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 Organizational Official or IRB chair institutes a Suspension of IRB Approval or when the Organizational Official institutes 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 Revisions required for AAHRPP accreditation; replaces version dated 9/6/13.

3 POLICY
3.1 The IRB chair may institute a Suspension of IRB Approval when in the opinion of the IRB chair 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 Organizational Official or designee may institute a Suspension of IRB Approval or Termination of IRB Approval for any reason.

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 by preparing and sending “TEMPLATE LETTER: External Report” along with the reasons for the decision within ten working days of instituting the suspension or termination.
5.2 Distribute copies of “TEMPLATE LETTER: External Report” along with the reasons for the decision to the following authorities:
   5.2.1 Organizational Official or IRB Chair as applicable
   5.2.2 Regulatory agencies when the research is overseen by those agencies and they require reporting:
      5.2.2.1 Suspensions and terminations of IRB approval are promptly (no longer than within 30 days) reported to OHRP, when appropriate.
      5.2.2.2 Suspensions and terminations of IRB approval are promptly (no longer than within 30 days) reported to FDA, when appropriate.
      5.2.2.3 Any suspension or termination of DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer.
5.3 Ask the investigator for a list of participants currently involved in the research.
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 subjects rights and welfare or to eliminate an apparent immediate hazard:
   5.5.1 Transferring subjects 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 Refer to the IRB staff to place on the agenda for a convened IRB meeting as an item of Suspension or Termination of IRB Approval.

6 MATERIALS

6.1 TEMPLATE LETTER: External Report

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