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 Institutional Official or 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 placed on the agenda for review by the convened IRB.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None.

3 POLICY
3.1 The IRB chair, IRB Director, or Assistant IRB Director may institute a Suspension of IRB Approval when in the opinion of the IRB chair or IRB manager subjects may be at risk of adverse effects on their rights and welfare before action may be considered by the convened IRB.
3.2 The Institutional Official or designee may institute a Suspension of IRB Approval or Termination of IRB Approval for any reason.
3.3 Whenever possible the individual following these procedures communicates with investigators orally and in writing.
3.4 For Veterans Administration (VA) research:
   3.4.1 An “administrative hold” is a voluntary interruption of research enrollments and ongoing research activities by an appropriate VA facility official, research investigator, or sponsor (including the Office of Research and Development (ORD) when ORD is the sponsor).
   3.4.2 The term “administrative hold” does not apply to interruptions of VA research related to concerns regarding the safety, rights, or welfare of human research subjects, research investigators, research staff, or others.
   3.4.3 An “administrative hold” must not be used to avoid reporting deficiencies or circumstances otherwise covered by VHA Handbooks or other federal requirements governing research.

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

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.
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 For Veterans Administration (VA) research report the Suspension of IRB Approval or Termination of IRB Approval directly (without intermediaries) in writing to the VA Medical Center Director within five business days with simultaneous copies to the Associate Chief of Staff for Research, the Research and Development Committee, and any other relevant research review committee.

5.6 Refer to the IRB 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. (Do not assign a Veterans Administration (VA) protocol to a commercial IRB.)

5.7 Complete and send to the investigator a “TEMPLATE LETTER: Suspension or Termination (HRP-515).”

6 MATERIALS

6.1 TEMPLATE LETTER: Suspension or Termination (HRP-515)

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