Malawi-Liverpool-Wellcome Trust
Clinical Research Programme

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

Tel. +265 1 876444 Fax +265 1 875774

Appendix 2 NC07: Participant Information Leaflet, Informed Consent Form for Healthcare Workers

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PARTICIPANT INFORMATION LEAFLET

STUDY TITLE: Evaluating the acceptability and feasibility of COVID-19 testing and linkage including self-testing: linked prospective studies in Malawi

STUDY SITE: Blantyre

PRINCIPAL INVESTIGATOR: Dr Augustine Talumba Choko

Participant ID:

INTRODUCTION

You are being asked to participate in a research study. This study is on enhancing access to COVID-19 test, isolate, care and treat interventions within healthcare systems in Malawi. Whether or not you take part is your choice. The study is funded by Unitaid and conducted by Malawi Liverpool Wellcome Trust in collaboration with Population Services International.

The study has been approved by College of Medicine Research Ethics Committee in Blantyre, Malawi and internationally from the World Health Organization Ethics Review Committee in Geneva, Switzerland, and London School of Hygiene and Tropical Medicine Research Ethics Committee in London, United Kingdom.

This Participant Information Leaflet will help you decide if you'd like to take part. It sets out why we are doing the study, 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 study. Before you decide you may want to talk about the study with other people, such as family, friends, or 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 this study, 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 study is, to monitor trends in COVID-19 incidence among health care workers in Blantyre to facilitate early detection and enable effective infection prevention and control, including linkage to appropriate COVID-19 care. The researchers have made sure that the study meets the best intervention available and has met all the equipoise standards. The study is a prospective Cohort design of at least 1200 healthcare workers.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been chosen to participate in this study because you meet the requirements of being a healthcare worker in Blantyre urban or rural. You will either be allocated to the Standard of Care (SOC) arm or the programmatic COVID-19 interventions (PCI) arm.

- If you are in the SOC arm, you will answer some questions at baseline and be followed up every months for three month.
- If you are in the PCI arm, you will give us information about yourself for us to obtain baseline data.
    - You will then collect self-test kits to use at your convenient time, day and place. You will receive at least two COVID-19 self-test kits per week for three months from a Population Services International (PSI) member of staff. This will help to shade light on incidence of COVID-19 and early detection of outbreaks among health care workers.
- You will be interviewed every four weeks to find out if you suffered from any COVID-19 related symptoms or tested positive for COVID 19.
- If you test positive for COVID 19 at any time, we will request you to give us a list of people aged 18 years and above you were in close contact with in the last 48 hours and give you test kits so that they also may self-test at home.
    - After 7 - 14 days, a study team member will contact you through your phone to find out how the self-testing for your contacts went on.
    - You will also receive quality facemasks for yourself and members of your household to prevent spread of the virus.
- At the end of 12 weeks, we will interview you about your experience during an “exit interview”.
- Those in PCI arm may be randomly selected, to be asked some additional questions about your experiences of the testing after 12 weeks, which means that the exit interview could take up to two hours. You can refuse to take part in the additional questions, without it affecting your overall study participation. During the discussion we will write down the information that you give us. We will also record the conversation using a digital recorder so that we do not miss anything that you say. Your voice record will not have your name on.

The study involves questions which may be sensitive, but the study staff will make sure that privacy and confidentiality are provided.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

- Potential direct benefits to you for participation in the study include easy access to COVID 19 testing, early detection COVID, and prevention of spread to high risk individuals you closely associate with.
- During participation in this study you may experience discomfort in your nose as the nasal swab is inserted. It is expected that this discomfort will go away soon after sample collection. If correct sampling technique is followed, the risk of complications from the procedure is low. Though rare, expected complications may be nasal bleeding or broken swab if excess pressure was applied. If you experience any of these problems, please report to study staff and you will be referred for appropriate treatment.
- You may also obtain a positive COVID-19 from your self-test, which may worry you. The researcher will discuss the meaning of the results with you and refer you to the national COVID-19 program where you will get help.
- On a more unlikely note, although we will conduct the study activities in private, it is possible that some people may know of your study participation and assume that you have COVID-19. This may affect your social or business relationships.

WHO PAYS FOR THE COSTS OF PARTICIPATING IN THIS STUDY?

You will not receive payment for participating in the study. However, since participating in this study will take you away from your home and work, we will offer you MWK3000 as a token of our appreciation for your having taken the time to take part in this study.

The study team must not ask you for any favours (financial, physical or sexual) in return for participating in this study.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, which is unlikely, you would be eligible for compensation through the no-fault study participant insurance. Please contact your study team for assistance in filing a claim.

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. When we write reports about this research or present it at conferences, any information we tell others about the interviews will not identify what any individual person said.

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.

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. Augustine Choko,
Position: Principal investigator
Telephone number: +265(0) 999 577 452
Email: achoko@mlw.mw

Alternatively, you may contact the chairperson of the College of Medicine Research Ethics Committee which oversees the research, by telephone on 0888 118 993, 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 in Blantyre. This is a committee that ensures research participants are protected from harm.

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PARTICIPANT CONSENT FORM

Participant Name _____ Participant ID____

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

Evaluating the acceptability and feasibility of COVID-19 testing and linkage including self-testing: linked prospective studies in Malawi

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 study and have had details of the study explained to me.	
2.	My questions about the 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 study at any time without giving a reason for my withdrawal without any consequences to accessing 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.	
6.	I feel well enough to comfortably do the activities set out in the Participant Information Leaflet.	

Optional

7.	I agree to research staff following me at home during the study period as part of study activities	
8.	I consent to be re-contacted by the research team for re-consenting to participate in additional research questions not mentioned in the Participant Information Leaflet but related to this research project	

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Name of participant	Date	Signature/Thumb print for illiterate participants
Name of guardian (for minors or incapacitated participants) **	Date	Signature /Thumb print for illiterate guardian
Name of Impartial witness (for illiterate participants and/or guardians)***	Date	Signature
Name of study team member administering consent	Date	Signature

** Relationship of guardian and study participant: _____

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