

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

General Responsibilities of the Principal Investigator
Effective 08/09/2007; Revised 10/14/2010, 09/16/2011
Page 1 of 6

Purpose:

To establish policy and procedures related to the principal investigator's responsibilities for submitting research protocols that provide sufficient information to evaluate the study protocol, the equity of subject selection, the experiment's risks and benefits, the manner in which informed consent will be sought, when appropriate the provisions for monitoring the data collected to ensure safety of subjects, how the privacy of subjects and the confidentiality of data will be maintained, and the qualifications of the researchers.

Definitions:

None

Policy:

1. Information the principal investigator (PI) provides to the IRB.
 - a) The PI provides study-related information to the IRB using the appropriate forms - New Protocol Form (Submission Form for Initial Review) (Attachment A), Submission Form for Continuing Review of IRB Approved Studies (Attachment B). Or Submission Form for Amendment of IRB Approved Studies (Attachment C) are available at www.nova.edu/irb.
 - b) The PI provides a completed New Protocol Form for initial submission that includes the following information:
 - Title of the study and brief overview
 - Names, contact information, biographical sketch, CVs (when appropriate) and human subjects training of the PI and all Co-Investigators (Co-I)
 - Any research assistants
 - Funding/Sponsorship information
 - Notification of any conflicts of interest
 - Dates of the study
 - Location of where the research is to be conducted
 - Multiple site information and any other external IRB review(s)

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

**General Responsibilities of the Principal Investigator
Effective 08/09/2007; Revised 10/14/2010, 09/16/2011
Page 2 of 6**

- Subject/Participant information
 - Sample Size and Compositions
 - Gender
 - Description of the potential subjects. This section should provide sufficient information in connection with other sections of the New Protocol Form to allow the IRB to determine that subject selection is equitable
 - Conditions that would make the subjects a vulnerable population, such as children or pregnant women
 - Subject Selection, Recruitment and Eligibility Requirements
- Study Design and Methodology
 - Purpose and Potential Benefits
 - Brief background to the research, including brief historical or literature review
 - Rationale and nature of the proposed research
 - Significance of the proposed research
 - Potential benefits of the research to scientific/professional knowledge
 - Goals and Justification of the Study
 - Steps in the Research Study
 - Sources of Data Information
- Additional Study Information
 - Clinical testing
 - Applicable FDA information
 - Clinical procedures
- Sensitive Information
- Non-English speaking participants
- Subject Compensation
- Inclusion/Exclusion criteria
- Subject Recruitment
- Potential for Coercion in Subject Recruitment
- Informed Consent
- Protected Health Information Use (if applicable)
- Student/Academic Information Use (if applicable)
- Risks, Discomforts, & Inconveniences
- Benefits to Subjects
- Data Analysis Plan
- Scientific Benefit
- Risk/Benefit Ratio
- Safety Monitoring Plans

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

General Responsibilities of the Principal Investigator

Effective 08/09/2007; Revised 10/14/2010, 09/16/2011

Page 3 of 6

- c) Investigators also provide copies of the proposed informed consents/assents .
Investigators should review the Informed Consent policy for more information as to informed consent requirements. Once the consent forms are approved, the IRB provides researchers with copies that are stamped “approved” and indicate the date of approval of the document and the date of continuing review of the research.
 - d) For clinical trials where an Investigator’s Brochure exists, this must also be provided to the IRB during initial review. Any changes to the investigator’s brochure or sponsor protocol must also be transmitted to the IRB.
 - e) For federally funded studies, the investigator must also provide the IRB with a copy of the funded proposal.
 - f) As noted in the Adverse Event/Unanticipated Problems policy, investigators must report adverse events, unanticipated problems, or safety reports to the IRB. Please see that policy for further information and applicable forms. The process is also described in the procedures section of this policy.
 - g) As noted in the Monitoring of Approved Research, Approval Duration, and Continuing Review policy, investigators must report to the IRB information related to the study during continuing review periods.
 - h) For all studies approved at the expedited or full review levels the PI are requested to provide a closing report within 30 days of the completion of the study. Completion of the study occurs when research activities with subjects and the analysis of data have stopped. For protocols that reach the date of continuing review without a request for continuing review and no closing report form submitted, the IRB staff will request a closing report. If an investigator fails to provide the report, his or her supervisor or appropriate individual within the academic unit or department may be contacted at the discretion of the Director.
2. Ensuring prompt reporting to the IRB of changes (amendments) in research activities
- An investigator must notify the IRB of any proposed changes in the protocol or consent forms prior to the initiation of these changes. The investigator does this via the Submission Form for Amendment of IRB Approved Studies. Changes may include (but are not limited to): modification of protocol procedures, modification of informed consent procedures, or changes in data collection instruments. These changes may not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards. This is also referenced in the Amendments to Research policy.

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

**General Responsibilities of the Principal Investigator
Effective 08/09/2007; Revised 10/14/2010, 09/16/2011
Page 4 of 6**

3. Equitable Subject Selection

Subject selection must be equitable. In making this assessment, the IRB will need to take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Professional Qualifications to Conduct Research

An investigator must demonstrate to the IRB that he/she is qualified to conduct the research. Additionally, as noted in the Human Subjects Research Training policy, the investigators must demonstrate completion of the CITI training.

5. Federal/State Regulations

An investigator must follow all federal and state regulations when he/she conducts research.

6. Record Retention

Investigators are required to retain all research records (including any signed informed consents/assents) for a minimum of three (3) years from the end-date/closing of the research study. In the case of funded research, the investigator must adhere to the funding source's requirements of record retention which may exceed the three year minimum. Included in the research records must be copies of all documented informed consent form materials. Researchers are reminded that for FDA-related research, the retention period begins on the date the study is closed by the sponsor—which may be many months after the study was closed at NSU. For some clinical research at NSU the retention period may be longer. Investigators are encouraged to discuss retention of their records with the applicable individuals in clinical operations.

7. Audit/Review

Investigators conducting research approved by the NSU IRB agree to onsite audit by individuals identified by the NSU IRB and/or the Vice President for Institutional Effectiveness.

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

**General Responsibilities of the Principal Investigator
Effective 08/09/2007; Revised 10/14/2010, 09/16/2011
Page 5 of 6**

8. Communication from Regulatory Agencies

Investigators conducting research approved by the NSU IRB agree to notify the NSU IRB of any communications received from regulatory agencies, including but not limited to, the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP).

References:

45 CFR 46.108(a)
45 CFR 46.109
45 CFR 46.111
21 CFR 56.103(a) and 56.115(a)(1)
21 CFR 56.111 (a)(1 - 2, 4 - 5)
21 CFR 56.108(a)(1, 4)
21 CFR 56.108(b)(1), 56.115(a)(3 - 4)
21 CFR 56.113
21 CFR 56.115(a)(1, 3 and 4)
21 CFR 56.115(b)(1)
21 CFR 312.55

Procedures:

1. The PI submits the submission form (which will be either a New Protocol Form, Submission Form for Continuing Review, or Submission Form for Amendment. Where applicable, the PI will also submit informed consent/assents following the IRB models for the consent/assent forms provided on the IRB website (www.nova.edu/irb). The submission may also include, but is not limited to, recruitment materials, test instruments, letters of authorization or approval from other entities outside of NSU (including other IRBs), sponsor protocol, clinical investigator brochure, funded proposal, and applicable licensure/professional experience documents.
2. The PI must follow the policies and procedures the unanticipated problems, adverse events, and IND safety reporting policy. For unanticipated problems or adverse events, the PI must submit the report to the IRB the events as follows: serious adverse events within 24 hours all other adverse events and unanticipated problems within 5 working days. The unanticipated problem or adverse event is reported using the Unanticipated Problem/Adverse Event Report/Unanticipated Adverse Device Effect for NSU Subjects form. IND safety reports are submitted along with the IND safety report form that the investigator has personally reviewed the IND safety report of a

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

**General Responsibilities of the Principal Investigator
Effective 08/09/2007; Revised 10/14/2010, 09/16/2011
Page 6 of 6**

- serious adverse event. IND safety reports and the IND safety report form must come to the IRB by the last business day of the month in which the IND safety report was received. The IRB Director, at his/her discretion, may also report investigator failure to submit a closing report to the appropriate individuals within the researcher's department.
3. The PI must follow the procedures noted in the amendments to approved research; informed consent; and monitoring of approved research, approval duration, and continuing review policies.
 4. The PI must forward any communications received from regulatory agencies with respect to an approved or exempted research study to the IRB within 2 business days of receipt of the communication. The information may be forwarded electronically to the IRB office at irb@nova.edu or via hardcopy to the IRB Office.
 5. The PI must submit the closing report to the IRB office either by hardcopy or electronically. The closing report should briefly describe the research that occurred, report the findings of the study, and provide pertinent information related to subject participation. The IRB requests that the report be transmitted within 30 days of the conclusion of the research. In instances where the report has not been received by the time of continuing review (for expedited or full review approved studies), the IRB office will request via electronic communication submission of the report.

Attachment A

Nova Southeastern University
Institutional Review Board for Research with Human Subjects (IRB)
 New Protocol Submission

Center Rep:	To be completed by IRB Office
Date Sent to IRB:	Protocol Number:

Instructions: In order to comply with federal regulations and with the university's IRB guidelines, the Principal Investigator (PI) is required to complete all of the following items. After completing, submit this document and all consent forms and research instruments (questionnaires, interviews, etc.) to the appropriate IRB College/Center Representative. You can find your college/center representatives using the following link:
<http://www.nova.edu/irb/membership.html>.

- ◆ If your study qualifies for center level exemption from further review, the Center Representative will exempt your study, provide you with a memo to that regard, and give you copies of the stamped, approved consent/assent form(s), if applicable. The Center Representative will log your study into the IRB database and forward a copy of the complete submission to the IRB office.
- ◆ If your study appears to qualify for expedited review, then once the Center Representative believes the submission is complete, the Center Representative will log your study into the IRB database and forward **ONE** complete submission packet to the IRB office for review.
- ◆ If full review is required, the Center Representative will log the study into the IRB database and will provide the PI with instructions for submitting 23 stapled or rubber banded copies (AND 1 unstapled original) of the submission and all supporting materials (research protocol, consent/assent forms, letters of authorization, etc.) to IRB. Please note: **ONLY ONE** copy of all research instruments (tests instruments, interview protocols, etc.) needs to be submitted. The completed package must be received by the IRB by the last business day of the month prior to the next scheduled IRB meeting. Because mail, including express delivery, takes at least a day to be delivered within the university, please make allowance for this in your planning. Incomplete submissions will delay review by the IRB. The IRB reserves the right to postpone review of protocols at convened meetings due to needed revisions.

Use a word processor to complete this form. You do not need to be concerned about where page breaks fall. You are to complete all **BLUE** sections. Be sure that all pages, including any appendices or attachments, except for consent/assent forms and advertisements, are numbered sequentially. For further information, refer to <http://www.nova.edu/irb/manual/policies.html> and <http://www.nova.edu/irb/process.html>

Do not approach subjects about being in the research study until you have received NSU IRB approval.

Form Version: December 2009

1. General Information

1.A. Research Project Title:
1.B. Insert Principal Investigator's (PI) Last Name and Date of Submission in the footer.
1.C. Brief Overview (Max 250 Words):

1.D. Principal Investigator (PI) Information			
Name		Relationship to NSU	
Mailing Address (for Students)			
Interoffice Mail Code (for Faculty/Staff)		Student	
Daytime Phone		Faculty	
Alternate Phone		Staff	
NSU Email Address		NSU Center/College/Dept	
Alternate Email Address			
Degree/Academic Information		PI CITI Completion Date*	
Please briefly describe your applicable professional, educational, employment, professional licensure, and research experience. Do <u>NOT</u> attach your vitae.			

1.E. Co-Investigators (Co-I) Information (including faculty advisers)			
	Co-Investigator 1	Co-Investigator 2	Co-Investigator 3
Name			
Mailing Address			
Contact Phone Number			
Email Address			
Degree/Academic Information:			
CITI Completion Date*			
Please briefly describe applicable professional, educational, employment, professional licensure, and/or research experience for all co-investigators. Do <u>NOT</u> attach vitae.			

1.F. Research Assistant Information (if applicable)			
	Research Assistant 1	Research Assistant 2	Research Assistant 3
Name			
Mailing Address			
Phone Number			
Email Address			
CITI Completion Date*			

*NOTE: CITI must have been completed within the last 3 years. If a member of the research team is affiliated with another institution, please include a copy of that individual's training certification.

1.G. Funding Information				
Funding status	Unfunded <input type="checkbox"/>	Funding Applied For <input type="checkbox"/>	Funded <input type="checkbox"/>	
If you indicated "Funded" or "Funding Applied For," complete the following.				
Source of Funding				
Project Title (if different from above)				
Principal Investigator (if different from above)				
Type of Application	Grant <input type="checkbox"/>	Subcontract <input type="checkbox"/>	Contract <input type="checkbox"/>	Fellowship <input type="checkbox"/>
Award Amount:				

1.H. Management of Conflict of Interest			
Read the conflict of interest guidelines at http://www.nova.edu/ogc/forms/ogc9906.pdf			
I certify that I, as PI, have read these guidelines, and have verified that my co-investigators and research assistants also have read these guidelines.	PI Initials <input type="text"/>		
Do any investigators have a significant financial interest (as defined by NSU policy) in relation to this study?	<table border="1"> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> </tr> </table>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Yes <input type="checkbox"/>	No <input type="checkbox"/>		
If yes, please describe the nature of the conflict of interest below			
If you answered yes, please be sure to include the following statement, or a similar statement, within the description section of the consent forms: "The principal investigator and/or co-investigator(s) of this research study have a significant financial interest as it relates to this study." Continue, describing the conflict in the consent/assent documents.			

1.I. Dates and Phases of Study			
Proposed Start Date			
Shortly after IRB approval <input type="checkbox"/>	Other (list date) <input type="text"/>		
Proposed Duration of Research (including analysis of the results)			
One year or less <input type="checkbox"/>	Other (describe, please note minimum annual continuing review required) <input type="text"/>		
Is this a multi-part study?	<table border="1"> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> </tr> </table>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Yes <input type="checkbox"/>	No <input type="checkbox"/>		
If "Yes," please note that procedures used in later phases may affect the review status of this study. Briefly describe the later stages.			

1.J. Multiple Site Information			
Will the study be conducted at an NSU location?	<table border="1"> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> </tr> </table>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Yes <input type="checkbox"/>	No <input type="checkbox"/>		
If "Yes," provide the location within NSU, e.g. department or clinic.			
Will the study be conducted at a non-NSU location?	<table border="1"> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> </tr> </table>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Yes <input type="checkbox"/>	No <input type="checkbox"/>		

Will any of the activities be done online or via telephone (e.g., completion of surveys, delivery of instructional content)? Yes No

If "Yes", for the Internet based activities, will these be done via a secure site? Yes No

If "Yes," please complete the following for the non-NSU sites. Include these sites on the consent form in the "site information" section.

	Site 1	Site 2	Site 3
Site Name			
Address			
Phone Number			

You will need documentation of permission to conduct the research at non-NSU sites. Attach the permission letter(s) or IRB approvals to this document.

1.K. Cooperative Research

Cooperative research projects are those that involve more than one institution or when an investigator is employed at or is an agent of an institution other than NSU, (For more information, see <http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>). Each participating institution is responsible for safeguarding the rights and welfare of human subjects and for complying with all regulations.

Does this research involve cooperative research? Yes No

Has this proposal been submitted or will the proposal be submitted to another Institutional Review Board (or authorizing individual, entity, or ethics review board) for review? Yes No

If "Yes," please complete for each site. Please attach documentation of approval. (Copy the section of the table and add if there are multiple sites.)

Name of Institution				
IRB/Administrative Decision (check applicable)				
Approved <input type="checkbox"/>	Submitted (not yet approved) <input type="checkbox"/>	Not yet submitted <input type="checkbox"/>	NSU IRB approval required prior to submission <input type="checkbox"/>	
Date of Review <input type="text"/>	Contact Person <input type="text"/>		Level of Review (if IRB Reviewed)	
	Phone Number <input type="text"/>		Exempt <input type="checkbox"/>	Expedited <input type="checkbox"/>

2. Subject/Participant Information

2.A. Overview of Proposed Subjects/Participants
(complete all that apply and provide maximum number proposed within each category):

Subject Group	Fetus in Utero/ non-viable fetuses/ abortuses	Newborns or Infants	Children (aged 2-6)	Children (age 7-12)	Adolescents (aged 13-17)	Adults (18+)	Pregnant Women	Adults with Guardians
Mark X for each proposed subject type								
# of Proposed Subjects*								

Please briefly describe your potential subjects:

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*By proposed subjects, the IRB means subjects who will consent to be in the study and begin the study activities.

2.B. Subject Vulnerability

Do any subjects have limited decision-making autonomy, have communication problems that would limit ability to dissent to study procedures, belong to a group that is vulnerable to coercion, or belong to a group defined by regulation as requiring greater care?

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

If you indicated "Yes", please mark with an X next to each applicable category in the column to the right and complete the remainder of this section

Prisoners	<input type="checkbox"/>
Pregnant Women	<input type="checkbox"/>
Cognitive impairment or emotional problems that potentially limit decision making	<input type="checkbox"/>
Communication impairments that may preclude communicating a decision to discontinue participation or refuse participation	<input type="checkbox"/>
Students of the investigator or investigator's department	<input type="checkbox"/>
Employees of the investigator or investigator's department	<input type="checkbox"/>
Children (minors)	<input type="checkbox"/>
Terminally ill	<input type="checkbox"/>
Other (specify):	

--

If you indicated any of the above, please justify your rationale for including these subjects.

--

If you are using potentially vulnerable subjects as described above (infants, children, pregnant women/fetuses, terminally ill, decision-impaired, communication-impaired, students/employees, or prisoners), does the research create greater than minimal risk?

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

If your subjects have a vulnerability that arises from their being students in your class or department, you will be asked for more information in Section 3.G. If the subjects have one of the other vulnerabilities, please describe proposed safeguards to protect vulnerable subjects.

--

If not evident from the researcher qualification information in 1.D. or 1.E., please describe the researcher(s) qualifications for working with vulnerable subjects

--

2.C. Study Design and Methodology

Part 1 – Purpose

Please briefly describe the **purpose** of your study. Note: Examples of study purposes are "to determine if a new reading intervention program improves 4th graders' reading scores" or "to survey patients on their perception of physical therapy services".

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Part 2 – Goals and Justification

Briefly elaborate on the main **goals and justification** for the study. Summarize the background, rationale, nature, and significance of the proposed research. Include a brief overview of your prior research in the area, or literature that supports the need for this study. This section should be a brief overview, and typically is not more than a few paragraphs in length. You will be asked about procedures and instruments later in the submission.

Part 3 – Steps in the Research Study

In the box below, please outline in detail the **steps in the research study** in order as they will occur after consent has been secured. If there are different requirements for different groups/types of subjects within the study, please separate out the steps per group. Indicate how long the subject spends completing the different steps/procedures. Be specific about the tests given and/or treatments used, when they will occur, and their frequency.

Part 4 – Sources of Data Information

Are you using questionnaires, tests, instruments, or forms?

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

If "Yes", list them below and include a copy of each as appendices.

Do you plan to use any data from records or archives?

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

If "Yes", please describe (such as data originally created for non research purposes or data created as a result of a previous study).

Do you plan to use any de-identified data?

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

If "Yes", please describe the data and how it will be de-identified.

3. Additional Study Information

3.A. Clinical Testing

**Food and Drug Administration
Investigational Drugs and Devices**

Does the study involve the use of an investigational drug?

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

If "Yes", has an Investigational New Drug application been submitted for the drug?

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

Does the study involve the use of an investigational device?

	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If "Yes", has an Investigational Device Exemption (IDE) been, or will be, secured prior to the start of the study?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Does the study use any device (either as a part of the experiment or to collect data) that has not received FDA approved for clinical/medical use or is being used in a manner not consistent with its cleared/marketing status?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If "Yes", please describe the device and how its use differs from its approved status by the FDA.		
Clinical Procedures		
Does the study involve the use of any procedure that is not used in routine clinical practice?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If "Yes", please list the procedures.		

3.B. Sensitive Information		
Are you asking questions about sensitive issues, such as illegal activity, sexual history, or anything else that, if made public, could jeopardize a person's reputation, employability, safety, or quality of life?		
	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If "Yes", please describe the information.		
Does the study involve the collection of data from voice, video, digital, or image recordings made for research purposes?		
	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If "Yes", please describe the procedures associated with these recordings.		

3.C. Non-English Speaking Participants		
Will the study involve non-English speaking participants?		
	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Will the study require translation of consent forms?		
	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If you answered "Yes," please specify the language(s) that the consent forms will be translated in to:		
If you are including non-English speaking participants, when you complete section III.H., please discuss how you will ensure that the participants understand the study, including the use of a qualified translator to provide oral consent information.		

3.D. Subject Compensation		
Will your subjects receive any payments, incentives, or gifts?		
	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If "Yes," please indicate the types of compensation. Otherwise move on to section E.		
Monetary Payment <input type="checkbox"/>	Gift <input type="checkbox"/>	Extra credit (Students) or Workplace Incentive (Employees) <input type="checkbox"/>

Other incentive

Please describe:

Describe the payment(s)/gift(s)/incentive(s), and if it is a gift, estimate its monetary value. Indicate whether all participants are given the payment/gift/incentive, or if only some are eligible. (Note: the value of the payment/gift/incentive should not be so significant that it might compromise the subject's good judgment.)

Describe when the subject will receive the payment/gift/incentive, and whether the amount differs depending upon whether different portions of the study are completed or is limited if the subject discontinues participation during the study.

3.E. Inclusion / Exclusion Criteria for Subjects

Describe the inclusion and exclusion criteria for the proposed subjects. Please list the criteria in bullet or outline format rather than narrative. If the study limits participation based on gender, age or race, please justify the exclusion criteria. (Subject protection and appropriate study design may require specific inclusion or exclusion criteria, but the IRB does not permit subject selection that is not equitable or prevents a subpopulation from benefiting from the scientific discoveries of the study.)

Inclusion Criteria

Exclusion Criteria

3.F. Subject Recruitment

How will you recruit subjects (approach/invite/or ask people to be in your study)?

Recruitment Advertisements, Fliers, and Letters

Are you using any letters, fliers, or advertisements?

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

If you answered yes, please list the type(s) below and attach a copy of the proposed materials as an appendix (do not copy and paste the flyer into this form).

(Note: Materials should list "Nova Southeastern University".)

3.G. Potential for Coercion in Subject Recruitment

Are any of the subjects a student or advisee of the PI or a Co-I?

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

Does the PI or a Co-I serve in any capacity (e.g., administrative, therapeutic) that might affect a subject's willingness to participate?

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

If "Yes" to either of the above, then describe the relationship of the subjects and investigator.

If you answered yes, please read the NSU policy about use of students in research.

http://www.nova.edu/irb/manual/forms/research_students_subjects.pdf

Are any of the subjects employees of, or report to, the PI or a Co-I?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Are any of the subjects a patient of the PI or a Co-I?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Are any of the subjects a patient within a PI or a Co-I's clinical practice?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Are any of the subjects informed about the study by their doctor / clinician?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

If you answered "yes" to any of the questions in this section (3.G.), please describe how you will ensure that the subjects will feel free to decline participation without fear of reprisal. If the subjects are patients, how will you prevent "therapeutic misconception" (the mistaken belief that when a care provider provides information about a study, it means that the provider thinks that study participation will benefit the patient).

If you are providing any incentive to the student/employee subjects, discuss whether there is a mechanism for students / employees to receive the incentive by doing something other than participating in the research project (see http://www.nova.edu/irb/manual/forms/research_students_subjects.pdf).

3.H. Informed Consent

Part 1 – Consent Process

Informed consent is a process that begins with advertising or telling potential subjects about your study, continues as the investigator or staff provides details to potential subjects via dialog, and is formalized by the signing of the consent.

Note: Minors must have consent of their parents or guardians before you can approach the minor about participating in the study.
Note: Allow as much time as possible and feasible for the subject to think about whether to enroll in the study. Generally, the greater the study risks, the longer the decision period.

Please overview the steps in the consent process in your research study. If there is more than one group of subjects, separately describe the process for each group.

Part 2 – Consent Process and Document Waiver/Alteration Information

In most cases, subjects need to participate in a meaningful consent process and receive a consent/assent form that documents agreement to participate in research. However, in a few cases the subject's confidentiality is protected by waiving/altering consent procedures or the requirement for signed consent forms. Please read the IRB's policy on informed consent for explanations, including what the IRB must demonstrate to permit waiver or alteration (http://www.nova.edu/irb/manual/forms/informed_consent.pdf). Please note, however, that while your study may qualify for waiver or alteration, that determination is at the discretion of the IRB.

One case where a signed informed consent form is NOT used is when a researcher is only reviewing existing/archival data that were collected for non-research purposes. If the data are obtained from the records by someone with authorization, and the data are de-identified, then it may be appropriate not to ask subjects (those whose data you are collecting) to provide consent, because the research involves no more than minimal risk, the waiver or alteration will not adversely affect the rights or welfare of subjects, the research could not practicably be carried out without the waiver or alteration, and, when appropriate, the subject will be provided pertinent information about participation. (NOTE: If your study has other procedures that require interaction with subjects or prospective collection of data, it is unlikely that waiver or alteration of consent procedures or the signing of consent forms would be appropriate.) If this describes your study, then you may request a waiver of the requirement for informed consent and the documentation of signed consent.

If you think this applies in your study, please describe your rationale.

Another situation involving waiver or alteration of the requirement to obtain a signed consent form is when the research only entails conducting anonymous surveys that are not intrusive. If there is no way that the subjects' responses could be linked to them, then waiving the requirement for a signed consent form would minimize a risk to their confidentiality and privacy because the only record linking the subject and the research would be the consent form. If the principal risk would be potential harm resulting from a breach of confidentiality and the research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research context, then the elements of informed consent are put into the survey itself. The person indicates his/her voluntary participation by completing the survey after being advised about the study and voluntary nature of his/her participation.

If you think this applies in your study, please describe your rationale.

There may be other cases where you would wish to ask for a waiver or alteration of informed consent or signed consent documentation.

If you are seeking a waiver or alteration, please describe your rationale.

Part 3 – Consent and Assent Document Information

Typically, you are asked to use the NSU format consent and assent forms. However, if this is cooperative research, or sponsored research that requires the use of a different template or model, you may use their format.

I will use NSU format consent/assent forms	<input type="checkbox"/>
I will be using another institution's format for consent/assent forms (NOTE: Please review the other institution's consent forms and the NSU requirements to be sure that all of the NSU requirements are present. You may also want to discuss the consent forms with your college/center representative)	<input type="checkbox"/>
As noted above, I am requesting a waiver/alteration of consent and/or signed consent form requirements	<input type="checkbox"/>

If you have different procedures for different groups of subjects, you will need a separate consent and/or assent form for each group. If the reading level of different groups of subjects differs, this may also require you to have different consent and/or assent forms (e.g. young children vs adolescents). If your subjects are children, you will also need parental consent.

What is the total number of consent/assent form types that you plan to use?

If using more than one consent form, create a list below that describes the different forms that you will be using (e.g. 1. Teacher consent form, 2. Parent consent form, 3. Assent form for children age 7-12, 4. Assent form for adolescents).

Include copies of the consent / assent forms. When you attach the consent forms, put them in this order. Please note that the IRB prefers that the consent document be written using the simplest language possible, and strongly recommends the question and answer format (see [Document Model #1 for Adult/General Consent Form](#) [Readability Score: Grade 6]).

3.I. Protected Health Information Use

Are you obtaining any data from the subject's medical record?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Are you asking the subject about his or her health information, and doing so in a clinic or entity that would normally be subject to HIPAA regulations on protected health information?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

If you answered "Yes" to either question, continue. Otherwise go on to section 3.J.

Please review the NSU HIPAA research policies available at (<http://www.nova.edu/irb/manual/policies.html>) for more information.

Please note that effective 12/10/2009 the NSU IRB no longer reviews separate HIPAA authorizations for research. It is the principal investigator's responsibility to use the correct HIPAA authorization as outlined in the aforementioned policy. In instances where the HIPAA authorization must be a part of the informed consent form for research, the NSU IRB will review the compound consent.

Specify the exact data to be gathered (e.g., weight, blood pressure, IQ score, diagnosis, depression rating, number of treatments, etc.).

Which procedure are you proposing to use? (Check)

I will obtain the subject's authorization to obtain the protected health information via the NSU Authorization for Use and Disclosure of Protected Health Information in Research (research activities will be occurring at an NSU clinic).

I will obtain the subject's authorization to obtain the protected health information via the authorization for use and disclosure of protected health information in research provided by the non-NSU covered entity.

The protected health information data are a fully de-identified data set (data obtained without recording any patient information, with the data accessed by an employee of the institution).

The data are part of a limited data set agreement as defined by the Office of Human Research Protections. (Attach a copy of the agreement.)

If part of a limited data set agreement, what is the justification that confidentiality is protected?

I have a waiver provided by a duly constituted privacy board. (Attach a copy of the waiver.)

HIPAA Research Authorization

If the research is to be conducted at an NSU clinic, have you created a HIPAA authorization form as outlined in the HIPAA Research Policy No. 1 (<http://www.nova.edu/irb/manual/policies.html>) and in keeping with the Instructions for Preparing the Authorization For Use and Disclosure of Protected Health Information in Research Form and the model form provided (<http://www.nova.edu/irb/manual/forms.html>)?

Please note, do NOT submit a copy of the HIPAA authorization form if you are following the model noted in the aforementioned policy. Yes No

If the research is to be conducted at a non-NSU covered entity, have you reviewed the HIPAA Research Policy No. 6: Guidance on Research at Outside Entities (<http://www.nova.edu/irb/manual/policies.html>)? Yes No

Researchers are advised to discuss the proposed research with the applicable HIPAA privacy officer at the non-NSU covered entity.

Does the researcher sponsor or cooperating agency require the incorporation of the HIPAA authorization within the consent document (Compound Consent)? Yes No

If yes, please briefly indicate who requires that this be in the informed consent document.

Please note, consent forms that include the HIPAA authorization may need approval from the university Office of Corporate Compliance.

3.J. Student/Academic Information Use

Are you obtaining any data from the subject's academic records? Yes No

If you answered "Yes", continue. Otherwise go on to section K.

Specify the exact data to be gathered (e.g., GPA, standardized test score, IQ score, medical/psychological information stored in academic files, attendance records, disciplinary records, etc.).

Specify how you will obtain the data.

Which procedure are you proposing to use? (Check all that apply)

I will obtain the subject's consent to obtain the academic information.

The academic information will be a part of a fully de-identified data set (data obtained without recording any subject information, and provided to you in keeping with the institution's policies and the Federal Educational Rights and Privacy Act [FERPA]).

3.K. Risks, Discomforts, & Inconveniences

In this section, discuss all potential risks (physical, economic/financial, legal, psychological, social, etc.), discomforts, or inconveniences to the subjects.

- All studies using identifiable subject information must address the issue of possible loss of subject confidentiality
- Some possible risks include physical, psychological or emotional harm, breach of confidentiality, and invasion of privacy.
- Discomfort includes anticipated risk for mild physical or emotional pain.
- Study inconveniences include loss of time or pay.

Each risk, discomfort and inconvenience should be addressed individually in the following format (use the tables provided and copy if the study presents more than 3).

- List each item individually
- Discuss likelihood: How likely is it that this risk/discomfort or inconvenience will occur? This is usually classified as minimal, moderate, or high.
- Discuss magnitude/duration: How dire is the risk/inconvenience/discomfort, and if it occurs, how long do you expect that the subject will be affected?
- Discuss risk minimization: Describe the procedures undertaken to minimize the risk that this specific risk/discomfort/inconvenience will occur.

Risk/Discomfort	
Likelihood	
Magnitude/Duration	
Risk Minimization	

Risk/Discomfort	
Likelihood	
Magnitude/Duration	
Risk Minimization	

Risk/Discomfort	
Likelihood	
Magnitude/Duration	
Risk Minimization	

One way in which confidentiality is partially protected is to destroy study documents containing identifiable information when they are no longer needed. The IRB requires that study materials be kept for a minimum of three years from the end of the study to permit study auditing; you may elect to keep them for a longer period of time and study sponsors may have their own data retention requirements. Please indicate when and how you plan to destroy data that contains identifiable subject information, such as consent forms, lists that link subject identity to data coding, or raw data containing subject names.

3.L. Benefits to Subjects

In this section, discuss all direct benefits of the study to participants. This does not include “helping research” or other generalities, nor does it include compensation for participation. Some examples of benefits include receiving free treatment, receiving a list of reputable local services, or obtaining tutoring. The value of any such benefits should be listed as well. If there are no direct benefits to the participants, this should be indicated.

Are there any direct benefits to the research participants?

There are no direct benefits to study participants

This study provides benefit to, or is likely to benefit, the participants

List/describe each benefit

3.M. Data Analysis Plan

Please describe preliminarily proposed data analysis procedures.

3.N. Scientific Benefit

Briefly discuss how generalization of the information obtained from this study will be scientifically useful, or useful to your research site.

3.O. Risk/Benefit Ratio

To be approved, a study needs to have greater benefits than risks. Why do you believe this study has a positive benefits-to-risks ratio?

3.P. Safety Monitoring Plans

All researchers are required to report adverse events and unanticipated problems in keeping with the NSU IRB policy (http://www.nova.edu/irb/manual/forms/adverse_events.pdf).

Studies that entail significant risk to subjects, such as randomized controlled drug trials, may warrant safety monitoring by an outside safety board. Does your study utilize a Data Safety Monitoring plan?

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

If "Yes," please describe the safety monitoring plans. Please specify if the study will be monitored by the investigators, sponsors (if applicable), or a Data Safety Monitoring Board (DSMB). Sponsored studies may reference an attached Investigator Brochure.

3.Q. Other Information

If there is other information about this study that is required in order for those reviewing the study to fully understand the study, its risks and benefits, please describe below.

3.R. Principal Investigator Assurance and Obligations

I certify that all information provided in this submission (including any supporting documents) is a complete and accurate description of the proposed study. I agree to the following:

This study will be conducted in the manner described in this submission and will not be implemented (including subject recruitment or consenting) until all applicable IRBs have granted permission to conduct the research. No changes to this study will be implemented until an amendment form has been submitted and approved by the IRB.

PI Initials

If the IRB approves this study via expedited or full procedure, I will submit for continuing review as stipulated in the approval letter. If the study or data analysis will exceed the approval period, I will submit a Submission Form for Continuing Review of IRB Approved Studies in a timely manner (well in advance of the renewal date). I understand that study activities may not continue past an approval period.

PI Initials

I will provide a copy of the signed consent form to the subject or patient, if applicable.

PI Initials

I will retain all signed informed consent documents and study-related records for a minimum of three (3) years (or longer as stipulated by funding agencies) from the date the study is concluded.

PI Initials

I will report in writing any serious adverse events to the IRB within 24 hours and all other adverse events and unanticipated problems within 5 working days.

PI Initials

I will provide participants with any significant new information obtained during the course of the study and submit reports of new information to the IRB as a Study Amendment.

PI Initials

If my study has been approved at the Expedited or Full Review levels, I will report to the IRB when this study has closed (no further data collection or analysis). This report will be provided no later than 30 days after the end of the study via the IRB Closing Report Form.

PI Initials

Principal Investigator's Signature: _____ Date: _____

3.S. Co-Investigator Assurance and Obligations (for Student PIs)

If this study is for the completion of a degree requirement, the thesis adviser or dissertation chair must sign the attestation below.

- All departmental approvals by the student's committee (if applicable) and chair or thesis adviser have been completed.
- I accept that the University and IRB consider the faculty advisor's responsibility to be equal to that of the student in regard to
 - The quality of the research design AND the accuracy of the protocol
 - The appropriateness of the recruitment methods, the design of the process for informing the subjects about the nature of the study, and the process of obtaining informed consent
 - The readability, accuracy, and format of the informed consent/assent document(s) and the explanation of all informed consent procedures.

My signature below attests that I have read this submission in its entirety and believe that it is accurate, complete, appropriate, and adheres to the principles of the Belmont report and that all departmental approvals by the student's committee have been completed.

Chair/Adviser's Signature: _____ Date: _____

Attachment B

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
Insert Principal Investigator's (PI) Last Name and Date of Submission in the footer.

IRB Protocol #	Initial IRB Approval Date
Previous Reapproval Date(s)	Current Continuing Review Due Date

II. Principal Investigator (PI) Information			
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. Status of the Research
Please provide a summary of the methods and procedures of the study.

[Empty light blue box for text entry]

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

[Empty light blue box for text entry]

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

[Empty light blue box for text entry]

IV. Subject/Participant Information and Study Timelines

Types of Subjects/Participants (complete all that apply)

	Fetus/ abortuses	Newborns/ Infants	Children (2-7)	Children (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

Anticipated end date of subject participation

Anticipated end date of data analysis and interpretation

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).

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.

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.

Attachment C

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.

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

IRB Protocol #	Initial IRB Approval Date

II. Principal Investigator (PI) Information			
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.