

Protocol Title:

Principal Investigator:

Co-Investigators: List all collaborators

Study Coordinator: If a coordinator / research nurse / research assistant has been identified

Population: Include sample size, gender, age, general health status, geographic location

Number of Sites: Single site / Lead site of multi-site study / Participating in multi-center study / Data coordinating center

Study Duration: State duration of study

Subject Duration: State duration per subject

General Information

- A brief description of the research project.

Background Information

- Include study hypothesis, summary of findings from studies that have potential significance to proposed study and a discussion of important literature and data that are relevant to the study and that provide background for the study.
- Applicable clinical, epidemiological or public health background or context of the study.

Objectives

- Primary and secondary objectives.
- Include statement of purpose e.g., to assess, to determine, to compare, to evaluate and method of assessing how the objective is met, i.e., the study outcome measure.

Study Design

- A description of the design of the study to be conducted (e.g. randomized controlled double blind, chart review, case cohort, non-interventional etc.).
- Expected duration of study and subject participation.
- A specific statement of the primary and secondary outcomes to be measured during the study (must be consistent with Study Objectives, as stated in Section).
- Assessment of efficacy.
- Assessment of safety.

Study Population

- The study population and inclusion/exclusion criteria should be clearly defined in this section of the protocol.

- This section should include a discussion of selection of the study population and inclusion/exclusion criteria.
- Describe the recruitment strategy.

Study Procedures

- For research involving interaction with participants, describe the number of study visits, what procedures will occur at each visit and how long each visit will take. Indicate the total amount of time required of each subject to participate in the project.
- Specify the type of information the PI will gather, along with the means for collecting and recording it.
- Methods for collecting specimens and data. List all laboratory evaluations, if applicable. Include specific test components and estimated volume and type of specimens needed for each test.
- If biological specimen are going to be stored, describe the plans for storage, duration of storage and procedure to maintain confidentiality.

Data and Safety Monitoring

- State if adverse events are expected, if yes, describe how these events will be identified, assessed and graded.
- Describe plans for reporting unanticipated problems (including adverse events, protocol deviations, other problems).
- Describe the safety monitoring plan (periodic review by research team, external review, formal data and safety monitoring board).

Statistics

- A description of the statistical methods to be employed, including timing of any planned interim analysis.
- The number of subjects planned to be enrolled. In multicentre trials, the numbers of enrolled subjects projected for each trial site should be specified. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.
- The level of significance to be used.
- For clinical trials, list criteria for the termination of the trial.
- The selection of subjects to be included in the analyses (e.g. all randomized subjects, all dosed subjects, all eligible subjects, evaluable subjects).

Ethics

- State whether IRB approval will be sought from CPHS or another IRB (under UT System Reciprocity Agreement).
- Describe the consent process. If waiver of consent or waiver of documentation will be sought, describe the plan to protect privacy of subjects.

Data handling and record keeping

- Access to source documents.
- Procedures for maintaining subject confidentiality, any special data security requirements, and record retention per the sponsor's requirements.
- State whether human subjects will be identifiable directly or through identifying information.
- State how the data will be linked to the subjects during the study.

- State how and where the data will be stored, and how it will be protected.

Quality control and assurance

- Describe steps to be taken to assure that the data collected are accurate, consistent, complete and reliable. (source data verification, audits or self – assessment)
- Describe whether there are plans to have ongoing third party monitoring.

Publication Plan

- Describe plans for publication of research results.
- State if results will be returned to research subjects.

ATTACHMENTS

1. Schematic of Study Design
2. Study Schedule
3. Consent Document
4. Case Report Form