Does My Project Require IRB Review?
Human Subjects Research Self-Assessment Checklist

This checklist is designed to help faculty, staff, and students determine whether a proposed project requires submission to the Institutional Review Board (IRB). Complete the questions below before beginning your project. This checklist is for personal guidance only and does not need to be submitted to the IRB.

Step 1. Is Your Project Research?

1. *Does your project involve a systematic investigation?*
Examples include surveys, interviews, observations, experiments, or the systematic collection and analysis of information.

☐ Yes ☐ No ☐ Unsure

2. *Is your project designed to develop or contribute to generalizable knowledge?*
In other words, is the project intended to produce findings or conclusions that extend beyond the specific class, program, organization, or individuals being studied?

☐ Yes ☐ No ☐ Unsure

If you answered YES to both questions: Continue to Step 2.

If you answered NO to either question: Your project may not meet the federal definition of research. If you are confident in your answers and no additional review requirements apply, an IRB application is generally not necessary.

If you answered UNSURE: *Contact the IRB office for guidance before proceeding*.

Step 2. Does Your Research Involve Human Subjects?

3. *Does your research involve living individuals?*
☐ Yes ☐ No ☐ Unsure

4. *Will you obtain information or biospecimens through interaction or intervention with individuals?*

Examples include surveys, interviews, focus groups, experiments, or collecting biological samples.

☐ Yes ☐ No ☐ Unsure

5. *Will you obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens?*

Examples include identifiable student records, medical records, confidential survey responses, or information that can readily be linked to an individual.

☐ Yes ☐ No ☐ Unsure

Step 3. Determine Your Next Step

IRB Application Required
If you answered YES to Questions 1 and 2, AND YES to Question 3 and either Question 4 or 5, your project likely constitutes human subjects research.

Submit an IRB application before beginning research activities involving human subjects.

IRB Application is Generally Not Required
If your project does not meet the definition of research or does not involve human subjects, an IRB application is generally not required under the Common Rule.

You may proceed in accordance with other applicable institutional policies and requirements, provided you are confident in your determination.

Additional Guidance Needed
If you answered **UNSURE** to any question or cannot confidently determine whether your project requires review, contact the IRB at irb@northpark.edu before beginning the activity. The PI is responsible for confirming the classification of their proposed study. Failing to seek assistance with this determination could significantly impact the proposed research.

Important Reminders

- Research involving human subjects may qualify for an exemption from certain IRB requirements. **Do not assume that exempt research requires no submission.** Follow the University's established exemption determination procedures.
- Classroom activities, internal program evaluations, and quality-improvement projects may not require IRB review when they do not meet the federal definition of research.
- Intent to publish or present findings does not automatically make a project human subjects research.
- Certain activities, including FDA-regulated research, may be subject to additional requirements.

**This checklist is a self-assessment resource based on the definitions of research and human subjects in 45 CFR § 46.102. It does not constitute an official IRB determination.*