Guidelines for Writing the Research Proposal

Title: Appropriate description of the study; avoid talking of 'A Study of', 'An Investigation of', "A comparative Study of".

Introduction:

- Use the 3-paragraph rule
- First paragraph: Background of the problem, magnitude of the problem, Rationale of the study
- Second paragraph: Previous studies that addressed the problem, Deficiencies/gap in the previous studies
- Third paragraph: Hypothesis, aim of the study, significance of the study

Literature Review – Appropriate and comprehensive

Objectives: clear and specific

Methodology

(Should be described in sufficient details such that other competent researchers will be able to repeat the study. Details are important! Use verbs in the present or future tense. Don't use verbs in the past tense!)

- **Research design** – what research design is used in the study? Is it a Descriptive study or an Analytic study? Is it an observational or Experimental study? If observational, specify Cross-sectional, Case-control or Cohort. If Experimental, specify.
- **Study Population and Study Site** – This is the population where you will get your samples. Define/Describe your study population, the place and the time period you will do the study. If your sampling population involves patients with a disease, define the criteria for making a diagnosis of the disease. If your study is a case-control, describe/define as well who is the control, and how will they be diagnosed.
- **Eligibility criteria –** these are attributes a respondent must possess to qualify in the study. (from the eligibility criteria, we will know if the participants selected are representative of the target population).
  - Inclusion criteria – characteristics that the prospective participants must have to be included in the study; describe who will to be included in the study.
  - Exclusion criteria – characteristics that disqualify prospective participants from being included in the study; describe who will be excluded. (This is not the opposite of the inclusion criteria). Exclude the participants who have fulfilled the inclusion criteria but have characteristics that can influence or affect the outcome/results of the study. Do not put those who refuse to sign the informed consent, those who are not willing to participate!

- **Study procedure**: **For Interventional/Experimental studies**:
  - Recruitment of participants – how will participants be recruited? When do you ask them to participate in the study? When will informed consent be obtained?
  - Method of assignment to study groups – how do you assign the treatment? Will you do randomization? If so, describe specifically how.
  - Description of procedure/s for the experimental and control group – describe how treatment and control are given.
  - Laboratory procedures – will there be laboratory exams to be requested? Where, when and how often? If blood will be extracted, specify amount of blood per extraction.
  - Follow-up procedures – will there be follow up? Specify where, when and how often.
  - Method of dealing with adverse events and/or serious adverse events – should there be adverse events, describe how to deal with them, e.g., hospitalization., giving of drugs specifying the name, manner of administration, strength, dosage, frequency and duration, etc.
  - Blinding procedure – are participants and/or investigators or observers blinded? Describe how.
  - Data to be collected – How will data be collected? What are the data to be collected?
  - Criteria for withdrawal of subjects – specify when do you withdraw the participants?
  - Criteria for stopping the study as a whole – when do you decide to stop the study as a whole?
- **Study procedure**: **For Observational studies**
  - Sampling methodology – how will you select your participants? Describe specifically the type of sampling methodology to be used.
  - Recruitment of participants – how will participants be recruited? When do you ask them to participate in the study? When will informed consent be obtained?
  - Data collection method – how will data be collected? What method will you use? Do you review of records, use a questionnaire, or do observation? Describe in detail how they will be done.
  - Data to be collected – what are the data to be collected? Specify all data or variables that you will collect, demographic characteristics, exposure variables, outcome variables, etc.
  - Instrument/s to be used for measuring an exposure &/or an outcome (if applicable) – what instruments will you use to measure the exposure and/or the outcome? Is/are the instrument/s used validated?
  - Laboratory procedures (if applicable) – do you do laboratory procedure? What, when, where and how frequent? Do you do blinding of Laboratory personnel? (If applicable)
  - Follow-up (if applicable) – do you follow up participants? When, where and how frequent?
  - Biosafety Clearance (if applicable, attach Clearance in the Appendix)

- **Variable description/Operational definition** – define only the variables you will collect! Don't define the participants of the study here. (They would have been defined under the Study population.) Definition should be operational so you can classify your participants as to what classification they belong. For example, if the variable is quality of life (QOL), state that QOL is defined using a validated questionnaire. Then state how it will be measured. Do you measure it using the actual score, or do you categorize/classify it into meaningful categories?
  - Dependent variable/s – define operationally. If categorical, provide codes for the categories.
  - Independent variable/s and confounders – define operationally. If categorical, provide codes for the categories.
  - Confounders/Control variables – identify each of them and define each too
- **Sample size calculation** – calculate sample size based on the objectives. Give the assumptions
- **Data Management and Analysis**
  - Data Processing and Encoding – where do you process and encode data? What Statistical software will be used?
  - Data Analysis - Identify Statistical test/s to be used for each objective. What is the Level of significance?
  - Dummy tables – make dummy tables for objective.
- **Ethical Consideration** – Describe Conflict of Interest, or if there is none, assurance of confidentiality & anonymity, Informed Consent process, Assent for minors, Vulnerability issues, in anticipated risks and discomforts and risk assessment, expected benefits to the subjects, Incentives and/or Compensation, Community considerations including issues like stigma or draining of local capacity, sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of study.
  - Informed Consent – get a template of an informed consent from the WHO
- **Schedule of Activities** – better presented as a Gantt chart
- **Budgetary Requirement**
- **Appendix**- Data collection tool (Coding Manual) o Questionnaire o Biosafety Clearance