

IRB Office Input for Safe Return to Campus Research
May 22, 2020

One of the goals of the Northwestern University IRB Office is to enable human research to safely resume on campus during the COVID-19 pandemic. The following guidelines are to ensure the safety of all research staff and human research participants. These guidelines refer only to human research activities that cannot be conducted off-campus and may require direct contact with research participants.

At this time, this guidance is only to be used for planning purposes while the Illinois stay-at-home order and Northwestern University campus restrictions are in effect.

General Requirements:

- On campus activities for non-essential human research should only be resumed if all the following criteria are met:
 - the research activity cannot otherwise be carried out remotely, virtually, or off-campus;
 - *Note: activities that can be performed remotely/virtually/off-campus should continue in that manner until further notice.*
 - the PI creates a safety plan demonstrating that they can conduct the on campus activities within the parameters of current university campus requirements
- Review of PI safety plans and the decision to allow non-essential human research activity to resume on campus is ultimately at the discretion of department chairs, school deans, or institute directors.
 - *Note: while not considered the IRB's purview, we also recommend an accountability mechanism that ensures chairs/deans/directors seriously consider whether the safety plan is sufficient and it is appropriate or urgent to resume non-essential research activity.*
- Follow the [IRB Office COVID-19 Memo to Research Community](#) if making any changes to study procedures because of the COVID-19 pandemic.
- The IRB Office does not consider risk of COVID-19 exposure study-related, and thus it should not be included in protocols or informed consent forms. If those changes to the documents have been made, please remove.
- COVID-19 pre-screening procedures should not be added to protocols or informed consent forms. If those procedures have been added to the documents, please remove.

In-Person Study Visit Requirements:

- Researchers and participants conducting human research activities in university buildings must comply with current Northwestern University campus requirements. **At present, the University is prohibiting visitors to campus, including research participants.**
- Researchers and participants conducting human research activities in clinical spaces must comply with current clinical visit and clinical space requirements mandated by the respective clinical entity.
- Follow current [CDC guidelines](#) during participant interactions and in study visit areas.
- To limit interaction time, consider whether some visit procedures may be completed
 - via telephone, online, or virtually; or
 - at the participant's local clinic facility.
- Participants must be remotely pre-screened for COVID-19 symptoms prior to any in-person study visit.
 - Researchers in a clinical setting may use the hospital/clinic's screening protocol.
 - Researchers may also use the [pre-screening questionnaire](#) recommended by the IRB Office.
 - *Note: pre-screening may not be a conclusive indicator of COVID-19 transmission probability due to possibility of asymptomatic carriers.*
 - Cancel the study visit if participant does not pass pre-screening.
- Only individuals necessary to carry out the research activities should be present for in-person study visits.
- Limit participant companions at visits to individuals who must be present for

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- helping to make health care and/or research-related decisions;
- minors and seniors; or
- vulnerable individuals.

Recommendations:

- Contact the [Office for Research Safety](#) at researchsafety@northwestern.edu if you need guidance regarding the appropriate personal protective equipment (PPE) use for your research activities or for instructions on how to obtain or order PPE through the Procurement Department.
- Prior to study visits, inform participants of procedures they need to follow while on site.
- Where possible, minimize the number of people touching the same research equipment.

If you have questions about the above in regards to your human research project, contact the IRB Office at irb@northwestern.edu or sbsirb@northwestern.edu.