## Eastern Illinois University

**Institutional Review Board**

**REPORT OF PROBLEMS INVOLVING RISK, ADVERSE EFFECTS, OR NONCOMPLIANCE**

All problems involving risk to subjects or others, injury or other adverse effects experienced by subjects in research, and incidents of noncompliance must be reported to the IRB immediately. This report should be submitted as soon as possible, but **no later then 5 working days** after first awareness of the problem.

|  |  |  |  |
| --- | --- | --- | --- |
| Issue Reported by: |  | | |
| Date Reported: |  | Protocol IRB File #: |  |
| Report Completed by: |  | Completion Date: |  |

**Project Information:**

|  |  |  |  |
| --- | --- | --- | --- |
| Title of Project: |  | | |
| **Principle Investigator** | | | |
| Name: |  | | |
| Status: | Faculty Student EAP Staff Other: | | |
| Department or Unit: |  | | |
| E-mail: |  | Phone: |  |
| **Co-Investigator or Sponsor**  Note: Students engaging in research are required to have a faculty sponsor or executive, administrative, or professional (EAP) staff sponsor. | | | |
| Name: |  | | |
| Status: | Faculty Student EAP Staff Other: | | |
| Department or Unit: |  | | |
| E-mail: |  | Phone: |  |
| List any additional co-investigators on a separate sheet and include the above information. | | | |

**Incident Information:**

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| --- | --- | --- | --- |
| Provide a description of the problem involving risk to subjects or others, adverse effect, or noncompliance: | | | |
|  | | | |
| Date(s) of occurrence(s): | |  | |
| Effect on human subjects: | | Mild  Moderate  Severe  Fatal | |
| Was the event related to the research procedure? | | | Yes  No  Maybe  Unknown |
| Was treatment provided to the subject or other affected person? | | | |
|  | N/A –Treatment was not necessary | | |
|  | Yes – Describe the treatment provided. Include the date(s) of treatment and who provided it: | | |
|  | No – Explain why necessary treatment was not provided: | | |

**Potential Corrective Action:**

Changes necessitated by the problem involving risk to subjects or others, adverse effect, or noncompliance

|  |  |
| --- | --- |
| In your judgment is a change in your protocol necessary to reduce or eliminate risk? | |
|  | Yes - Provide revised protocol with changes highlighted:  **Note: data should not be collected until the revised protocol is approved by the IRB** |
|  | No - Provide a brief rationale: |
| Informed Consent/Assent Document(s): Are any changes required in the informed consent/assent document(s) to better inform and protect the rights and welfare of the subjects? | |
|  | Yes - Attach the revised consent/assent form with changes highlighted:  **Note: New subjects may not be enrolled in the study until the revised consent/assent form(s) is approved by the IRB.** |
|  | No - Provide a brief rationale: |

**Notification:**

|  |  |
| --- | --- |
| Is it necessary to inform presently enrolled subjects or legal representatives of the adverse event? | |
|  | Yes - Describe how subjects or legal representatives will be informed. If necessary, attach a revised consent or assent form: |
|  | No - Provide a brief rationale: |

**Additional Information:**

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| --- |
| Please provide any additional necessary information or comments: |
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Principal Investigator’s Signature Date

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Faculty or EAP Staff Sponsor’s Signature Date

(required when a student is the PI)