

OUTLINE FOR RESEARCH PROPOSALS

YOUR PROPOSAL SHOULD INCLUDE ALL OF THE INFORMATION THAT FOLLOWS.

All units of measurement should conform to the S.I. system (Système International d'Unités) of reporting with explanation as appropriate.

1. ABSTRACT:

A half-page abstract should be prepared that contains information on the background, methods, expected results and implications for the field.

2. OBJECTIVE OF THE STUDY:

Briefly list the objectives of the study.

- *State briefly the reason(s) for doing the study.*
 - *What question(s) is the study designed to answer and why is the question being asked?*
- *State the hypotheses or objectives for the proposed research and present supporting rationale.*
- *Include references as 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 a better understanding of 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 (e.g., chronologically) to provide context for the proposed 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.*
 - *To the extent that your proposed research overlaps with previous research, show how your prospective study will differ 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. Study overview and design

In a few sentences outline the design and activities of the study, identifying the study groups, evaluations and time points, and any interventions.

B. 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 numbers of participants to be recruited in all groups.

- *Indicate the criteria for the selection of study 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 overall and group sample sizes were determined. Base this on estimates of experimental effects drawn from your pilot data or literature. Critically evaluate the relevance of effects cited in terms of factors including subject groups, experimental design, and treatment exposures.*
- *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 research participants. Provide copies of any advertisements to be used for recruitment.*
- *Informed consent (State whether it is planned to obtain informed consent from each subject of the research activity. If informed consent will be obtained, use the Consent Form Template as the model. If it is not planned to do so, provide a thorough justification for its omission. (Note: 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; contact IRB for additional guidance.)*

C. Research procedures

Concisely describe how the study will be conducted by explaining the variables involved, units of measurement, measuring instruments or equipment, and techniques and conditions.

- *Indicate how data are to be gathered, recorded, stored, retrieved and used.*
- *If the study will include an intervention, describe the intervention.*
- *If the study is to be conducted according to a detailed protocol of a pharmaceutical company or other outside agency, include a summary in this section and attach the full protocol as an appendix.*
- *If the study involves the use of an attitude scale, questionnaire, or structured interview, attach the text of such instruments as appendices.*
- *Risks: State, in adequate detail, any anticipated physical, mental, or emotional risk to the subjects and the degree of likelihood that such risk may occur. If no such risk is anticipated, state why this is so.*
- *Adequacy of protection against risks: State the measures taken to protect subjects against the risks listed. If no risks are anticipated, simply state not appropriate.*
- *Drugs: 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."*
- *Blood sampling: 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."*
- *Radioactive isotopes: Give the identity and dose of each isotope. If none is to be administered, enter this statement: "No radioactive isotopes will be given."*

D. Analysis

Concisely describe how the data collected in the proposal will be analyzed and how the results of the analysis will address the hypotheses of the study.

- *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". Data should never be collected and then some statistical design 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. PROJECT STAFFING AND RESEARCH SUBJECT COMPENSATION:

- *Provide a chart including all research staff (PIs, co-investigators and research assistants (named and unnamed) who will work on this projects and the percent of their time each will spend on it.*
- *Provide the amount and type of compensation (if any) that will be given to research subjects and the funding source for the compensation.*

8. 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.