

1. Purpose

This document provides comprehensive guidance for University of New England (UNE) researchers on ethical and legal considerations when recruiting students as research participants. UNE considers students to be a potentially vulnerable population.

For an overview of important terminology used within this guidance document, please refer to Section 9 '<u>Key Definitions</u>' below.

2. General Principles



Please refer to <u>The Belmont Report</u> for more information.

3. General Considerations when Recruiting Students for Research Participation

The use of students as research participants presents a special set of concerns, whether the students are at UNE or other educational institutions or environments. When recruiting students for research participation, researchers are expected to minimize any undue influence. Both UNE researchers and the IRB need to carefully consider how to ensure that students' participation is truly voluntary, especially when the research participants are students taught by the researchers. Students might feel compelled to participate either to gain favor with their teacher or out of fear that not participating could harm their academic relationship. This concern extends to potential impacts on their grades, recommendations, and other academic opportunities. Students' cultural or religious backgrounds may also play a role in their decision to participate, particularly if their background emphasizes deference to authority.

Proposed research involving the recruitment of students that is deemed greater than minimal risk without the prospect of direct benefit to participants will be scrutinized by the IRB to ensure (1) the study has scientific merit, (2) the study could not be feasibly conducted without the recruitment of students, and (3) there are appropriate measures in place to minimize potential coercion or undue influence. Additionally, the study may be subject to post-approval monitoring per request from the IRB, the Institutional Official, and/or the Provost to ensure on-going compliance and welfare of human participants. Post-approval monitoring activities may include observation of the consent process, observation of study procedures, review of study records, and/or interviews with the study team.

3.1 Research involving One's Own Students

Although proposals from faculty members who wish to recruit their own students as research participants are permitted, faculty are encouraged to seek alternative participant pools that are equally relevant to their research question whenever possible. This might include students from another class section not taught by the researcher, those recruited by a different instructor, or the use of data that has been anonymized by a research assistant, ensuring the researcher cannot identify participants. Additionally, the IRB may ask investigators to provide justification for including students as research participants from courses for which they are the instructor.

To maintain ethical standards, the UNE IRB suggests two research designs for cases where involving one's own students is crucial:

a) Third-Party Data Collection

When the research activities are optional and not a required part of class activities, it is advised that an independent third party collect the data. This approach ensures the instructor does not know who has chosen to participate and cannot access any identifiable information about participants until after final grades are posted. Note that a graduate teaching assistant from the same class does not qualify as an independent third party.

Example: An instructor aiming to assess the effectiveness of a curriculum with pre- and post-tests could have these tests administered by a colleague in the instructor's absence, ensuring proper consent is obtained beforehand.

b) Instructor Data Collection with Consent

If it is not possible to use a third party for data collection, the instructor may collect data directly, such as test scores or assignments. However, consent from students must be obtained after the course concludes and grades are finalized.

Example: If a specific teaching method is applied throughout a course without an opt-out option for students, the instructor should inform students at the course's start about the research study. Students will then have the chance to consent to the use of their data in the research after the course ends and grades are submitted, ensuring voluntary participation.

Offering Credit for Participation

If participation involves course credit or extra credit, students must be provided with an alternate way to earn equivalent credit that requires a similar commitment of time and effort. This policy ensures that students do not feel coerced into participating. For instance, offering the choice between completing a short questionnaire for research versus writing a lengthy paper as a non-research alternative might be seen as coercive due to the disproportionate effort required for the paper.

Consent materials should include the following details:

- State alternative activities are available for students who decline to participate in the research.
- Specify the amount and types of credit offered, and required unit of time per credit for both research participation and the alternative activity.
- Describe the parameters for earning the credit whether for the research or the alternative activity.
- Explain how instructors will be notified of their students' research participation (when applicable).

Withdrawal from the Study

Before participating, students need to understand what happens if they decide to withdraw from a study before it ends. If a study offers course credit for participation, students who choose to withdraw should still receive the full course credit promised. In cases where participation is compensated monetarily, students earn their payment progressively as the study advances, proportional to their involvement. This payment is not dependent on completing the entire study.

3.2 Considerations for Research Involving Students Who are Minors

Students may be below the age of consent, which in the state of Maine is 18 years. Therefore, the special requirements for studies involving minors apply to such studies. Typically, parental permission and child assent are required (including high school students taking UNE courses, and any other students under the age of 18) who meet the regulatory definition of children.

Please refer to HHS' Research with Children FAQs for more information.

3.3 Considerations for Research with UNE Students

If your project will recruit UNE students, they should be informed that their decision to engage/not engage in the study will not affect their academic status, class grade(s), or relationship with any instructor at UNE. This information should be relayed in the protocol summary, consent document(s), and recruitment materials.

3.4 Considerations for using Participant Pools

Please be aware that when recruiting participants either from the broader student population or a specific participant pool (e.g., SONA, the UNE Psychology Department's secure online research study sign-up software), there's a good chance faculty might enlist one of their own students. The IRB does not view this as direct recruitment of the faculty member's own students, which mitigates some concerns about coercion. However, the requirement for students to engage in research activities as a graduation prerequisite does introduce a degree of coercion, and mitigation strategies will still need to be in place. It is recommended that students be provided a number of research projects to choose from if participating as a subject in research is a course requirement.



4. Recruitment Strategies

It is recommended that potential participants be recruited from a wide pool of individuals who fit the study's criteria, avoiding the direct recruitment of specific students through personal solicitation. To reduce the influence researchers might have when recruiting their own students, methods such as broad announcements, postings, sign-up sheets, or other approaches that allow students to take the initiative to contact the researchers to obtain more information about the study should be employed.

If aiming to recruit participants for research in a class, it is recommended that researchers recruit at the beginning or end of class time. Students should have the option to leave class early or come to class late if they do not wish to listen to the research recruitment script.

For proposed research that involves the recruitment of students and is deemed greater than minimal risk, researchers may not directly solicit participation in a research study from any student whom the researcher teaches or academically advises.

5. Safeguarding Privacy & Confidentially

When conducting research involving student participants, there are unique challenges to safeguarding their privacy interests. Classroom environments can complicate the confidentiality of a student's involvement in research. This is especially concerning in cases where there might be a stigma attached to the research topic or when the research involves peer pressure. To reduce these risks, researchers should evaluate the feasibility of conducting the study outside the usual school setting and/or after school hours.

Additionally, the issue of protecting students' personal information extends beyond maintaining confidentiality. Researchers must carefully consider who might gain access to personal data and research results, such as parents, teachers, or others not part of the study. It is crucial to communicate these considerations to potential participants and their parents or guardians through the informed consent and assent processes, ensuring all parties are aware of how privacy and data access will be handled.

6. FERPA Compliance

Certain additional protections for students and parents are provided by federal regulations. The proposed use of student education records for research must comply with the requirements of the <u>Family</u> <u>Educational and Rights Privacy Act (FERPA)</u>. For researchers conducting research at other institutions, please note that FERPA restricts researchers' access to student records without written permission from parents of minors, or permission from students over the age of 18. While some exceptions to FERPA may be available in a particular case, investigators must contact each institution in which they will be conducting research and follow that institution's FERPA policy, in addition to the requirements of the IRB. At UNE, research involving UNE students that triggers compliance with FERPA will require a separate ancillary review for FERPA compliance from the UNE Registrar's Office (the UNE Office of Research Integrity (ORI) will coordinate the ancillary review after submission to the ORI/IRB).



7. PPRA Compliance in Elementary & Secondary Schools

Research involving surveys with students in elementary and secondary schools that receive funding from the Department of Education must also comply with the <u>Protection of Pupil Rights Amendment (PPRA)</u>.

• Per the Department of Education, research or experimental program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.

PPRA governs the administration to students of a survey, analysis, or evaluation that concerns one or more of the following eight protected areas:

- 1. Political affiliations or beliefs of the student or the student's parent.
- 2. Mental or psychological problems of the student or the student's family.
- 3. Sex behavior or attitudes.
- 4. Illegal, anti-social, self-incriminating, or demeaning behavior.
- 5. Critical appraisals of other individuals with whom respondents have close family relationships.
- **6.** Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.
- 7. Religious practices, affiliations, or beliefs of the student or student's parent; or
- **8.** Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

PPRA also concerns marketing surveys and other areas of student privacy, parental access to information, and the administration of certain physical examinations to minors. The rights under PPRA transfer from the parents to a student who is 18 years old or an emancipated minor under state law.

8. Conclusion

This guidance emphasizes the importance of ethical practices in recruiting students as research participants. Researchers are encouraged to consult with the UNE Office of Research Integrity at irb@une.edu for further clarification or assistance.

9. Key Definitions

- Student applies to any student participant, UNE students, or otherwise. Where policies are specific to UNE students, it will be noted.
- <u>Coercion</u> in research occurs when a person faces an overt or subtle threat of harm from another, aimed at securing their compliance. An example of this would be a researcher telling a potential participant that their access to educational services depends on their participation in a study. While actual coercion is uncommon in research settings, the perception of coercion can significantly impede the process of obtaining truly voluntary informed consent.



Undue influence, on the other hand, involves offering a prospective participant an excessive or inappropriate incentive to secure their participation. For instance, a scenario where a researcher offers extra credit to psychology students exclusively through participation in a study constitutes undue influence, as it does not provide students with alternative avenues to earn extra credit. To avoid this, researchers must ensure that participants have access to comparable non-research options for obtaining such incentives.

Please refer to <u>Advarra's The Many Faces of "Coercion" and "Undue Influence"</u> for more information.

- Situational Vulnerability emphasizes the dynamic nature of vulnerability, which can be heightened by external circumstances, affecting individuals and groups in varying degrees based on their specific context.
- Power Imbalance results when one person or group of people exerts power and control over another. The power of the dominant party has the potential to control the decision-making and other aspects of the other's lives in ways that disadvantage them. For example, when the invitation to participate in a study is extended from an individual who is in a position of power such as a course instructor, the power differential may make it difficult for the student to decline the invitation.
- Minimal risk is defined by the federal regulations [45 CFR 46.102(j)] as 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 life or during the performance of routine physical or psychological examinations or tests.

Please reach out to the UNE Office of Research Integrity if you are unsure if your proposed research study meets the federal definition of minimal risk or should be classified as greater than minimal risk.

10. Resources

- UNE IRB Website
- UNE IRB FAQ Website
- UNE Policies, Procedures, and Guidance on Research with Human Subjects (PDF)