**GUIDELINE FOR RESEARCH PROPOSAL FOR MEDICAL AND HEALTH SCIENCES**

1. **TITLE**

A concise title which covers all the study objectives

1. **INTRODUCTION**

Brief explanation on the scope of the study.

1. **LITERATURE REVIEW**

Critical review of previous published studies related to topic of interest.

1. **PROBLEM STATEMENT AND STUDY RATIONALE/ JUSTIFICATION**

Why are you conducting this study? Describe gaps of knowledge

What is the importance of your study finding(s)? Justify your study rationale

1. **BENEFITS OF THE STUDY**

Provides information to the reader on how the study will contribute. It must be specifically stated, however, what the study will contribute and who will benefit from it. Your problem statement can guide you in identifying the specific contribution of your study.

1. **LIMITATIONS OF THE STUDY**

Influences that the researcher cannot control. They are the shortcomings, conditions or influences that cannot be controlled by the researcher that place restrictions on your methodology and conclusions. Any limitations that might influence the results should be mentioned. When considering what limitations there might be in your research, be thorough. Consider all of the following:

* your analysis.
* the nature of self-reporting.
* the instruments you utilized.
* the sample.
* time constraints.

1. **RESEARCH QUESTION(S)/ HYPOTHESES**

What are the questions that you derived based on your problem statement that you would like to answer with this study?

What is the hypothesis of the study?

1. **RESEARCH OBJECTIVE(S)**

**General:**

The overall objective which covers all specific objectives

1. **Specific:**

The itemised objective that in line with research question. You may use these verbs:

* To describe
* To explore
* To identify
* To determine the proportion
* To determine the association between the
* To determine the validity of

1. **CONCEPTUAL FRAMEWORK**

Diagrammatic illustration of the study concept based on literature review with some text to explain the diagram.

1. **METHODOLOGY**
2. **Study Design**

You may need to split into phases of study

You may use these type of study designs:

* Cross sectional study – including questionnaire based study and study that use secondary data
* Cohort or prospective study
* Case control study
* Interventional study –non-randomised controlled trial, randomised controlled trial, interventional study without control, any matching or blinding applied

1. **Study Period**

When will your study start and ends? What is the total duration?

1. **Study Location**

Where will you collect your data? Introduce the place if necessary

1. **Reference Population**

The overall or big population that your study findings is able to represent. Must be appropriate for the level of your study design

E.g.: Type 2 diabetic patients in Terengganu

1. **Source Population/ Sampling Pool**

The source where your subject will be recruited

E.g.: Type 2 diabetic patients attended Klinik Kesihatan in Kuala Terengganu and Besut

1. **Study Participants**

Who will be in this study? Explain qualities of the participants needed.

1. **Inclusion and Exclusion Criteria**

Inclusion and exclusion criteria (for each group if more than one group)

1. **Sample Size Determination**

Determine sample size for each objective as much as possible. Add if necessary sample size estimation when considering non response or drop out percentage.

State the software/formula used and the measures used to calculate. State the 95% CI, power of study 80%

1. **Sampling Frame**

The list / register from where you will sample your subject

E.g.: Klinik Kesihatan attendance list for Type 2 diabetic patients’ TCA

1. **Sampling Method(s)**

Sampling method – how you select a subject from the sampling frame

1. **Randomization (if applicable)**

If your study involves intervention trials, state how randomization will be conducted. If no randomization is planned, state the reason(s)

1. **Blinding (if applicable)**

If your study involves intervention trials, state type of blinding will be administered. If no blinding is planned, state the reason(s)

1. **Data Collection**

How you will collect the data, may be written in phases. What EACH subject will undergo and the quality assurance of data collected.

How you handle sample – ensuring confidentiality, labelling, sample flow chain and storage, sample destruction post study (whenever applicable). This is applicable in both the interventional and non-interventional and allows researcher to explain how they store specimens collected from subjects. Mainly this is related to privacy protection, although this also allows evaluation on the methodology itself (suitability of sample storage method, ie. storing RNA will be different from storing DNA, etc).

Include “what, who, where, when, how” as a guide in explaining the data collection method.

1. **Variable Under Study**

Explain all variables under study and state which is independent and dependent variables.

1. **Measurement Tool(s)**

List all measurement tool(s) and its validity, reliability, or source whenever applicable

1. **Operational Definition**

Definition of main outcomes or variables used in study

1. **Study Flowchart**

Diagrammatic illustration of the how the study will be conducted.

1. **Intended Statistical Analysis**

You may use these as a general template for descriptive statistics [note that software & its version may need to be revised accordingly]

Data will be entered and analysed using SPSS version 22. Descriptive statistics will be used to summarise the socio-demographic characteristics of subjects. Numerical data will be presented as mean (SD) or median (IQR) based on their normality distribution. Categorical data will be presented as frequency (percentage).

State statistical analysis to be used for each objective.

1. **EXPECTED RESULTS**

Use dummy tables/ figures to show expected results

1. **POTENTIAL ETHICAL ISSUES AND THEIR MANAGEMENT (*choose the applicable ones*)**
2. **Subject Vulnerability**

Identify and state how you are going to handle the issue. A participant is considered vulnerable if his/her ability to give true and informed consent has a potential for abuse and exploitation due to conditions such as:

1. They lack capacity to give consent such as people with mental problem
2. There is an increase in susceptibility to coercion or exploitation.
3. There is increased risk of harm

(Taylor, 2004; Lange et al, 2013)

Vulnerable groups include those who are:

1. Economically and medically disadvantage
2. Unable to give or refuse consent for themselves. These may include the underage, women and elderly
3. not getting any benefit personally from the research
4. whom the research is combine with care

(Carl H. Coleman, 2009)

Please state how you will handle the vulnerability issues:

Example:

1. The subject is a patient under your care as a doctor. However, the patient will be given full freedom to participate or not without affecting his/her medical condition management and care.
2. The subject is your subordinate in your entity of management. The data will be independent and will not be disclose to the management authority to be used for any achievement assessment and decision related to work.
3. **Declaration of Absence of Conflict of Interest**

Conflict of interest (COI) is any circumstances by other secondary bodies that may create influence on researcher’s professional judgements or actions on the conduct of the study procedure or the interpretation and reporting the study findings. These may include:

1. Payment to researcher(s) in company driven study
2. Benefits in any form of any researchers in the team from the study findings

Declare the relevant situation and your absence of COI.

State how you will ensure and preserved study integrity

1. **Privacy, Anonymization and Confidentiality**

* You may use these as a general template [note that this is only for the confidentiality of the data that you have collected. You may need to add relevant information accordingly]
* All forms are anonymous and will be entered into SPSS software. Only research team members can access the data. Data will be presented as grouped data and will not identify the responders individually.
* State feedback to subject if applicable
* Please add relevant information with regard to your study

1. **Participants Benefits**

Explain what are the participants’ benefits from taking part in this research

1. **Participants Sensitivities**

* If applicable in case of issues that can triggers social stigma etc
* This study will benefit the community by …. (please state if you plan to give feedback to subject)
* Example:
* The questionnaire or interview questions may cause distress or anxiety or are socially sensitive. Explain how you will minimise the sensitivity.

1. **Potential Risk and Burden to Research Subject**

Explain all the potential risk and burden to research subject

1. **Potential Risk and Burden to Researcher**

Explain all the potential risk and burden to researcher

1. **Honorarium and Incentives**

Example:

1. Token of appreciation will be given to all responders.
2. Cost for transportation will be covered by the research funding
3. **Other Ethical Board Review Approval**

Please state

1. The name of the relevant board (e.g.: National Medical Research Review [NMRR, MOH])
2. Status of application – pending or approve. If approved, please attach the approval letter
3. **GANTT CHART**

Provide table to illustrate the time plan of study process according to month and year in line with the study duration.

1. **MILESTONES**

Milestone of study progress may be presented as monthly or 3-monthly.

1. **REFERENCES**

List all references for this study proposal