



Consent To Participate In A Research Study

“Febrile Illness Surveillance in Northern Tanzania” (Version 3.0, 01 September 2011)

Consent Form Version Date: 01 December 2011

Duke IRB # Pro00016134, KCMC EC #295

Minor – Febrile Illness

INTRODUCTION

You are being asked to take part in a research study because your child has been admitted to medical services or evaluated in the outpatient department or casualty department at Kilimanjaro Christian Medical Centre (KCMC) or Mawenzi Regional Hospital (MRH) with a fever. Research studies include only people who choose to take part. Please read this consent form carefully and take your time making your decision about your child’s participation. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you allow your child to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if your child is taking part in another research study.

Dr. John A. Crump from the Duke University Health System (DUHS) in the United States, Dr. Grace Kinabo of KCMC, and Dr. Wilbroad Saganda of Mawenzi Regional Hospital (MRH) will conduct the study. The sponsor of this study, Fogarty International Center (U.S. NIH), will pay for this research.

If you agree to allow your child to take part in this study, you will be asked to sign this consent form. You will be given a signed and dated copy to keep.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to find out the common causes of fever in children who present for medical evaluation in Northern Tanzania. Illness with fever is very common in children receiving health care, therefore it is important to understand the causes so that it may be treated effectively.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

There will be at least 800 participants per year enrolled in this study.

HOW LONG WILL I BE IN THIS STUDY?

Your child’s participation may last for the duration of your child’s admission in KCMC or MRH and may include one follow-up visit at the Child Centered for Family Care Clinic at KCMC four weeks after your child’s admission into the hospital or evaluation in the outpatient department or casualty department.



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You can choose to have your child stop participating at any time without penalty or loss of any benefits to which your child is entitled. However, if you decide to have your child to stop participating in the study, we encourage you to talk to your child’s doctor first.

WHAT IS INVOLVED IN THE STUDY?

Screening

If you agree to allow your child to be in this study, you will first be asked to sign this consent form. We will determine if your child is eligible to enter the study by reviewing his/her hospital chart. We will explain the purpose of the study and its requirements. If eligible, you will be fully informed of the study and then asked to provide written consent for your child to participate. If your child is twelve years of age or older, he/she will be asked to provide written agreement (called assent) in addition to your written permission.

On Study Procedures

During the first 24 hours of your child’s hospital admission or during the child’s outpatient evaluation:

- A doctor will conduct a physical examination on your child and review your child’s medical history.
- A study worker will ask about your child’s fever. Some basic information about your child’s age, where you live and information about your child’s medical history, findings of the physical examination and laboratory results will be collected. We may also ask questions about your home, your animals, your occupation, and you and your child’s daily activities.
- Blood will be drawn for tests which are routinely offered at KCMC or MRH for children admitted with a fever but we would like to send the tests to the KCMC research laboratory (rather than the routine KCMC laboratory) as we have more specialist equipment there. The amount of blood we draw will depend on your child’s weight and age. The tests listed below may be offered through the study. Any tests performed as part of the study are free. Any other tests taken as part of routine care will be charged by KCMC or MRH at the normal rates.
- HIV-1/2 antibody test (to determine if your child has HIV infection). Prior to collecting your child’s blood, we will do HIV pre-test counseling.
- Complete blood count [(CBC) (to look at the type and amount of cells in your blood)]
- Malaria smear (to check for malaria parasites) and ward point-of-care test (a rapid bedside blood or body fluid test) for malaria parasites.
- Blood cultures and other blood tests to look for causes of infection

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As soon as they are available, the results of all the investigations above will be given to the medical team looking after your child in order to improve your child’s clinical care while in the hospital.

About 2 teaspoons of blood will be stored and may be tested in the future for signs of infection.

If an HIV test is performed, you will be notified of the results of your child’s HIV testing, and counseled as to the meaning of the results, whether they are positive or negative. If the test indicates that your child is infected with HIV, you will receive additional counseling. We are required to report all positive HIV test results to the Tanzanian Ministry of Health. The test results will be kept confidential to the extent permissible under the law. If you do not want your child to be tested for HIV, then you should not agree to participate in this study.

If the HIV test result shows that your child is infected with HIV, a CD4 lymphocyte count (to check the number of white blood cells that fight infections) may be offered. We will also refer your child to the KCMC Child Centred Family Care Clinic for further management and for antiretroviral (ART) therapy, when needed. If your child is found to have active tuberculosis (TB – a germ that infects the lungs), we will refer your child to the district TB control program.

We may also collect approximately 2 teaspoons of urine from your child. Your child’s urine may be stored for future analysis. It may also be used right away to look for causes of fever.

Your child may also have additional tests performed (such as chest x-ray, lumbar puncture or collection and analysis of stool samples) based on their symptoms. This decision will be made by the KCMC or MRH medical team caring for your child and not the study. If the KCMC or MRH team offers these tests and if they are needed, we would like to record the results. The study will not pay for these extra tests.

Your child’s blood, urine and CSF collected during the study along with information about you will be stored at the Biotechnology Research and Teaching Laboratory at KCMC and may be shipped and stored at Duke University Health System in the United States, the Center for Disease Control (CDC in the U.S.) or other reference labs. All samples will be kept and stored in a secure place. Your child’s sample will be identified by a unique code, which means his or her name will not be on the sample so no one outside of the study team will be able to identify your child.

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In order to see if certain areas where people live might cause them to be at a greater risk for diseases that cause fever, we will use some of your child’s information such as where you live and what type of disease your child was diagnosed with. This information may be sent to the University of Michigan in the United States or to the University of Glasgow in Scotland to help the researchers make a map of where people with fevers live to see if there might be common areas that put people at risk for different kinds of diseases. Your child will not be identified by name but by a coded study number.

Follow-Up Visit

You child may have one follow-up visit in the Child Centred Family Care Clinic at KCMC four weeks following his/her discharge from KCMC or MRH.

At the follow-up visit the following procedures will be performed:

- We will collect 1-2 teaspoons of your child’s blood. These blood samples will be stored for future, including not yet determined, testing to further determine the cause of your child’s fever.
- If your child’s red blood count was low, we may check his/her hemoglobin to make sure he/she has recovered.

Household visit

As part of the study, a field worker may travel to your/your child’s home to document its location and make observations about the types and numbers of animals seen around your home.

WHAT ARE THE RISKS OF THE STUDY?

Discussion of a new illness could cause feelings of discomfort, sadness, or anxiety. These are also social risks from participating in a HIV research study. Family, friends and others may think your child is HIV positive because he/she is participating in an HIV study when your child may not be HIV positive.

There are minimal physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this can not be guaranteed.

Risks of Drawing Blood

Risks associated with drawing blood from your child include minimal discomfort and/or bruising, infection, excess bleeding, clotting or fainting are also possible, although unlikely.

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Your child may need a lumbar puncture or chest x-ray as part of regular medical care. The risks of lumbar puncture include severe headache, bleeding, injury to the spine and infection. The risks of a chest x-ray include exposure to a small amount of radiation. The KCMC medical team caring for your child will provide you with more information if they feel these tests are necessary.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to allow your child to take part in this study, there may be direct medical benefit to him/her. Your child may benefit from this study because we will perform numerous blood tests to determine or confirm the cause of your child’s fever. Knowing the cause of your child’s fever will allow the doctors to select an appropriate treatment option. We hope that in the future the information learned from this study will benefit other people with your child’s condition.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Study records that identify your child will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security and authorized access. Except when required by law, your child will not be identified in study records disclosed outside of Duke University or KCMC. For records disclosed outside Duke University or KCMC, you will be assigned a unique code number. The key to the code will be kept in a locked filed in the research staff offices.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your child’s identity will not be revealed.

The study results will be retained in your child’s research record forever. Any research information in your child’s medical record will also be kept indefinitely.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW

You may choose not to allow your child to be in the study, or, if you agree to allow your child to be in the study, you may withdraw your child from the study at any time. If you withdraw your child from the study, no new data about your child will be collected for study purposes other than data needed to keep track of your child’s withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.



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Your decision not to allow your child to participate or to withdraw from the study will not involve any penalty or loss of benefits to which your child is entitled, and will not affect your child’s access to health care. If you do decide to withdraw your child, we ask that you contact Dr. Grace Kinabo at Kilimanjaro Christian Medical centre (Department of Medicine, KCMC, PO Box 3010, Moshi) in writing and let him know that you are withdrawing your child from the study. At that time we will ask your permission to continue using all information about your child that has already been collected as part of the study prior to your child’s withdrawal.

WHAT ARE THE COSTS?

There will be no additional costs to your child as a result of being in this study. However, routine medical care for your child’s condition (care you would receive whether or not you were in this study), such as a lumbar puncture or chest x-ray, will be charged to you. If antimycobacterial therapy for TB and/or anti-HIV therapy are needed, they are available free of charge to patients through national programs.

WHAT ABOUT COMPENSATION?

The study will provide transportation reimbursement depending on where your home is, as outlined below, to cover the cost of transportation for each follow-up visit:

<u>District</u>	Amount (Tshs)
Moshi urban	2,000
Moshi rural	5,000
Hai	5,000
Mwanga	7,000
Same	8,000
Arusha	14,000
Rombo	10,000
Beyond Same	12,000

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at KCMC in the event that your child is injured as a result of your child’s participation in this research study. However, there is no commitment by Duke University Health System, KCMC, Mawenzi Hospital, or your physicians to provide monetary compensation or free medical care to your child in the event of a study related injury.



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WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or research-related injury or if you have complaints, concerns or suggestions about the research, contact Dr. Kinabo at 02754377. For questions about your child’s rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact Duke University Health System Institutional Review Board (IRB) Office at +1-919-668-5111 or the KCMC Ethics Committee at 255-27-275-3909.

There may be left over specimens after all testing from the main study is completed. With your consent we will store and use these specimens for future unspecified (not yet determined) research, this includes HIV-related research, research on diseases that cause fevers, and may involve genetic research. The remaining samples will be stored at the Biotechnology Research and Teaching Laboratory at KCMC. All samples will be kept and stored in a secure place. Your sample will be identified by a unique code, which means your child’s name will not be on the sample. Later, at any time, if you change your decision to store your child’s blood, the sample will be destroyed. These samples may be stored for many years, or even for an indefinite length of time. The researchers do not plan to contact you or your child’s regular doctor with results from the studies done on stored samples. This is because these studies will most likely be performed many months to years after they are collected, and results would no longer be important for treatment. If a condition is found that may still require treatment, then we will make an effort to notify you at the last address you provided to us. It is possible that this study will identify information about your child that was previously unknown (such as disease status or risk). Such incidental findings, if any, will not be shared with you or anyone related to you unless the incidental finding regards an inherited risk for a disease known at the time of testing to be likely to cause premature death if untreated. Should such life-threatening results be uncovered through these genetic research studies or other studies performed on stored samples, and if they are directly applicable to your child, you will be notified via certified mail to contact Dr. John Crump at Duke University, Dr. Venance Maro or Dr. Grace Kinabo at Kilimanjaro Christian Medical Centre. Notification will be sent to the last address you provided to us. The KCMC-Duke staff will not release these specific research findings over the telephone or in the mail. Drs. Crump, Maro and Kinabo will arrange for you to meet with the appropriate health care provider at a medical institution near your residence to review the research information.

Initial or sign on ONE line below:

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_____ I agree to allow my specimens to be stored for future, as-yet-undesignated research that may include genetic research

OR

_____ I agree to allow my specimens to be stored for future, as-yet-undesignated research but not for genetic research

OR

_____ I do not agree to have my specimens stored for future as-yet-undesignated research. At the end of the study, after all study-required laboratory tests are performed, I am requesting that any leftover samples be destroyed.

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to my child and me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told that I may contact the KCMC Ethics Committee at 255-27-275-3909 or Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if I have questions about my rights as a research subject, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree for my child to be in this study, with the understanding that I may withdraw my child at any time. We have discussed the study with my child, who agrees to be in the study. I have been told that I will be given a signed and dated copy of this consent form."

Signature of Participant Date
(if participant between 12 and less than 18 years of age)

Signature of Parent/Legal Guardian Date

Signature of Person Obtaining Consent Date

Signature of Witness (If applicable) Date