

SOP: 901	UNANTICIPATED PROBLEMS INVOLVING RISKS TO PARTICIPANTS OR OTHERS
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Approved by IRB executive committee: January 9, 2008
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 AAHRPP Element: I.3.J

DEFINITIONS

- a) Unanticipated Problems** Unanticipated problems involving risks to participants or others are defined as any incident, experience or outcome that meets all of the following criteria:
- Unforeseen (not expected by the researcher or the research participant) given the research procedures and the subject population being studied;
 - Related or probably related to participation in the research or if the event or problem probably or definitely affects the safety, rights and welfare of current participants; and
 - 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.
- b) Unexpected Adverse Events** An unexpected adverse event is any adverse event occurring in one or more subjects participating in a research protocol, whose nature, severity, or frequency is **not consistent** with, either:
- The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in the protocol related-documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and other relevant sources of information, such as product labeling and package inserts; or
 - The expected natural progression of any underlying disease or condition of the subject(s) experiencing the adverse event.
- c) Related Adverse Event** It is the responsibility of the Utah Principal Investigator to make the initial determination of a relationship between an adverse event (either internal or external) and any investigational agent(s), intervention, or research study procedure.
- An adverse event is “related to the research” if in the opinion of the principal investigator, it was more likely than not related to the investigational agent(s) or intervention.

POLICY

It is the policy of the University of Utah IRB to require researchers to submit reports of events that may represent unanticipated problems involving risks to participants and others including unexpected and related adverse events. Researchers are required to

submit the report as soon as possible after the Principal Investigator (PI) learns of the event, but in all cases within ten working days.

PROCEDURES

1. The PI reports problems under this policy by completing and electronically submitting a Report Form in the ERICA System. The list of reportable events/problems is posted on the IRB web site.
2. Researchers are required to submit the report as soon as possible after the PI learns of the event, but in all cases within ten working days.
3. The submission is assigned by the IRB staff through the ERICA system to either an IRB administrator or to a member of the IRB Unanticipated Problems Subcommittee for review and evaluation.
4. The assigned IRB administrator may request clarifications, corrections, or revisions to the report from the PI if further information is needed to evaluate the event.
5. If the IRB administrator determines that the problem is not an unanticipated problem involving risks to participants or others as defined in this policy, the reviewer acknowledges the event as submitted, indicating the event is not considered to be an unanticipated event involving risks to participants. ERICA notifies the PI via e-mail. No further action is taken.
6. If the IRB administrator determines the problem might be an unanticipated problem involving risks to participants or others as defined by this policy, the event is referred to a member of the IRB Unanticipated Problems Subcommittee for review.
7. If the IRB subcommittee member determines that the problem is not an unanticipated problem involving risks to participants or others as defined by this policy, the IRB subcommittee member acknowledges the event as submitted, indicating the event is not considered to be an unanticipated event involving risks to participants. ERICA notifies the Principal Investigator via e-mail. No further action is taken.
8. If the IRB subcommittee member determines the problem might be an unanticipated problem involving risks to participants or others as defined by this policy, the event is referred to the convened IRB for review.
9. When problem reports are reviewed by the convened IRB, the IRB staff ensures board members are notified and the documents listed below are made available in the ERICA system three working days prior to the meeting. All IRB members are expected to review the information and be prepared to discuss it at the meeting.
 - Report Form;
 - the currently approved protocol;
 - the currently approved consent document;
 - previous reports of unanticipated events and problems involving risks to participants or others, if they exist;
 - the Investigator's Brochure, if one exists.
10. Based on the nature of the event and the expertise required to assess it, the IRB Chair or designee acts as the primary reviewer and presents his/her findings to the convened IRB. The convened IRB evaluates the event by considering whether the problem is an unanticipated problem involving risks to participants or others as defined by this policy. The convened IRB votes on whether the report is an unanticipated problem involving risks to participants or others. IRB staff records the discussion, rationale for any action and vote in the minutes.
11. If the convened IRB determines that the problem is not an unanticipated problem involving risks to participants or others as defined by this policy the convened IRB acknowledges the event as submitted, indicating the event is not considered to be an

unanticipated event involving risks to participants. ERICA notifies the PI via e-mail. No further action is taken.

12. If the convened IRB determines that the problem is an unanticipated problem involving risks to participants or others as defined by this policy, the convened IRB may consider any of the following actions, but is not limited to:
 - modification of the protocol
 - modification of the information disclosed during the consent process provided by the investigator
 - providing additional information to current participants (this must be done whenever the information may relate to the participant's willingness to continue participation)
 - providing additional information to past participants
 - requiring current participants to re-consent to participation
 - alteration of the frequency of continuing review
 - observation of the research or the consent process
 - requiring additional training of the investigator
 - notification of investigators at other sites
 - obtaining additional information
 - administrative hold, termination or suspension of the research according to SOP 904, Administrative Hold, Suspension, Termination and Non-compliance of Approved Research
13. If the IRB determines that the event was an unanticipated problem involving risks to participants or others, the matter is referred to the IRB staff to handle according to SOP 905, Reporting Procedures.