MERU UNIVERSITY OF SCIENCE AND TECHNOLOGY (MUST)
INSTITUTIONAL RESEARCH ETHICS REVIEW COMMITTEE (MIRERC)
INFORMED CONSENT FORM (ICF)

Study Title: [insert title]

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

Co-Investigators: [insert names]

Name of Institution: [include address and telephone number of organization]

Name of Sponsor: [insert title]

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]

This Informed Consent Form has two parts:

- Information Sheet (to share information about the study with you)
- Certificate of Consent (for signatures if you choose to participate)

You will be given a copy of the signed Informed Consent Form

Part I: Information Sheet

Introduction:

You are being asked to take part in a research study. This information is provided to tell you about the study. Please read this form carefully. You will be given a chance to ask questions. If you decide to be in the study, you will be given a copy of this consent form for your records.

Taking part in this research study is voluntary. You may choose not to take part in the study. You could still receive other treatments. Saying no will not affect your rights to health care or services. You are also free to withdraw from this study at any time. If after data collection you choose to quit, you can request that the information provided by you be destroyed under supervision- and thus not used in the research study. You will be notified if new information becomes available about the risks or benefits of this research. Then you can decide if you want to stay in the study

Purpose of the study:

The purpose of the study is to find out whether…..

[Explain the research question in lay terms. Use local and simplified words rather than scientific terms and professional jargon]

Type of Research Project/Intervention:

[Briefly state the type of project or intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a questionnaire, or a series of finger pricks]

Why have I been identified to Participate in this study?

[Indicate why you have chosen this person to participate in this research. People wonder why they have been chosen and may be fearful, confused or concerned]

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]

What will happen to me during the study?

A. Provide a brief introduction to the format of the research study.

We are asking you to help us learn more about ….. If you accept, you will be asked to…. [Explain study procedures. If study is long or there are multiple procedures, a table of events is very helpful. If appropriate, the table should specify which procedures are routine care and which are additional for the research]

B. Explain the type of questions that the participants are likely to be asked in the focus group, the interviews, the survey or other relevant approach. If the research involves questions or discussion which may be sensitive or potentially cause embarrassment, inform the participant of this.

What side effects or risks I can expect from being in the study?

[Separate out by "Likely" "Less Likely" and "Rare but Serious]

Are there benefits to taking part in the study?

a) The possible benefits to you from this study are… **or**
b) You may not benefit personally from this study…
c) The possible benefits to society may include…

Reimbursements:

[State clearly what you will provide the participants with as a result of their participation. These may include, for example, travel costs and reimbursement for time lost. The amount should be determined within the specific contexts]

Who do I call if I have questions about the study?

Questions about the study: PI Contact Info…

Questions about your rights as a research subject: You may contact Institutional Review Ethics Committee (IREC) 053 33471 Ext.3008. IREC is a group of people that reviews studies for safety and to protect the rights of study subjects.

Will the information I provide be kept private?

All reasonable efforts will be made to keep your protected information (private and confidential. Protected Information is information that is, or has been, collected or maintained and can be linked back to you. Using or sharing ("disclosure") of such information must follow National privacy guidelines. By signing the consent document for this study, you are giving permission ("authorization") for the uses and disclosures of your personal information. A decision to take part in this research means that you agree to let the research team use and share your Protected Information as described below.

As part of the study, [name of PI] and [his or her] study team may share the results of your [List information to be collected: e.g. laboratory tests, x-rays, ECG etc.]. These may be study or non-study related. They may also share portions of your medical record, with the groups named below:

- The National Bioethics. Committee,
- The Institutional Review and Ethics Committee,
- [Add others as appropriate, e.g., national institutes of health, representatives of {sponsor name},etc].

National privacy regulations may not apply to these groups; however, they have their own policies and guidelines to assure that all reasonable efforts will be made to keep your personal information private and confidential.

[OPTIONAL: The sponsor may give your personal health information, not containing your name, to others or use it for research purposes other than those listed in this form. In handling your personal information, the sponsor, [PI] and associated staff will keep your information in strict confidence, and shall comply with any and all applicable laws regarding the confidentiality of such information.]

The study results will be retained in your research record for at least six years after the study is completed. At that time, the research information not already in your medical record will be [INFORM PARTICIPTANT WHAT WILL HAPPEN TO THE RECORD AT THAT TIME]. Any research information entered into your medical record will be kept indefinitely.

Unless otherwise indicated, this permission to use or share your Personal Information does not have an expiration date. If you decide to withdraw your permission, we ask that you contact [PI] in writing and let [him/her] know that you are withdrawing your permission. The mailing address is [ADDRESS]. At that time, we will stop further collection of any information about you. However, the health information collected before this withdrawal may continue to be used for the purposes of reporting and research quality.

[OPTIONAL: You have the right to see and copy your personal information related to the research study for as long as the

study doctor or research institution holds this information. However, to ensure the scientific quality of the research study, you will not be able to review some of your research information until after the research study has been completed.]

Your treatment, payment or enrollment in any health plans or eligibility for benefits will not be affected if you decide not to take part. You will receive a copy of this form after it is signed.

Part II: Consent of Subject:

I have read or have had read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts and side effects as well as the possible benefits (if any) of the study. I freely volunteer to take part in this study.

[This section must be written in the first person. It should include a few brief statements about the research. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the informed consent and not a stand-alone document, the layout or design of the form should reflect this]

_____	_____	_____
Name of Participant (Witness to print if the subject is unable to write	Signature of subject/thumbprint	Date & Time

_____	_____
Name of Representative/Witness	Relationship to Subject

_____	_____	_____
Name of person Obtaining Consent	Signature of person Obtaining Consent	Date

_____	_____	_____
Printed name of Investigator	Signature of Investigator	Date