

CATEGORIES FOR EXEMPTED REVIEW AFTER JANUARY 2019

45 CFR 46.104(a): Research activities in which the only involvement of human subjects will be in one or more of the following categories are **exempt from 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.
- 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; **or**
 - (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; **or**
 - (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required.

PLEASE NOTE: *An exemption cannot be granted when children are involved in research involving survey or interview procedures or observations of public behavior, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed. [45 CFR 46.401(b)]*

- 3) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording, if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
 - (i) information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; **or**
 - (ii) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or

be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **or**

- (iii) information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.

PLEASE NOTE: *A benign behavioral intervention is defined as being brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive and embarrassing. [45 CFR 46.104(d)]*

- 4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
 - (i) identifiable private information or identifiable biospecimens are publicly available; **or**
 - (ii) information which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; **or**
 - (iii) the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is for the purposes of "health care operations" or for "public health activities and purposes"; **or**
 - (iv) the research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities
- 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 contaminants 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 US Department of Agriculture.

PLEASE NOTE: *The University of Tennessee Knoxville does not utilize Broad Consent and Exempt Categories 7 and 8 are not applied.*

CATEGORIES FOR EXEMPTED REVIEW PRIOR TO JANUARY 2019

45 CFR 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 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.
- 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: *An exemption cannot be granted when children are involved in research involving survey or interview procedures or observations of public behavior, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed. [45 CFR 46.401(b)]*

- 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 (b)(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 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 contaminants 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 US Department of Agriculture.