

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

Lead Reviewers

Effective 03/12/2009; Revised 10/14/2010; 08/29/2011

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Purpose:

To establish policy and procedures related to the IRB's use of lead reviewers for new protocols, the continuing review of protocols, and at the discretion of the Chair amendments to previously approved protocols, requiring full board review.

Definition:

1. Lead Reviewers: Individuals appointed by the IRB Chair to provide thorough protocol review prior to presentation to the convened Board.

Policy:

In order to facilitate the review of new protocols at convened meetings of the board, whenever possible two lead reviewers will be assigned to each new protocol or continuing review in advance of the convened meeting at which that protocol is to be discussed. The Chair, at his/her discretion may appoint lead reviewers for amendments to protocols. Each individual will be responsible for advanced review of the submission, noting areas requiring further inquiry or that may require revision. When necessary, lead reviewers will communicate with the principal investigator, either directly or via the IRB Director, to secure information to facilitate the review of the protocol. The reviewers will submit their analysis of the proposed research to the IRB in writing sufficiently in advance of the convened meeting to allow for duplication and dissemination.

The Board members will be provided the information related to the study, irrespective of the use of lead reviewers. The convened membership of the Board may elect to accept any or all aspects of the reports provided by the reviewers. The Board will not be limited by the reviews conducted and may seek further clarification or revision as necessary.

Protocols may be reviewed at the convened meeting of the IRB even if only one lead reviewer was identified or if the IRB only receives the completed checklist of one lead reviewer. In addition, at the discretion of the Board, review of a protocol may also occur in the absence of lead reviewer information.

References:

45 CFR 46

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Procedures:

1. The IRB Chair in collaboration with the IRB Director will assign two lead reviewers for each protocol by the date of distribution of the meeting packets. Assignment of the lead reviewers will be based on fair distribution of workload of the IRB and in consideration of expertise; however, no member of the IRB may reject assignment more than twice consecutively. At the Chair's discretion, the member who rejects a second consecutive request to be a lead reviewer will be referred to the Vice President for Institutional Effectiveness and the VP may refer the member's dean/director to discuss the situation. Whenever possible, neither of the lead reviewers will come from the originating center of the research and will have served on the Board for a minimum of two months. Neither the IRB Director nor the IRB Chair may serve as a lead reviewer; however, the reviewers may call upon the IRB Chair or IRB Director for guidance as necessary. Should either reviewer be unable to fulfill his or her duties, the IRB Chair or designee will appoint new reviewers in keeping with the aforementioned procedures.
2. The IRB Director, or his/her designee, will contact the lead reviewers, notifying them of the appointment and will send them an electronic version of the protocol for review if requested.
3. For new protocols, the lead reviewers will evaluate the protocol using the IRB Checklist Form for Reviewers—Initial Review (see attachment A). For studies involving FDA regulated products, when there is a sponsor protocol and/or clinical investigator brochure copies of these documents will be provided to the lead reviewers for their assessment of the protocol. Lead reviewers will need to determine whether the sequence as described in the sponsor's protocol is reflected in the NSU IRB New Protocol Form. For continuing review, the lead reviewers will evaluate the protocol using the IRB Checklist Form for Reviewers—Continuing Review (see attachment B). For amendments, the lead reviewers will evaluate the materials submitted using the IRB Checklist Form for Reviewers—Amendments (see attachment C).
4. In completing the checklist, should the reviewers find it helpful to contact the principal investigator, they may do so. Reviewers may elect to contact the principal investigator individually, together, or nominate one person to present all questions that the reviewers may have. Alternatively, reviewers may elect to give questions to the IRB Director, who will relay them to the principal investigator.
5. Communications with the principal investigator will be documented. If the principal investigator provides additional information or documentation, then the principal investigator will be encouraged to submit that documentation in writing.
6. The reviewers will submit their checklist forms to the IRB Director for dissemination and duplication no later than 48 hours prior to the convened meeting of the Board.

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7. The IRB Director will send an electronic copy of the forms to all members and will duplicate the completed checklist forms for dissemination at the convened meeting at which the protocol is scheduled for review. While the IRB Chair or Director may review the checklist form prior to the IRB meeting, they may not make revisions to the checklist prior to Board review.
8. At the convened meeting, the lead reviewers will be responsible for providing substantive summarizing information about the study. The center representative will provide additional information from his or her review.
9. The IRB office will include copies of the lead reviewer checklist forms in the applicable meeting minutes.

Attachment A

**Nova Southeastern University
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**IRB Checklist Form for Reviewers—Initial Review
(v. 10/14/2010)**

Principal Investigator	Center/Academic Unit
Lead Reviewer #1	Scheduled IRB Meeting Date
Lead Reviewer #2	Date Submitted to IRB Office

Please use this checklist for reference when reviewing this protocol. One section of the checklist is intended for each of the lead reviewers. When you submit a final version of the checklist to the IRB office, each portion should be completed. Please refer to the following documents in reviewing this research study IRB application/research protocol, informed consent and assents (when applicable), relevant questionnaires, interview protocols or survey instruments, all recruitment materials, and any other additional documents.

Please contact the investigator with your questions *prior to submitting the form*. You may elect to have the IRB administrator make the contact. If feasible, note investigator replies within the review. Copy the IRB administrator on email communications and encourage the PI to put information in writing. If you see any significant problems with this study, including the possibility that its review should be deferred, please contact the IRB Administrator in advance of the meeting. Lastly, if either reviewer has a perceived or real conflict of interest in the IRB review of this study, please contact the IRB Chair immediately so that the protocol may be reassigned.

Lead Reviewer - Evaluation of Protocol

Appropriateness of Study Design

Is the study purpose, and are the study procedures, clearly described?	Yes	No
Is the use of human subjects necessary to answer the research question(s)?	Yes	No
Is the proposed research scientifically sound?	Yes	No

Risks and Benefits

Are risks to participants minimized, and the benefits maximized? (Please consider physical, psychological, social, legal, and economic risks, and list any additional safeguards that you recommend.)	Yes	No
Do you believe that this study has a favorable risk/benefit ratio?	Yes	No

Subjects

Are the inclusion and exclusion criteria appropriate?	Yes	No
Is the subject selection process clear?	Yes	No
Is the subject selection equitable? (Will the risks and benefits of the study be justly apportioned?)	Yes	No
Does the researcher fully describe how recruitment will occur, and are the recruitment procedures appropriate?	Yes	No
Does the study involve a vulnerable population, or participants who may be subject to influence or coercion? (If so, is the use of this population appropriate or could the study be conducted using less vulnerable subjects?)	Yes	No
Does the study involve pregnant women or women of childbearing potential? If so, have the effect of the procedures been evaluated in pregnancy or is it a goal of the study to define safety in pregnancy?	Yes	No
Does the study involve non-English speaking participants? If so, is it clear which documents will be translated? Will the staff be able to communicate with these participants?	Yes	No

Consent and Assent

Are there appropriate procedures to obtain voluntary, fully informed consent? (If waiver of consent or consent documentation is requested, please discuss.)	N/A	Yes	No
Is deception a part of the experiment? (If so, is deception necessary, and will the subject be informed of the deception)		Yes	No

and its purpose after the experiment?)		
If the study involves assent, is parent/guardian consent obtained first?	Yes	No

Privacy and Confidentiality

Does the study involve the use of audio and/or video recording? If yes, is the rationale for these clearly described and appropriate?	Yes	No
Are there appropriate procedures for protecting privacy of study participants? Are there appropriate procedures for protecting confidentiality of study data?	Yes	No

Compensation

Is the compensation associated with the study appropriate and equitable? Is the distribution clearly described in the protocol?	Yes	No
Does the study involve extra credit? If so, is there an alternative means for those not participating in the experiment to receive extra credit?	Yes	No

Study Location

Does the study involve non-NSU sites? If yes, is permission from the other sites included? (Please indicate if the reason for not securing permission is that NSU approval is required before the site will grant permission.)	Yes	No
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Duration of Approval

Do you recommend that continuing review of the research occur more often than annually?	Yes	No
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Format

Does the protocol follow NSU format requirements?	Yes	No
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Lead Reviewer - Evaluation of Forms and Documents

Submission Form Review

Are all required signatures present?	Yes	No
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Verifications

Is the information in the consent form consistent with the research protocol?	Yes	No
Does the nature of the study, such as a collaboration or activity at another site, require modification to the NSU consent form?	Yes	No
For research at sites other than NSU, does the site require the use of its own consent form?	N/A	Yes No
If another consent form is being submitted, does it reflect the “spirit” of the items noted below?	N/A	Yes No

Consent Form Components

Basic Federal Regulation Required and Appropriate Additional Elements of Consent Disclosure

Does the consent form include a statement that the study involves research?	Yes	No
Is the study purpose clearly explained?	Yes	No
Are the participant’s time commitment, study’s duration, and inconveniences clearly delineated?	Yes	No
Does the consent form contain a description of the procedures to be followed? Is that description clear and understandable to a lay person? Is the description appropriate for the proposed population? Do the procedures match the research protocol?	Yes	No
Is it clear which procedures/treatments are experimental?	N/A	Yes No
Does the consent form contain information regarding risks? Does the consent form contain a description of any reasonably foreseeable risks or discomforts to the subject?	N/A	Yes No
Is the description of the risks in keeping with those presented in the protocol?	Yes	No
Does the consent form indicate that there is a benefit? If it does, are those benefits then listed? Are the benefits presented in keeping with those described in the protocol? Is it clear that benefits are not guaranteed?	Yes	No
If there are alternative procedures or courses of treatment that might be advantageous, is that information appropriately communicated? Are these alternative procedures the same as those noted in the protocol if any were noted in the protocol?	N/A	Yes No
Is there a statement describing the extent to which confidentiality of records identifying the subject will be maintained? Does the description indicate how long research records will be maintained? Does it detail where/how those records will be maintained? Is it clear the extent to which patient privacy will be maintained? Is it clear that regulatory bodies, including the NSU IRB, may review the research records? For FDA studies, is it clear that the FDA may inspect records? If confidentiality will not be maintained, is that clearly stated to the subject?	Yes	No
If the research poses greater than minimal risk, is there information on available compensation and/or medical treatments for injuries? Is it clear what the compensation or medical treatments consist of? Is there information as to where further information about either may be obtained? Is the language appropriate (does not contain exculpatory language)?	N/A	Yes No
Does the consent form indicate whom to contact for answers to pertinent questions, concerns, and complaints about the research? Does this information include both the researchers as well as the IRB (as an independent body)?	Yes	No
Does the consent form indicate whom to contact for answers to pertinent questions about the research subjects’ rights?	Yes	No
Does the consent form indicate whom to contact in the event of a research-related injury?	Yes	No
Is there a statement that indicates that participation is voluntary, that refusing to participate or withdrawing from the study at any time does not incur penalty or loss of benefits to which the subject is otherwise entitled?	Yes	No

Additional Federally Required Elements, As Appropriate

Does the study have the potential to create risks to subjects (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseen? If so, does the consent form indicate the potential for those risks and which procedures may pose them?	N/A	Yes	No
Do the researchers retain the right to terminate subject participation without regard to patient consent? If so, is that made clear to the subject? Are there any other anticipated circumstances under which the subject’s	N/A	Yes	No

participation may be terminated? Is that included in keeping with the research protocol?			
Is the compensation, or absence of compensation, for participation clear? If the study proposes a prorated system for compensation, is that clear?	N/A	Yes	No
Is the information with respect to additional costs to the subject that may result from participation in the research presented? If there is, does this information match the research protocol?	N/A	Yes	No
Is it clear what the consequences would be, if any, if the participant withdraws from the research, and if appropriate, are the procedures for orderly termination described?	N/A	Yes	No
Does the consent form inform the subject that new findings, developed during the course of the research, which may relate to the participant's willingness to continue in the research, will be provided to the participant?	N/A	Yes	No
Does the consent document indicate the approximate number of subjects? If no, do you think that it is relevant and should be required?	N/A	Yes	No
If the study involves random assignment or the use of placebo, are these clearly described?	N/A	Yes	No
For VA Research			
Does the consent form contain a statement that in the event of a research-related injury the VA has to provide necessary medical treatment to a participant injured by participation?		Yes	No
Is there a statement that a veteran-participant would not be required to pay for care received as a participant in a VA research project except in accordance with federal law and that certain veterans are required to pay co-payments for medical care and services provided by the VA?		Yes	No

NSU Requirements for Disclosure			
Does the consent form have the sections, if required, to address video/audio taping? Is the section in keeping with the NSU stated requirements?	N/A	Yes	No
Is it clear that the study-related records are retained for the NSU-required minimum of three years? Is it clear if, when, and how subject-identifiable data will be destroyed?		Yes	No
Does the study involve costs to the subject and/or his/her insurance company? (If so, does the consent form address this appropriately?)		Yes	No

NSU-Format Requirements		N/A	
First page (only) on letterhead		Yes	No
Is the language understandable to participants / their representatives?		Yes	No
Title is in the format (Consent Form for the Research Study Entitled . . . ; "Parent/Guardian Consent Form for the Research Study Entitled . . . "; "Assent Form for the Research Study Entitled . . .)		Yes	No
All of the NSU IRB information is present, including the toll free number and IRB email address		Yes	No
Research site information is provided		Yes	No
All pages have an X of Y notation		Yes	No
All pages have initial and date place holders and these are at the bottom of the page		Yes	No
Section headings are bold		Yes	No
Section headings follow an approved template		Yes	No
Voluntary consent section is in keeping with the list presented in the template/model and includes study title.		Yes	No

Attachment B

**Nova Southeastern University
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**IRB Checklist Form for Reviewers—Continuing Review
(v. 10/14/2010)**

Principal Investigator	Center/Academic Unit
Lead Reviewer #1	Scheduled IRB Meeting Date
Lead Reviewer #2	Date Submitted to IRB Office

Please use this checklist for reference when reviewing this protocol for continuing review. One section of the checklist is intended for each of the lead reviewers. When you submit a final version of the checklist to the IRB office, each portion should be completed. Please refer to the following documents in reviewing this research study IRB application/research protocol, informed consent and assents (when applicable), relevant questionnaires, interview protocols or survey instruments, all recruitment materials, and any other additional documents.

Please contact the investigator with your questions *prior to submitting the form*. You may elect to have the IRB administrator make the contact. If feasible, note investigator replies within the review. Copy the IRB administrator on email communications and encourage the PI to put information in writing. If you see any significant problems with this study, including the possibility that its review should be deferred, please contact the IRB Administrator in advance of the meeting. Lastly, if either reviewer has a perceived or real conflict of interest in the IRB review of this study, please contact the IRB Chair immediately so that the protocol may be reassigned.

Lead Reviewer - Evaluation of Protocol

Status of the Research

Has the principal investigator summarized the methods and procedures of the study?	Yes	No
Does the summary presented match the most current version of the research protocol, which must reflect all previously approved amendments?	Yes	No
Did the principal investigator provide any new literature with respect to the study?	Yes	No
If the investigator did provide such literature, does it appear to require a change in the status of the research?	Yes	No
Were any changes to the risks or benefits associated with the research study described? If so, are these reflected in the proposed consent? Do these appear to impact the proposed research?	Yes	No

Subject/Participant Information

Did the principal investigator include information with respect to subject enrollment/activity in section IV?	Yes	No
Does the information presented in this section reflect what was originally approved by the IRB?	Yes	No
Did the principal investigator include sufficient information with respect to race/ethnicity of subjects in order to allow the IRB to review that subject selection was equitable?	Yes	No
Were subjects withdrawn or did they withdraw? If yes, is there sufficient information to determine the reason for the withdraw?		
If there is subject withdrawal information, does the information presented indicate that the study requires modification?		

Changes

Did the investigator indicate any substantive changes since the protocol was initially approved by the IRB?	Yes	No
Do those changes match the revised protocol that was attached with the NSU IRB Submission Form for Continuing Review?	Yes	No
Are those changes reflected in the most current consent form?	Yes	No

Participant Complaints

Were there any complaints by participants?	Yes	No
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Does the nature of the complaint(s) indicate that a change to the study is required?	Yes	No
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Unanticipated Problems/Adverse Events

Have there been any unanticipated problems or adverse events associated with this study?	Yes	No
Does the nature of these events suggest that risks have changed?	Yes	No

Future Recruitment and Consent

Does the investigator indicate that future enrollment is planned?	Yes	No
If yes, has a the investigator included clean current consent/assent forms and/or recruitment materials?	Yes	No

Lead Reviewer - Evaluation of Forms and Documents

Submission Form Review

Are all required signatures present?	Yes	No
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Verifications

Is the information in the consent form consistent with the research protocol? If the continuing review document reflects previously approved substantive amendments does the consent form submitted reflect those changes?	Yes	No
Does the consent form submitted for future recruitment reflect the most current requirements of the NSU IRB?	Yes	No

Attachment C

**Nova Southeastern University
Institutional Review Board**

**IRB Checklist Form for Reviewers—Amendments
(v. 10/14/2010)**

Principal Investigator	Center/Academic Unit
Lead Reviewer #1	Scheduled IRB Meeting Date
Lead Reviewer #2	Date Submitted to IRB Office
<p>Please use this checklist for reference when reviewing this protocol for amendments submitted by investigators. One section of the checklist is intended for each of the lead reviewers. When you submit a final version of the checklist to the IRB office, each portion should be completed. If necessary, please refer to the following documents in reviewing amendment(s): NSU IRB Submission Form (the NSU IRB protocol), informed consent and assents (when applicable), relevant questionnaires, interview protocols or survey instruments, all recruitment materials, and any other additional documents. If these documents were not submitted with the amendment, please contact the IRB office and they will be provided to you.</p> <p>Please contact the investigator with your questions <i>prior to submitting the form</i>. You may elect to have the IRB administrator make the contact. If feasible, note investigator replies within the review. Copy the IRB administrator on email communications and encourage the PI to put information in writing. If you see any significant problems with this study, including the possibility that its review should be deferred, please contact the IRB Administrator in advance of the meeting. Lastly, if either reviewer has a perceived or real conflict of interest in the IRB review of this study, please contact the IRB Chair immediately so that the protocol may be reassigned.</p>	

Lead Reviewer - Evaluation of Protocol

Amendment Information

Has the principal investigator summarized previously approved changes since the study was initially approved?	Yes	No
Has the principal investigator summarized the current study protocol?	Yes	No
Is that summary sufficient for you to understand the significance of the proposed changes?	Yes	No
Has the principal investigator presented the proposed changes?	Yes	No
Are any of these changes significant, including changes to the study design that may affect the risks associated with the research?	Yes	No

Lead Reviewer - Evaluation of Forms and Documents

Submission Form Review

Are all required signatures present?	Yes	No
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Forms

Do the proposed study changes require modification to consent/assent forms or recruitment materials?	Yes	No
If the changes do require modification to consent/assent forms or recruitment materials, have those been included with the amendment?	Yes	No
Are the modified documents as a result of the amendment(s) consistent with current NSU IRB policies and procedures?	Yes	No