



The University of Southern Maine

Policy on Review of Student Classroom Projects

June, 2009

Introduction

The purpose of this policy is to set forth the criteria by which the University of Southern Maine'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 review by the IRB.¹ The intended audience for this document is faculty members who have courses where classroom projects are likely to be assigned. Student researchers are encouraged to review the IRB's [Student Handbook on Human Subject Research](#).

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 of these student class projects involving human subjects pose little or no risk to the participants. Therefore 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.

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 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.

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 general approval or an individual 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.**

- **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 or data about individuals to teach research methods or to help students understand concepts covered by the course. For the most part, they are not intended to create new knowledge or to lead to scholarly publication or presentation.

University Policy

This University policy provides the criteria that guide the IRB in whether to classify a research assignment as a student classroom project. If a project does not meet these criteria it must be submitted as an individual research protocol to the IRB. In addition, the IRB submission process for individual applications should be completed. If after reading these guidelines a faculty member believes that their assigned classroom projects qualify for general approval, the appropriate IRB submission process will need to be completed.

The University policy on oversight of student classroom projects turns on the following determinations, rules, and exceptions:

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. A student presentation to fellow class members sharing the results of a survey taken of USM 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 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. Please see the USM-IRB [Student Handbook on Human Subject Research](#) for more details.

3. Are there any other Student Classroom Projects 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, however a special population or sensitive topic area is part of the project, the students' projects cannot qualify for general approval.*

- a. Categories of sensitive information include 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 reasonable damage an individuals 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;
 - 7) Genetic Information.

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 encountered in daily life or during the performance of routine psychological examinations or tests.

- b. Categories of special subject population:
 - 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, 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. It is the responsibility of faculty members to:
 - 1) Ensure student classroom projects are conducted to the ethical standards of human subject research and their discipline.
 - 2) Ensure that students understand and implement these ethical standards in carrying out their projects.
- b. Take the [CITI on-line training on Human Subject Protection](#).
- c. When a faculty member believes their assignment for a course qualifies for general approval, it is their responsibility to submit an application to the ORC using a Student Classroom Project form.
- d. Even when a general approval is granted by the IRB, it is always the responsibility of the faculty member to:
 - 1) Teach students about the ethical conduct of human subject research, including basic human subject rights and the role of the IRB.⁴
 - 2) Strongly encourage students to take the [CITI on-line training on Human Subject Protection](#) before collecting data.
 - 3) Provide guidance to students collecting information in order to minimize any unintentional harm to other students or individuals.

⁴See the [Belmont Report](#).

- 4) Review students' plans for classroom or group projects and, when necessary, suggest improvements in design and protections for confidentiality.
- 5) Suggest 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) Instruct students about privacy and security vulnerabilities associated with networked computers and the internet.
- 7) Follow all USM policy and procedures including Internet security, biosafety, and privacy. A general IRB approval for projects does not extend to other relevant policies and procedures which may apply to the project.

How to Apply for Student Classroom Project General Approval

The following section provides an outline of the necessary information and documents needed to submit a *Student Classroom Project* form. Faculty should:

1. **Read the Student Classroom Project's *Instructional Sheet*** before filling out the form. Your project might not fall under the exemption category for general classroom approval.
2. **Fill the *Student Classroom Project* form out completely;** leaving spaces blank could delay your approval.
3. Include a copy of their **syllabus** for the course, along with any other relevant documents.
4. Include a copy of their **CV** with each submission.
5. **Include** their recent [CITI certificate for Human Subjects Protection](#) (no older than 3 years).
6. **Send an electronic submission** to usmirb@usm.maine.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 needs 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 individuals.
 - Have information identifying individuals be kept 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.
 - Encourage the use of passive consent forms.
3. **Ask for help!** Ask the Office of Research Compliance (ORC) staff for guidance when you are unsure of what review process is needed for a student classroom project. The ORC staff contact information may be found on the ORC website: <http://www.usm.maine.edu/orc/irb/contact.htm>.

Applying for an Individual Research Project

In reviewing an application for student research conducted in the context of a course that does not qualify as part of a general approval, the IRB may determine that the proposal falls under one of several defined categories of "exempt" research. A declaration of exemption means that, so 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. The review time for an "exempted" protocol is **approximately 10 business days after receipt by ORC office, if no revisions are required.**

In reviewing an application for research, the IRB may determine that it falls 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. The review time for an "expedited" protocol is **approximately 20 business days after receipt by ORC office, if no revisions are required.**

In reviewing an application for research, the IRB may determine that it is neither exempt nor expeditable. In such a case, the application must be reviewed at a convened meeting of the full board.

The full Board meets on a monthly schedule, and reviews are on a first come, first serve basis. Sometimes a review may take longer depending upon how many studies are already being processed. The typical time frame for a full board review is **approximately 30-45 business days after receipt by IRB office**, *if no revisions are required*.

University Policy

STUDENT CLASSROOM PROJECT

Informational Sheet

University policy provides the criteria that guide the IRB as to whether or not to classify a research assignment as a student classroom project. If, after reading these abbreviated guidelines, a faculty member believes that their assigned classroom projects qualify for general approval, faculty should fill out the [Student Classroom Projects Form](#) below. A full description of USM's Student Classroom Projects policy may be found on the [USM IRB website](#).

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 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, would qualify as a Student Classroom Project.
- Interviewing individuals for a project where the results will only be shared with the faculty member who is teaching the class or fellow class members would also qualify as a Student Classroom Project.
- Student classroom projects involving a program evaluation, quality assurance, or needs assessment for a third party agency, where the collected information will remain in the classroom and disseminated to the third party agency, **may** qualify as a Student Classroom Project depending on the individual project.

What is not a Student Classroom Project?

- If the intent is to have the information collected for the student classroom projects is to produce generalizable knowledge, you probably will not qualify for a general approval. If you have further question, we encourage you to call the [Office of Research Compliance](#) for assistance at (207) 780-4268.

Given the nature of most Muskie Capstone projects and independent research projects conducted by students (e.g., theses, honors projects, and/or independent study projects that collect data through interactions with living people or access private information) it is unlikely they will qualify for a general approval. Please call the [Office of Research Compliance](#) for clarification on your specific class assignment at (207) 780-4268.

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

Student classroom projects which include a special subject population or deal with categories of sensitive information will not qualify for general approval and must be submitted as individual protocols. (See table below.)

<p style="text-align: center;"><u>Categories of Sensitive Information</u></p> <ul style="list-style-type: none"> • Information relating to sexual attitudes, preferences, or practices. • Information relating to the use of alcohol, drugs or other addictive products. • Information pertaining to illegal conduct. • Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community. • Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination. • Information pertaining to an individual's psychological well-being or mental health. • Genetic information. 	<p style="text-align: center;"><u>Special Subject Populations</u></p> <ul style="list-style-type: none"> • Minors (under 18 years of age). Please contact the Office of Research Compliance for more information. • Fetuses or products of labor and delivery • Pregnant women (in studies that may influence maternal health) • Prisoners Individuals with a diminished capacity to give informed consent
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A Note about Ethical Responsibilities:

It is the responsibility of faculty members to:

- Take the [CITI on-line training on Human Subject Protection](#).
- Ensure student classroom projects are conducted to the ethical standards of human subject research, as well as to the ethical standards of their individual discipline.
- Ensure that students understand and implement these ethical standards in carrying out their projects.

It is always the responsibility of the faculty member to:

- **Teach** students about the ethical conduct of human subject research, including basic human subject rights and the role of the IRB.⁵

⁵See the [Belmont Report](#).

- **Suggest** students take the [CITI on-line training on Human Subject Protection](#) before collecting data.
- **Provide guidance** to students collecting information in order to minimize any unintentional harm to other students or individuals.
- **Review students' plans** for classroom or group projects and, when necessary, suggest improvements in design and protections for confidentiality.
- **Suggest 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.
- **Instruct** students about privacy and security vulnerabilities associated with networked computers and the internet.

Remember, even though you obtain general IRB approval for your classroom project, it still remains your obligation to follow all USM policy and procedures, including internet securities, biosafety, and privacy.