Exempt research are human subjects studies that present no greater than minimal risk to subjects and do not have to be reviewed by an IRB Board member.

Exempt categories here do not apply to research involving prisoners.

Check all that apply:

☐ 1. EDUCATIONAL PRACTICES: Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students opportunity to learn required educational content of the assessment of educators who provide instruction. This includes most:

- ☐ 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.

*This category does not apply to use of school records of identifiable students or interviewing instructors about specific students.

2. EDUCATIONAL TESTS: Research involving the use of educational tests (COGNITIVE, DIAGNOSTIC, APTITUDE, ACHIEVEMENT), SURVEY PROCEDURES, INTERVIEW PROCEDURES, OR OBSERVATION OF PUBLIC BEHAVIOR, unless: Research involving these procedures is exempt, IF one of the following is correct:

- ☐ i. Any information obtained is recorded in such a manner that subjects CANNOT be identified, directly or through identifiers linked to the subjects; OR
- ☐ ii. Any disclosure of the subject's responses outside of the research could NOT reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation; OR
- ☐ iii. Any information obtained is recorded by the investigator in such a manner that the identity of the human subjects CAN readily be identified, directly or through identifiers linked to the subjects, AND an IRB conducts a Limited IRB review to make the determination required by 45 CFR 46.111(a)(7) and the research is not subject to 45 CFR 46 Subpart D.

*This exemption does not apply to children except for research involving observation of public behavior when the investigator does not interact with the children. Workplace meetings and activities, as well as classroom activities, are not considered "public behavior".

Exempt research are human subjects studies that present no greater than minimal risk to subjects and do not have to be reviewed by an IRB Board member.

3. BENIGN BEHAVIORAL INTERVENTIONS: RESEARCH INVOLVING Benign Behavioral Interventions in conjunction with the collection of information from adult subjects through verbal or written response (including data entry) or audiovisual recording, if the subject prospective agrees to the intervention and information collection, is exempt, IF

   - ☐ i. Any information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be identified, directly or through identifiers linked to the subjects, OR
   - ☐ ii. Any disclosure of the subject's responses outside of the research could NOT reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; OR
   - ☐ iii. Any information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be identified, directly or through identifiers linked to the subjects, and an IRB conducts a Limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

4. EXISTING DATA: Secondary Research involving collection or study of existing data, documents, records, or biospecimens, for which consent is not required is exempt, IF:

   - ☐ i. The identifiable private information or identifiable biospecimens are publicly available; OR
   - ☐ ii. Information, which may include information about biospecimens, is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify the subjects; OR
   - ☐ iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subpart A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 1.512(b); OR
   - ☐ iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 298(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 5521, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501et seq.

Exempt research are human subjects studies that present no greater than minimal risk to subjects and do not have to be reviewed by an IRB Board member.

5. RESEARCH AND DEMONSTRATION PROJECTS CONDUCTED BY OR SUBJECT TO THE APPROVAL OF DEPARTMENT OR AGENCY HEADS: This research is exempt IF it is designed to study, evaluate, or otherwise examine:

   - ☐ i. Public benefit or service programs;
   - ☐ ii. Procedures for obtaining benefits or services under those programs; OR
   - ☐ iii. Possible changes in or alternatives to those programs, OR
   - ☐ iv. Changes in methods or levels of payment for benefits or services under those programs.

   Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts of consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 115A of the Social Security Act, as amended.

   Note: Each Federal department or agency conducting or supporting research [post on Website]

6. TASTE AND FOOD QUALITY EVALUATION AND CONSUMER ACCEPTANCE STUDIES: This research is exempt, 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 by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service (FSIS) of the US Department of Agriculture (USDA); OR
   - ☐ iii. A food is consumed that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the EPA or the FSIS of the USDA.

7. STORAGE OR MAINTENANCE OF INFORMATION FOR SECONDARY RESEARCH FOR WHICH BROAD CONSENT IS REQUIRED: The protocol is eligible for exemption if:

   - ☐ i. It involves storage or maintenance of identifiable private information or identifiable biospecimens for secondary research use; AND
   - ☐ ii. All the identifiable information or identifiable biospecimens that are to be stored and/or maintained for secondary research have been or will be collected for another "primary" purpose; AND
   - ☐ iii. Broad consent for the storage or maintenance of their identifiable information or identifiable biospecimens for secondary research use will be obtained from ALL subjects; AND
   - ☐ iv. The protocol does not include any activities that do not qualify for exemption; AND
   - ☐ v. The protocol is not for an FDA regulated clinical investigation; AND
   - ☐ vi. The IRB conducts a Limited IRB Review and makes the determinations required by 45 CFR 46.111(a)(8)

Exempt research are human subjects studies that present no greater than minimal risk to subjects and do not have to be reviewed by an IRB Board member.

8. SECONDARY RESEARCH FOR WHICH BROAD CONSENT IS REQUIRED: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use is eligible for exemption, if the following criteria are met:

   - ☐ i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d); AND
   - ☐ ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117; AND
   - ☐ iii. An IRB conducts a Limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; AND
   - ☐ iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.