
The COVID-19 emergency and attendant disruptions to University life mean that the Institutional Research Board (IRB) has reevaluated the risk to benefit considerations for human subjects research. While most human subjects research at Princeton falls into the category of social and behavioral rather than biomedical research, it is still necessary that it be conducted in a way that minimizes risk to subjects. At the same time, the IRB is mindful that limiting contact with subjects will affect the research plans of faculty, research staff, and our graduate and undergraduate students. In this context, the IRB notes that the University is committed to ensuring that all students are able to complete their work, including research, even though it may be necessary to adjust assignments.

Guidance from the National Institutes of Health (NOT-OD-20-087, March 16, 2020) indicates that, “Institutions should take all steps necessary to ensure the safety of all human subjects and research staff involved in NIH-funded clinical trials and human subjects studies,” and provides investigators and IRBs with broad latitude in adjusting or modifying study protocols in order to do so. With this guidance in mind, the IRB has divided human subjects research into studies that are essential to the well-being or health of subjects, and those that are non-essential to the well-being or health of subjects. Virtually all human subjects research at Princeton will fall into the non-essential category. Principal investigators or their designees should inform their study sponsors of the following University restrictions.

Essential Research

A research visit is essential if it "necessary to the health and/or well-being" of a subject. This is determined by the principal investigator of the research study, the subject, and the subject's care provider if relevant, and should be informed by current public health and other University guidance regarding the COVID-19 emergency. Research visits that cannot be performed remotely, and are essential to a subject's health or well-being, may be performed in-person but must exercise social distancing at all times. Very few research studies will fall into this category.

Non-Essential Research

Research visits that cannot be performed remotely and are not essential to a subject's health or well-being must be postponed until further notice.
Consistent with this University mandate, investigators must refrain from the following human subjects research activities: 1) use of imaging or sensing equipment which involves personal contact with the subject; 2) in-person surveys, interviews, or ethnographic research; 3) administration of surveys or questionnaires at any facility or gathering in which there are groups of ten or more; and any other study that does not follow social distancing guidelines recommended by the Centers for Disease Control.

In contrast, remote research visits may continue. Data review and analysis as well as processing of already-collected samples is also permitted, consistent with other guidance provided by the University.

In summary:

- Research visits essential to a subject’s health or well-being are allowed but social distancing must be practiced at all times.
- Non-essential in-person research activity is not allowed.
- Due to these special circumstances, investigators may make changes to research without obtaining prior approval from the IRB if the changes are necessary to implement this announcement. This flexibility afforded to principal investigators is only to be used in protecting human subjects in the context of the current COVID-19 pandemic. Investigators who use this flexibility to make changes without prior IRB approval must report the change to the IRB via submission of a Reportable New Information form. The submission of the form must be done before September 1, 2020. A Help Guide to submit the form can be found here: https://ria.princeton.edu/eria/help-guides

If you have questions about this announcement, please contact the IRB at irb@princeton.edu or (609) 258-0865.