**Protocol Shell/Template:**

Project Title/PI:

Background/Study Rationale:

Describe the basis for the proposed research, including a presentation of the problem to be studied and a review of current literature. Describe how this proposal will enhance this medical knowledge.

Objective/Purpose/Aims:

Describe the purpose of the study, including identification of specific primary objectives/hypotheses. Secondary objectives/hypotheses should be described as necessary.

Study Design:

* 1. Experimental design of the study (e.g., single-blind, double-blind)
  2. Study population general description
     1. Inclusion/Exclusion criteria
  3. Number of participants needed
  4. Sample size determination and power analyses
  5. Study outcomes/endpoints

Statistical Methods:

Describe statistical analysis methods as appropriate. For example, will intention-to-treat methodology be used in the analysis? Will there be any sample stratification?