1.0 Purpose
The purpose of this SOP is to describe the process for determining whether a research proposal is eligible for exempt status.

2.0 Policy
It is the policy of the IRB that all proposed exempt research is reviewed by the IRB staff, in consultation with the IRB Chair or HRPP Director, to determine that the research meets at least one of the categories of exemption from federal regulations for protection of human research participants in accordance with Health and Human Services regulations at 45 CFR §46.101(b).

2.1 Categories of research eligible for exempt status
A. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular or special education instructional strategies; or (ii) research on the effectiveness of, or the comparisons, among instructional techniques, curricula, or classroom management methods.

Educational research proposals are exempt providing all of the following conditions are met:
1. All of the research is conducted in a commonly accepted educational setting (e.g., public school).
2. The research involves normal educational practices (e.g., comparison of instructional techniques).
3. The study procedures do not represent a significant deviation in time or effort requirements from those educational practices already existent at the study site.
4. The study procedures involve no increase in the level of risk or discomfort attendant in normal, routine educational practices.
5. Provisions are made to ensure the existence of a non-coercive environment for those students who choose not to participate.
6. The school or other institution grants written approval for the research to be conducted.

NOTE: Educational projects that do not meet the above-listed conditions are not exempt and must undergo expedited, continuing, or full board review.
B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. If the research involves any of the following, then this exemption does not apply: (1) Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; AND b) any disclosure of the human participants’ responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, or reputation. (2) The research involves surveys, interviews or participant observation with children. (3) The research involves observation or sensitive aspects of a participant’s behavior.

NOTE: Projects involving oral histories are not considered research unless the projects a) utilize a “systematic investigation” with analysis of data to answer a scientific question and b) are designed to develop or contribute to generalizable knowledge.

C. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under B above, if: (1) the human participants are elected or appointed public officials or candidates for public office, or (2) federal statute(s) require(s), without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

D. Research involving the collection or study of EXISTING data, documents, and records, pathological specimens, or diagnostic specimens, if: (1) these sources are publicly available or (2) the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Note: ALL of the data must exist prior to the start of the research for this exemption to apply.

E. Research and demonstration projects which are designed to study, evaluate, or otherwise examine public benefit or service program heads, and which are designed to study, evaluate or otherwise examine: (1) public benefit or service programs; (2) procedures for obtaining benefits or services under those programs; (3) possible changes in or alternatives to those programs or procedures; or (4) possible changes in methods or levels of payment for benefits or services under those programs, if: (i) The projects are conducted by or subject to the approval of Federal Department or Agency heads, and (ii) there is no statutory requirements for IRB review, and (iii) the research does not involve significant physical invasions or intrusions upon the privacy of participants, and (iv) the exemption is invoked with authorization or concurrence by the funding agency.

NOTE: ALL of these criteria must be met for this exemption to apply.

F. Taste and food quality evaluation and consumer acceptance studies, if (1) wholesome foods without additives are consumed, and (2) a food is consumed that contains a food ingredient at or below the level 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.

NOTE: Research which involves photographing, audiotaping, or videotaping of participants during the research may be granted an exemption with some discretion as it relates to identifiability or sensitivity of the research. Projects involving photographing, audiotaping, or videotaping will be reviewed on a case by case basis to determine the risk in relation to the identifiability of the photographs, audios, and/or videos along with the sensitivity of the questions being asked. The use of scrambling technologies, such as voice alteration or blurring/masking, also will be taken into consideration.

2.2 Ineligible Research

A. Sensitive survey research that is identifiable where the disclosure of the human participants’ responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, or reputation.

B. The research involves survey, interviews, or participant observation with children.

C. Research involving prisoners, persons who are decisionally or psychologically impaired, persons who are economically or educationally disadvantaged and other participant populations determined to be vulnerable upon review.

2.3 Ethical Considerations

Although exempt research is not covered by the federal regulations, this research is not exempt from the ethical guidelines of the Belmont Report. The individual making the determination of exemption may require additional protections for participants in keeping with the guidelines of the Belmont Report.

2.4 Process of Review

A. The PI must complete and submit the IRB application form on-line via NUgrant.

B. Utilizing the Exempt Determination Checklist, the IRB specialist, in consultation with the IRB Chair or IRB Administrator, will determine whether an exemption should be granted. The complete exempt protocol application will be reviewed (HRPP Policy 2.014).

C. All exempt research involving human participants must maintain an ethically appropriate standard, which serves to protect the rights and welfare of the participants. This involves informed consent as necessary and confidentiality of data. In some exempt research projects, standard written informed consent must be obtained.

D. If the HRPP office determines that the research qualifies for exempt status, the investigator will be notified within approximately two weeks following receipt of the IRB application.

E. Exempt research, once approved, does not require annual review. Projects that are approved as exempt are valid for five years.
F. All modifications of protocols including *exempt* research must be submitted to the IRB. *Exempt* research, which requires modification during the course of the study whereby it is no longer *exempt*, must be resubmitted to the IRB prior to implementation of the modification.

G. The HRPP office reserves the right to refer applications for *exempt* research to either the *expedited review* procedure or the full IRB for review as necessary.

**NOTE:** Two checklists are used in the exempt review process. They are the *Human Participants Determination Checklist* and the *Exemption Determination Checklist.*

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**Administrative Approval:**

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<tr>
<th>Name</th>
<th>Position</th>
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<tbody>
<tr>
<td>Dan R. Hoyt, Ph.D.</td>
<td>IRB Chair</td>
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<tr>
<td>Kimberly Andrews Espy, Ph.D.</td>
<td>Associate Vice Chancellor for Research</td>
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