

Comments:

This research falls under exemptions set forth by federal regulations [45 CFR 46.101(b); 21 CFR 56.104(d); 38 CFR 16.102(b)]. Specifically there are six categories:

- 1) Research conducted in established or commonly accepted educational settings, involving normal education practices, such as:
 - Research on regular or special educational instructional strategies, **or**
 - 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:
 - 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 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 (b) 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 department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - The projects conducted pursuant to specific federal statutory authority such as programs under the Social Security Act, or other federal statutory public benefit or services programs;
 - Procedures for obtaining benefits or services under those programs;
 - Possible changes in or alternatives to those programs or procedures; or
 - Possible changes in methods or levels of payment for benefits or services under those programs.
 - Projects for which there is no statutory requirement for IRB review;
 - Projects that do not involve significant physical invasions or intrusions upon the privacy interests of subjects;
 - Authorization or concurrence by funding agencies that exemption from IRB review is acceptable.

- 6) Taste and food quality evaluation and consumer acceptance studies:
- If wholesome foods without additives are consumed; **or**
 - 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

After a careful review of this request it was determined that the proposed research is exempt under category 5. The following sections of the November 2002 Reauthorization of the Juvenile Justice and Delinquency Prevention Act (JJDP) specifically state:

(b) Statistical Analyses.--The Administrator may--

(1) plan and identify the purposes and goals of all agreements carried out with funds provided under this subsection; and

(2) undertake statistical work in juvenile justice matters, for the purpose of providing for the collection, analysis, and dissemination of statistical data and information relating to juvenile delinquency and serious crimes committed by juveniles, to the juvenile justice system, to juvenile violence, and to other purposes consistent with the purposes of this title and title I.

--42 U.S.C. 5661

Signature:



Chair, CSR Institutional Review Board