Guidance to Investigators During COVID-19 for Human Subject Research

The SIUE Office of Research and Projects (ORP) is providing the following guidance for face-to-face human subject research (HSR) on campus and for research field work, in accordance to Governor Pritzker's *Restore Illinois* plan and the University's plan for phasing in general operations. The priority is to protect the health and safety of our faculty, staff, students, and research subjects. This plan does not provide specific dates regarding moving forward, or reverting to an earlier phase of "Restore Illinois" if necessary, but rather the plan adheres to guidance provided by the Governor and the University.

HSR IRB Review and Training during COVID-19

IRB protocol reviews and notifications of approval will continue as usual using Kuali Research for exempt and expedited reviews. As we may be unable to conduct convened, in- person, full-board reviews during this time, the IRB will work to be as timely as possible using video conferencing such as Zoom.
Human subjects training will continue as usual using the CITI electronic training program.

Revising HSR Methods during COVID-19 for New and Previously-Approved Protocols

Investigators proposing face-to-face research with human subjects and those who have previously IRB approved projects involving face-to-face human subject research should consider the risks to yourself and to your participants and consider alternative research methods or a temporary suspension.
The IRB recommends, when possible, to move from face-to-face contact with participants to electronic contact which may include:

a) conducting surveys using Qualtrics
b) conducting interviews using an online system (such as Zoom or Skype) or phone
c) using Amazon MTurk or email to recruit participants
d) obtaining verbal consent from participants.

For those Investigators who wish to use face-to-face-contact, include the following in your new Kuali Research protocol and/or amendment to your previously approved protocol.

a) Investigators will obtain from each participant a signed **Research Participant Safety Acknowledgement Form**.
b) Investigators will keep this signed form with the participant's signed informed consent.

Exempt studies do NOT need to submit a modification unless the change would alter the review category of the study.

Review Priority for Protocol Amendments due to COVID-

The IRB will grant priority review to new projects and to amendments that are related to COVID-19 research. Include COVID-19 in the protocol title.

Additional Resources:

The guidance is subject to change given any changes to the state's or university's operations guidance. Any changes will be announced.

FDA guidance

The FDA has released the following guidance regarding COVID-19: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency.