TOM MBOYA UNIVERSITY

KNOWLEDGE FOR SUSTAINABLE INNOVATION ENTERPRISE

TOM MBOYA UNIVERSITY-SERC

Informed Consent Form Template

Adopted March 2026

(This template is for either clinical trials or clinical research or research involving human participants)

I. *The language used throughout the form should be at the level of a local student of class 6th/8th*

II. ***Avoid any exculpatory language:*** *Language through which a subject is made to waive or appear to waive any of his or her legal rights, or release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence. For example:*

- *I waive any possibility of compensation, including any right to sue, for injuries that I may receive because of participation in this research.*
- *If you suffer a research-related injury, neither the institution nor the investigator can assume financial responsibility or liability for the expenses of treatment for such injury.*
- *If you suffer a research-related injury, your medical expenses will be your responsibility or that of your third party payer.*

III. *Principal Investigators are advised to always refer to the ICH guidelines when developing their Informed Consent Forms*

The informed consent form consists of two parts: the information sheet and the consent certificate.

[YOUR INSTITUTIONAL LETTERHEAD]

[Name of Principle Investigator]

[Informed Consent form for _____ _____]
Name the study population for whom this informed consent form is written. For example, Adults, Children, pregnant women etc.

[Name of Principal Investigator]
[PI phone contacts and email]
[Name of Organization]
[Name of Sponsor]
[Name of Proposal and version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

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

PART I: Information Sheet

Introduction

Concisely state who you are and explain that you are inviting your prospective participant to participate in the research you are doing.
Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

Purpose of the research

Highlight whatever you are doing is research "trying to answer a question safely in order to contribute new knowledge".
Explain in a simple language why you are doing the research. Avoid use of scientific or complex terms

Type of Research (Observation or Intervention)

Briefly state the type of research intervention that will be undertaken. For example, this study involves Interviews, obtaining blood, testing of a new medication etc.

Participant selection

Provide reasons why the prospective participant has been chosen for this research.

Voluntary Participation

State at the beginning of the form that participation is voluntary. Specify clearly that they, the prospective participant can choose to participate or not. Specify, what the alternative - in terms of the treatment/ care offered by the clinic - will be, if they decide not to participate. State, if applicable, that they will still receive all the services they usually receive or will receive whether they choose to participate or not.

In case of a clinical trial provide:
Information on the Trial Drug [Name of Drug] or investigational product [Name of product]
1) Give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.
2) Provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
3) Explain the known experience with this drug
4) Explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

Procedures and Protocol

Describe or explain all procedures in a simple and clear chronological order using simple language

1. Include Screening, selection, and randomization
2. Access to medical records, Interview, physical examination, sample collection in including blood draw and other tests / procedures (imaging, biopsy, etc.).
3. Identify any procedures that are experimental or routine
4. Indicate for how long and how many times the participant will be involved in these procedures.
5. Indicate which procedures are routine and what is expected of them.
6. Indicate how many times and how many samples will be taken and what will be done with the samples including storage or use for this study and/or any other study.
7. If the samples are to be used only for this research, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research and will be destroyed after ____ years, when the research is completed. If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study.
8. Explain if these procedures have to be paid for or not including any additional costs the participants may experience as a result of the study
9. Explain unfamiliar procedures

Unfamiliar Procedures

This section should be included if there are procedures which are not familiar to the participant. First explain what the usual standard of care is for their condition then follow up with a simple explanation how the procedure will be performed including indications, risks, benefits, and alternatives.

Description of the Process

Provide a summary description of the whole process to the participant, what will happen on a step-by-step basis. It may be helpful to the participant if you use drawings or props to better illustrate the procedures. A small vial or container with a little water in it is one way of showing how much blood will be withdrawn.

Duration

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.

Risks and discomforts

Explain and describe any possible or anticipated risks. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it. **A risk can be thought of as being the possibility that harm may occur.** Provide enough information about the risks that the participant can make an informed decision. Mention what plans you have to prevent or mitigate these risks.

Side Effects (were appropriate)
Potential participants should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

Benefits
Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.

Reimbursements/ compensations
State clearly what you will provide the participants with because of their participation. State what reimbursements for expenses incurred because of participation in the research be provided. These may include, for example, travel costs and money for wages lost due to visits to health facilities.
These should be free of any undue influence (an offer of an excessive, unwarranted, inappropriate or improper reward or other overture to obtain compliance).

Confidentiality
Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant which would otherwise be known only to the physician but would now be available to the entire research team. Note that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized. However, highlight the steps taken to maintain confidentiality.

Sharing the Results
Where it is relevant, your plan for sharing the information with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You should also inform the participant that the research findings will be shared more broadly, for example, through meetings, media, publications and conferences.

Right to Refuse or Withdraw
This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent.

Safe withdrawal

To ensure safe withdrawal, explain the potential concerns of a participants' decision to withdraw from the research and procedures for orderly termination of participation by the subject. This should be free of any coercion (an overt threat of harm is intentionally presented by one person to another to obtain compliance).

Alternatives to Participating

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

Termination of participation

Describe any anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent

Who to Contact?

Provide the name and contact information of the principal investigator.
If you have questions at any time about this study, or you experience adverse effects as the result of participating in this study, you may contact the principal investigator on Mobile number XXXXXXXXX
State also that the proposal has been approved and by whom.

This proposal has been reviewed and approved by [AKUNH ISERC], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the ISERC or have any safety concerns regarding this study, contact [name, address, telephone number.]

PART II: Certificate of Consent

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes, No

I agree to have (define specimen) preserved for later study: Yes, No, Not sure

(A separate consent for storage of samples required)

I agree to provide contact information for follow-up: Yes, No, Not sure

Participant printed name

Participant signature / Thumb stamp _____ Date _____

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumbprint as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:
1.
2.
3.
I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year