APPLICATION FOR EXEMPTION FROM THE REQUIREMENT FOR IRB REVIEW

Lake Erie College of Osteopathic Medicine

TITLE OF PROJECT:

PRINCIPAL INVESTIGATOR:

- **Please choose which exemption you believe applies to your project. In the space beneath that exemption, please describe your project in sufficient detail to permit an analysis of its qualification for exempt status. If you believe your project will require a "limited IRB review," please see the last page of this application.**

1. Research conducted in established or commonly accepted educational settings that 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.

 Please describe the setting in which the research will be conducted.
 Please describe the instructional strategy or techniques, curricula, or classroom management methods to be used, as well as how effectiveness will be measured or any comparison made.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
    (i) Information obtained is recorded in such manner that human subjects can be identified, directly or through identifiers linked to the subjects, and
    (ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

[The exemption for survey procedures, interview procedures, or observation of public behavior is not available for research involving children, except for observations of public behavior when the investigators do not participate in the activities being observed.]

NOTE: Research involving these methodologies but for which the data is recorded such that the identity of human subjects may be ascertained may qualify for "Exemption Following Limited IRB Review." Please see the last page of this application.

□ *Please attach a copy of the survey, test, script, or any other form to be used and describe how you plan to distribute and collect the surveys.*
□ *If you plan to have subjects participate in the study anonymously, please describe how you will maintain the anonymity of all subjects.*

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 apply:

    (i) Information obtained is recorded in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects
    (ii) 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, or reputation

    [For the purposes of this provision, "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.]

    NOTE: 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.

    NOTE: Research involving these methodologies but for which the data is recorded such that the identity of human subjects may be ascertained may qualify for "Exemption Following Limited IRB Review." Please see the last page of this application.

    □ *please describe the benign behavioral intervention. (Examples include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.)*
    □ *please describe your method for having the subjects prospectively agree to the study.*
    □ *Please describe the method for collecting, recording, and storing data.*
    □ *If you plan to have subjects participate in the study anonymously, please describe how you will maintain the anonymity of all subjects.*
    □ *If the research involves deceiving the subjects, please describe the deception and how you will have subjects prospectively agree to participating in a study where they will be unaware of or misled regarding the nature or purpose of the research.*

4. Secondary research using identifiable private information or biospecimens if at least one of the following criteria is met:
    (i) Those sources are publicly available,
    (ii) If the information is recorded by the investigator in such a manner that the identity of subjects cannot be readily ascertained directly or through indirect identifiers linked to subjects, the investigator does not contact subjects, and the investigator will not re-identify subjects,
    (iii) The research is regulated under HIPAA as “health care operation,” “research,” or “public health activities or purposes,” 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 nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology subject to federal regulations, if all the identifiable information will be maintained in systems of records subject to the Privacy Act of1974, and, if applicable, the information used was collected subject to the Paperwork Reduction Act of 1995.

    Please identify the data you wish to gather and the method for doing so.

5. Research and demonstration projects which are conducted or supported by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:
    (i) Public benefit or service programs;
    (ii) Procedures for obtaining benefits or services under those programs;
    (iii) Possible changes in or alternatives to those programs or procedures; or
    (iv) Possible changes in methods or levels of payment for benefits or services under those programs.

    Please identify the federal department or agency that is conducting or supporting the research.
    Please identify the public benefit or service program that is being examined and/or changed.

6. 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 be safe, or agricultural 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.

    Please describe the food product(s) that will be tested.
    Please provide the ingredients for the food item to be tasted.

7. Storage or maintenance of identifiable private information or biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the following determinations:
    (i) Broad consent is obtained according to statute;
    (ii) Broad consent for storage is appropriately documented or waiver of documentation is appropriate; and
    (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

    - *Please describe the source of private information or biospecimens.*
    - *Please describe the method for obtaining broad consent.*
    - *Please provide a copy of the applicable consent form.*

8. Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following conditions are met:
    (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or biospecimens was obtained in accordance with statute;
    (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with statute;
    (iii) An IRB conducts a limited IRB review (please see the last page of this application); and
    (iv) The investigator does not include returning individual research results to subjects as part of the study plan.

    - *Please describe the source of private information or biospecimens.*
    - *Please describe the method for obtaining broad consent.*
    - *Please provide a copy of the applicable consent form.*

EXEMPTION FOLLOWING LIMITED IRB REVIEW

For exemptions number 2, 3, and 8 above, exemption may be granted following a limited review as noted. To do so, the IRB must determine that there are adequate measures to protect the privacy of subjects and maintain the confidentiality of data.

In the space below, please explain what measures you will take to protect the privacy of subjects and maintain the confidentiality of data.