**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(s):

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

School/Department: Address:

Tel No.:

Co-Investigator(s):

Estimated Time Period for This Project:

Source of Funds/Funding Agency:

Project Title:

Please check one of the following:

1. This project meets the requirements of [Paragraph 46.101(b)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML) and is exempt.

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

2. This project does not meet the requirements of [Paragraph 46.101(b)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML) and is

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

Principal Investigator’s Signature:

Date:

=====================================================================

Has the Principal Investigator and Co-Investigator(s) previously completed a responsible conduct of research (RCR) training course, such as ones provided by the NIH or CITI?

Check one: YES\* NO\*\*

\*If you checked yes, please include a copy of your completion certificate when you submit this form for review.

\*\*If you checked no, you are required to complete a training course and submit the completion certificate before your proposal can be approved. Please contact a member of the IRB if you need access to one of these training courses.

SECTION A

 EXEMPT RESEARCH PROJECTS

 [[Par. 46.101(b)]](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML)

\_\_\_ 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

1. Provide a concise description (~1-2 paragraphs) of your proposed project, including purpose and objectives.

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

a. **Subject selection procedure**, including a description of your target population, recruitment procedures, intended sample size, and sampling method:

b. **Informed consent procedures**, including how participants will receive the consent form (e.g., hard copy, electronically) and how participants will indicate consent. Please attach a copy of the Informed Consent form at the end of this document.

c. **Measures to be collected on Human Subjects**. Please describe all measures (i.e., tests, surveys, observations, questionnaires, interview questions, assessment scales to be collected or used on your participants). Provide a copy of each measure at the end of this document.

3. Is this an experimental project? That is, does your project any manipulation of human behavior or assigning participants to experimental/control groups?

Check one: YES\* NO

\*If you checked “yes,” please describe your manipulation below.

|  |
| --- |
|  |

4. Are any risks pertaining to participants’ physical well-being likely to occur?

Check one: YES\* NO

\*If you checked yes, please describe the nature of the physical risk present in this study and what protections you will put in place to protect against this risk.

|  |
| --- |
|  |

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

Check one: YES\* NO

\*If you checked yes, please describe the nature of the psychological or emotional risks present in this study, and what protections you will put in place to protect against this risk.

|  |
| --- |
|  |

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

Check one: YES\* NO

\*If you checked yes, please justify the need to identify participant data and explain how these data will be secured.

|  |
| --- |
|  |

7. Does this study involve significant deception to the participants?

Check one: YES\* NO

\*If you checked yes, please justify why deception is necessary to conduct this study and why the potential value of the findings merits this deception.

|  |
| --- |
|  |

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:**

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 IRB 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 IRB if any changes or modifications are made in the study's design, procedures, etc.

Research projects in the "full review" category must be reviewed and approved annually by the IRB. It is the investigator(s) responsibility to notify the IRB 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.

**INFORMED CONSENT FORM**

Lee University

Project Title:

You have been asked to take part in a research project described below.  The following instructions will explain the project to you in detail. If you have questions after completing the following surveys, please contact [NAME] at [PHONE#] or [EMAIL].

**Description of the project:**

**Procedures:**If you decide to take part in this study, here is what will happen:

**Risks or discomfort:**The risks that you will be exposed to in this study are minimal.

**Benefits of this study:**It is hoped that results of this study will be presented or published in a scientific setting that will allow for better understanding of…

**Compensation:**There is no compensation for participating in this study.
**Confidentiality:**Your part in this study is confidential within legal limits.  The researchers and Lee University will protect your privacy, unless they are required by law to report information to city, state or federal authorities, or to give information to a court of law. Your data will be matched by code to your identity so your results can be tracked over time.  However, all reported, presented, and published data will have all identifying information removed. All data will be collected on paper or on password-protected computers, to which only members of the research team have access. After completion of the research, all paper data will be securely stored in the locked lab rooms, and all computer data will be stored on password-protected computers.

**Voluntary participation and withdrawal:**All participation is voluntary.  Refusal to participate in any or all aspects of this project will be immediately honored.  If you decide to be in the study and change your mind, you have the right to drop out at any time. If you drop out during this study, please contact the researcher to obtain credit for participating.

**Questions, Rights and Complaints:**If you have questions after completing the following surveys, please contact [NAME] at [PHONE#] or [EMAIL]. If you have any questions or concerns about your rights as a research participant in this study, please contact the IRBirr at Lee University (bpoole@leeuniversity.edu).

**Consent statement**By reading and moving to the next screen you consent to participating (or having your child participate) in this project being given by the [INSERT DEPARTMENT/SCHOOL HERE] Department at Lee University.  This statement certifies the following: that you are 18 years of age or older and you have read the consent and all your questions have been answered.  You understand that you may withdraw from the study at any time.  All of the answers you provide will be kept private.  You have the right to see the results of this study if you wish.   A copy of the informed consent will be given to you if requested.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Please copy and paste all measures and manipulations below**

**COMMITTEE USE ONLY**

EXPEDITED REVIEW

Protocol No. Date Received:

This project does does not meet requirements for exemption.

Comments:

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

FULL REVIEW

 Committee Review

Date of Disposition:

Approved Modified Disapproved

Comments:

Reviewers:

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