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

<table>
<thead>
<tr>
<th>Name</th>
<th>Relationship to NSU:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Faculty □</td>
</tr>
<tr>
<td>Home Mailing Address (for students)</td>
<td>Staff □</td>
</tr>
<tr>
<td></td>
<td>Student □</td>
</tr>
<tr>
<td>City/State/Zip:</td>
<td>NSU Center/College/Dept:</td>
</tr>
<tr>
<td>Office Phone:</td>
<td>Fax:</td>
</tr>
<tr>
<td>Home Phone (for students):</td>
<td></td>
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<tr>
<td>Email Address:</td>
<td></td>
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</tbody>
</table>

Principal Investigator’s Signature ______________________ Date ___________
Please list all Co-Investigators and their contact information:

<table>
<thead>
<tr>
<th>Co-Investigator</th>
<th>E-mail address</th>
<th>Contact Phone Number</th>
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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):

<table>
<thead>
<tr>
<th>Fetus in Utero/ non-viable fetuses/ abortuses</th>
<th>Newborns/ Infants</th>
<th>Children (aged 2-7)</th>
<th>Children (age 8-12)</th>
<th>Adolescents (aged 13-17)</th>
<th>Adults (18+)</th>
<th>Pregnant Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled #</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Future #</td>
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</table>

Do any of the checked subjects belong to a special population (e.g., prisoners, mentally disabled)?
Yes □ No □

If you answered yes, please specify in detail the nature of the special population(s)?
B. Other (Check **all** that apply):

<table>
<thead>
<tr>
<th>Use of investigational drugs or devices</th>
<th>□</th>
</tr>
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<tbody>
<tr>
<td>Information to be collected may require special sensitivity</td>
<td>□</td>
</tr>
<tr>
<td>(e.g. substance abuse, sexual behavior)</td>
<td></td>
</tr>
<tr>
<td>Please specify:</td>
<td></td>
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</table>

G. Does this study involve the use of protected health information (PHI) from client charts or other records? Yes [□] No [□]

If Yes, will consent be obtained from the client for all PHI collected? Yes [□] No [□]

If consent is **not** obtained, which of the following applies?

- [□] The data will be collected in a fully de-identified data set.
- [□] The data will be collected as part of a limited dataset agreement.
- [□] 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.
________________________________________________________________
________________________________________________________________