RUSANGU UNIVERSITY RESEARCH ETHICS INVESTIGATOR BROCHURE

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A. INTRODUCTION

The conduct of research is a very noble task that should be conducted with integrity and respect of research participants. The respect and protection of research participants is of paramount importance. Our role as Rusangu University Research Ethics Committee (RUREC) is to protect both research participants and investigators. This brochure is specifically designed to help you submit a research proposal that addresses ethical issues, is scientific and will hopefully yield meaningful outcomes. While researches being conducted vary greatly, we recommend that you present your proposal close to this format:

B. RUSANGU UNIVERSITY RESEARCH ETHICS COMMITTEE (RUREC) RESEARH PROPOSAL SUBMISSION FORMAT

CHAPTER ONE: Background and Introduction

- Some background information or introduction to your intended study
- Rationale for study.
- Significance.
- Aim or main objective
- Specific objectives.
- Research questions
- Hypotheses where applicable
- Conceptual/Theoretical framework where applicable

CHAPTER TWO: Literature Review

- Appropriate literature pertaining to your study needs to be reviewed.

CHAPTER THREE: Materials and Methods

- This needs to be very explicit and all tools to be used in the study should be attached.
- Ethical consideration

Your methodology component should address in detail how ethical issues will be managed. In high risk studies such as some clinical trials ensure that you highlight how adverse events will be managed.

- The management of study related injuries should not be passed on to participants but should be addressed by the researcher (for example by taking insurance or a health scheme with a health care facility). Pointing the participant to a clinic is not an acceptable way of managing study related injuries.
- Plan for prompt reporting of adverse event (especially serious adverse events - SAEs within 24 hours). Other adverse events should be reported within the week or as per approved schedule.

4. **Budget.**

While this is not mandatory, generally students need to present this so that we assess their understanding of the scope of the study.

5. **Work plan**

This needs to be realistic. In cases of resubmissions, this may need to be adjusted.

6. **Reference List.**

References should be cited in text and listed in the reference list. This can be presented in a preferred style (APA) or as recommended by your learning institution in case of students. Of note is that whatever method is selected there is need for consistency in the document. It is the responsibility of the researcher to ensure that all cited references in text are reflected in the reference list.

7. **Appendices.**

- Information sheet.
- Consent forms.
- Questionnaires.
- Permission letters.
- Approval letters from other institutions (for external student or researchers from other institutions).
    - Students from all learning institutions in and outside Zambia need to attach an approval letter from their learning institution.
    - Other researchers also need to attach an approval letter from their reviewing REC outside the country.
    - Please note that approval from your institution does NOT guarantee approval by RUREC.
    - Ensure that the proposal addresses itself to the local setting to which the study will be anchored.

- Clearance letters from the Pharmaceutical Regulatory Authority (PRA) in cases of some drug trials that fall under this category. Please note that submission to PRA can be done concurrently with your submission to RUREC but the approval will await clearance from PRA.

The section below gives you a little more detailed information to work with as you address some of the heading presented above:

C. EXPECTED INFORMATION TO WRITE A RESEARCH PROPOSAL

1. Begin by giving a general outline of the research proposal. Sufficient detail of the protocol must be given to allow the Committee to make an informed decision without reference to other documents. (Additional material should only be attached if considered absolutely necessary).

2. State the intended value of the project (if this project or a similar one has been done before what is the value of repeating it?).

3. Specify the sample size (with scientific justification), age, sex, source and method of recruiting participants for the study. Attach a copy of any advertisement to be used.

4. State the likely duration of the project, and where it will be undertaken.

5. Specify the procedures (including interviews) involving human participants.

6. State the potential hazards, and their likelihood, that research participants may be exposed to (these may include physical, biological and/or psychological dangers). What precautions are being taken to control and modify these hazards. Include information on hazardous substances that will be used or produced, and the steps being taken to reduce risks.

7. State the procedures or activities which may cause discomfort or distress and the degree of discomfort or distress likely to be entailed by the participants.

8. Specify the degree of confidentiality to be maintained with respect to the data collected and the method of achieving this. When small numbers are involved, indicate how possible identification of individuals will be avoided.

9. State the personal experience of the applicant and of senior collaborators in the study in the field concerned, and their contribution to the study.

10. State the manner in which consent will be obtained and supply copies of the information sheet and consent form. Written consent is normally required wherever possible. Where not possible, or where a waiver is being requested, detailed explanation for either of these

should be given. **Section "D"** below gives you additional detail that RUREC will look out for in your information sheet and consent form.

11. State what medical care is available and its location in relation to the participants.

12. Is the study initiated/sponsored by a pharmaceutical or other industrial company?
    (a) Does the project involve pre-making use of a drug/appliance or a new use for a marketed product?
    (b) As indicated above, all new drug studies should be submitted to the PRA for clearance.
    (c) Should your study drug be made available to study participants after the study if found to be beneficial to the participants?

13. In high risk studies, "no fault insurance" or medical scheme should be taken and a copy of this should be submitted.

14. Describe the measures to be taken to communicate the results of the study to study participants and RUREC. Depending on type of the study, dissemination of study outcomes may include participant representatives, local leaders, National Health Research Ethics Committee, Government or other relevant bodies who could use the results of the study to improve the lives of the study participants, community or country as a whole.

15. If the study requires **exportation of samples** the following should be included:

    - Justification for exportation
    - Details of country, town and name of laboratory.
    - Please note that additional clearance will need to be obtained from the National Health Research Ethics Committee (NHREC) under the Ministry of Health.

16. Include any other relevant information.

D INFORMATION SHEET/CONSENT TO INCLUDE THE FOLLOWING:-

As indicated above detailed information required in the information sheet and consent form are given below.

- Language: simple non-technical
- Introduction: state who you are (Caution: being a member or employee of a particular organisation does not necessarily mean that your research reflects your institution).
- Procedures: Blood sample (and amounts), biopsy, surgery, asking questions etc

- Confidentiality: It is a very important aspect of any research involving human (studies/research) participants
- Risks/Benefits
- Voluntary participation
- Right to withdraw or seek clarification
- Provision for standard of care (inclusive of mention of health scheme or insurance were relevant). Please note that in cases where research participants are patients, close monitoring of patient applies to all patients and not only those who consent to participate in the study.
- The Investigator must give his/her name, address and telephone and RUREC contact details in case participant needs some clarification.
- Provision for participant signature (or thumbprint for illiterate participants who additionally need a literate witness – not the researcher).
- Assent forms for minors (i.e. capable participants below 18 years)
- All consent procedures should be witnessed to assure voluntary participation.

E. APPLICATION FORMS

Application forms when needed can be obtained from Rusangu University Research Ethics office by:

- visiting the office at the following physical address:
  Rusangu University, Science Building
  First floor, Room Number 192
  Monze
  Zambia
- sending an email to rurec@ru.edu.com
- phoning the office on +260 97 653 6815
  +260 974731071

Application forms can be obtained **Monday to Thursday (08:00 AM to 17:00 hours)**
Friday (08:00 to 13:00 hours)

F. PROGRESS REPORT FORMS

RUREC needs to be updated of the progress of approved research every six (6) months. The progress report forms can be obtained from the above address.

G. SUBMISSION OF DOCUMENTS

Submit a letter requesting RUREC to review your proposal.

- Submit **four (4) copies** of the following:
  - Research Proposal and any appendices
  - Application form (All students must ensure that their supervisors sign the application form prior to submission.
  - Clearance letters

- **Curriculum Vitae**
  - PhD candidates should submit their CVs as well as that of their supervisor.
  - BSc/BA and MSc students only need to submit CVs of their supervisors.

It is the responsibility of the researcher to ensure that the documents are arranged and complete before submission. Incomplete documents will not be accepted.

- Upon submission RUREC will give your document a REFERENCE number. Pease ensure that this cited number is cited in all your communication with the RUREC.
- All external studies need a local PI who will be responsible to all matters pertaining to the study.

Please note that your research proposal and all correspondence pertaining to the same will be archived by RUREC for a minimum of **five (5) years post completion** of your study in line with local and international regulations.