

SOP: RR 407 Version No: 02 Effective Date: 12/3/10	SUSPENSION OR TERMINATION OF IRB APPROVAL	Supersedes Document Dated: 7/1/08
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1. POLICY

Steering Committee approved 10/17/11

All currently approved research that is not being conducted in accordance with the policies of the Aurora IRB or federal, state, and local requirements, or that has been associated with unexpected serious harm to subjects may be subject to suspension or termination of IRB approval.

Specific Policies

Terms used in this policy, but not defined herein shall have the meanings set forth in the Glossary.

1.1. Definitions

1.1.1. “Suspension for cause” is an action initiated by the IRB to stop temporarily some or all research activities pending future action by the IRB or by the Investigator.

1.1.2. “Termination for cause” is an action initiated by the IRB to stop permanently some or all activities of a currently approved research study.

1.2. Suspensions or terminations for cause.

The IRB Chair may determine that currently approved research be suspended or terminated for the following reasons, including but not limited to:

- Serious and Continuing Noncompliance with federal, state or local regulations; or Aurora IRB policy;
- Failure to respond to an Aurora IRB request for more information relative to an Administrative Hold;
- Failure to obtain IRB-approved informed consent; or
- Change in the risk-benefit ratio of the research, i.e., the study has been associated with unexpected serious harm to subjects.

The IRB Chair, in consultation with the Institutional Official as necessary, has the authority to suspend or terminate previously approved research. Such action will be reported and reviewed at a fully convened IRB meeting.

IRB determinations at the fully convened meeting may necessitate further investigation of allegations under the Non-compliance policy (CO 601) and/or Scientific Misconduct policy (CO 602).

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1.2.1. Following IRB determination, the RSPP Manager prepares, in consultation with the IRB Chair, a letter to the Investigator containing the following information, as applicable:

(i) The reasons for the IRB’s actions.

(ii) Requires that the Investigator submit to the IRB proposed procedures for the withdrawal of currently enrolled subjects that considers their rights and welfare. The IRB will review the proposed procedures. The IRB may mandate oversight by or transfer responsibility to another Investigator to assure implementation of these procedures.

(iii) Requires that the Investigator submit to the IRB a proposed letter/script notifying all currently enrolled subjects affected by the suspension/termination of research activities. The IRB will review the proposed letter/script. If follow-up of subjects is required by the IRB for safety reasons, subjects should be so informed. The IRB may directly contact subjects to fulfill this notification.

(iv) Requires the Investigator to report any events to the IRB or sponsor that would have required reporting had the subjects continued to be enrolled in the research. The IRB may mandate oversight by or transfer responsibility to another Investigator to assure implementation of these procedures.

1.3. Reporting

All suspensions and terminations will be reported according to IRB policy RR 408.

2. SCOPE

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

3. APPLICABLE REGULATIONS AND GUIDELINES AND STANDARDS

45 CFR 46.113

21 CFR 56.113

AAHRPP Element II.2.G.

4. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.