SOP: Suspension or Termination Issued Outside of Convened IRB

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<td>Executive Director, IRB Office Northwestern University</td>
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1 PURPOSE
1.1 This procedure establishes the process for the Vice President for Research, Institutional Official/Organizational Official (IO/OO), IRB Chair, IRB Office Executive Director, or designee to institute a Suspension of IRB Approval or a Termination of IRB Approval, outside of a convened IRB meeting.
1.2 The process begins when the Vice President for Research, IO/OO, or designee, suspends or terminates research approved by the Institution’s IRB or the IRB of record in accordance with a signed agreement or an IRB chair, IRB Office Executive Director, or their designee institutes a Suspension of IRB Approval or a Termination of IRB Approval.
1.3 The process ends when the Suspension of IRB Approval or a Termination of IRB Approval has been reviewed by the convened IRB.

2 PREVIOUS VERSION
2.1 Revised from previous version dated 11/22/2018.

3 POLICY
3.1 The Vice President for Research, IO/OO, IRB Chair, IRB Office Executive Director, or their designee may institute a Suspension of IRB Approval when participants may be at risk of adverse effects on their rights and welfare before action can be considered by the convened IRB.
3.2 The Vice President for Research, IO/OO or designee may institute a Termination of IRB Approval of any research approved by one of the Institution’s IRB panels for any reason.
3.3 Whenever possible the individual following these procedures communicates with investigators promptly in writing.

4 RESPONSIBILITIES
4.1 The individual issuing a Suspension of IRB Approval or Termination of IRB Approval follows these procedures.

5 PROCEDURE
5.1 The Vice President for Research, IO/OO, IRB Chair, IRB Office Executive Director, or their designee may become aware of a situation in which participants may be at risk of adverse effects on their rights and welfare, and therefore the Vice President for Research, IO/OO, IRB Chair, IRB Office Executive Director may need to suspend or terminate a study before consideration by the convened IRB can occur.
5.2 Notify the investigator of the Suspension of IRB Approval or Termination of IRB Approval and the reasons for the decision in writing by email and in the IRB electronic database.
5.3 Ask the investigator whether any actions are required to protect those participants’ 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 participants’ rights and welfare or to eliminate an apparent immediate hazard:
5.4.1 Transferring participants to another investigator.
5.4.2 Arranging 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 participants 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 participants.
5.4.7 Notification to former participants.
5.5 A member of the Compliance team will notify the IRB Manager and work with the IRB Analyst to place a Reportable New Information (RNI) notification on the agenda for the next available convened IRB meeting with appropriate expertise as an item of Suspension of IRB Approval or Termination of IRB Approval. Follow “SOP: IRB Meeting Conduct (HRP-041)” for convened review of the item. If any other submissions (modification, continuing review, Reportable New Information) are currently under review, a member of the compliance team will contact the IRB Analyst member to ensure that no approvals are issued after termination or until the suspension is lifted.

5.6 The IRB Analyst issues a determination letter for the RNI under review.

5.7 Following the meeting and IRB determination, the IRB Analyst or Compliance Analyst will complete and send to the investigator a “TEMPLATE LETTER: Suspension of IRB Approval (HRP-715) or TEMPLATE LETTER: Termination of IRB Approval (HRP-716).”

5.8 The Principal Investigator may submit a response to the Suspension or Termination letter via email to irbcompliance@northwestern.edu. The IRB Compliance staff member will instruct the PI regarding next appropriate steps, which may include submission of an RNI in eIRB+, or other applicable action.

5.9 Notify the IRB Compliance manager of the Suspension of IRB Approval or Termination of IRB Approval by email.

5.10 A member of the Compliance Team will report the suspension or termination to 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.

6 MATERIALS
6.1 GENERAL DOCUMENT: Human Research Protection Program Plan (HRP-101)
6.2 GENERAL DOCUMENT: Investigator Manual (HRP-103)
6.3 SOP: External Reporting Process (HRP-094)
6.4 SOP: Suspension or Termination by a Convened IRB (HRP-029)
6.5 SOP: IRB Meeting Conduct (HRP-041)
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)