

REVIEW CRITERIA

I. Introduction

In accordance with federal and institutional regulations, any undertaking in which a faculty, staff or student investigates and/or collects data on human subjects for research purposes **MUST BE REVIEWED** by the Institutional Review Board (IRB). It is the **PRINCIPAL INVESTIGATOR'S RESPONSIBILITY** to submit a proposed study involving subjects prior to initiation of the project.

The IRB is charged with the institutional responsibility for assurance of protection of human subjects involved in research or related activities. The IRB has the authority to review, approve, disapprove or require changes in research activities involving human subjects.

Under federal regulations, an investigator's application to conduct a research project involving human subjects can be processed by the IRBs in four (4) ways:

BY EXEMPTION CERTIFICATION
BY EXPEDITED REVIEW
BY FULL REVIEW
BY EMERGENCY WAIVER

The preliminary determination that a research project is eligible for exemption certification, expedited or emergency review is made by the investigator. Below are the federally-mandated criteria which serve as a guide in making this determination.

The investigator should carefully review the information below. Questions of interpretation may be directed to the IRB. After the type of review required for the project has been determined, the appropriate review application packet may be selected.

II. Exemption certification eligibility requirements

Research activities in which the **ONLY** involvement of human subjects will be in one or more specified categories are eligible for exemption certification. Note, however, that the exemption categories (1 through 6 below), **do NOT** apply when the research activities include the following:

- a. Prisoners, fetuses, pregnant women or human in vitro fertilization.
- b. The review of medical records; if the information is recorded in such a way that subjects can be identified, directly or through identifiers linked to the subjects.
- c. Survey or interview techniques which include minors as subjects.
- d. Research involving the observation of the public behavior of minors.
- e. Techniques which expose the subject to discomfort or harassment beyond levels encountered in daily life.
- f. The deception of the subjects.

Exemption Categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special educational 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) 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 category (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.
5. Research and demonstration projects which are conducted by or subject to the approval of government department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefit 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.
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 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.

III. Expedited review eligibility requirements

According to federal regulations, a research study is only eligible for expedited review if:

- A. The research activities involve no more than minimal risks.

As defined in U.S. Department of Health and Human Service, 45 Code of Federal Regulations, Part 46.102i, "minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- B. Research protocol does not involve **any** of the following groups:

1. Minors (<21 years)
2. Pregnant Women
3. Prisoners
4. Mentally Retarded
5. Mentally Disabled
6. Fetuses
7. Abortuses

- C. Research protocol does not include questionnaires with **sensitive areas** (alcohol/drug abuse, sexual behavior, HIV status).

- D. The only involvement of human subjects is one or more of several specified categories listed below.

1. Collection of hair and nail clipping in a non-disfiguring manner; deciduous teeth and permanent teeth if patient care indicates a need for extraction.
2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
3. Recording of data from subjects 21 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to

electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

4. Collection of blood samples by venipuncture in amounts not exceeding 450 milliliters in an eight week period and no more often than two times per week, from subjects 21 years of age or older and who are in good health and not pregnant.
 5. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
 6. Voice recordings made for research purposes such as investigations of speech defects.
 7. Moderate exercise by healthy volunteers.
 8. Research on individual or group behavior or characteristics of individuals such as studies of perception, cognition, game theory, or tests development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
 9. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required. (**Note: if an FDA approved drug is to be used for an unapproved use, the research is NOT eligible for expedited review.**)
 10. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- E. In addition, the IRB may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. In case where any drugs are involved in the proposed study, at least one IRB member must be a medical physician for the expedited review.

IV. Full Board Review

All proposed research deemed by the IRB chair to fit neither the exempt or expedited review must be reviewed by the full IRB. In addition, the IRB may require full review of any research submitted or approved under expedited review and any research not approved by expedited review.

The primary criteria for full board review are the risk to participants during the procedures and interactions between participants and researchers. Examples of research activities that must be reviewed by the full IRB include:

- Research in which potential participants may not be given enough information to make decisions about whether to participate and accept potential risks. This may include research in which outright deception or incomplete disclosure of the purpose of the study might reasonably affect a person's decision to participate in the study
- Research involving more than minimal risk, where defined as "the probability and magnitude of harm or discomfort are not greater in and of themselves than those ordinarily encountered in the daily life or during the performance of routine physical psychological examinations or tests"
- Non-curricular, interactive research in primary and secondary schools.
- Research in which participation per se in the study constitutes a risk (i.e. identification as a participant in a drug-use survey). This would include research in which researchers have applied for a waiver of documentation of consent, which can be used as a method of reducing risks to participants who may be placed at risk simply by being involved in the study.
- Research on special populations, i.e., minors, prisoners, pregnant women and mentally incompetent persons.
- Research involving potential risks to participant's right to privacy and /or threats to confidentiality.