

TO IRB or NOT IRB?

GUIDANCE FOR HEALTH PROFESSIONS STUDENTS, RESIDENTS, AND FACULTY

So, you are thinking about doing a research project and you don't know if you need the guidance of the Institutional Review Board (IRB)?

Below is a list of guiding questions before moving forward with a protocol application.

WHO IS ENGAGED IN THIS PROPOSED PROJECT?

When we talk about "engaged" we are asking who is conducting the research and where is the research being conducted.

- a. The researcher(s):
 - If you are a student, you will need to identify a faculty Principle Investigator who will mentor you, review all materials regarding your proposed research, and take responsibility for the responsible conduct of the research.
 - If you are a resident or faculty, do you have an appointment at NEOMED? If you do not, the review of your proposed research must be done by another study board or IRB.
- b. If you are a resident or faculty and have an appointment at NEOMED, will your proposed research be conducted at NEOMED or at another facility or institution?
 1. If at NEOMED, proceed to item #2
 2. If at another facility or institution, do you have a Federal Wide Assurance (FWA)? [FWA Guidance](#)
 3. If you have an FWA, proceed to item #2
 4. If you do not, you will need to acquire one before conducting human subjects research (see item #2 for determining whether your proposal falls under the definition of human subjects research).

DOES YOUR PROPOSED PROJECT FALL UNDER THE DEFINITION OF HUMAN SUBJECTS RESEARCH?

Only projects that fall under the definition of human subjects research are reviewed by an Institutional Review Board. Projects that fall under the definitions of Quality Improvement, Program Evaluation, or Climate Survey are NOT human subjects research, see item #3.

- a. According to [45 CFR 46](#), a human subject is "a living individual about whom an investigator (whether professional or student) conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
 2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."
- b. **Human Subjects Research must also be generalizable.** Generalizability is the extension of research findings and conclusions from a study conducted on a sample population to the population at large. If your research is focusing on a limited, unique sample in which you cannot generalize data, your project does not fall under human subjects research.
- c. If you believe your project is a Quality Improvement or Program Evaluation study, please go to our guidance materials under "Research v. Quality Improvement v Program Evaluation": [IRB Forms and Guidance](#).

IF YOUR PROJECT FALLS UNDER THE DEFINITION OF QUALITY IMPROVEMENT OR PROGRAM EVALUATION AND YOU HAVE FACULTY STATUS AT NEOMED, DOES IT INVOLVE A SURVEY?

- a) If yes, please contact the following department: [Office of Institutional Research](#)
- b) If no, your institution or facility may have a research review committee (NOT IRB) that evaluates QI or Program Evaluation research, and you will need to seek their approval.
- c) If your institution or facility does not have a research review committee, please use your own discretion. Your project is not federally regulated if it is a QI or Program Evaluation project, and so the above guidance materials will be essential for you to confirm what type of project you have.