

COMMITTEE ON INVESTIGATIONS INVOLVING HUMAN SUBJECTS
UNIVERSITY OF CALIFORNIA - SAN DIEGO
VETERANS ADMINISTRATION SAN DIEGO HEALTHCARE SYSTEM

_____ CERTIFICATION of approval for the above-referenced project is attached.

- NB:** (1) **Modifications/Changes** in this project must be received and approved by the appropriate Human Subjects Committee before they are initiated except where necessary to eliminate apparent immediate hazard to the subject.
- (2) The Human Research Protection Program Office (HRPPO) should be notified immediately of any injuries to human subjects and/or any unanticipated problems that involve risks to human subjects or others.

_____ Because you have indicated that your research will involve VAMC patients and/or facilities, copies of approved documents have been forwarded to the VAMC Research Administration Office for processing.

_____ If you plan to use Clinical Research Center facilities, contact Cheryl Ward at UCSD Medical Center Extension 36180 for specific instructions.

_____ "Approved" consent forms are attached. (Copies of the approved consent forms must be used for all investigational studies involving human subjects.)

_____ Consent may be obtained orally.

_____ All subjects must be given:

- (1) A copy of the consent form to keep, and
(2) A copy of "The Experimental Subject's Bill of Rights" (sample copy enclosed.)

_____ You must submit a progress report for this study using the UCSD IRB PROTOCOL MONITORING FORM by _____.

For studies that involve hospitalized patients, make certain that the Medical Director and Nursing Supervisor of the unit where the study will be done are aware of the study.

Attached for your use is the UCSD RESEARCH SUBJECT INJURY REPORT form. This form must be used to report all serious and unexpected, or unusual incidents of injury associated with an investigational drug/device/or procedure by UCSD/VASDHS subjects or others **WITHIN 10 WORKING DAYS** after first awareness of the problem.

For assistance in recruiting subjects, contact Health Sciences Communications, 543-6163.

cc: _____

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.