## Eastern Illinois University

**Institutional Review Board (IRB)**

**Request for** **CONTUNIATION of PROTOCOL**

Federal guidelines (45 CRF 46.109e) require that Institutional Review Boards (IRB) “conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year.” In conducting the continuation review, the IRB will review, at a minimum, a protocol summary and informed consent/assent forms, as well as a status report on the progress of the research.

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| --- | --- |
| 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 Information:** |
| Project begin date: |  | Estimated project end date: |  |
| Approximate total number of subjects who will be enrolled: |  |
| Number of subjects actually enrolled as of this date: |  |
| Number of subjects who have dropped out: |  |
| Number of subjects who have formally withdrawn:  |  |
| If subjects have withdrawn, please summarize reason(s) for withdrawal: |
|  |
| 1. Since the last IRB review, have any injuries or adverse events occurred?
 |
| [ ] No [ ] Yes: summarize injuries or events:  |
| 1. Since the last IRB review, have any unanticipated problems involving risks to subjects or others occurred?
 |
| [ ] No [ ] Yes: summarize problems:  |
| 1. Since the last IRB review, have any complaints about the research been received?
 |
| [ ] No [ ] Yes: summarize complaints: |
| 1. Are there any proposed changes in the protocol requested?
 |
| [ ] No: Attach a protocol summary. Include IRB approved amendments or modifications to the research since the last review. [ ] Yes: describe proposed changes below and submit protocol with revisions incorporated. Include IRB approved amendments or modifications to the research since the last review.  |
| 1. Are there any proposed changes to the informed consent/assent form(s)?
 |
| [ ] No: Attach a copy of the informed consent/assent forms [ ] 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. Summarize any relevant recent literature and interim findings.
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|  |
| 1. If this is a multi-center trial, summarize any relevant trial reports.
 |
|  |
| 1. Summarize any other relevant information, especially information about risks associated with the research, not requested above.
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|  |

**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).**