**LEE UNIVERSITY**

**HUMAN SUBJECTS REVIEW FORM**

Completion of this form is required for each research project using human subjects. This document acts as a statement by the investigator that the project complies with The Public Health Service Act (P.L. 93-348) as implemented by HHS regulation 45 CFR 46 and Lee policies.

Principal Investigator:

(If a student, please list faculty advisor as co-investigator)

Department: Address: Tel No.

Co-Investigator:

Department: Box No. Tel No.:

Estimated Period for This Project:

Source of Funds/Funding Agency:

Project Title:

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Please check one of the following:

1. This project meets the requirements of Paragraph 46.101(b) and is exempt.

(Please complete sections A[check the appropriate exemption category] and B and

attach a copy of the survey if applicable).

2. This project does not meet the requirements of Paragraph 46.101(b) and is

not exempt from committee review. (Please complete Section B and C and

attach a copy of the survey and/or Informed Consent form if applicable.)

Signature:

Principal Investigator

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**COMMITTEE USE ONLY**

EXPEDITED REVIEW

Protocol No. Date Received:

This project does does not meet requirements for exemption.

Comments:

Chairperson of IRRB (or assigned representative) [Signature if approved]

FULL REVIEW

Committee Review

Date of Disposition:

Approved Modified Disapproved

Comments:

Reviewers:

Chairperson: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION A**

EXEMPT RESEARCH PROJECTS

[Par. 46.101(b)]

\_\_\_ 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

a. research on regular and special education instructional strategies or

b. research on the effectiveness of or the comparison among instructional techniques,

curricula, or classroom management methods.

\_\_\_ 2.Research involving the use of educational tests such as (cognitive, diagnostic, aptitude,

achievement, personality), survey procedures or observation of public behavior **unless**:

a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

b. 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

\_\_\_ 3. Research involving the use of educational tests such as (cognitive, diagnostic, aptitude

achievement, personality), survey procedures or observation of public behavior that is not

exempt under paragraph (b)(2) of this section if:

a. the human subjects are elected or appointed public officials or candidates for public

office; or

b. 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 Department or Agency (federal govt.) heads, and which are designed to study, evaluate, or otherwise examine:

a. Public benefit or service programs;

b. Procedures for obtaining benefits or services under those programs;

c. Possible changes in or alternatives to those programs or procedures; or

d. 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,

a. if wholesome foods without additives are consumed or

b. 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 FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S. Dept. of Agriculture.

**SECTION B**

TITLE OF PROJECT:

PRINCIPAL INVESTIGATOR:

CO-INVESTIGATOR:

1. Project Description: Provide a concise description including purpose and objectives.

2. Provide a detailed description of all procedures involving human subjects including (but not limited to):

a. Subject Selection Procedure:

b. Informed Consent Procedures (attach a copy of the Informed Consent) Describe the process to be followed for obtaining consent. If children are involved in your research, describe the process to be followed for also assuring their assent to participate.

c. Measures to be collected on Human Subjects -- Describe all measures (i.e. tests, surveys, observations, questionnaires, interview questions, assessment scales to be collected or used on your subjects). Attach a copy of each measure.

3. Is this an experimental project? (involves any manipulation of human behavior or assigns subjects to experimental versus control groups?

YES NO

4. Are any risks pertaining to subject's physical well being likely to occur?

YES NO

5. Do you expect any possible psychological or emotional risks? YES

NO

6. Will the responses or data be recorded in such a manner that the human subject can be identified?

YES NO If yes, describe how the collected data will be secured.

**PLEASE NOTE:**

**If an "expedited review" project extends beyond a 5-year period, you are required by federal law to submit a new application to be reviewed at the end of five years. The IRRB may require this more often if they deem it necessary. Please check with the chairperson. Exempting an activity from review does not absolve the investigator(s) from ensuring that the welfare of the subjects participating in the research is protected and that methods used and information provided to gain subject consent are appropriate to the activity. Also, it is the investigator(s) responsibility to notify the IRRB if any changes or modifications are made in the study's design, procedures, etc.**

SECTION C

Please attach a copy of the proposal for the study (typed, double-spaced). This should be similar to the proposal for a dissertation in the field of study and should include categories that are specific to the discipline and the type of research under study. If the research is being submitted to or is supported by an external or internal funding agency or program, a copy of the grant or proposal that will be submitted for funding can be used. Since this research involves human subjects all proposals must also include: a discussion and analysis of all possible risks in the proposed methodology , rationale as to why the benefits of this study outweigh the risks, proposed method for absolving any negative consequences (such as debriefing, etc.)

**PLEASE NOTE:**

**Research projects in the "full review" category must be reviewed and approved annually by the IRRB. It is the investigator(s) responsibility to notify the IRRB if any changes or modifications are made in the study's design, procedures, etc. or if any accidents or problems have occurred involving the human subjects.**