

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

**Monitoring of Approved Research, Approval Duration, and Continuing Review
Effective 03/08/2007; Revised 10/14/2010; 8/29/2011
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Purpose:

To establish policy and procedures for the monitoring of approved research, the approval duration of protocols, and continuing review requirements.

Definitions:

None

Policy:

1. Continuing Review and Approval Duration

It is 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 conduct—as prescribed by regulation—continuing review of approved research not less than once a year. When approving the study, the IRB (or IRB Chair/Designee in the case of an expedited review) will determine if the risks are of a sufficient magnitude that continuing review is required more often than annually. Continuing review is required for any active protocol including those where the only activity that remains is data analysis.

The factors that shall be considered to determine whether a study requires continuing review more frequently than annually include, but are not limited to;

- studies that involve experimental therapies or procedures in which a clear potential for significant adverse experiences has been identified at the time of review,
- the nature, probability and magnitude of anticipated risks to subjects,
- the medical, psychological, or physical conditions of the proposed subjects,
- age of subjects,
- qualifications of the PI and other members of the research team,
- nature and frequency of adverse events observed in similar research,
- vulnerability of the population being studied including familiarity with the language on consent forms and other documents, and
- other facts the IRB deems relevant.

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2. Audits of Research/Monitoring of Informed Consent Procedures

The IRB and the institution have the right to conduct audits of approved research to ensure that all requirements have been met—in particular, the manner in which informed consent has been conducted. The IRB is authorized to monitor or to have a third-party monitor the informed consent process. Additionally, governmental agencies may also review research records. The university may randomly audit approved studies and may elect to target audit studies.

References:

45 CFR 46.103(b)(4)(i-iv) and 46.109(e)
21 CFR 56.108(a)(1) and 56.109(a - f)
21 CFR 56.108(a)(1) and 56.109(e)
21 CFR 56.108(a)(2)
21 CFR 56.115(a)(3)

Procedures:

1. For Continuing Review:
 - a. PIs who require continuation of study approval must request continuation with sufficient time to allow for continuing review without a lapse in approval. As a result, the IRB recommends that investigators submit for continuing review at least two months prior to the continuing review date. Federal regulations and university policy do not allow for any form of grace period. As a result, research with human subjects and/or their data must end should approval of continuing review not be obtained before the end of the approval period and may not begin again until the study has been approved for another continuing review period.
 - b. The Submission Form for Continuing Review (attachment) will be reviewed at the appropriate level (expedited or full review). Typically, studies are reviewed at the same level for continuing review as for initial review. For this reason, the PI will submit 23 copies of the submission form for continuing view, a copy of the current informed consent and any newly proposed consent document, and one copy of the complete protocol including any modifications previously approved by the IRB if his/her study was originally reviewed by the full board. In some instances, continuing review of full reviewed protocols may be conducted at the expedited level; however, this will be determined by the IRB office in keeping with the expedited categories enumerated by the OHRP and FDA. The policy Level of Review and Decision describes the situations in which a renewal/revision of a study, initially receiving Full Review, qualifies for an

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expedited approval. For studies involving FDA regulated products, if there is a sponsor protocol and/or clinical investigator brochure then the investigator must submit eight copies of the current document(s) for distribution as follows: the IRB Chair, the IRB Director, a copy each to two members of the adverse events subcommittee, a copy to each lead reviewer, the Assistant VP, and the IRB file.

- c. Once a decision has been made the PI and Center Representative are notified in writing by electronic mail. Additionally, in the case of student investigators, faculty sponsors are also included in the electronic communication.
 - d. The IRB maintains all records of continuing review within the respective protocol's file. For continuing review conducted at convened meetings, the minutes also reflect any discussions related to the continuing review process and list the items submitted for review by the investigator or his/her staff.
2. For audits of research:
- a. The university will contact the PI in writing to request delivery of research records within thirty (30) days to the vice president of research, planning, and governmental affairs.
 - b. Studies that have been concluded may also be reviewed by the institution, IRB, or governmental agencies, and as a result the investigator should retain research-related (including informed consent) documents for a minimum of three years from the date the study was concluded or in the case of funded research, the time specified in the award document if longer than three years. For multi-site studies, researchers are reminded that the date of conclusion of the study is the date when the sponsor closes the research and/or the last research site had concluded research activity—not the date research activities ended at the local site.
 - c. Informed consent documents must state that the university, the IRB, and regulatory agencies are permitted to review research records which may contain personal/confidential information.
 - d. Researchers may be asked to meet with the individuals conducting the audit. Prior to submitting the audit report to the vice president, feedback will be solicited from the researchers.
 - e. At the conclusion of the audit, the final report will be submitted to the vice president.

Attachment

**NSU-IRB Submission Form for
Continuing Review of IRB Approved Studies**

Version: 10/14/2010

Instructions: In order to comply with federal regulations requiring **continuing review**, as well as to conform to guidelines of the university's Institutional Review Board (IRB), the principal investigator is required to complete all of the following items for projects that will continue beyond the period of approval granted by the IRB. Continuation of a study includes data analysis, even if no further subject interaction occurs. Investigators are advised to submit this form and all necessary documents at least three months before the expiration date of the study's approval. For further information, refer to the *Monitoring of Approved Research, Approval Duration, and Continuing Review* policy available on the IRB Web site (<http://www.nova.edu/irb/manual/policies.html>). Please contact your center representative for information regarding submitting this form. This form should be sent directly to the IRB Office at NSU, Office of Grants and Contracts, 3301 College Avenue, Fort Lauderdale, FL 33314, ATTN: IRB.

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. Fill in all questions; if not applicable, write NA.

I. General Information
Project Title <div style="background-color: #e0f0ff; height: 30px; width: 100%;"></div>
Insert Principal Investigator's (PI) Last Name and Date of Submission in the footer.

IRB Protocol # <div style="background-color: #e0f0ff; height: 20px; width: 100%;"></div>	Initial IRB Approval Date <div style="background-color: #e0f0ff; height: 20px; width: 100%;"></div>
Previous Reapproval Date(s) <div style="background-color: #e0f0ff; height: 20px; width: 100%;"></div>	Current Continuing Review Due Date <div style="background-color: #e0f0ff; height: 20px; width: 100%;"></div>

II. Principal Investigator (PI) Information			
Name	<div style="background-color: #e0f0ff; height: 30px; width: 100%;"></div>	Relationship to NSU (Check Applicable)	
Mailing Address (for students)	<div style="background-color: #e0f0ff; height: 30px; width: 100%;"></div>	Faculty	<div style="background-color: #e0f0ff; width: 30px; height: 15px;"></div>
		Staff	<div style="background-color: #e0f0ff; width: 30px; height: 15px;"></div>
		Student	<div style="background-color: #e0f0ff; width: 30px; height: 15px;"></div>
Daytime Phone	<div style="background-color: #e0f0ff; height: 20px; width: 100%;"></div>	NSU Center/College/Dept <div style="background-color: #e0f0ff; height: 40px; width: 100%;"></div>	
Alternate Phone	<div style="background-color: #e0f0ff; height: 20px; width: 100%;"></div>		
NSU Email Address	<div style="background-color: #e0f0ff; height: 20px; width: 100%;"></div>		
Alternate Email Address	<div style="background-color: #e0f0ff; height: 20px; width: 100%;"></div>		
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. Status of the Research

Please provide a summary of the methods and procedures of the study.

Please describe any new literature or findings related to the study.

Please describe any changes to the risks or benefits associated with the study.

IV. Subject/Participant Information and Study Timelines

Types of Subjects/Participants (complete all that apply)

	Fetus/ abortuse s	Newborn s/ Infants	Children (2-7)	Childre n (8-12)	Adolescents (13-17)	Adults (18+)	Pregnant Women
Total # Originally Approved							
# Entered in Study to Date*							
# Of Screen Failures**							
# Completing Study to Date							
# Who Withdrew							
# Currently Active							
# to Enroll in the Future***							

*By Entered the IRB means any subjects who consented to participate in the study and began study activities.

**By Screen Failure the IRB means individuals who signed the consent form, but later proved not to qualify for the study during screening procedures.

***Please remember that your future number of subjects cannot exceed the total number of subjects originally approved by the IRB. If you need to exceed that number, please submit an amendment as well.

Subject Selection Information

	Subjects by Gender	Subjects by Race						Hispanic or Latino
	Gender	White	Black or African American	Asian	American Indian or Alaska Native	Native Hawaiian	Other Pacific Islander	If any of the individuals listed to the left also identify themselves as Hispanic or Latino please provide that information here.
# Recruited for the Study								
# Actually Entered into the Study*								

If the design of your study did not allow you to collect this information, please describe how you assured equitable subject selection.

*By Entered the IRB means any subjects who consented to participate in the study and began study activities.

Please provide a detailed description as to why the subjects withdrew or were withdrawn.

Anticipated end date of subject recruitment	<input type="text"/>
Anticipated end date of subject participation	<input type="text"/>
Anticipated end date of data analysis and interpretation	<input type="text"/>

V. Changes

Please describe below any substantive amendments since the protocol was initially and approved by the IRB.

VI. Summary of Results to Date

Please describe significant findings to date in the box below.

VII. Participant Complaints

Were there any complaints from subjects?

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

If "Yes," please provide a detailed description of the subjects' complaint(s). If more than one subject complained, please provide the information by subject. For example, "Subject 1: Nature of complaint. Nature of resolution."

Is this study multi-site?

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

If "Yes," please attach any related reports from the other sites.

VIII. Unanticipated Problems/Adverse Events

List ALL adverse events or unanticipated problems (for multi-center studies, from NSU researchers only) and their resolution. (If none, state none). Attach copies of all adverse reaction reports, even if previously reported.

Unexpected/Adverse Reaction and Resolutions

Do the results of the study to date suggest that the study risks differ from what was originally described in the research submission?

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

If "Yes," please describe.

IX. Consent Forms

Are you seeking approval to continue to enroll new subjects?

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

If "Yes," then please review and complete the following.

ATTACH CURRENT CONSENT FORM(S) (STAMPED)
ATTACH CLEAN CONSENT FORM(S) FOR STAMPING

Please see <http://www.nova.edu/irb/manual/forms.html> for instructions regarding consent forms.

Please note: If your study also requires changes/amendments please use the NSU-IRB Submission Form for Amendment of IRB Approved Studies. Amendments include, but are not limited to, changes in funding source, number of subjects to be enrolled, methods, procedures, or the content of the consent documents or recruitment materials.

If you will not be enrolling new subjects, only provide a copy of the current consent form(s).

As IRB and legal requirements continually evolve, all consent forms must be reviewed using current IRB guidelines as found on the IRB website. Have you reviewed and confirmed that the attached consent forms have been modified as necessary to meet current IRB guidelines.

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

If "No," please explain (e.g., requirement of grantor, the study is conducted at another site and their consent forms are used, or other reason).

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Did the consent forms require translation?

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

If "Yes," please attach the original English version along with all translations, and submit the consent forms to be used during the study continuation.

Were subjects enrolled whose primary language was not English?

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

If "Yes," and consent forms were not translated into that language, please explain how it was determined that subjects could understand the informed consent process and form.

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X. Recruitment Materials

Are you continuing to recruit subjects?

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

Are you using flyers or other recruitment materials to continue to recruit?

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

Please attach the most current recruitment materials. Please include a copy of the previously approved (and stamped) materials and a clean unstamped version.

X. Research Protocol

If your study was approved at the expedited level, you must submit a copy of the complete protocol including any modifications previously approved by the IRB incorporated into the protocol. It is recommended that you also include a brief overview of the amendments approved.

If your study was approved at the full review, you must submit 23 copies and one original of the complete protocol including any modifications previously approved by the IRB incorporated into the protocol. It is recommended that you also include a brief overview of the amendments approved.