Unanticipated Problems Involving Risks to Subjects or Others

Modified: February 2018

Background:

Federal regulations require the university to have written procedures for ensuring that unanticipated problems involving risks to participants or others are promptly reported to the IRBs, appropriate institutional officials, and federal agencies. Based on those reported events, the IRB has the authority to suspend or terminate approval of research if appropriate.

Unanticipated problems can occur in any type of research (medical or non-medical) and may include occurrences such as adverse events, subject complaints, protocol deviations, and other untoward events involving risk. Events requiring prompt reporting by investigators and research staff may involve physical, psychological, social, legal, or economic harms.

1. **Q: What is an unanticipated problem that may involve risk to study subjects?**

Unanticipated problem involving risk to participants or others, defined on the basis of whether the event:

- Is unanticipated or unexpected.
- Is related to the research
- Involves new or increased risks to participants or others.
  a. A new or increased risk may be defined as one that requires some action (e.g., modification of the consent process or informing participants)
  b. A new risk might be a greater-than-minimal risk, or a minimal risk

In order to determine if the unanticipated problem places subjects at greater risk of harm than was previously known or recognized is dependent on whether the event was related to study participation in the research. The harm can be physical, psychological, economic, or social in nature.

2. **Q: What are examples of Unanticipated Problems that present risk to subjects or others?**

The following are examples of Unanticipated Problems that present risk to subjects or others:

- Any unapproved change or modification to an IRB approved protocol (deviation), intentional or unintentional, that places one or more subjects at risk or affects the integrity of study data;
- Changes to the protocol taken without prior IRB review to eliminate apparent immediate hazard to a subject;
- Complaints that indicates unexpected risks, or complaint that cannot be resolved by the principal investigator;
- Malfunctioning of research equipment that results or could result in risk to subjects or others;
- Suspension of enrollment (by the investigator, sponsor) due to issues identified with the study that may involve risk to subjects;
- Events that requires prompt reporting to the sponsor (i.e. subject’s pregnancy)
- Data and Safety Monitoring Board (DSMB) reports, interim analyses, or other oversight committee/monitoring reports altering the risk/benefit profile
- Events requiring prompt reporting according to the protocol, sponsor, or funding agency
- New information indicating an unexpected change in risks or potential benefits (e.g., literature/scientific reports or other published findings)
- Unapproved changes made to the research to eliminate an apparent immediate hazard to a subject
• Audit findings, inquiry, or written report by a federal agency (e.g., FDA Form 483)
• Suspension by the sponsor, investigator, or institutional entity
• Other problem or finding (e.g., loss of study data or forms, a subject becomes a prisoner while participating in research, etc.) that an investigator or research staff member believes could influence the safe conduct of the research.

3. **Q: How are Unanticipated Problems reported to the IRB?**

   • When you submit an Adverse Event, a Deviation or a Miscellaneous report, the IRB will make a determination if that event is also an Unanticipated Problem.
   • When submitted as a revision or something similar, the IRB may have you also submit an Unanticipated Problem.
   • An Unanticipated Problem can be reported directly to the IRB by choosing the Unanticipated Problem option.

4. **Q: How soon do unanticipated problems be reported to the IRB and how are they reported?**

   • For an event submitted directly as an Unanticipated Problem, if the risk to subjects or others is felt to be greater-than-minimal, the event should be reported to the IRB using the Event Report application in myIRB within 5 working days of the event occurring or learning of the event via myIRB Reportable Events.