

FORM A

Certification for Exemption from IRB Review for Research Involving Human Subjects

A. PRINCIPAL INVESTIGATOR(s) and/or CO-PI(s) (For student projects, list both the student and the advisor.):

B. DEPARTMENT:

C. COMPLETE MAILING ADDRESS AND PHONE NUMBER OF PI(s) and CO-PI(s):

D. TITLE OF PROJECT:

E. EXTERNAL FUNDING AGENCY AND ID NUMBER (if applicable):

F. GRANT SUBMISSION DEADLINE (if applicable):

G. STARTING DATE (NO RESEARCH MAY BE INITIATED UNTIL CERTIFICATION IS GRANTED.):

H. ESTIMATED COMPLETION DATE (Include all aspects of research and final write-up.):

I. RESEARCH PROJECT

1. Objective(s) of Project (Use additional page, if needed.):

2. Subjects (Use additional page, if needed.):

3. Methods or Procedures (Use additional page, if needed.):

4. CATEGORY(s) FOR EXEMPT RESEARCH PER 45 CFR 46 (See instructions for categories.):

J. CERTIFICATION: The research described herein is in compliance with 45 CFR 46.101(b) and presents subjects with no more than minimal risk as defined by applicable regulations.

Principal Investigator:

Name

Signature

Date

Student Advisor:

Name

Signature

Date

Department Review Committee Chair:

Name

Signature

Date

APPROVED:

Department Head:

Name

Signature

Date

COPY OF THIS COMPLETED FORM MUST BE SENT TO COMPLIANCE OFFICE IMMEDIATELY UPON COMPLETION.

INSTRUCTIONS FOR COMPLETING FORM A
PLEASE TYPE THE INFORMATION REQUESTED ON THE FRONT OF THIS FORM

Provide the required information in the space available if at all possible. If additional space is necessary, attach a separate sheet. Submit one copy of this form to the Chair of your Departmental Review Committee for review and approval. [PLEASE NOTE: This form may be reproduced on a personal computer and printed on a high

ALL SIGNATURES MUST BE ORIGINAL on this form. When certified by your department or unit head, a copy of the signed Form A will be returned to the Principal Investigator and a copy will be returned to the Research Compliance Services Section, Office of Research.

I.1. OBJECTIVES: Briefly state, in non-technical language, the purpose of the research, with special reference to human subjects involved.

I.2. SUBJECTS: Briefly describe the subjects by number to be used, criteria of selection or exclusion, the population from which they will be selected, duration of involvement, and any special characteristics necessary to the research.

I.3. METHODS OR PROCEDURES: Briefly enumerate, in non-technical language, the research methods which directly involve use of human subjects. List any potential risks, or lack of such, to subjects and any protection measures. Explain how anonymity of names and confidentiality of materials with names and/or data will be obtained and maintained. List the names of individuals who will have access to names and/or data.

I.4. CATEGORY(S) FOR EXEMPT RESEARCH PER 45 CFR 46: Referring to the extracts below from Federal regulations, cite the paragraph(s) which you deem entitle this research project to certification as exempt involvement of the human subjects will be in an **IRB** review:
45 CFR 46.101(b) Research categories in which the only

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(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 a 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.

PLEASE NOTE : *An exemption cannot be used when children are involved for research involving survey or interview procedures or observations of public behavior, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed. [[45 CFR 46.401\(b\)](#)]*

(3) 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 paragraph (2) above, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

(5) Research and demonstration projects which are conducted 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.

(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 contaminants 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 US Department of Agriculture.

For additional information on Form A, contact the Office of Research

phone at (865) 974-3466. Compliance Officer by e-mail or by