procedures I should follow if the research was approved by a non-ISU IRB?

Consult the Reviewing IRB for guidance on:

- Any COVID-19 restrictions or requirements associated with human-subjects research;
- Whether COVID-19 screening requires prior IRB approval;
- Whether and how to modify an approved study to allow remote procedures; and

- Whether and how to share information about the risk-mitigation plans and procedures required by Iowa State.