



SOP: Suspension or Termination Issued Outside of Convened IRB

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1 PURPOSE

- 1.1 This procedure establishes the process for someone other than the convened IRB to institute a suspension of IRB Approval or a Termination of IRB Approval.
- 1.2 The process begins when the IRB, the Institutional Official or designee institutes a suspension or termination of approval of a research activity.
- 1.3 The process ends when the Suspension of IRB Approval or a Termination of IRB Approval has been placed on the agenda for review by the convened IRB, and the investigator and appropriate regulatory authorities are notified of the suspension or termination of approval.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised to include suspensions and terminations of approval by the IRB and to clarify actions to protect human subjects and comply with notification requirements.
- 2.2 Revisions made for clarity.
- 2.3 Revisions made for clarity, reporting requirements documented, removal of requirement for list of enrolled subjects.
- 2.4 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021.

3 GUIDING PRINCIPLES

- 3.1 The institution or IRB may suspend or terminate approval of all research activity or of a specific activity such as enrollment or administration of the test article.
- 3.2 The IRB may institute a suspension or termination of approval when, in the opinion of the Committee, subjects may be at risk of adverse effects on their rights and welfare and/or the data collected or created will not be reliable.
- 3.3 The following individuals may institute a Suspension of IRB Approval when, in their opinion, subjects may be at risk for adverse effects on the rights and welfare before action may be considered by the convened IRB:
 - 3.3.1 The IRB Chair
 - 3.3.2 Executive Vice President
 - 3.3.3 Provost
 - 3.3.4 Vice Provost for Research & Scholarly Activities
 - 3.3.5 Executive Director, Human Subject Research Office (HSRO)
 - 3.3.6 Director, HSRO
- 3.4 The Institutional Official or designee (Executive Vice President and Provost, Executive Director HSRO, may institute a Suspension of IRB Approval or Termination of IRB Approval for any reason.
- 3.5 Whenever possible, the individual following these procedures communicates with investigators both orally and in writing.
- 3.6 The institution notifies institutional officials and regulatory authorities, when applicable, of any suspension or termination of research activity.

4 RESPONSIBILITIES

- 4.1 The individual or committee instituting the Suspension of IRB Approval or Termination of IRB Approval follows these procedures.
- 4.2 If other than the Vice Provost for Research or Executive Director HSRO institutes the Suspension of IRB Approval or Termination of IRB Approval, the individual must ensure the Vice Provost for Research and the Executive Director HSRO are informed of the action.

5 PROCEDURE

- 5.1 Notify the investigator of the Suspension of IRB Approval or Termination of IRB Approval along with the reasons for the decision.



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- 5.2 Ask the investigator for a list of Human Subjects currently involved in the research.
- 5.3 Ask the investigator whether any actions are required to protect those subjects' rights and welfare or to eliminate an apparent immediate hazard.
- 5.4 Consider whether any of the following additional actions are required to protect those or other subjects' rights and welfare or to eliminate an apparent immediate hazard:
 - 5.4.1 Transferring subjects to another investigator.
 - 5.4.2 Making arrangements for clinical care outside the research.
 - 5.4.3 Allowing continuation of some research activities under the supervision of an independent monitor.
 - 5.4.4 Requiring or permitting follow-up of subjects for safety reasons.
 - 5.4.5 Requiring adverse events or outcomes to be reported to the IRB and the sponsor.
 - 5.4.6 Notification to current Human Subjects.
 - 5.4.7 Notification to former Human Subjects.
- 5.5 If other than the IRB institutes the Suspension of IRB Approval or Termination of IRB Approval, refer the action to the HSRO staff to place on the agenda for a convened IRB meeting in an IRB with appropriate scope as an item of Suspension of IRB Approval or Termination of IRB Approval and ensure sufficient information is available to the IRB for determining whether the suspension or termination should remain in effect and whether additional action(s) should be implemented.
 - 5.5.1 The IRB will consider the information provided and determine whether the suspension or termination should be affirmed or rescinded.
 - 5.5.2 The IRB will consider if any additional actions are required to protect the subjects' rights and welfare.
- 5.6 Complete and send to the investigator HRP-515 - LETTER - Suspension or Termination or equivalent within two business days of the suspension or termination.
- 5.7 For federally funded studies, notify the appropriate federal agency/department within 30 days of the suspension or termination.
- 5.8 For FDA regulated studies, notify the appropriate FDA Division within 30 days of the suspension or termination.
- 5.9 Send copies of the regulatory notifications to the investigator's Department Chair, the Institutional Official, Executive Director Research Compliance and Associate Vice President of Regulatory Affairs and Assessment, Executive Director, Research Compliance and Quality Assurance (RCQA) and General Counsel.

6 MATERIALS

- 6.1 HRP-041 - SOP - IRB Meeting Conduct
- 6.2 HRP-515 - LETTER - Suspension or Termination

7 REFERENCES

- 7.1 21 CFR §56.108(b)(3), 21 CFR §56.113
- 7.2 45 CFR §46.103(b)(5)(ii), 45 CFR §46.108(a), 45 CFR §46.113
- 7.3 AAHRPP elements I-9, II.2.D, II.2.G, II.2.H