

SOP: 411
SUSPENSION OR TERMINATION
OF IRB APPROVAL

1. POLICY

Approved research that is not conducted in accordance with IRB policies/procedures, federal/state/local regulations, and/or laws, or that has been associated with unexpected serious harm to participants is subject to suspension or termination. Suspension is defined as a temporary or permanent halt to all research activities. Suspended research is still subject to continuing review. Termination is defined as a permanent halt to all research activities. Terminated research is no longer subject to continuing review. The IRB may suspend or terminate approval of research that:

- Is not being conducted in accordance with the IRB's requirements.
- Is associated with unexpected serious harm to participants.

The IRB may suspend or terminate research based on information received during its continuing review, from the findings of a Quality Improvement audit, or from participant (or other) complaints made to the IRB.

The IRB, IRB Chair, and IRB Vice-Chair have the authority to suspend or terminate research activities, giving consideration to protections necessary for current participants' rights and welfare. Should the IRB Chair or Vice-Chair act independently to suspend or terminate research, this action shall be reported to the IRB at the next convened meeting.

An investigator may decide to voluntarily suspend or terminate some or all research activities that are under current review or investigation. If this occurs even following a verbal or written prompt by the IRB, IRB Chair, or IRB Vice-Chair, it is not considered a suspension or termination of IRB approval.

Specific Policies

1.1 Suspension/Termination by the IRB.

The IRB shall review the information it receives to determine whether the investigator failed to comply with IRB-approved conduct of research or the research is associated with unexpected serious harm to participants. When study approval is suspended or terminated by the IRB, the IRB must consider:

- Actions to protect the rights and welfare of currently enrolled participants.
- Whether procedures for withdrawal of enrolled participant considered their rights and welfare.
- Whether participants should be informed of the termination or suspension.
- Whether to require any adverse events or outcomes to be reported to the IRB.

The IRB shall suggest a course of corrective measures and establish a time frame in which the corrective measures are to be implemented. The particular details of suspension and termination are documented in the Minutes as per SOP 303C, Meeting Minutes.

The IRB shall continue to monitor the investigator's progress at resolving the suspension. If sufficient progress is not made and this issue has been unresolved longer than two (2) months, the IRB may immediately terminate the research.

1.2 Suspension by an IRB Chair or Vice Chairperson.

An IRB Chair or Vice Chair is not authorized to terminate research. However, both are authorized to suspend research and report the suspension to the convened IRB. The IRB monitors the investigator's resolution of the suspension. If after two (2) months the suspension has not been resolved, the IRB Chair or IRB Vice Chair shall bring the suspension before the IRB in order to proceed with study termination.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. RESPONSIBILITY

The Institutional Official is responsible for creating and maintaining a coercion-free environment with respect to the ongoing review of research and any decisions that come from that review, whether the outcome is approval, contingent approval, deferral, suspension, or disapproval/termination.

The IRB Administrator is responsible for posting items to the IRB agenda, per SOP 303A, Meeting Agenda; following distribution procedures, per SOP 302, Administrative Review and Distribution of Materials; and creating IRB Minutes, per SOP 303C, Meeting Minutes. The IRB Administrator is responsible for coordinating with the IRB Chair or designee the drafting, finalizing, and distributing of all IRB correspondence. The IRB and/or QI Coordinator is responsible to monitor the resolution of all suspensions.

The IRB Chair or designee is responsible for the review of all information received regarding the conduct of the research in question and whether the information supports a determination of suspension and/or termination. The IRB Chair or designee is responsible for forwarding all issues of research termination to the IRB for review. The IRB Chair or designee is responsible for contacting the investigator regarding decisions of suspension/termination prior to sending formal written IRB communication. If after two (2) months adequate progress has not been achieved with respect to research suspension, the IRB Chair or designee will notify the IRB of the research and recommend termination of the research to the IRB.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50, 56
45 CFR 46

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 302, Administrative Review and Distribution of Materials
SOP 303A, Meeting Agenda
SOP 303C, Meeting Minutes
SOP 308, Reporting to Regulatory Agencies and Institutional Officials.

6 ATTACHMENTS

None.

7. PROCESS OVERVIEW

7.1 The IRB Administrator receives, processes, and either posts the item to the appropriate agenda or forwards it to the appropriate IRB Chair or designee for review.

7.2 The IRB or IRB Chair reviews the information and may suspend the research if the research has not been conducted as previously approved by the IRB. Research may be suspended if it is associated with unexpected serious harm to participants.

- 7.3 The IRB Chair or designee contacts the investigator with a suspension determination. The IRB Chair or designee, in conjunction with the IRB Administrator, drafts and finalizes a formal letter outlining the reason(s) for suspension and proposes corrective measures with completion timeline or requests corrective measures and completion timeline from the investigator.
- 7.4 The IRB Administrator monitors the progress of suspension resolution. If after two (2) months acceptable progress has not been made, the IRB Administrator notifies the IRB Chair or designee and posts the research suspension item as a discussion item for IRB review.
- 7.5 The IRB may terminate the research. The IRB discusses provisions for the rights and safety of participants, appropriate follow-up care, and the risk(s) to current participants prior to terminating any research. Formal communication with the investigator and other entities is accomplished as per SOP 308, Reporting to Regulatory Agencies and Institutional Officials.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012