Tip Sheet 15: Reporting Unanticipated Problems Involving Risks to Participants or Others, Terminations or Suspensions of IRB or EC Approval, and Serious or Continuing Non-compliance

Related Accreditation Elements: I.5.D., II.2.G., II.2.H., and III.2.C.

Some laws, regulations, codes, and guidance contain reporting requirements of the Organization, IRB or EC, or the Researcher. This Tip Sheet describes the DHHS and FDA regulations for reporting in three situations: (i) unanticipated problems involving risks to participants or others, (ii) serious or continuing noncompliance, and (iii) suspensions or terminations of IRB or EC approval of research. Policies and procedures for reporting unanticipated problems involving risks to participants or others, serious or continuing non-compliance, and terminations and suspensions of IRB or EC approval of research may be combined into a single policy, or may be described in separate reporting policies.

Recommended Content:

Describe the circumstances under which reporting is required:

1. An unanticipated problem involving risks to participants or others (See Tip Sheet – Unanticipated Problems Involving Risks to Participants or Others).
2. An incident of serious or continuing non-compliance with the Organization's policies or the requirements or determinations of the IRB or EC (See Tip Sheet – Non-compliance).
3. A suspension or termination of IRB or EC approval of research (See Tip Sheet – Suspensions and Terminations of IRB or EC Approval).

Describe the process for drafting and finalizing a report:

1. Identify the entity (title of the person or office) that drafts the report.
2. Identify the entity that approves the report.

Describe the contents of the report:

1. The nature of the event.
2. The findings of the Organization or IRB or EC.
3. Actions taken by the Organization or IRB or EC.
4. Reasons for the Organization's or IRB's or EC's actions.
5. Plans for continued investigation or action.

Describe the distribution of the report:

1. Specific organizational officials. This should include, at a minimum, the organizational official responsible for the Human Research Protection Program.
2. List the government agencies and other organizations that have regulatory oversight due to funding, conduct, or an assurance of compliance.
    a. OHRP, when research is covered by DHHS regulations.
    b. FDA, when the research is FDA-regulated.
    c. Other government agencies when the research is overseen by those agencies, and they require reporting separate from that to OHRP.
    d. Other organizations, such as sponsors or contract research organizations, when appropriate.
    e. Other sites involved in the research, when appropriate.
    f. Indicate that your Organization need not report to regulatory agencies already made aware of the event through other mechanisms, such as reporting by the Researcher, sponsor, or another Organization.

Describe the timing of distribution:

1. Describe the time frame for reporting:
    a. Unanticipated problems involving risks to participants or others.
    b. Serious or continuing non-compliance.
    c. Terminations and suspensions of IRB or EC approval of research.