Exempt Categories
Common Rule 45 CFR 46.101(b)

Review Procedure:

Verification of the exemption status of a research proposal is achieved through a review by the CCI Chairperson or by one or more experienced reviewers from among members of the CCI in accordance with the requirements set forth in 45 CFR 46.110. A completed Exemption form and protocol will be reviewed in accordance with CCI Guidelines. Written verification of exemption status will be issued to the Principal Investigator.

Research activities that are considered Exempt, are those in which the only involvement of human subjects will be in one or more of the following:

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: Survey or interview procedures involving minors (0-17) are not exempt, as well as observations of public behavior except when the investigator(s) do not participate in the activities being observed.

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 item #2 above, if:
   i. The human subjects are elected or 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. Existing Data or Specimens:* 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.

*Left-over specimens must be completely de-identified or identified with a code that is not derived from individual personal information (e.g. name, medical record #, date of birth, etc.). Kindly explain in the protocol how specimens will be obtained and anonymity ensured.

NOTE: Ongoing Collection of Data or Specimens: The ongoing collection of data or specimens does not meet the definition of human subject research, as defined by 45 CFR 46.102(f), provided:

i. the data/specimens are not collected specifically for the currently proposed research project, **and**

ii. the data/specimens received by the investigator do not contain a code derived from individual personal information (e.g. name, medical record #, date of birth, etc.).

NOTE: Data/Specimen Analysis: The analysis of coded data/specimens by a local researcher in a multi-site study is not subject to the requirements of 45 CFR 46, provided:

iii. the local PI’s sole research activity in the proposed project is to analyze data/specimens, **and**

iv. the local PI and the holder of the key enter into an agreement prohibiting the release of the key to the local researcher(s) under any circumstances.

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 service 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