

## Protocol Outline

Protocol Title:

Protocol Version:

Protocol Date:

Principal Investigator:

Research Team:

**I. Abstract**

Provide a summary of the study background, aims, and design.

**II. Background and Significance/Preliminary Studies**

Describe the current environment that is the basis for the proposed research, including a presentation of the problem (with references) and a review of current literature. Include a critical evaluation of current knowledge and preliminary studies related to the proposed research and describe how this proposal will enhance this knowledge.

**III. Study Aims**

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

**IV. Administrative Organization**

Describe the participating units, including other participating study sites, laboratories, data management center, and coordinating center as applicable.

**V. Study Design**

- a. Experimental design of the study (e.g., single-blind, double-blind)
- b. Study population general description
- c. Sample size determination and power analyses
- d. Study outcomes/endpoints

**VI. Study Procedures**

- a. Subject selection procedures
  - i. Sampling plan including Inclusion/Exclusion criteria (subject and disease characteristics)
  - ii. Recruitment procedures
    1. Where will recruitment occur?
    2. Where and when will consent be obtained?
    3. Who will obtain consent?
    4. What is the advertising plan, if applicable?
    5. What recruitment materials will be provided to the potential participant (brochures/information sheets/video presentation)?
  - iii. Screening procedures

1. What procedures are required for screening?
  2. What is the screening schedule (number of visits, length of visits)?
  3. Which screening tests/procedures are part of standard care and which are for research purposes only?
  4. What happens with screen failures (including any data gathered during screening)?
- b. Randomization procedures (if applicable)
  - c. Study Intervention
    - i. For Drug/device studies:
      1. Active study agents
      2. Placebo study agents
      3. Blinding/labeling/preparation of agents
      4. Storage
      5. Administration
      6. Toxicities and guidelines for adjustments
    - ii. For Other types of intervention studies:
      1. Active intervention description
      2. Control group, if applicable
  - d. Study Assessments and Activities
    - i. Describe all study procedures, assessments, and subject activities
    - ii. Provide a schedule of all study assessments and subject activities, including a tabular representation or timeline as applicable

## **VII. Safety Monitoring Plan**

- a. Definition of adverse events, serious adverse events
- b. What procedures will be used to monitor subject safety?
- c. Who (list names) will identify, document, and report adverse events?
- d. What is the frequency for review of summarized safety information and who will perform the review (e.g., safety monitoring board)?
- e. What are the stopping rules with regard to efficacy and safety?

## **VIII. Analysis Plan**

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

## **IX. Literature Cited**