1 PURPOSE
1.1 This procedure establishes the process for someone other than the convened HRRC to institute a Suspension of HRRC Approval or a Termination of HRRC Approval.
1.2 The process begins when the Institutional Official or designee, institutes a Suspension of HRRC Approval or a Termination of HRRC Approval.
1.3 The process ends when the Suspension of HRRC Approval or a Termination of HRRC Approval has been placed on the agenda for review by the convened HRRC.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Correction of spelling and grammatical errors throughout SOP.
2.2 Replaced all references to “IRB” with “HRRC.”
2.3 Section 3.3, Policy. Updated to include reporting to the HRRC if Institutional Official or designee suspends or terminates HRRC approval.
2.4 Removed procedural details not applicable to this SOP.

3 POLICY
3.1 The HRRC chair may institute a Suspension of IRB/HRRC Approval when, in the opinion of the HRRC chair, subjects may be at risk of adverse effects on their rights and welfare before action may be considered by the convened HRRC. Reference SOP: New Information (HRP-024).
3.2 The Institutional Official or designee may institute a Suspension of HRRC Approval or Termination of HRRC Approval for any reason and will report such actions to the HRRC when the research is under its purview.
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 HRRC Approval or Termination of HRRC Approval follows these procedures.

5 PROCEDURE
5.1 Notify the investigator of the Suspension of HRRC Approval or Termination of HRRC 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 HRRC 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 HRRC Approval or Termination of HRRC Approval directly (without intermediaries) in writing to the VA Medical Center Director within 5 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 HRPO staff to place on the agenda for a convened HRRC meeting in an HRRC with appropriate scope as an item of Suspension of HRRC Approval or Termination of HRRC 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)
6.2 SOP: New Information (HRP-024)

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