SOP: Suspension or Termination Issued Outside of Convened IRB

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 IRB chair, Organizational Official / Institutional Official (IO/OO) 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 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 IO/OO 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.

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 to provide for the status of all Human Subjects currently involved in the research (e.g., actively receiving investigational treatment, follow-up only).

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 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. Follow HRP-041 - SOP - IRB Meeting Conduct for convened IRB review of the item.

5.6 Complete and send to the investigator HRP-515 - LETTER - Suspension or Termination.

6 MATERIALS

6.1 HRP-041 - SOP - IRB Meeting Conduct

6.2 HRP-515 - LETTER - Suspension or Termination

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 AAHRPP elements I-9, II.2.D, II.2.G, II.2.H