

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

**Verification of Compliance with Approved Protocols from Sources Other than Investigators**

**Effective 10/11/2007; Revised 01/02/2008; 01/08/2009; 09/16/2011**

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**Purpose:**

To establish policy and procedures relative to the Board's ability to investigate compliance with issues related to both IRB-approved and unapproved research and to provide the IRB with authority to seek information about the study or other research activity from others, if needed.

**Policy:**

In keeping with the IRB's responsibility to conduct ongoing monitoring of approved research, the IRB may, as appropriate, independently inquire into allegation of non-compliance and verify that research is being conducted in accordance with approved protocols and/or that study procedures are not harming subjects.

The IRB may undertake independent verification in circumstances including but not limited to the following:

- To assure that no material changes have occurred since the previous IRB review;
- if the study involves experimental therapies or procedures in which a clear potential for significant adverse experiences has been identified at the time of review;
- if complaints from a subject or a third-party are received;
- if one or more of the investigators has/have an actual or apparent conflict of interest;
- if there is allegation of scientific misconduct;
- if the nature and frequency of adverse events observed in similar research, or the nature and frequency of adverse events observed in the protocol under review, warrants concern; and/or
- if the study involves a vulnerable population, including those who may be unfamiliar with the language on consent forms and other documents;
- if there is allegation that research activity is being or has been conducted with IRB approval.

**References:**

21 CFR 56.108(a)(2)  
45 CFR 46.103(b)(4)(2)

**Procedures:**

1. The IRB chair will review the information presented from the investigator as well as other sources and determine if further investigation is necessary.

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2. The IRB may implement verification of the protocol using sources other than the researcher without first contacting the researcher; however, the researcher will be given the courtesy of being informed prior to verification whenever feasible and appropriate.
  
3. The IRB chair will present the results of the verification to the full Board for review. The Board may suspend or terminate the research in keeping with the Suspension and Termination of Research Policy. Appeals of the decision may be submitted in keeping with the Appeal of IRB Actions/Determinations Policy. If the IRB chair believes that continuation of the research, prior to the Board meeting, may cause harm to subjects, the IRB chair may request that the Vice President of Institutional Effectiveness review the information and use his or her authority to force compliance with the approved protocol or to suspend or terminate the research.
  
4. The IRB will notify the PI if any additional action is warranted.