All investigators conducting research with human subjects are required by the US Dept. of Health and Human Services (DHSS) to report every incident of an adverse event to the Institutional Review Board (IRB) in a timely fashion. Adverse events are defined by DHHS as an undesirable and unintended, although not necessarily unexpected result of research participation. Some examples of adverse events are: intestinal bleeding associated with aspirin therapy, psychological distress during an interview, and a breach of confidentiality.

A UCSD Report of Subject Injury form, along with a copy of the signed consent form (if applicable), should be submitted to HRPP as soon as possible after the first awareness of the problem. Title 21 of the Code of Federal Regulations and the HRPP require that a report be made of unexpected, fatal or life-threatening experiences in writing no later than 10 working days of the event. The form is available online at http://irb.ucsd.edu.

Following receipt of an adverse event report, the IRB will review all additional information regarding the protocol to determine whether the study should be continued as originally approved, modified, or discontinued.

NOTE: There are situations where a serious or unexpected adverse event requires an immediate change to a protocol in order to relieve an apparent immediate hazard to research subjects. In these situations, the principal investigator may implement a change necessary to protect the welfare of the research subjects. Investigators are encouraged to contact the HRPP if this type of situation arises prior to implementation of the protocol change. Investigators are required to notify the HRPP in writing of the change within 72 hours, and include a written description of the change and events which necessitated immediate implementation.

In addition, any injuries that require care within UCSD Healthcare facilities should be immediately reported to Medical Risk Management. They can be reached at 619-543-6630.

Questions regarding any aspect of this policy or process, please contact the HRPP office at 858-455-5050 or send e-mail to hrpp@ucsd.edu