

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

Non-compliance

Effective 10/01/2008; Revised 02/11/2010, 10/14/2010, 09/16/2011

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Purpose:

To establish policy and procedures for the prompt reporting and management of instances of non-compliance with applicable federal, state or local laws or regulations, university policies, and/or IRB requirements.

Definitions:

1. Non-compliance is the failure to act in accordance with university policies, IRB policies and procedures, federal, state, or local laws that relate to human subjects research.

Policy:

1. The IRB encourages those who are aware of, or concerned about the potential misconduct by researchers, to report their concerns to the IRB. University employees and students are required to report their concerns promptly. The IRB will maintain a climate that fairly evaluates reports of potential misconduct, and protects the “whistleblower” from retaliation.
2. The IRB will review, and investigate where appropriate, all reports of non-compliance, and will report serious and continuing non-compliance issues to appropriate university supervisors, granting agencies, and federal agencies.
 1. Examples of non-compliance considered “serious” by the IRB include, but are not limited to, the following:
 - actions that increase risk to participants and/or adversely affect their rights and welfare;
 - actions or activity that have harmed research participants or that may cause injury (physical, psychological, emotional etc);
 - actions or activity that has compromised privacy and confidentiality of research participants or compromised ethical principles;
 - actions or activity that decrease potential benefits or compromise the integrity or validity of the research;
 - conducting human subject research without prior IRB review
 - substantive modifications to IRB-approved research carried out without IRB approval;

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- enrollment of subjects who fail to meet the inclusion criteria of the protocol or who meet exclusion criteria;
 - enrollment or continued participation of research subjects while study approval has lapsed;
 - enrollment of research subjects without approved informed consent; and/or
 - willful or knowing misconduct by the principal investigator or study personnel.
2. Examples of non-compliance that shall be considered “continuing” by the IRB include, but are not be limited to, the following:
- repeated instances of failure to follow federal regulations and/or university and/or IRB policies and procedures particularly after the IRB has informed the principal investigator and his/her personnel of the problem(s) and that corrective action needs to be taken;
 - the principal investigator has multiple problems with non-compliance over a lengthy period of time or has a problem with multiple existing or previously approved studies;
 - a pattern of minor non-compliances with multiple studies by the same investigator(s) that reflect a lack of knowledge, apparent unwillingness to comply with IRB requirements, or a lack of commitment by the investigator and/or study team that, if unaddressed, may compromise the integrity of the human research or the human subjects’ protection program; and/or
 - actions that suggest a likelihood that non-compliance will continue without intervention.
3. The IRB will investigate allegations of non-compliance promptly and expeditiously and report to applicable regulatory agencies, administration, investigators, and/or sponsors in a timely manner. Non-compliance that is determined by the Director as being serious and/or continuing will be reviewed by the full convened board, which will vote on appropriate corrective action. The Director of Human Subjects Protection Program/IRB (Director), IRB Chair, or an IRB member who serves as his/her designee has discretion to take corrective actions for non-compliance issues that are neither serious nor continuing.

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References:

45 CFR 46.103(b)(5)

45 CFR 46.113

21 CFR 56.108(b)(2)

Procedures

1. Researchers, university students or employees who have knowledge of, or concerns about research conducted without IRB approval and/or not being conducted as approved by the IRB, shall contact the IRB chair or the IRB office to discuss concerns within one business day. The Director of Human Subjects Protection Program/IRB, IRB chair, or IRB member designated by the Director will review the information presented, as well as other sources of information, and determine if further investigation is necessary. The Director or other designee may obtain information from sources other than the investigator, following the policies and procedures outlined in *Verification of Compliance with Approved Protocols from Sources Other than Investigators*. The Director or designee will initiate investigation within 72 hours of receiving a report of potential non-compliance. The Director may request assistance from the IRB members, staff, or administration. The Director will track reports of non-compliance via a non-compliance tracking file. That file will contain the name of the investigator, the project title, IRB protocol number (if assigned) and pertinent information associated with the non-compliance investigation as determined by the Director. In addition, a separate file for the applicable report will be created to store all documents associated with the non-compliance investigation. In the instance of multiple reports associated with the same study, the Director may, at his/her discretion, store the non-compliance records in one file.

2. If the Director or designee determines that there are non-compliance practices or other circumstances that may immediately jeopardize the safety and welfare of human subjects, the Director or designee will convene a subcommittee comprised of at least five members of the IRB. Members of this subcommittee may be either center representatives or alternates and may meet either in-person or by teleconference. The action of this subcommittee is based on a majority vote of the members of the subcommittee present. The Director or designee will only vote in cases of tied results. If the Director or designee is unable to secure at least

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five members, he or she may approach university administration for further guidance and action.

3. If the Director or designee believes that the non-compliance is not serious and is not a continuing problem, the Director or designee has the discretion to determine the needed corrective measures and require them of the researcher(s). Records will be maintained for a minimum of seven years. If the researcher is not in agreement with the finding and corrective action, the researcher may appeal the matter to the full convened IRB.
4. If the Director or designee believes the report of non-compliance has possible merit and is serious and/or continuing, the Director or designee may convene an emergency meeting of the IRB to review the concerns, or may discuss the situation at the next convened meeting.
 - The vote of the IRB will determine the corrective action required. The IRB may suspend or terminate research, using the policies and procedures outlined in *Suspension and Termination of Research*.
 - The decision of the IRB will be reflected in the minutes of the Board meeting. The principal investigator may appeal the Board's decision in keeping with the *Appeal of IRB Actions/Determinations* policy.
 - The Director or designee will communicate information to the signatory official (Vice President for Institutional Effectiveness).
 - Record of the IRB's determination and documentation associated with the non compliance will be retained for seven years following the last date of correspondence associated with the non-compliance.
5. The Director or designee will report the Board's decision in writing to the principal investigator, the researcher's immediate supervisor, the signatory official (Vice President for Institutional Effectiveness), the Office of Grants and Contracts (in the case of funded research), and the Office of Clinical Research (in the case of a clinical trial) within 72 hours after the Board meeting in writing. Notification may be sent electronically or via postal mail at the discretion of the IRB Director. The Vice President for Institutional Effectiveness

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will report cases of serious and/or continuing noncompliance to applicable funding agencies, in the case of a sponsored project, the Food and Drug Administration (FDA) when applicable, and the Office for Human Research Protections (OHRP) within one month after the IRB board meeting at which the matter was discussed and adjudicated, under the advice of counsel, unless the matter is under appeal. Further reporting may be delayed if the researcher indicates intent to appeal the decision, and if the Vice President for Institutional Effectiveness approves a delay in reporting until the appeal has been heard.