OUTLINE FOR RESEARCH PROPOSALS

YOUR PROPOSAL SHOULD INCLUDE <u>ALL</u> OF THE INFORMATION THAT FOLLOWS.

1. ABSTRACT:

A half-page abstract should be prepared for the lay reader with a glossary of technical terms. All units of measurement should conform to the S.I. system (Système International d'Unités) of reporting with explanation as appropriate.

2. OBJECTIVE OF THE STUDY:

List the objectives in outline form to reduce wording and also in order of priority.

- State briefly the reason for doing the study.
- What question(s) is the study designed to answer and why is the question being asked?
- If enough background information has been gathered (through an effective review of the literature) to allow prediction of results, then <u>state hypotheses</u> for the proposed research.
- If the study is prototypical or exploratory in nature, it is more appropriate to state objectives.
- Include references if appropriate.

3. SIGNIFICANCE OF THE STUDY:

This section is a justification for undertaking the study.

- Briefly explain the magnitude of the problem and why time and effort should be spent on this research.
- Provide supporting evidence for the practical or theoretical importance of the research by presenting an
 argument as to what the study is expected to contribute to the problem or to a certain body of
 knowledge.

4. REVIEW OF THE LITERATURE:

Present only the most pertinent research studies supporting your argument and discuss only the highlights of the cited studies.

- Outline the information in a logical sequence (chronologically, if applicable) to demonstrate a knowledge of previous research.
- Detail how previous research has not answered your specific research question nor tested your stated hypothesis.
- Point out any technical flaws detected in previous research.
- If any current studies overlap the problem in your proposal, show how your prospective research differs from these studies and how it will complement them.
- If little or no previous work can be found in the area of the proposed study, cite those studies most closely related to the proposed research.

5. METHODOLOGY:

A. Participants

- Give a brief description of the participants (sex, age, physical or mental status, and ethnicity), method of selection (random, stratified, convenience sample, etc.) and approximate number of participants to be studied in all experimental and control groups.
- Indicate the criteria for the selection of the proposed kinds and numbers of participants.

- If populations at special risk (children, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons) are to be studied, provide the reason(s) for their inclusion.
- Specify population groups to be excluded (e.g., pregnant women).
- Provide details on how the sample size was determined and the likelihood of finding statistically significant results, if you can.
- If possible, provide an estimate of the magnitude of your experimental effect and the normal variation in your dependent measures. The Research Department will help you make these calculations, if needed.
- State, in adequate detail, any anticipated physical, mental, or emotional risk to the subjects and the degree of likelihood that it may occur. If no such risk is anticipated, state why this is so.
- Describe, in adequate detail, what measures will be taken to protect the confidentiality of the data to be obtained and the subjects' rights to privacy.
- Indicate and justify the type and/or amount of payment to subjects and controls. Provide copies of any advertisements to be used for subject recruitment.
- <u>Informed consent</u> (State whether it is planned to obtain informed consent from each subject of the research activity. If informed consent will be obtained, use Attachment D as the model. If it is not planned to do so, provide a thorough justification for its omission. (<u>Note</u>: Federal regulations provide that written informed consent be obtained from each subject of a research activity, but this requirement may be waived by the IRB under specific circumstances; see Attachment B, pages 6-8.)

B. <u>Research procedures</u>

- Concisely describe how the study will be conducted by elucidating the variables involved, units of measurement, measuring instruments or equipment, techniques and conditions as well as controls to be used.
- Indicate how data are to be gathered, recorded, stored, retrieved and used.
- If the study is to be conducted according to a detailed protocol of a pharmaceutical company or other outside agency, <u>include a summary in this section and attach the full protocol as an appendix</u>.
- If the study involves the use of an attitude scale, questionnaire, or structured interview, attach the text of such instruments as appendices.
- <u>Drugs</u> (provide specific information on proposed dosage levels and schedules. Include both the generic and commercial name of each drug and summarize available information on efficacy and side effects. If none is to be administered, enter this statement: "No drugs will be given.")
- <u>Blood sampling</u> (state the volume to be drawn on each occasion and the frequency of sampling from the same subject. If none is to be drawn, enter this statement: "No blood will be drawn.")
- <u>Radioactive isotopes</u> (give the identity and dose of each isotope. If none is to be administered, enter this statement: "No radioactive isotopes will be given.")

C. Analysis

- The statistical design to be used should be stated by name; for example, "a two-tailed, paired t-test at the 5 percent level of significance". <u>Data should never be collected and then some statistical design</u> found to fit the data always fit the data to the pre-selected design.
- Briefly give the procedures for analyzing and synthesizing the data.

6. WORK SCHEDULE:

This section pertains to the administrative planning for the project.

- Give a brief estimate of the time requirements for each phase of the study. This information may be presented in a Gant Chart.
- Particular attention should be paid to the expected rate at which subjects will enter the study.

7. COST ANALYSIS (BUDGET):

Prepare a budget for the proposed research project keeping in mind the various costs incurred: salaries of personnel; equipment and supplies; computer time for analysis of data or costs for a statistician to analyze the data; art work for illustrations; slides for presenting the findings; consultants; literature searches when computers are used for the search; reprints; travel locally or to national meetings; rental of space or renovation of rooms; and construction of equipment not commercially available. Also to be included in the budget are the total costs for overhead. <u>Note: Neither the Research Committee nor the IRB approves funding</u>.

8. PUBLICATION OF RESEARCH:

The investigator must also ensure that the research proposal includes:

- A timeline on when the research paper will be published;
- The name of the journal to which it will be submitted; and
- A designation of primary and secondary authors as well as individuals to be acknowledged in the article.

9. REFERENCES:

References cited should be listed in alphabetical order in standard medical reference format (Index Medicus). If the journal to which the investigator intends to submit the article requires references in another format this may be used instead.