**Eastern Illinois University**

For IRB use only

Level of Review:

**Institutional Review Board (IRB)**

**PROPOSED** **MODIFICATIONS TO PROTOCOL AFTER IRB APPROVAL**

**Directions:** All items require a response unless otherwise indicated. Changes to informed consent/assent form(s) must also be review by the IRB. The completed application should be e-mailed to eiuirb@eiu.edu

|  |  |
| --- | --- |
| IRB Number: |  |
| Title of Project: |  |
| **Investigator(s)** |
| Principal Investigator: |  | Status: | Choose an item. |
| Email: |  | Phone: |  |
| Department or Unit: |  |
| Co-Investigator:  |   | Status: |  Choose an item. |
| Email: |  | Phone: |  |
| Department or Unit: |  |
| If there is more than one Co-Investigator, complete the [Application for IRB Review Addendum: Additional Co-Investigators](https://www.eiu.edu/grants/Application%20for%20IRB%20Review%20Addendum%20Additional%20Co-Investigators.docx) and include it with this submission.  |
| **Project Modification Information:** |
| 1. Are there any proposed changes in the protocol requested?
 |
| [ ] No [ ] Yes: describe proposed changes below and submit protocol with revisions incorporated:  |
| 1. Are there any proposed changes to the informed consent/assent form(s)?
 |
| [ ] No [ ] Yes: describe changes below and attach new consent/assent form(s) with changes highlighted:  |
| 1. Are there any additions and/or changes in location where data are being collected?
 |
| [ ] No [ ] Yes: list additional sites or changes below. Attach approval letters when required. |
| 1. Are there changes in key personnel assisting in the research project?
 |
| [ ] No [ ] Yes: list changes (i.e., who is being added, who has left project). If there are personnel being added to the project, complete the complete and attach the [Application for IRB Review Addendum: Additional Co-Investigators](https://www.eiu.edu/grants/Application%20for%20IRB%20Review%20Addendum%20Additional%20Co-Investigators.docx): |
| 1. Describe any proposed changes not listed above.
 |
|  |

**Investigator Assurance:**

All boxes must be checked, and the form must be signed, either by pen or electronically

[ ]  I certify that the information provided for this project is accurate and compiled by me.

[ ]  I agree to conduct this research as described in this form and in the attached supporting documents, and that no other procedures will be used in this research.

[ ]  I will request approval from the IRB for changes to the study’s protocol and/or consent forms and will not implement the changes until I receive IRB approval for these changes.

[ ]  I will comply with the IRB policy for the conduct of ethical research. I will promptly report significant or adverse effects to the IRB in writing within 5 days of occurrence.

[ ]  I will complete, on request by the IRB, the Continuation Request or Completion of Research Activities Forms.

If there are co-investigators other than faculty/EAP sponsors involved in this project:

[ ]  I assure that the co-investigator(s) is knowledgeable about the regulations and policies governing research with human subjects, and will monitor study progress and compliance with IRB policy for the conduct of ethical research.

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Principal Investigator’s Signature Date

**Faculty or EAP Staff Sponsor Assurance (required when PI is a student):**

All boxes must be checked, and the form must be signed, either by pen or electronically

[ ]  This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project.

[ ]  I assure that the investigator(s) is knowledgeable about the regulations and policies governing research with human subjects.

[ ]  I agree to meet with the investigator on a regular basis to monitor study progress and compliance with IRB policy for the conduct of ethical research.

[ ]  I will promptly report any significant or adverse effects that I am made aware of to the IRB in writing within 5 days of occurrence.

[ ]  I understand my responsibilities and what is required of me when sponsoring student research

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Faculty or EAP Staff Sponsor’s Signature Date

Signed forms can be e-mailed as attachments to the Office of Research and Sponsored Programs at eiuirb@eiu.edu.

While e-mail submission is preferred, paper copies will also be accepted. Deliver unstapled paper copies to the Office of Research & Sponsored Programs, 1102 Blair Hall.

**Do not submit forms via links to personal or shared drives
(such as OneDrive or Google docs).**