

Section 24: Unanticipated Problems Involving Risks to Participants or Others

The investigator or study staff must promptly receive all reports of unanticipated problems involving risks to participants or others. Unanticipated problems involving risks to participants or others can take many forms. The following items should be reported to the IRB within 5 working days:

1. Any adverse events that have all of the following characteristics:
 - a. Serious (meaning an event that results in any of these outcomes or required medical intervention to prevent any of these outcomes: Death, a life-threatening experience, inpatient hospitalization, prolongation of existing hospitalization, a persistent or significant disability/incapacity); and
 - b. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the population being studied and
 - c. Related or possibly related to participation in the research (meaning there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
 - d. Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. Greater risk of harm is defined as a new or increased risk for which the IRB would require some action, such as informing participants or modifying the consent document.
2. Protocol violations (meaning an accidental or unintentional change to the IRB approved protocol procedures, including changes necessary to eliminate apparent immediate hazards to a study subject) that:
 - a. Result in actual or potential harm to the participant; or
 - b. Alter the potential for study benefit; or
 - c. Have the potential to occur again.
3. Any event that requires *prompt* reporting to the sponsor.
4. Interim findings that indicate an unexpected change to the risks or potential benefits of the research. (For example, interim analysis indicates that the experimental group has an unexpectedly high rate of cure or an unexpectedly high rate of death.)
5. Publications in the literature that indicate an unexpected change to the risks or potential benefits of the research. (For example, a paper is published from another study that shows that the experimental arm of your research study is of no therapeutic value.)
6. Safety monitoring reports that indicate an unexpected change to the risks or potential benefits of the research.

7. Any complaint of a participant that indicates previously unforeseen risks, or any complaint of a participant that cannot be resolved by the research staff.
8. Any other event that indicates participants or others might be at risk of serious harms that were not anticipated. For example:
 - a. A laptop with confidential information about participants in an AIDS study is stolen.
 - b. A group email sent to your participants accidentally discloses the names of all other participants in the study.
 - c. A participant in a group counseling session becomes emotionally upset and physically assaults a staff member.
 - d. The laboratory loses blood samples obtained to monitor critical serum drug levels.
 - e. A member of the staff has a needle stick injury while drawing blood for a research study.
 - f. Through blood typing or HLA testing done as part of a research study, a man unexpectedly discovers that he is not the father of his wife's daughter.