KABARAK UNIVERSITY RESEARCH ETHICS COMMITTEE

ADULT INFORMED CONSENT FORM (TEMPLATE)

(The form is written in English language but can be translated to Kiswahili or any other appropriate language)

STUDY TITLE_____

PI_____ Affiliated Institution_____

Co-investigator(s)_____ Affiliated Institution(s)

_____

INTRODUCTION

You are invited to participate in this research study being undertaken by the above listed investigators. This form will help you gather information about the study so that you can voluntarily decide whether you want to participate or not. You are encouraged to ask any question regarding the research process as well as any benefit or risk that you may accrue by participating. After you have adequately been informed about the study, you will be requested to either agree or decline to participate. Upon agreeing to participate in the study, you will be further requested to affirm that by appending your signature/thumbprint on this form. Accepting or declining to participate in this study does not in any way waive the following rights which you're entitled to:

a) Voluntary participation in the study;
b) Withdrawing from the study at any time without the obligation of having to give an explanation and;
c) Access to services which you're entitled to

A copy of this form will be provided to you for your own records

Should I continue YES/NO _____

This study has been reviewed and approved by Kabarak University Research Ethics Committee (KUREC)

What is the Purpose of the Study?

The main reason(s) for conducting this study is to answer the following questions:

1……..

2……..

3……..

(In order to answer these research questions, you are requested to voluntarily answer question(s) and/or accept some procedures performed on you)

Who can Take Part in the Study?

Outline the inclusion and exclusion criteria

Specify the sample size

In Case You Agree to Participate in the Study, What Will Happen?

This is what is going to happen once you have agreed to participate in the study:

- *First, 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.*
  _____
  _____
  _____
- *Second, a qualified and well-trained interviewer will ask you questions in a private place where you will feel comfortable. In case there is any question you feel uncomfortable responding to, you will not be coerced to respond. The questions will be on the following areas: (list the areas below)*
  _____
  _____
  _____
  _____
- *Third, after the interview, the following procedures will be done {detailed information on any procedures to be undertaken by the investigator(s)}*
  _____
  _____
  _____
- *Last, you are requested to provide your contact details (phone number or any other reliable form of contact). This will help reach you in case new information regarding the study emerges. Other reason(s) for requesting your contact details is (are)*

_____
_____
_____

- *The contact details you will provide shall remain confidential to the lead researcher (PI).*

What Potential Risks are Associated with Participation in this Study?

Any research involving human subjects has the potential of imposing a number of risks/harms or discomfort including psychological, physical, emotional, environmental, cultural etc.
{*The risks depend upon the nature and type of study and the interventions. State and explain the risk to the participant. Explain to the participant how this risk will be mitigated*}

_____
_____
_____
_____

Privacy & Confidentiality

Privacy is the right of an individual to have some control over how his or her personal information/data is collected, used, and/or disclosed. Confidentiality is the duty to ensure information (data) is kept secret only to the extent possible/reasonable. {*Explain to the participants how privacy and confidentiality will be upheld. Explain to the participant any extra precautions, you will take to ensure safety and anonymity. How well data will be handled and after how long will the data be discarded and how the data will be discarded*}

_____
_____
_____
_____

In case you aren't comfortable answering any of the questions during the interview because of feeling embarrassed or uncomfortable, it will be within your rights to decline. Otherwise every measure has been taken to ensure that the interview is conducted in a private area with minimal to no interference so that you feel comfortable.

In case of clinical procedures: You may experience some discomfort/pain after {*State the procedure*} _____. This may even cause some {*state the effects of the procedure*}

If at all you suffer any injury, illness or complication(s) by participating in this study, kindly contact us immediately using the contact details provided at the bottom of this form. you will be attended to by the study clinician and if there is need for further assessment or treatment you will be referred accordingly

What Benefits are you Going to Accrue by Participating in the Study

{*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. Mention those that will be actual benefits not entitlements*}

{*Highlight the significance of the study*}

_____
_____
_____
_____

What Will it Cost You to Participate in the Study?

{*Will the participant incur any cost in order to participate in the study? Explain it clearly to the participant*}

_____
_____
_____

Will Any Expenditure that You Incur by Participating in the Study be Refunded? Or will you be Paid for Participating in the Study? {*Explain clearly to the participant whether or not they will be reimbursed*}

_____
_____
_____
_____

In Case I Have any Further Questions/ Concerns in Future Whom Should I Contact?

In the event that you need further clarification or questions regarding your continued participation in the study feel free to contact the PI {*Provide the contacts of the PI*}. In case of concerns regarding your rights and/or obligations as a research participant do not hesitate to contact the secretary, KUREC on {*KUREC contact*}

What Alternative Options are Available to Me?

The decision on whether to participate or not is absolutely voluntary. You will be free to withdraw from the study at any point during the study without providing any explanation.

How Will the Findings of this Study be Communicated or Shared?

{*Provide a detailed plan of how feedback of the study findings will be given*}

_____
_____
_____
_____

Statement of Consent

I have comprehensively read the consent form or/the information has been comprehensively read to me by the researcher. I have understood what the study is about and all the questions and concerns that I had have been responded to in a clear and concise. The study benefits and foreseeable risks have been explained to me. I totally understand that my decision to participate in this study is voluntary and I have the right to withdraw at any point during the study.

I freely consent to participate in this study

Signing this form does not in any way imply that I have given up the rights am entitled to as a participant

I agree to participate in this research YES_____ NO_____

I agree to provide my contact details for follow-up YES_____ NO _____

Participant's Name _____

Participant's Signature/Thumb print_____ Date _____