Consent form for cross-sectional survey participants (Adults)

Evaluation of the LINEA intervention

Name of researcher responsible for project:

Dr Joyce Wamoyi

National Institute for Medical Research, Mwanza Research Centre

Medical Street, Isamilo, P.O. Box 1462 Mwanza

Type of data collection:

- **Cross-sectional survey**

PART ONE: Participants information sheet

Introduction

We would like to invite you to take part in a research study. Joining the study is voluntary. Before you decide, you need to understand why the research is being done and what it would involve. One of our team members will go through this information sheet with you and answer any questions you may have. Ask questions if anything you read is not clear or you would like more information. Please feel free to talk to others about the study if you wish. Take time to decide whether or not to take part.

What is the purpose of the study?

National Institute for Medical Research (NIMR), Amani Girls Home (AGH) and The London School of Hygiene and Tropical Medicine (LSHTM) are conducting research to improve the health and wellbeing of adolescent girls, men and their communities in Mwanza and Geita. We will ask you questions about your thoughts on girl's and men's health and how to improve the general wellbeing of your community in Mwanza and Geita.

Why have I been asked to take part?

You have been invited because you live in one of the communities where this research study is planned to be implemented. Your community can be either one which is reached by the radio drama program called Msichana wa Kati which is aired on the local radio station, and possibly one where the LINEA curriculum sessions will be implemented with groups of peers, or a comparison community where none of these interventions have yet to be implemented. We are inviting adult men, adult women, girls and boys aged 13 years and older to take part in the study to understand views of different people in the community.

Do I have to take part?

No, your participation is voluntary and confidential. This means you are allowed to not take part in this study, but your views and experiences are very important to us. Your decision will not affect the activities you have/will engage in as part of this research, or other activities happening in your community.

What will happen if I take part?
You will be invited to take part in a survey which will be conducted at your house or any place of your choosing depending on your availability and willingness. This survey will be conducted by a person of the same gender as you. During the survey, a researcher will ask you some questions regarding the health and wellbeing of men, adolescent girls and your community at large. We will also ask general questions about your sexual and reproductive health, including HIV status and relationships. We will discuss the study together and give you a copy of this information sheet. If you agree to take part, we will then ask you to sign a consent form.

What will I have to do?
Taking part in this research involves participating in the community-based survey where you will share views and opinions in response to questions asked by the researcher. You will need to answer the questions the researcher asks to the best of your ability. Your views may not necessarily concur with others. We are interested in your personal views and therefore there are no right or wrong answers, all answers are correct, and you can share your opinions freely. This survey will take about 60 minutes. You will also be offered a stipend of 5,000/Tanzanian shillings to thank you for your time.

What are the possible risks and disadvantages?
We don't foresee this study having any major risks for you, your family or community. It is possible that some of the questions the researcher asks might make you feel uncomfortable, or make you remember difficult things about your past, in which case please share this with the researcher and they will be able to support you.

What are the possible benefits?
We cannot promise the study will help you individually. However, the information we get from the study will help us improve the health and wellbeing of men, girls and other people in your community, and other communities across Tanzania.

What if something goes wrong?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to make a formal complaint you can contact the Tanzanian National Health Research Ethics Committee (NatHREC) at ethics@nimr.or.tz or +255 22 2121400.

Physical Address:
NIMR Headquarters
2448 Barack Obama Drive
Ground Floor, NatHREC office

Post Address:
Chairperson, NatHREC
National Institute for Medical Research
P.O. Box 9653
Dar es Salaam, Tanzania

NIMR and Amani Girls Home will work together to refer you to any help you might need from what you may share during this interview. This can be legal, protection or counseling assistance.

Can I change my mind about taking part?
Yes. You can withdraw from the study at any time. You just need to tell one of the researchers that you don't want to be in the study anymore and this will not affect you in any way. We may still use the data collected up until your withdrawal unless you ask us to delete it.

What will happen to information collected about me?
All information collected about you will be kept private. Only the study staff from NIMR and the authorities who checks that the study is being carried out properly will be allowed to look at information about you. Data will also be sent to study staff at the London School of Hygiene and Tropical Medicine, but this will be anonymised. This means that any information about you will have your name and address removed so that you cannot be recognised.

Your personal details will be kept in a different safe place to the other study information and will be destroyed within 10 years of the end of the study. The data may be made available to other researchers worldwide for research and to improve knowledge and the health and wellbeing of men, girls and their communities. Your personal information will not be included and there is no way that you can be identified.

What will happen to the results of this study?
The study results will be published in journals and shared at conferences so that other researchers, implementers and policy makers can learn from them. Your personal information will not be included in the study report and there is no way that you can be identified from it. We may describe your responses along with others who take part, but only without your name or personal information attached to them.

Who is organising this study?
The National Institute for Medical Research is the sponsor for the research and they have full responsibility for the project including the collection, storage and analysis of your data.

Who has checked this study?
All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by The London School of Hygiene and Tropical Medicine Research Ethics Committee. The Ethics Committee at the National Institute of Medical Research (NIMR) in Tanzania has also reviewed the study and has agreed that it is safe for us to ask people to take part.

Further information and contact details

Thank you for taking time to read this information leaflet. If you think you will take part in the study I will review the comprehension list of questions with you and later you will sign the consent form.

If you would like any further information, please talk to the NIMR staff member who is showing you the information sheet, who can answer any questions you may have about the study. You can also contact the supervisor of the study.

Study Principal Investigator: Dr Joyce Wamoyi
Address: P.O. Box 1462, Mwanza
Phone number: [redacted]

PART TWO: Comprehension assessment

The researcher obtaining informed consent from an adult participant or an adolescent should also complete this short questionnaire.

Ask the participant(s) the following questions to check they understand everything on the information sheet. If there are any questions that the participant cannot answer, return to the information sheet to help explain it to the participant.

Can you tell me in your own words what this research is about?

[Interviewer: ensure participant understands that this research is about men and girl's health and wellbeing. If they do not understand this, please clarify.]

Do you have any questions about the research?

[Interviewer: answer any questions from the participant.]

Can you tell me in your own words what you will need to do to take part?

[Interviewer: ensure participant understands that to take part in this research they will need to participate in a survey that will take about 60 minutes.]

Do you understand that it is ok to stop taking part at any time?

[Interviewer: ensure participant understands that they can stop the interview at any time.]

Can you describe in your own words the possible consequences (negative and positive) of taking part in the research?

[Interviewer: ensure the participant understands that there are likely no negative consequences of taking part in this research. While we cannot promise an individual gain, their participation will also likely benefit their community. In the unlikely event that they do experience any negative consequences, they will be referred to someone who can help.]

Can you tell me what will happen to the data collected about you if you choose to take part in this study?

[Interviewer: ensure the participant understands that all information collected about them will be kept private and confidential. Information about what they have said in the survey may be used in publications, but their name and any information linking their answers back to them will be excluded. Their information will be destroyed within 10 years.]

Do you know who to contact if you have any questions or concerns?

[Interviewer: ensure participant understands that they can contact the study supervisor Dr Joyce Wamoyi if they have any questions or concerns. Her contact information is on the information sheet provided to them.]

Are you happy to take part in the research study?

[Interviewer: ensure participant is happy to take part in the research study before proceeding.]

PART THREE: Consent form

Statement	Participant: please initial or thumbprint* each box
I have had the information explained to me by study personnel in a language that I understand. I have had the opportunity to consider the information, ask questions and the questions have been answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my access to services or legal rights being affected.	
I understand that data collected during the study may be looked at by authorised individuals from the National Institute for Medical Research and the London School of Hygiene and Tropical Medicine. I give permission for these individuals to have access to information I will provide.	
I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers.	
I agree that my answers without my name attached can be used for future studies.	
I agree to take part in this study	
I confirm I have not participated in another LINEA survey recently called the cohort study* **Only applicable to men. Your data collector will explain further.*	

Printed full name of participant	Signature of participant	Date

Thumb print of participant*

Printed full name of impartial witness*	Signature of impartial witness*	Date

I attest that I have explained the study information accurately in Kiswahili and was understood to the best of my knowledge by the participant, and that he/she has freely given their consent to participate* in the presence of the above-named impartial witness who is literate; able to read and understand Kiswahili (where applicable).

Printed name of person obtaining consent	Signature of person obtaining consent	Date

[*Only required if the participant is unable to read or write]