

Human Subjects Research COVID-19 Guidance for Wake Forest University

Wake Forest University issues the following updated guidance for the conduct of human subjects research during the COVID-19 global pandemic.

For ongoing research:

The safest approach is to **modify your active protocol** to replace in-person interactions with appropriate remote methods. To do so, you must file an application amendment in eIRB. If you plan to return to in-person interactions after the COVID-19 crisis, draft your revised methods to allow for it. By doing so, a second application amendment will not be necessary to reverse the first.

If in-person interactions are necessary, please refer to the **Human Subjects Research section** of the [Research Restart Guide](#) for important conditions and standards that must be met before resuming your research. **Please contact irb@wfu.edu to initiate the required review of your study's methods to screen for COVID-19 risks.** You cannot proceed with any in-person participant interactions until you receive this additional clearance from the IRB.

If an **external IRB** reviewed and approved a study being conducted at WFU, the research activities are also subject to this guidance. Contact the external IRB to determine what, if anything, you must officially report to them, the sponsor, or the participants.

For new eIRB applications:

The WFU Institutional Review Board will only accept new eIRB applications that involve in-person interactions or interventions with human research participants if the methods are deemed necessary and the conditions described in the Research Restart Guide can be met. New applications currently under review must also comply with this guidance.

Research on the diagnosis, treatment, interventions, or other research activities directly focused on COVID-19 and for which there is a substantial likelihood of direct and meaningful biomedical or behavioral health-related benefit or outcome will continue to receive priority for review.

If your research study team includes **undergraduate students**, please review the [Protocol for the Safe Return of Undergraduates to Mentored Research and Scholarship Activities of Wake Forest Faculty](#).

ORSP IRB Administrators are available to answer questions at irb@wfu.edu.