



FORDHAM UNIVERSITY

THE JESUIT UNIVERSITY OF NEW YORK

COVID-19 Impact on Human Subjects Research

Guidelines for Researchers

In the context of rapidly evolving circumstances regarding COVID and the mandate for social distancing for the health and well-being of the community, the Fordham IRB has determined that ALL human subjects research involving face-to-face interaction with study participants must be paused or amended to remove face to face interaction if possible until further notice.

If you have an active human subjects research approval that involves direct interaction (including face to face recruitment, data collection or procedures, etc.) and would like to continue the research, please submit an amendment to change such procedures so that NO face to face interactions are required. If this is not possible, then you are required to pause the research until further notice.

The review processes of the Fordham IRB are still continuing and running remotely. There is NO break in Fordham IRB review processes or in the assistance or guidance available to you.

Please contact the IRB at irb@fordham.edu or IRB Manager, Michele Kuchera at mkuchera@fordham.edu with any questions or concerns.

FAQ's

Office Functions

Is the IRB Office closed, or is it open during the COVID-19 pandemic?

The IRB office is open and working remotely.

What is the best way to contact the IRB Office?

Please email us at irb@fordham.edu or mkuchera@forham.edu.



FORDHAM UNIVERSITY
THE JESUIT UNIVERSITY OF NEW YORK

Submissions

Is the IRB still reviewing submissions?

Yes, the IRB is still reviewing submissions. Studies involving in-person interactions will be approved with the condition that no in-person interactions may occur until the pause is lifted. Investigators are encouraged to design protocols that include either only remote interactions or include the option to conduct both remote and in-person interactions. In-person activities included in approved protocols may be conducted once the pause is lifted without requiring a modification.

Will review turn-around times be affected by office closure?

The IRB Office staff are working remotely. As the Mentor system is internet based there should be little change to the current review and submission process. Exempt and expedited reviews submitted are reviewed in the usual estimated time span of 10-15 business days. The IRB will be convened during teleconference or videoconference if there are any applications submitted requiring full board review. If you are submitting a research study that requires a quicker turn-around time, please email irb@fordham.edu to notify us.

My study requires in-person contact with study subjects. Can it be approved now?

The IRB will review your study for a delayed start of in-person interactions, but, in most cases if not all, these interactions cannot commence until the IRB lifts the pause.



FORDHAM UNIVERSITY
THE JESUIT UNIVERSITY OF NEW YORK

Active Protocols

Do I need to notify the IRB if I will be pausing my research during this time?

No, you do not need to notify the IRB.

Are there any exceptions for human subjects research studies that do not have to be paused?

Yes, there are limited exceptions to the pause, including:

- *studies in which the direct benefits outweigh the risks of exposure to COVID-19,*
- *ongoing studies in which suspending in-person interactions would place subjects at apparent immediate harm,*

Please email irb@fordham.edu to notify us if your study meets one of these exceptions and you intend to continue with your research study.

Can I change my research study to include virtual data collection, e.g. online survey, Skype, Zoom, phone calls during this time?

Yes, please submit an amendment via Mentor explaining the changes you are making to your study. The Amendment Summary Form can be found on the Info Page in Mentor. This completed form along with any applicable documents, e.g. revised consent form, online survey, etc. can be submitted via the Amendments tab located at the bottom of your protocol page.