



Human Research Protection Program / Institutional Review Board
Standard Operating Procedure
2018 Common Rule

**For Studies Initially Approved on
or After January 21, 2019**

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1 Exempt Determinations

Review Reminder: For Exemptions 2(iii) and 3(i)(C) limited IRB review is required for privacy and confidentiality protection under 45 CFR 46.111(a)(7).

All research using human subjects must be approved by MaineHealth. Although certain categories of human subject research are exempt from IRB oversight, at MaineHealth the determination of exempt status must be made by ORC staff. MaineHealth may also choose to accept an exempt determination made by an external IRB, MaineHealth will consider such requests on a case by case basis.

Individuals involved in making the determination of an IRB exempt status of a proposed research project cannot be involved in the proposed research. Reviewers must not have any apparent conflict of interest.

Unless otherwise required by law or by Federal department or agency heads, exempt studies are exempt from the requirements of the [Common Rule](#) (i.e., IRB approval and full research consent are not required) *other than as specified within the regulations (e.g., the conditions that permit exemption, and when limited IRB review is required)*. Exempt research is not exempt from ethical considerations, such as honoring the principles described in the [Belmont Report](#). The individual/s making the determination of exemption will determine whether to require additional protections for subjects in keeping with ethical principles (e.g., requiring disclosure/consent, etc.).

1.1 Limitations on Exemptions

The following limitations are applied to exemptions, regardless of funding source:

Children: Exemption #2(i) and (ii) for research involving survey or interview procedures or observations of public behavior does NOT apply to research in children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. Exemption #2(iii), where identifiable information is obtained and the IRB conducts a limited IRB review, is NOT applicable to research in children. Exemption #3 does NOT apply to research involving children.

Prisoners: Exemptions do not apply except for research aimed at involving a broader subject population that only incidentally includes prisoners.

1.2 Exempt Research

With the above-referenced limitations, *and any other limitations or restrictions due to applicable law, regulation, or agency policy*, research activities not regulated by the FDA (see Section 5.4 for FDA Exemptions) in which the only involvement of human subjects is determined to be in one or more of the following categories may be determined exempt from IRB approval:

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.

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:
 - 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;
 - 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
 - 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 an IRB conducts a limited IRB review to make the determination required by .111(a)(7): *When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.*

3. (i) 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:
 - A. 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;
 - B. 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
 - C. 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 an IRB conducts a limited IRB review to make the determination required by .111(a)(7): *When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.*

- (ii) 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.

- (iii) 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.

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:
 - i. The identifiable private information or identifiable biospecimens are publicly available;
 - 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;
 - 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
 - iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch 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. 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.
 - i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website 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.

6. Taste and food quality evaluation and consumer acceptance studies,
 - (i) If wholesome foods without additives are consumed; or
 - (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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

1.3 Flexibility

With the above-referenced limitations in Section 5.1, the MaineHealth ORC will follow the exemption categories at 45 CFR 46. Although MaineHealth had previously developed exempt categories not found in the federal regulations, for projects that do not directly conform to a specific exempt category according to 45 CFR 46, the changes made to the Common Rule in 2018 negated the need for these 'flex categories'.

1.4 FDA Exemptions

The following categories of clinical investigations are exempt from the requirements for prior IRB review and approval:

1. Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article is subject to IRB review. [[21 CFR 56.104\(c\)](#)]
See Section 17.7.1.2 and 17.7.2.3 for detailed discussion of this exemption for investigational drugs and devices (respectively).
2. 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. [[21 CFR 56.104\(d\)](#)]

1.5 Procedures for Exemption Determination

To request an exempt determination, investigators submit the following materials in IRBNet:

Required:

1. A completed **Exemption Request** form;
2. The MaineHealth Smartform Wizard;
3. Departmental Review Sign-Off

As Applicable:

1. Information Sheets (i.e. information to be provided to participants to obtain prospective agreement as applicable) with the following points addressed:

- a. A statement that the activities involve research
 - b. A description of the procedures to be performed
 - c. A statement that participation is voluntary
 - d. The investigator's name and contact information
 - e. For Category 3 research that involves subject deception: A statement that subjects will be unaware of or misled regarding the nature or purposes of the research
 - f. Patient Reimbursement Information (if applicable)
2. Subject materials (questionnaires, diaries, interview scripts/guides, data collection forms, surveys, etc.)
 3. Recruitment materials
 4. HIPAA Forms (applicable only if the research activity involves seeing, using or disclosing protected health information- PHI)
 - Authorization to Use and Disclose PHI
 - HIPAA Request for Waiver or Alteration of Authorization
 - HIPAA Certification Form-Deidentification (This form is typically used for retrospective chart review for which none of the 'HIPAA identifiers' are recorded)
 - HIPAA Certification Form- Limited Data Set (LDS; with requirement for a Data Use Agreement if the LDS is proposed to be disclosed outside of Maine Health)
 - HIPAA Research on Decedents Request
 5. Internal Services Sign-off
 6. Letter(s) of permission from any non-MaineHealth sites; or, when applicable, documentation of IRB approval or exemption from the external site;
 7. The Grant Application (if the project is federally-funded and MaineHealth is the IRB or serving as the IRB of record for the prime awardee)
 8. When Tufts students are the subjects in a research study, a Letter of Support from Dean Scott K. Epstein

The ORC staff reviews all requests for exemptions and determines whether the request meets the criteria for exempt research. The reviewer's determination is documented on the **Exemption Determination Checklist** and uploaded into IRBNet. If the request does not appear to meet the definition of human subject research, the reviewer evaluates the proposal as described in Section 4.

When the research requires limited IRB review or a HIPAA determination (i.e., waivers or alterations of the requirement for HIPAA authorization), the review may be conducted using expedited review procedures by the IRB Chair or an experienced Chair-designated member of the IRB. As with all other research subject to IRB review requirements, when conducting limited IRB review the IRB has the authority to approve, require modifications in (to secure approval), or disapprove all research activities; and to suspend or terminate IRB approval. Actions of disapproval may only be made by the convened IRB.

Proposed modifications to the aspects of research subject to limited IRB review must be submitted to and approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the subject(s), in which case the change must be promptly reported to the IRB (i.e., within 2 business days).

Continuing review is generally not required for research determined to be exempt, even when that research is subject to limited IRB review. However, the IRB may determine that continuing review is required for a particular study subject to limited IRB review, in which case it shall document the reasons for its determination in the IRB record and communicate the requirement to the investigator in the IRB determination letter.

The individual making the determination of exemption will determine whether to require additional protections for subjects in keeping with the guidelines of the Belmont Report.

The exempt application, review documentation, and determination letter are maintained in the same manner and for the same length of time as other IRB review documentation.

Exempt determinations will include a termination date, with the maximum time allotted being 6 years. If the investigator wants the research to extend beyond the termination date, the investigator must request another exemption determination. This process will allow the investigator and the organization the opportunity to review and update the research activity and determine whether it still qualifies for exemption.

Investigators must report any proposed additions to study personnel so that CITI training can be verified, and COI evaluated prior to their involvement with the research. Proposed modifications to the research itself must be submitted for a determination of whether the research still qualifies for exemption. Finally, investigators must submit a closure report when an exempt research project is complete so that the organization can maintain an accurate database of research activities.