

Guidance on Resuming In-Person Human Research

As states begin to remove restrictions on non-essential travel, researchers are anticipating the opportunity to resume in-person human subject research. This set of guidelines has been developed by the University of Notre Dame Institutional Review Board (IRB) to answer questions about the process of resuming research that requires direct contact with human subjects.

State and local authorities

While the IRB is allowing studies to resume under certain conditions, any restrictions in place at the location of the research must be followed. If a city, county, or state currently limits non-essential travel, assembly of groups, contact with others, or any other activities included in a study, researchers may not be able to resume research until those limits are removed. Most public health agencies have information available online regarding COVID-19 restrictions, but if researchers are uncertain please contact the relevant authorities to confirm.

Research at external organizations

For research conducted at an external organization like a business, the IRB recommends that researchers contact them ahead of any activities. Some organizations are asking individuals to take specific measures to protect themselves and others, and factors like hours of operation may have changed.

If researchers are planning to conduct studies in a hospital or long-term care facility, contact the facility well in advance of any planned visit. Most health care and long-term care facilities have restricted all but essential visitors, and are unlikely to allow external research to continue at this time.

Any research planned at educational sites (schools, day cares, universities) will require confirmation from the appropriate officials at the site that research can proceed. Contact these organizations, and request written permission to begin or continue research at these locations (email may be sufficient).

Research on the University of Notre Dame campus

Ensure that plans to conduct in-person human subject research on the University campus follow all institutional requirements, including the planned [Notre Dame COVID-19 playbook](#). An approved IRB protocol does not confer authority to conduct research outside of any health and safety requirements on

the University campus. Where University guidelines make explicit requirements, these are not superseded by IRB approval. For more on University requirements, please visit the “Return to Campus” site, here: <https://here.nd.edu/>

If you will be conducting in-person human subject research in a laboratory, studio, or core facility at the University, approval to use the facility must have been granted through the “Request to Reopen,” found here: <https://research.nd.edu/research-continuity/phased-reopening-of-research/>. In addition, resources like a “Resumption of Research Checklist” can be found on this site, and should be reviewed to ensure compliance.

IRB steps to resume in-person human subjects research

1. Complete human research COVID-19 risk evaluation checklist

The IRB has developed a [human research COVID-19 risk evaluation checklist](#) that must be completed by all principal investigators, for each protocol. It is a self-assessment, and intended to assist the study team in identifying if in-person research is presumed to present no more than minimal (everyday) risk to human subjects, or if it has the potential to expose subjects to elevated risk. The human research COVID-19 risk evaluation checklist will guide researchers to a determination of whether changes to approved research are needed (by way of IRB protocol amendment), or if the research can proceed with minor changes that do not require IRB review (e.g., implementation of safety procedures).

2. Incorporate pre-study communication

Any study which plans to continue (or begin) enrolling human subjects into a study which requires in-person contact will be required to provide any potential subject a standard [pre-study informational communication](#) that was developed by the Notre Dame IRB. The document generally discusses the risks that exist with respect to COVID-19, measures that are recommended to prevent infection, and how these risks have changed human subject research. The communication is not an informed consent form, but serves to provide basic information for subjects. The study team should familiarize themselves with the document, but understand that they are not expected to provide health care advice to subjects – a statement that is included in the document.

3. Revise Informed Consent Form

All studies will need revisions to be made to the informed consent documents, but whether an amendment is required depends on the results from the human research COVID-19 risk evaluation checklist. If a study is identified as potentially elevating risk to subjects, an amendment to IRB must be submitted. The amendment should include the completed human research COVID-19 risk evaluation checklist, the pre-study information communication, and also a revised informed consent form, which a [guide can be found for here](#) and identifies procedures or conditions in the research that elevate the risk of infection to subjects.

If a study is identified in the human research COVID-19 risk evaluation checklist as presumptively standard risk, no amendment is needed. A paragraph has been added to the IRB informed consent template that highlights the general risk of any interpersonal contact at this time. This paragraph should be added to all informed consent documents for studies considered to present standard risk to subjects, but it may be added without submission to the IRB.

Vulnerable subject populations

When the IRB asks researchers to consider vulnerable subjects in the context of a study, it does so with respect to the principles of ensuring that subjects are able to understand the consequences of enrolling (children), and do not feel coerced to participate (prisoners, pregnant women). The subject populations identified on the human research COVID-19 risk evaluation checklist have been identified by public health authorities as being the most likely to be affected by COVID-19. Consider implementing methods in your research to ensure the safety of subjects by recognizing these particular vulnerabilities, but the IRB is not asking researchers to stop enrolling subjects falling within those particular categories. The addition of safety procedures may adequately address concerns, and the IRB wants to continue to ensure that equitable subject selection in research is maintained at the University as well.

Collection of human specimens

If your research requires the collection of human specimens, ensure that the laboratory conditions under which they were approved to occur (within biosafety committee approval) can proceed, or an amendment is submitted to both the IRB and IBC to account for any changes.

Contact

If you have any questions about resuming a specific IRB protocol, please contact the IRB at compliance@nd.edu.