UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-032
AAHRPP:	Element II.4.A. & Element III.1.C.
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Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	Vulnerable Subjects

1.0 Objective

1.1. To describe the policies and procedures for reviewing research involving vulnerable subjects.

2.0 Responsibility

2.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Protections Administrator (RCA), Institutional Review Board (IRB), and investigators to execute this SOP.

3.0 General Description

3.1. The University of Southern Maine (USM) Institutional Review Board (IRB) gives special consideration to protecting the welfare of vulnerable subjects.

3.1.1. Vulnerable subjects include but are not limited to:

3.1.1.1. Children, minors;
3.1.1.2. Pregnant women, fetuses, human in vitro fertilization;
3.1.1.3. Prisoners; institutionalized, elderly individuals;
3.1.1.4. Military persons and students in hierarchical organizations;
3.1.1.5. Terminally ill, comatose, physically challenged;
3.1.1.6. Visually or hearing impaired;
3.1.1.7. Ethnic minorities, refugees, international research;
3.1.1.8. Individuals with impaired decision-making capacity, intellectually challenged; and/or
3.1.1.9. Economically or educationally disadvantaged persons.

3.1.2. The IRB also recognizes that additional populations such as students may qualify as vulnerable populations and need safeguards in place for their protection during study participation.

4.0 Procedures

4.1. Submission and Screening

4.1.1. The Principal Investigator (PI) identifies, with ORIO guidance, if required, the categories of vulnerable subjects involved in the research in the IRB application submitted to ORIO.

4.1.1.1. When research on vulnerable subjects is conducted outside the state of Maine, the PI identifies the state law(s) applicable to the determination of legally authorized representatives and contacts the University of Maine System Counsel for confirmation before submission to the IRB.

4.1.2. The PI submits a completed IRB application to the ORIO, including specific information regarding the ethical and regulatory issues pertaining to the conduct of research involving vulnerable subjects.

4.1.3. Upon receipt of the application, the ORIO staff screen the application, including the informed consent process and documentation for completeness and accuracy.

4.1.3.1. ORIO staff contact the PI for any additional information needed for a thorough review.

4.1.3.2. If it is clear to the designated ORIO staff that the application does not include the required information regarding the conduct of research involving vulnerable subjects, the designated ORIO staff contacts the PI and recommends the application be amended.

4.1.3.2.1. After screening the application, the ORIO staff sends the application to the RCA or designee.

4.1.3.2.2. The RCA or designee makes the final determination regarding whether the research involves vulnerable subjects.

4.1.4. IRB membership includes representation with expertise in selected vulnerable populations routinely reviewed by the IRB, such as children or prisoners.

4.1.4.1. The RCA or designee ensures that designated representatives review research involving vulnerable populations when necessary.

4.1.4.2. The RCA or designee requests a consultant review if additional expertise is needed. (See *HRPP-022 IRB Use of Additional Expertise*)

4.2. Protocol Review Process

4.2.1. The IRB reviewer evaluates the IRB application to determine whether the protocol includes enrollment of vulnerable subjects and whether appropriate safeguards are in place.

4.2.2. As applicable, the IRB considers the following elements when reviewing research involving vulnerable subjects:

4.2.2.1. Inclusion/exclusion criteria;
4.2.2.2. Selection or exclusion of certain groups based on perceived limitations (i.e., targeting prisoners as research subjects because they are a readily available "captive" population); and
4.2.2.3. Knowledge of applicable or local context/laws that bear on the decision-making process (i.e., emancipated individuals, legally authorized representatives, age of majority for research consent).

4.2.3. The IRB follows applicable federal and state regulations and IRB policy to assist in reviewing and approving proposed research that involves vulnerable subjects, such as but not limited to:

4.2.3.1. Pregnant women, human fetuses and neonates;
4.2.3.2. Research involving prisoners;
4.2.3.3. Research involving children;
4.2.3.4. Research involving individuals with impaired decision-making capacity
4.2.3.5. Research involving economically or educationally disadvantaged persons; and
4.2.3.6. Research involving students recruited by their professors or advisors for research participation.

4.2.4. The IRB considers each of the specific findings discussed in the IRB application forms for research involving vulnerable subjects as documented by IRB approval.

4.2.4.1. IRB approval also documents that the IRB members acknowledge and agree with the preliminary description of safeguards and the risk assessment of the protocol as described in the application by the PI.
4.2.4.2. ORIO staff document discussions of controverted issues at convened meetings in the meeting minutes.

4.2.5. Specific findings are either documented by ORIO staff in the meeting minutes or by exempt/expedited reviewers in their determinations

4.2.6. The IRB may require more frequent review (i.e., issue an approval period shorter than 12-months) for protocols involving vulnerable populations based on the nature of the research and the level of risk.

5.0 References

5.1. 45 CFR 46 Subpart B;
5.2. 45 CFR 46 Subpart C;
5.3. 45 CFR 46 Subpart D;
5.4. 21 CFR 50 Subpart D;
5.5. 34 CFR 97 Subpart D.