UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

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AAHRPP:	Element I.1.D. & Element I.1.G.
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Procedure Title:	Ethical and Legal Principles

1.0 Objective

1.1. To describe the primary ethical and legal principles applied to human subject research covered by the University of Southern Maine (USM) Human Research Protection Program (HRPP).

2.0 General Description

2.1. The primary ethical principles applied to research at USM are those set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

2.2. The primary legal principles applied to research at USM are those set forth in applicable federal and state law.

2.3. The USM HRPP will be knowledgeable of and follow state and local laws in the jurisdiction in which the organization resides and outside the jurisdiction where the organization resides when research is conducted in other places. The University of Maine System Counsel will assist in informing the HRPP of relevant laws with updates when appropriate.

3.0 Responsibility

3.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA), Institutional Review Board (IRB), and investigators to execute this Standard Operating Procedure (SOP).

3.2. Training on the ethical and legal principles governing human subject research is provided through the Collaborative Institutional Training Initiative (CITI) and is required of all research investigators, IRB members, and ORIO staff.

4.0 The Principles

4.1. The three main ethical principles of the Belmont Report are:

4.1.1. Respect for Persons

4.1.1.1. All researchers are required to seek and obtain, whenever possible, voluntary, written informed consent from all potential human subject participants. Informed consent must provide potential participants with sufficient information to:

4.1.1.1.1. Understand what they are participating in;
4.1.1.1.2. Understand the voluntary nature of their involvement;
4.1.1.1.3. Understand that they are not under duress; and
4.1.1.1.4. Provide sufficient information to allow the person to decide if they wish to participate or not.

4.1.1.2. The consent process must be written or explained in an easy-to-understand/easy-to-read nature.

4.1.1.3. Respect for persons also includes honoring the privacy of individuals and maintaining the confidentiality of their information.

4.1.2. Beneficence

4.1.2.1. This guiding principle requires that researchers maximize the potential benefits to the participants or to society while minimizing the potential risks of harm. The extent of protection depends on the risks and benefits of the proposed research to the participants and to society. All participants should be treated in an ethical manner. Ideally, direct benefits to the subjects should always outweigh the risks of participating in the research. At a minimum, the proposed research must present sufficient benefits to society at large to outweigh the risks the research presents to the research participants.

4.1.3. Justice

4.1.3.1. This guiding principle requires that participants be selected fairly and that both the risks and benefits of research are distributed evenly among the subjects. Researchers should always take precautions not to select participants simply because of convenient availability, manipulability, compromised positions or based on social, racial, sexual, economic, or cultural biases institutionalized in society.

4.2. All parties involved in the conduct of research are expected to also adhere to the principles of expertise (competent to do the work) and integrity (faithfully adhere to professional principles).

4.3. Ethical principles from other sources may also be applied to research, for example:

4.3.1. To an individual research project because its particular circumstances raise a type of ethical issue that most other projects do not;

4.3.2. When they are recognized by the federal or other funding source or the state or country where the research will occur;

4.3.3. When they have been developed for specific areas or types of subjects.

4.4. The basic legal principles governing human subject research are:

4.4.1. Federal Policy for the Protection of Human Subjects (Common Rule) in 45 CFR Part 46;

4.4.1.1. The USM HRPP applies the Common Rule to all research at the University except where different but equivalent standards and requirements are noted in policies and procedures.

4.4.2. Food and Drug Administration Regulations for the Protection of Human Subjects (FDA) in 21 CFR Parts 50 and 56;

4.4.3. Standards for the Privacy of Individually Identifiable Health Information (HIPAA Privacy Rule) in 45 CFR Parts 160 and 164;

4.4.4. Family Educational Rights and Privacy Act Regulations (FERPA) found in 34 CFR Part 99;

4.4.5. The Protection of Pupils' Rights Amendment (The Hatch Amendment) when research is supported wholly or in part by the U.S. Department of Education;

4.4.6. Relevant additional requirements of any federal U.S. Department when research is supported wholly or in part by that Department; and

4.4.7. Applicable state law.

4.4.7.1. University of Maine System Counsel provides ORIO and the IRB with legal guidance and decisions regarding the interpretation of state law and conflicts of law.

5.0 Ethical Responsibilities

5.1. All parties involved in the review and conduct of research (IRM members, ORIO staff, investigators, etc.) are expected to:

5.1.1. Understand and make decisions based on the ethical and legal principles outlined above;

5.1.2. Adhere to the principles of expertise (“competent to do the work”) and integrity (“faithfully adhere to professional principles”); and

5.1.3. Make decisions free from coercion, undue influence, or potential conflicts of interest.

6.0 References

6.1. The Belmont Report;

6.2. 45 CFR Part 46;

6.3. 21 CFR Parts 50 and 56;

6.4. 45 CFR Parts 160 and 164;

6.5. 34 CFR Part 99.