

**HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD**

**Incident Report**

*Any incidents which include unanticipated problems, adverse events, or injuries to human subjects during research must be reported to the Institutional Review Board upon discovery of the incident by the primary investigator within no more than 7 calendar days. If this incident report concerns a student protocol, it should be filled out by the faculty supervisor.*

|  |  |
| --- | --- |
| **Study Title:** |  |
| **IRB Protocol Tracking Number:** |  |
| **Name of Primary Investigator:** |  |
| **Phone of Primary Investigator:** |  |
| **Email of Primary Investigator:** |  |
| **Date of Incident:** | Select a date |
| **Date Incident was Discovered by Research Personnel:** | Select a date |

**Describe the incident:**

(Include where the incident occurred, severity, duration, timing of events, action taken, outcome, personnel involved, and corrective action plan, as applicable)

Enter your response here

|  |  |
| --- | --- |
| **In the opinion of the primary investigator, the incident appeared to be:** (Check one) | |
|  | **Unexpected** (in terms of nature, severity, or frequency) in relation to the IRB-approved research procedures described in protocol documents. |
|  | **Expected** (in terms of nature, severity, or frequency) in relation to the IRB-approved research procedures described in protocol documents |
| **In the opinion of the primary investigator, the incident appeared to be:** (Check one) | |
|  | Directly related to the research. |
|  | Indirectly related to the research. |
|  | Unrelated to the research. |

**If applicable, what plan will be implemented to ensure that this type of incident will not occur again?**

(If a modification to the approved protocol is required, please complete the Request for Modification Form).



**Signature of Primary Investigator:**