Participant ID: _____

PARENT/GUARDIAN INFORMATION LEAFLET (HEALTHY COMMUNITY)
Version 5.0 21/05/2025

STUDY TITLE: Nasopharyngeal resistome evolution under selective pressure and association with adverse health outcomes
STUDY SITE: Blantyre
CHIEF INVESTIGATOR: Dr Brenda Kwambana-Adams
PRINCIPAL INVESTIGATOR: Lucy O'Connor

INTRODUCTION

Your child is invited to take part in a research study on the carriage of germs and antibiotic resistance in the nose of children. It is your choice whether or not your child takes part.

The study is funded by the Wellcome Trust (a charity located in the UK) and conducted by the Malawi Liverpool Wellcome Research Programme (MLW; located in Blantyre, Malawi) in collaboration with the Kamuzu University of Health Sciences (KUHeS; also located in Blantyre, Malawi) and the Liverpool School of Tropical Medicine (LSTM; located in Liverpool, UK). LSTM is the study sponsor. The study will run for approximately 18 months. A total of 312 participants are expected to be enrolled in this study.

The study has been approved by the College of Medicine Research and Ethics Committee (COMREC; affiliated with KUHeS, and located in Blantyre, Malawi) and the LSTM Research Ethics Committee (located in Liverpool, UK).

This Participant Information Leaflet will help you to decide if you would like your child to take part in this study. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to your child 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 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.

In this study, we will be taking your consent using this Participant Information Leaflet and consent form. If you are able to read, you will be given this information to read at your own pace. However, if you are unable to read, a trained field worker will read out this information to you in the presence of a witness. Whether you are reading this information by yourself, or someone is reading this information to you, you are free to ask questions at any point.

If you decide you want your child to participate in this study, you can confirm your consent for the study by signing this form, or by using an inkpad to place a thumbprint on this form if you are unable to read and write. You will be provided with a copy of the Participant

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Information Leaflet and consent form for you to take home with you. Please keep this form safe. The information that you give in the study will be handled confidentially. Your information will be assigned a code number. Your name and/or fingerprint will not be analysed or used in any report.

Please make sure you have read, or someone has read to you and that you have understood all the pages of this Participant Information Leaflet.

WHAT IS THE PURPOSE OF THE STUDY?

Chest infections can make young children very unwell. Germs that cause chest infections can develop new ways to avoid being killed by the antibiotics used to treat them; this is called antibiotic resistance, and makes treating severe chest infections more difficult. The germs that cause chest infections live in the nose of healthy children, causing an infection when they invade the lung.

The purpose of this study is to examine how the germs found in the nose of children, and the genes that make these germs resistant to antibiotics, change after antibiotic treatment and/or hospital admission with a chest infection. The study will explore whether these changes affect how children respond to antibiotics for a chest infection.

This study will enrol 175 children in the community and 175 children in hospital aged 12-24 months. The study will look at the germs that healthy children, and children with chest infections, carry in their nose, and whether these germs are resistant to antibiotics. To do this, we will take a swab from the nose of healthy children and children with chest infections, then use a tool called metagenomic sequencing to discover which germs are present and what antibiotic resistance they carry, by decoding the genetic material found on the nose swab.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Your child has been chosen to participate in this study because they are generally well and not currently in hospital. Participation in this study will involve collecting personal data and samples from your child on one study visit only; this will take approximately 1 hour.

In this study visit we will use two thin swabs to collect samples from the back of your child's nose; these swabs will be tested for germs, including viruses and bacteria. One swab will be tested using metagenomic sequencing to identify bacterial germs and their antibiotic resistance; the other swab will be tested for the genetic material of viral germs using another technique, polymerase chain reaction. We will also collect one urine sample from your child to test for the presence of antibiotics; this will be collected either via a urine bag for children, or directly into a clean container.

We may perform additional investigations on the samples to answer the research questions. The nose swab taken from your child may be transported to the UK for further tests that are

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not available in Malawi. Therefore, the results from this study will not change the treatment your child receives if they have a chest infection. Any of your child's genetic material found in the nose swab will be discarded and not used for any investigations. Genetic material from the germs found in the nose swab from your child will be anonymised, and shared with other researchers. The purpose of these procedures is to collect data for us to answer the research questions.

We will also ask you questions about your child's health and other personal information, including any recent antibiotic treatment, hospital admissions and underlying health problems your child may have experienced. We will also collect information about your child's nutritional status. Your child's identity and responses to study questionnaires will be kept confidential. Any personal data will be stored on anonymised electronic databases behind institutional firewalls.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Your child's participation in the study will help us to understand how antibiotic treatment and hospital admission change the type of germs and antibiotic resistance found in the nose of children. We hope that this study will help us to identify if there are patterns of germs and antibiotic resistance in the nose of children that can lead to more serious chest infections that do not respond to treatment. It is important to understand that there will not be any direct or immediate benefits to your child for participating in this study; your child will receive the same standard of care in the health centre or hospital whether or not they participate in the study. However, there may be benefits in the future if this study changes how antibiotics are used to treat chest infections in children. The study could also inform development of improved systems of caring for children with pneumonia in Malawi and other places with limited resources.

During participation in this study, your child may experience slight discomfort or some irritation from the swabbing at the back of the nose. In some rare instances, usually when a child has a pre-existing condition that makes them vulnerable to bleeding, they may briefly experience light bleeding from the nose after sample collection. It is the investigator's responsibility to ensure that your child gets appropriate care during your participation in this study.

WHO PAYS FOR THE COSTS OF PARTICIPATING IN THIS STUDY?

Each participant will be reimbursed with 17,000 Kwacha for their transportation to and from the study visit and time spent on the visit. The payment will be made following each of the scheduled visits.

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WHAT IF SOMETHING GOES WRONG?

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

If your child has private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

WHAT ARE MY RIGHTS?

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

If you decide to not let your child join this study, you and your child will not be penalized in any way. You and your child will receive all the standard care normally given in Malawi. If you choose to let your child participate, you are also free to change your mind and withdraw your child from the study, or certain aspects of the study, at any time. You do not have to give a reason. There is no penalty for withdrawing from the study. Even if you withdraw your child from the study, you will still get the standard care given in Malawi.

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

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 or your child for any financial, physical, or sexual favours in return for your child taking part in this research. If you or your child experiences any abuse, harassment, or neglect by a study team member, you can contact the MLW Safeguarding Team by calling 0993474061. You may call this number 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 including COMREC, the Malawi Ministry of Health and other stakeholders. Typically, this will be within 2 years of study completion. The provisional results of the study will be shared with participants prior to study completion through community engagement

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and involvement activities. Final study results will also be shared with participants within 2 years of study completion through similar activities.

Study data directly linked to you, or your child will be stored for a maximum of 10 years after the study ends. Data which are not linked to you or your child may be retained for further analysis specifically related to this study beyond this period. All specimens collected during the research will be kept for 5 years after its conclusion.

The samples collected from your child will be stored in the freezer in our laboratories before they can be tested. We request for your permission to store these samples; retention of these samples for future studies is optional. We also request for your permission to ship some of these samples to laboratories outside the country for later testing. These countries may include the UK and possibly other countries. We will store your samples in freezers with your study number only. The samples will not have your child's name, or address. The laboratories in other countries will thus not be able to identify your child. These samples will be used for research only. If you do not wish to have your child's samples shipped to other countries or if you change your mind later, you can ask for your child's samples to be destroyed.

Contact in the future for other studies with MLW, KUHeS and LSTM is optional.

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, your child can contact:

Name: Roseline Nyirenda
Position: Project Manager
Telephone number: +265 998 45 12 98 or +265 882 44 98 70
Email: rnyirenda@mlw.mw

Alternatively, you may contact the chairperson of the College of Medicine Research and 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, Kamuzu University of Health Sciences, 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 (HEALTHY COMMUNITY)
(for Participant Information Sheet V5.0 21/05/2025)

Participant Name _____

[Participant name and Participant ID are completed after the parent/guardian has signed/fingerprinted the consent form]

NASOPHARYNGEAL RESISTOME EVOLUTION UNDER SELECTIVE PRESSURE AND ASSOCIATION WITH ADVERSE HEALTH OUTCOMES

Please answer the following questions by putting your initials or your fingerprint if illiterate to the response that applies.

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 I am free to withdraw my child from the study at any time without giving a reason for my withdrawal and without any consequences to access standard medical care. ☐
4. I agree to research staff visiting my child at home during the study period as part of study activities. ☐
5. I consent to be re-contacted by the research team for re-consenting for future use of my child's samples for other/secondary studies or to participate in additional research questions not mentioned in the Participant Information Leaflet but related to this research project. I understand that my child can still participate in this study even if I do not wish to be re-contacted or re-consented. ☐
6. I agree to share my child's anonymised data (i.e. not containing private information such as your name and address) 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. ☐
7. I agree that researchers may access my child's health passport and summarise relevant information in an anonymised format (i.e. not containing private information such as your name and address). ☐
8. I agree that samples will be collected from my child's nose and urine, and stored for 5 years after study completion for the purpose of this study. ☐

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9. I understand some of my child's samples may be tested overseas and I agree that specimens be sent overseas for this research. ☐

10. I understand that the participation of my child is voluntary. I understand that I can withdraw my child from the study at any time. ☐

11. I understand that my personal data will be processed under the lawful basis of research being undertaken in the performance of a task being carried out in the public interest and for the purposes of Archiving, Research and Statistics. ☐

Name of parent or guardian (legally acceptable representative)*	Date	Signature (or thumb print for illiterate parent/guardian)
Name of impartial witness (for illiterate parents or guardians)**	Date	Signature
Name of study team member administering consent	Date	Signature

*Relationship of parent or guardian and study participant:_____
**Relationship of impartial witness and parent or guardian:_____