Malawi-Liverpool-Wellcome Trust
Clinical Research Programme

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

Tel. +265 1 876444 Fax +265 1 875774

# PARENT/GUARDIAN INFORMATION LEAFLET CHILDREN 1 - 5 YEARS – COMMUNITY

STUDY TITLE: **TIMASAMALA** (**T**uberculosis **Im**munore**a**ctivity **S**urveill**a**nce in **Mala**wi)

STUDY SITE: **Community**

PRINCIPAL INVESTIGATOR: Dr Hannah Rickman

## INTRODUCTION

Your child is invited to take part in a research study on tuberculosis infection in young children. It is completely up to you whether you wish your child to participate in the study, and if you do not wish to take part it will not affect their care in any way. We will go through this information with you and answer any questions you may have.

The study is funded by The Wellcome Trust and conducted by Malawi Liverpool Wellcome Programme in collaboration with the London School of Hygiene & Tropical Medicine and Blantyre District Health Office. The study will run for 2 years. 4,500 participants are expected to be enrolled into this study. The study has been approved by the Kamuzu University of Health Sciences College of Medicine Research Ethics Committee, and by the London School of Hygiene and Tropical Medicine Research Ethics Committee.

This Participant Information Leaflet will help you decide if you'd like your child to take part. It sets out why we are doing the study, what their participation would involve, what the benefits and risks to them might be, and what will happen after the study ends.

You do not have to decide today whether your child 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 for your child 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.

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## WHAT IS THE PURPOSE OF THE STUDY?

Tuberculosis (TB) is a big health problem in Malawi. We want to see whether testing children in healthcare centres and in their homes can identify children who have been exposed to TB, and find areas of Blantyre where the risk is high and communities might benefit from more screening and support.

## WHAT WILL MY CHILD'S PARTICIPATION IN THE STUDY INVOLVE?

We are asking you for consent for your child to participate because they are aged 1-5 years old and live in an area we are surveying in Blantyre. If you agree for them to take part, we will do a blood test called an "IGRA test" which looks to see whether a child has been in contact with TB during their lifetime.

| | |
|---|---|
| 1. A nurse will ask you some questions about the child's health and household. |    |
| 2. A nurse will take a 5mL (about one teaspoon) blood sample from the child. This will be tested for TB infection. In future the remainder of the sample may be tested for signs of immune responses to TB and other infections. |    |
| 3. If the test is negative we will send you an SMS within two weeks, OR you can phone 0992090160 OR attend Bangwe / Limbe / Ndirande clinic to collect the result after two weeks.<br>If the test is positive we will contact you and may visit the child, to arrange for them to have further assessment and treatment. |   |

**What blood test will be done?**

The blood test will be tested in the TB laboratory for signs of exposure to TB. In addition, other tests may be performed on the blood which look at other infections, and markers of the immune system against tuberculosis. For these other tests, you will only be informed of the results if you ask for them, or if they reveal information which may affect the child's health. All specimens collected during the research will be kept for 5 years after its conclusion and then destroyed.

**What if the test is positive?**

It is quite common for children in countries like Malawi to have a positive result. It means they may have been in contact with someone with TB. It does not necessarily mean that the child has TB now, and it is very unlikely that they are infectious to other people. If the child has any signs of TB now, we will give you a referral slip to go to the children's TB clinic at Queen Elizabeth Central Hospital for review. Some children with a positive test will go on to develop TB in future, so even if they are well, we will refer them to your local TB clinic, where they may be given treatment to reduce the risk of developing TB. This service is free. We would also recommend that other members of the child's household are screened for TB and will give you sputum pots for this.

**Information about the child**

We will ask questions about the child's health and that of their household members, which may include some sensitive questions. All the answers will be kept strictly confidential.

**Other studies**

We may also contact you to ask about your experience of the blood test and of being in the study. In this case we would invite you to an additional interview, for which we would compensate you for our time. This will also be kept strictly confidential. You can take part in these interviews even if you do not want to take part in the main study.

## WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Potential direct benefits to the child from participation in the study are that we may detect early TB infection, which can be treated to prevent the child from becoming unwell. We may also be able to identify TB in the child's family members. Additionally, the child's participation will contribute valuable scientific knowledge which may help people in Malawi and all around the world to get better at diagnosing, monitoring and preventing TB infection.

One risk is that blood tests can also be uncomfortable for the child. We will only be taking a teaspoon of blood, and this will not cause problems for the child. Another risk is that the child may have a "false positive" result for TB exposure. This means they might be recommended treatment to prevent TB when in fact they are not at very high risk, and this can have side effects.

## 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 3000 Kwacha for your time participating in the study. If the test is positive and the child needs additional tests, we will provide money for transport. Additionally if the test is positive we will give you sputum pots for household members to take to the clinic, and if you return the pots we will give you 2500 Kwacha for your time and transport. Participants who take part in additional interviews around their experiences will be compensated an additional 5000 Kwacha for their time.

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## WHAT ARE MY RIGHTS?

Participation in this study is voluntary. You are free to decline for your child to participate, or to withdraw them from the study at any time, without experiencing any disadvantages.
You have the right to access information about the child collected as part of the study and be informed about any new information that becomes available during the study. Their privacy and confidentiality will be safeguarded during your participation period in this study. Their 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 at any time. Alternatively, you may seek direct support from the One Stop Centre at Queen Elizabeth Hospital (0999 777 292, 0887 360 740 (counselling) or 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. If you agree, anonymised data (which cannot be linked to you or you child) may be shared with researchers around the world for further research.

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

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

Frank Chikapa, Senior Fieldworker, Public Health Group
0999981674 | fchikapa@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 (COMREC) in Blantyre. This is a committee that ensures research participants are protected from harm.

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## PARENT/GUARDIAN CONSENT FORM FOR CHILDREN 1- 5 YEARS - COMMUNITY

Participant Name:_____

Participant ID: _____

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

**TIMASAMALA**

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

| **Question** | **Initials/ Thumbprint (for illiterate parent/guardian)** |
|---|---|
| I have read/I have been read the Participant Information Leaflet for this study and have had details of the study explained to me. | |
| My questions about the study have been answered to my satisfaction and I understand that I may ask further questions at any point. | |
| I understand that I am free to withdraw my child from the study at any time without giving a reason for my withdrawal without any consequences to access standard medical care | |
| I agree to provide information to the researchers under the conditions of confidentiality set out in the Participant Information Leaflet. | |
| I agree for the study team to contact me with the results. If the blood test is positive for exposure to TB and they cannot contact me, I agree for them to visit my home to make sure that I receive the results of the test | |
| I agree to research staff accessing my child's medical records for reasons related to this research study | |
| I agree for my child's anonymised data to be share with researchers around the world (open data access) indefinitely and for any purpose, and to have the information they learn put in scientific publications. | |
| I agree for my child to participate in the study under the conditions set out in<br>the Participant Information Leaflet. | |
| **Optional** | |
| 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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| | |
|---|---|
| I consent for my child's blood samples to be used for additional research questions not mentioned in the Participant Information Leaflet but related to this research question | |

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## PARENT/GUARDIAN CONSENT FORM – CHILDREN 1 – 5 YEARS

Participant Name _____ Participant ID _____

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

**TIMASAMALA**

| Name of participant | | |
|---|---|---|
| | | |
| Name of guardian | Date | Signature /Thumb print for illiterate guardian |
| | | |
| Name of Impartial witness | Date | Signature |
| | | |
| Name of study team member administering consent | Date | Signature |
| | | |

Relationship of guardian and study participant: _____

Relationship of impartial witness: _____