[ INSERT INSTITUTIONAL LOGO]

Study Title: [insert title]

Name of Principal Investigator(s): [insert names]

Co Investigators: [insert names]

Name of Organization: [insert address and telephone number of organization]

Name of Sponsor: [insert sponsor where necessary]

Informed Consent Form for: [Name the group of individuals for whom this consent is written. Research for a single project is often carried out with a number of different groups of individuals in the community. It is important that you identify which group this particular consent is for]

Investigator(s)–Local and International Collaborators: [insert names]

My name is ………………………………………………… I am the Principal Investigator/ Research Assistant working under …………………………………, who is the Project PI (Delete as applicable)

**Purpose of study/project:**

Why is this study being done?

We would like to invite you to be part of this research study. A research study is a way of searching for information. In this case we are looking for information regarding… [Explain the purpose of the study in simple language understandable to a lay person. Ensure that you describe the gap/study problem. Then justify why you want to include this participant or why you chose this participant for the study] e.g. For this reason, we want to understand if ...] This form tells you about this research study and the choice that you have to take part in it. You can ask any questions that you have at any time.

**Who will take part in this study?**

The study participants in this study will include (Specify nature of the participants) They will be …years old and above/below. You have been selected as a respondent or participant because you meet the selection criteria for this study.

**How long will the study last?**

You will be in this study for….

[Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant]

**Do I have to be in the study? Can I say no?**

Participating in this study is your choice. You can choose to take part in this study, or you can choose not to take part in the study. You can also decide to stop being in this study at any time. {[In case it is a clinical trial/intervention research add] If you say no, or if you stop being in the study, your regular doctor will still care for you as he/she normally would. This will not affect your medical care your will not be penalised.

[*For the study involving or likely to affect the health of the participants add*…] Talk to your doctor if you want to stop being in the study.}

Procedure:

To participate in this study, you are asked to: [list all procedures including data collection methods]. Your participation in this study will take approximately [Indicate the estimated duration for interview, sample collection etc]

**Benefits**

Are there good things that can happen from this study?

Sometimes good things can happen to people when they are in a study. These good things are called “benefits”. This study will help us better understand ... That is a benefit.

Not everyone who takes part in this study may have a benefit. [For clinical Trials add] {The study drug may help to …. Where necessary dislose the potential limitations i.e. we cannot promise that the study will help.} The results from this study could benefit other people or solve the problem dealing with… [Include benefit to scientific knowledge]

**Risks**

Are there bad things that can happen from this study?

[State the anticipated risks] Potential discomforts, inconveniences, injuries, harm or risks:

(Declare any known cases of harm or risks from this study, Indicate proposed interventions e.g. (for clinical trials and high risk research: Insurance etc especially in research with more than minimal risks such as injury/disability/death as a result of participation of research. Indicate alternative procedures especially where non-validated procedures, devises or procedures)

Explain plans to mitigate the risks and the steps to be taken in case of adverse events]

**Are there any costs for me if I agree to join the study?**

There will be no monetary costs to you for participating in this study [In case there is state what and why]

[State whether there is any form of payment or not e.g. travel funds including stipends and reimbursements will]

**Confidentiality:**

(Indicate whether private information will be requested, how the identity of the participant and or group will be protected and confidentiality maintained during and after the project. In such conditions under which regulatory authorities may access information during M&E etc. this must be clearly stated and such persons who may access data indicated)

**Contact: Who do I call if I have questions about the study?**

*Indicate who should be contacted in Case of questions or clarifications*:

**Questions about the study:** If you have any questions regarding this study or you want any clarification pertaining this research you may contact the study Principal Investigator/Lead researcher indicated here:

 [Name, Physical address, email, Telephone/Cellphone number]

**Questions about your rights as a research participant:**

If you want to know more about your rights while participating in this research or if you feel that your rights have been violated you may contact the Egerton University Research Ethics Committee (EUREC), P.O. Box 536-20115, EGERTON-Kenya, Egerton University, email: eurec@egerton.ac.ke, Phone number: (Chairperson): +254720235707. A research ethics committee is a group of people that review studies for safety and to protect the rights of study participants.

**Consenter statement**

I have read the information provided or has been read to me. I have been given an opportunity to ask questions and the questions have been answered satisfactorily. I consent voluntarily to participate in the project knowing that I have a right to withdraw at any time.

Participant’s Name (Optional):…………………………………………………………………….

Signature--------------------------------or Thumb print-----------------------

Date:…………………………………………………………………………………….

[In case it the adult is unable to consent and a Legally Authorized Representative (LAR) is consenting on behalf of the participant]

I have read the information provided or has been read to me as the legally authorized representative. I have been given an opportunity to ask questions and the questions have been answered satisfactorily. I consent voluntarily for the person I am representing to participate in the project knowing that I have a right to withdraw the consent and stop the person I am representing from further participating in the research at any time.

LAR’s Name (Optional):…………………………………………………………………….

Signature--------------------------------or Thumb print-----------------------

Date:…………………………………………………………………………………….

I the undersigned affirm that the consent have been sought with full disclosure of project details to the participant to consent. (I have explained the study to the extent compatible with the participant’s capability, and the participant has agreed to be in the study)

Name of the presenter (who presented/explained the consent document):………………….…………………………………………………………………………………

Signature: ……………………………………………………………………………………

Date:…………………………………………………………………………………………

Principal Investigator:…………………………………………………………………………..

Signature:……………………………………………………………………………………….

Date:…………………………………………………………………………………………….