UMASS GLOBAL
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# UMASS GLOBAL INSTITUTIONAL REVIEW BOARD

## Exempt Criteria

Unless otherwise required by the IRB, research activities designated in **45 CFR 46 or 21 CFR 56.104(ad),** in which the only involvement of human subjects will be in one or more of the following categories, may be considered by exempt review by the IRB:

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. Educational research proposals are exempt providing all of the following are met:
    a. All of the research is conducted in a commonly accepted educational setting (e.g., a private or public school).
    b. The research involves normal educational practices (e.g., comparison of instructional techniques).
    c. The study procedures do not entail a significant deviation in time or effort from those educational practices already existent in the study site.
    d. The study procedures do not involve an increase in the level of risk or discomfort beyond normal, routine educational practices, including physical education.
    e. The study procedures do not involve deception or withholding of information.
    f. The study procedures do not involve sensitive topics, such as sexual behavior of individual subjects.
    g. A sensitive survey is one that deals with socially questionable or highly personal issues or alcohol and/or drug abuse.
    h. Provisions are made to ensure the existence of a non-coercive environment for all students, including those who choose not to participate.
    i. The school or other agency grants written approval for the research to be conducted.
    j. Educational tests of (i) knowledge, (ii) mastery, or (iii) skills.
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 subjects' 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 paragraph (2) (b) of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office or (b) Federal statue(s) require(s) without exception that the confidentiality of the personally identifiable information be maintained throughout the

research and thereafter. Copies of the informed consent form and questionnaire or survey instrument(s) to be used must be forwarded to the IRB for review.

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.
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: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs. This category may also be applied to service/program evaluations of State, city or county programs providing: (a) the program being studies delivers public benefits or services; (b) there is specific statutory authority over the program; (c) there is no statutory requirement that the program evaluation plan be reviewed by an IRB; and (d) there is no significant intrusion or invasion of the privacy of the participant.
6. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed; (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency or the Food Safety and Inspection Services of the U.S. Department of Agriculture. The following categories of clinical investigations regulated by the FDA (21 CFR 56) are exempt from the requirements of this part for IRB review:
    1. Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.
    2. Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.
    3. 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 at the institution is subject to IRB review.
    4. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed; (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency or the Food Safety and Inspection Services of the U.S. Department of Agriculture.