**Exempt from Further Review**

Exempt from Further Review is defined as no risk to participants and includes research such as anonymous surveys.

To qualify for Exempt level review, the research study must fall into any of six (6) categories delineated in the Federal regulations listed below. Exempt **DOES NOT** mean the study is exempt from IRB review; the IRB must make the determination that the project meets at least one of the Federal exempt categories criteria. The categories represent studies that present no risk to subjects. Risk is reduced through anonymity of responses, use of data from human subjects that are existing or publicly available, or through the use of non-invasive paradigms that will not harm subjects.

Examples of studies that are exempt from review are ones involving anonymous questionnaires or surveys that do not involve a sensitive topic or utilize minors, research being conducted in educational settings involving normal curriculum and research on archival data. The following exempt conditions have been developed and described within the Federal Common Rule (45 CFR 46).

**Exempt Review Categories**

(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.

*Note: Surveys on sensitive or personal topics which may cause stress to study participants are not considered Exempt.*
The section of this category pertaining to standardized educational tests may be applied to research involving children. This category may also apply to research with children when the investigator observes public behavior but does not participate in that behavior or activity.

Note: this section is not applicable to survey or interview research involving children.

(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.

Pathological or diagnostic specimens which are considered waste and are destined to be destroyed can be used in research and are considered exempt from IRB review if there are no patient identifiers linked to the specimen and if the data is not intended to be used in the diagnosis or treatment of a patient. (If either of these conditions apply, consent of the research subject is required and a higher level of IRB review is required.) Specimens retrieved as "extra" during a clinical procedure require review at a higher level and require written consent from the subject.

(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.

Exemptions do not apply to research involving:

Pregnant Women
Fetuses
Prisoners
Minors/Children (< 18 years of age)
Persons with Cognitive Disabilities

To address the issues for dealing with minors on Exempt Protocols, include the following statement on surveys, questionnaires, etc., "DO NOT participate in this survey if you are under 18 years of age."