1 PURPOSE

1.1 This SOP 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, IO designee, HRPP Director or IRB Chair 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 Revised from the 5/30/2017 version.

3 SOP Statement

3.1 The Vice President for Research, IO, IRB Chair. HRPP Director or their designee may institute a Suspension of IRB Approval for some or all research procedures when in the opinion of the IRB chair or HRPP Director the previously approved research is not being conducted in accordance with the Texas A&M University IRB's requirements or the 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 Administrative or Voluntary Holds:

3.4.1 An "administrative hold" is a voluntary interruption of research enrollments and ongoing research activities by the research investigator or sponsor.

3.4.2 An administrative hold cannot be used to extend IRB approval beyond the expiration date of a protocol without approval of continuing review.

3.4.3 The term "administrative hold" does not apply to interruptions of research related to concerns regarding the safety, rights, or welfare of human research subjects, research investigators, research staff, or others.

3.4.4 An "administrative hold" cannot be used to avoid reporting deficiencies or circumstances otherwise covered by institutional policies or other regulatory requirements governing research.

3.4.5 An Administrative Hold directed by the IRB is a suspension and must be classified and reported as such.

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, when applicable.

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 The IRB/HRPP staff will move the study to a 'Suspended' status in the IRB electronic system.

5.6 Refer to the IRB/HRPP staff to place on the agenda for the next available convened IRB meeting in an IRB with appropriate scope as an item of Suspension of IRB Approval or Termination of IRB Approval.

5.7 Complete and send to the investigator a 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 I.5.D, II.2.D, II.2.G, II.2.H