Human Research Protection Program / Institutional Review Board

Standard Operating Procedure

Pre-2018 Common Rule

For Studies Initially Approved on or Before January 20, 2019

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1 Exempt Determinations

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.

Exemptions are determined or granted, rather than approved. Exempt studies are exempt from the requirements of the Common Rule (i.e., IRB approval and full research consent are not required). They do require a determination/confirmation of exemption status. Although exempt research is not covered by the federal regulations, this 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: The exemption for research involving survey or interview procedures or observations of public behavior (#2) 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, or if the research is not federally funded and meets criteria for MaineHealth Flex Category Exemption 2a.

Prisoners: Exemptions do NOT apply. IRB review is required**.**

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, involving normal educational practices, such as
    (i) research on regular and special education instructional strategies, or
    (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
    (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2, if:

   (i) the human subjects are elected or appointed public officials or candidates for public office; or

   (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

   NOTE: To be eligible for this exemption, all of the materials must already be in existence at the time the research is proposed for an exempt determination.

5. Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:

   (i) Public benefit or service programs;

   (ii) Procedures for obtaining benefits or services under those programs;

   (iii) Possible changes in or alternatives to those programs or procedures; or

   (iv) Possible changes in methods or levels of payment for benefits or services under those programs.

   The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).

   The research demonstration project must be conducted pursuant to specific federal statutory authority, there must be no statutory requirements of IRB review, the research must not involve significant physical invasions or intrusions upon the privacy of subjects, and the exemption must be invoked only with authorization or concurrence by the federal funding agency.

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, the MaineHealth ORC will follow the exemption categories at 45 CFR 46. Research activities not regulated by the FDA (see section 5.4 for FDA Exemptions) may also be reviewed and granted Exempt status based on the MaineHealth Flexibility Policy, the terms of which allow an appropriate level of flexibility for research involving no greater than minimal risk.

MaineHealth has 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. These projects will be reviewed using an approval process identical to that used for exempt research categories 1-6 under 45 CFR 46.101(b).

MaineHealth Exemption 2a: Minimal risk research that involves a non-invasive intervention followed by data collection via survey, interview (including focus groups), or observation, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. Research that is federally funded, FDA-regulated or was issued a Certificate of Confidentiality is not eligible for this category. Research involving children is eligible for this category.

MaineHealth Exemption 7: Research in which study activity is limited to analysis of identifiable data existing at the time the research is proposed or that will be collected in the future for non-research purposes. For purposes of this research study, all research subject interactions and interventions have been completed and the data continues to contain subject identifiers or links. Research that is federally funded, FDA-regulated or was issued a Certificate of Confidentiality is not eligible for this category.

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 the Dean

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.

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.