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 when the convened IRB has reviewed the Suspension of IRB Approval or a Termination of IRB Approval.

2 PREVIOUS VERSION

2.1 Previous version dated 04/30/2021.

3 POLICY

3.1 The convened IRB may institute a Suspension of IRB Approval or a Termination of IRB Approval for some or all research activities on a protocol if the convened IRB 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.

3.2 Whenever possible, the individual following these procedures promptly communicates with investigators in writing.

4 RESPONSIBILITIES

4.1 If the **Investigator** suspends or terminates a research study without the prior agreement of the sponsor, the Investigator should promptly inform the sponsor and the IRB, and should provide a detailed written explanation of the suspension or termination via a Reportable New Information (RNI) application in the eIRB+ system.

4.2 If the **sponsor** suspends or terminates a trial, the Investigator should promptly inform the institution by supplying the IRB with a detailed written explanation of the suspension or termination via an RNI application in the eIRB+ system.

4.3 In cases where the **IRB** suspends or terminates its approval determination of a study, the IRB Office will inform the Investigator. The Investigator should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the suspension or termination.

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 to assess the submission and vote to issue a Suspension of IRB Approval or Termination of IRB Approval.

5.3 The IRB Analyst and or the IRB Lead Analyst will notify the IRB Compliance Team immediately of the suspension issued by the IRB panel.

5.4 The IRB Compliance Analyst will place the study in a suspended state in the eIRB+ system.

5.5 The IRB Compliance Analyst will complete and send the Principal Investigator the determination through the eIRB+ system using letter template Suspension of IRB Approval (HRP-715) or 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.

5.6 The Compliance Analyst will send a copy of the suspension / termination letter to the Principal Investigator, primary contact, IRB Office Executive Director, the IRB Analyst and the IRB Lead

Analysts, the Principal Investigator's department chair or division chief, and entity administrators via email.

5.7 The IRB Compliance Analyst will add the suspension or termination to the appropriate compliance tracking mechanism.

5.8 A copy of the letter and other related correspondence will be saved in the Suspended Projects folder in the Compliance unit's shared drive.

5.9 The Principal Investigator may ask the Chair to allow actions that are required to protect participants' rights and welfare or to eliminate an apparent immediate hazard.

5.10 The IRB Chair or the convened IRB will consider whether any of the following additional actions are required to protect participants' rights and welfare or to eliminate an apparent immediate hazard:

- 5.10.1 Transferring participants to another investigator.
- 5.10.2 Arranging for clinical care outside the research.
- 5.10.3 Allowing the continuation of some research activities under the supervision of an independent monitor.
- 5.10.4 Requiring or permitting follow-up of participants for safety reasons.
- 5.10.5 Requiring adverse events or outcomes to be reported to the IRB and the sponsor.
- 5.10.6 Notification to current participants.
- 5.10.7 Notification to former participants.

5.11 The IRB Analyst will issue a determination letter for the submission under review.

- 5.11.1 If any other submissions for the study, such as a modification, continuing review, Reportable New Information, are under review, a member of the Compliance Team will contact 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.

5.12 Should the Principal Investigator need additional information, the Principal Investigator or designee may contact the IRB Compliance unit and the IRB analyst assigned to the submission.

5.13 To lift the suspension, the Principal Investigator (PI) must address the issues from the determination letter and submit a response to the suspension in eIRB+ via the submission under review.

5.14 The convened IRB panel that instituted the suspension will review the response and provide a determination.

5.15 The IRB Analyst will issue a determination letter with a note to indicate that the suspension was lifted, for the submission to which the suspension response pertains.

5.16 If the Principal Investigator wishes to reinstate a terminated study, the PI must submit a new study application and include in the application a formal response to the issues outlined in the termination letter.

5.17 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 is instituted by an investigator or sponsor does not apply to interruptions of research that are 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), this must be promptly reported to the IRB via an eIRB+ Reportable New Information submission. Such voluntary action, proactively taken by 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, in order 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 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)