



<b>SOP: Suspension or Termination Issued Outside of Convened IRB</b>			
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**1 PURPOSE**

- 1.1 This procedure establishes the process for the Vice President for Research, Institutional Official (IO), IRB Chair, IRB Office Executive Director, or designee to institute a Suspension of IRB Approval or a Termination of IRB Approval outside a convened IRB meeting.
- 1.2 The process begins when the Vice President for Research, IO, IRB Chair, IRB Office Executive Director, or designee institutes a Suspension of IRB Approval or the Vice President for Research issues a Termination of IRB Approval for research approved by the Institution's IRB or the IRB of record in accordance with a signed agreement.
- 1.3 The process ends when the IRB Compliance Team reports the suspension or termination to institutional officials and the applicable federal agencies, such as the Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), and the IRB Chairpersons, at their monthly meeting.

**2 PREVIOUS VERSION**

- 2.1 Revised from previous version dated 11/13/2023.

**3 POLICY**

- 3.1 The Vice President for Research, IO, IRB Chair, IRB Office Executive Director, or their designee may institute a suspension of IRB Approval for some or all research activities on a protocol if one of the aforementioned individuals determines the previously approved research is not being conducted in accordance with the Northwestern University IRB's requirements, or that the research has been associated with unexpected serious harm to participants, or upon receipt of an allegation of non-compliance that may impact a human research participant's safety, rights and welfare.
- 3.2 The Vice President for Research or their designee may institute a termination of IRB Approval and disallow research approved by the Institution's IRB or an external IRB.
- 3.3 The individual following these procedures promptly communicates with the Principal Investigator in writing, when appropriate.

**4 RESPONSIBILITIES**

- 4.1 The individual facilitating the review of a Suspension of IRB Approval or Termination of IRB Approval performs the following procedures.

**5 PROCEDURE**

- 5.1 The Vice President for Research, IO, IRB Chair, IRB Office Executive Director, or their designee is made aware of a situation in which research is not being conducted in accordance with the Northwestern University IRB's requirements, or that the research has been associated with unexpected serious harm to participants, or has received an allegation of non-compliance that may impact the research participant's safety, rights and welfare.
- 5.2 The Vice President for Research, IO, IRB Chair, IRB Office Executive Director, or their designee will institute a Suspension of IRB Approval or Termination of IRB Approval outside of the review by a convened IRB.
- 5.3 The IRB Compliance Team will place the study in a suspended state in the eIRB+ system.
- 5.4 The IRB Compliance Team will complete and send the Principal Investigator by email and in the eIRB+ system a TEMPLATE LETTER: Suspension of IRB Approval (HRP-715) or TEMPLATE LETTER: Termination of IRB Approval (HRP-716) to notify the Investigator of the Suspension of IRB Approval or Termination of IRB Approval and the reasons for the decision in writing.



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- 5.5 The IRB Compliance Team will send a copy of the suspension/termination letter to the IRB Office Executive Director, the Principal Investigator's department chair or division chief, and entity administrators via email.
- 5.6 The IRB Compliance Team will notify the IRB Office Associate Directors and Managers of the Suspension of IRB Approval or Termination of IRB Approval by email.
- 5.7 If any other submissions for the study, such as a modification, continuing review, or reportable new information, are under review, a member of the Compliance Team will inform the IRB Analyst assigned to the submission to ensure that no approvals are issued after the study is terminated or until the suspension is lifted.
- 5.8 The Principal Investigator may ask the IRB Chair to allow actions that are required to protect participants' rights and welfare or to eliminate an apparent immediate hazard.
- 5.9 The IRB Chair will consider whether any of the following additional actions are required to protect participants' rights and welfare or to eliminate an apparent immediate hazard:
  - 5.9.1 Transferring participants to another investigator.
  - 5.9.2 Arranging for clinical care outside the research.
  - 5.9.3 Allowing the continuation of some research activities under the supervision of an independent monitor.
  - 5.9.4 Requiring or permitting follow-up of participants for safety reasons.
  - 5.9.5 Requiring adverse events or outcomes to be reported to the IRB and the sponsor.
  - 5.9.6 Notification to current participants.
  - 5.9.7 Notification to former participants.
- 5.10 Documentation of the suspension and any request for continuation will be saved within the IRB Office share drive and uploaded as a comment to the study's eIRB+ submission history.
- 5.11 Should the Principal Investigator wish to respond or need additional information, the Principal Investigator or designee may contact the IRB Compliance Team.
- 5.12 To lift the suspension, the Principal Investigator (PI) must submit a formal response to the suspension letter via email to [irbcompliance@northwestern.edu](mailto:irbcompliance@northwestern.edu).
- 5.13 A member of the IRB Compliance Team will instruct the Principal Investigator regarding the next appropriate steps, including the submission of a Reportable New Information (RNI) application in eIRB+ or other applicable action.
- 5.14 IRB staff will place the submission on the agenda for a convened IRB with the appropriate scope.
- 5.15 The convened IRB will assess the submission and provide a determination following "SOP: IRB Meeting Conduct (HRP-041)"
- 5.16 The convened IRB will also vote to lift the Suspension as part of the determination for the associated submission.
- 5.17 The IRB Analyst will issue a determination letter for the submission under review.
- 5.18 A member of the IRB Compliance Team will report the suspension or termination to institutional officials and the applicable federal agencies, such as the Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA), using the procedures outlined in the External Reporting Process SOP (HRP-094), and at the next IRB Chairs meeting.

**Note on Voluntary Holds:** A voluntary hold of research activities that an investigator or sponsor institutes does not apply to interruptions of research related to concerns regarding the safety, rights, or welfare of human research participants or others. When an Investigator/Sponsor voluntarily places a hold on any research activity (e.g., enrollment or procedures), the Investigator or designee must promptly report the hold to the IRB via an eIRB+ Reportable New Information submission. Such voluntary action, proactively taken by



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the Investigator/Sponsor, may not result in a subsequent IRB determination of suspension or termination of IRB approval, as appropriate.

During a voluntary hold, all research activities are still subject to the requirements of continuing review (when applicable) and the prompt reporting of Unanticipated Problems Involving Risk to Subjects or Others (UPIRSOs) and incidents of non-compliance.

Implementation of a voluntary hold is not permissible in instances related to safety or violation of participants' rights. When a voluntary hold is in place, for the paused research activities to be resumed, the Investigator must first obtain IRB approval to lift the voluntary hold via an eIRB+ modification submission. The modification submission requesting to lift the voluntary suspension must address the actions the Investigator has taken and/or provide new information that resolves the concerns that initially warranted the voluntary hold of research activities.

### 6 MATERIALS

- 6.1 SOP: Suspension or Termination by a Convened IRB (HRP-029)
- 6.2 SOP: IRB Meeting Conduct (HRP-041)
- 6.3 SOP: External Reporting Process (HRP-094)
- 6.4 GENERAL DOCUMENT: Human Research Protection Program Plan (HRP-101)
- 6.5 GENERAL DOCUMENT: Investigator Manual (HRP-103)
- 6.6 TEMPLATE LETTER: Suspension of IRB Approval (HRP-715)
- 6.7 TEMPLATE LETTER: Termination of IRB Approval (HRP-716)

### 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 §46.112, 45 CFR §46.108(a), 45 CFR §46.113
- 7.3 32 CFR §219.103(b)(5), 32 CFR §219.113, 32 CFR §219.108(a)