**IRB**

IRB File No.:

Date Received:

# Mod Instances:

 **Modification Review Checklist for Exempt Protocols**

**Protocol Information**

**Title of Project:**

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

**Department: Original Approval Date:**

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| **Verification of Exempt Review Status** |
| The research activities present: [ ]  No more than minimal risk to subjects\*[ ]  More than minimal risk to subjects (document justification in comments) *\*A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(i)]* |
| Do the research activities involve only procedures in one or more of the exempt categories? [ ]  Yes: specify category below [ ]  No: Review Type [ ]  Expedited [ ]  Full |
| **Certification of Exemption** |
| [ ]  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.[ ]  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.

[ ]  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. [ ]  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.­­

[ ]  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. [ ]  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.
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| Does the modification(s) cause any potential concerns in this study regarding inclusivity or potential points of tension with exclusivity?  | [ ]  Yes [ ]  No |
| Are there any potential concerns regarding the scientific merit of this study and the competency of the investigator(s) to conduct the study?  | [ ]  Yes [ ]  No |
| Are there any potential concerns regarding the investigators’ knowledge about the regulations and policies governing research with human subjects? | [ ]  Yes [ ]  No |

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| **IRB Action** |
| [ ]  Study remains certified as exempt from 45 CFR 46[ ]  Modifications required to secure approval of this modification (*see comments*)[ ]  More information needed prior to review of this modification (*see comments*)[ ]  IRB review of this modification is not required Comments: |
| **Signature of Reviewer:** | **Date:** |