EGERTON UNIVERSITY

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EGERTON UNIVERSITY ETHICS REVIEW COMMITTEE (EUREC)

GUIDELINES FOR APPLICATION FOR ETHICAL APPROVAL OF A RESEARCH PROJECT

All research involving human participants or human biological materials (cells or tissues or fluids), or the work requires access to medical records, must be subjected to ethical review for approval by the Institutional Research Ethics Committee.

Submit a copy of the following documents in both soft form

- Application form
- A proposal (consent forms, questionnaires, instruments, drug information summary, data collection forms, debriefing statements, advertisements),
- copy of the payment slip (check the Application fee guidelines)
- grant or contract agreement (where applicable)

NOTE: Students applying for individual projects should indicate themselves as Principal Investigators. Graduate students must have their proposals cleared by the **Board of Post Graduate Studies.**

1.0 TITLE (As it is in the original proposal):

2.0 PRINCIPAL INVESTIGATOR

Provide full details as in the application form

3.0 PROJECT SUMMARY (Should include a clear description of the research problem, project background, objectives, methodology, expected results in lay language, not more than 300 words)

3.2 RESEARCH METHODOLOGY

Provide a summary of the research design, data collection and analysis.

For medical related projects

- Medication: source, amount or dosage to be used,
- Devices: a description summary and its uses
- Specimen: type, amount, use and destination

- study flow chart sheet/work plan describing the sequence and timing of all study procedures that will be performed, ***where applicable.***

3.3 **Study Location**: Include a statement about the site (s) where the study will take place.

4.0 PARTICIPANT INFORMATION

a. **Inclusion Criteria**: What specific characteristics potential subjects must have to be included in this study (answer for each group of subjects, if different)

b. **Exclusion Criteria**: What specific characteristics would exclude potential subjects who are otherwise eligible to be included in this study (answer for each group of subjects, if different)

c. **Mode of Recruitment**: Explain how you will recruit each group of subjects. Attach the advertisements, flyers, contact letters, telephone etc.

d. **Participant's Recruitment Approach**: Explain who will be recruiting, and how they will be approached to participate in the study. Attach letters of Cooperation from agencies, institutions or others involved in subject recruitment.

e. **Non-Coercive Contact**: Provide an explanation of how you will ensure that subjects will feel free to decline participation in the study and will not be coerced into participation.

f. **Compensation/Payment**: Explain why compensation/payment in cash or in kind, if any is necessary, and non-coercive for the participant's or third-party while participating in the study.

g. **Privacy and confidentiality:** Explain how you will ensure privacy and confidentiality of participant(s) during interviews/specimen collection.

5.0 DETAILS OF RISKS/DISCOMFORT AND BENEFITS

a. Risks/discomfort includes but not limited to physical or psychological danger or interference with normal activities that might be suffered by the participant.

b. Describe potential benefits to participants, community and/or society.

5.3 SAFEGUARDS

a. Describe how you will protect participant's information/data/specimen against unauthorized access e.g. data encryption, use of identifiers/coding, etc.

b. Specify duration of storage and measures to be taken to ensure security of data/specimen; identify custodian and who shall have access to information/data/specimens.

c. Provide a description of where research study/project data/specimens being collected shall be stored.

Submit your application to:
The Deputy Vice Chancellor,
Division of Research and Extension, Egerton University,
P. O. Box 536-20115, Egerton,
soft copy through the email: eurec@egerton.ac.ke