Appendix 1: Participant information sheet (English)

*LOSCM Study: Long-term Outcomes of Severe Childhood Malnutrition*

**PARTICIPANT INFORMATION LEAFLET**

STUDY TITLE: LOSCM Study

STUDY SITE: Queen Elizabeth Central Hospital

PRINCIPAL INVESTIGATOR: Dr Amir Kirolos

**INTRODUCTION**

We would like to invite you to take part in the LOSCM Study. Before deciding whether you want to take part, it is important for you to understand why the research is being done and what will happen if you agree to take part.

The study is funded by the Wellcome Trust and conducted by Malawi Liverpool Wellcome Trust (MLW) in collaboration with the University of Liverpool.

The study has been approved by the College of Medicine, Research Ethics Committee and the University of Liverpool ethics committee.

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 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?

Malnutrition is a problem for many children in Malawi and other countries. Severe malnutrition in children can be very dangerous and thankfully treatment has improved in recent years so that many more children catch-up with growth and recover. However, even those who are treated for severe malnutrition can experience ongoing problems with their health which can last into adult life. These may include poor growth, development, and health. In this research we want to understand what the long-term effects of malnutrition are. We will do this by comparing teenagers and young adults who have been malnourished in childhood with those who have not (siblings and neighbors). We hope that the results of this research will help us and others improve the treatment of malnutrition in future. Your contribution to the research is therefore very valuable.

What will my participation in the study involve?

We will ask you to come to Queen Elizabeth Central Hospital, Malawi and will arrange a visit on a suitable day. The visit will take about 4-5 hours – food and transport expenses will be provided.

We would like to ask you some questions about yourself, your health and wellbeing, your house and about your family. We would also like to take some weight, height and body measurements. We would like to measure blood pressure and do a fitness test. We would also like to take a blood and a hair sample. These samples will be used to look for risk factors for chronic disease by analysis in a laboratory. We may ask for some participants to attend having not eaten anything in the morning, where we will take more than one blood sample which will also look for evidence of risk factors for chronic disease such as diabetes. We will also ask you to do some exercise and physical tasks. Finally, we would like to do some interactive tests on a computer which will involve some memory and problem solving skills and tests which will look at how your response to simple images on a screen. We will also ask if we can store data collected in this study anonymously which will allow other researchers to use our results for additional research.

We are doing all this to help us understand the health effects of childhood malnutrition later in life.

We will let you know if we find any health problems and will advise you on what you can do / where you can go for treatment.

What are the possible benefits and risks of this study?

There are no direct benefits to you for participating in this study, however, your participation will contribute valuable scientific knowledge. If we identify any urgent health problems we can refer you to appropriate health services for medical care.

We aim that by your participation in this study will help improve the future management of children with malnutrition.

The risks of participating in this study are low. There is a small risk of infection at the site of blood sampling and of minor bleeding however we will reduce this risk using careful cleaning technique. Blood sampling may cause some mild discomfort to you, but this is mild and does not last long. The amount of blood that will be taken from you is small and will not cause any adverse effects.

**COVID-19 specific risks**

Our staff have been trained in the appropriate use of personal protective equipment, social distancing and hand washing to keep themselves and yourself safe during assessments. If you have any questions or concerns regarding these practices, please address them to the study team lead using the contact number below.

Who pays for the costs of participating in this study?

The study team must not ask you for any favours in return for participating in this study.

Those participating in the study will receive 7,000 Malawian Kwacha compensation in accordance with local guidance. Those who agree to have extra blood sampling done as part of one of our tests or have to travel greater distances may receive more up to 7,900 Malawian Kwacha.

What are my rights?

All information collected during the study will be kept strictly confidential. Your study data are accessible to the study team in addition the Ethics Committee in charge, Malawian Regulators and study monitors. You have the right to access information about yourself collected as part of the study. We will also ask if we can store data collected in this study anonymously which will allow other researchers to use our results for additional research.

You can stop taking part in the study at any time. You do not need to explain why. We will ask your permission to use any information or results we have obtained up until the point you stop taking part. If you do not give us permission to do this, we will remove all files and data relating to you. Deciding to stop taking part in the study will not affect your healthcare in anyway.

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 0881537472. 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?

The results of the study will be published in medical journals freely available to everyone and presented at medical conferences in Malawi and other countries. We will also share the results with the media in Malawi through the MLW communications team.

All specimens collected during the research will be kept for 5 years after its conclusion. Hair and blood samples will be sent abroad for testing in India and the UK to carry out tests in specialist labs.

Who do I contact for more information or if I have concerns?

Feel free to ask any of our study team any questions at any time.

You can also call our study team:

*Name: Dr Takondwa Chimowa*

*Position: Doctor, Paediatric Department, Queen Elizabeth Central Hospital*

*Telephone number:* +265 1 876 213

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.