

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

**Amendments to Research**

**Effective 04/12/2007; Revised 02/12/2009, 10/14/2010, 9/16/2011**

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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)

Amendments to research must be submitted in a timely fashion. Amended documents that reflect a version date that is greater than two months prior to the date of submission to the IRB must be clarified by the investigator.

Amendments to the informed consent form, assent form, or protocol may require that active subjects be re-consented using the revised consent/assent form after they are approved by the IRB. The IRB, or the expedited reviewer on behalf of the IRB for expedited approved research and the exempt reviewer for exempted research, may waive this requirement for minor changes to either the protocol or consent documents. Minor changes to informed consent forms are limited to changes in location of activities, changes to the title of the study, formatting changes, or at the discretion of the Chair or reviewer changes in investigators. Any other changes to the consent/assent form as a result of an amendment

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approval necessitate the re-consent of active subjects. Active subjects must always be re-consented if the amendment approved changes the consent/assent form information with respect to risks or benefits of the study or there are the addition of new activities associated with the study.

In some instances, at the discretion of the IRB Chair or expedited/exempt reviewer, amendments also may necessitate the re-consent of subjects who have completed the study or who withdrew themselves/were withdrawn. This type of amendment includes, but is not limited to, a change in the study whereby new risk information is known and is being added to the consent form and protocol information. .

**References:**

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

21 CFR 56.108(a)(3)

**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 (attachment). 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.

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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.
3. The investigator is to communicate amendments to the active subjects, and subjects not currently active as described in the policy section above, in the period and manner as determined by the IRB.

**Attachment**

**NSU-IRB Submission Form for  
Amendment of IRB Approved Studies**

Version: 10/14/2010

**Instructions:** Federal regulations and NSU policy require researchers to obtain approval for study modifications before implementing changes to approved research. If your original study submission approval was at the center level (exempt determination), then submit this form to your center representative. If it was approved after expedited or full board review, then please submit the form directly to the IRB office (NSU, Office of Grants and Contracts, 3301 College Avenue, Fort Lauderdale, FL 33314, ATTN: IRB). For further information, refer to the *Amendments to Research* policy on the IRB Web site <http://www.nova.edu/irb/manual/policies.html>. Please contact your center representative or the IRB administrator (954-262-5311) if you have questions.

Please download this document and fill in the BLUE sections using a word processor. You may expand the size of sections if needed to answer the questions. Do not be concerned about where page breaks fall.

<b>I. General Information</b>
Project Title
<b>Insert Principal Investigator's (PI) Last Name and Date of Submission in the footer.</b>

IRB Protocol #	Initial IRB Approval Date

<b>II. Principal Investigator (PI) Information</b>			
Name		Relationship to NSU (Check Applicable)	
Mailing Address (for students)		Faculty	
		Staff	
		Student	
Daytime Phone		NSU Center/College/Dept 	
Alternate Phone			
NSU Email Address			
Alternate Email Address			
Principal Investigator's Signature: _____		Date: _____	
If the PI is a student, the thesis adviser/dissertation chair must also sign this form.			
Chair/Adviser's Signature: _____		Date: _____	

### III. Prior Approved Changes

Had you previously requested study changes since the study was approved initially?

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

If "Yes," please list those changes in the box below. (You may be asked for a revised protocol if the study has changed significantly since the initial review as a result of the combined past and proposed changes. You may submit a copy of the revised protocol, following the same format as the original submission, if you believe it will be helpful.)

### III. Summarize the Current Study Protocol and Your Proposed Changes

If your study was approved at the Center level (exempt), then submit the original protocol. If your study was reviewed at the expedited or full review levels, then your original submission is on file, so you do not need to submit another copy. Your summary of the study should be sufficient to allow the reviewer to understand the significance of the proposed changes.

#### Current Study Protocol

#### Proposed Changes

#### Version Date Explanation

If the version date on any of the amendments is greater than two months from the date associated with the investigator's signature, please explain the rationale for the delay in submission to the IRB for review.

### IV. Consent Forms and Recruitment Materials

Do the proposed study changes require any modification to the consent/assent forms or to recruitment materials?

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

If "Yes," please explain the changes made to the consent/assent forms and include a copy of the revised forms. Please use the most recent consent form template (see <http://www.nova.edu/irb/manual/forms.html> ).

Please note that the IRB may request re-consent/assent of subjects depending on the nature of the amendments.