

SOP: Suspension and Termination by the Organization

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1. PURPOSE

- 1.1. This procedure establishes the process to institute a <Suspension of IRB Approval> or <Termination of IRB Approval> outside of a convened IRB meeting.
- 1.2. This procedure begins when an authorized individual institutes a <Suspension of IRB Approval> or <Termination of IRB Approval>.
- 1.3. This procedure ends when the authorized individual has notified the HRPP staff.

2. POLICY

- 2.1. The officials authorized by "POLICY: Human Research Protection Program (HRP-010)" to institute a <Suspension of IRB Approval> or <Termination of IRB Approval> may take these actions when in their opinion the rights and welfare of subjects may be at risk before action can be taken through <Committee Review>.

3. RESPONSIBILITY

- 3.1. The individual who institutes a <Suspension of IRB Approval> or <Termination of IRB Approval> carries out these procedures.

4. PROCEDURE

- 4.1. Notify the investigator of the <Suspension of IRB Approval> or <Termination of IRB Approval> and the reasons for the action.
- 4.2. Ask the investigator for a list of currently enrolled subjects and their level of involvement in the research (e.g., active intervention or long-term follow-up.)
- 4.3. Consider whether the rights and welfare of currently enrolled subjects may be adversely affected. If so, consider the following actions:
 - 4.3.1. Transfer subjects to another investigator
 - 4.3.2. Make arrangements for clinical care outside the research
 - 4.3.3. Allow continuation of some research activities under the supervision of an independent monitor
 - 4.3.4. Require follow-up of subjects
 - 4.3.5. Require adverse events or outcomes to be reported to the IRB
 - 4.3.6. Notify current subjects
 - 4.3.7. Other actions
- 4.4. Notify the HRPP staff member handling the protocol of the action to place on the agenda of a convened IRB meeting.

5. REFERENCES

- 5.1. 21 CFR §56.108(b)(3), 21 CFR §56.113
- 5.2. 45 CFR §46.103(b)(5)(ii), 45 CFR §46.108(a), 45 CFR §46.113