ADVERSE EVENT REPORTING FORM

SUBMISSION INSTRUCTIONS

The Principal Investigator (PI) should complete and sign this form following upon knowledge of:

* + Unanticipated problems involving risks to subjects or others; and
	+ Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

HHS guidelines for adverse events (per 45 CFR part 46) can be found at: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html>

Submit the Adverse Event Reporting Form and any other supporting documentation to the IRB office electronically (esc-irb@email.laccd.edu) with in 72 hours. No handwritten forms will be accepted.

LACCD IRB

770 Wilshire Boulevard

Los Angeles, CA 90017

esc-irb@email.laccd.edu

ADVERSE EVENT REPORTING FORM

1. **IRB Protocol Identification Number:** XXXX - XX - XXX
2. **Title of Study:** Click here to enter title.
3. **Campus:** Choose LACCD Campus:
4. **Principal Investigator (PI):** Click here to enter text.
5. **What type of event occurred?**

[ ]  Internal Event (subject enrolled at this study site)

[ ]  External Event (for multi-centered studies)

1. **What type of report?**

[ ]  Initial Report

[ ]  Follow-Up Report

1. **Date of Report to the IRB:** Click here to enter a date.

**Date the PI received notification of adverse event:** Click here to enter a date.

1. **Manufacturer Report number (if applicable):** Click here to enter text.
2. **Date of Adverse Event:** Click here to enter a date.

**Location of Adverse Event:** Click here to enter text.

1. **Was the adverse event unexpected?**

 [ ]  Yes [ ]  No

**Either way, please explain:**

Click here to enter text.

1. **Was the adverse event serious?**

 [ ]  Yes [ ]  No

For example: the adverse event results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapability, or results in a congenital anomaly or birth defect.

**Either way, please explain:**

Click here to enter text.

1. **Describe the Adverse Event:**

Click here to enter text.

1. **Subject Identifier:** Click here to enter text.
2. **List all drugs (investigational and otherwise) listed in this protocol:**

 Click here to enter text.

1. **On-site Investigator’s Assessment of Causality:**

[ ]  Possibly Related [ ]  Probably Related [ ]  Unlikely Related

[ ]  Related [ ]  Not Related [ ]  Unknown

1. **What treatment for the adverse event was provided to the subject?**

Click here to enter text.

1. **Date of treatment for adverse event?** Click here to enter a date.
2. **Describe the subject’s prognosis:**

Click here to enter text.

1. **Is the study closed to enrollment?**

[ ]  Yes [ ]  No

1. **Are subjects still on drug?**

[ ]  Yes [ ]  No [ ]  Not Applicable

1. **Have similar adverse events been reported previously?**

[ ]  Yes [ ]  No

**If Yes, please provide a brief description of events:**

Click here to enter text.

1. **In your judgment, is the overall risk-benefit relationship of the research still acceptable in light of the information concerning this adverse event report?**

[ ]  Yes [ ]  No

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

[ ]  Yes *(If Yes, you must submit an Amendment Application)*

[ ]  No

1. **Are any changes required in the informed consent documents(s) to better inform and protect the rights and welfare of subjects?**

[ ]  Yes *(If Yes, you must submit an Amendment Application)*

[ ]  No

1. **It is necessary to re-consent this subject?**

 [ ]  Yes [ ]  No

**Either way, please explain:**

Click here to enter text.

PRINCIPAL INVESTIGATOR CERTIFICATION

Your signature here certifies that you have assessed the information concerning the adverse event and that in your judgment the risks of this research are minimized to the greatest extent possible and continue to be outweighed or balanced by the potential benefits.

**Signature of PI:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_