



## RECOMMENDED FORMAT FOR THE RESEARCH PROTOCOL

- I. Study Title
- II. Funding Agency (aside from PSEDM)
- III. Category of the Proposal/Grant being applied for
- IV. Summary (abstract)
- V. Introduction [SUBHEADINGS ARE NOT REQUIRED]
  - A. Identify what is being studied (efficacy/effectiveness or quality of care. etc)
  - B. Significance
  - C. Pertinent literature: to identify the gaps in current knowledge for which the current study is needed; to bring the field up to date and clarify the state of the art
  - D. Justification for the methodology: Explain why the study is being done this way
- VI. Objectives
  - A. General objective
  - B. Specific objectives
- VII. Study design
- VIII. Methods
  - A. Study subjects
    - i. Define target population
    - ii. Define how sample size is selected
      1. inclusion criteria
      2. exclusion criteria
  - B. Sample size
  - C. Description of study procedure/exp'tal maneuver
    - i. Patient allocation
    - ii. Interventions
  - D. Description of outcome measures
- IX. Data analysis
- X. Ethical considerations
- XI. Indemnification policy
- XII. Time schedule
- XIII. Duties and responsibilities of the research personnel
- XIV. Bibliography
- XV. Budget
- XVI. Appendices
  - A. Consent form
  - B. Dummy tables
  - C. Questionnaire

***SUBMISSION OF THE STUDY IN THE PROPER FORMAT IS A REQUIREMENT FOR CONSIDERATION OF THE PROTOCOL FOR ANY OF THE RESEARCH GRANTS.***