

Human Subjects Research COVID-19 Risk Mitigation Plan Guidance

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. 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 and research staff.** 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 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. A template for drafting the plan can be found [here](#).

HSR Risk Mitigation Requirements and Planning Considerations

Risk Mitigation Requirements	Planning Considerations ¹
Remote activities whenever possible – Any research procedures that <i>can be</i> performed online or remotely (e.g., recruitment, consent, data collection, debriefing, follow-up) <i>must be</i> performed online or remotely.	Identify activities that can be completed via telephone, video conference, or online (e.g., informed consent, questionnaire completion, interviews, etc.) Alter the timing of visits and procedures to minimize the number and duration of face-to-face interactions. See guidance on: <u>Working Remotely with Human Subjects Research: Privacy and Confidentiality Considerations</u>

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.

	<p><u><i>IRB Guidance – Special Considerations for Human Subjects Research During the COVID-19 Pandemic</i></u></p>
<p>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 Participant Information Sheet advises those at increased risk to carefully consider participation.</p>	<p>Eligibility criteria and recruitment plans and materials should reflect this criterion.</p> <p>Critically evaluate the location of the research space in relation to potential non-participant high-risk populations (i.e., public).</p> <p>Consult CDC guidance frequently as changes occur.</p>
<p>COVID-19-related risks are mitigated to the greatest extent possible to prevent exposure of research participants or research staff. Risk mitigation includes, but is not limited to:</p> <p>1. COVID-19 screening</p> <p>Research participants must be screened within 24 hours prior to each study visit using the questions in Research Participant COVID-19 Screening and Expectations.</p> <p>Research staff – all researchers, research assistants, and lab/setting workers must be screened immediately prior to direct interaction with participants with the questions in Research Staff COVID-19 Screening.</p> <p>Individuals cannot be involved with the study if they:</p> <ul style="list-style-type: none"> ○ 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. <p>Individuals who report possible exposure through recent high-risk activities (Screening Question 3) should delay involvement until 14 days after the possible exposure.</p>	<p>Review ISU’s Guide for Returning to the Workplace for general expectations, guidance, example signage and fact sheets, etc.</p> <p>Develop methods to protect participant and research staff privacy during screening.</p> <p>Responses to screening questions should not be retained or used as data unless doing so aligns with the IRB-approved protocol for the project.</p>

<p>2. Maintain physical distancing of at least 6 feet to the greatest extent possible.</p> <p>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.</p>	<p>Review Physical Distancing Guidelines for Campus Supervisors for guidance.</p> <p>Ensure research space supports physical distancing (i.e., research cannot be performed in small or poorly ventilated spaces).</p> <p>Design or alter research procedures and/or locations to facilitate physical distancing.</p> <p>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).</p> <p>Apply wearable equipment to participant with minimal to no physical contact;</p> <p>Minimize potential contact between participants:</p> <ul style="list-style-type: none"> ○ 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. <p>Coordinate with other research teams who have shared or adjacent space.</p> <p>Post signage and other visible reminders (traffic path arrows, floor markers, etc).</p>
<p>3. Face coverings are REQUIRED whenever two or more people are present in the research space and as required by Iowa State’s COVID-19 Face Covering Policy.</p> <p>Choice of face covering should be appropriate for the study procedures. Cloth face coverings may be appropriate for some interactions; face masks or face</p>	<p>Ensure disposable face coverings are available for research staff and participants who do not have their own.</p> <p>Follow current guidance on proper use.</p> <p>Post signage on mask/face covering use.</p>

<p>shields may be necessary in others. Consult CDC guidance to determine which type of face covering is appropriate.</p>	
<p>4. Frequent hand-washing/sanitizing.</p> <p>Research staff must wash their hands before interacting with research participants. If hand-washing is not possible, hand sanitizer should be used.</p> <p>Hand washing/sanitizing should occur frequently during long visits or if there is contact between participants and research staff.</p>	<p>Post signage to promote hand washing.</p> <p>Have hand sanitizer readily available and visible in the research space.</p>
<p>5. Clean and disinfect surfaces, touch points/surfaces, equipment, supplies, and materials prior to and between each participant visit.</p>	<p>See Cleaning and Disinfection Procedures for All Employees and Cleaning and Disinfection Procedures for COVID-19 (Laboratory Settings) for guidance.</p> <p>Identify specific areas, equipment, supplies, and materials that require cleaning/disinfecting, appropriate cleaning/disinfecting methods, and the person(s) responsible for cleaning/disinfecting.</p> <p>Provide each participant with sanitized and/or disposable equipment to use (e.g., keyboard/mice; table, manipulatives, audio/video devices, wearables).</p> <p>Ensure necessary cleaning supplies are available.</p>

<p>Plan to handle COVID-19 exposure</p> <p>All research staff and participants must be instructed to immediately report to ISU 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. Note: Participants should be instructed to select “Other” in the “Relationship with the University Field,” state their relationship (research participant), and enter text (e.g., RESEARCH) in the University ID Number field.</p> <p>A visitor log documenting individuals who enter the research space must be kept to facilitate contact tracing, should it be needed. Researchers should use this template. Information can be used ONLY to facilitate contact tracing. Visitor logs should be securely destroyed after 60 days if they are not used.</p>	
<p>Advance communication to prospective participants about ISU’s COVID-19 risk mitigation procedures using the <u>most current version</u> of the prepared Research Participant COVID-19 Information Sheet.</p> <p>The approved study Informed Consent Form should be shared in conjunction with the Research Participant COVID-19 Information Sheet to ensure complete information is available as participants consider willingness to participate.</p> <p>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 Participant COVID-19 Information Sheet describes general participant expectations.</p>	<p>The Research Participant COVID-19 Information Sheet will be updated as needed to reflect current conditions. Researchers MUST ALWAYS download the current version to provide to participants.</p> <p>Consider posting COVID-19 signage at facility/research-space entrances (e.g., Stay Home if You Are Sick, others).</p>
<p>Training, supervision, and monitoring research staff and project activities</p> <ol style="list-style-type: none"> All research staff must complete online training <i>Returning to Iowa State University -- COVID-19</i>, available in Learn@ISU. 	

<p>2. Provide research team members with study-specific written procedures and instructions for implementing risk-mitigation practices.</p>	
<p>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; exposure is reported, etc.).</p> <p>Provide instructions for handling and reporting issues or problems (e.g., what to report, to whom, reporting timelines).</p>	
<p>4. Plan regular and frequent mechanisms to monitor the conduct of the study and strict adherence to all ISU COVID-19 policies and guidelines, this Risk Mitigation Plan, and the IRB-approved protocol.</p>	
<p>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.</p>	

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](#)