PEPPERDINE IRB

ADVERSE EVENTS REPORTING FORM

Date:       IRB Application/Protocol #:

**Principal Investigator:**

Faculty  Staff  Student  Other

School/Unit:  GSBM  GSEP  Seaver  SOL  SPP

Administration  Other:

Street Address:

City:       State:       Zip Code:

Telephone (work): (   )    -     Telephone (home): (   )    -

Email Address:      @     .

Faculty Supervisor: *(if applicable)*

School/Unit:  GSBM  GSEP  Seaver  SOL  SPP

Administration  Other:

Telephone (work): (   )    -

Email Address:      @     .

**Project Title:**

Type of Project (Check all that apply):

Dissertation  Thesis

Undergraduate Research  Independent Study

Classroom Project  Faculty Research

Other:

1. Provide a detailed description of the adverse event, noncompliance, and/or unresolved dispute including date, time, and location of the event.
2. How long has the participant(s) been involved in the study?
3. What is the age and gender of the participant(s)?
4. Provide a detailed description of the course of action taken by the investigator in response to this event (including modifications in study protocol).
5. Provide a detailed description of any medical/professional services that were required for treatment.
6. Describe any planned follow-up action for treatment for the participant(s):
7. In your judgment, is the overall risk-benefit relationship of the research still acceptable considering the information regarding this significant adverse event?

YES  NO Explain your response.

1. In your judgment, is a change in your protocol necessary to reduce or eliminate risk?

YES NO

*If yes*, attach a revised protocol with changes highlighted.

*If no*, provide a brief rationale.

1. Is this event already listed on the approved consent form?  YES  NO
2. In your judgment, is a change in the consent form necessary? YES  NO

*If yes*, attach a revised consent form with changes highlighted.

*If no*, provide a brief rationale.

1. Has the principal investigator been notified of this event?  YES  NO
2. (If applicable): Has the supervising faculty member

been notified of this event?  YES  NO

1. Who is submitting this report?

What is your relationship to the study?

|  |  |
| --- | --- |
|  |  |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Faculty Advisor (if applicable) Date