

Student Research with Human Subjects

Both graduate and undergraduate students at Duke conduct research with human subjects. The purpose of this policy is to clarify when student research must be reviewed by the IRB for the Protection of Human Subjects in Non-medical Research.

The applicable definition of research is any systematic investigation, including research development (pilot testing); designed to develop or contribute to generalizable knowledge. A human subject is a living individual about whom a researcher (faculty or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

Generally, student research involving human subjects falls into one of two categories: (1) research practica, and (2) directed or independent research projects.

Research Practica

Research practica are class projects designed to provide students an opportunity to practice various research methods such as interview, observation and survey techniques, as well as data analysis. Such projects typically do not lead to generalizable knowledge and are not undertaken with that goal in mind.

Research practica do not require IRB review unless, due to the vulnerability of subjects or the potential risk to subjects, the project falls into one of the following categories:

1. Studies in which children will be interviewed.
2. Any study asking subjects about illegal activities, such as underage drinking, which place the data at risk of subpoena.
3. Studies in which subjects are at risk of breach of confidentiality, such as one that asks about socially stigmatized behaviors and attitudes.
4. Studies that place subjects at risk due to emotionally charged subject matter.

Research Projects, Directed or Independent

Any research conducted by students, graduate or undergraduate, that does not fall under the definition of a research practicum, which uses human beings as subjects, and which is intended to contribute to generalizable knowledge, must be reviewed and approved by the IRB. This includes, but is not limited to, independent undergraduate research projects and honors theses, masters' theses and dissertations. It is possible that a research project may be exempt from ongoing IRB review, but it must meet explicit criteria and the IRB staff must approve the exemption.

Responsibility of Student Advisors

It is the responsibility of faculty advisors to ensure that research practica are conducted according to the ethical standards of the relevant discipline.

It is the responsibility of faculty advisors to determine when an undergraduate student project does not meet the definition of a practicum and must be reviewed by the IRB.

When student research activities are not practica, it is the responsibility of faculty advisors to assist students in preparing review materials for the IRB and to ensure that the research is conducted in accordance with Duke's agreement with the federal government (the Multiple Project Assurance for Non-medical Research) and with applicable Duke policy.