1 PURPOSE

1.1 This procedure establishes the process for the convened IRB to institute a Suspension of IRB Approval or a Termination of IRB Approval.

1.2 The process begins when the convened panel disallows research approved by the Institution’s IRB or an external IRB and institutes a Suspension of IRB Approval or a Termination of IRB Approval.

1.3 The process ends after the Principal Investigator (PI) has been informed of the Suspension of IRB Approval or a Termination of IRB Approval.

2 PREVIOUS VERSION

2.1 Previous version dated 04/02/2018.

3 POLICY

3.1 The IRB Chair, IRB Executive Director, or IRB Manager(s) may institute a Suspension of IRB Approval when, in the opinion of the convened IRB, participants may be at risk of adverse effects on their rights and welfare before action may be considered by the convened IRB.

3.2 The Vice President for Research, Institutional Official or designee may disallow research approved by one of the Institution’s IRBs.

3.3 The IRB Executive Director, Vice President for Research, Institutional Official, or designee may institute a Termination of IRB Approval.

3.4 Whenever possible the individual following these procedures communicates with investigators in writing.

4 RESPONSIBILITIES

4.1 If the investigator suspends or terminates a research study without prior agreement of the sponsor, the investigator should promptly inform the sponsor and the IRB, and should provide both a detailed written explanation of the suspension or termination.

4.2 If the sponsor suspends or terminates a trial, the investigator should promptly inform the institution where applicable. The investigator should promptly inform the IRB and provide the IRB a detailed written explanation of the suspension or termination.

4.3 In cases where the IRB suspends or terminates its approval determination of a trial, the IRB should inform the investigator where applicable, and the investigator should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the suspension or termination.

4.4 The individual facilitating the review of a Suspension of IRB Approval or Termination of IRB Approval follows these procedures.

5 PROCEDURE

5.1 The convened IRB will assess a submission (such as a continuing review, modification or reportable new information) that is under consideration.

5.2 The convened IRB will enter a separate motion and vote to issue a Suspension of IRB Approval or Termination of IRB Approval.

5.3 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.

5.4 Ask the investigator whether any actions are required to protect those participants’ rights and welfare or to eliminate an apparent immediate hazard.

5.5 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:

5.5.1 Transferring participants to another investigator.
5.5.2 Making arrangements for clinical care outside the research.
5.5.3 Allowing continuation of some research activities under the supervision of an independent monitor.
5.5.4 Requiring or permitting follow-up of participants for safety reasons.
5.5.5 Requiring adverse events or outcomes to be reported to the IRB and the sponsor.
5.5.6 Notification to current participants.
5.5.7 Notification to former participants.

5.6 The IRB Analyst issues a determination letter for the submission under review.
5.7 The IRB Analyst notifies the IRB Compliance Team of the Suspension of IRB Approval or Termination of IRB Approval by email.
5.8 The IRB Analyst or Compliance Analyst completes and sends the investigator a “TEMPLATE LETTER: Suspension of IRB Approval (HRP-715) or TEMPLATE LETTER: Termination of IRB Approval (HRP-716).”
5.9 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.
5.10 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.
5.11 To lift the suspension, the Principal Investigator (PI) must submit a formal response to the suspension letter, which will undergo review by the convened panel that instituted the suspension.
5.12 If the Principal Investigator wishes to reinstate a terminated study, the PI must submit a new study application and a formal response to the issues outlined in the termination letter.

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 (HRP-094)
6.4 SOP: Suspension or Termination Issued Outside of Convened IRB (HRP-026)
6.5 TEMPLATE LETTER: Suspension of IRB Approval (HRP-715)
6.6 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 §46.108(a), 45 CFR §46.113
7.3 32 CFR §219.103(b)(5), 32 CFR §219.113, 32 CFR §219.108(a)