

Neuroimaging Plus Study of Children in Malaria Fever RCT

Your child was a participant in the Malaria Fever Study. We are seeking your permission to get additional information for this study by getting a picture of your child's brain and evaluating how they are thinking and behaving. This information may help us understand more about the risks and benefits of treating malaria fevers with ibuprofen and paracetamol for three days instead of just paracetamol when fevers occur. In this neuroimaging plus study, we are asking all of the malaria Fever study participant's parents if we can obtain a picture of their child's brain, take a urine and blood sample (by fingerprick) to see how their child's kidneys are working after the malaria infection, and also assess how their child is thinking and behaving. If you agree to allow your child to participate in this research study, we will schedule a time for your child to come in for the evaluation which should take less than three hours excluding travel time. There will be some evaluations by a nurse of your child's thinking and behavior, a fingerprick and urine sample will be collected and then we will have the picture of your child's brain taken at the hospital. To do this, your child will need to lie still quietly for several minutes for an MRI. If your child is not able to do this, we will discuss with you the option of giving your child a sedative that will make them sleepy and help them lie quietly.

What are the specific risks to your child if he/she participates in this research project? Your child may be annoyed at the testing that evaluates thinking and behavior. The fingerprick is quick but somewhat painful. They may also be unhappy about being expected to lie quietly for the picture which will take about 30 minutes. Our staff are very comfortable working with children and most children are not too upset about this. If your child cannot lie still for the MRI, we have a sedative we can use that is given by mouth. In some children this can cause headache, nausea, vomiting or diarrhea. Some children also react strangely to this sedative and get MORE active rather than sleepy. This effect lasts only a few hours. If too much sedation is used, problems breathing can result, so we only use a small dose of medicine. If your child has any side effects from the sedation, there will be a clinician with you to help manage the problem.

What are the possible benefits to your child if he/she participates in this research project? If we find your child has problems with thinking or behavior or an abnormality on the brain picture, we will refer them for care to the appropriate medical services near you. We can also communicate with their teachers and school to explain any problems related to thinking or behavior and how it related to the malaria infection your child had since this can sometimes help teachers understand problems and manage them better in the classroom. If your child has evidence of kidney problems after recovering from severe malaria, we will make sure you have a referral to monitor this problem and start treatment, if needed.

Your child's participation in this research study is entirely voluntary. If you do not wish for your child to participate in this study, there will be no problems for you. If you agree to your child's participation now, but later decide you do not wish for your child to be part of our study, you may withdraw the child from participation at any time. On the side of investigators, there are no foreseen circumstances under which the principal investigator may terminate a subject's participation in the study.

There are no anticipated costs to be incurred by your family as a direct result from participating in this study. If you agree for your child to be in this study, *(staff seeking consent please circle the appropriate option below)*

- In Malawi, for each study visit participants and their families will be reimbursed for the roundtrip travel costs for the child and guardian. They will also receive remuneration consisted with published guidelines which is MWK4500.
- In Lusaka, for each study visit participants and their families will be reimbursed for the roundtrip travel costs for the child and guardian. They will also receive a total of ZMW260 for their time from work, food during the testing day and their child's completion of the assessments.
- In Chipata, for each study visit we will provide round trip transportation and overnight accommodation for the child and a parent/guardian to travel to Lusaka. They will also receive ZMW1060 for their time from work, food while traveling and the child's completion of the assessments.

The information about your child from this study will be kept here in locked study offices. This information will be used by researchers on this study. In addition, this information will be made available to the Independent Study Monitors, the Research Ethics Committees at this hospital and the University of Rochester, Michigan State University, the Malawi Pharmacy Medicines & Poisons Board and the US National Institute of Health. Your privacy will be protected to the maximum extent allowable by law. Your child will be assigned a study

identifier and information sent outside of this facility will include this identifier, not your child's name. The study records will be kept for a minimum of three years following the completion of the study.

SARS-Cov-2 is the virus that causes COVID-19 or coronavirus. This infection is now common in the community. Your child was admitted with malaria but your child might also have coronavirus without other obvious signs of this infection. Children with both infections might have more long term problems than children with malaria alone so we are asking if we can test your child for covid as well? This is NOT required to be in the MRI Ancillary study. You may decline this COVID test and your child may be in the study anyway. If you agree to the COVID test and the results are not available by the time your child is ready for discharge, we can provide the results to you by phone call.

Do you consent for your child to have a covid test?

[☐ Yes, you may test my child for the coronavirus. If my child has already been tested this admission, you may include the results in the data you are collecting in this study

[☐ No, I do not wish to have my child tested for the coronavirus

If you have any questions about your child's participation as a subject in human research or need to contact someone about a research-related injury, you may contact the investigators in charge here:

<u>In Malawi</u> Dr. Gretchen Birbeck 0995-008069 Dr. Karl Seydel 0999-452989 Dr. Mac Mallewa 0995-835083 QECH, Blantyre Malaria Project PO Box 30096 Blantyre #3	<u>In Zambia</u> Dr. Gretchen Birbeck 0978-086957 Dr. Manoj Mathews 0977-625727 Dr. Suzanna Mwanza 0977-674471 UTH Neuro Research Office Private Bag RW-1X Ridgeway UTH, Lusaka
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Or, you may contact the Chair for the Research Ethics Committee (circle appropriate one)

<u>In Malawi</u> College of Medicine Research and Ethics Committee Private Bag 360, Chichiri Blantyre 3, Malawi Tele 01874377 Fax 01874740 Email: comrec@medcol.mw	<u>In Zambia</u> Chair: UNZA Research Ethics Committee Ridgeway Campus PO Box 50110 Lusaka, Zambia Tele 252641 Email: unzarec@zamtel.zm
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"I voluntarily agree for this child to participate in this study"

Name of the child _____

Name of parent/ guardian: _____ Guardian's
relationship to child _____

Parents/guardian's Signature or thumbprint: _____

Date: _____ (dd/mm/yyyy)

I affirm that I have witnessed the above explanation to the child's guardian, and that the guardian has confirmed that s/he understands and has given consent to the child's enrollment in this study.

Witness's Name: _____

Printed Signature: _____

Date: _____

Name of Nurse/Doctor Obtaining Consent _____

Signature of Nurse/Doctor _____

Date _____ (dd/MMM/yyyy) Time: _____

STUDY ID: _____

Please accept a copy of this form to keep.