**FORM**

**Checklist for Research Qualifying for Full Review with**

**Guidelines for Protocol Preparation**

Directions: If you believe that your project qualifies for Full 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 be considered for Full Review when at least one of the items in Part A applies.***

**I. General Information**

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| --- |
| 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 |
| TelephoneNumber | EmailAddress |
| Date of Completion of IRB Training Certification: | Mailing Address |
| **Co-Principal Investigator Information** |
| Co- Principal Investigator | Department |
| TelephoneNumber | EmailAddress |
|  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 |
| TelephoneNumber | EmailAddress |
|   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 targets as participants: prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects.

2. \_\_\_\_\_ The research involves the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability, be stigmatizing, or be damaging to the subject's financial standing, employability, insurability, or reputation.

3. \_\_\_\_\_ The research involves the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

4. \_\_\_\_\_ The procedures of this research present more than a minimal risk to the subject (where minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are no greater than those ordinarily encountered in daily life or during the performance of routine physical/psychological examinations or tests).

5. \_\_\_\_\_ Research that involves deception [NOTE: Deception must be scientifically justified and de-briefing procedures must be outlined in detail. Based upon the judgment of the reviewers, some protocols involving deception may qualify for expedited review. In other cases, the deception will be of sufficient consequence to require full IRB review.]

6. \_\_\_\_ Collection of data through the use of invasive biomedical procedures including: a) invasive procedures routinely employed in clinical practice; b) physical sensors that are applied either to the surface of the body or at a distance and involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; c) excessive exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

**Part B**

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. If deception is to be employed, provide a scientific justification for its use and describe debriefing procedures. [NOTE: If the research is such that debriefing cannot be carried out, the project must be submitted for full committee review.]

6. If biomedical procedures are to be employed, provide a scientific justification for their use and describe debriefing procedures. [NOTE: If the research is such that debriefing cannot be carried out, the project must be submitted for full committee review.]

7. 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.

8. 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 C**

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 and a justification of the need for recruiting that subject sample for the study. If subjects under the age of 18 will participate in your research, indicate the expected age range of the samples. If subjects are members of another protected class of participants, provide a justification for the recruitment of those subjects.

3. How will subjects be recruited and selected?

4. Describe all research methods and procedures that will be employed in this study including proposed data analysis.