

Decision Guide: You have two decisions to make in relation to an IRRB application for your planned research:

1. *First, does the research you are planning require review by the Institutional Research Review Board (IRRB)?*
2. *If the answer to the above question is yes, the second decision is which category of IRRB review should you check on your IRRB application?*

Following is information to help you with each decision.

Decision 1. Does your research require an IRRB review?

In making a determination about whether your work constitutes research involving human subjects and required review, ask yourself the following questions:

A) Will the data collected be publicly presented or published?

B) Do my research methods involve a) direct and/or indirect interaction with participants via interviews, assessments, surveys, or observations, or b) access to identifiable private information about individuals, e.g., information that is not in the public domain?

C) Does my research involve minors, that is, anyone under the age of 18?

If the answer to **any one** of these questions is “yes,” a project is considered research with human subjects and is subject to federal regulations. It will require a thorough IRRB review via one of the three review processes defined below.

Decision 2. Using the questions under Decision 1, my work constitutes research with human subjects. What category of IRRB review should I check on my application?

There are three levels of IRRB review: *Exempt*, *Expedited* and *Full*. The differences between the levels are about the type of data collection being done, and whether the research subjects are considered vulnerable populations. The number of IRRB members taking part in the review increases over the three levels.

Below, the federal regulatory language for each level is summarized, followed by some unpacking of what the language means.

Exempt: Research requiring an exempt review level involves only minimal risk to the human subjects involved. An experienced IRRB member carries out the exempt review, and the IRRB chair(s) sign off based on the recommendation of the reviewer.

Your research calls for the exempt review level if it falls into *only one* of these three categories:

- 1) it is carried out in common educational settings and involves regular or special educational

practices, **or 2)** it involves educational tests, surveys, interviews, or observation that do not involve children and that maintain confidentiality and do not place the participants at risk through disclosure **or 3)** it involves the study of existing data that is publicly available or recorded by the researcher in a manner that maintains confidentiality. For the exempt review process, one IRRB member carries out the review, and the IRRB chair(s) give final approval according to the review.

Some unpacking: The title of ‘exempt’ can be confusing. What’s important to remember is exempt doesn’t mean exempt **from** IRRB review. Instead, it means that **through** review, the IRRB determines that the project is exempt from certain federal regulations governing human subject research. The IRRB has to carry out a thorough review to determine whether a project *is* exempt.

Expedited: Research requiring an expedited review first fits one of two criteria: 1) involves no more than minimal risk to the participants OR 2) proposes minor changes to previously approved research

Your research is expedited if it fits one of those two criteria AND falls into at least one of these four categories: 1) The collection of biological specimens or data for research purposes by non-invasive means; 2) involves materials (data, documents, records, or specimens) collected solely for non-research purposes (such as medical treatment or diagnosis; 3) uses survey, interview, program evaluation, or quality assurance methodologies; and 4) involves original data collection from minors or other vulnerable populations.

An IRRB member and an IRRB chair both carry out reviews for the expedited level, and the IRRB chairs sign off.

Some unpacking: Categories 3 & 4 are the most relevant for the school and the community-based research most often carried out at NLU. In classroom research, the two important distinctions between exempt and expedited categories of research are 1) whether the research is carried out through regular classroom processes and activities, or whether data is being collected outside standard processes for the purpose of the research and 2) how the data is shared. For example a teacher’s implementation of a new reading strategy and subsequent analysis of student work is within regular classroom practices and would be exempt research. In contrast, when new information is collected systematically and specifically for research, not as part of regular classroom practice, as for example individual interviews with students on topics that go beyond regular classroom practices, that is original data collection from minors, and would be exempt research.

Full Review: Any research that doesn’t meet the criteria for Exempt or Expedited reviews requires a Full Review by the IRRB Board. Examples are research projects in which participants would undergo significant risk from identifying disclosure of research results, such as past or current drug use, or criminal activity. Experts may be called in for reviews of research in particular contexts or areas, such as prisons or locations with volatile circumstances.