

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

Version: 03/2009

**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 grey 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.

<b>I. General Information</b>
Project Title

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

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

## II. Support Documents

ATTACH A SUMMARY OF THE STUDY AND ANY NEW LITERATURE RELATED TO THE RESEARCH.

Are you seeking approval to continue to enroll new subjects?

Yes

No



**If "Yes," then please attach the following.**

CURRENT CONSENT FORM(S) (STAMPED).

COPY OF 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.

## III. 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*							
# Completing Study to Date							
# Who Withdrew							
# to Enroll in the Future**							

\*By Entered the IRB means any subjects who consented to participate in the study.

\*\*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.

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 approved amendments since the protocol was last reviewed 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

**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

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

**If "Yes," please describe.**

**IX. Consent Forms**

Are you seeking approval to continue to enroll new subjects?

Yes  
No  
**If "Yes," then please review and complete the following.**ATTACH CURRENT CONSENT FORM(S) (STAMPED)  
ATTACH CLEAN CONSENT FORM(S) FOR STAMPINGPlease 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.

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

Are you continuing to recruit subjects?

Yes  
No  

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

Yes  
No  

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