



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.