



Office of Research Administration

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April 2003

ORA POLICY AND PROCEDURE:

Guidelines for Types of Research Exempt from Review by the IRB

Certain human subjects protocols may not require review by the Institutional Review Board (IRB). The Health and Human Services has set up guidelines for the types of research which may be exempt from review. **PLEASE NOTE: These guidelines are provided online strictly as a service to Principal Investigators (PIs); per the Multiple Project Assurance (MPA) for Compliance with DHHS Regulations, the determination of exemption must be done by the Office of Research Administration (ORA) in conjunction with the IRB, not by the principal investigator.** Please contact the ORA via e-mail (ora@umsl.edu) or call 516-5899 for more information.

Title 45 of the Code of Federal Regulations, Public Welfare Part 46 - Protection of Human Subjects, Subpart A - Basic HHS Policy for Protection of Human Research Subjects, 464.101b, provides the following guidelines for the types of research which are exempt from 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.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (3) Research involving survey or interview procedures, except where all of the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the subject's responses, if they became known outside of the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt,

- without exception, when the respondents are elected or appointed public officials or candidates for public office.
- (4) Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the observations recorded about the individual, if they became known outside of the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.
 - (5) 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.
 - (6) Unless specifically required by statute (and except to the extent specified in paragraph (i)), research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other 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.