**FORM**

**Checklist for Research Qualifying as Exempt with**

**Guidelines for Protocol Preparation**

Directions: If you believe that your project qualifies for Exempt Review, please submit the following materials to the IRB: (a) a completed copy of this form; (b) an indication of the date of completion of the IRB training program in Part I General Information (Note: faculty members submit an indication of the date of completion of IRB training certification and students submit the date of completion of the course serving as training certification); (c) a research proposal or thorough document of your procedures and materials. a research proposal or thorough documentation of your procedures and materials indicated in Part C and D. Please check all applicable items in Parts A and B and provide all relevant information in Part C. Either complete or attach a complete research proposal that addresses the items outlined in Part D.

***Research activities will only be considered for exemption from further review when all items in Part A and at least one item in Part B apply.***

**I. General Information**

|  |  |
| --- | --- |
| A. Protocol Information | |
| Protocol Title: | |
| Is this research part of a thesis or dissertation proposal? No Yes    If yes, has the thesis or dissertation proposal been approved? No Yes | |
| B. **Principal Investigator Information** | |
| Principal  Investigator | Department |
| Telephone  Number | Email  Address |
| Date of Completion of IRB Training Certification: | Mailing  Address |
| **Co-Principal Investigator Information** | |
| Co- Principal  Investigator | Department |
| Telephone  Number | Email  Address |
| Faculty Staff Grad. Student Undergrad. Student | Mailing  Address |
| Course Number and date of completion certifying training or Date of IRB Training Certification: | |
| **Co-Principal Investigator Information** |  |
| Co- Principal  Investigator | Department |
| Telephone  Number | Email  Address |
| Faculty Staff Grad. Student Undergrad. Student | Mailing  Address |
| Course Number and date of completion certifying training or Date of IRB Training Certification: | |

**II. Principal Investigator Assurance**

**As Principal Investigator, I certify that to the best of my knowledge**:

**1.** The information provided for this project is correct

**2**. No other procedures will be used in this protocol

**3.** I agree to conduct this research as described in the attached supporting documents

**4.** I will request and receive approval from the IRB for changes prior to implementing changes (including but not limited to

changes in cooperating investigators or any changes in procedures).

**5.** I will comply with IRB and LINCOLN COLLEGE policies for conducting ethical research.

**6.** I will be responsible for ensuring that the work of my co-investigator(s)/student researcher(s) complies with this protocol.

**7.** Any unexpected or otherwise significant events in the course of this study will be promptly reported to the IRB.

**8.** In the case of student research, I assume responsibility for ensuring that any student will comply with College and Federal regulations regarding the use of human subjects in research.

**9**. In the case of externally funded research, I willrequest a modification to my approved protocol if any relative changes to the project’s scope of work are requested by the agency.

**Principal Investigator Signature Date**

**Part A:**

1.\_\_\_\_\_ The research does not involve prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects.

2.\_\_\_\_\_ The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

3.\_\_\_\_\_ The research does not involve the collection of information regarding sensitive aspects of the subjects’ behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

4.\_\_\_\_\_ The research does not involve subjects under the age of 18 (Exception: research with subjects under the age of 18 may still be subject to exempt review if they are participating in projects that fall under categories 1, 3, 4 and/or 5 in Part B). Studies under Part B-2 that include minors should be submitted for expedited review.

5.\_\_\_\_\_ The research does not involve deception.

6.\_\_\_\_\_ The procedures of this research are generally free of foreseeable risk to the subject.

**Part B**

(Check all categories that apply to your research project):

1.\_\_\_\_\_ The research will be conducted in established or commonly accepted educational settings and will involve normal educational practices (e.g., research on regular and special education instructional strategies, research on instructional techniques, curricula, or classroom management methods).

2.\_\_\_\_\_ The research will involve any of the following (indicate the letter of all that apply):

(a) the use of educational tests (cognitive, diagnostic, aptitude, achievement),

(b) survey procedures,

(c) interview procedures or observation of public behavior in which information will be recorded anonymously (i.e., so that the human subject cannot be identified, directly or through identifiers linked to the subject).

3.\_\_\_\_\_ The research will involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. These sources are either publicly available or the information will be recorded anonymously (i.e., in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject).

4.\_\_\_\_ The research (including demonstration projects) will be conducted by or subject to the approval of federal department or agency heads, and is designed to study, evaluate, or otherwise examine:

a. public benefit or service programs (e.g., social security, welfare, etc.);

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

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

d. possible changes in methods or levels of payment for benefits or services under those programs.

5. \_\_\_\_ The research involves taste or food quality evaluations or consumer acceptance studies and the tested products are wholesome foods without additives or foods which contain additives at or below levels found to be safe by the FDA or approved by the EPA of the Food Safety and Inspection Service of the US Department of Agriculture.

**Part C**

1. Describe approximately how much time each subject is expected to devote to the research.

2. How data will be collected and recorded (with or without identifiers? what instruments, materials, or equipment will be used? will audio-or videotapes be employed in data collection?). Append copies of all written instruments and/or describe any apparatus with which subjects will be in direct contact.

3. Describe the methods for obtaining informed consent (or assent in the case of minors).

4. Describe the methods for preserving confidentiality (including plans for storing/disposing of tapes and other data records.

5. Indicate any benefits that are expected to accrue to subjects as a result of their participation in the research. In the event that subjects will be paid, describe all payment arrangements, including how much subjects will be paid should they choose to withdraw from the study prior to completion of the research.

6. Describe any relationship between researcher and subjects, such as: teacher/student; superintendent/principal/teacher, employer/employee. If such a relationship exists, how will it affect the subject's ability to participate voluntarily and how will the Principal Investigator handle it?

**Part D**

Please provide the information that is requested below. A research proposal may be attached.

1. What is the purpose of the proposed study (the research question) and what is the research hypothesis?

2. Describe the proposed subject sample. If subjects under the age of 18 will participate in your research, indicate the expected age range of the samples.

3. How will subjects be recruited and selected?

4. Describe all research methods and procedures that will be employed in this study.