

## Tip Sheet 23: Unanticipated Problems Involving Risks to Participants or Others

### Related Accreditation Elements: II.2.G. and III.2.D.

Organizations must have written procedures for ensuring prompt reporting to the IRB or EC, appropriate organizational officials, and appropriate government officials of unanticipated problems involving risks to participants or others.

### Recommended Content:

#### *Define terms:*

1. Unanticipated problem involving risk to participants or others, defined on the basis of whether the event:
  - a. Is unanticipated or unexpected.
  - b. Is related to the research.
  - c. Involves new or increased risks to participants or others.
    - i. A new or increased risk may be defined as one that requires some action (e.g., modification of the consent process or informing participants).

#### *Define the reporting requirements of Researchers and research staff:*

1. Describe the list of problems that need reporting and include:
  - a. Internal adverse events that are unexpected, related to the research, and involve new or increased risks to participants or others.
  - b. External adverse events that have been determined to be unanticipated problems involving risks to participants or others.
  - c. Changes made to the research without prior IRB or EC approval in order to eliminate apparent immediate harm.
  - d. Other unanticipated events, incidents, or problems that are related to the research and that indicate participants or others might be at new or increased risks.
    - i. Any event that requires prompt reporting according to the research protocol or plan or the sponsor.
    - ii. Any accidental or unintentional change to the IRB- or EC-approved research protocol or plan that involved risks or has the potential to recur.
    - iii. Any change to the research protocol or plan taken without prior IRB or EC review to eliminate apparent immediate hazard to a research participant.
    - iv. Any publication in the literature, safety monitoring report, interim result, or other finding that indicates an unexpected change to the risks or potential benefits of the research.

- v. Any complaint of a participant that indicates an unanticipated risk or that cannot be resolved by the research staff.
- vi. Any other event appropriate to the local context.
2. The above should be reported regardless of whether they occur during the study, after study completion, or after participant withdrawal or completion.
3. Describe the time frame for Researchers to report problems to the IRB or EC.
4. Describe the types of information that must be submitted in a report.

*Describe the process for handling reported events:*

1. Describe the entity (e.g., the title of position or office) that reviews reportable events.
2. Describe the entity that determines whether an event is an unanticipated problem involving risks to participants or others.
3. Describe the entity that decides what actions may be taken.
4. Describe when the convened IRB or EC becomes involved in the decisions.
5. The convened IRB or EC reviews unanticipated problems involving risks to participants or others involving more than minimal risks to participants or others.
  - a. Describe the documents distributed to primary reviewers, if a primary reviewer system is used.
  - b. Describe the documents distributed to all IRB or EC members.
  - c. Describe the range of actions the IRB or EC might take:
    - i. Required in policies and procedures:
      - A. Suspension of the research (See Tips – Suspensions and Terminations of IRB or EC Approval).
      - B. Termination of the research (See Tips – Suspensions and Terminations of IRB or EC Approval).
      - C. Notification of current participants (required when such information might relate to participants' willingness to continue to take part in the research).
    - ii. Optional in policies and procedures:
      - A. Modification of the research protocol or plan.
      - B. Modification of the information disclosed during the consent process.
      - C. Additional information provided to past participants.
      - D. Requirement that current participants re-consent to participation.
      - E. Modification of the continuing review schedule.
      - F. Monitoring of the research.
      - G. Monitoring of the consent process.
      - H. Referral to other organizational entities (e.g., legal counsel, risk management, organizational official).
      - I. Other actions appropriate for the local context.

- d. If the convened IRB or EC does not review unanticipated problems involving risks to participants or others when the risks are no more than minimal risks to participants or others, describe the process for review.
  - i. Describe the types of actions that might be taken.
- e. Describe how decisions are documented.
- f. Describe how decisions are communicated.
- g. Describe how unanticipated problems involving risks to participants or others are reported (See Tips – Reporting Unanticipated Problems Involving Risk to Participants or Others, Terminations or Suspensions of IRB or EC Approval, and Serious or Continuing Non-compliance).

*Other Suggestions:*

1. Write supporting documents, guidelines, and training materials so they are consistent with the policies and procedures for reporting and handling unanticipated problems involving risks to participants or others.
2. Adverse events may be handled under this policy or in a separate policy.
3. Adverse events that fall under the reporting requirements of this policy should be processed according to this policy.
4. Protocol deviations, violations, and exceptions that fall under the reporting requirements of this policy should be processed according to this policy.