Florida Memorial University
Institutional Review Board for Research with Human Subjects (IRB)
New Protocol Submission Form

To be completed by School/Division Representative	
Date Received:	**FMU School/Division:**
School/Division Representative:	
Protocol Qualifies for: **Full Review □ Expedited Review □ Exempt Review □**	
To be assigned by Office of Grants and Sponsored Programs	
Protocol Number:	

Instructions: In order to comply with federal regulations 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 contained in the Submission Form and the IRB Protocol. Upon completion of all information, the principal investigator must submit the original Submission Form and one copy of the IRB Protocol, including all consent forms and research instruments (questionnaires, interviews, etc.) to the appropriate IRB School/Division Representative for review and action. Once reviewed, if the protocol requires full review, the School/Division Representative will direct the principal investigator to submit the original Submission Form along with 13 copies of the Submission Form and all supporting materials to the Office of Grants and Sponsored Programs. In addition, 13 copies of all research instruments (questionnaires, interviews, etc.) must be submitted. The completed package must be received by the Office of Grants and Sponsored Programs by the last business day of the month prior to the next scheduled IRB meeting. The Office of Grants and Sponsored Programs' Web site should be consulted for IRB meeting dates. Incomplete forms may delay review by the IRB. For further information, refer to the *Procedure Manual for Research with Human Subjects.*

I. General Information

Project Title

_____

_____

Proposed Start Date_____

Proposed Duration of Research_____

Performance Site(s) _____

_____

Principal Investigator Information

Name		Relationship to FMU: Faculty □ Staff □ Student □
Office Mailing Address (Home Address if Student):		
Office Phone (Home Phone if Student):	Alternate Phone	FMU School/Division:
Email Address:		Fax:

Co-Investigators' Information (including faculty advisers):

	Co-Investigator 1	Co-Investigator 2	Co-Investigator 3
Name			
Address			
Contact Phone Number			
Email Address			

Note: If a student is the principal investigator, both the responsible faculty and student must co-sign.

II. Funding Information (if applicable)

Are you applying for funding, or have you received funding? Yes □ No □
If yes was indicated, please provide the following information:
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 _____
F. Grant Amount _____

Does the primary investigator or any co-investigators have a significant financial interest (i.e., salary/payments, equity interests, intellectual property rights) in relation to this study? Yes □ No □

If you answered yes, please be sure to include within the description section of all applicable consent forms the following statement: "The principal investigator and/or co-investigator(s) of this research study have a significant financial interest as it relates to this study."

III. Cooperative Research

Cooperative research projects are those that involve more than one institution/ organization and can be designed to be both multi-site and multi-protocol in nature. Each participating institution/organization is responsible for safeguarding the rights and welfare of human subjects and for complying with all regulations. If this proposal has been submitted to another Institutional Review Board (or authorizing individual/entity), please provide the following:

Name of Institution _____
Date of Review _____ Contact Person _____
IRB Recommendation _____

IV. Subject/Client Information

A. Types of Subjects/Clients (check **all** that apply and provide number of subjects):

Subject Group	Newborns or Infants	Children (aged 2-7)	Children (age 8-12)	Adolescents (aged 13-17)	Adults (18+)	Pregnant Women	Adults with Guardians
Check if in Study	☐	☐	☐	☐	☐	☐	☐
# of Subjects							

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

If you indicated Yes, please specify:

☐ Prisoners ☐ Pregnant women
☐ Mentally disabled ☐ FMU students
☐ Mentally ill ☐ Other (specify): _____

Will the study require translation of consent forms?
Yes ☐ No ☐

If you answered yes, please specify the language(s) that the consent forms will be translated into:

B. Other:

Information to be collected may require special sensitivity ☐
(e.g. substance abuse, sexual behavior)
Please specify:

C. Total Number of Research Subjects _____

D. Approximate time commitment for each subject/client _____

E. Compensation to subjects/clients: Yes ☐ No ☐

F. If you answered yes to letter E, please indicate the form of Compensation (e.g. cash, taxi fare, meals, gifts) _____
Amount (value)_____ (per person)

G. Does this study involve the use of protected health information (PHI) from subjects' records? Yes ☐ No ☐

If Yes, will consent be obtained from research subjects? Yes ☐ No ☐
If checked yes, please skip to V.

H. 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.)

I. Gaining Access to the Research Site:
If you will be conducting your research at Florida Memorial University and your participants are either students or personnel of FMU, you will need to get the supervisor or administrator responsible for your participants to agree to grant you access to the proposed participants.

Department: _____ Administrator:_____
Please Print Please Print

Signature: _____

V. Submission Checklist (to be completed by primary investigator)

□ Research Protocol
□ Consent Form(s)
□ Data Collection Instruments
□ Cooperative Research IRB/Administration Approval Letter(s)

VI. Principal Investigator Assurance and Obligations

I certify that all information provided in this submission (including information provided in the research protocol and 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. No changes to this study will be implemented until a revision form has been submitted and approved by the IRB.
- This study will be conducted during the one year approved by the IRB (or less as stipulated by the IRB). If the study will exceed the approval period, I will submit in a timely manner a Continuation/Renewal/Revision form. I understand that the study may not continue past an approval period.
- When applicable, I will provide a copy of the signed informed consent form to the subject or patient.
- I will retain all signed informed consent documents for a minimum of three (3) years (or longer as stipulated by funding agencies) from the date the study is concluded.
- I will report in writing any serious adverse events to the IRB within 10 business days.
- I will provide participants with any significant new information obtained during the course of the study.
- If my study has been approved at the Expedited or Full Review levels, I will report to the IRB when this study has closed.

Principal Investigator's Signature: _____ Date: _____

If applicable, Co-Principal Investigator's Signature _____ Date: _____