UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

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AAHRPP:	Element I.1.A. & Element III.1.A.
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Procedure Title:	Social Work Undergraduate Student 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 the review of student projects in the undergraduate Social Work program (SWO).

2.0 General Policy

2.1. The IRB recognizes that an important aspect of a University education is for students to engage in innovative projects assigned by their instructor. The IRB recognizes that many of these student 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 approval for the SWO course and ORIO will conduct a limited review of the student projects within the course.

2.2. Protocols that present enhanced risk to the human subject participants or other individuals, 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.

3.0 Definitions

3.1. U.S. Department of Health and Human Services (DHHS)/The Common Rule

3.1.1. **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

3.1.1.1. 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.

3.1.1.2. For purposes of this definition, the following activities are deemed not to be research:

3.1.1.2.1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

3.1.1.2.2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3.1.1.2.3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

3.1.1.2.4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

3.1.1.3. This definition applies to activities subject to the Health Insurance Portability and Accountability Act (HIPAA).

3.1.2. **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research:

3.1.2.1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

3.1.2.2. Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

3.1.3. **Intervention** includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

3.1.4. **Interaction** includes communication or interpersonal contact between investigator and subject.

3.1.5. **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

3.1.6. **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

3.1.7. **An identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

3.1.8. **Clinical Trial** means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

3.1.9. **An investigator** is any USM faculty, staff member, student, or individual so designated who is responsible for the design, conduct, or reporting of research.

3.1.10. **Written**, or in writing, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

3.2. Special Populations include:

3.2.1. Minors (under eighteen years of age);

3.2.2. Fetuses or products of labor and delivery;

3.2.3. Pregnant women (in studies that may influence maternal health);

3.2.4. Prisoners; and/or

3.2.5. Individuals with a diminished capacity to give informed consent.

3.3. Sensitive Topic Areas include information:

3.3.1. Relating to sexual attitudes, preferences or practices;

3.3.2. Relating to the use of alcohol, drugs or other addictive products;

3.3.3. Pertaining to illegal conduct;

3.3.4. That if released could reasonably damage an individual's financial standing, employability, or reputation within the community;

3.3.5. That would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;

3.3.6. Pertaining to an individual's psychological well-being or mental health; and/or;

3.3.7. Genetic information.

3.4. SWO Student Projects are conducted during or outside of class with students enrolled in an official SWO course (for credit or not for credit), as well as activities in fulfillment of SWO 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.

3.4.1. Examples of SWO Student Projects that do not require individual IRB review:

3.4.1.1. A student presentation to fellow class members that share the results of a survey taken of USM students over eighteen years of age concerning a non-sensitive topic area;
3.4.1.2. Interviewing individuals for a project where the results will only be shared with the faculty member teaching the class and fellow class members; and/or
3.4.1.3. 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.

3.4.2. Examples of SWO Student Projects that require individual IRB review:

3.4.2.1. A student research project in which data was gathered systematically with an intent to produce generalizable knowledge;
3.4.2.2. A student research project in which the student intends to publish results and add to scientific literature;

3.4.2.3. A student research project conducted by a student for academic course requirements such as a thesis, honors project, and/or capstone; and/or

3.4.2.4. 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 Compliance Administrator (RCA), and Faculty Advisor 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 Faculty Advisor to review and comply with the Role and Responsibilities of the Faculty Advisor: USM IRB Guidance document and seek guidance when appropriate.

5.0 Procedure

5.1. The Faculty Advisor submits a Student Classroom Project (SCP) Form in compliance with the *HRPP-001 Student Classroom Projects.* 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. The Faculty Advisor assists each Student Principal Investigator (PI) to submit an SWO Student Project Form to the ORIO.

5.3. ORIO staff screen the submission for completeness and accuracy. If the submission is incomplete, ORIO staff will request additional information from the Student PI, which they will then forward to the RCA upon receipt.

5.4. The RCA will review the submitted form and will make a determination regarding the student project.

5.5. The RCA will forward the submitted form to a designated member of the IRB Student Project Review Sub-Committee. This committee will consist of representatives from the IRB and ORIO office who volunteer to review student projects.

5.6. The sub-committee member will review the submission and provide the RCA with comments to be shared with the student PI and Faculty Advisor.

5.7. The RCA will email/issue a determination letter to the Student PI along with comments provided by the sub-committee member.

5.8. The student may begin their project at this time. However, the Faculty Advisor will first choose what committee manager comments to require the student to change before beginning their project.

6.0 References

6.1. 45 CFR 46.102