

**UNIVERSITY OF UTAH INSTITUTIONAL REVIEW BOARD
REPORTING POLICY
VERSION: JULY 2008**

UNANTICIPATED PROBLEMS INVOLVING RISKS TO PARTICIPANTS OR OTHERS

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 (UPs) including unexpected, related adverse events. Researchers are required to submit the report as soon as possible after the PI learns of the event, but in all cases within 10 working days.

What is an unanticipated problem involving risks to participants or others (UPs)?

UPs 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

What needs to be promptly reported?

- **Potential unanticipated problems involving risks to participants or others (see above definition) including but not limited to:**
 - Unexpected, related adverse events
 - A breach of a confidentiality or privacy that involves real or potential risk such as unauthorized use or disclosure of protected health information (PHI)
 - Unanticipated adverse device effects (*new information about the effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem or death was not previously identified in nature severity, or degree of incidence or any other unanticipated, serious problem associated with a device that relates to the rights, safety or welfare of subjects*)
- **New Information indicating a change to the risks or benefits of the research including but not limited to:**
 - DSMB summary reports that indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB
 - Publication that shows that the risks or potential benefits of the research may be different than initially presented to the IRB
- **Change in FDA labeling or withdrawal from marketing** of a drug, device, or biologic used in a research protocol
- **Incarceration** of a participant in a protocol not approved to enroll prisoners
- **Complaints** from participants or others involved in the research that indicate unexpected risks or cannot be resolved by the research team
- Warning or determination letters issued by any funding agency or regulatory body including Office of Human Research Protections (OHRP), Department of Health and Human Services (DHHS), Food and Drug Administration (FDA).
- **Protocol deviations**, if:
 - Intended to eliminate apparent immediate hazard to a research participant or
 - Harmful (caused harm to participants or others, or placed them at increased risk of harm - including physical, psychological, economic, or social harm), or
 - Possible serious or continued noncompliance

Why do these events/problems need to be reported?

The above events, problems or information may be unanticipated problems involving risks to participants and others. The IRB will review the events to identify and report any unanticipated problems involving risks to participants and others as required by federal regulations.

What does "prompt" reporting mean?

Prompt reporting means that the report should be submitted as soon as possible after the PI learns of the event, but in all cases within 10 working days. The deadline for reporting begins at the time the investigator learns of the event. If the report is submitted late, a written explanation of its tardiness must accompany the report.

How is a report made?

To report a problem, an event or information, log on to ERICA, select the study in question, click on the "Report Form" tab, and follow the instructions on that form.

Where can I find more information?

[Office for Human Research Protections \(OHRP\) Policy Guidance on Unanticipated Problems and Adverse Events \(January 2007\)](#)

UNEXPECTED, RELATED ADVERSE EVENTS

Only a subset of adverse events needs to be reported to the IRB. The IRB requires the prompt reporting of adverse events that may represent unanticipated problems involving risks to participants or others (UPs).

How do you determine which adverse events are unanticipated problems?

The adverse event must be unexpected and related and suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized. [Click here for help in determining whether an adverse event needs to be reported to the IRB.](#)

The Investigator will be asked to determine if the adverse event is an unanticipated problem in the report form. Please be advised that adverse events which do not meet the IRB's definition of an Unanticipated Problem (that is, an unexpected, related adverse event that places subjects at greater risk) should not be reported to the IRB. Report forms will be automatically withdrawn and will not be reviewed by the IRB if the Investigator indicates that the adverse event does not meet these criteria.

What is an unexpected adverse event?

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.

What is a 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.

Is follow-up information concerning an adverse event required?

A follow-up report is NOT required unless you receive information that suggests the event is more likely to be related to the study than currently thought, OR seems to affect the rights and welfare of current participants.

PROTOCOL DEVIATIONS

A protocol deviation is any departure from the defined procedures and treatment plans as outlined in the protocol version submitted and previously approved by the Institutional Review Board (IRB). Protocol deviations have the potential to place participants at risk and can also undermine the scientific integrity of the study thus jeopardizing the justification for the research.

Protocol deviations are unplanned and unintentional events. Any changes in the research protocol during the period, for which the IRB approval has already been given, may not be initiated without submission of an amendment for IRB review and approval.

The IRB recognizes that some protocol deviations pose no conceivable threat to participant safety or scientific integrity. As such, reporting is left to the discretion of the PI within the context of the guidelines below.

Only a subset of protocol deviations needs to be reported to the IRB. The IRB requires the **prompt reporting** of protocol deviations which are:

- Intended to eliminate apparent immediate hazard to a research participant or
- Harmful (caused harm to participants or others, or placed them at increased risk of harm - including physical, psychological, economic, or social harm), or
- Possible serious or continued noncompliance

What is a serious non-compliance?

An act or omission to act that resulted in increased physical, psychological, safety, or privacy risk that compromised the rights and welfare of research participants.

Examples of serious non-compliance include, but are not limited to the following:

- Deliberate or repeated failure to obtain prior review and approval of new protocols and on-going human participants research by the IRB.
- Deliberate or repeated failure to obtain or document informed consent from human participants.
- Deliberate or repeated omission of a description of serious risks of the experimental therapy when obtaining informed consent.
- Deliberate or repeated failure to limit administration of the investigational drug or device to those participants under the investigator's supervision.
- Deliberate or repeated failure to maintain accurate study records, report changes to the research, or report unanticipated problems posing risk to subjects or others to the IRB.
- Deliberate or repeated failure to comply with the conditions placed on the study by the University, the IRB, sponsor, or the FDA.

What is continued non-compliance?

A pattern of repeated actions or omissions to act that suggests a future likelihood of reoccurrence and that indicates a deficiency in the ability or willingness to comply with Federal regulations, VA Handbook 1200.5 or the policy, requirements, and determinations of the IRB governing human subject research.

Examples of continuing non-compliance include, but are not limited to the following:

- Consistently late submission of continuing review or items that require prompt reporting.
- Repeated failure to comply with IRB requirements for completion of human subjects training before initiating study procedures.
- Repeated failure to submit the required documents to the IRB.
- Repeated refusal to comply with an IRB request.
- Repeated failure to submit progress reports.