

**Nova Southeastern University
Institutional Review Board
Policies and Procedures**

Suspension and Termination of Research

Effective 04/12/2007; Revised 8/29/2011

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Purpose:

To establish policy and procedures for the suspension and/or termination of research.

Definitions:

None

Policy:

The IRB has authority to suspend or terminate research that is not being conducted in accordance with the IRB's requirements, other institutional and federal requirements, or has been associated with any unexpected serious harm to subjects. Concerns regarding the conduct of research must be reported immediately to the IRB Chair by any individual having such knowledge.

References:

45 CFR 46.113

21 CFR 56.108(b)(3)

21 CFR 56.113

Procedures:

1. Researchers or other university students or employees who have knowledge of, or concerns of a research protocol harming subjects, shall contact the IRB chair or IRB administrator to discuss concerns within one business day. If an adverse or serious adverse event or an unanticipated problem has occurred, the researcher shall follow the adverse events/unanticipated problems policy.
2. The IRB chair will then convene an emergency meeting of the IRB, if warranted, to review the protocol and any new information.
3. If the IRB decides to suspend or terminate research, the IRB will provide a statement of the IRB's action and determinations. If any corrective actions may be taken to reinstate the research, this statement will include such information.
4. The IRB will report its decision promptly to the principal investigator, the Office of Grants and Contracts, the funding agency, in the case of a sponsored project, and the Food and Drug Administration and/or the Office for Human Research Protections when applicable.