

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 004
SECTION: IRB REVIEW PROCEDURES
REVIEW RESPONSIBIITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.101

SUBJECT: Exempt Research Activities

1. Certain research activities involving human subjects are exempt from the requirement that they receive IRB full or expedited review, and are provided in 45 CFR 46.101(b)(1) through (6). **However, the FSU Assurance with OHRP provides that all research, including those which may qualify as exempt, receive review and approval by the FSU IRB.** Only the IRB may determine which activities qualify for an exempt review. Investigators are not authorized to make an independent determination that research involving human subjects is exempt and must contact the IRB concerning the status of proposed research or changes in ongoing research.
2. Protocols receiving exempt status receive the same review process as expedited protocols at FSU. The Chairperson and two IRB members will review the initial application to determine eligibility for exempt status. The research activities in the application proposal must meet one of the specific categories of exempt activities listed in paragraph 3 below. A determination that a research activity is exempt must be documented on the review form, and include a citation of the specific category justifying the exemption pursuant to federal regulation. Note that all research activities, even those which meet the definition of eligible for exemption pursuant to 45 CFR 46.101, must still be reviewed and approved by the FSU IRB according to FSU policy and FSU's assurance with OHRP.
3. The six specific categories of research activities determined to be eligible for exempt status are as follows:
 - a) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special educational instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 - b) 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 subject's response outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.
 - This exemption is NOT available for research involving children, unless the research is limited to observation of public behavior when the investigators do not participate in the activities being observed (see 45 CFR Part 46, Subpart D – Protections for Children Involved as Subjects in Research).
- c) 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 (b) above, if:
- The human subjects are elected or appointed public officials or candidates for public office; or
 - Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- d) Research involving the collection or study of existing data, documents, records, pathological 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.
- e) 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:
- Public benefit or service programs;
 - Procedures for obtaining benefits or services under those programs;
 - Possible changes in methods or levels of payment for benefits or services under those programs.
- f) Taste and food quality evaluation and consumer acceptance studies. This exemption is applicable if wholesome foods without additives are consumed, or if a food is consumed, that it 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.

4. The exemptions provided in 45 CFR 46.101(b) do NOT apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. Additionally, the exemption at 45 CFR 46.101(b)(2), 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) do not participate in the activities being observed.