**Research title:**

**Principal investigator (MMC No. if applicable):**

**Co-researchers: (MMC No. if applicable):**

**Introduction**

*Introduce study scope*

**Problem statement & Study rationale**

*Why you do this study?*

*What is the use of your study finding?*

**Literature review**

*Justify the need of your study –important to be done*

*Justify your methodology*

**Conceptual framework**

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

**Target Research Question(s)**

*What are the questions that you derived based on your problem statement*

**Objective**

**General:**

**Specific:**

1. *To describe*
2. *To explore*
3. *To identify*
4. *To determine the proportion*
5. *To determine the association between the*
6. *To determine the validity of*

**Research design**

*You may need to split into phases of study*

**Study area**

*Where will you collect your data. Introduce the place if necessary*

**Study population**

*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*

*Eg: Type 2 diabetic patients in Kelantan*

*Source population – The source where your subject will be recruited*

*Eg: Type 2 diabetic patients attending Hosp. USM*

*Target population- the specific target group that you will recruit from the source population*

*Eg: Type 2 diabetic patients who attended outpatient KRK, Hosp USM*

*Sampling frame – The list / register from where you will sample your subject*

*Eg: KRK Attendance list for Type 2 diabetic patients TCA*

**Subject criteria**

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

***Sample size estimation***

*Estimate 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%*

**Sampling method and subject recruitment**

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

**Research tool**

*List all research tool, its validity, reliability, or source whenever applicable*

**Data collection method**

*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).*

**Data analysis**

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*

*Dummy tables*

**Ethical consideration:**

1. **Subject vulnerability**

*If applicable – identify and state how you going to handle the issue*

*Eg:*

*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 used for any achievement assessment and decision related to work.*

*Please refer to glossary for vulnerable group*

1. **Declaration of absence of conflict of interest**

 *If applicable – state how you will ensure study integrity*

*Please refer to glossary for COI*

1. **Privacy and confidentiality**

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. **Community sensitivities and benefits**

*If applicable in case of issues that can triggers social stigma etc*

*This study will benefits the community by …. (please state if you plan to give feedback to subject)*

1. **Honorarium and incentives**

*Eg:*

1. *Token of appreciation will be given to all responders.*
2. *Cost for transportation will be covered by the research funding*