

Approved By:

UNLV Office of Research Integrity- Human Subjects and Institutional Review Board Standard Operating Procedures		
SOP #: ORI(HS) - 11.01 Revision #: 2.0	TITLE: Problems and Adverse Events, Record and Report	Page 2 of 2

2. related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

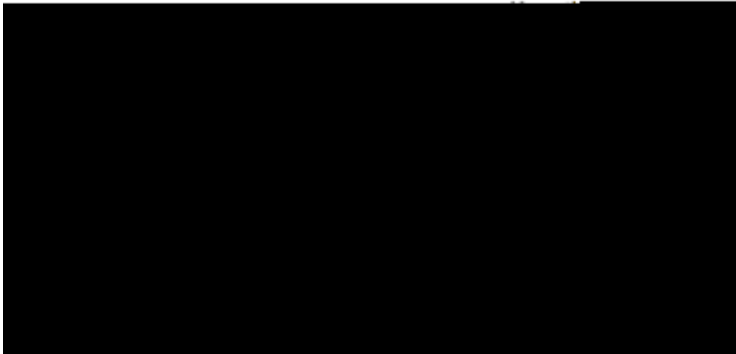


Diagram taken from the OHRP Guidance on Unanticipated Problems and Adverse Events (January 15, 2007)

3. Roles & Responsibilities

Execution of SOP: Principal Investigators (PI)/Study Personnel (SP), IRB Chair, IRB, Office of Research Integrity (ORI) Staff.

It is the primary responsibility of the Principal Investigator and research team to address and record any problems that occur during the course of research. If the research team member who encounters a study problem, it is recommended that he or she report the problem to the PI in a timely or immediate manner.

*Immediate action, including changes to approved study procedures, may be taken to avoid apparent or immediate harm to subjects or others.

Using the basic classification system described in the procedures section below provides an indication when (not if) a problem needs to be reported to the IRB. All problems need to be reported to the IRB, though, not all problems require immediate reporting or follow-up. There may be additional requirements or desire to report certain problem events and/or any follow up actions to federal agencies, or other outside entities.

It is the responsibility of the IRB to assess the problems reported by researchers. Problems that adversely affect the rights and/or welfare of subjects, and/or the integrity of the study may warrant further action (discussed in more detail below). There may be additional requirements or desire to report certain problem events and/or any follow up actions to federal agencies, or other outside entities.

4. Procedures

It is highly recommended that the PI utilize the following classification system when recording and assessing problem events. The IRB and ORI will utilize the following classification system in assessing problems reported by the PI or other researchers.

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1) Assessment

Rate the problem on the following three scaled criteria:

Not Serious Serious

Seriousness as being most closely associated with the safety, rights and/or welfare of study subjects or others.

Anticipated Unanticipated

The anticipated nature of the event as being most closely associated with potential problem events previously outlined in the study protocol as an expected occurrence, for which there is likely a procedural measure to help any reduce risk of harm. If the problem event is not previously discussed as expected in the study protocol, then it may be classified as unanticipated.

Not Study Related Study Related

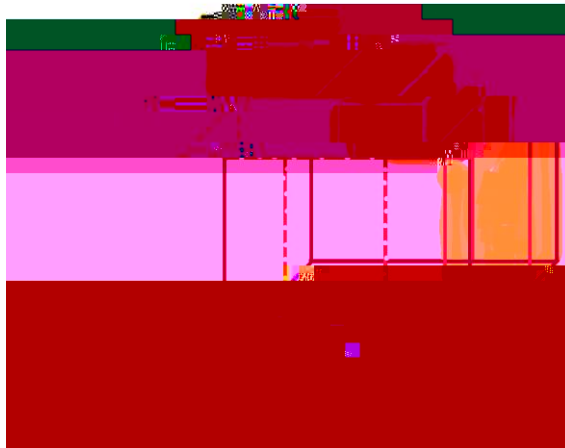
The relatedness of the event as being most closely associated with participation in the study, or having been affected by the presence of the study.

2) Reporting

If the problem event is found to have any two of the scaled assessment criteria: serious, unanticipated, or study related, then timely reporting of the event needs to be made to the IRB office. If the problem event is found to have all three of the qualities serious, unanticipated, and study related, then an immediate report needs to be made to the IRB office. If the event is found to have only one or none of the qualities serious, unanticipated, or study related, then the problem event may be recorded for reporting to the IRB office at the time of continuing review.

* Immediate action, including changes to approved study procedures, may be taken to avoid apparent immediate harm to subjects or others.

A diagram of the above discussion is provided below:



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- x a redetermination of the risk level of the study
- x modification to an approved study procedure(s) and/or the information provided during the consent process
- x notification to current participants of relevant information
- x reconfirming consent of current participants
- x requiring additional monitoring for current and/or past participants
- x monitoring of the research (including audits) and/or consent process
- x education, training, or mentoring for the principal investigator and/or research team members
- x modification to the continuing review schedule

4) Considerations for Additional Reporting

Where outside entities, or funding agencies/sponsors are involved with the research, additional reporting of the event(s) and any subsequent actions may be required or desired and should seek to be made in a timely manner. ~~3~~ , - V V ~~6~~ ~~10~~ ~~11~~ ~~12~~ ~~13~~ ~~14~~ ~~15~~ ~~16~~ ~~17~~ ~~18~~ ~~19~~ ~~20~~ ~~21~~ ~~22~~ ~~23~~ ~~24~~ ~~25~~ ~~26~~ ~~27~~ ~~28~~ ~~29~~ ~~30~~ ~~31~~ ~~32~~ ~~33~~ ~~34~~ ~~35~~ ~~36~~ ~~37~~ ~~38~~ ~~39~~ ~~40~~ ~~41~~ ~~42~~ ~~43~~ ~~44~~ ~~45~~ ~~46~~ ~~47~~ ~~48~~ ~~49~~ ~~50~~ ~~51~~ ~~52~~ ~~53~~ ~~54~~ ~~55~~ ~~56~~ ~~57~~ ~~58~~ ~~59~~ ~~60~~ ~~61~~ ~~62~~ ~~63~~ ~~64~~ ~~65~~ ~~66~~ ~~67~~ ~~68~~ ~~69~~ ~~70~~ ~~71~~ ~~72~~ ~~73~~ ~~74~~ ~~75~~ ~~76~~ ~~77~~ ~~78~~ ~~79~~ ~~80~~ ~~81~~ ~~82~~ ~~83~~ ~~84~~ ~~85~~ ~~86~~ ~~87~~ ~~88~~ ~~89~~ ~~90~~ ~~91~~ ~~92~~ ~~93~~ ~~94~~ ~~95~~ ~~96~~ ~~97~~ ~~98~~ ~~99~~ ~~100~~ ~~101~~ ~~102~~ ~~103~~ ~~104~~ ~~105~~ ~~106~~ ~~107~~ ~~108~~ ~~109~~ ~~110~~ ~~111~~ ~~112~~ ~~113~~ ~~114~~ ~~115~~ 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