**Synopsis of Research Protocol**

**for MD/MS Dissertation**

# **Name of Post-Graduate (PG) Student**:

# **Subject/Department:**

# **Name of PG Guide:**

# **Study title:**

Should be self-explanatory, clearly stated.

Title should be indicative of study design, indication and condition.

# **Introduction and background:**

Need for the present study or study rationale

Brief note on what is known to the science on the given topic

What ‘new’ will be added by doing the present study

How this study is going to benefit the current state of practice/medical care/education

# **Brief Review of Literature:**

Some known facts and some existing gaps in the knowledge.

What is happening at international level, national level and regional level in the same area.

Explore the strengths and limitations in the previously reported studies.

# **Research question:**

Clearly stated research question which forms the basis for study objectives and study hypothesis.

# **Study objectives:**

Study objectives should be clearly defined

## **Primary objective**

Clearly defined primary objective based on the research question.

Based on this objective the main outcome is based.

Sample size should be estimated based on the primary objective of the study.

## **Secondary objectives**

Clearly defined secondary objectives to be stated.

Study can have multiple secondary objectives.

## **Exploratory objectives**

Exploratory objectives if any which may be unforeseen at planning stage could be stated here.

# **Study hypothesis:**

## **Hypothesis for primary outcome/objective**

State the null and alternate hypothesis for primary objective/outcome.

## **Hypotheses for primary outcome/objective**

State the null and alternate hypothesis for primary objectives/outcomes.

# **Methods:**

## **Study setting / site**

Hospital/department/laboratory/institute/community where the study will be conducted.

## **Study design**

Please specify the study design.

## **Study duration and timelines**

Study period and duration should be specified.

A Gantt Chart can be provided for study timelines.

* Planning / Review of literature
* Protocol preparation
* IEC submission and approval
* Study start
* Study end
* Data collection
* Data compilation, analysis and results
* Dissertation preparation and approval
* Submission to University

## **Study participants/subjects**

Clearly defined source of study participants/subjects and/or the study sample(s).

Clearly defined study eligibility criteria for study sample/patients/subjects.

### **Sampling method**

Type of sampling method and sampling procedure if any to be used for the study.

### **Inclusion criteria**

Clearly defined study inclusion criteria for study sample/patients/subjects.

Type of patients/subjects/samples.

Age, gender, diseases, conditions.

### **Exclusion criteria**

Clearly defined study exclusion criteria for study sample/patients/subjects.

Type of patients/subjects/samples to be excluded from the study.

Age, gender, diseases, conditions to be excluded.

Other factors which would exclude the subjects/patients from the study.

## **Sample size**

Sample size planned for the study.

Justification for sample size needed for the study based on the primary study outcome/parameter.

## **Randomization and blinding**

Procedures to be used for randomization and blinding wherever applicable.

## **Study outcomes / parameters**

Study parameters / outcome measures should be reliable, measurable and valid.

In case of questionnaire base study follow standard questionnaire development practices.

Please check copyright/permission issues if you are using a standard questionnaire.

Please specify the timepoints at which assessments shall be done.

### **Primary outcome**

Clearly defined primary study outcome measure / parameter to be used for assessment based on the primary study objective.

### **Secondary outcomes**

Clearly defined study outcome measures / parameters to be used for assessments based on all secondary study objectives.

## **Study interventions**

All treatments and interventions to be used in the study to be provided.

Treatment of study and comparator groups (as applicable).

## **Study schedule**

Detailed study schedule including activities and procedures to be done in subjects/patients at screening, baseline and each follow-up visits.

Total number of visits and visit schedule can be presented in tabular form.

## **Ethics and informed written consent**

Clear statement that the study shall be conducted only after favourable approval from the Institutional Ethics Committee (IEC) is obtained.

Informed written consent shall be obtained from all study subjects/patients before performing any study related subjects. Informed written consent should be obtained in vernacular language and complete study information should be provided in the Participant Information Sheet (PIS).

Statement that the study conduct shall be as per the guidelines on Good Clinical Practice (GCP) for human research and CPCSEA guidelines in the conduct of animal experiments.

## **Method of data analysis:**

### **Calculations of sample size**

Basis for sample size and methods/formulae used for sample size calculations.

### **Data analysis tools to be used**

Software to be used for data handling and analysis

### **Statistical Analysis –**

How data shall be expressed for different measurement parameters.

Statistical methods used for data analysis and hypothesis testing.

# **Sponsor / source of funding:**

Any source of funding and contributions to be specified.

# **Conflict of interest:**

Statement of conflict of interest if any.

# **References:**

Vancouver style to be used for references in the document.

# **Signature of PG Student:**

# **Remarks of Guide/ Head of Department:**

# **Name, Designation & Signature of PG Guide:**

# **Name and Signature of Head of Department:**

# **Annexures (as appliable)**

## **Informed Consent Form (ICF)** *Hindi, Marathi, English*

## **Participant Information Sheet (PIS)** *Hindi, Marathi, English*

## **Case Record Form (CRF) or Study Proforma**

## **Waiver of consent form (If applicable)**

## **Study questionnaires**

## **Information on study interventions/treatments**

## **Agreement / MOU / Letter for collaboration / funding / support**

## **Permissions for copyrighted material**

## **Other documents**