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Subject: Types of IRB Review
Division: IRB
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IRB Policy 105.2: EXEMPTIONS FROM IRB REVIEW

Policy

The IRB Chairperson, with assistance from the IRB Administrator, will determine whether research protocols qualify as exempt from IRB review, under 45 CFR 46.101(b). Investigators must submit a protocol to the IRB office, so that the IRB Chairperson and Administrator can make an independent determination if the research qualifies as exempt or not. The investigator should also submit the following if applicable: (1) informed consent document; (2) information sheet; and (3) questionnaires.

Exemptions do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. In addition, research involving survey or interview procedures in which children are participants and research under FDA jurisdiction (except in emergency circumstances) are *not* exempt from federal regulations.

A claim of exemption does not automatically mean the IRB will grant exempt status. The IRB is not obligated to grant exemptions to proposed research. In fact, the IRB may require review of all such activities, whether funded or not, to ensure that the research meets the federal requirements for a "Claim of Exemption." Therefore, in order to fulfill the requirement for the proper review of research, investigators cannot "self-exempt" from IRB review.

If a protocol is determined to be Exempt, investigators will not be required to submit materials to the IRB. However, should any additional study procedures change that could affect the exempt status of the study, the investigators should contact the IRB office immediately. The IRB Administrator will review the change and determine if the Exempt status has changed. If the IRB Administrator determines that the study's Exempt status has changed, the information will be forwarded to the IRB Chairperson for final determination. If the IRB Chairperson determines that the study is no longer Exempt, than the study will undergo either an expedited (if eligible) or full-board review.

Research Exempt from IRB Review

Research in categories described below is considered exempt from IRB review with the exceptions as noted:

1. Research conducted in established or commonly accepted educational settings involving normal education practices, such as:
    - Research on regular and special education instructional strategies, or
    - 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:
    - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and
    - 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 subjects' financial standing, employability, or reputation.
    - **Note: The exemption regarding educational tests is applicable to children. However, the exemption for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) does not participate in the activities being observed.**

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 paragraph (2) of this section, if:
    - The human subjects are elected or appointed public officials or candidates for public office; or
    - 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: Chart reviews may only be considered exempt if patient/subject identifiers are NOT retained by the investigator.**

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
    - Public benefit or service programs;
    - 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.

6. Taste and food quality evaluation 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Responsibility

The IRB Chairperson is responsible for evaluating applications for exemption from IRB review. IRB Administrator is responsible for providing consultation in the review of claims of exemption.

Applicable Regulations and Guidelines

45 CFR 46.101
21 CFR 56.104, 105