



SUSPENSION AND TERMINATION OF IRB-APPROVED RESEARCH

1. Overview

The IRBs have the authority to suspend or terminate previously approved research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to subjects.

This policy describes the conditions under which the IRBs may suspend or terminate previously approved research and the procedures to be followed when suspending or terminating previously approved research.

2. Definitions

Suspension: An action taken by the IRB Chairs, Vice Chairs, or convened IRBs to withdraw approval for some research activities, temporarily or permanently, or all research activities temporarily, short of permanently withdrawing approval for all research activities. The Institutional Official may also suspend research on an urgent basis. *Note: Similar actions taken by investigators or sponsors to stop research activities are not suspensions as described by HRPP policy.*

Termination: An action taken by the convened IRBs to permanently withdraw approval for all research activities (except for those follow-up procedures that may be necessary to protect the health and/or welfare of participants). *Note: Similar actions taken by investigators or sponsors to stop research activities are not terminations as described by HRPP policy.*

3. General Information on Suspensions and Terminations

- A. Information indicating that research is not being conducted in accordance with IRB requirements or that it has been associated with unexpected harm to subjects may arise from various sources, including (but not limited to) continuing reviews, event reports, allegations of potential noncompliance, and/or subject complaints.
- B. When further investigation is required to determine whether suspension or termination is warranted, the investigation will be conducted as described in HRPP policy [\[Noncompliance\]](#) or [\[Event Reporting\]](#).
- C. Corrective actions (e.g., modification of the research procedures, education for investigators and/or research staff) will be considered in association with suspensions or terminations as described in HRPP policy [\[Noncompliance\]](#) or [\[Event Reporting\]](#).
- D. The IRBs will report all suspensions or terminations of IRB approval to IRB members, investigators, regulatory agencies, and institutional officials as described in HRPP policy [\[IRB Reporting – Unanticipated Problems, Noncompliance, Suspensions, and Terminations\]](#).



4. Suspensions

- A.** When there is reason to believe that research activities should be stopped, the IRB Chair, Vice Chair, or applicable convened IRB may suspend approval of any or all research activities in order to protect participants. The Institutional Official may also suspend research, as needed, on an urgent basis.
- B.** When IRB approval of research is suspended, the Institutional Official, IRB Chairs, Vice Chairs, or convened IRBs will consider actions such as the following to protect the rights and welfare of participants, as appropriate:
- Notification of current and/or former participants
 - Transferring responsibility for the research and participants to another investigator
 - Continuation of participants in the research with an independent monitor
 - Withdrawal of current participants from the research
 - Requiring arrangements for care of participants outside the research
 - Requiring or permitting follow-up of participants (e.g., for safety reasons)
 - Arranging for compensation of current and/or former participants.
- C.** When participants are to be withdrawn from the research, the Institutional Official, IRB Chairs, Vice Chairs, or convened IRBs will evaluate whether the procedures for withdrawal consider the rights and welfare of enrolled participants.
- D.** When study approval is suspended, the reason(s) will be communicated to the investigator(s), along with any actions required to protect the rights and welfare of current or past research participants. Other IRBs responsible for oversight of the investigator(s)' research will also be notified, if applicable.
- E.** Suspensions of approval may be lifted by the Institutional Official, IRB Chairs, Vice Chairs, or convened IRBs if there are no longer concerns about:
- Potential harm(s) to research participants
 - Investigator or research staff noncompliance
 - Other issues that were related to or resulted in suspension (e.g., drug manufacturer's recall).
- F.** Modifications made to the research (if any) as a result of the suspension will be reviewed by the convened IRBs when changes represent more than minor changes, as defined by HRPP policy [[Expedited and Administrative Review Procedures](#)].
- G.** When the Chair, Vice Chair, or Institutional Official suspends research, the suspension will be reported to the applicable convened IRB at the next available meeting. The convened IRB will determine whether to continue the suspension, re-instate IRB approval, or terminate approval of the research.



5. Terminations

- A. The convened IRBs may terminate previously approved research when the research is not being conducted in accordance with IRB requirements or when the research is associated with unexpected serious harm to subjects as described in HRPP policy [[Noncompliance](#)] and [[Event Reporting](#)]. *Note: Similar actions taken by investigators or sponsors to stop research activities are not terminations as described by this policy.*
- B. When IRB approval of research is terminated, the convened IRBs will consider actions such as the following to protect the rights and welfare of participants, as appropriate:
- Notification of current and/or former participants
 - Transferring responsibility for research participants to another investigator
 - Withdrawal of current participants from the research
 - Requiring arrangements for care of participants outside the research
 - Requiring or permitting follow-up of participants (e.g., for safety reasons)
 - Arranging for compensation of current and/or former participants.
- C. When participants are to be withdrawn from the research, the convened IRBs will evaluate whether the procedures for withdrawal consider the rights and welfare of enrolled participants.
- D. When study approval is terminated, the reason(s) will be communicated to the investigator(s), along with any actions required to protect the rights and welfare of current or past research participants. Other IRBs responsible for oversight of the investigator(s)' research will also be notified, if applicable.

6. Investigator Responsibilities

Upon notification that research has been suspended or terminated by the IRB, the investigator(s) is responsible for the following:

- Stopping enrollment and research activities as required by the IRB
- Cooperating with any investigation directed by the IRB or IRB Investigative Committee
- Assisting with and/or carrying out actions required by the IRB to protect the rights and welfare of participants (e.g., notification, withdrawal, follow-up, etc.)
- Reporting to the IRB any adverse events or outcomes encountered during suspension or termination of the research in accordance with HRPP policy [[Event Reporting](#)].

7. Applicable Regulations/Guidance

21 CFR 56.108, 21 CFR 56.113, 45 CFR 46.103, 45 CFR 46.113, OHRP "Guidance on Reporting Incidents to OHRP" (06/20/11)



8. History

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