UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

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Procedure Title:	Exempt Determinations

1.0 Objective

1.1. To describe the policies and procedures for the review of research activities exempt from IRB review.

2.0 General Description

2.1. Research activities that meet the categories set forth by the federal regulations may qualify for exemption from Institutional Review Board (IRB) review.

2.1.1. Certain categories require a limited IRB review of research activities before an exemption is granted.

2.2. Although such research activities are exempt from IRB review, the activities must be reviewed for compliance with University of Southern Maine (USM) ethical standards and protections of human subjects.

2.2.1. USM retains the authority to suspend or terminate IRB approval of research approved with an exempt review.

3.0 Responsibility

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

3.2. It is the sole responsibility of the RCA or designees to determine whether an activity is exempt from the human research protection regulations.

4.0 Definitions

4.1. **Department or agency head** means the head of any federal department or agency; for example, the Secretary of Health and Human Services (HHS), and any other officer or employee of any federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.

4.2. **Federal department or agency** refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates.

4.3. **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).

4.4. **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.

4.5. **Identifiable biospecimen** means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

5.0 Categories

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

5.1.1. Category 1. Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

5.1.2. Category 2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

5.1.2.1. (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

5.1.2.2. (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil

liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

5.1.2.3. (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and limited IRB review is conducted to determine there are adequate provisions to protect the privacy interests of research participants and the confidentiality of identifiable data.

5.1.3. Category 3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

5.1.3.1. (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

5.1.3.2. (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

5.1.3.3. (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and limited IRB review is conducted to determine there are adequate provisions in place to protect the privacy interests of research participants and the confidentiality of identifiable data.

5.1.3.3.1. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

5.1.3.3.2. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she

will be unaware of or misled regarding the nature or purposes of the research.

5.1.4. Category 4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

5.1.4.1. (i) The identifiable private information or identifiable biospecimens are publicly available;

5.1.4.2. (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

5.1.4.3. (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

5.1.4.4. (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5.1.5. Category 5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

5.1.5.1. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

5.1.6. Category 6. Taste and food quality evaluation and consumer acceptance studies:

5.1.6.1. (i) If wholesome foods without additives are consumed, or
5.1.6.2. (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

5.1.7. Category 7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use by a limited IRB review conducted to determine:

5.1.7.1. (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of Sec. 16.116(a)(1) - (4), (a)(6), and (d); (see HRPP-029 Informed Consent)
5.1.7.2. (ii) Broad consent is appropriately documented, or waiver of documentation is appropriate, in accordance with Sec. 46.117 (see HRPP-029 Informed Consent); and
5.1.7.3. (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

5.1.8. Category 8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

5.1.8.1. (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with Sec. 46.116(a)(1) through (4), (a)(6), and (d); (see HRPP-029 Informed Consent)

5.1.8.2. (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with Sec. 46.117; (see HRPP-029 Informed Consent)

5.1.8.3. (iii) A limited IRB review is conducted to determine that there are adequate provisions to protect the privacy interests of research participants and the confidentiality of identifiable data and the research to be conducted is within the scope of the broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens; and

5.1.8.4. (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

5.2. 45 CFR part 46, Subparts B, C, and D

5.2.1. Each of the exempt categories may be applied to research subject to subpart B, additional protections for pregnant women, human fetuses, and neonates if the conditions of the exemption are met.

5.2.2. None of the exempt categories apply to research subject to subpart C, additional protections for prisoners except for research aimed at involving a broader subject population that only incidentally includes prisoners.

5.2.3. The exempt categories (1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D, additional protections for children if the conditions of the exemption are met.

5.2.3.1. Exempt category (2)(i) and (ii) may only apply when the investigator(s) do not participate in the activities being observed.

5.2.3.2. Exempt category (2)(iii) of this section may not be applied to research subject to subpart D.

5.3. Food and Drug Administration (FDA)

5.3.1. Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA).

6.0 Procedures

6.1. Submission and Screening

6.1.1. The Principal Investigator (PI) makes a preliminary determination that a protocol is eligible for exempt review based on an assessment of the protocol, establishing that it falls into one or more of the categories specified in the federal regulations. The investigator may call the ORIO with questions.

6.1.1.1. The RCA or designee makes the final determination regarding whether a protocol is eligible for exemption.

6.1.2. The PI submits a completed IRB application to the ORIO.

6.1.2.1. There is one form for all research regardless of the applicable review categories.

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

6.1.4. ORIO staff review the PI's exempt category selection for appropriateness.

6.1.4.1. If it is clear to the designated ORIO staff the application does not meet the criteria for exempt review, the designated ORIO staff contacts the PI and recommends either an expedited or full review application be submitted.

6.1.5. ORIO staff screen for the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and/or Family Educational Rights to Privacy Act (FERPA) concerns.

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

6.1.7. After screening the application, the ORIO staff sends the application to the RCA or designee to serve as the reviewer.

6.1.7.1. The reviewer of any protocol; seeking an exemption or limited IRB review will:

6.1.7.1.1. Be an IRB member;
6.1.7.1.2. Have the authority to represent USM;
6.1.7.1.3. Have no direct involvement in the activity being reviewed;
6.1.7.1.4. Be familiar with laws, regulations, codes, and guidance governing the research;
6.1.7.1.5. Be familiar with USM policies;
6.1.7.1.6. Be familiar with the nature of the research; and
6.1.7.1.7. Be able to make sound judgments.

6.1.7.2. If the RCA has a conflict of interest a designee will be appointed.

6.1.8. The RCA or designee will make an exemption determination or conduct a limited IRB review.

6.2. Exempt Review Process

6.2.1. The reviewer for exempt protocols receives a completed IRB application which includes the following:

6.2.1.1. Personnel information
6.2.1.1.1. Potential Conflict of Interest
6.2.1.1.2. Proof of Human Subject Research Training
6.2.1.1.3. Resume/CV
6.2.1.2. Study location
6.2.1.3. Funding
6.2.1.4. Purpose
6.2.1.5. Study procedures
6.2.1.6. Background
6.2.1.7. Provisions to monitor data if applicable
6.2.1.8. Investigator experience
6.2.1.9. Subject population
6.2.1.10. Subject compensation and costs
6.2.1.11. Recruitment
6.2.1.12. Potential benefits to participants
6.2.1.13. Risks
6.2.1.14. Provisions to maintain the confidentiality of data
6.2.1.15. Provisions to protect the privacy interests of participants
6.2.1.16. Informed consent or broad consent if appropriate
6.2.1.17. Informed assent
6.2.1.18. HIPAA
6.2.1.19. Attachments

6.2.2. The reviewer determines that all of the research procedures fit one or more of the exemption categories specified in the federal regulations.

6.2.3. The reviewer conducts a limited IRB review when applicable.

6.2.4. The reviewer ensures that the research meets ethical principles and standards for protecting research subjects including, but not limited to, the following:

6.2.4.1. The research holds out no more than minimal risk to participants;
6.2.4.2. Selection of participants is equitable;
6.2.4.3. If there is a recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data;
6.2.4.4. There are adequate provisions to maintain the privacy interests of participants; and

6.2.4.5. If there are interactions with participants, consent process will disclose such information as:
6.2.4.5.1. A statement that the activity involves research;
6.2.4.5.2. A description of the procedures;
6.2.4.5.3. That participation is voluntary; and
6.2.4.5.4. Name and contact information for the researcher and RCA;
6.2.4.6. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants, when appropriate.

6.2.5. The reviewer contacts ORIO staff for any additional information needed to determine exempt status or required revisions needed to qualify study for exemption.

6.2.6. If the research is FDA regulated, the protocol must be consistent with FDA regulations.

6.2.7. The reviewer completes the initial review process within 10 days.

6.2.8. Using the IRB Approval Notes, the reviewer documents:

6.2.8.1. A determination regarding exempt eligibility;
6.2.8.2. The applicable exemption category (or categories);
6.2.8.3. Whether the research meets the federal criteria of limited IRB review when applicable; and
6.2.8.4. One of the following recommendations:
6.2.8.4.1 Determination of Exemption;
6.2.8.4.2 Revisions and/or Additions Required; or
6.2.8.4.3 Expedited or Full Board Review Required.

6.3. Review Outcomes

6.3.1. Determination of Exemption

6.3.1.1. A Determination of Exemption indicates that the reviewer concluded that the research meets the federal criteria for exemption and limited IRB review when applicable.
6.3.1.2. The RCA or designee processes the determination and the PI is provided with a determination letter.
6.3.1.3. There is no requirement for continuing or annual reviews of projects determined to be exempt.
6.3.1.3.1 The PI must file a final report when a project determined to be exempt is completed.

6.3.2. Revisions and/or Additions Required

6.3.2.1. The reviewers withhold a determination pending submission of revisions/additional information.
6.3.2.2. The RCA or designee returns the protocol to the PI to address concerns/questions provided by the reviewers.
6.3.2.3. The PI responds to comments, makes any required changes or additions to the protocol, and re-submits the application within fourteen (14) days of receiving the requested revisions.
6.3.2.3.1. Barring extenuating circumstances, if a PI does not respond to requested revisions in the 14-day time-period, the application is administratively withdrawn, and a new protocol submission is required.
6.3.2.4. The RCA or designee assigns the PI's resubmission to the reviewer who made the initial recommendation.
6.3.2.5. This process continues until the reviewer recommends a determination of exemption or that expedited or full board review is required.

6.3.3. Expedited or Full Board Review Required

6.3.3.1. The reviewer may determine that the protocol requires full review by the IRB at a convened meeting or is eligible for expedited review procedures.
6.3.3.2. If the reviewer finds that research is greater than minimal risk, the reviewer must document the rationale for this determination and the rationale for review by the convened IRB.

7.0 Closure

7.1. HRPP 026 Study Closure requires an Administrative Check-in three (3) years post the initial approval for Exempt research.

8.0 References

8.1. 45 CFR 46.104 (c);

8.2. 21 CFR 56.104(d);

8.3. 45 CFR 46.101(b);

8.4. 45 CFR 46.401(b);

8.5. OHRP Guidance: Exemption for Research and Demonstration Projects on Public Benefit and Service Programs