

Tip Sheet 21: Suspensions and Terminations of IRB or EC Approval

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

The IRB or EC should have the authority to suspend or terminate IRB or EC approval of research that is not being conducted in accordance with IRB or EC requirements or that has been associated with unexpected serious harm to participants. Suspensions and terminations represent an action by the IRB or EC to temporarily or permanently withdraw approval for some or all research procedures. IRBs or ECs should have policies and procedures for suspending or terminating previously approved research.

Recommended Content:

Define:

1. Suspension of IRB or EC approval.
2. Termination of IRB or EC approval.

Describe the circumstances under which the IRB or EC may suspend or terminate previously approved research:

1. When research is not conducted in accordance with IRB or EC requirements.
2. When research is associated with unexpected serious harm to participants.

Describe the process the IRB or EC uses to suspend or terminate previously approved research:

1. Include procedures (including the members of the IRB or EC) for making suspension and termination determinations on an urgent basis, including the entity that is authorized to suspend or terminate on an urgent basis.
2. When IRB or EC approval is suspended or terminated, have the IRB or EC or the person ordering the suspension or termination:
 - a. Consider actions to protect the rights and welfare of currently enrolled participants.
 - b. Consider whether procedures for withdrawal of enrolled participants take into account their rights and welfare (e.g., making arrangements for medical care off a research study, transfer to another Researcher, and continuation in the research under independent monitoring).
 - c. Consider informing current participants of the termination or suspension.
 - d. Have any adverse events or outcomes reported to the IRB or EC.
3. Describe how determinations are reported (See Tip Sheet - Reporting Unanticipated Problems Involving Risks to Participants or Others, Terminations or Suspensions of IRB or EC Approval, and Serious or Continuing Non-compliance).