

## Exempt Criteria

Research activities are exempt from the federal policy for the Protection of Human Subjects when the ONLY involvement of human subjects falls within one or more of the categories below. Check the appropriate categories that apply to your research project:

\_\_\_\_\_ 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.

\_\_\_\_\_ Research only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, public observation if at least ONE of the following criteria is met:

- (i) recorded information cannot readily identify the subject (directly or indirectly/linked); OR
- (ii) any disclosure of responses outside of the research would reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); OR
- (iii) information is recorded with identifiers or code linked to identifiers & IRB conducts Limited Review

\_\_\_\_\_ Research involving benign behavioral interventions (BBI) through verbal, written responses, (Including data entry or audiovisual recording) from adult subject who prospectively agrees and ONE of the following met: :

- (A) recorded information cannot readily identify the subject (directly or indirectly/linked); OR
- (B) any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); OR
- (C) information is recorded with identifiers & IRB conducts Limited Review.

\_\_\_\_\_ Secondary research for which consent is not required: use of identifiable information or identifiable biospecimen that have been or will be collected for some other “primary” or “initial” activity, if ONE of the following criteria met:

- (i) biospecimens or information is publicly available; OR
- (ii) information is recorded so subject cannot be readily identified (directly or indirectly/linked); investigator does not contact subjects and will not re-identify the subjects; OR
- (iii) Collection and analysis involving investigators use of identifiable health information when use is regulated by HIPAA “health care operations” or “research” or “public health activities and purposes”; OR
- (iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities

\_\_\_\_\_ 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:

- (v) public benefit or service programs;
- (vi) procedures for obtaining benefits or services under those programs;
- (vii) possible changes in or alternatives to those programs or procedures; or
- (viii) possible changes in methods or levels of payment for benefits or services under those programs.

\_\_\_\_\_ 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 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.