



## Format of the Research Proposal

### **Ethics Review Committee Faculty of Medicine General Sir John Kotelawela Defence University**

#### **1. Cover page**

- Protocol title and the version
- Name and title of the investigator(s) conducting the research, and their affiliations (official address, e-mail addresses and telephone number(s) of the research site(s))
- Name(s) and address (es) of the collaborating institutions.

#### **2. Introduction - background information and rationale/justification for the research**

- Should include background of the research and a literature review related to current topic
- Should state clearly of the need of the research/ research problem/ the basis of the project
- Expected outcomes of the study (how the study will contribute to advancement of knowledge)
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#### **3. Study objectives**

- General objective – A broad statement of what the current proposal expects to achieve
- Specific objectives - statements of specific research question(s) that the proposal hopes to answer

#### **4. Study design**

- type of study,
- research population
- sampling frame and method
- inclusion and exclusion criteria, withdrawal criteria etc
- duration of the study

#### **5. Methodology**

- This is the most important part of the protocol. You need to include detailed information on the procedures, interventions, measurements to be taken.

- Sample/data processing and laboratory investigations to be done need to be clearly written
- Standard procedures to be used, should be described with references.
- Instruments to be used to collect information (eg: questionnaires, data collection booklets etc.) must also be provided.

## **6. Data storage and statistical analysis**

- how the data will be processed and stored and who will have the access to data.
- The statistical methods which are intended to be used for the analysis.

## **7. Ethical considerations**

- should include a description of ethical considerations relating to the study
- should describe the informed consent process and all other relevant ethical procedures.
- Safety considerations
- Quality assurance

## **8. Limitations of study**

- List if any

## **9. Dissemination of results**

- How the findings of the research is disseminated.

## **10. Conflict of interest**

- Declare conflicts of interests. If you don't have any conflicts of interests, mention "Investigators don't have any conflicts of interests"

## **11. References**

- List of references formatted according to an accepted referencing style.

## **12. Source of funding**

## **13. Estimated budget**