



SOP 901: UNANTICIPATED PROBLEMS INVOLVING RISKS TO PARTICIPANTS OR OTHERS

PURPOSE

This SOP outlines the requirements for reporting of events at the University of Utah.

SCOPE

This policy applies to human subject research conducted at the University of Utah.

DEFINITIONS

- A. A **related adverse event** is an adverse event that is more likely than not related to the investigational agent(s) or intervention, in the opinion of the responsible investigator. It is the responsibility of the responsible investigator to make the initial and subsequent determination of a relationship between an adverse event (either internal or external) and any investigational agent(s), intervention, or research study procedure. The sponsor and other monitoring entities may provide information after the responsible investigator has made an initial determination (for example, after running analysis across all sites, an adverse event is determined to be likely to be related). Upon receipt of additional information from the sponsor or other monitoring entities, the responsible investigator may make a subsequent determination.
- B. **Responsible Investigator (RI)** is the individual who is the principal investigator and responsible for all ERICA tasks and requirements for the application they are listed on. This person holds the same responsibilities as a principal investigator (PI), but with the added understanding that they will be the primary contact for the study at the University of Utah. In this policy, both terms may be used interchangeably but are used to identify the principal investigator at the University of Utah site.
- C. **Unanticipated problems** involving risks to participants or others are defined as any incident, experience or outcome that meets all of the following criteria:
 - Unexpected (not foreseeable 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.
- D. An **unexpected adverse event** is any adverse event occurring in one or more subjects participating in a research protocol, that's 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

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- the IRB-approved research protocol, any applicable investigator brochure, 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 participant(s) experiencing the adverse event.

POLICY

The University of Utah Institutional Review Board (IRB) requires researchers to submit reports of events that may represent unanticipated problems involving risks to participants or others including unexpected and related adverse events. Researchers are required to submit the report as soon as possible after the responsible investigator learns of the event and in all cases within ten working days.

PROCEDURES

1. The responsible investigator reports problems under this policy by completing and electronically submitting a report form in the University of Utah Electronic Research Integrity and Compliance Administration system (ERICA). The list of reportable events/problems is posted on the IRB website.
2. Researchers are required to submit the report as soon as possible after the responsible investigator learns of the event and in all cases within ten working days.
3. The submission is assigned by the IRB staff through ERICA to an IRB administrator for review and evaluation. The IRB administrator may subsequently assign a member of the IRB subcommittee to review the submission for a possible unanticipated problem as described below.
4. The assigned IRB administrator or subcommittee member may request clarifications, corrections, or revisions to the report from the responsible investigator if further information is needed to evaluate the event.
5. If the IRB administrator determines that the event is not an unanticipated problem involving risks to participants or others as defined in this policy, the reviewer completes a checklist indicating the event is not considered to be an unanticipated problem involving risks to participants or others. ERICA notifies the responsible investigator via e-mail. No further action is taken.
6. If the IRB administrator determines the event **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 subcommittee for review.
 - 6.1. If the IRB subcommittee member decides that the event does not represent an unanticipated problem involving risks to participants or others as defined by this policy, the IRB subcommittee member completes a checklist confirming this determination. ERICA notifies the responsible investigator via e-mail. No further action is taken.
 - 6.2. 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.

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7. If the IRB administrator determines the problem is likely to be an unanticipated problem involving risks to participants or others as defined by this policy, the event is referred to the convened board for review without needing additional review by an IRB subcommittee member.
8. When adverse event and/or 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 ERICA three or more 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.
9. 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 their 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.
10. 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 indicates the event is not considered to be an unanticipated event involving risks to participants or others. ERICA notifies the responsible investigator via e-mail. No further action is taken.
11. If the convened IRB determines that the event 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

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- notification of investigators at other sites
 - obtaining additional information
 - administrative hold, termination, or suspension of the research according to IRB SOP 904: Administrative Hold, Suspension, Termination and Non-compliance of Approved Research
12. If the IRB determines that the event is an unanticipated problem involving risks to participants or others, the matter is referred to the IRB staff to handle reporting according to IRB SOP 905: Reporting Procedures.

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