Title of Study: _____

The following summary must accompany your proposal. Be specific about exactly what subjects will experience when they participate in your research and about the protections that have been included to safeguard them. (Careful attention to the following may help facilitate the review process).

1. In a sentence or two, describe the background and purpose of the research.

2. What is the duration of the proposed research?

3. Who will be the subjects in this study? How will they be solicited or contacted? Subjects must be informed about the nature of what is involved for a participant, including a description of anything that they might consider unpleasant or as a risk. Please provide an outline or script of the information that will be given to subjects before they volunteer to participate. Include a copy of the written solicitation and/or an outline of the oral solicitation.

4. Briefly describe the involvement of human subjects in the study.

5. What measures or observations will be taken in the study? If any questionnaires or other instruments are used, provide a brief description and include a copy for review.

6. Will the subjects encounter the possibility of psychological, social, physical or legal risk? Yes ____ No____ If so, please describe.

7. If there are any risks involved in the study, are there any offsetting benefits that might accrue to either the subjects or society? Please explain.

8. Will there be any physical or mental stress on the subjects? Yes___ No____ If so, please describe.

9. Will the subjects be deceived or misled in any way? Yes ___ No___ If so, please describe and include an outline or script of the debriefing.

10. Will there be a request for information that subjects might consider personal or sensitive? Yes ___ No ___ If so, please describe.

11. Will the subjects be presented with materials that they might consider to be offensive, threatening, or degrading? Yes ___ No ___ If so, please describe.

12. Approximately how many subjects will be participating in the study? Approximately how much time will be demanded of each subject? If subjects will be participating in more than one session, please indicate the total number of sessions and the amount of time demanded by each.

13. What steps will be taken to ensure that each subject's participation is voluntary? What, if any, inducements will be offered to the subjects for their participation?

14. How will you ensure that subjects give their consent prior to participating? Will a written consent form be used? Yes ___ No ___ If so, please include the form. If not, will oral informed consent be obtained? If so, please submit a copy of the script. If neither written nor oral informed consent will be obtained, please indicate why not and complete and attach the *Request for Waiver or Alteration of Requirement to Obtain Informed Consent* form. If either written or oral consent is to be obtained, please complete and attach the IRB *Informed Consent Document Check List.*

15. Will any aspect of the data be made a part of any permanent record that can be identified with the subject? Yes ___ No ___ If so, please explain.

16. Will the fact that a subject did or did not participate in a specific experiment or study be made a part of any permanent record that can be identified with the subject? Yes___ No ___ If so, please explain.

17. What steps will be taken to ensure the confidentiality of the data collected? Be specific.

18. Will any data from files or archival data be used? Yes ___ No ___ If yes, please explain.

19. Does the research require approval from any of the following Xavier University Committees: The Animal Care Committee (Yes ___ No___); The Biohazards Committee (Yes ___ No___); The Radiation Safety Committee (Yes___ No___)? If you answered "yes" to any of the proceeding, has the appropriate clearance been obtained'? Yes ___ No___ If so, please attach the letter of approval to this questionnaire. If it has not, when do you anticipate that clearance will be granted?

20. What are the sources of funding for the proposed research?

21. List the clinical sites to be utilized during the investigation (If applicable).

22. List the contracted facilities for diagnostic tests and procedures, etc. (if applicable).

23. Attach a copy of the 1572 to the summary (if applicable).

24. Attach a copy of the Principal Investigator's resume/CV.

25. Please insure that 24-hour telephone numbers and emergency instructions are included in the consent forms.

Informed Consent Document Check List

Prospectively obtained and legally effective informed consent is to be acquired from each research subject who participates in the study, or from the subject's legally authorized representative or guardian. The following check list is provided to assist investigators in the preparation of their informed consent forms. In general, all of the following must be present in the document:

___(a) A statement that the study involves research, and an explanation of the purposes of the research,

___(b) the expected duration of the subject's participation, and the approximate number of subjects who will participate in the study,

___(c) a description of the procedures to be followed,

___(d) the identification of any procedures that are experimental,

___(e) a description of any reasonably foreseeable psychological, physical, or legal risks or discomforts to the subjects,

___(l) a description of any benefits to the subject or to others that may reasonably be expected from the research,

___(g) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject,

___(h) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained,

___(i) for research involving more than minimal risk, an explanation as to whether any compensation can be expected, and an explanation as to whether any medical treatments are available if injury occurs, and, if so, what those treatments consist of or where further information may be obtained,

___(j) an explanation of who to contact for answers to pertinent questions about the research and the research-subjects' rights, and who to contact in the event of a research-related injury to the subject,

___(k) a statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

A completed copy of this checklist should accompany your proposal when it is submitted for review.

REQUEST FOR WAIVER OR ALTERATION OF REQUIREMENT TO OBTAIN INFORMED CONSENT

___ 1) The research involves no more than minimal risk to the subjects. "Minimal" risk means that the probability and magnitude of harm or discomfort anticipated in the research is not greater than the risks ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

___ 2) The waiver or alteration will not adversely affect the rights and welfare of the subjects.

___ 3) The research could not practicably be carried out without the waiver of informed consent.

___ 4) Whenever appropriate, the subjects will be provided with additional pertinent information after their participation.

Please explain in detail in the space below how each of the above conditions is met in your proposal. Attach additional sheets if necessary.