TEMPLATE FOR A CLINICAL TRIAL PROTOCOL

Cover Page:

TITLE

The title should clearly reflect the study design with a commonly used term, if it is an RCT, Quasi experimental design etc.

INVESTIGATORS'/SITE INFORMATION:

Name and title of the Principal Investigators and other investigator(s) who is (are) responsible for conducting the trial

Address and telephone number(s) of the trial site(s).

Name(s) and address of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial.

STATEMENT OF COMPLIANCE:

This study is in compliance with the Good Clinical Practice (GCP) Guidelines.

INTRODUCTION

The introduction should comprise of the scientific background and an explanation of the study rationale. The introduction might cover (but not limited to) the following aspects of the study:

-description of the condition

-description of the intervention/variables

-how the intervention might work/biological pathways

-why is the trial necessary

OBJECTIVES

Describe the primary and secondary objectives that the trial intends to achieve. The components of a crisp objective might include the study participants, intervention/control, outcome and setting.

HYPOTHESIS

This section could also include the study hypothesis that are more specific than objectives and are amenable to explicit statistical evaluation.

OPERATIONAL DEFINITIONS

Define the variables of interest (including, but not limited to, intervention, control and outcome variables, adverse events) in context to study objectives. This section describes how the study researcher intends to define and measure the study variables.

METHODS

STUDY DESIGN:

This section describes the design and the key elements of the trial.

PARTICIPANTS:

This section describes the eligibility criteria (inclusion/exclusion) used to select the participants. Also add details pertaining to the sources and methods of recruitment for intervention and control arms.

STUDY SETTINGS:

This section should include information on the settings and locations (for e.g. primary, secondary, or tertiary health care or from the community). Also include the country (single site, multi-site, multi-country), city if applicable, and immediate environment (for example, community, office practice,

hospital clinic, or inpatient unit). Also describe relevant dates, including periods of recruitment, exposure, follow-up, and data collection.

RANDOMIZATION, BLINDING (AS APPLICABLE):

- A description of the measures taken to minimize/avoid bias, including randomization and blinding.

- A time/event matrix (timeline) of the trial procedures to determine activities involved during each clinic visit (e.g. blood tests).

- Maintenance of randomization codes and procedures for breaking codes in case of blinding.

- A description of the "stopping rules" or "discontinuation criteria" for individual subjects, parts of trial and entire trial

- Expected duration of the trial including recruitment time, follow up time, time for study close out procedures etc. Define the expected duration of subject participation, their follow up time and the end of the trial.

INTERVENTION(S):

This section includes detailed description of the interventions with sufficient details to allow replication, including the intervention (number of intervention arms), controls/ placebo, how and when they were administered.

OUTCOME(S):

This section should include all the pre-specified primary and secondary outcome measures. Each outcome must be clearly defined including the details pertaining to how and when they will be assessed.

DATA COLLECTION:

- Details on the methods for collection of data and appropriate tool descriptions (questionnaire etc.)

MEASURES TO MINIMISE BIAS:

Describe any measures that will be taken to minimise bias in the study. Some of the design-specific bias to tackle might include: similarity in baseline outcome measurements, similarity in baseline characteristics, incomplete outcome data, protection against contamination and selective reporting.

SAMPLE SIZE AND SAMPLING:

This section describes how the sample size will be determined. The elements of sample size calculation include consideration of the alpha error, beta error, clinically meaningful difference, variability or standard deviation, a safety margin and the dropout rate. Sampling technique (probability, non-probability) should be mentioned.

STATISTICAL METHODS:

This section should include details pertaining to:

- Statistical methods to be used to compare groups for primary and secondary outcomes.

-Criteria for the termination of the trial if needed.

- Procedure of accounting for missing data analysis.

ETHICAL CONSIDERATIONS:

-Include a statement that the trial will be conducted in compliance with the principles of the Declaration of Helsinki, the principles of Good Clinical Practice (GCP) and all of the applicable regulatory requirements.

-State the name and address of the ERC to which the study protocol and other documentation will be submitted.

-Mention about the informed consent forms (ICF), the language in which it will be translated and administered. Also mention that a copy of the ICF will be provided to the study participants.

-Maintain data confidentiality, regulatory approvals (ERC, NBC, DRAP as applicable) and voluntary participation of the participants.

-In case of dealing with the pediatric patient population, assent and parental consent is mandatory.

- Data archiving process should be mentioned as per GCP guidelines.

REPORTING AND RECORDING PROCEDURES OF ADVERSE EVENTS:

- *Identify the possibility of any AEs related to the trial*
- *Mechanism for AE reporting and recording to ERC, funding agency should be mentioned.*

REFERENCES

Annotated bibliography.

APPENDICES:

This will include (but not limited to):

1. Process flow for the patient recruitment and study processes
2. Informed consent
3. Study questionnaires
4. Theoretical framework/model