GUIDANCE DOCUMENT:
EXEMPT REVIEW – DOES YOUR STUDY QUALIFY?

Attention Investigators/Sponsors! Although the IRB currently reviews all research involving human subjects, the regulations provide that certain human research activities, detailed below, may be eligible for a determination of "exempt" status by the IRB.

A Principal Investigator may request exemption from review by submitting an Exempt Application. A Principal Investigator must obtain such a determination from the IRB prior to initiating the study. Note: an exemption from IRB review does not equate to an exemption from the HIPAA requirement for authorization or waiver of authorization when the research involves a covered entity's protected health information. Researchers who receive an exemption determination but whose research involves protected health information (*see PHI guidance document for list of 18 identifiers*) must still seek a waiver of authorization from the IRB or a data use agreement form (where a limited data set will be used).

Generally, anonymization makes a protocol eligible for exemption from IRB review; for a protocol to qualify as "anonymized" the data **may not contain any ready identifiers or any linking code or field**. Anonymized data is not automatically considered de-identified data under the Privacy Rule though. To be considered truly anonymized data, the subjects cannot possibly be identified by any means.

Research may be exempt from review when the only involvement of human subjects in the research falls into one of the following categories (1-6):

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. However, when a study involves children being interviewed, questioned or surveyed, that study must be reviewed by the IRB and may not be exempt. Similarly, studies involving children and observation of public behavior in which the Principal Investigator (or other investigator) participates in the activities being observed must be reviewed by the IRB.

3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures (e.g. anonymous questionnaire), interview procedures, or observation of public behavior that is not otherwise exempt 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.