Human Subjects Research
COVID-19 Risk Mitigation Plan Guidance for
Off-Campus Research

Protecting the safety and well-being of volunteers who participate in Iowa State University human subjects research is of critical importance. Of equal importance is protecting the researchers who conduct this research and individuals in off-campus/community settings. Careful planning is critical to mitigate risk and support health and safety.

Toward this end, lead principal investigators and supervising investigators (for student projects) must develop a risk-mitigation plan that minimizes risk of COVID-19 exposure for research participants, research staff, and other individuals present at the research site. Plans must be tailored to the specific project(s), personnel, and location(s) in which face-to-face human subjects research will occur. One plan may cover multiple projects when appropriate. Before initiating any face-to-face interactions with research participants, the Off-Campus COVID-19 Risk Mitigation Plan must be approved by the lead PI’s department chair or unit director.

This document provides guidance toward developing the Risk Mitigation Plan. Materials referenced below and a template for drafting the plan can be found here.

HSR Risk Mitigation Requirements and Planning Considerations

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<tr>
<th>Risk Mitigation Requirements</th>
<th>Planning Considerations¹</th>
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<tbody>
<tr>
<td><strong>Remote activities whenever possible</strong> – Any research procedures that can be performed online or remotely (e.g., recruitment, consent, data collection, debriefing, follow-up) must be performed online or remotely.</td>
<td>Identify activities that can be completed via telephone, video conference, or online (e.g., informed consent, questionnaire completion, interviews, etc.)&lt;br&gt;Alter the timing of visits and procedures to minimize the number and duration of face-to-face interactions.</td>
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¹ IMPORTANT: Considerations are examples provided for guidance—this is not an exhaustive list. The Risk Mitigation Plan must reflect the totality of the circumstances associated with the research procedures, participant characteristics, setting/lab space, etc.
Avoid inclusion of individuals considered at increased risk of severe illness from COVID-19. Refer to the Centers for Disease Control and Prevention (CDC) for a description of those at higher risk. Persons at increased risk of severe illness cannot be specifically targeted for inclusion in the study. The COVID-19 Research Participant Information Sheet advises those at increased risk to carefully consider participation.

Eligibility criteria and recruitment plans and materials should reflect this criterion.

Critically evaluate the location of the research space in relation to potential non-participant high-risk populations (i.e., public).

Consult CDC guidance frequently as changes occur.

Advance communication with authorized person(s) at off campus sites to:

- Identify a point of contact at the site who can assist with coordinating the research visit(s). The point of contact should be knowledgeable about the COVID-19 related policies, procedures, etc. at the research site.
- Ascertain site-specific COVID-19 risk mitigation practices to which research team must adhere.
- Inform site of required Iowa State COVID-19 risk mitigation practices for research, and ensure plans are feasible (e.g., cleaning, physical distancing, face-coverings, etc.).
- Share most current version of the COVID-19 Off-Campus Research Site Information Sheet. Encourage the site to share with its personnel so non-participating persons are informed.

The COVID-19 Off-Campus Research Site Information Sheet will be updated as needed to reflect changes. Researchers must always download the current version before sharing with an off-campus site.

Information about permission from off-campus sites:

- Permission must be granted by 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.

See guidance on:

Working Remotely with Human Subjects Research: Privacy and Confidentiality Considerations

IRB Guidance – Special Considerations for Human Subjects Research During the COVID-19 Pandemic
- Determine plans to avoid contact with non-participating third parties (e.g., reception staff, co-workers of participants, customers/clients, etc.). *Particular care is necessary to avoid contact with persons at high risk for serious illness from COVID-19.*
- Obtain documented permission to conduct research at the site.

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<tr>
<th>COVID-19-related risks are mitigated to the greatest extent possible to prevent exposure of research participants, research staff, and others present in off-campus/community settings. Risk mitigation includes, but is not limited to:</th>
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<tr>
<td>1. <strong>COVID-19 screening</strong></td>
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**Research participants** must be screened within 24 hours prior to each study visit using the questions in *COVID-19 Participant Screening Questions and Expectations*.

**Research staff** – all researchers, research assistants, and lab/setting workers must be screened within 24 hours prior to direct interaction with participants with the questions in *COVID-19 Research Staff Screening Questions*.

Any change between time of screening and time of visit should be disclosed. Individuals cannot be involved with the study if they:
- have current symptoms of COVID-19,
- tested positive within the past 10 days, or
- have been exposed to someone with COVID-19 in the past 14 days, or
- previously had symptoms, until symptoms have improved, 10 days have passed since onset of symptoms, and no fever for 24 hours.

Individuals who report possible exposure through recent high-risk activities (Screening Question 3) should delay involvement until 14 days after the possible exposure.

| 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 policies of the location. |

Review Iowa State’s [Guide for Returning to the Workplace](#) for general expectations, guidance, example signage and fact sheets, etc.

Develop methods to protect participant and research staff privacy during screening.

Responses to screening questions should not be retained or used as data, unless doing so aligns with the IRB-approved protocol for the project.
2. **Maintain physical distancing of at least 6 feet** to the greatest extent possible.

   The number of persons in a research space at one time is limited to that which permits physical distancing of at least 6 feet between individuals.

   Ensure off-campus sites can support physical distancing (e.g., verify size, number of persons present, etc. prior to research activities).

   Establish plans that minimize contact with non-participating individuals who may be present at the research site (e.g., reception staff, co-workers of participants, customers/clients, etc.). *Particular care is necessary to avoid contact with persons at high risk for serious illness from COVID-19.*

   Review [Physical Distancing Guidelines for Campus Supervisors](#) for guidance.

   Ensure research space supports physical distancing (i.e., research cannot be performed in small or poorly ventilated spaces).

   Design or alter research procedures and/or locations to facilitate physical distancing.

   Minimize the number of researchers and participants in the setting (i.e., stagger participant appointments, decrease staff to the smallest safe number for conducting study).

   Visit the site at times when fewer people are present.

   Apply wearable equipment to participant with minimal to no physical contact;

   Minimize potential contact between participants:

   - use scheduling/tracking systems to minimize overlap before and after visits;
   - avoid “waiting rooms” unless there is sufficient space to support physical distancing;
   - provide 'one-way' or appropriately distant traffic paths for participants entering and leaving.

3. **Face coverings are REQUIRED whenever two or more people are present in the research space.** Face coverings are strongly recommended at all times during the study.

   Choice of face covering should be appropriate for the study procedures. Cloth face coverings may be appropriate for some interactions; face masks or face shields may be necessary in others. Consult [CDC guidance](#) to determine which type of face covering is appropriate.

   Ensure disposable face coverings are available for research staff and participants who do not have their own.

   Follow current guidance on proper use.
Verify off-campus research site compliance before visit.

| 4. Frequent **hand-washing/sanitizing**.       | Have hand sanitizer readily available and visible in the research space.  
| Research staff must wash their hands before interacting with research participants. If hand-washing is not possible, hand sanitizer should be used.  
| Hand washing/sanitizing should occur frequently during long visits or if there is contact between participants and research staff. | Researchers should take hand sanitizer to the research site.  

| 5. **Clean and disinfect surfaces, touch points/surfaces, equipment, supplies, and materials** prior to and between each participant visit. | See [Cleaning and Disinfection Procedures for All Employees](https://example.com) and [Cleaning and Disinfection Procedures for COVID-19 (Laboratory Settings)](https://example.com) for guidance.  
| Identify specific areas, equipment, supplies, and materials that require cleaning/disinfecting, appropriate cleaning/disinfecting methods, and the person(s) responsible for cleaning/disinfecting.  
| Provide each participant with sanitized and/or disposable equipment to use (e.g., keyboard/mice; table, manipulatives, audio/video devices, wearables).  
| Ensure necessary cleaning supplies are available. Researchers should take necessary cleaning/disinfecting supplies with them to the research site.  
| Consider any additional cleaning necessary as equipment/supplies are continually transported between sites and/or used by others at Iowa State. |
### Plan to handle COVID-19 exposure

A visitor log documenting individuals who enter the research space must be kept to facilitate contact tracing, should it be needed. Researchers should use the *Research Space Visitor Tracking Template*. Information can be used ONLY to facilitate contact tracing. Visitor logs should be securely destroyed after 60 days if they are not used.

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.

If an off-campus site requires notification if any research staff who visited the site tests positive for COVID-19, the individual who tested positive should notify the site.

### Advance communication to prospective participants

**Advance communication to prospective participants** about Iowa State’s COVID-19 risk mitigation procedures using the [most current version](#) of the prepared *COVID-19 Research Participant Information Sheet*.

The approved study Informed Consent Form should be shared in conjunction with the *COVID-19 Research Participant Information Sheet* to ensure complete information is available as participants consider willingness to participate.

All participants must comply with the PPE and sanitation requirements for the study (e.g., physical distancing, handwashing/sanitizing, face coverings, etc.). Those that are unwilling to comply should be dismissed from study participation. The *COVID-19 Research Participant Information Sheet* describes general participant expectations.

The *COVID-19 Research Participant Information Sheet* will be updated as needed to reflect current conditions. Researchers MUST ALWAYS download the current version to provide to participants.
### Training, supervision, and monitoring research staff and project activities

1. All research staff must complete online training *Returning to Iowa State University -- COVID-19*, available in [Learn@ISU](#).

2. Provide research team members with study-specific written procedures and instructions for implementing risk-mitigation practices. Provide instructions specific to the off-campus research site(s).

3. Plan and prepare for expected and unexpected situations (e.g., a participant refuses to wear a face covering; a participant or research staff member arrives and is symptomatic; cleaning supplies or face coverings are missing or forgotten; exposure is reported; etc.).

   Provide instructions for handling and reporting issues or problems (e.g., what to report, to whom, reporting timelines).

4. Plan regular and frequent mechanisms to monitor the conduct of the study and strict adherence to all Iowa State COVID-19 policies and guidelines, requirements of off-campus site(s), this Risk Mitigation Plan, and the IRB-approved protocol.

5. A communication plan for the research team is required. The plan will generally include regularly scheduled phone calls, videoconferences, or electronic communications with research team members. **Extra attention and supervision of student researchers is critical.**

### Resources
- [Iowa State University COVID-19 Response](#)
- [Vice President for Research – COVID-19 and Research](#)
- [Centers for Disease Control Coronavirus (COVID-19)](#)
- [Iowa Department of Public Health](#)
- [Iowa State University Positive COVID-19 Reporting Form for Campus](#)
- [HSR COVID-19 Risk Mitigation Planning Guidance – Off-Campus Research v.1, 10.8.2020](#)