**Format of research proposal for Ethics Review Committee, Faculty of Medicine, University of Ruhuna**

All the authors are kindly requested to adhere to the following format and order of content of the research proposal as appropriate when they submit the research proposal to Ethics Review Committee, Faculty of Medicine, University of Ruhuna. This is formulated in view of directing the investigators and also to facilitate the review process. This will be effective from 1st March 2021.

*\*Please note that this is the general format that can be used in biomedical research in humans. For animal studies you alter the structure as appropriate.*

**Main sub headings**

1. Title
2. Introduction and justification
3. Literature review
4. Objectives
5. Methodology
6. Referencing
7. Gantt chart
8. Budget

**1**. **Title:**

The title should

* make the general objective clear
* refer to the study population
* reflect the study setting
* be free of phrases such as “a study on” and abbreviations and acronyms
* not be too long

**2. Introduction: (word count 1000-3000)**

**2.1 Background Information should**

* provide a concise description of the nature of the problem
* refer to the existing situation of the research problem
* be supported by relevant references

**2.2 Justification:**

Justification should

* be able to address the need for the study; discuss how your research would fill the knowledge gap in a particular field by critically analysing the current situation and how the research findings would address the limitations identified
* refer to the potential benefits of the research findings

**3. Literature review (1000-3000 words)**

Literature review should

* be focused with the theme and the objectives of the research
* include the references from the international and local literature where relevant

**4. Objectives**

**4.1 The general objective should**

* clearly addresses the aims of the study

**4.2 Specific objectives should**

* be derived from the general objective
* arrange in a logical sequence
* state in measurable terms using action verbs
* refer to the study population and the study area

**5. Methodology**

Under methods, the following aspects are to be written.

**5.1. Study design**

**5.2. Study setting**

**5.3. Study population/s and the sample**

* mention about inclusion criteria and exclusion criteria

**5.4. Sample size calculation**

* use an appropriate formula

**5.5. Sampling technique**

**5.6. Data collection procedure and study instruments**

* include all the instruments (as annexures) and assay procedures required to achieve the objectives
* define variables specific to the research problem
* include details on data collection (about data collectors and their training, data collection procedure)
* describe in details about collection of biological samples if any (type of sample collected, amount/volume of the sample and the procedure of collection, transport, storage disposal and fate of the samples, safety measures related to sample handling.)

**Intervention** (Applicable only for intervention studies)

* describe briefly and clearly about the intervention
* state clearly the expected outcomes

**5.7. Data analysis**

* mention the appropriate plan of data analysis based on specific objective

**5.8. Ethical Clearance**

The researcher should

* describe the general ethical aspects that need to be considered (informed consent, risks-benefits of the research, maintenance of privacy and confidentiality, addressing the vulnerability, conflict of interest)
* identify the ethical aspects specific to the study proposed as per relevance
* briefly indicate measures to be taken to minimize ethical issues
* include evidence on valid consent given by the original owners if copyright tools/instruments are used
* attach the information and consent forms according to the guidelines given in the ERC web site (as annexures)
* identify authorities from where the administrative clearance are to be sought for the study and attach drafts of permission seeking letters (as annexures)
* indicate the fate of the samples collected and how they to be discarded and how long to be stored
* describe on data management (data protection and accessibility, storage and data sharing)
* mention how the dissemination of findings is done adhering to the ethical standards.
* For multicenter collaborative studies with foreign collaborations (include material transfer agreement, indicate the fate of biological samples if planned to be sent to overseas laboratories and the benefit and relevance of the study to the local population and the local co-investigators, ownership of data)
* If copyright protected study instruments/questionnaire are to be used, clarify whether the permission from original authors/inventors is obtained

**6. Referencing (maximum number of references <50)**

* need to follow a standard referencing system (eg: Harvard referencing, Vancouver referencing style)

**7. Gantt chart**

* include all the main activities need to be with workable appropriate timelines

**Gantt chart**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Activity** | **Time period** | | | | | |
|  | Month/Year | Month/Year | Month/Year | Month/Year | **……..** | **….** |
| Writing project proposal & Literature search | **X** |  |  |  |  |  |
| Ethical Approval |  | **X** | **X** |  |  |  |
| Data Collection |  |  |  | **X** |  |  |
| Data Analysis |  |  |  |  | **X** |  |
| Publishing |  |  |  |  |  | **X** |

**8. Budget**

* include all likely costs for the project
* indicate the source of funding