

**Nova Southeastern University  
Office of Grants and Contracts  
Institutional Review Board  
Policies and Procedures**

**Amendments to Research**

**Effective 04/12/2007; Revised 02/12/2009**

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**Purpose:**

To establish policy and procedures for the review of amendments (researcher-initiated revisions) to research prior to their implementation.

**Definitions:**

None

**Policy:**

It is within the responsibility of the IRB to govern research that has been approved to ensure that research is conducted in accordance with governmental guidelines and regulations and with IRB requirements. In order to effectively do this, the IRB must review amendments (researcher-initiated revisions) to previously approved research prior to their implementation except when immediate implementation is necessary due to apparent hazard to subjects.

These changes to research include, but are not limited to:

- Changes to research staff, including principal investigator or co-investigators, or changes to the contact information of research staff
- Changes to the types of or number of subjects to be recruited or enrolled in the study
- Changes to study procedures or locations of where research is going to be conducted
- Changes in instruments or data collection procedures
- Changes in methods of recruitment, advertisement of the study, or to the wording of the informed consent(s)

**References:**

45 CFR 46.103(b)(4)(iii)

21 CFR 56.108(a)(3)

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**Procedures:**

1. Irrespective of the original level of review, the PI must submit amendments for review via the IRB Submission Form for Amendment of IRB Approved Studies. Any revised documents must also be included with this submission. The PI should describe all proposed changes to the protocol and include the rationale for these changes. If a change to the informed consent procedures or consent form is proposed, the PI will include one copy of the consent form that notes deletions with strike-outs and deletions with underlined additions. Additionally, the PI will attach a copy of the informed consent form on letterhead and in the format for use in the study.

Amendments to studies approved via the expedited procedure are typically reviewed via an expedited procedure. Amendments to studies approved via full review may only be reviewed via expedited procedure if the amendments are minor and do not affect the risk/benefit ratio. All other amendments to full reviewed studies must be reviewed by the full board and the PI must submit 23 copies of the amendment documents. Amendments to a center-level approved study require submission of a revision to the center representative. If the amendment alters the risk/benefit ratio or adds procedures whereby exempt status no longer applies (i.e., the addition of tape recording, etc.), then the amendment will be forwarded to the IRB office for either expedited or full review.

Minor revisions include, but are not limited to:

- Changes in PI/Co-Investigator
- Changes to contact information for research staff
- Minor changes to the number of subjects
- Minor changes to advertisement (e.g. location of posting, grammatical changes)

2. Once the amendment(s) to a study reviewed by the full Board or via expedited review has/have been reviewed, the IRB staff notifies the PI in writing. If the amendment is reviewed at the Center Level, and the modification does not alter the criteria for exempting the study from higher level review, then the Center Representative will notify the PI in writing and forward the documentation to the IRB office. If the amendments are approved, then they may be implemented after the PI receives notification. A PI may implement proposed changes before approval only when necessary, to eliminate immediate apparent hazards to the subject.