Adverse Event Report

Investigators are required to report Serious or Significant and Related to the Research Adverse Events to Human and Animal Protections when discovered during the course of the research and/or no later than 5 days after their occurrence.

Protocol Title:

Principal Investigator:
Faculty Advisor and Contact Information:
Phone:
Email:
Date of Event:

Event occurred: □ At SFSU
□ Off-campus site

Describe the Adverse Event (include where the event occurred, severity, duration, action taken, outcome, personnel involved and corrective action plan, if applicable):

In the opinion of the Principal Investigator:

☐YES ☐NO
Did this even cause harm to the participant or others?
☐YES ☐NO
Was the event unanticipated?

Was the event related to the research?
☐YES ☐NO

Is this event listed:

In the protocol? ☐YES ☐NO
In the consent form? ☐YES ☐NO

Is a modification required:

In the protocol? ☐YES ☐NO
In the consent form? ☐YES ☐NO

If applicable, what plan has been implemented to ensure that this type of event will not occur again?

If a modification is required, please complete the Modification Form.

Signature of Principal Investigator: ________________________   Date: ____________