

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 risks to the human subject participation, including (a) research involving (1) research that is not for the purpose of general evaluation, designed to develop or contribute to generalizable knowledge

². 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. Research projects that involve Human Subjects needs to have some level of IRB review whether 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.

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

- 7) Which includes Genetic Information.
- b. Specialsubject populations include
 - 1) Minors (under eighteen years of age).
 - 2) Fetuses or products of labor and delivery;
 - 3) Pregnant women (in studies that ma

- 1) Teaching students about the ethical conduct of human subject research, including basic human subject rights and the role of the IRB.
- 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 UNF 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 Faculty Guidance Document and Checklist before filling out the form.

Fill the *Student Classroom Project*

4. Send an electronic submission to mirb@une.edu and send your signed paper copy to the

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

