

NSU-IRB Submission Form for Continuation or Amendment of IRB Approved Studies

Instructions: In order to comply with federal regulations requiring **continuing review** as well as to conform with 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 or for requests to amend/revise previously approved protocols. Investigators are advised to submit this form and all necessary documents at least three months before the expiration date of the study's approval. Please contact your center representative for information regarding submitting this form.

For further information, refer to the *Policy and Procedure Manual for Research with Human Subjects*. Please attach additional typed sheets if there is inadequate room for your answers to any question. Fill in all questions; if not applicable, write NA.

I. General Information

Project Title

IRB # _____

Continuation (Renewal) _____

Amendment (Revision) _____

Initial IRB Approval Date _____

Subsequent Approval Date(s) _____

Performance Site(s)

Principal Investigator Information

Name		Relationship to NSU: Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Student <input type="checkbox"/>
Home Mailing Address (for students)		
City/State/Zip:		
Office Phone:	Home Phone (for students):	NSU Center/College/Dept:
Email Address:		Fax:

Principal Investigator's Signature _____ Date _____

Please list all Co-Investigators and their contact information:

Co-Investigator	E-mail address	Contact Phone Number

II. ATTACH A PROTOCOL SUMMARY (FOLLOWING THE SAME LAYOUT AS THE STANDARD PROTOCOL) SUMMARIZING THE STUDY AND ALL CURRENT CONSENT FORMS

III. Funding Information

If this protocol is part of an application to an outside agency, please provide:

- A. Source of Funding _____
 B. Project Title (if different from above) _____
 C. Principal Investigator (if different from above) _____
 D. Type of Application: Grant Subcontract Contract Fellowship
 E. Date of Submission _____

IV. Cooperative Research

Cooperative research projects are those that involve more than one institution and can be designed to be both multi-site and multi-protocol in nature. If this proposal had been submitted to another Institutional Review Board please provide:

- Name of Institution _____
 Contact Person _____
 Renewal Date: _____
 Revisions Approved? ___ Yes ___ No ___ NA _____
 IRB Recommendation _____

V. Subject/Patient Information

A. Types of Subjects/Patients (check all that apply):							
	Fetus in Utero/ non-viable fetuses/ abortuses	Newborns/ Infants	Children (aged 2-7)	Children (age 8-12)	Adolescents (aged 13-17)	Adults (18+)	Pregnant Women
Enrolled #							
Future #							
Do any of the checked subjects belong to a special population (e.g., prisoners, mentally disabled)? Yes <input type="checkbox"/> No <input type="checkbox"/>							
If you answered yes, please specify in detail the nature of the special population(s)?							

B. Other (Check all that apply):
Use of investigational drugs or devices <input type="checkbox"/>
Information to be collected may require special sensitivity <input type="checkbox"/> (e.g. substance abuse, sexual behavior) Please specify:

G. Does this study involve the use of protected health information (PHI) from client charts or other records? Yes <input type="checkbox"/> No <input type="checkbox"/>
If Yes, will consent be obtained from the client for all PHI collected? Yes <input type="checkbox"/> No <input type="checkbox"/>
If consent is not obtained, which of the following applies?
<input type="checkbox"/> The data will be collected in a fully de-identified data set.
<input type="checkbox"/> The data will be collected as part of a limited dataset agreement.
<input type="checkbox"/> The data will be collected under a waiver from a duly constituted privacy board. (Please attach a copy of the waiver to this form).

VI. Changes

A. Are there any changes since initial IRB approval (or last renewal, if applicable)? Yes____ No____

If Yes, please list all proposed changes:

Change(s) previously approved (you may attach a separate page if necessary):

Attach additional documentation as necessary to support any previously unapproved changes.

VII. Summary of Results to Date (CONTINUATION/RENEWAL ONLY)

VIII. Progress Report (CONTINUATION/RENEWAL ONLY)

Total Number of Subjects Originally Approved by IRB _____
Total Number of Subjects Entered into Study to Date _____
Total Number of Subjects Completing the Study to Date _____
Total Number of Subjects Currently Enrolled _____
Total Number of Subjects Who Withdrew _____
Additional subjects to be Recruited _____
Expected time until completion of the Study: _____

List ALL adverse or unexpected reactions and their resolution (if none, state none). Attach copies of all adverse reaction reports, even if previously reported.

Unexpected/Adverse Reaction Resolution

IX. Consent Forms

As IRB and legal requirements continually evolve, all consent forms must be reviewed using current IRB guidelines as found on the IRB website. The investigator certifies that these requirements have been reviewed and 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 or other reason):

Do the consent forms require translation? _____ Yes _____ No
If yes, please attach the original English version along with all translations.

X. Recruitment Materials

Are any changes or updates proposed to the recruitment material?
_____ Yes _____ No

If Yes, please describe the changes and include samples of the old and new materials.
