



Tulane University Human Research Protection Program Does my Project/Research Need IRB Approval?

Introduction

In accordance with federal regulations, the Tulane University Institutional Review Board committee must prospectively review all research involving human subjects. Use the following questionnaire to determine whether your project needs to be submitted to the IRB committee for approval.

Initial Screening of your Project:

If you are doing research with people, then you must submit your research project to the IRB.

Question 1: How do I know if I am doing research?

Research is defined as a systematic investigation designed to develop knowledge that can be generalized. If you plan to present or publish the work or otherwise share results of the study, it is probably research.

Are you planning on presenting the data of the project on human subjects at an academic conference, publish the data in an academic journal, or use the human subjects research data in a master's thesis or doctoral dissertation ?

If NO: your project is not considered research and does not require IRB review.

If YES: your project is considered research and requires IRB review. It may however be EXEMPT.

Note: If your project is not hypothesis-driven, does not use research protocols and methodologies, and the anticipated data are intended for publication of an article in a newspaper or magazine, no IRB review is needed

Note 2: If no public dissemination is planned at the time the data is gathered, but the possibility of future dissemination exists, you are advised to submit the project for IRB review and approval before initiating the research project.

Question 2: How do I know if I am using people?

Human participants are defined as: living individual(s) about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual; or (2) identifiable private information.

Does your project involve subjects/participants or data identifiable to specific human subjects?

Some examples of subjects/participants include:

- *individuals who are asked to complete questionnaires, participate in interviews, or whose behavior is observed in daily activities*
- *oral history interviewees whose subjective perceptions are studied*

- *students and teachers observed in the classroom for the study of various teaching methods or development of curricula*

If NO: you do NOT need IRB approval

If YES: Your projects most likely needs IRB review.

Question 3: Do Classroom Projects Require IRB review ?

Certain activities have the characteristics of research but do not meet the regulatory definition of research needing IRB review.

Examples of activities that may not need IRB review are:

- Data collection for internal departmental, school, or other University administrative purposes (e.g. teaching evaluations, course evaluations)
- If your research is a class project or term paper and will not be published in any form at any time.
- Reviews and Searches of existing literature and research involving a living individual, such as a biography, that is not generalizable beyond that individual.

Use the following guidelines to determine if your activities in the classroom are subject to IRB review. IRB review is NOT required if *all* of the following are true:

- a. The project is limited to surveys/questionnaires/interviews/observations of public behavior directly related to topics being studied in an official college course.
- b. The above surveys/questionnaires/activities, etc. contain no sensitive personal questions (e.g., no questions about drug use, sexual behavior or attitudes, criminal activity, grades, medical history) or other personal information that could stigmatize an individual.
- c. No identifying information is recorded to link a person with the data such that it could reasonably harm the individual's reputation, employability, financial standing, or place them at risk for criminal or civil liability.
- d. The participants in the project are not from a vulnerable or special population (e.g., pregnant women, prisoners, minors, cognitively impaired individuals).
- e. The collected data does not leave the classroom setting, or if the project involves collecting data on an organization, agency or company, the data are shared only with that entity.
- f. No Tulane University employee or student is receiving financial compensation for collecting, organizing, analyzing, or reporting the data.

If not ALL of these conditions are met, or if your project does not fall into any of these categories, your project will require IRB notification and formal IRB approval before you can start with your project.

The following are examples of projects that do require IRB notification but are exempt from IRB review. Nonetheless, formal paperwork needs to be submitted to the IRB prior to the start of the project since the decision on the exempt status is the sole responsibility of the IRB committee.

- The study of or comparison among instructional techniques, curricula, or classroom management methods.
- The use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless this involves any one under the age of 18.

- The collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is collected in a way that cannot be linked either directly or through identifiers to an individual.

Question 4: Do Pilot Projects Require IRB review ?

Pilot projects are preliminary investigations performed to determine if a study is feasible. The purpose is to refine data collection procedures and research design on a small scale.

The questions asked usually do not contribute to generalizable knowledge and as such do not qualify as research and do not need IRB review.

Exceptions that require IRB approval PRIOR to the start of the pilot project:

- Vulnerable populations, methods with more than minimal risk, or sensitive data will be used.
- The possibility exists that the collected data will be used in some form or another for publication purposes

Question 5: Does "Existing Data" Analysis require IRB review ?

Existing data are also called Secondary data. Such secondary data analysis involves using existing data from others sources to answer new questions.

IRB review and approval is NOT needed if the source of the data is public (data from public libraries or newspapers) and analysis of the data will not make the data individually identifiable

IRB review and approval IS needed if the source of the data is not public (government and private data bases) the existing data has not been previously received IRB approval

Question 6: Do Internet/Online based projects require IRB review?

If the data collected via the Internet and computers involves human subjects and is intended for eventual publication purposes, then it requires IRB review and approval.

All such studies involving internet technologies must ensure compliance with the principles of voluntary participation and informed consent, the anonymity and confidentiality of the participants, and address the potential risks to the human subjects involved.

Final Considerations

1. ALL research with children, including adolescents, must be reviewed by the IRB committee.

Children are considered a vulnerable research population. They are less able to give fully-informed consent with respect to the research involved. Safeguard procedures and considerations are, therefore, required by the Federal regulations for the review of research involving children.

In almost all cases, written consent from a parent or legal guardian must be obtained if the research involves children under the age of 18.

2. Even in the case where a project is not subject for review, the instructor/faculty member is responsible to uphold all applicable (e.g., American Psychology Association, American Counseling Association, National Institute of Health, etc.) ethical standards and guidelines in course-related research activities when it comes to the treatment of human subjects.
3. It is the responsibility of the supervising instructor/faculty member to determine whether projects are subject to review. It is always best to err on the safe side and seek consultation from the IRB committee if a question arises regarding human subjects, research and classroom activities.