TEMPLATE FOR A CROSS SECTIONAL STUDY PROTOCOL

Cover Page:

TITLE

The title should clearly reflect the study design with a commonly used term, cross sectional descriptive, analytical.

INVESTIGATORS'/SITE INFORMATION:

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

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

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/issue

-description of the variable/s of study in the existing literature

-description of the exposure and outcomes of study and the biological pathways

-why is the study necessary

OBJECTIVES

Describe the primary and secondary objectives that the study intends to achieve. The components of a crisp objective might include the study participants, exposure and outcome.

OPERATIONAL DEFINITIONS

Define the variables of interest (including, but not limited to, exposure and outcome variables) in context to study objectives. This section describes how the study authors intends to define and measure the study variables.

METHODS

STUDY DESIGN:

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

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.

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.

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 patient recruitment, 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. Also mention the provision of replacing the drop outs if any. 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 outcome

ETHICAL CONSIDERATIONS:

-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.

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

-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.

-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 as per GCP guidelines.

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