

UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

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| Procedure #: | HRPP-001 |
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| Prepared By: | Casey Webster |
| Updated By: | Sheilan Hamasoor |
| Reviewed By: | IRB; IRB Chair; ORIO |
| Procedure Title: | Student Classroom Projects |

1.0 Objective

1.1 The objective of this Standard Operating Procedure (SOP) is to describe the policies and procedures for the Institutional Review Board (IRB) and the Office of Research Integrity and Outreach (ORIO) to follow in their review of student classroom projects.

2.0 General Policy

2.1. The IRB recognizes that an important aspect of a university education is for students to engage in innovative classroom projects assigned by their Course Instructor (CI). The IRB recognizes that many of these student classroom projects involving human subjects pose little to no risk to participants and do not meet the definition of research. Therefore, such projects do not warrant individual review by the IRB. The IRB will instead grant a general classroom approval of “not research” or “not human subject research” determination for these student classroom projects based on the CI submission of the classroom project.

2.2. Protocols that present enhanced risk to the human subject participants or other individuals outside the classroom, or those that are intended to create new knowledge or that lead to scholarly publication, will not qualify for general student classroom approval. These projects will instead warrant individual review by the IRB and/or ORIO to ensure the protection of human subjects.
(See also *HRPP 008 Determination of Activities Requiring IRB Review*)

3.0 Definitions

3.1. **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

3.2. Human Subject means a living individual about whom an investigator conducting research (whether professional or student) obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

3.3. Special Populations include:

- 3.3.1. Minors (under eighteen years of age);
- 3.3.2. Fetuses or products of labor and delivery;
- 3.3.3. Pregnant women (in studies that may influence maternal health);
- 3.3.4. Prisoners; and/or
- 3.3.5. Individuals with a diminished capacity to give informed consent.

3.4. Sensitive Topic Areas include information:

- 3.4.1. Relating to sexual attitudes, preferences or practices;
- 3.4.2. Relating to use of alcohol, drugs or other addictive products;
- 3.4.3. Pertaining to illegal conduct;
- 3.4.4. That if released could reasonably damage an individual's financial standing, employability, or reputation within the community;
- 3.4.5. That would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;
- 3.4.6. Pertaining to an individual's psychological well-being or mental health; and/or
- 3.4.7. Genetic information.

3.5. Student Classroom Projects are 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 or data about individuals to teach research methods or to help students understand concepts covered by the course. The projects are not intended to create new knowledge or to lead to scholarly publication or presentation.

3.5.1. Examples of Student Classroom Projects:

- 3.5.1.1. A student presentation to fellow class members that shares the results of a survey taken of USM students over eighteen years of age concerning a non-sensitive topic area;
- 3.5.1.2. Interviewing individuals for a project in which the results will only be shared with the faculty member teaching the class and fellow class members; and/or
- 3.5.1.3. Classroom projects involving a program evaluation, quality assurance, or needs assessment for a third party, in which the collected information will remain in the classroom and only be disseminated to the third-party agency.

3.5.2. Examples of student projects that require IRB review:

- 3.5.2.1. A student research project in which data was gathered systematically with an intent to produce generalizable knowledge;
- 3.5.2.2. A student research project in which the student intends to publish results and add to scientific literature;
- 3.5.2.3. A student research project conducted by a student for academic course requirements such as a thesis, honors project, and/or capstone; and/or
- 3.5.2.4. A student project conducted with the intent to share results outside of the classroom or subject community, such as through a presentation at the Thinking Matters symposium.

4.0 Responsibility

- 4.1. It is the responsibility of the IRB Chair, IRB Members, ORIO Staff, Research Integrity Officer (RIO), Research Compliance Administrator (RCA), and Faculty Course Instructor (CI) or student acting as Principal Investigator (PI) to execute this SOP.
- 4.2. It is the sole responsibility of ORIO to determine whether an activity or project constitutes research with human subjects.
- 4.3. It is the responsibility of the Course Instructor to review and comply with the Responsibilities for Student Classroom Projects Guidance document and seek guidance when appropriate.

5.0 Procedure

- 5.1. The Course Instructor submits a Student Classroom Project (SCP) online Google Form to the ORIO office. Which includes:
 - 5.1.1. Copy of the course syllabus;

- 5.1.2. The Course Instructor's CV/resume;
- 5.1.3. A Social Behavioral Basic/Refresher online course completion report from Collaborative Institutional Training Initiative (CITI) online (*see HRPP-031 Education Requirements*).
- 5.2. ORIO staff screen the submission for completeness and accuracy. If the submission is incomplete, ORIO staff will request additional information from the Course Instructor, which they will then forward to the Research Compliance Administrator (RCA) upon receipt.
- 5.3. The RCA, or designee, will review the submitted SCP form and will make a determination regarding the student classroom projects.
- 5.4. If the RCA determines that the student classroom project will not constitute human subject research and does not involve a special population or sensitive topic area, a general classroom approval letter of "not research" or "not human subject research" determination will be drafted and sent to the Course Instructor.
- 5.5. If the RCA determines that the student classroom project will constitute human subject research, the Course Instructor will be instructed to have students file group or individual IRB or HRPP submissions.
- 5.6. If the RCA determines that the student classroom project will involve a special population or sensitive topic area, the submission will additionally be reviewed by an IRB member.
- 5.7. The IRB member will review the submission and may request additional information or revisions before determining whether a protocol qualifies for general classroom approval.
- 5.8. If the IRB member determines that the student classroom projects do qualify for general classroom approval, a general classroom approval letter of "not research" or "not human subject research" determination will be drafted and sent to the Course Instructor.
- 5.9. If the IRB member determines the student classroom project does not qualify for general approval, the Course Instructor will be instructed to have students file group or individual IRB or Human Research Protection Program (HRPP) submissions.

6.0 References

- 6.1. 45 CFR 46.102