

IRB Statement on Undergraduate Work Involving Human Subjects Faculty/Student worksheet for determining IRB review

Learning how to conduct ethical research is a vital part of a student's educational experience, especially when human subjects are involved. To facilitate this process, and to ensure the ethical and safe treatment of human participants, the Institutional Review Board (IRB) and the Human Research Protection Program (HRPP) provide the below guidelines.

I. Undergraduate work that does not require IRB/HRPP oversight:

Undergraduate projects that are designed with the objective of providing students with training about and experience with human subjects research do not require IRB review if ALL of the following conditions are met:

- The activity is designed for learning purposes only
 - Results of the project are not presented outside of the classroom
 - Data collection procedures present no more than minimal risk to the subjects
 - Vulnerable populations (children, prisoners, cognitively impaired individuals) are not used
 - Data is collected/obtained in a manner such that the subjects are not identifiable
 - The "Letter of Introduction for Undergraduate Work Involving Human Subjects" is used
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II. Undergraduate work that requires IRB/HRPP oversight:

If the intent of the undergraduate project is to present the information at a department, school, or college symposium **and** it meets the following conditions, then an "Undergraduate Project IRB Application" must be submitted to the HRPP for its records.

- Results of the research are not presented outside of the University setting
- Data collection procedures present no more than minimal risk to the subjects
- Vulnerable populations (i.e., children, prisoners, cognitively impaired) are not used
- Data is collected/obtained in a manner such that the subjects are not identifiable
- The "Letter of Introduction for Undergraduate Work Involving Human Subjects" is used

III. Undergraduate work that requires a standard protocol submission:

Any undergraduate project involving human subjects that falls outside of the above conditions requires a standard IRB protocol submission with the Faculty Advisor acting as the Principal Investigator.

Responsibilities of Faculty Advisors

- Faculty Advisors have the primary responsibility for ensuring that human subjects are treated ethically.
- Faculty Advisors must mentor their student researchers regarding ethical principles for the protection of human subjects, which includes completion of the CITI training course (required for all undergraduates whose work does not meet the criteria in I. above).
- Faculty Advisors are responsible for reviewing and making the final determination regarding appropriate level of IRB review and materials to be submitted to the IRB, including any survey instruments or interview questions.
- Faculty Advisors should contact the HRPP (IRB@brown.edu or 863-3050) with any questions regarding undergraduate projects involving human subjects.

DEFINITIONS

RESEARCH

The Common Rule (45 CFR 46) defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

Research involves the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question.

HUMAN SUBJECT/PARTICIPANT

A human subject is a living individual *about whom* an investigator conducting research **obtains** data through **intervention or interaction** with the individual or through **identifiable private information**.

Obtaining means receiving or accessing identifiable private information or identifiable specimens for research purposes. OHRP interprets “obtaining” to include an investigator's use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be **individually identifiable** (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

VULNERABLE POPULATIONS

Vulnerable populations are groups of people considered likely to be vulnerable to coercion or undue influence. The regulations in 45 CFR 46 specify three groups of vulnerable populations and mandate special protections are in place to protect their rights and welfare. These populations include children/minors, pregnant women, human fetuses and neonates, and prisoners. There are other groups of people that the IRB may consider to be vulnerable, even though they are not specified as such in the regulations. Some examples of these vulnerable populations are students, employees, homeless persons, and persons unable to give consent.

If you have questions about whether a population you would like to include in your project would be considered vulnerable, contact the HRPP office for guidance.

MINIMAL RISK

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Examples of minimal risk procedures include surveys, questionnaires and focus groups about non-sensitive topics and where data is collected without identifying information. Information is considered to be identifiable if it is audio- or video-recorded.