NASREC FORM 1a

THE UNIVERSITY OF ZAMBIA
DIRECTORATE OF RESEARCH AND GRADUATE STUDIES
NATURAL AND APPLIED SCIENCES RESEARCH ETHICS COMMITTEE

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Zambia
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APPLICATION FOR ETHICAL APPROVAL FOR PROPOSED RESEARCH INVOLVING HUMAN PARTICIPANTS

1. **TITLE OF STUDY**:

2. Principal Investigator:

Name: Qualifications:

Present Appointment/Affiliations:

3a. **OTHER INVESTIGATORS**:

Name: Qualifications:
Present Appointment/Affiliations:

Name: Qualifications
Present Appointment/Affiliations:
(Other names to be included on a separate page)

3b. **SUPERVISORS**: **FOR STUDENTS ONLY**

Name: Qualifications:
Present Appointment/Affiliations:

Name: Qualifications:
Present Appointment/Affiliations:

3c. Co-Supervisor/Mentor in Zambia (This section is for all researchers outside Zambia)

Name: Qualifications:
Present Appointments/Affiliations:

Name: Qualifications:
Present Appointments/Affiliations:

4. **SUMMARY OF PROPOSED RESEARCH**

A summary of the project proposal should include background to the study, aims and objectives, participants to be studied and research methods to be used. Technical terminology should be avoided as much as possible.

(Use not more than one additional A4 sheet if necessary)

5. **ARE THE PARTICIPANTS DEPENDENT ON ANY OF THE INVESTIGATORS**

As students: Yes ☐ No ☐ As employees: Yes ☐ No ☐

As patients: Yes ☐ No ☐ In other ways: Yes ☐ No ☐

If 'Yes' to any of the above, give details

6. **POSSIBLE BENEFITS TO PARTICIPANTS**: These are extracted from the information sheet and presented as a summary

7. **POSSIBLE RISKS TO PARTICIPANTS:** These are extracted from the information sheet and presented as a summary and the investigator specifies steps to minimize them

8. **POSSIBLE BENEFITS TO THE COMMUNITY:** These are extracted from the information sheet and presented as a summary

9. **BUDGET**

(a) Financial support (requested or granted): Yes ☐ No ☐

SPONSOR

(b) Are there costs which will be carried by other institutions Yes ☐ No ☐

(c) Are there costs which will be carried by the participants involved (e.g. travel, accommodation, meals, treatment)? Yes ☐ No ☐

If 'Yes' to any of the above, give details:

10. SUBMISSION (Please take note of NASREC Forms1a and 1b**)**

A. **For Normal Review** at regular monthly meetings**,** attachments should include (**Tick to show that you have provided these**):

(i) 4 copies of Full Protocol Yes ☐ No ☐

(ii) 9 copies of Summary of Protocol. Yes ☐ No ☐

(iii) 4 copies of Questionnaire and/or interview schedules Yes ☐ No ☐

(iv) 4 copies of Information Sheet Yes ☐ No ☐

(v) 4 copies of Consent Form Yes ☐ No ☐

(vi) 4 copies of letter approving of or giving ethical clearance to the project proposal if it is a sponsored research related to another University Yes ☐ No ☐

(vii) 4 copies of Budget Yes ☐ No ☐

(viii) 4 copies of Time Line Yes ☐ ☐

B. For Expedited Review, attachments should include (**Tick to show that you have provided these**):

(i) 4 copies of Full Protocol (to include the following): Yes ☐ No ☐

(ii) 9 Summary of Protocol Yes ☐ No ☐

(ii) 4 Questionnaire and/or interview schedules Yes ☐ No ☐

(iii) 4 Information Sheet Yes ☐ No ☐

(iv) 4 Consent Form Yes ☐ No ☐

(v) 4 Letter approving the project proposal if it is a sponsored research related to another University Yes ☐ No ☐

(vi) 4 Budget Yes ☐ No ☐

(viii) 8 Time Line Yes ☐ No ☐

11. DECLARATION

I……
(Full Name) Apply to the Natural and Applied Sciences Research Ethics Committee of the University of Zambia apply for ethical 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.

Signed: ……. Date: ……...

PRINCIPAL INVESTIGATOR

Contact Address:

Local Contact Address:

Telephone No: Fax No:

Cell phone No: E-mail address

Full name and address of Local Co-Supervisor/Member (if applicable):

Signed: Date:

Full name and address of Head of Department or Head of relevant Organization:

Signed: Date:

Full name of Assistant Dean Postgraduate[1]

Signed: Date:

[1] The Assistant dean should provide a confirmatory letter that the candidate made a proposal presentation to the school/department.

12. Checklist for Documentation:

For a thorough and complete review, all research proposals should be submitted with the following documents:

1) Name of the applicant with designation
2) Name of the institution, field area where research will be conducted.
3) Approval of the Head of the Department / Institution/Supervisor superintending the study.
4) CV of supervisor for students and of PI if the study does not involve a student.
5) Protocol of the proposed research with sufficient detail (see form)
6) Ethical issues in the study and plans to address these issues.
7) Proposal should be submitted with all relevant enclosures like case questionnaires, interview, and Focus group discussion guides, follow - up cards, etc. (Questionnaires interview schedules and focus group discussion guides should be in English and in the study site local language(s).
8) Informed consent process, including information sheet and informed consent form in local language(s) of ALL categories of respondents or participants based the reason they are being recruited in the study (see type of tool relevant for respondents or participants) .
9) Curriculum vitae of all the investigators with relevant publications in last five years or supervisors for students.
10) Any regulatory clearances or authority to do a study in a particular site is required.
11) Source of funding and financial requirements for the project.
12) Other financial issues including those related to insurance
13) Statement of conflicts of interest, if any.
14) A statement describing any compensation for study participation (including expenses) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions(e.g., those leading to a negative decision or modified protocol) by other IRBs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
15) Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.
16) Any other information relevant to the study.
17) Items prescribed in section 10 of this form.