KAMUZU University of Health Sciences
Department of Paediatrics and Child Health

KAMUZU UNIVERSITY
OF HEALTH SCIENCES

IMPALA

Research Participant Information and Screening Consent Form

Study Title: IMPALA Clinical Study
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Sponsor: Amsterdam Institute for Global Health and Development (AIGHD)

1. INTRODUCTION

- *You are being asked if your child can participate in a research study.* Your child is a possible participant in this study because he / she has been admitted to the Paediatric High Care / Dependency Unit. This study is being conducted at QECH and ZCH by the department of Paediatrics and Child Health of the Kamuzu University of Health Sciences (KUHeS). Six other Malawian and foreign institutes participate in the project including the Malawi University of Business and Applied Sciences ("Polytechnic"), the Training Research Unit of Excellence in Zomba, the English Imperial College London, and three Dutch organizations (AIGHD, NeLL, GOAL 3). We plan to include 1000 children in this study ranging from the age of 28 days to 5 years if they are admitted to the high dependency beds. Your child's participation in this study will only occur during the stay of your child in the high dependency beds of the hospital. During admission to these beds, we will monitor your child and collect data, a blood sample, a urine sample and a bit of mucus from the nose. These samples will be used to study if children are at risk of becoming very sick. Researchers are required to provide a consent form to inform you about the research study, to tell you that participation is voluntary, to explain risks and benefits of participation, and to allow you to make an informed decision. You should feel free to ask the researchers any questions you may have.

2. PURPOSE OF RESEARCH

- You are being asked to allow your child to participate in a research study of children who are admitted to High Dependency Beds of Queen Elizabeth Central Hospital/Zomba Central Hospital. From this study, the researchers hope to learn what 'signs' the body gives to best predict if a child is going to get very sick. These vital signs will help doctors and nurses in the future to recognize earlier that the child is getting sicker and give treatments to prevent getting very sick or even die. Examples of the 'vital signs' that we want to record are the blood pressure and how fast the heart beats. Nurses and doctors often use small machines to record these vital signs e.g. three times a day. Some of these machines can measure these signs all the time, they are called monitors, they are uncommon in Malawi but are used in many hospitals in other countries. With this study we will record the vital signs of your child using such a monitor whilst he/she is in a high dependency bed. The vital signs from the monitor combined with other health information will hopefully help us to predict severe diseases in future and save children's lives.

- Your child will always be observed and treated in the normal way, using the normal monitoring methods available as part of normal care, this study will not change that. The standard observations which are done 3-4 times a day by the hospital nurses. If you agree to have your child participate in this study, in addition to the normal care, we will also record your child's vital signs (heart and breathing rhythms, level of oxygen in blood, and blood pressure) with the new monitor we are using for the study. To collect the

vital signs we will place sensors: a sticker or clip on your child's toe or finger, three stickers placed on the chest, a sleeve around the arm or leg and we will use a thin mattress to record the movement and breathing of your child. None of the sensors are uncomfortable and most children do not even notice them. However, your child will have to stay close (1 meter) to the monitor as the sensors are attached to the monitor are 1 meter. Lastly, we will collect data from the hospital notes during and until the end of your child's stay at the hospital.

- The blood, urine and nasal mucus will be studied to see if we in the future can develop a test that can predict severe illness. Like the monitor this may help doctors and nurses in the future to early detect a problem and start an effective treatment. Such a test may prevent children from getting severely ill or even die.

3. ALTERNATIVE OPTIONS

- If you decide not to have your child take part in this research study, your child will receive the normal care.

4. WHAT WE WILL DO

- When you allow your child to participate in this study, the study nurses will place some sensors (the stickers and the clip) on your child to record your child's vital signs. These instruments are not invasive, meaning that they remain on the outside of the body and will not cause any pain to your child. This includes:
  - an equipment to measure the heart rate of your child called electrocardiogram (the three stickers on your child's chest),
  - a sticker or clip attached to the finger or toe to measure the oxygen level called 'pulse oximeter',
  - a sleeve/cuff placed around the arm or leg to measure the blood pressure, and
  - a thin mattress that will be placed under the cloth or mattress your child will lie on that will record your child's breathing and body movements.
- The monitor will be used until your child gets better and can move to a normal hospital or when your child does not require constant monitoring anymore.
- We will read and collect from the hospital file the test results and treatments your child receives.
- We will ask you questions concerning your child's health on admission and perform a short physical examination.
- We will collect a venous blood sample a nasal swab and urine on admission. The blood will be collected on admission to the high care beds using a standard technique used in hospital. The study nurse will take it with a syringe and needle from a vein in the hand/foot or arm. Urine will be collected using a plastic bag that we will place in the diaper of your child.
- If the hospital team thinks a new infection could have affected your child and decides to take blood from a vein for a blood culture we will ask the hospital team to also collect 2 ml of blood and we will take a new nasal swab. Your child will not be pricked extra for the blood sample.

5. POTENTIAL RISKS

- There are no potential risks associated with the monitoring systems based on previous experience in the Netherlands and Malawi.
- However, if your child finds the monitoring discomforting you can always stop your child's participation in the study, or decide that a certain element of the study should stop. Our nurses are always around to discuss these options.
- The blood and nasals mucus will be taken using routine care approaches and will carry the usual risks associated with these techniques.

6. POTENTIAL BENEFITS

- The potential benefits to your child taking part in this study are:
  - If an abnormality in routine vital signs is noted while your child is being observed for the study, a doctor or clinical officer will be informed and your child will be assisted accordingly.
  - If we measure the condition of your child all the time, we may also detect a problem earlier which may benefit the treatment of your child.

7. PRIVACY AND CONFIDENTIALITY

- Conversations you or your child may have with any of the medical personnel will remain confidential.
- The information we collect for this project will be stored for at least 10 years. All information about your child will remain private.
  - We store the paper records and tablets in locked filing cabinets in locked offices. Electronically stored information does not have your child's name on it and is stored in password-protected computers.
  - People who have access to this information include:
    - Researchers and Research Staff involved in the IMPALA project in Malawi (KUHeS, TRUE and MUBAS), the Netherlands (including Amsterdam Institute of Global Health and Development and partners, GOAL3, Leiden University) and the United Kingdom (Imperial College London) or third party service providers such as collaborators and commercial companies involved in the project.
    - People serving on the Data Safety and Monitoring Board
    - The Institutional Review Boards of the University of Malawi.
- The results of this study may be published or presented at professional meetings, but your child's personal information will not be included in published or presented material. This means that other people will not be able to identify your child.
- The data of your child will be de-identified as soon as possible. This means that the information will be stored without key information that could be used by others to recognize that the data belongs to your child, for example your child's name or yours and your address.
- You have the right to request us to see the information we have collected about your child, and if the information is wrong, to request to correct it. You also have the right to ask the research team to delete your child's information.

In addition to your child's participation in this study, we will ask you separately if the de-identified information can be used for future ethically approved research projects about health and disease. Access will only be granted after a board of Malawian and international scientists from this project reviews the objectives of the project and <u>all</u> agree that the scientist will comply with the agreement we made with you in this form.

8. YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW

- Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you or your child are otherwise entitled. You may stop your child's participation at any time without penalty or loss of benefits to which you are otherwise entitled.
- You have the right to say no to your child being enrolled in this study.
- Choosing not to participate or withdrawing from this study will not make any difference in the quality of any treatment your child may receive. Your child will receive the normal care for children who are admitted to the paediatric ward.
- You may change your mind at any time and withdraw.
- You may choose not to answer specific questions or to stop participating at any time.
- Upon withdrawal we will ask you if we should remove the data from our systems. Unless you approve we will delete all gathered data and destroy the samples.
- You will be told of any significant findings that develop during the course of the study that may influence your willingness to continue to participate in the research.

9. COSTS AND COMPENSATION FOR PARTICIPATING IN THE STUDY

- There are no costs to participate in this study.
- To compensate you for your time and effort we will support you and your child's transport back home after discharge from hospital by giving you a once off amount of 4000MKW.

10. CONTACT INFORMATION

- If you have concerns or questions about this study, such as scientific issues, concerns about a part of the study, or to report an injury, please contact Dr Jenala Njirammadzi (mobile phone +265 999282885) or Job Calis (mobile phone +265 998690163). You can also contact the paediatrician on duty at your hospital.

- Your child's information will be managed by the Training Research Unit of Excellence in Zomba Central Hospital. You can request to get in contact with them and with the Data Officer, please refer to Mr William Nkhono +265-993204898.

- If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the:

  - The Chairperson
    College of Medicine Research and Ethics Committee (COMREC)
    Kamuzu University of Health Sciences (KUHeS)
    3rd floor John Chimphangwi Learning Resource Centre
    Private Bag 360
    Blantyre 3
    Malawi
    Phone: 08 881 189 93
    E-mail: comrec@medcol.mw

DOCUMENTATION OF INFORMED CONSENT

- YOUR SIGNATURE OR THUMBPRINT BELOW CONFIRMS THAT YOU AGREE FOR YOUR CHILD TO PARTICIPATE IN THIS RESEARCH STUDY
  - I confirm that I have been explained the information provided in this 'Research Participant Information and Screening Consent Form'.
  - I confirm that I have had the opportunity to ask questions and all questions raised by me have been answered to my satisfaction.
  - I confirm that I have had time to consider the information given to me and discuss it with others and decide whether or not to take part in the study.
  - I understand who will have access to personal data provided, how the data will be stored and what will happen to the data at the end of the project.
  - I understand that others will not be able to identify my child from any publications or other project's outputs.
  - I have been given a copy of this Consent Form. It has been explained to me that I am free to withdraw from the study at any time without incurring any disadvantage to my child or me in the future.
  - I consent to my child's participation in the study.

Parents/guardian's Signature or Thumbprint _____

Printed Name: _____

Date: _____

Witness's Signature _____

Printed Name: _____

Date: _____

_____	_____	_____
Person Giving the Consent Explanation	**Signature**	**Date**

You will be given a copy of this form to keep.

Additional Consent on future use of the data (Tick boxes)

- ☐ **I agree that the research data, without any personal information that could identify me (not linked to me) may be shared with others and can be stored indefinitely.**
- ☐ **I give permission to store the blood, urine and nasal swab sample indefinitely. Samples will not be labeled with names, but study numbers.**
- ☐ **I give permission for the blood and nasal swab sample to be stored and used in future research (except for human genetic research)**
- ☐ **None of the additional options above apply**

Parents/guardian's Signature or Thumbprint _____

Printed Name: _____

Date: _____

Witness's Signature (if thumbprint is used): _____

Printed Name: _____

Date: _____

_____	_____	_____
Person Giving the Consent Explanation	**Signature**	**Date**

You will be given a copy of this form to keep.