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 (IO), the IRB Chair, or designee, or the Convened IRB, institutes a Suspension of IRB Approval or the IO or Convened IRB institutes a Termination of IRB Approval (see 5.002 (HRP-041) for consistency in process).

The process ends when the written notice of a Suspension of IRB Approval or a Termination of IRB Approval has sent to the Principal Investigator (PI).

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 The IRB Chair, IO or designee may institute a Suspension of IRB Approval when subjects may be at risk of adverse effects of their rights and welfare before action may be considered by the convened IRB.

3.2 The IRB Chair, IO, or designee may institute a Suspension of IRB Approval when there is reason to believe that the research may not be conducted in compliance with IRB requirements, federal regulations, state or local laws or Rutgers policies and/or SOPs applicable to human subjects research and an opportunity to conduct an investigation to confirm compliance is appropriate, or for any reason that may warrant a pause in the conduct of the research study.

3.3 The Convened IRB (e.g., Executive IRB Committee) may terminate a study whenever it determines that the risk benefit ratio for subjects is not appropriate, or the safety and wellbeing of subjects can no longer be ensured, or the integrity of the study has been jeopardized to the extent that any of these concerns cannot be resolved.

3.4 The individual following these procedures communicates with the PI in writing and whenever possible orally.

4 RESPONSIBILITIES

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

5 PROCEDURE

Upon receipt of any information that raises concern regarding the conduct of the study and/or safety and welfare of the subjects, the person/s authorized to suspend or terminate the study will review the information and consult as necessary to make the appropriate decision. At a minimum, there should be an oral communication with the PI to discuss whether any actions are required to protect those enrolled subjects' rights and welfare or to eliminate an apparent immediate hazard. Every effort will be made to reduce risks or harm to enrolled subjects or others resulting from suspension or termination of IRB approval.

5.1.1 The discussion should the implications of a suspension or termination of IRB approval with respect to the well-being of subjects and the integrity of the study and how a suspension or termination should be implemented and communicated to subjects so to minimize any negative impact to subjects.

5.2 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:

5.2.1 Ask the PI for a list of Human Subjects currently involved in the research.

5.2.2 Transferring subjects to another investigator.

5.2.3 Making arrangements for clinical care outside the research.

5.2.4 Allowing continuation of some research activities that are necessary for the well-being of the subjects (e.g., continuing any intervention or investigational treatment, safety monitoring, etc.), or when appropriate have continuation provided under the supervision of another investigator or overseen by an independent monitor.

5.2.5 Requiring or permitting follow-up of subjects for safety reasons.

5.2.6 Requiring adverse events or outcomes to be reported to the IRB and the sponsor.

5.2.7 Notification to current Human Subjects.

5.2.8 Notification to former Human Subjects.

5.3 Refer to the IRB 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. Follow 5.002 (HRP-041) -SOP: IRB Meeting Conduct for convened IRB review of the item.

5.4 The determination to terminate study approval will be clearly documented in the convened IRB meeting minutes along with the reasons for the termination.

5.5 Complete and send to the PI an 10.305 (HRP-515) - LETTER -Suspension or Termination to include:

5.5.1 The reason(s) for the suspension or termination.

5.5.2 The effective date, notification of the sponsor (if applicable), any restrictions or further actions imposed by the IRB or institution (if applicable) and copying need-to-know officials.

5.5.3 Notice that the investigator may make an appeal. An appeal will be considered by the convened IRB.

6 MATERIALS

6.1 5.002 (HRP-041) - SOP: IRB Meeting Conduct

6.2 10.305 (HRP-515) - LETTER: Suspension or Termination (in eIRB+)

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