Face-to-Face Human Subjects Research Activities Restricted

Given the rapidly evolving circumstances regarding COVID-19 and Iowa State University’s focus on the health and safety of faculty, staff, students, and the community, the Office of the Vice President for Research and the Office for Responsible Research have issued revised standards related to research involving human participants.

Effective March 18, 2020 and until further notice, research interactions with human research participants must be performed remotely (e.g., phone or other university-supported online tools such as Webex, Qualtrics, etc.). Remote methods of data collection may be conducted if part of the originally approved protocol or an approved modification. Research procedures involving face-to-face interaction with research participants must be postponed, unless the research procedure(s) is essential to ensure participant health, safety, or well-being (see the Exception for Essential Research Visits described below).

Exception for Essential Research Visits: Research visit(s) that are essential to ensure participant health, safety, or well-being may continue using face-to-face interactions if no remote options are available. The decision about whether a research visit is essential to the health, safety, or well-being of a participant is determined by the principal investigator (including supervising investigators when applicable), the participant, and/or the participant’s care provider. Decisions must be informed by current public health guidance regarding the COVID-19 outbreak. Decisions about visits should be especially conservative for participants at heightened risk. Researchers must work with their department chairs, research center directors, and associate deans for research to make appropriate decisions on whether a research visit(s) is essential.

Please note: Given ISU’s research portfolio, it is extremely unlikely that any studies involve visits or procedures that are essential to ensure participant health, safety, or well-being.

Face-to-face essential research visits must adhere to current guidelines to reduce COVID-19 exposure for study participants and research staff. These steps include, but are not limited to:

1. Remotely screen all participants just prior to an in-person visit for possible exposure to the novel coronavirus or symptoms of respiratory illness such as fever, cough, and shortness of breath or difficulty breathing. Consult current public health guidance to determine appropriate screening questions. Research participants with possible exposure or symptoms may not participate in face-to-face interactions until after the time recommended by current public health guidance. This screening does not require prior ISU IRB approval.
2. **Ensure every day that all research staff who interact with participants** are symptom-free and have not been exposed to the novel coronavirus.

3. **Ensure appropriate infection control measures** are taken at the site of the face-to-face visit. For example, ensure availability of hand sanitizer, hand washing facilities, disinfectant wipes, etc. Train staff on appropriate cleaning and infection control procedures necessary to mitigate COVID-19 spread. Use appropriate personal protective equipment when handling human specimens.

4. **Stay aware of and abide by all applicable recommendations, policies, and actions** of federal and state public health authorities, Iowa State University, non-ISU facilities where research is conducted, etc.

**Effect of the restriction on pending IRB applications**

IRB review of submitted applications will continue as usual. Studies that involve face-to-face interaction may be approved with the condition that face-to-face interactions cannot begin until after the restrictions are lifted.

**Notifying participants of visit cancellations**

If a study visit needs to be cancelled, 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.*

**Notifying the ISU IRB**

Visit cancellations related to COVID-19 do not need to be reported to the IRB.

A modification application may be required to change from face-to-face to remote data collection procedures. See [COVID-19 and Research](#) guidance for details.

**For research approved by a non-ISU IRB**

Consult the Reviewing IRB for guidance on:

- Whether COVID-19 screening requires prior IRB approval
- Whether/how to report the restrictions on face-to-face study procedures
- Whether/how to modify an approved study to allow remote procedures