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/VDSDS 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 ;

Supportive Treatment Required ; Subject Remains On Study ;

Resulted In Disability ; 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.