PACE UNIVERSITY INSTITUTIONAL REVIEW BOARD

PROPOSAL SUMMARY

TITLE OF PROPOSAL __________________________________________________________

___ New proposal, not previously reviewed? ___ Continuation of previously approved proposal?
___ Modification of previously submitted proposal?

IND (Investigational New Drug) # (if applicable) _____ PACE IRB Code # _____ (to be assigned)

PROJECTED STARTING DATE _______ PROJECTED COMPLETION DATE ________

SPONSOR/FUNDING SOURCE __________________________________________________

FUNDING APPLICATION DEADLINE DATE (if applicable) __________________________

PRINCIPAL INVESTIGATOR _________________________________________________
(Name and Title)

Telephone Number: E-mail Address:

ADDITIONAL INVESTIGATOR(S) _____________________________________________
(Name(s) and Title(s))

DEPARTMENT/SCHOOL _______________________________________________________

___ Yes ___ No The proposal involves human subjects.

___ Yes ___ No The proposal involves animal subjects.

___ Yes ___ No The proposal may involve human subjects who are:
___ minors (under age 21); ___ over 70;
___ prisoners or others involuntarily institutionalized;
___ developmentally disabled; ___ physically ill;
___ adults lacking decisional capacity/whose condition creates a reasonable likelihood of decisional impairment during the research.

___ Yes ___ No The proposal may involve human subjects who are:
___ reproductively active (may become pregnant/cause pregnancy);
___ pregnant women; ___ fetuses; ___ nursing women.

___ Yes ___ No The proposal involves administration of prescription or non-prescription drugs or pharmaceuticals or medical devices.

___ Yes ___ No The proposal may involve exposure to radioactive material.

___ Yes ___ No The proposal may involve use of recombinant genetic material.

___ Yes ___ No The proposal is: ___ not submitted for funding; or (check all that apply)
submitted for: ___ Federal funding; ___ other external funding,
___ faculty development funding.

The Investigator should provide succinct summary statements addressing the following points of information. Incomplete information may result in delay of the review and approval process. Where indicated, include the proposal page number(s) that contain(s) detailed information. Use supplemental pages if necessary. Investigators may request to meet with either the primary IRB reviewers or the full IRB during the review process.
1. PURPOSE OF THE STUDY:

2. CHARACTERISTICS OF SUBJECT POPULATION:
Describe the characteristics of members of the subject population, such as their anticipated number, age ranges, sex, ethnic background, and health status. Identify the criteria for inclusion and exclusion, and identify any classes of subjects likely to be excluded by the use of applicable medical inclusion/exclusion criteria. Justify the inclusion or exclusion of any special classes of subjects such as reproductively active men or women or nursing women, fetuses, children, physically or mentally disabled, substance abusers, adults lacking decisional capacity or whose condition creates a reasonable likelihood of decisional impairment during the course of the research, or others who are likely to be vulnerable. (This applies to control group also.)

Does the design of your proposal, if applicable, comply with the FDA Guidelines for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs (i.e., will produce data on any gender differences in the pharmacokinetics and/or pharmacodynamics of the drug studied, and ensures adequate numbers of subjects of both genders to allow for detection of clinically significant gender-related differences in drug response)?
Does the design of your proposal, if applicable, comply with the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (i.e., provide for appropriate recruitment and retention of subjects of both genders and diverse racial and ethnic groups)?

Proposal Page Number(s)_____

3. **METHOD OF SUBJECT SELECTION:** Describe the method(s) to be used to identify and recruit potential subjects and to randomize subjects; and techniques to be used to assure equitable access of potential subjects to this proposal.

Proposal Page Number(s)_____

4. **METHODS AND PROCEDURES APPLIED TO HUMAN SUBJECTS:** Describe the study design and all procedures (sequentially) to be applied to subjects. Please include plan, if any, of crossing subjects over from one group to another.

Proposal Page Number(s)_____

IRB.3
5. RISKS TO THE SUBJECT:  ____Yes  ____No
Describe all potential risks: physical, psychological, social, legal, or other. Assess the probability, severity, potential duration and reversibility of each risk.

Proposal Page Number(s)____

6. PROTECTION AGAINST RISKS: For all studies involving greater than minimal risk, describe the procedures utilized to prevent/minimize any potential risks.

Proposal Page Number(s)____

7. BENEFITS:  ____Yes  ____No
Describe any potential benefits to be gained by the subject as well as benefits that may accrue to society in general.

Proposal Page Number(s)____

IRB.3
8. **RISK-BENEFIT ANALYSIS:** Explain why the risks to subjects are reasonable in relation to the anticipated benefit(s) to the subject and/or in relation to the importance of the knowledge that may reasonably be expected to result.

Proposal Page Number(s)_____

9. **THERAPEUTIC ALTERNATIVES:** Describe any therapeutic alternatives (whether standard, conventional, or nonstandard or experimental) that may be available.

Proposal Page Number(s)_____

10. **INFORMATION INTENTIONALLY WITHHELD:** ___ Yes ___ No
Describe any information to be intentionally withheld from subjects and justify this non-disclosure. Explain circumstances and personnel proposed for debriefing of and disclosure to subjects, if appropriate.

Proposal Page Number(s)_____

IRB.3
11. **INFORMED CONSENT:** Describe completely how informed consent will be sought, by whom, and the method of documenting consent. (Copies of all proposed consent documentation should be included in the proposal.)

Proposal Page Number(s)____

12. **CONFIDENTIALITY:** Describe how confidentiality of data and privacy of subjects will be protected and maintained.

Proposal Page Number(s)____

13. **DURATION OF STUDY:** Describe anticipated duration of each subject's participation.

Proposal Page Number(s)____

14. **NUMBER OF, AND TIME INTERVALS BETWEEN, MEASUREMENTS:** (e.g., lab evaluations, physical examinations) for diagnostic, evaluative and subject safety purposes.

Proposal Page Number(s)____

IRB.3
15. **STATISTICAL ANALYSIS-METHOD:**

Proposal Page Number(s)_____

16. **COMPENSATION TO SUBJECTS:** Describe amount and payment schedule, if applicable.

Proposal Page Number(s)_____

17. **LIST OF DRUGS USED IN STUDY:** For each drug or pharmaceutical used, describe method and route of administration, dosage, and potential/known adverse effects, including risks of interaction with other unauthorized medication.

Proposal Page Number(s)_____

18. **SPECIAL QUALIFICATIONS/EXPERIENCE OF INVESTIGATORS AND/OR OTHER PERSONNEL WHO WILL INTERACT WITH SUBJECTS:**

Proposal Page Number(s)_____

IRB.3
19. **COLLABORATION WITH OTHER INSTITUTIONS/SPONSORS:**
Describe terms of such collaboration, if applicable.

Proposal Page Number(s)____

20. **CERTIFICATION OF INVESTIGATOR:** Signature certifies the investigator is familiar with and is in full compliance with the Federal Regulations and New York State Statutes governing human subjects research. If the investigator is not familiar with these, IRB Coordinator will supply on request.

______________________________________________  ____________________
SIGNATURE OF PRINCIPAL INVESTIGATOR   DATE

21. **ADDITIONAL COMMENTS:**

**INVESTIGATOR CHECK LIST:**
Please be sure that you have submitted or complied with the following:

1. **Informed Consent Form(s)**
   (Are parental, youth, or child consent/assent forms provided where appropriate?)

2. **Detailed Research Proposal** (Is the proposal sufficiently detailed and complete?)

3. **Is an IND required for this study?** If so, are papers properly filed with FDA?

4. **C.V. of Principal Investigator.**