



University of New England Institutional Review Board (IRB)

Student Classroom Projects Involving Human Subjects (Guidance for Faculty)

The University of New England (UNE) supports a wide range of both undergraduate and graduate student projects involving human subjects – from course-related research exercises to dissertation studies. Such projects may be undertaken by individual students (as in an independent study) or as part of a course in which all of the students undertake a research project, separately or together, either inside or outside the classroom (“student classroom projects”).

The purpose of this document is to set forth the criteria by which UNE’s Institutional Review Board (IRB) will grant general approval for student classroom projects. Protocols that present enhanced risk to the human subject participants, to other individuals outside the classroom, or that are intended to create new knowledge or to lead to scholarly publication, will not qualify for general student classroom project approval and will instead warrant individual project review by the IRB.¹ The intended audience for this document is faculty members who have courses where classroom projects involving human subjects are likely to be assigned.

The IRB recognizes that an important aspect of a University education is for students to engage in innovative classroom projects assigned by their instructor. In many cases these projects involve the participation of human subjects. If human subjects are involved, these classroom projects must be reviewed by the IRB. These projects may include questionnaires, interviews or other interactions with individuals, such as those commonly used in a research methods course.

The IRB recognizes that many student classroom projects involving human subjects pose little or no risk to the participants. Such projects do not need to be individually reviewed by the IRB to ensure the protection of the human subjects. In these specific cases, the IRB will instead grant a general approval for the classroom-based assignment.

Definitions

For the purpose of this policy, the IRB will use the following definitions for key terms:

- **Research:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge². Activities which meet this definition constitute research for purposes of this policy, whether or not

¹ It is important to note that the IRB will be the sole determiner of whether a project is “Human Subject Research”. The IRB is also the sole determiner of what level of approval a project needs. All research projects that involve Human Subjects needs to have some level of IRB review whether it is a general classroom project approval or an individual project approval.

² **For purposes of this policy, research will be defined using the definition found in The Common Rule, 45 Part C.F.R. §46.102 (2005).** The term “Research” found in this policy is based on this definition, and not the common academic use of the term.

they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

- **Generalizable Knowledge:** Conclusions or insights which may be extended to populations outside the subset which is the focus of inquiry. Other characteristics of generalizable knowledge include, but are not limited to, the potential for replication, and the potential to contribute to the knowledge base of the field of inquiry.
- **Human subject:** A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.
- **Student Classroom Projects:** Projects conducted during or outside of class with students enrolled in an official course (for credit or not for credit), as well as activities in fulfillment of class assignments involving interactions with individuals other than the members of the class. These assignments are typically initiated and completed within a course. Faculty members may design assignments that engage students in interaction with individuals and involve collecting data from individuals to teach research methods or to help students understand concepts covered by the course. For the most part, these projects are not intended to create new knowledge or to lead to scholarly publication or presentation.

Key Considerations

1. What is a Student Classroom Project?

In general, if the intent of the classroom project is not to produce generalizable knowledge, but to teach research methodology or to demonstrate course material and concepts, then the student classroom project does not require an individual IRB submission and approval. For example:

- a. Data collection to support or complete a student presentation to fellow class members sharing the results of a survey taken of UNE students over eighteen years of age concerning a non-sensitive topic area would qualify as a Student Classroom Project.
- b. Interviewing individuals for a project where the results will only be shared with the faculty member teaching the class and fellow class members would qualify as a Student Classroom Project.
- c. Student classroom projects involving a program evaluation, quality assurance, or needs assessment for a third party, where the collected information will remain in the classroom and only be disseminated to the third party agency, may qualify as a Student Classroom Project depending on the individual project.

2. What is not a Student Classroom Project?

When class assignments are intended to collect information systematically, with the intent to produce generalizable knowledge, the individual assignments must be reviewed by the UNE IRB and will not qualify as a student classroom project.

- a. For example, the intent to publish the results of the activity is one clear indication that the activity is intended to develop or contribute to generalizable knowledge.
- b. Independent research projects conducted by students, such as theses, honors projects, and/or independent study projects, that collect data through interactions with living people or access private information do not qualify as student classroom projects and the student researcher must submit an individual application to the IRB for review.
 - 1). Instructors who engage with students in independent research projects must have each separate student proposal submitted to the IRB separately for individual review and approval before beginning the project.
 - 2). Application to the IRB for these student research projects must include an endorsement and acceptance of overall responsibility by a faculty mentor.

3. Are there any other Student Classroom data collection activities that must be submitted individually to the IRB?

Student classroom projects which include a special subject population or a sensitive topic area will not qualify for general approval and must be submitted as individual protocols. Please note that *even if the intent is to not produce generalizable knowledge, but a special population or inclusion of a sensitive topic is part of the project, the students' projects shall not qualify for general approval.*

- a. Projects involving sensitive topics are those that collect information:
 - 1) Relating to sexual attitudes, preferences or practices;
 - 2) Relating to use of alcohol, drugs or other addictive products;
 - 3) Pertaining to Illegal conduct;
 - 4) That if released could reasonably damage an individual's financial standing, employability, or reputation within the community;
 - 5) That would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;
 - 6) Pertaining to an individual's psychological well-being or mental health³;

³ The standard of review for psychological well-being and mental health is an objective one and will measure the potential harm or discomfort to participants to ensure it is not greater than one ordinarily encounters in daily life or during the performance of routine psychological examinations or tests.

7) Which includes Genetic Information.

b. Special subject populations include:

- 1) Minors (under eighteen years of age).
- 2) Fetuses or products of labor and delivery;
- 3) Pregnant women (in studies that may influence maternal health);
- 4) Prisoners;
- 5) Individuals with a diminished capacity to give informed consent.

4. Does it matter if the data for the Student Classroom Project may be used for publication and/or presentation at a later date?

Yes. In most cases, if a participant has not consented prior to data being collected or if the protocol has not been reviewed by the IRB, then the data cannot be used for future publication or presentation. Therefore, if the faculty member or student believes there is any possibility of using the data for a future thesis, publication, or presentation, they are strongly encouraged to:

- a. File an individual submission to the IRB;
- b. Draft an informed consent form or cover letter to human subject participants which states explicitly that there is a possibility the data may be used for a future publication or presentation.

5. What are the faculty member's responsibilities for Student Classroom Projects that are submitted to the IRB for review?

a. Faculty are responsible for:

- 1) Ensuring that student classroom projects are conducted to the ethical standards of human subject research and their discipline.
- 2) Ensuring that students understand and implement these ethical standards in carrying out their projects.
- 3) Completing the [CITI on-line training on Human Subject Protection](#).

b. When a faculty member believes their assignment for a course qualifies for general approval, it is their responsibility to submit the *Application for Exclusion from IRB Oversight of Student Classroom Projects*.

c. Even when a general approval is granted by the IRB, faculty members whose students are conducting research involving human subjects are always responsible for:

- 1) Teaching students about the ethical conduct of human subject research, including basic human subject rights and the role of the IRB.⁴
- 2) Strongly encouraging students to take the [CITI on-line training on Human Subject Protection](#).
- 3) Providing guidance to students collecting information in order to minimize any unintentional harm to other students or individuals.
- 4) Reviewing students' plans for classroom or group projects and, when necessary, suggest improvements in design and protections for confidentiality.
- 5) Suggesting that a written explanation of how the data will be used in the course, along with the name and contact number of the instructor, be included when written questionnaires are to be used.
- 6) Instructing students about privacy and security vulnerabilities associated with networked computers and the internet.
- 7) Following all other applicable UNE policies and procedures relating to the classroom activity (e.g. HIPAA, FERPA, Laboratory Safety).

6. **If my request for Exclusion from IRB Oversight is approved, do I need to resubmit for another approval if I teach the same or a different class again?**

Yes. Each determination of exclusion is specific to that course with that particular instructor and syllabus. A new request should be submitted by the instructor each year prior to the start of each course which includes a classroom project involving human subjects.

Applying for Student Classroom Project General Approval

The following section provides an outline of the necessary information and documents needed to submit an *Application for Exclusion from IRB Oversight of Student Classroom Projects* . Faculty should:

Read the Student Classroom Project's Faculty Guidance Document and Checklist before filling out the form.

Fill the *Student Classroom Project* form out completely; leaving spaces blank could delay your approval.

1. Include a copy of the **syllabus** for the course, along with any other relevant documents.
2. Include a **CV** with each submission.
3. Include **their most recent** [CITI certificate for Human Subjects Protection](#) (no older than 2 years).

⁴See the [Belmont Report](#).

4. Send an electronic submission to irb@une.edu, and send your signed paper copy to the address on the *Student Classroom Project* form. (Sending both electronic and paper copies will speed up the approval process.)

Suggestions for Faculty Members

Novel and imaginative classroom exercises help students learn and are, therefore, integral to high quality teaching. All teaching assignments, however, must respect the rights and welfare of all individuals involved. The following suggestions for the faculty members provide guidance concerning student classroom projects:

1. **Consider the nature and intent of the activity.** If the course assignment involves systematic data collection and if any intent of the activity is to develop or contribute to generalizable knowledge -- an indication of which is intent to publish the data -- then the student classroom project is probably research and will thus need to be individually reviewed and approved by the IRB.
2. **Minimize risks whenever possible.** Faculty members should help students understand that they are obligated to minimize risks for human subjects with whom they interact during the completion of their assignments. Depending on the circumstances, faculty members may find some of the following suggestions for students helpful:
 - Have students take the CITI on-line training on human subject protection before collecting information from others.
 - Encourage the use of anonymous data collection so that data is not linked to individual identities.
 - If necessary to collect, keep individually identifying information separately from the information collected from those individuals.
 - Collect project data at the end of the course, or within a short time afterward, and request all copies in the student's possession be destroyed.
 - Discourage the use of passive consent forms.
3. **Ask for help!** Ask Research Compliance staff (irb@une.edu) for guidance when you are unsure of what review process is needed for a student classroom project.

Applying for an Individual Research Project IRB Review

In reviewing an application for student research conducted in the context of a course that does not qualify as part of a Student Classroom Project general approval, the IRB may determine that the proposal falls under one of several federally recognized categories of "exempt" research. A declaration of exemption means that, as long as there are no changes in the research, its conduct does not need to be overseen on a continuing basis by the IRB. A declaration of exemption does not mean, however, that students should act any less professionally or be any less respectful of individuals with whom they interact or about whom they collect private information. It is UNE policy that only the IRB may determine exempt status.

Rarely, student classroom research may fall under one of several defined categories of "expeditable" research. Such a determination means that the IRB Chair or other designated person may approve a project on behalf of the entire IRB. If such an application is well formulated and contains all the information required by the IRB, this process may speed approval.

Generally, student classroom research will not be eligible for full board review (i.e. the project is neither exempt nor expeditable). In such cases, the faculty member will be required to submit an application for such review, listing the student researcher as a co-investigator. The full Board meets on a monthly schedule, and reviews are on a first come, first serve basis.

Student Classroom Projects Involving Human Subjects Checklist

This checklist is intended to assist UNE faculty instructors in assessing whether [program evaluation or] classroom research conducted by students may be excluded from oversight by the UNE Institutional Review Board (IRB). In those instances, faculty instructors are required to submit an *Application for Exclusion from IRB Oversight – Student Classroom Projects* and satisfy all submission requirements. Instructors are encouraged to contact the IRB Administrator at irb@une.edu with questions relating to such projects. For such activities to be approved as Excluded from IRB Oversight, *all* of the following criteria must be met:

- ✓ The instructor is fully aware of all aspects of the project and will take responsibility for overseeing the project and assuring that ethical principles are adhered to in the conduct of those activities.
- ✓ The project will be performed by students enrolled in a graduate or undergraduate course at UNE, as a requirement for completion of the course.
- ✓ The overriding and primary purpose of the project is as a learning experience in the methods and procedures of research.
- ✓ There is no intent on the part of the instructor or student to produce generalizable knowledge or to disseminate the findings beyond presentation to instructors or peers in a UNE classroom and/or institutional setting.
- ✓ The project entails no more than **minimal risk** to subjects (i.e., when "the risks of harm anticipated in the proposed research are not greater considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests").
- ✓ The project does not include persons from any **vulnerable population** as participants.
- ✓ The project does not investigate **sensitive topics** or **confidential information** that could place a participant at risk if disclosed.
- ✓ The project involves the **voluntary participation** of individuals without any coercion or pressure being placed upon them. The instructor/students have considered whether a consent document should be provided to participants.
- ✓ The project involves **no deception**.
- ✓ The project does not include the performance of **invasive or noninvasive procedures**.