**Checklist for Exempt IRB Review**

This checklist must accompany all IRB applications requesting to be exempt from significant IRB review. Check all categories, as defined by 45 CFR 46.104(d), that apply to the proposed research project. Studies that fall under an exempt category MUST be submitted for minimal review by the IRB in order to determine and grant exemption.

**Exempt Categories**

The following categories of human subjects research are exempt from significant IRB review.

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes

i. most research on regular and special educational 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.

3. Research involving benign behavioral interventions (which are 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 or embarrassing) 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 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.

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:

1. the identifiable private information or identifiable biospecimens are publicly available.
2. 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;
3. The research involves only information collection and analysis involving the investigator's use of identifiable health information (not specimens).

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

1. 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, if:

i. wholesome foods without additives are consumed or

ii. 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.

**Applicability**

Even though a project meets one or more of the above criteria, an exemption cannot be granted for research that also includes aspects that require higher levels of review such as:

* The study of prisoners
* The study of children, unless the research falls under category 1 or only involves the educational testing component of category 2