TITLE: **Suspension or Termination of IRB Approval**

PURPOSE: Outline the process for someone other than the convened IRB to institute a Suspension of IRB Approval or a Termination of IRB Approval

RESPONSIBILTIES: Organizational Official or Designee

PROCEDURES:

The Organizational Official or designee, in place of the convened IRB, can institute a Suspension of IRB Approval or a Termination of IRB Approval when:

- IRB approval is no longer required;
- When in the opinion of the IRB chair or HSPP Director, subjects may be at risk of adverse effects on their rights and welfare before action may be considered by the convened IRB; or
- The Organizational Official or designee suspended or terminated IRB approval for any reason.

Notify the investigator in writing of the Suspension of IRB Approval or Termination of IRB Approval along with the reasons for the decision, if necessary.

Projects Suspended or Terminated for Cause:

1. Obtain a list of Human Subjects currently involved in the research and a determination of any actions that are required to protect those subjects' rights and welfare from the investigator.
2. Ask the investigator to consider whether any of the following additional actions is required to protect subjects' rights and welfare:
    a. Transferring subjects to another investigator;
    b. Arranging for clinical care outside the research;
    c. Allowing continuation of some research activities under the supervision of an independent monitor;
    d. Requiring or permitting follow-up of subjects for safety reasons;
    e. Requiring adverse events or outcomes to be reported to the IRB and the sponsor;
    f. Notification to current Human Subjects; and/or
    g. Notification to former Human Subjects.
3. If continued care of subjects is necessary, follow SOP-016: Continuation of Subjects in Expired Research.
4. Refer the item to the Director or designee to place on the agenda for a convened IRB meeting.
5. Prepare and send an external report as discussed in the Operations Manual.

Whenever possible the individual following this process communicates with investigators orally and follows up with written communication.

MATERIALS:

- SOP-016 - Continuation of Subjects in Expired Research
- Operations Manual

- T516 - External Report

REFERENCES:

- 21 CFR §56.108(b)(3), 21 CFR §56.113
- 45 CFR §46.102, 45 CFR §46.103(b)(5)(ii), 45 CFR §46.108(a), 45 CFR §46.113

REVIEW/REVISIONS:

From 10/01/10 version: Added termination of IRB approval based on determination that IRB approval is no longer required because the project no longer meets the DHHS definitions of 'research' or 'Human Subjects'; Clarified that suspension or termination for cause require additional measures; Removed reference to Assistant Director, Process Improvement and Compliance; Removed reference to the VA.

From 01/2014 version: Renumbered from P&P-026; Reference to P&P-061 to SOP-016 to reflect new numbering system.