

Phased Return of Human Research Activities on Campus

The Northwestern University IRB Office is implementing certain requirements to help minimize the risk of SARS-CoV-2 infection as human research resumes on campus during the COVID-19 pandemic. The following requirements are intended to minimize risk to all research staff and human research participants, and may evolve as guidance from the public health officials changes. These requirements refer only to human research activities that cannot be conducted remotely and requires in-person contact with research participants. The same requirements apply both to new IRB-approved research studies as well as to those previously approved studies resuming in-person visits.

General Requirements:

- Until further notice, on-campus and in-person activities for non-essential human research should only be resumed if all the following criteria are met:
 1. 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. For recommendations and additional information about performing virtual/remote human research activities, including conducting virtual study visits through Zoom or other Northwestern IT-verified platforms, please refer to the [IRB Office's COVID-19 Resources webpage](#).*
 2. The PI creates a safety plan demonstrating that they can conduct the on-campus or in-person activities within the parameters of current University campus requirements.
 - Researchers may choose to use the [Pandemic Research Plan](#) template as a tool or guide for developing their safety plan, unless otherwise directed by their school/department. The plan should be specific to one's research space(s), including all areas that researchers/participants may occupy, and identify all areas and job tasks with potential exposures to COVID-19 and include control measures to eliminate or reduce exposures for the study team and research participants.
 - Review of safety plans and the decision to allow non-essential human research activity to resume on campus or in person is ultimately at the discretion of department chairs, school deans, or institute directors (or appointed designees). **Do not submit safety plans to the IRB Office.** PIs should contact their chair, dean, or director's office for guidance regarding submission and review of plans. PIs and/or research units within the Feinberg School of Medicine should refer to the clinical research section of [FSM return to campus guidelines](#) and submit their plans to: FSMReactivationPlans@northwestern.edu. To the extent possible, FSM PIs should send a single plan for all projects.
- 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 for that reason the risk of COVID-19 exposure and standard COVID-19 pre-screening procedures should not be added to protocols or informed consent forms.

In-Person Study Visit Requirements:

- Research participants and researchers conducting human research activities in University facilities must comply with current Northwestern [campus requirements](#). Research participants and researchers conducting human research activities in clinical spaces must comply with current clinical visit and clinical space requirements mandated by the respective clinical entity.
 - For Northwestern Memorial HealthCare, contact the clinical/operations manager of the respective NMHC clinical area for additional information on the reactivation guidelines and operational procedures required by NMHC.
 - For questions about Shirley Ryan AbilityLab requirements contact Melissa Mitchell at mmitchell2@sralab.org.
 - For questions about Ann and Robert H. Lurie Children's Hospital of Chicago requirements contact Christy Anton at CAnton@luriechildrens.org.
- Follow current [CDC guidelines](#) during participant interactions and in study visit areas.
- To limit in-person interaction time, consider whether some study visit procedures may be partially completed off campus before the participant arrives in person:
 - via telephone, online, or virtually; or
 - at the participant's local clinic facility or another off-campus location.
- Participants must be remotely pre-screened for COVID-19 symptoms within 24 hours prior to any in-person study visit, whether off-campus or held in a University-owned facility.
 - Researchers conducting study visits in a clinical facility should use the hospital/clinic's screening protocol.
 - Researchers not conducting study visits in a clinical facility must use the [pre-screening questionnaire](#) provided by the IRB Office.
 - *Note: pre-screening may not be a conclusive indicator of COVID-19 transmission probability due to possibility of asymptomatic carriers.*
 - If a participant does not pass pre-screening, cancel the visit or have the PI make an assessment as to whether the visit should be cancelled. PIs may re-screen participants after 14 days, but they must pass pre-screening before proceeding with the in-person study visit.
 - Safety plans may include a second pre-screening when the participant arrives for the in-person study visit, which may also include a temperature check.
- Only those individuals who are required to carry out the research activities should be present for in-person study visits. This includes limiting both study staff and participant companions at visits.
 - Participant companions should be limited to only those who must be present to assist research participants with making health care and/or research-related decisions, such as minors, seniors, people with disabilities, and other vulnerable individuals.

Recommendations:

- Contact the [Office for Research Safety](#) at researchsafety@northwestern.edu for a consultation if you need guidance regarding the appropriate personal protective equipment (PPE) to use for your research activities.
- Contact the [Procurement Department](#) at procurement@northwestern.edu for instructions on how to obtain or order both standard and non-standard PPE, cleaning supplies, or thermometers. All non-standard PPE should continue to be purchased by the researcher through Fisher and Schein.
- Prior to study visits, researchers must fully inform participants of what to expect and the procedures they need to follow while on site, such as whether their temperature will be taken and the requirement to wear a mask and other applicable preventative measures. If research participants have a disability that prevents them from wearing a mask, please follow the clinical entity's requirements, or if the research is being conducted in University space or off-campus, please consult with the [Office for Research Safety](#) regarding appropriate PPE measures.

- Upon their arrival for the in-person study visit, it is recommended that participants and anyone accompanying them have their temperatures taken to confirm they do not have a fever (>100.4°F). Individuals who have a fever should be treated as a failed pre-screen for COVID-19 symptoms.
- If your research requires external study monitors to come on site to conduct routine monitoring activities that cannot be accomplished remotely, please include these monitoring activities in your safety plan for review by your chair/dean/director (or appointed designee). **At present, the University and NMHC are prohibiting external study monitors on-site unless the monitoring visit is deemed essential.** For questions about essential on-site monitoring:
 - Contact Megan Carney at megan.carney@nm.org for NMHC-related inquiries; or
 - Abby Cosentino-Boehm at a-cosentino-boehm@northwestern.edu for FSM-related inquiries.
- Where possible, minimize the number of people touching the same research equipment.
- Include a disinfection/cleaning protocol in your safety plan for equipment, surfaces and research spaces. This should include paper forms and pens used by research participants to sign forms.

If you have questions about any of these points above, contact the IRB Office at irb@northwestern.edu or sbsirb@northwestern.edu.