**SAN JOSE STATE UNIVERSITY**

**HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD**

**Incident Report**

*Any incidents which include unanticipated problems, adverse events, or injuries to human subjects during the course of research must be reported to the Office of Research within no more 7 calendar days by the primary investigator upon discovery of the incident. 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:**

**Email:**

**Date of Incident:
Date Incident was Discovered by Research Personnel:**

**Describe the incident (include where the incident occurred, severity, duration, timing of events, action taken, outcome, personnel involved and corrective action plan, if applicable):**

**In the opinion of the primary investigator, the incident appears 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 appears 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:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 *Options for signing this form: The* [*DocuSign application*](http://its.sjsu.edu/service-catalog/software-apps/docusign/) *provided by SJSU; converting this form to PDF once it has been filled out and adding a digital signature; providing a handwritten signature once the form has been filled out and scanning the document into pdf.*