 IRB Protocol #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

irb

**Request for Determination**

**This form is to be used to determine if this project is Human subjects research**

*If you choose to use this form, you do not need to attach supporting information*

*However, if the project is determined to be human subjects’ research, you will need to submit the “Request for Review” form001*

Research projects that involve human subjects must be reviewed and determination made by the LU Institutional Review Board prior to beginning the research.

Note: LU Policy requires that all persons listed on this document show successful completion of training in the protection of human subjects in research. Please attach documentation of training for all listed persons. \*This protocol will not be reviewed until all CITI training certificates are attached.

|  |  |
| --- | --- |
| Principal Investigator | Email: |
| Department: | Phone: |
|  |  |
| Co-Principal Investigator: | Email |
| Department: | Phone:  |
|  |  |
| Co-Principal Investigator: | Email: |
| Department: | Phone: |
|  |  |
| Co-Principal Investigator: | Email: |
| Department: | Phone: |
|  |  |
| Co-Principal Investigator: | Email: |
| Department: | Phone: |
|  |  |
| Faculty Advisor:(If PI or Co-PI is a student) | Email: |
| Department: | Phone: |
|  |  |
| Project Title: |  |
|  |  |
| Agency: |  |
|  |  |
| Anticipated start date: | Anticipated End date:  |
| Will data be owned solely by the Agency? | Yes |  | No |

**Description of human subjects:**

Are any subjects under 18 years of age? Yes No

Are any subject confined in a correctional or detention facility? Yes No

Are personal records (medical, academic, etc.) used without written consent? Yes No

Are personal records (medical, academic, etc.) directly or indirectly identifiable? Yes No

Are data (quantitative or qualitative) from subjects used without written consent? Yes No

Are data (quantitative or qualitative) directly or indirectly identifiable? Yes No

Is pregnancy a prerequisite for serving as a subject? Yes No

Is any of the research conducted at a location other than LU? Yes No

If YES, where:

***Provide the information listed below:***

|  |
| --- |
| 1. **Describe the significance of the project?**
 |
| What is the significance/purpose of the study?/Please provide a brief 1-2 paragraphs explanation in lay terms. |
|  |

|  |
| --- |
| 1. **Describe the methods and procedures**
 |
| Describe the data collection procedures and what participants will have to do: |
| How long will this take participants to complete: |
| Will follow-ups or reminders be sent? If so, explain: |

|  |
| --- |
| 1. **Describe the recruiting procedures**
 |
| How will the names and contact information for participants be obtained: |
| How ill participants be approached about participating in the study? |
| Please attach copies of recruitment fliers, ads, phone scripts, emails, etc. |

Electronic submission is not accepted without all signatures. We will accept an electronic signature.

**Principal Investigator:**

I certify that the information provided above is correct and that, to the best of my ability, this research will be conducted in accordance with Federal Regulations and LU policies and procedures on research with Human subjects.

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

**Departmental Chairperson/Supervisor**: (**if PI is a Student**)

I certify that I have reviewed and approve this PI/student submission. I agree to supervise the research conducted by the PI/student and I am aware that Ian the responsible party for this research. I certify that this research will be conducted in accordance with the Federal regulations and Lu IRB Policies and procedures on research with Human subjects.

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

Send completed electronic submission to Lu-rb@lincoln.edu. If mailed, to :

**IRB Administrator,**

**Research and sponsored Programs,**

**Wright Hall, Rm 118**

**Tel: 484-365-7696**

**Checklist for the Informed Consent Form (cover letter, email, etc).**

**Basic information that MUST be included:**

Project description

|  |  |
| --- | --- |
|  | Is the project title identified? |
|  | Is it stated that the study involves research |
|  | What is the purpose of the research? |
|  | How long will it take to participate? |
|  | Why participants was selected |
|  | Is the age of participant stated (under 18 needs [parental consent) |
|  | Are procedures described |
|  | Where will it take place |
|  | Are experimental procedures identified? (include if applicable) |
| Risks, benefits and alternatives |
|  | Are risks and discomfort to participants explained? If no risks, does it say no known risks |
|  | If there are risks, what will be done to minimize the risks? Referrals? |
|  | Are benefits to participants and to others that might be expected from the research explained? |
|  | Are alternative procedures or course of treatment that might be advantageous to the participant identified? |
|  | If the study offers course credit, are alternative ways to earn the credit explained? |
|  | What is the alternative for those who choose not to participate? |

Confidentiality

|  |  |
| --- | --- |
|  | Will confidentiality of records identifying participants be maintained? |
|  | How will data be reported scientific journal, professional meeting aggregated data, report? |

Compensation

|  |  |
| --- | --- |
|  | Is compensation offered? |
|  | Are medical treatments available if injury occurs? |
|  | Who will pay for treatments (participant, etc)? |
|  | What conditions would exclude participants from participants? |

Right to ask Question

|  |  |
| --- | --- |
|  | Is it stated that participants have the right to ask questions and to have those questions answered? |
|  | Is contact information for the primary investigators provided? |
|  | Does it refer individuals with questions to the IRB and provide the contact information and email? |

Freedom to Withdraw

|  |  |
| --- | --- |
|  | Does it state: “You are free to decide not to participate in this study. You can also withdraw at any time without harming your relationship with the researchers or the Lincoln University of Pennsylvania”. |
|  | Does it state that participation is voluntary? |