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?

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| --- | --- |
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Signature Date

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Signature of Faculty Advisor (if applicable) Date