

WEST COAST UNIVERSITY INSTITUTIONAL REVIEW BOARD

## Unanticipated Problem/Adverse Event Report

This form must be completed and submitted to the WCU IRB for each unanticipated problem/adverse event that occurs on an approved research project. **This form must be received by the WCU IRB within 5 days of initial notification of the investigator about the event.** Refer to XXX for definitions and reporting requirements.

IRB NUMBER:

DATE SUBMITTED:

PRINCIPAL INVESTIGATOR:

PROJECT TITLE:

DATE OF EVENT:

**1. TYPE OF EVENT:**

- ☐ Event which in the opinion of the Principal Investigator (1) was unexpected and (2) was related to the research procedures;
- ☐ Event that requires prompt reporting according to the research sponsor (if any);
- ☐ Accidental or unintentional change to the IRB approved protocol that involves risks or has the potential to recur;
- ☐ Deviation from the protocol without prior IRB approval to eliminate any apparent immediate hazard to a research participant;
- ☐ Publication in the literature, safety monitoring report, interim result or other finding that indicates an unexpected change to the risk/benefit ratio of the research;
- ☐ Breach in privacy/confidentiality/data security/loss of study data that may involve risk to participant(s);
- ☐ Complaint of a participant that indicates an unanticipated risk or which cannot be resolved by the research staff.

(NOTE: EVENTS THAT DO NOT FIT INTO THE ABOVE CATEGORIES DO NOT REQUIRE REPORTING TO THE IRB UNTIL THE CONTINUATION-RENEWAL FORM IS FILED. HOWEVER, THE EVENT MAY REQUIRE REPORTING BY THE PI TO THE SPONSOR OR DATA MONITORING PLAN.)

**2. Briefly describe the unanticipated problem or adverse event. (Use additional pages as necessary)**

**3. If a participant was involved, will he/she continue with the study?**

- ☐ Yes                      ☐ No – Date Stopped: \_\_\_\_\_

**NEED TO ADD SOMETHING RELATED TO “IF MEDICAL ATTENTION WAS NECESSARY...”**

**4. Will the research project itself continue?**

- ☐ Yes                      ☐ No – Date Stopped: \_\_\_\_\_

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- 5. What actions have been taken? What will be done to minimize reoccurrence? (Use additional pages as necessary)**

**Signatures:**

\_\_\_\_\_  
Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Student Advisor (if applicable)

\_\_\_\_\_  
Date

**Submit one original copy of this form to:**

IRB/University Research Compliance  
WEST COAST UNIVERSITY  
Center for Graduate Studies  
590 North Vermont  
Los Angeles CA 90004  
[irb@westcoastuniversity.edu](mailto:irb@westcoastuniversity.edu)