DUKE UNIVERSITY HEALTH SYSTEM

Kilimanjaro Christian Medical Centre

TUMAINI UNIVERSITY KILIMANJARO CHRISTIAN MEDICAL COLLEGE

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

Adult – Febrile Illness

INTRODUCTION

You are being asked to take part in a research study because you have 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. 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 decide 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 you are taking part in another research study.

Dr. John A. Crump from the Duke University Health System (DUHS) in the United States, Dr. Venance P. Maro 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 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 people who present for medical evaluation in Northern Tanzania. Illness with fever is very common in people seeking 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 participation may last for 4 weeks or for as long as 6 months if tests show that you have disseminated tuberculosis (TB).

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

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WHAT IS INVOLVED IN THE STUDY?

Screening

If you agree to be in this study, you will first be asked to sign this consent form. We will determine if you are eligible to enter the study by reviewing your hospital chart.

On Study Procedures

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

- A doctor will conduct a physical examination and review your medical history
- A study worker will ask questions about your fever. Some basic information about you like your age and where you live, education level and marital status, then information about your medical history, findings of the physical examination and laboratory results will be collected. We may also ask questions about your occupation, your home, contact with animals and your daily activities.
- We will draw up to 40-50 mL (8-10 teaspoons) of blood and may perform the following tests:
  - HIV-1/2 antibody test (to determine if you have HIV, the virus that causes AIDS, in your blood). Prior to collecting your blood, you will undergo HIV pre-test counseling.
  - CD4 lymphocyte count (white blood cells that fight infections) (for HIV infected subjects only)
  - Complete blood count [(CBC) (to look at the type and amount of cells in your blood)] and malaria smear (to check for malaria parasites)
  - Blood to look for bacteria, mycobacteria or fungi
  - Blood to study the cause of your fever
  - Stored blood for future not yet determined research related to HIV and other infections that cause fever.
  - Collect approximately 10 mL (2 teaspoons) of urine. Your urine may be stored and analyzed in the future for bloodstream infections. It may also be used right away to look for causes of fever.

As part of your routine medical care (the care you would receive if you were not participating in this study), if we suspect that you have meningitis (inflammation of the three layered tissues that covers the brain and spinal cord) the KCMC or MRH medical team may perform a lumbar puncture. This is a test to evaluate the fluid (cerebrospinal fluid, or CSF) that surrounds your brain and spinal cord. A local anesthetic (numbing medicine) will be inserted underneath your skin to numb the area where the needle will be placed. The needle is then inserted into your spinal canal through your lower back in order to withdraw the CSF. Some of the leftover fluid after all routine testing is done with your permission may be stored for future not yet determined testing, to further study the cause of your fever.

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As part of your routine medical care you may have a chest radiograph, this is an x-ray that takes a picture of the organs and structures with your chest, to check for pulmonary diseases (diseases that affect the lungs).

You may also have additional evaluations performed [such as collection and analysis of stool or sputum (spit) samples] based on your clinical presentation. If your medical team does any of these tests, we may review and collect results for this study.

The results of the HIV-1/2 antibody test, CBC, malaria film and blood culture will be provided to the medical team to share with you as soon as they are available in order to improve your clinical care while in the hospital. After the first 24 hours if you remain in the hospital any additional testing done on you will be part of your routine medical care. There is no treatment provided by the study. The KCMC or MRH medical team will manage your care according to local practices.

If the HIV test result show that you are HIV positive, we will refer you to the KCMC Infectious Diseases Clinic (IDC) for further management and for anti-HIV therapy, when needed. If you are found to have active TB, we will refer you to your district tuberculosis control program for direct observed therapy (DOT). Antimycobacterial therapy for TB and anti-HIV therapy are available free of charge to patients through national programs.

Your 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 sample will be identified by a unique code, which means your name will not be on the sample so no one outside of the study team will be able to identify you.

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 information such as where you live and what type of disease you were 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. You will not be identified by name but by a coded study number.

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Follow Up Visit (4 weeks after your entry visit)
You may have a follow-up visit in the KCMC Clinic 4 weeks after your study enrollment. This will be your last visit. The following procedure will be performed:

- We will collect approximately 10 mL (2 teaspoons) of blood. These blood samples with your permission may be stored for future, including not yet determined, testing to study the cause of your fever.

Other Follow-Up Visits
If you are found to have disseminated tuberculosis (TB), you may have follow-up visits at the KCMC Clinic 4 weeks after your admission to KCMC or MRH and every month for six months. At each visit, we will do a follow-up questionnaire with you about your TB. This will take about 30 minutes. At your first follow-up visit, we may collect approximately 10 mL (2 teaspoons) of blood. These blood samples will stored for future not yet determined testing to study the cause of your fever.

Household visit
As part of the study, a field worker may travel to your 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 you are HIV positive because you are participating in an HIV study when you 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 arm include minimal discomfort and/or bruising, infection, excess bleeding, clotting or fainting are also possible, although unlikely.

You 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

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include exposure to a small amount of radiation. The KCMC medical team caring for you 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 take part in this study, there may be direct medical benefit to you. You may benefit from this study because we will perform numerous blood tests to determine or confirm the cause of your fever. Knowing the cause of your fever will allow your 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 condition.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security and authorized access. Except when required by law, you 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 identity will not be revealed.

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

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

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care. If you do decide to withdraw, we ask that you contact Dr. Venance Maro at Kilimanjaro Christian Medical centre (Department of Medicine, KCMC, PO Box 3010, Moshi) in writing and let him know that you are

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withdrawing from the study. At that time we will ask your permission to continue using all information about you that has already been collected as part of the study prior to your withdrawal.

WHAT ARE THE COSTS?
There will be no additional costs to you as a result of being in this study. However, routine medical care for your 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 study visit:

District	Amount (TSh)

District	Amount (TSH)
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 you are injured as a result of your 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 you in the event of a study related injury.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

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For questions about the study or research-related injury or if you have complaints, concerns or suggestions about the research,, contact Dr. Maro at 0754 581444. For questions about your 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.

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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 of 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 name will not be on the sample. Later, at any time, if you change your decision to store your 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 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 you 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 you, 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:

_____ 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 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 to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Obtaining Consent Date

_____ _____
Signature of Witness (If applicable) Date