



San Francisco State University

Office for the Protection of Human and Animal Subjects

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Protocol Deviation Report

Investigators are required to report Protocol Deviations to the Committee for the Protection of Human Subjects when discovered during the course of research but 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 Protocol Deviation (include where the event occurred, nature of event, action taken, outcome, personnel involved and corrective action plan, if applicable):

Has this protocol deviation (or similar deviations) previously occurred in this study? If yes, please describe the event(s) and when the event(s) occurred.

In the opinion of the Principal Investigator, does this protocol deviation affect the safety of subjects? If yes, corrective action plans must be stated in the space below, including measures taken to ensure that similar deviations do not occur in the future. If no, please explain why the safety of subjects was not affected.

In the opinion of the Principal Investigator, does the protocol deviation affect the integrity (i.e., validity and ethics) of the study data? If yes, corrective actions must be stated in the space below, including measures taken to ensure that similar deviations do not occur in the future. If no, please explain why the integrity of the study was not affected.

Signature of Principal Investigator: _____ Date: _____

Last Rev.11/07