Northwestern | RESEARCH

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## **IRB Office Memo – Return to Campus**

In alignment with the recent <u>communication from VPR Milan Mrksich</u> regarding the State of Illinois Phase 5 re-opening and lifted restrictions for vaccinated University community members, the IRB Office is adjusting its policies supporting human research to clarify how these changes impact our on-campus research activities.

On-campus and in-person activities for human research may be resumed in accordance with the above Office for Research (OR) guidelines, which mirror <u>University-wide guidance</u>. This includes the removal of social distancing and density restrictions for research spaces, meetings and gatherings, and optional masking for vaccinated individuals. Unvaccinated individuals are expected to continue masking.

Researchers conducting activities in University facilities must comply with Northwestern University's requirements. Researchers conducting activities in clinical spaces must comply with the requirements of the respective clinical entity, which may require masking in patient-facing clinical spaces. On-campus study monitoring activities may also resume in University research spaces, but if a study monitor needs to enter clinical spaces, the requirements of the respective clinical entity must be followed.

IRB-approved studies may resume on-campus activities, and may enroll new participants without restrictions, in alignment with the approved protocol. Hybrid options may be implemented, as needed. Reportable New Information submissions and/or protocol modifications are not required for researchers to resume activities on their current IRB-approved protocols.

Study teams should respect the choice of research participants to continue to mask if participants wish to do so. Also, many research teams work with participants less than 12 years of age who may not be eligible for vaccinations at this time and so researchers should continue the appropriate safety measures for those studies that enroll minors.

Researchers should continue to pre-screen research participants coming to campus for symptoms within 24 hours, prior to any in-person study visit. Researchers conducting study visits in clinical facilities should use the hospital/clinic screening protocol. Researchers <u>not</u> conducting study visits in a clinical facility should continue to use the <u>Pre-screening Questionnaire</u> provided by the IRB Office.

Researchers should ensure that participants do not feel compelled or pressured to continue in-person visits unrelated to their clinical care or safety. Participants must maintain their voluntary consent, and thus are not required to continue research participation if they are not comfortable doing so for any reason.

Please continue to reference OR's <u>COVID-19 Updates</u> and the IRB Office's <u>COVID-19 Resources and News</u> for any current updates. If you need further guidance, please contact the IRB Office at <u>irb@northwestern.edu</u>.