

IRB CLAIM FOR EXEMPTION

Notice:

Advertising, recruitment of subjects, mailing or distribution of surveys, and the collection of data may begin only after this claim has received approval (completed applications are processed on the 1st and 15th of each month). Upon review of this claim, the IRB may deny the request for an exemption and route the proposal for more detailed review.

PI's Last Name:

Abbreviated Title:

BASIS OF CLAIM FOR EXEMPTION. Federal regulations require that in order for research to be exempt from review at least one of the following blocks (1-8) must be checked. (45 CFR 46.104).

Note:

- The exemptions listed below may be applied to research subject to Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates involved in research.
- The exemptions listed below **do not apply** to research subject to Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, except for research aimed at involving a broader subject population that only incidentally includes prisoners.
- Exemptions 1, 4, 5, 6, 7, and 8 may be applied to research subject to Subpart C – Additional Protections for Children Involved as Subjects in Research. Exemption 2(a) or 2(b) only may apply to research involving children when educational tests or the observation of public behavior occurs when the investigator(s) do not participate in the activities being observed. Exemption 2(c) **may not** be applied to research involving children.

1. The research will be conducted only in established or commonly accepted educational settings (like classrooms) **AND** it 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 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 is met:
 - a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects;

- b. Any disclosure of the human subject's response outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation;
- c. 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 Section .111 (a) (7)

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written response (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:

- a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects;
- b. Any disclosure of the human subject's response outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation;
- c. 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 Section .111 (a) (7)

For the purpose of Exemption 3, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Examples being: video games or doing puzzles under various noise conditions.

If the research involves deceiving the subjects regarding the nature or purpose 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 purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable bio-specimens if at least one of the following criteria are met:

- a. The identifiable private information or identifiable bio-specimens are publicly available;
 - b. Information, including information about bio-specimens, 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;
 - c. 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 or purposes as described under 45 CFR 164.512(b);
 - d. The research is conducted by, or on behalf of, a federal department or agency using 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 208(b) of the E-Government Act of 2002;
 - i. 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 a systems of records subject to the privacy act of 1974.
 - ii. 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 et seq.
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, and that 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 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. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as the sections 1115 and 1115A of the Social Security Act, as amended.
- a. Each Federal department conducting or supporting the research and demonstrating projects must establish, on a publicly accessible Federal Website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects the Federal department or agency conducts or supports published on this list prior to commencing the research involving human subjects.

- 6. Taste and food quality evaluation and consumer acceptance studies:
 - a. If wholesome foods without additives are consumed;
 - b. If a food is consumed that contains a food ingredient at or below the level and for the 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 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 bio-specimens for potential secondary research use if an IRB conducts a limited review and makes the appropriate determinations required by Section .111 (a) (8).

- 8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable bio-specimens for secondary research use if the following criteria are met:
 - a. Broad consent for the storage maintenance, and secondary research use was obtained in accordance with Section .116(a)(1) through (4), (a)(6), and (d);
 - b. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with Section .117;
 - c. An IRB conducts a limited IRB review 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;
 - d. 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.

The research activities of this proposed study involve no minimal risks beyond those of everyday life.

Signature of WTAMU Principal Investigator

Date

Signature of Co-investigator (if applicable)

Date

Signature of Co-investigator (if applicable)

Date

Signature of Co-Investigator (if applicable)

Date