

HUMAN SUBJECTS REVIEW - INSTITUTIONAL REVIEW BOARD OFF-SITE ADVERSE REPORT

Type all answers

Adverse event refers to any event, circumstance, or occurrence that was not anticipated, or accounted for, in the original HSRC application and may have a negative impact on the research project as a whole.

1. General Information

Principal Investigator: _____

Address: _____

College: _____ Telephone/Fax: _____

Chairperson: _____

2. Information

Title of Project _____

3. Adverse Event Information

a. In the space below, please list all attached report numbers applicable to the report of the AE, i.e., Sponsor's Letter, etc.

b. Does this AE significantly change the risk/benefit? ___ Yes ___ No Explain

c. Does this Adverse Event require change in the Informed Consent? ___ Yes ___ No

If yes, attach a copy of the revised consent form and highlight all revisions.

4. Principal Investigator Statement of Assurance

"I understand that I cannot initiate this project before I have received approval and/or complied with all contingencies made in connection with that approval."

Signature of Principal Investigator

Date

Please return this application and any attachments to:

Attn: Chairperson

Argosy University, San Francisco Bay Area

999A Canal Boulevard

Point Richmond, CA 94804

Argosy University, San Francisco Bay Area

IRB# _____

Date Rcvd _____