Criteria for Exempt Review

The IRB may exempt from Full Board and/or continuing review research activities in which the only involvement of human subjects will be in one or more of the following categories. These categories are established by the Federal Regulations and require submission to the institutional designee to determine appropriateness. At the University of Oklahoma Health Sciences Center the institutional designee is the IRB Chair or Vice Chair(s).

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
a) research on regular and special education instructional strategies, or
b) 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 on subjects 18 years of age or older, unless:
a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
b) any disclosure of the human subjects' response 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 paragraph 2 (b) of this section, if:
a) the human subjects are elected or appointed officials or candidates for public office; or,
b) federal statute(s) require 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 (i.e. on the shelf, already collected and/or banked prior to the date the study is to start) 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:
a) public benefit or service programs;
b) procedures for obtaining benefits or services under those programs;
c) possible changes in or alternatives to those programs or procedures; or
d) 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,
a) if wholesome foods without additives are consumed or
b) 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 Food Safety and Inspection Service of the U.S. Department of Agriculture.

NOTE: These categories represent minimal requirements of review by 45 CFR 46, The OUHSC Institutional Review Board reserves the right to require a more stringent review of any study as deemed appropriate.