**IRB**

Name:

IRB File No.:

Date Received:



**Exempt Review Checklist**

**Protocol Information**

**Title of Project:**

**Principal Investigator:**   **Co-PI / Faculty Sponsor:**

**Department:**  **Type of Review:**

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| --- | --- |
| **Certification of Exemption** | |
| The research activities involve only procedures in one or more of the exempt categories:  \_\_\_\_ 1. Research, conducted in established or commonly accepted educational settings, that specifically  involves normal educational practices that are not likely to adversely impact students’ opportunity to  learn required educational content or the assessment of educators who provide instruction.  This includes most research on regular and special education instructional strategies, and research  on the effectiveness of or the comparison among instructional techniques, curricula, or classroom  management methods.  \_\_\_\_ 2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude,  achievement), survey procedures, interview procedures, or observation of public behavior  (including visual or auditory recording), if at least one of the following criteria is met:  \_\_\_ The information obtained is recorded by the investigator in such a manner that the identify of  human subjects cannot be readily ascertained, directly or through identifiers linked to the  subjects;  \_\_\_ Any disclosure of the human subjects’ responses outside the research would not reasonably  place subjects at risk of criminal or civil liability or be damaging to the subjects’ financial  standing, employability, educational advancement, or reputation; or  \_\_\_ The information obtained is recorded by the investigator in such a manner that the identity of  the human subjects can be readily ascertained, directly or through identifiers linked to the  subjects, and an IRB conducts a limited IRB review to make the determination required by  §\_\_\_.111(a)(7)¹.  \_\_\_\_ 3. Research involving benign behavioral interventions in conjunction with the collection of information  from an adult subject through verbal or written responses (including data entry) or audiovisual  recording if the subject prospectively agrees to the intervention and information collection and  at least one of the following criteria is met:  \_\_\_ The information obtained is recorded by the investigator in such a manner that the identity of  human subjects cannot be readily ascertained, directly or through identifiers linked to the  subjects;  \_\_\_ Any disclosure of the human subjects’ responses outside the research would not reasonably  place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial  standing, employability, educational advancement, or reputation; or  \_\_\_ The information obtained is recorded by the investigator in such a manner that the identity of  the human subjects can readily be ascertained, directly or through identifiers linked to the  subjects, and an IRB conducts a limited IRB review to make the determination required by  §\_\_\_.111(a)(7)¹.  Note: If the research involves deceiving the subjects regarding the nature or purposes of the  research, this exemption is not applicable unless the subject authorizes the deception through a  prospective agreement to participate in research in circumstances in which the subject is informed  that he or she will be unaware of or misled regarding the nature or purpose of the research.  \_\_\_\_ 4. Secondary research for which consent is not required: Secondary research uses of identifiable  private information or biospecimens, if at least one of the following criteria is met:  \_\_\_ The identifiable private information or identifiable biospecimens are publicly available.  \_\_\_ Information, which may include information about biospecimens, is recorded by the investigator  in such a manner that the identity of the human subjects cannot readily be ascertained directly  or through identifiers linked to the subjects, the investigator does not contact the subjects, and  the investigator will not re-identify the subjects;  \_\_\_ 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,  subparts 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 164.512(b); or  \_\_\_ The research is conducted by, or on behalf of, a Federal department or agency using  government-generated or government-collected information obtained for nonresearch  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 208(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. 552a, and, if applicable, the information used in the  research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 etseq.­­  \_\_\_\_ 5. Research and demonstration projects that are conducted or supported by a Federal department or  agency, or otherwise subject to the approval of department or agency heads (or the approval of the  heads of bureaus or other subordinate agencies that have been delegated authority to conduct the  research and demonstration projects), and are designed to study, evaluate, improve, or otherwise  examine public benefit or service programs including procedures for obtaining benefits or services  under those programs, possible changes in or alternatives to those programs or procedures; or  possible 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 or consulting arrangements, cooperative agreements, or grants. (i) Each Federal  department or agency conducting or supporting the research and demonstration projects must  establish, on a publicly accessible Federal Web site or in such other manner as the department or  agency head my determine, a list of the research and demonstration projects that the Federal  department or agency conducts or supports under this provision. The research or demonstration  project must be published on this list prior to commencing the research involving human subjects.  \_\_\_\_ 6. Taste and food quality evaluation and consumer acceptance studies:  \_\_\_ If wholesome foods without additives are consumed, or  \_\_\_ 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.  \_\_\_\_ 7. Storage or maintenance for secondary research for which broad consent is required: Storage or  maintenance of identifiable private information or identifiable biospecimens for potential secondary  research use if an IRB conducts a limited IRB review and makes the determinations required by  §\_\_\_.111(a)(8).  \_\_\_\_ 8. Secondary research for which broad consent is required: Research involving the use of identifiable  private information or identifiable biospecimens for secondary research use if the following  criteria are met:  \_\_\_ Broad consent for the storage, maintenance, and secondary research use of the identifiable  private information or identifiable biospecimens was obtained in accordance with  §\_\_\_.116(a)(1) through (4), (a)(6), and (d);  \_\_\_ Documentation of informed consent or waiver of documentation of informed consent was  obtained in accordance with §\_\_\_.117;  \_\_\_ An IRB conducts a limited IRB review and makes the determination required by  §\_\_\_.111(a)(7)¹ 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  \_\_\_ 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.  ¹ \_\_\_.111(a)(7) – When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. | |
| **IRB Action** **(*check one*)**:  Certified as exempt from 45 CFR 46  Modifications required to secure approval  More information needed prior to review  IRB review not required  Comments: | |
| **Signature of Reviewer:** | **Date:** |