

POLICY: Suspension and Termination by the Institution

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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 IRB 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 Full Board 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. Determine with the assistance of the investigator, if the protocol is a therapeutic study, if any subjects are still undergoing therapeutic study interventions, and if there is a perceived risk to subjects if those therapeutic study interventions are stopped. The IRB Chair or designee will decide if those therapeutic study interventions may continue on those subjects involved. If the study is being conducted at the VAMC, the NF/SG Chief of Staff will be consulted. A decision must be made by the IRB Chair or designee within 2 working days.
- 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 the study to a new PI
 - 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. Notify current subjects
 - 4.3.6. Take Other actions, as necessary
- 4.4. Notify the IRB staff member handling the protocol of the action to place on the agenda of a convened IRB meeting.
- 4.5. Suspensions and terminations will be reported by the Institutional Official to the applicable regulatory agency within 30 days of the action.

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