

Appendix A

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) for Consideration as Exempt

Research activities in which the only involvement of human subjects are in one or more of the following categories may be reviewed for exempt status by the IRB. (See 1-4 below). **No exemption categories apply to research involving prisoners, fetuses, pregnant women or human invitro fertilization. Only certain exemptions pertain to children (see items 1 and 2 below). To qualify for certification of exemption, human subject involvement may not exceed minimal risk (physical, psychological, social, undue stress and/or invasion of privacy).** If after consulting these sections, it is not clear whether the research meets the criteria for certification of exemption, it is the responsibility of the investigator to follow the procedures and to allow sufficient time for full IRB review.

(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. **(Please note that research on classroom management methods in special education will not qualify for exempt certification.)**

(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 manner 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 reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. **Please note that research using survey, interview or observational procedures with vulnerable populations (including children) is not exempt.**

(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 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:

(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.