

UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

**GUIDE FOR FORMAT FOR INVESTIGATOR'S COMMENTS
ON SPONSOR-SUPPLIED ADVERSE EVENT REPORTS**

Before an Adverse Event Report can be reviewed by the IRB and/or placed in the appropriate files, the following must occur:

1. The P.I. writes a memo to the IRB that identifies the UCSD IRB Project Number and title to which this report pertains. Please submit one memo for each Project Number.
2. A clear, concise summary of the reported events.
3. The P.I.'s assessment of the report. Does the report relate to his/her study? If so, how?
4. Does the P.I. need to include/discuss the AE in the protocol/consent? If not, clarification as to why it is not necessary at this time.
5. Does the report require modification of the protocol, risk-management procedures, or consent document, for example? If this is the case, copies of the revised protocol and revised consent must be included with the response.
6. If the adverse event report **DOES NOT** require modification of the protocol, the risk management procedures, or the consent document only **1** copy of The Adverse Event Report along with a memo containing the information outlined in numbers 1-3 above must be sent to the HRPP Office, 0052.
7. If the adverse event report **DOES** require major modification of the protocol, the risk management procedures, or the consent document, then **2 copies** of the following information must be submitted to the Human Subjects office, 0052, in order to process the adverse event report.

If the adverse event report requires minor modification to the protocol, risk management procedures, or consent, only **1 copy** of the following is needed.

- a. The memo from the investigator;
- b. The revised protocol, if appropriate, with the highlighted changes;
- c. The revised consent, if appropriate, with highlighted changes & 1 clean copy for stamping;
- d. The adverse event report supplied by the sponsor;

For a more detailed explanation of number 5 please refer to the Human Research Protections Program information sheet titled **AMENDMENTS/ MODIFICATIONS/CHANGES TO A PROTOCOL**. For further information and/or clarification regarding reporting sponsor-supplied Adverse Event Reports, please call the HRPP Office at (858) 455-5050 or visit our website at irb.ucsd.edu.

aerept.adv