UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-008
AAHRPP:	Element I.1.A. & Element III.1.A.
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Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	Determination of Activities Requiring IRB Review

1.0 Objective:

1.1. To describe the policies and procedures for determining the types of activities that qualify as human research or clinical investigations and therefore require Institutional Review Board (IRB) review and approval.

2.0 General Description

2.1. The primary responsibility of the IRB is to ensure the protection of the rights and welfare of research subjects. In accordance with federal and institutional regulations, prior to project initiation, the Office of Research Integrity and Outreach (ORIO) and/or IRB must approve any activity in which a University of Southern Maine (USM) community member is engaged in research involving 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. Food and Drug Administration (FDA)

3.2.1. **Research** means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act (Act), or is not subject to requirements for prior submission to the FDA under these sections of the Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

3.2.1.1. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous.

3.2.2. **Human subject** means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

3.2.2.1. For research involving medical devices, an individual on whose specimen is an investigational device is used as a human subject.

3.2.2.2. For research involving medical devices, in-vitro diagnostics, and unidentified tissue specimens, the unidentified tissue specimens are human subjects.

3.2.3. **Subject** means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as

a control. A subject may be in normal health or may have a medical condition or disease.

3.3. University of Southern Maine (USM)

3.3.1 **Investigation** means a searching inquiry for ascertaining facts or a detailed or careful examination.

3.3.2. **Systematic** means having or involving a system, method, or plan.

3.3.3. **Designed** means done with purpose or intent.

3.3.4. **Develop** means to elaborate or expand in detail.

3.3.5. **Contribute** means to be an important factor in.

3.3.6. **Knowledge** means truth, facts, or information.

3.3.7. **Generalizable** means relevant beyond the population or program from which it was collected.

3.3.8. **About** means the information concerns the individual whose information is collected.

3.3.9. **Biospecimen** means material such as urine, blood, tissues, cells, Deoxyribonucleic acid (DNA), Ribonucleic acid (RNA), and proteins.

4.0 Responsibility

4.1. It is the responsibility of the ORIO staff, Research Compliance Administrator (RCA), and investigators to execute this Standard Operating Procedure (SOP).

4.2. It is the sole responsibility of the RCA or their designee to determine whether an activity constitutes research with human subjects.

4.3. It is the responsibility of each investigator to seek IRB review and approval prior to initiation of any research involving human subjects or before conducting any clinical investigation.

5.0 Procedure

5.1. ORIO must determine whether any data collection activities meet either the DHHS or the FDA definitions of research with human subjects with consideration of relevant USM definitions.

5.2. Any individual collecting data must submit a Request for Determination of Research Involving Human Subjects form to the ORIO for the ORIO to determine the applicability of federal regulations and USM policy to the activities unless the individual has or will submit a Request for IRB Review.

5.3. The ORIO may ask the investigator to supply additional information detailing the proposed activities.

5.4. The ORIO may require the investigator to contact the applicable regulatory agency to assist in making the determination.

5.5. The RCA or their designee makes the final determination on whether activities meet the federal definitions.

5.6. If the RCA determines the activities meet the federal definitions, IRB approval is required prior to initiation of any research activities.

5.7. If activities involve any of the following, FDA regulations apply, and IRB approval is required prior to implementation:

5.7.1. Any use of a drug in research other than the use of an FDA-approved drug in the course of medical practice;

5.7.2 Any use of a medical device in studies wherein the purpose is to determine the safety or effectiveness of the device; or

5.7.3. Data will be submitted to or held for inspection by FDA as part of a marketing permit.

5.8. The ORIO communicates the decision of the RCA or designee to the investigator.

5.9. All decisions and communications on determination of human subjects research will be documented in the IRB records.

5.10. An Administrative Check-in may be set to either update their activity or close the project.

6.0 References

6.1. 45 CFR 46.102;

6.2 21 CFR 56.102;

6.3. 45 CFR 812.3;

6.4. 45 CFR 164.501