UCSD RESEARCH SUBJECT REPORT OF ADVERSE EVENT

Incidents of illness, adverse events, or injuries that are both serious and either unexpected, or unusual and are experienced by subjects in studies under the supervision of the UCSD/VASDHS IRB must be reported to the Human Research Protections Program (HRPP) Office, 0052. This form, ALONG WITH A COPY OF THE SIGNED CONSENT FORM should be submitted as soon as possible, but NO LATER THAN 10 WORKING DAYS after first awareness of the problem.

PRINCIPAL INVESTIGATOR: PROJECT NUMBER:  
SUBJECT'S INITIALS: PATIENT UNIT NUMBER:  
DATE OF INCIDENT: DATE KNOWN TO YOU:  

Name of Drug, Device, or Procedure:

DESCRIBE IN DETAIL THE NATURE AND TIMING OF EVENT(S). (Include Dates and Times in Relationship to Exposure to Drug, Device, Procedure. Example: Renal Failure occurred at week 2 of a 5 week randomized, open label phase):

--------If this is a VA study, you must send a copy of this report to VA Research Administration, Mailcode: 9151.--------

The Likelihood The Injury Was Caused By The Study Is:  
Unlikely _____; Possible _____;  
Probable______; Definitely Unrelated ______;

Event Appears To Be:  
Directly _____; Indirectly _____;  
Not Related To Research Treatment ______;

Check All That Apply:

Subject Died _____; Resulted In, Or Prolonged Hospitalization _____; Resulted In Disability _____;
Supportive Treatment Required_____; Subject Remains On Study _____; Blind Has Been Broken _____;

DESCRIBE TREATMENT AND ITS ESTIMATED COST TO PATIENT, SPONSOR, UNIVERSITY, OR PI:

By Whom: Where:

DID PI REPORT THIS INCIDENT TO?: FDA_____; Sponsor _____; Co-Investigator(s)_____; DSMB_____  
Additional Comments: A Letter Explaining Any Other Details Should Be Attached If Needed.

Signature Of PI: ___________________________ Date:________________________

Printed Name Of PI: ______________________________________ Phone:____________________

Signature Of Person Reporting: ___________________________ Date:________________________

Printed Name of Person Reporting: ___________________________ Phone:____________________

DOES THIS EVENT REQUIRE REVISION TO THE PROTOCOL? Yes_____ No_____  
DOES THIS EVENT REQUIRE REVISION TO THE CONSENT? Yes_____ No_____

If YES To Either, Please Submit Appropriate Paperwork

NOTE: Serious Injuries Should Be Reported To Medical Risk Management (Mailcode: 8976; x36630) As Well.