RUSANGU UNIVERSITY RESEARCH ETHICS COMMITTEE (RUREC)

Rusangu University

P.O Box 660391

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APPLICATION FORM FOR ETHICS APPROVAL

For Official use of Ethics Committee only	Application No.	
Name, date and signature of RUREC Secretary receiving the application	Name:_____ Signature:_____ Date: _____	

Please note that this form should be submitted with a letter from the PI or CO-PI requesting RUREC to review your proposal. Address all correspondence to the Secretary.

INSTRUCTIONS:

1. All applications for ethics approval should be submitted using this form. The Principal Investigator is required to ensure the information provided is accurate and will sign on this form to indicate that he/she approves the content.

2. Although it is required that the final protocol approved by the sponsor and other relevant documents are submitted for review together with this form, the information provided in this form is expected to be complete and adequate for reviewers to make a decision on the final disposition of the proposal.

3. First (initial) submission: YES/NO Revised/Amended submission: YES/NO

4. Protocol Version/Revision No……Protocol Version Date……..,

Part A: Personal Details

Title of Project:	
Name of the Principal Investigator [PI] (Title, First name and Surname in full)	
Qualifications of PI	
Position	
Institution and Department/Unit	
Signature of the PI	
Contact details for correspondence of the PI (Telephone, email address, postal Address)	
Names of other investigators	
Name: Qualifications: Present Appointment/Affiliations:	
Name: Qualifications: Present Appointment/Affiliations: (Other names to be included on a separate page.)	
This part should be filled if the Researcher is a student.	
Current qualifications	
Student ID number (if applicable)	
Degree for which protocol is being submitted	

Research student: Name, signature and approval of Supervisor (include letter from the institution or university)	
Contact details for correspondence (include the name of contact if different from the PI)	
If this study involves more than one institution, name the overall study PI, institution and contact address	
Name of other institutions involved in the study if this study involves more than one institution	
Supervisor's Names Qualifications of supervisor Contact Details of Supervisor (Telephone and email)	
Co - Supervisor's Names Qualifications of supervisor Contact Details of Supervisor (Telephone and email)	

Part B: DETAILS OF RESEARCH PROPOSAL

*This part requires you to give a **SUMMARY** of the proposed research or protocol and should be in simple terms. All parts of this section should be completed electronically.*

SUMMARY of the proposed research or protocol	
1.	Provide brief and succinct scientific background, study design and objectives and hypotheses e.t.c.
	Title of proposed research
	Purpose of the research
	Scientific Background
	Statement of the problem
	State the intended value of the project or Rationale/Justification. Why it is important to conduct this study? Provide relevant references as appropriate.
	Study Objectives
	Study Hypotheses/Research Question
	Methodology (design, sampling, data collection methods and tools)
2.	State the total duration of the project, and where it will be undertaken (and also in other countries if appropriate).
3.	Provide evidence (such as commitment/endorsement letter) to show that local government officials in the region(s)/district(s) where the proposed research will be conducted have been informed about this study. IF THIS HAS NOT BEEN DONE, describe how you plan to achieve this BEFORE the study starts.
4.	Specify the number of the study participants, with scientific justification for sample size, age, breed, etc.

5.	Specify recruitment methods, inclusion and exclusion criteria and study end points.
6.	Specify data collection procedures, including interviews and sample collection, involving animals with brief details of actual methods. Attach copies of questionnaires and other data collection tools in English and local language
	Ethical considerations:
	Timelines:
	Plans to disseminate research findings:
12	Specify data management procedures and methods to be used during data analysis.
13	If data will be taken overseas, please describe why are being taken outside the country. Please note that before data are take outside, clearance is required by completing a Data Transfer Management Agreement Form
17	State the manner in which consent will be obtained and documented in writing. Provide copies of the informed consent forms and other relevant documents in English. Describe steps to be taken to minimize coercion/undue influence during the consent process.
18	Describe how you are going to assess comprehension of the information provided during the consent process.
21	Please describe how project staff (PI and other staff) will be trained on the protection of study participants in research. In case already trained attach certificate.

22	Please give details of the funder.
23	Please give details of research sponsor. This is not necessarily the funding body. The sponsor is responsible for the initiation and management of the study. All clinical trials should have an identified sponsor.
24	DECLARATION: (This Declaration including signatures should be on single typed page) I (Full Name) Certify that the information provided by me is complete and correct. I hereby apply to Rusangu University Research Ethics Committee (RUREC) for approval of the above research proposal involving human participants, as conforming with recognized ethical standards and as not impinging on the rights of the individuals. I understand that as principal Investigator, I will take full responsibility for the protection of rights and welfare of all trial subjects including the conduct of study and ethical performance of the project. I agree to comply will all rules and regulations of RUREC and NHRA of the conduct of the trial. I hereby declare that. 1. Qualified personnel according to research guidelines will conduct the study. 2. No change will be made in the protocol or consent form until approved by the RUREC. 3. Legally effective informed consent will be taken from Human subjects if applicable. 4. Adverse events will be reported to RUREC as per adverse event reporting policy. I further certify that the proposed research is not currently being conducted and will not begin until RUREC approval has been obtained. Signed: …… Date: …….. STUDENT/CANDIDATE

For all (undergraduate, PGCE programme, Masters and doctoral level) student applicants: A supervisor need to endorse this prior to submission, in accordance with your module processes for review.

For supervisors: Do you endorse this application for review?
YES ☐ NO ☐
Please feel free to add further comments and, where relevant, feedback here:

Part 3: Check List

Please ensure that you have attached and completed the following requirements as applications will not be processed if any documents are missing. All sections, especially participant facing materials must be carefully proof-read.

Document or relevant section	**Included**	**n/a**
Original completed and signed Application form *(tick)*	☐	☐
Proof /evidence of fee paid for ethical review *(tick)*	☐	☐
Full research proposal *(tick)*	☐	☐
Consent form *(tick)*	☐	☐
Participant information sheet(s) *(tick)*	☐	☐
Translated informed consent forms *(tick)*	☐	☐
Data collection tools in English (tick)	☐	☐
Translated data collection tools [where applicable] (tick)	☐	☐
Letter of support/endorsement from Academic Supervisor *(tick)*	☐	☐
CV of academic supervisor *(tick)*	☐	☐
Permission letter from head of institution where data is to be collected *(tick)*	☐	☐
DBS check (if required) *(tick)*	☐	☐
	☐	☐
Recruitment advertisements/details *(tick)*	☐	☐
Indicative measures e.g. questionnaires, interview schedule, focus group prompts, experimental stimuli. *(tick)*	☐	☐
Debrief statement *(tick)*	☐	☐