Does your project need IRB approval?

A.
Will you be interviewing or surveying human subjects as part of your research?

See Note 1

B.
Do your planned research activities meet the Federal definition of research?

See Note 2

If yes to both: IRB protocol should be submitted for review.

If no to either A or B, IRB approval is not required.

Note 1: Human subjects research involves interacting with another person through interviews, intervention, surveys, questionnaires, focus groups, etc. Such interactions could result in the collection of identifiable private information which is governed by IRB regulations. Although this definition could potentially encompass all interactions with others, IRB DOES NOT include the following:

- Journalism/documentary activities that focus on specific events with no intent to test a hypothesis;
- Certain types of oral history projects that only document historical events or people’s experiences without adding to generalizable knowledge;
- Program evaluation or quality improvement projects, as long as the resulting information will stay in the institution and not contribute to generalizable knowledge;
- Public use databases such as U.S. Census Bureau statistics, Bureau of Labor Statistics, etc.;
- Data from public libraries or newspapers;
- Course-related activities designed for educational or teacher purposes;
- Expert interviews in which someone is asked to provide information specific to his/her expertise or profession. For example, a welder asked to describe the formation of a weld bead is not disclosing information about him/herself and, as such, is not considered a human subject under IRB.

Note 2: Research is officially defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” This involves a predetermined system, method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing a theory.

Refer to the IRB Glossary of Terms for more information.

Questions? (574) 631-1389 or compliance@nd.edu