Malawi-Liverpool-Wellcome Trust

Clinical Research Programme

P.O Box 30096, Chichiri, Blantyre 3, Malawi.

Tel. +265 1 876444 Fax +265 1 875774

Participant Information Leaflet and Informed Consent Form

PARTICIPANT INFORMATION LEAFLET

STUDY TITLE: ……KUTETEZA PROJECT……

STUDY SITE: CHIKWAWA, BLANTYRE AND MANGOCHI

PRINCIPAL INVESTIGATOR: ……DR DONNIE MATEGULA…….

INTRODUCTION

You are invited to take part in a research project to evaluate the COVID-19 shielding of the elderly initiative that has been going on in your village (‘Kuteteza’). Whether or not you take part is your choice.

The study is funded and conducted by Malawi Liverpool Wellcome Trust and conducted by Malawi Liverpool Wellcome Trust in collaboration with Malawi College of Medicine, Society of Medical Doctors and Government of Malawi. The evaluation will run for approximately three months.

The Kuteteza initiative is currently in the implementation phase. When this phase is fully rolled out, we will commence the evaluation. The study has been approved by The Malawi College of Medicine Research Ethics Committee (COMREC).

This Participant Information Leaflet will help you decide if you’d like to take part. It sets out why we are doing the evaluation, what your participation would involve, what the benefits and risks to you might be, and what will happen after the study ends. We will go through this information with you and answer any questions you may have.

You do not have to decide today whether or not you will participate in this evaluation. Before you decide you may want to talk about it with other people, such as family, friends, or

Approved by College of Medicine
07-Jul-2021
(COMREC)
Research and Ethics Committee

healthcare providers. Feel free to do this. If you or family members and friends need further information, please do not hesitate to contact us.

If you agree to take part in the evaluation, you will be asked to sign the Informed Consent Form on the last page of this document. You will be given a copy of both the Participant Information Leaflet and the Informed Consent Form.

Please make sure you have read and understood all pages of this document.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of the Kuteteza initiative, is to help protect elderly people from the effects of COVID-19 disease. It is important that we can find out how this initiative is going, including learning about people's thoughts on COVID-19 and about how the Kuteteza intervention is working. This will help those involved with the project to make any improvements needed so that it can work better and be more effective and acceptable in the future. It is for this reason that we are doing the evaluation. The researchers have made sure that the initiative and its evaluation meet the best standards available.

The evaluation involves 9 focus groups involving different members of village communities and staff in areas where the Kuteteza initiative has taken place.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been chosen to participate in this evaluation because you have some involvement in a village where 'Kuteteza' is going on, either as a person being shielded, as a carer to a shielded person, or a member of staff involved in the project. We are interested to hear more about your experiences and perceptions around COVID-19 and the Kuteteza initiative. By participating in this evaluation, you will be involved in one recorded focus group discussion with a researcher and others like yourself (either members of the community or staff).

Questions will be asked to the group and you will have the chance to answer and share your thoughts in a discussion. The subjects of discussion will be explained to you before you consent to be involved but will generally relate to COVID-19 and the Kuteteza initiative so far.

Approved by
College of Medicine
07-Jul-2021
(COMREC)
Research and Ethics Committee

Malawi-Liverpool-Wellcome Trust

Clinical Research Programme

P.O Box 30096, Chichiri, Blantyre 3, Malawi.

Tel: +265 1 874 444 Fax: +265 1 875 774

This will allow us to understand more about how the Kuteteza initiative went in your area and how people felt about it.

The focus group discussion will take up to one hour and will represent the entirety of your involvement in the evaluation. There will be no follow-up and nothing else will be asked of you after the focus group discussion. The focus group discussion will be audio-recorded for the researchers to refer to later. Notes may also be made on paper. The recordings and

notes will be held confidentially and will not be accessible to anyone outside the research group. The findings will be written up and used as part of a research project.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

You might find it interesting or rewarding to be involved in the study. Information from the focus groups will help to guide the next steps for the Kuteteza project.

There are no big risks involved in this project. You will not be expected to provide any health information and the discussion is very unlikely to involve sensitive issues. If you feel uncomfortable or distressed at all during the focus group discussion, please let a researcher know. The discussion can be stopped at any point or you can leave without any advance consequences.

WHO PAYS FOR THE COSTS OF PARTICIPATING IN THIS STUDY?

The study team must not ask you for any favours (financial, physical or sexual) in return for participating in this study.
You will be reimbursed 6000 Kwacha as compensation for taking part in this study.
This will be given to you at the start of the focus group session.

WHAT IF SOMETHING GOES WRONG?

Your participation in the study involves taking part in a focus group discussion. While none of the topics discussed are particularly contentions or controversial, some of the issues discussed might make you feel uneasy or uncomfortable, and in that case you are free not to

Approved by
College of Medicine
07-Jul-2021
(COMREC)
Research and Ethics Committee

Malawi-Liverpool-Wellcome Trust

Clinical Research Programme

P.O Box 30096, Chichiri, Blantyre 3, Malawi.

Tel: +265 1 874411, Fax: +265 1 875772

take part on that particular point of the discussion. You will have the right to exit the discussion at any point. None of the discussion If you have any concerns, you may contact the study PI or COMREC using the contact details provided below.

WHAT ARE MY RIGHTS?

Your participation in this study is voluntary, you are free to decline to participate, or to withdraw from the study at any time, without experiencing any disadvantages.

You have the right to access information about yourself collected as part of the study and be informed about any new information that becomes available during the study. Your privacy and confidentiality will be safeguarded during your participation period in this study. Your study data are accessible to the study team in addition the Ethics Committee in charge, Malawian Regulators and study monitors may access the data.

SAFEGUARDING

The MLW study team and data collectors are expected to behave ethically and responsibly at all times and follow the MLW staff code of conduct. This means that they must not ask you for any financial, physical or sexual favours in return for taking part in this research. If you experience any abuse, harassment or neglect by a study team member you can contact the MLW Safeguarding Team by calling 0881 537 472. You may call this number at any time. Alternatively, you may seek direct support from the One Stop Centre at Queen Elizabeth Hospital (onestopcentre.bt@gmail.com).

WHAT HAPPENS AFTER THE STUDY?

Study findings will be made available to the public upon authorisation of all relevant stakeholders. Study data directly linked to your person will be stored for a maximum of 5 years after study ends. Data which are not linked to your person may be retained for further analysis specifically related to this study.

Approved by
College of Medicine
07-Jul-2021
(COMREC)
Research and Ethics Committee

Malawi-Liverpool-Wellcome Trust

Clinical Research Programme

P.O Box 30096, Chichiri, Blantyre 3, Malawi.

Tel. +265 1 876444 Fax +265 1 875774

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Name Dr Donnie Mategula
Position Study PI
Telephone number 0993025277
Email dmategula@mlw.mw

Alternatively, you may contact the chairperson of the College of Medicine Research Ethics Committee which oversees the research, by telephone on 0888118993, by email at comrec@medcol.mw or by postal address at COMREC Secretariat, College of Medicine, P/bag 360, Blantyre 3.

This study has been reviewed and approved by the College of Medicine Research and Ethics Committee (COMREC) in Blantyre. This is a committee that ensures research participants are protected from harm.

Approved by
College of Medicine
07-Jul-2021
(COMREC)
Research and Ethics Committee

Malawi-Liverpool-Wellcome Trust

Clinical Research Programme

P.O Box 30096, Chichiri, Blantyre 3, Malawi.

Tel. +265 1 876444 Fax +265 1 875774

PARTICIPANT CONSENT FORM

Participant Name _____ Participant ID____ _____

[Participant name and ID are completed after participant has signed the consent form]

'Kuteteza' COVID-19 shielding project evaluation

Please answer the following questions by putting your initials or your thumbprint to the response that applies

Mandatory

1. I have read/I have been read the Participant Information Leaflet for this evaluation study and have had details of the study explained to me. ☐

2. My questions about the evaluation study have been answered to my satisfaction and I understand that I may ask further questions at any point. ☐

3. I understand that I am free to withdraw from the evaluation at any time without giving a reason for my withdrawal without any consequences to access standard medical care ☐

4. I agree to provide information to the researchers under the conditions of confidentiality set out in the Participant Information Leaflet. ☐

5. I agree to participate in the study under the conditions set out in the Participant Information Leaflet. ☐

Approved by
College of Medicine
07-Jul-2021
(COMREC)
Research and Ethics Committee

Malawi-Liverpool-Wellcome Trust

Clinical Research Programme

P.O Box 30096, Chichiri, Blantyre 3, Malawi.

Tel. +265 1 876444 Fax +265 1 875774

Optional

6. I agree to share my anonymised data with researchers around the world (open data access) for a long time and for any purpose, and to have the information they learn put in scientific publications. ☐

Approved by
College of Medicine
07-Jul-2021
(COMREC)
Research and Ethics Committee

Malawi-Liverpool-Wellcome Trust

Clinical Research Programme

P.O Box 30096, Chichiri, Blantyre 3, Malawi.

Tel. +265 1 876444 Fax +265 1 875774

PARTICIPANT CONSENT FORM

Participant Name _____ Participant ID _____

[Participant name and ID are completed after participant has signed the consent form]

'Kuteteza' COVID-19 shielding project evaluation

Name of participant*	Date*	Signature/Thumb print for illiterate participants
Name of Impartial witness (for illiterate participants)***	Date	Signature
Name of study team member administering consent	Date	Signature

* These sections remain blank if study participant is illiterate

******* Relationship of impartial witness and study participant: _____

Approved by
College of Medicine
07-Jul-2021
(COMREC)
Research and Ethics Committee