Checklist for Resuming Face-to-Face Human Subjects Research

This checklist is a tool to assist researchers by listing actions to take before conducting human subjects research during the COVID-19 pandemic. It applies to new and ongoing research as well as research that is resuming after the COVID-19 restrictions on face-to-face interactions. This checklist will be updated as new or revised requirements are implemented. Therefore, researchers should always use the most current version.

<table>
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<tr>
<th>Allowable Research. Determine whether the research meets ALL criteria associated with the currently allowed Phase. If not, re-design the research procedures to satisfy all criteria or postpone until a future phase.</th>
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<tr>
<td>ISU COVID-19 Policies and Guidelines. Review and learn ISU policies and guidelines that are applicable to the research, facility, and research personnel.</td>
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**Coordination with Research Site (for off-campus research)**

- Identify a point of contact at the site who is knowledgeable about site-specific COVID-19 policies and procedures and can help coordinate visit(s).
- Review and learn site-specific COVID-19 policies and procedures to which research team must adhere.
- Verify site compliance with Iowa State COVID-19 risk-mitigation standards in the research space(s).
- Share most current version of the *Research Site COVID-19 Information Sheet* with the site. Encourage site to share with their personnel so non-participating persons are informed.
- Determine plans to avoid contact with non-participating third parties who may be present at the site.
- Obtain documented permission to conduct research at the site.

**Evaluate Research Space.** Identify the research space(s) where interaction/intervention with research participants occur. Consider physical distancing needs, minimizing contact as participants enter and exit, availability of handwashing facilities, scheduling for shared adjacent spaces, etc.

**Risk Mitigation Plan.** Create a Risk Mitigation Plan if the research involves face-to-face interaction with research participants. See [here](#) for guidance and templates for on-campus and off-campus plans. Risk Mitigation plans require approval from the lead PI’s department chair or unit director; **approval must be finalized before the face-to-face research interactions may commence.** Researchers are responsible for ensuring congruence between applicable elements in Risk Mitigation Plans and IRB applications.

*Risk Mitigation Plans DO NOT require IRB approval, and should not be submitted with IRB applications.*

**Research personnel training.**

- All researchers must complete ISU’s [online training](https://returningtoiowastateuniversity.iris.iastate.edu) *Returning to Iowa State University -- COVID-19.*
- Develop study-specific and site-specific written instruction for implementing risk-mitigation practices.
- Plan and prepare for expected and unexpected situations. Plan regular and frequent mechanisms to monitor the conduct of the study.
- Develop a communication plan to facilitate regular and frequent communication and ensure staff know whom to contact if issues arise. **Extra attention and supervision of student researchers is critical.**
| ☐ | **IRB Approval.** Obtain IRB approval for the research or for any changes to the research to support remote implementation of procedures. See [here](#) for guidance. |
| ☐ | **PPE and Cleaning Supplies.** Order/obtain all necessary PPE and cleaning supplies from [ISU Central Stores](#). Create supply kits to take to off-campus research sites (if applicable). |

**Develop COVID-19 Screening Plans.** All participants and research staff must be screened for symptoms and potential exposure within 24 hours prior to face-to-face study visits. Screening questions are available [here](#). Screening procedures can vary (paper, via phone or email, via Qualtrics, etc.). However, procedures must maximize privacy. Responses to screening questions should be used only to determine whether face-to-face interaction can occur. 

*Covid-19 screening procedures DO NOT require IRB approval.*

| ☐ | **Locate current version of the Research Participant COVID-19 Information Sheet.** Develop plans for providing to participants prior to their visit. The study informed consent document should be shared in conjunction with the Research Participant COVID-19 Information Sheet. 

*Use of this document DOES NOT require IRB approval.*