

# Institutional Review Board (IRB): Getting Started

## What is the Institutional Review Board (IRB)?

When using or collecting data about human subjects, you may be required to go through an Institutional Review Board (IRB) process. IRBs are committees based at research institutions (like Columbia University) that screen planned research methods for ethical considerations related to human research subjects.

Any Columbia University faculty, employee, or student conducting research with human subjects may need to go through a review process. Review by an IRB is federally mandated and is intended to ensure that human subjects' rights and wellbeing are protected during research. The review process must be completed before research with human subjects or data or personal information collected from human subjects can begin.

## Research and Human Subjects

The Columbia University Institutional Review Board Standard Operating Procedures (<https://bit.ly/ColumbialRBB2B>) define “research” and “human subject” in the following ways:

### Research

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. (Title 45 of the Code of Federal Regulations (CFR) Part 46.102(d); hereafter, regulatory citations will include only “CFR” and the numbers.)

Remember, research must be intended to contribute to generalized knowledge, which generally means that it will be published in some form. If your work will not be published or recorded for distribution, it likely does not meet the definition of “research.”

## Human Subject

Human subject: a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. (45 CFR 46.102(f)).

## Getting Started with the IRB Review

To determine whether an IRB review is necessary for your research, speak to a faculty member or advisor in your department. For class assignments, research with human subjects is not likely to be published, and it may be possible to modify your work so that IRB is not necessary. Keep in mind that IRB review can take months, so it’s important to start the process as soon as possible.

Columbia University has robust support for the IRB process through the Human Research Protection Office. This support includes consultations with IRB specialists who can answer questions and help ensure that the review process is as quick as possible. Click on the following links to learn more:

- Human Research Protection Office:  
<https://bit.ly/HumanResearchProtectionB2B>
  - IRB Specialists:  
<https://bit.ly/IRBConsultationB2B>
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