EXEMPT CATEGORIES (45 CFR Part 46.101(b))

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from full Institutional Review Board (IRB) review. The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners or some studies involving children. The following is an excerpt from the Code of Federal Regulations:

(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), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a way 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 be damaging to the subjects’ financial standing, employability, or reputation. **45CFR46.401(b) states: Research involving survey or interview procedures or observations of public behavior does not apply to research involving children as subjects, except for research involving observation 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: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statutes 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 federal department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) 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.

(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.

If you believe your study fits the criteria for exempt research, please complete an exempt application form which can be obtained from the Saint Louis University IRB web site. You may not begin your research until you receive confirmation that the research meets the exemption criteria. If you have questions, please call the IRB office at 314-977-7744 or email IRB@slu.edu.