

TYPICAL CONTENT FOR RESEARCH PROTOCOLS INVOLVING

HUMAN SUBJECTS

This protocol template is a tool to facilitate the development of a study protocol based on the review report of research protocol used by MREC for reviewing research protocol.

GENERAL INFORMATION

- Study title must be appropriate. (To be consistent with all related document e.g. PIS)
- Protocol identifying number and date (e.g. Version X dated --/--/--)
- Name and address of sponsor
- Name and institution of local investigator/s.
- Site and study team appropriateness in terms of facilities, expertise, patient populations (list all study sites).
- Declaration of conflict of interest among members of the study team. If any and how it is managed.

BACKGROUND/LITERATURE REVIEW

- Complete literature review with sufficient information on the disease or medical condition studied, the investigational product/process, preclinical and early clinical findings, etc
- State the known risks and potential benefits of the investigational product/process

OBJECTIVES AND PURPOSE

- State the societal value or beneficial outcome of the study
- Objective/s of the study should be clear.

STATEMENT ON ETHICAL ISSUES

- Discuss the ethical issues in study and how will the issues be addressed

TRIAL DESIGN

- Study endpoint(s) should be clearly mentioned
- Discuss the study design including all procedures. If placebo is used discuss any washout period, cross-over and also mention if any withholding of treatment

- Mention measure taken to minimize bias such as randomization, blinding, maintenance of randomization codes and procedures for breaking codes
- Discuss the description and justification for (a) route of administration, dosage, and treatment periods; (b) device/process specifications
- State study intervention(s) groups and distribution of subjects in the groups and duration of subject participation
- State the sequence and duration of all study periods including follow-up
- State the monitoring of compliance of subjects and accountability procedure for investigational products
- State the collection, storage and use of bio specimens. Mention if it is optional in the study and if the specimen will be used for future research. If so, discuss what will the research be about including the disease and drug that will be studied.
- State if personal information need to be collected.
- State how the dignity and privacy of the subject is protected in the future research
- State criteria for suspending or terminating the study

SELECTION AND WITHDRAWAL OF SUBJECTS

- Discuss the study population clearly
- State the number of subjects to be enrolled including reason and calculation for sample size
- Mention all inclusion and exclusion criteria
- Describe the process, place and timing for obtaining informed consent / assent
- State that participation is voluntary and will not affect medical services.
- State the subject withdrawal criteria, the follow-up processes, and whether withdrawn subjects are replaced

TREATMENT AND PROCEDURES

- Clearly state the permitted and not permitted medications / treatments during trial
- Discuss the rescue medication / procedure

ASSESSMENT OF EFFICACY

- Discuss methods and timing for assessment, recording and analysis

ASSESSMENT OF SAFETY

- Discuss the procedure and timing for getting reports of adverse events and intercurrent illnesses.
- Process and duration of follow-up of adverse events

STATISTICS

- Discuss the statistical plan and methods for data analysis to include information on the selection of subjects in detail

CONFIDENTIALITY AND SECURITY OF SOURCE DOCUMENTS AND STUDY DATA

- Discuss the means for protecting privacy and confidentiality of personal information
- Discuss if the subjects are given access to their personal information and study data
- Duration and means of storage and archival of medical records and study data and when the study data will be destroyed after period of storage

FINANCE AND INSURANCE

- Mention if there are insurance or indemnity letter from sponsor

PUBLICATION POLICY

- Discuss the publication policy for protecting the confidentiality of subjects' personal information

INVOLVEMENT OF VULNERABLE SUBJECTS

- Discuss if minors are involved as subjects .If minors are involved, there should be an appropriate assent form and parental agreement form
- Discuss if there are involvement of other vulnerable subjects and the appropriate protection for the vulnerable subjects