



University of New England Institutional Review Board (IRB)

Application for Exclusion from IRB Oversight Student Classroom Projects

Please refer to the Student Classroom Projects Involving Human Subjects (Guidance for Faculty) when completing this form. This form must be submitted electronically to irb@une.edu with all attachments referenced below. Additionally a hard copy, with required signatures, must be submitted to the IRB Administrator, Pickus Rm.108, 11 Hills Beach Road, Biddeford, ME 04005. For additional help completing this form, consult the IRB Administrator at irb@une.edu.

A. STAFF

Answer for all faculty instructors. If needed, add rows to this chart with the same information.

Table with 3 columns: Name, Role and Contact Information; CITI training taken? (yes/no*)

*UNE requires each faculty instructor to have taken or renewed the CITI web-based training course on Human Research Protection located at http://citiprogram.org within the past 24 months.

For each listed instructor, attach certificate of completion of CITI training and Faculty CV.

B. CRITERIA FOR EXCLUSION (STUDENT CLASSROOM PROJECTS ONLY)

Please refer to the Student Classroom Projects Involving Human Subjects IRB Guidance Document when completing the below criteria.

Please answer the following questions about the project:

- 1. Will the research be performed by students?
2. Is the research a course requirement?
3. Is the course requirement stipulated in the course syllabus?

Attach a copy of the course syllabus.

- 4. Is there greater than minimal risk to subjects?

'Minimal Risk' means 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 living or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102 (i)).

5. Does the research involve the collection or dissemination of **sensitive or private information**? yes* no
 Examples include, but are not limited to: (a) sexual attitudes, preference or practices, (b) use of alcohol, drugs or other addictive products, (c) illegal conduct, (d) information that could reasonably be expected to damage an individual's financial standing, employability, or reputation, or otherwise lead to social stigmatization or discrimination, (e) pertaining to an individual's psychological well-being or mental health, or (f) genetic information.
6. Does the research include persons from any vulnerable populations? yes* no
 Examples include, but are not limited to: (a) minors under 18 years of age, (b) pregnant women or products of conception, (c) prisoners, (d) physically or mentally challenged, or (e) persons with diminished capacity to give informed consent.
7. Does the project involve only **voluntary participation** of individuals? yes no*
8. Will the results lead to scholarly publication or presentation? yes* no
9. Will the results be disseminated outside of the UNE community? yes‡ no
 ‡ If yes, is the project a collaboration with a community partner, business or agency and will results be shared externally **only** with that partner, business or agency? yes no*
10. Will the project involve **deception**? yes* no
11. Does the project include the performance of **invasive or noninvasive procedures**? yes* no

* **This answer disqualifies the research from the Student Classroom Project exemption. The investigator must file an *Application for Initial Review and Approval of Research with Human Subjects*.**

C. CERTIFICATION

The undersigned investigator(s) accept(s) responsibility for this project(s) relative to the protection of the rights and welfare of subjects participating in the study as set forth in the Belmont Report. If during the course of the project, any of the above conditions are no longer met, then the project must halt while the faculty instructor seeks IRB review. If upon completion of the project the instructor or student wishes to disseminate the findings, the instructor should immediately submit a protocol describing the method and results to the IRB for review.

By signing this form, the Instructor attests that (s)he has the responsibility for: (1) assessing whether the student project(s) involving human subjects constitute research and whether they require IRB review; (2) overseeing these activities; (3) assuring that ethical principles are adhered to in the conduct of those activities; (4) maintaining student project files(including student protocol and IRB determination) for 2 years from completion of the activity, subject to IRB audit; and (5) compliance with other relevant UNE policies and procedures that fall outside the purview of the IRB.

(Print name of investigator(s) followed by signature).

1. Instructor _____

Because this form is new, the Board welcomes any and all feedback and suggestions for improvement. Please email your feedback to the IRB Administrator at irb@une.edu. It will have no effect on your application.

D. CHECKLIST OF ATTACHMENTS

Please apply a label to all attachments. Please list below the label and title of each attachment (use additional pages if necessary):

Label	Title

