INFORMED CONSENT/AUTHORIZATION FORM FOR PARTICIPATION IN RESEARCH

Validation of a Low-Cost, Point-of-Care Bilirubin Measurement to Diagnose Neonatal Jaundice and Monitor Phototherapy in Hospitals in sub-Saharan Africa

Principal investigators:

Dr. Queen Dube
College of Medicine, Blantyre, Malawi
Phone: +265 999 98 14 54
Fax Number: 0999981454 (Mobile)
Email: drdubefirst@yahoo.com

Dr. Msandeni Chiume
Kamuzu central Hospital-Paediatrics
P.O Box 30700
Lilongwe, Malawi
Phone: +265995674740
Email: msandeni@gmail.com

Co-investigators:

Dr. Rebecca Richards-Kortum
Stanley Malcolm Gillis University Professor at Rice University, Houston, TX
Phone: 713-348-3823
Fax Number: 713-348-5877
Email: rkortum@rice.edu

Dr. Maria Oden
PhD, Professor in Department of Bioengineering at Rice University, Houston, TX
Phone: 713-348-4156
Email: moden@rice.edu

1. Participant's Name _____ **Medical record number** _____

You are being asked if your child can take part in this research study at the Queen Elizabeth Central Hospital or Kamuzu Central Hospital. This consent form explains why the research study is being done and what will happen if you choose to participate. This form also describes the possible risks connected with being in this study. After reviewing this information and having your questions answered, you should know enough to be able to decide whether you want your child to participate in the study.

You are being asked to take part in this study because the clinician has asked that the concentration of bilirubin be measured in your child's blood.

2. PURPOSE OF THE STUDY

The goal of this laboratory study is to learn if a new, inexpensive test can help to measure the concentration of bilirubin in the blood.

3. DESCRIPTION OF RESEARCH

Study procedures
Your child is eligible for this study because your clinician would like to have a blood sample taken for measuring bilirubin concentration to diagnose jaundice. If you agree for your child to take part in this study, a fingerprick or heelstick will be performed to obtain approximately 2 drops of blood. One drop of blood will be tested with an existing method, and the other drop will be tested with the new method. They will also be measured using an existing device that touches the skin, but does not draw blood.

You will not be given the results of the new method, but you will receive the results obtained with the existing standard of care from the doctor.

If you do not participate in this study, the standard of care for jaundice will still be performed by the doctor, and analysis will not be performed using the research method.

When the research sample is collected, this sample will be given a code number. No identifying information such as your child's name or birth date will be directly linked to your research sample. A list linking the unique code number to your medical record and identity will be kept in a locked cabinet in the office of the lead researcher of this study. This record will allow medical information related to the sample to be updated if needed.

Length of Study
Your participation in this study is complete once the blood has been collected.

4. RISK, SIDE EFFECTS, AND DISCOMFORT TO PARTICIPANTS

There are minimal risks and discomfort associated with having a heelstick performed. The heelstick device is used in routine clinical care; the associated discomforts are minimal. Risks associated with the blood draw include pain and redness. Your child may feel slight discomfort when his or her heel is pricked, however, there are no known long-term effects.

There is a small risk of loss of confidentiality in this study. Researchers will take all precautions to ensure your personal information remains protected and confidential. As outlined above, the sample will be given a unique code and not be labeled with any identifying information.

The list that links the codes to patient identities will be kept in a locked cabinet in the office of the lead researcher of this study.

5. POTENTIAL BENEFITS

Compensation of 10USD (in local currency) will be given per visit. Your child might also benefit in other ways from this test. If they are at risk for jaundice they may benefit from participating in this study since other methods of accurate monitoring may not be readily available. Information gained in this study may help researchers learn more about creating a new, low-cost test for measuring bilirubin concentration. Future patients may benefit from this study.

6. CONSENTING TO PARTICIPATE

This is an investigational study. Up to 1000 patients will take part in this study. All patients will be enrolled at Queen Elizabeth Central Hospital or Kamuzu Central Hospital.

Your decision whether to participate or not in this study will not affect the medical care of your child. If you decide to participate, you are free to discontinue participation at any time.

You are deciding whether or not to participate. Your signature thumbprint or mark indicates that you have read the information provided above and have decided to participate. You may withdraw at any time after signing this form, should you choose to discontinue participation in this study.

If you have any questions, please ask me. If you have any additional questions later, Dr. Queen Dube (ph: 0999 98 14 54), Dr. Msandeni Chiume (ph: 0995 67 47 40), Dr. Rebecca Richards-Kortum at Rice University (713-348-3823), or Chairman, COMREC (ph: 01 871 911 ext. 334) will be happy to answer them.

Concerns may also be forwarded to COMREC at:

College of Medicine, 3rd Floor, John Chiphangwi Learning Resource Centre, Private Bag 360, Chichiri, Blantyre 3, Malawi

You will receive a copy of this form.

Name of Child or Guardian ……..

_____ _____

Signature thumbprint or mark of Guardian and Relationship to child Date

Name of witness ……..

_____ _____
Signature of Witness Date

Name of Researcher……..

_____ _____
Signature of Researcher Date