

## Guidelines for Synopsis

Synopses should be prepared in the following structured format.

- ❖ **TITLE:** Should be crisp, comprehensive and representative of the study.
  - ❖ **INTRODUCTION:** It should include the following headings:
    - A: Brief Review:** Please give a brief overview about the subject matter on which research is being conducted and provide an appropriate scientific background.  
It should be built in such a way as to lead to the rationale of the research project.
    - B: Rationale of study:** Why the research is being conducted?
  - ❖ **OBJECTIVE(S) OF THE STUDY:** These should be specific and relevant and point towards aims.
  - ❖ **HYPOTHESIS:** A hypothesis is a specific statement of prediction. It describes in a concrete manner, what you expect will happen in your research project.
  - ❖ **OPERATIONAL DEFINITIONS(S):** It is the definition of variables of interest in a particular study.
  - ❖ **METHODOLOGY:** Must include the following:
    - Study design:** e.g. Randomized controlled Trial
      - Non- Randomized Controlled Trial
      - Case control
      - Cross sectional Comparative/Descriptive etc.
    - Study setting:** Where is the study being conducted? (Both sampling & research/bench work)
    - Study duration:** For how long the study will be conducted?
    - Study population:** Who are the study participants?
    - Provide.....** Inclusion criteria
      - Exclusion criteria
    - Sample Size:** How the sample size was calculated. Also indicate which formula for sample size calculation was used and values put in it to calculate the given sample size.
    - Sampling Technique:** How sampling will be done? Whether the sample will be randomly chosen or non-probability convenient sampling will be done?
- Randomization: In case of randomized controlled trial, how randomization into groups will be done?

- Blinding: In case of randomized controlled trial, tell whether the patients will be blinded to the intervention/ control.
- Informed written or verbal consent from all participants.
- How the data will be collected?
- How many will collect data
- Technique: interviewing / Observation / Interaction/ Experiments/ Clinical trials/ Lab work
- Data collection tools: Performa / Questionnaire.

#### **Statistical analysis tools:**

- Give an outline of the plan of analysis along with the statistical software on which it will be performed.
- How the variables in the study will be measured?
- Give an outline of the statistical tests that will be conducted; for example, student t-test, chi-square test, odds ratio, correlation analysis, simple/multiple regression analysis etc.



#### **ETHICAL CONSIDERATION:** Address ethical issues like:

- How will the confidentiality and privacy of participants be ensured?
- Is the treatment being given in randomized controlled trial justifiable? What are its harm and benefits to the patient?
- Give an informed consent form in both English and Urdu Language that will be used to take written informed consent from the participants.
- Informed consent should be proper detailed, informative and explanatory.
- All additional tests to be done for research purpose are ethical, with no undue harm or risk for the subjects.
- Will there be any cost to subject for any medication, test or investigation done during the study.
- Highlight the risks involved in research (if any?)



#### **SIGNIFICANCE/ BENEFITS**



#### **FINANCIAL ESTIMATE AND SOURCE(S)**



#### **CONFLICT OF INTEREST**



**REFERENCES:** References should follow Vancouver style, which can be downloaded from: [http://library.vcc.ca/downloads/VCC\\_VancouverStyleGuide.pdf](http://library.vcc.ca/downloads/VCC_VancouverStyleGuide.pdf)



#### **ANNEXURE**

- Annexure should be placed after the references in the synopsis document. In the annexure of the synopsis, provide the following:
- **Annexure A:** proforma or the Data collection tool- the questionnaire
- **Annexure B:** Sample of Informed consent form in English and in Urdu.



#### **FORMATTING REQUIREMENTS:**

- The synopsis should be typed with 1.5 space on A-4 paper and one-inch (2.5 cm) margin on both sides.
- The font size should be 12", in Times New Roman or Calibri
- The main headings should be in Capital bold and 14" size
- The sub-heading should be bold and 12" size

**The researcher will have to submit 03 hard copies and a soft copy to Secretary IRB, Prof. Dr. Asma Irfan (Physiology Department, IMDC).**

## **CHECKLIST FOR RESEARCHER**

- Name(s) of the researcher(s)
- Name(s) of supervisor/co supervisor
- Department
- Title
- Introduction
- Objective(s) of the study
- Hypothesis (if any)
- Inclusion and exclusion criteria
- Type of study
- Material(s) and Methods
- Statistical analysis tools
- Financial estimate and source(s)
- Ethical consideration
- Conflict of interest
- References
- Annexures
  - Consent forms (English & Urdu)
  - Questionnaire/proforma