

IRB Guidance for Student Research and Class Projects

The provided document offers direction for faculty and students to ascertain whether course projects meet the criteria for human subject research, necessitating Institutional Review Board (IRB) approval before proceeding. Federal regulations and university policies mandate IRB approval for any study involving human subjects and involves patient information, any intervention (medical or otherwise; randomization or not), regardless of whether conducted by faculty members or students. Nonetheless, numerous classroom projects are pursued primarily for educational objectives rather than research aims, exempting them from the IRB approval requirement. In cases of ambiguity, consult the IRB or apply for IRB approval, as retroactive approval is not permissible.

The following endeavors are classified as research demanding IRB approval: honor's theses, master's degree dissertations, and doctoral dissertations.

What is Considered Research in a Class Project?

Research: Class projects are considered research if they involve:

- Systematic data collection
- Involves patient information or any intervention (medical or otherwise; randomization or not)
- A goal to develop or contribute to knowledge beyond the classroom

Projects NOT considered research:

- Projects solely focused on teaching research methods to students
- Projects where data is used only within the class and destroyed afterward

IRB review required:

- Projects involving research (as defined above)
- Projects involving protected populations or sensitive information (regardless of research intent)

When in doubt, consult IRB:

If you need clarification on whether your class project meets the definition of research, please submit it for IRB review.

Scenarios when IRB Is/Is not Required:

Scenarios	IRB Requirement
The study utilizes open-ended interviews in a structured way to systematically gather data. The analysis aims to generate findings that can be applied beyond the specific participants, ultimately informing policy, drawing broader conclusions, or contributing to generalizable knowledge.	IRB approval IS REQUIRED
The creation of archives aims to establish a lasting repository of information, allowing future researchers to access valuable data and materials to support their investigations.	IRB approval IS REQUIRED
Scholarship of Teaching & Learning (SOTL) inquiries intended for a broader audience, potentially leading to publications in scholarly journals or presentations at national conferences.	IRB approval IS REQUIRED
Systematic evaluations are designed to assess the effectiveness of existing, new, or modified procedures or programs applied to the environment outside D'Youville.	IRB approval IS REQUIRED
The project involves secondary data analyses for educational purposes, utilizing data that is publicly available, de-identified, or otherwise impossible to be linked back to any individual.	IRB approval IS NOT REQUIRED
Developing or adapting assessment methods within D'Youville courses to better measure student learning outcomes.	IRB approval IS NOT REQUIRED
Quality Assurance (QA) and/or Quality Improvement (QI) activities aimed solely at internal assessment and improvement within D'Youville. These evaluations focus on specific programs, procedures, or practices.	IRB approval IS NOT REQUIRED
Open-ended interviews document the unique perspectives of individuals involved in [historical event] or those with specific experiences. Their purpose is not to draw generalizable findings, but rather to preserve their personal narratives.	IRB approval IS NOT REQUIRED
Class projects involving the analysis of existing data sets, but with an added layer of security. These projects focus on secondary data analysis for educational purposes. Students work with this de-identified data.	IRB approval IS NOT REQUIRED
Class projects or practical involving the direct interaction with individuals, such as in-person, through mail, email, web-based surveys, or telephone communication. However, the primary objective is training, educational exercise, or professional development rather than research. The student poses questions to others as part of learning interviewing, surveying, history-taking, assessment administration, or conducting "in-house" evaluations requested by the practicum site, when the overarching purpose is educational rather than research-oriented. The focus is on skill development and practical experience.	IRB approval IS NOT REQUIRED Exception: If a student decides to further utilize data or information collected during a practicum activity for a subsequent master's project or paper, Institutional Review Board (IRB) approval may be required.

Protected Populations

This includes but is not limited to:

- **Children under 18:** Most research involving minors requires extra scrutiny. However, there are exceptions for established educational practices within schools or classrooms (contact the IRB for details).
- **Prisoners:** Research involving prisoners, including anonymized data that is not publicly available, needs special approval.
- **Pregnant women, fetuses, and products of conception:** Research involving these groups requires careful consideration.
- **People with limited ability to consent:** Individuals who may not fully understand the implications of participating in research require additional protections. This includes those with mental or physical challenges.

Sensitive Information in Research

Research involving the following types of information needs extra care:

- **Mental health or psychological well-being:** Information about a person's mental state requires careful handling.
- **Sexual behavior or preferences:** This information is susceptible and requires strong privacy protections.
- **Substance use (alcohol or drugs):** Information about a person's substance use requires confidentiality.
- **Illegal activities:** Research involving information about illegal behavior needs careful consideration.
- **Information that could harm participants** includes details that could lead to legal trouble, financial problems, or damage to someone's reputation.
- **Medical information:** Research using information typically found in medical records requires safeguards to prevent discrimination or stigmatization.

Faculty Responsibility

Faculty should meet with students promptly to review these guidelines and determine if a proposed class project could constitute research. If the class project falls under the definition of research, instructors are advised to apply for human subjects review to the IRB along with the student. Class projects involving protected groups or sensitive information require IRB approval.

Research Projects

If a project meets the research definition, the instructor should assist the student in preparing the appropriate review application and ensure all necessary reviews and signatures are obtained before submitting it to the IRB office.

Non-research projects

If a project does not meet the research definition, it is the instructor's responsibility to verify this and ensure the project adheres to the ethical standards of the relevant discipline. The faculty should advise students to identify it as a class project to participants and be mindful of any personal information collected. Students should inform participants that data will be destroyed after completion. Students must avoid collecting any personally identifying information when possible.

All class projects, regardless of needing IRB review, must include informed consent language explaining how students' data will be handled.

Informed Consent for Class Projects

All class projects involving human subjects, regardless of IRB review requirements, must utilize form DYUIRB 0006 to obtain informed consent from participants. This form outlines the project details, data usage, and participant rights.