

**PROTOCOL TEMPLATE V.003**

**GENERAL INSTRUCTIONS:**

1. The texts colored in **BLUE** are guides for the completion of the protocol. You must delete these portions after completing each section.
2. The texts colored in **BLACK** are the standard sections in a research protocol. These sections are REQUIRED be supplied with what is applicable in the study. However, the sections can always be modified (i.e.: added) for the benefit of the study.
3. If a specific section is not applicable to the study, just indicate “NA” or “Not Applicable.”
4. This template is already formatted in the recommendation of TMC-CTRI and TMC-IRB. **Do not change any formatting options**. Supply the necessary information for the header and footer. The formatting of the paper includes the following guidelines:

* Paper size is short bond paper (US Letter Paper Size; 8.5 x 11 inches)
* Font Size is 10 pt and font style is Arial
* Spacing between lines is set to 1.5
* Margins are set to 1 inch for all sides
* Headers include surname of investigators and the year of writing the protocol
* Footers include the version number of the protocol (starting with V.01), exact date of submission of the protocol and page number
* Watermark (CONFIDENTIAL) are present in each pages
* Continuous page number is present for all the pages
* Only the headings are in **BOLD** letters; main texts should be regular in thickness

1. Review the pages for any discrepancies in formatting and content.
2. Convert the file to Portable Document Format (PDF) before online submission and/ or printing.
3. Do not include this page (Page 0) in the submission of the protocol. Delete as necessary.

This template was derived from The Medical City-Institutional Review Board Outline for Research Protocol and from University of California-San Francisco Protocol Template.

**PROTOCOL INFORMATION**

|  |  |
| --- | --- |
| Protocol Name: | Complete title of the study |
| Version Number and Date: | The current version number and exact date of submission |
| Sponsor: | Complete name of the sponsoring agency  Address  Contact details |
| Principal Investigator: | Name:  Affiliation:  Telephone:  Fax:  Email: |
| Co-Investigator/s: | Name:  Affiliation:  Name:  Affiliation: |
| Investigational Product: | If applicable |
| Development Phase: | If applicable |
| Coordinating Center: | If applicable |

**TABLE OF CONTENTS**

This refers to the systematic arrangement of the contents of the protocol and its corresponding page numbers. Include all attachments if applicable. Follow the format below:

**Type chapter title (level 1)1**

Type chapter title (level 2)2

Type chapter title (level 3)3

**Type chapter title (level 1)4**

Type chapter title (level 2)5

Type chapter title (level 3)6

**LIST OF ABBREVIATIONS**

Include all abbreviations used in the protocol. The list should be in alphabetical order

**PROTOCOL SYNOPSIS**

|  |  |
| --- | --- |
| Protocol Title: | Provide the complete title |
| Sponsoring Agency: | Complete name of the sponsoring agency |
| Rationale of the Study: | This refers to a two-paragraph description of the study which highlights the reason for conducting the study. This may also include a brief background of the investigational product/s involved in the study |
| Objectives: | This refers to the primary objectives in conducting the study. Just a brief description of the main goal would suffice |
| Impact/ Implications of the Study: | A very brief description of the benefits/ risks of the product or procedure to the patient population or why the information gathered in the study is needed in the field |
| Subject Selection: | A general description of the inclusion and exclusion criteria used in the study |
| Investigational Product: | If applicable. This includes the name of the product, dose, route of administration, and control product/ placebo used. The descriptions of the process must be concise |
| Duration of the Study: | Includes the overall timeframe for the study |
| Endpoints: | This refers to the primary/ secondary events or factors that will determine the closure/ termination of the study |
| Statistical Analysis Plan: | Includes the rationale for the number of subjects, statistical tools to be used and/ or software and programs administered for the analysis |

**INTRODUCTION**

1. **Background**

Brief description of the study and/ or the investigational product. It may also include overview of non-clinical and clinical data which provide significant overview on what the study is all about.

1. **Scientific Significance**

Impact/ Implications of the Study - description of the benefits/ risks of the product or procedure to the patient population or why the information gathered in the study is needed in the field.

1. **Research Questions**

Indicate the research question based from the Population- Intervention- Comparison- Outcome (PICO) Tool

1. **Research Hypothesis**

In comparison or correlation studies, indicate the null and alternative hypotheses

1. **Objectives**
2. **General Objectives**- refers to the broad set of goals to be attained by the study. General objectives gives an overview of what the study wants to achieve at the end of the research period.
3. **Specific Objectives**- refers to the set of goals to be directly attained by the study. Specific objectives are derived from the general objectives.
4. **Literature Review-** refers to the systematic compilation of previous studies/ information that will support the ideas to be presented in the study.

**METHODOLOGY**

1. **Sample Population**
2. **Study Population-** a general description of the subjects to be used in the study
3. **Sample Size-** specific number of subjects planned to be enrolled and the reason for the sample size; should be consulted to the statistician
4. **Inclusion criteria-** the conditions and factors to be met in order to include the subject in the study population
5. **Exclusion criteria-** the conditions and factors present in the subject (whether or not it abides with the inclusion criteria) that excludes the subject in the study population
6. **Research Design**
7. **Study treatments-** refers to the design of administering the protocol to the subjects; only supply the following if applicable to the study
8. Method of assigning subjects to treatment groups (i.e.: randomization)
9. Sampling frame and techniques
10. Blinding mechanism
11. Formulation of test and/ or control products
12. Supply of the investigational product at the site
13. Investigational product accountability
14. Measure of treatment compliance
15. Supply others as necessary
16. **Study procedures-** refers to the conduct of study-related activities
17. **Study setting**- the exact place where the procedures will be conducted
18. **Clinical assessments-** refers to the non-laboratory assessments initially conducted in the study; may include the requirements for concomitant medications, demographics, medical history, physical examination, vital signs or whatever is applicable to the study
19. **Clinical laboratory measurements-** refers to the laboratory tests to be included in the study; may include hematology, blood chemistry, pregnancy test, urinalysis, pharmacokinetic measurements or whatever is applicable to the study; only supply if applicable to the study
20. Supply others as necessary
21. **Indication of transfer criteria for admission of patients to specialized wards for this research**- (Alternative: Is there an indication on the use of hospital-wide criteria for admission of patients to specialized wards)- set of criteria to be used for transferring/ admitting the patients to specialized wards (i.e. ICU, NICU, ACSU, etc.)
22. **Adverse Events Reporting**
23. **Adverse events and serious adverse events**- this refers to any untoward medical occurrences in a research; include some definitions of these events with respect to the nature of the proposed study; include criteria for grading severity of these events (see Table 1 as a guide) and assessment criteria for the relationship of the event to the investigational product (see Table 2 as a guide). The tables can serve as a guide but can be modified based from the needs of the study
24. **Reporting guidelines**- this refers to the process of reporting the adverse events/ serious adverse events to the Institutional Review Board and/ or Sponsor
25. **Monitoring-** includes the name and contact details of the person to be contacted (i.e.: the Principal Investigator) for reporting medical concerns or for addressing safety questions
26. Supply others as necessary

Table 1. AE Severity Grading

|  |  |
| --- | --- |
| **Severity (Toxicity Grade)** | **Description** |
| Mild (1) | Transient or mild discomfort; no limitation in activity; no medical intervention or therapy required. The subject may be aware of the sign or symptom but tolerates it reasonably well. |
| Moderate (2) | Mild to moderate limitation in activity, no or minimal medical intervention/therapy required. |
| Severe (3) | Marked limitation in activity, medical intervention/therapy required, hospitalizations possible. |
| Life-threatening (4) | The subject is at risk of death due to the adverse experience as it occurred. This does not refer to an experience that hypothetically might have caused death if it were more severe. |

Table 2. AE Relationship to Study Drug

|  |  |
| --- | --- |
| **Relationship to Drug** | **Comment** |
| Definitely | Previously known toxicity of agent; or an event that follows a reasonable temporal sequence from administration of the drug; that follows a known or expected response pattern to the suspected drug; that is confirmed by stopping or reducing the dosage of the drug; and that is not explained by any other reasonable hypothesis. |
| Probably | An event that follows a reasonable temporal sequence from administration of the drug; that follows a known or expected response pattern to the suspected drug; that is confirmed by stopping or reducing the dosage of the drug; and that is unlikely to be explained by the known characteristics of the subject’s clinical state or by other interventions. |
| Possibly | An event that follows a reasonable temporal sequence from administration of the drug; that follows a known or expected response pattern to that suspected drug; but that could readily have been produced by a number of other factors. |
| Unrelated | An event that can be determined with certainty to have no relationship to the study drug. |

**DATA COLLECTION AND STATISTICAL ANALYSIS**

1. **Data collection and monitoring-** refers to all the procedures for collection, retention and maintenance of the data from the study; may include the following:
2. **Data collection instruments-** brief description on how, where and when will the data will be collected
3. **Data management-** refers to the processing of the data on a database and initial data processing (i.e.: encoding)
4. **Data archiving**- refers to safekeeping procedures for the data collected, availability on the site and retention to the investigator
5. **Confidentiality of data-** procedures for the maintenance of confidentiality of data and subjects
6. **Statistical analysis**
7. **Data sets-** refer to the subjects (i.e.: all randomized subjects, all eligible subjects, etc.)and attributes (i.e.: age, race, gender, etc.) to be included in the statistical analysis
8. **Analysis procedures-** refers to the statistical tools, software and methods to be done on the data sets; may include analysis of endpoints, interim analysis and calculation of sample size

**ADMINISTRATIVE, ETHICAL AND REGULATORY CONSIDERATIONS**

1. **Institutional Review Board compliance-** includes the methods coordinated to the IRB in relation to the study (i.e.: ethical approval, submission of reports for adverse events, report of changes in the protocol, etc.); include what is applicable to the study
2. **Regulatory compliance**- includes methods coordinated to the Regulatory Authority (i.e.: Food and Drugs Administration) in relation to the study; include if applicable
3. **Responsibilities-** includes a list of responsibilities of the investigators, staff and personnel based from the agreement from the Sponsor, CTRI guidelines and ethical/ regulatory guidelines

**APPENDIX**

1. **Questionnaires/ Data collection forms-** provide what is applicable to the study
2. **Diagrammatic Workflow-** provide a conceptual flow of the methods to be used in the study
3. **Dummy tables for results-** consult statistician
4. **Gantt chart-** refers to the specific projected timeframe for conducting the several phases of the study; should be easily understandable and realistic
5. **References**