



**TUMAINI UNIVERSITY MAKUMIRA
KILIMANJARO CHRISTIAN MEDICAL UNIVERSITY COLLEGE
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Brucellosis research in northern Tanzania

Hospital Patient-Participant Information Sheet

INTRODUCTION

You are being invited to take part in this research study because the examination at this health facility has shown that you have fever. Brucellosis is a disease that can cause fever and other symptoms and we are carrying out a research study on this disease. Before you decide if you want to take part in this study, it is important that you understand why the research is being done and what it will involve. Please read, or listen to, this information sheet and consent form carefully and take your time making your decision. As the study member 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 study. The nature of the study, length of time it will take, risks, and other important information about the study are listed below. If you agree to take part in this study, you will be asked to sign or add your thumbprint to this consent form. You will get a copy to keep.

WHO IS DOING THIS RESEARCH?

This research will be conducted by experts in human and animal health from Tanzania and the United Kingdom. Dr. V Maro and Prof J. A. Crump from the Kilimanjaro Christian Medical Centre and Dr Gabriel Shirima from Nelson Mandela African Institute of Science and Technology, Tanzania; and Dr Jo Halliday from University of Glasgow will lead the field research for this project, other team members will also be involved. The research is funded by the Department for International Development (DFID) and five research councils in the UK.

WHAT IS THE PURPOSE OF THIS STUDY?

In Tanzania, data collected by other studies has shown that brucellosis occurs in different types of animals (e.g. cattle, sheep and goats) and that brucellosis is an important cause of disease in people. Brucellosis can be caused by several different types of *Brucella* bacteria. Each of these types of *Brucella* has different patterns of disease in animals. Information about which *Brucella* types are present in which animals in Tanzania is not well known. To develop plans for brucellosis control that are most likely to be effective and affordable, it is important to understand which animals are infected by which *Brucella* types, and which transmission routes are most important in transmitting brucellosis from animals to people. This three-year study will help to find out which *Brucella* types are found in different animal populations and which transmission routes are important for human disease. The information collected will help develop control strategies and will help improve *Brucella* identification in Tanzania.

WHY HAVE I BEEN CHOSEN?

You have been invited to take part in this study because you have fever. Fever is one of the main signs of brucellosis. We would like to do some tests to find out if you do have brucellosis. We expect that about 360 people will take part in this study.

DO I HAVE TO TAKE PART?

It is up to you to decide whether you do or do not to take part in this study. Participation is voluntary. If you agree to take part in this study, you will be asked to sign, or add your thumbprint to this consent form. You will get a copy to keep. If you decide to take part, you are free to stop at any time and you do not need to give a reason for stopping. If you decide to stop taking part in this study your contributions to the study would be removed from any study outputs produced after the date that you stop taking part.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you decide to take part in this study you will be asked to allow a member of the project team to take blood for brucellosis testing. Up to 50cc of blood will be collected. We will use the blood sample you give us to do tests for brucellosis and some other diseases including malaria. We will also use the sample to do more tests for brucellosis and other diseases at a later date. We will give you the results from some of these tests when they are available, if they tell us about your current illness. We will not give you the results of all the tests that are done with your samples. All of these tests are free. You will also be asked to respond to some questions about you, your household and your health. It will take a few hours for us to collect samples and ask you some questions, and we will complete this either today or possibly in the next few days if there is not time to complete our questionnaire today. We will also ask you to return to a follow-up clinic in 4-6 weeks time so that we can collect another blood sample for testing. Or, with your permission, the

project team may visit you at your household to collect samples later. You can choose to stop taking part at any time without any cost.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART IN THE STUDY?

The collection of blood samples may cause some pain, bleeding or bruising where the needle enters the body. A small blood clot may form where the needle enters the body or there may be swelling in the area. In a small number of people lightheadedness and fainting can also happen when a blood sample is collected.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?

Direct benefits include free tests for brucellosis, other blood infections and malaria. The project team will also provide you with information about brucellosis. The results of the whole project will help to improve medical care and identification of diseases in Tanzania. We hope that the information collected through this study will be used to control brucellosis and reduce the impact that this disease has on human and animal health in Tanzania.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

The samples we collect will be tested at Kilimanjaro Clinical Research Institute in Moshi. After this, more tests may be done at one of our partner institutions including the Animal and Plant Health Agency of the UK and University of Glasgow. We will store leftover samples after brucellosis testing so that they can be used for studies in the future. This may include studies of other diseases that cause fever. We do not plan to contact you with the results from tests done on stored samples. This is because the studies will most likely be performed many months or years after the samples were collected and the results would no longer be important for your treatment. The results from this study may be used by local and international institutions, responsible ministries, individuals and scientists.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

All information which is collected about you, or responses that you provide, during the course of the research study will be kept strictly confidential. You will not be identified by name in the study records shared outside KCMC or the University of Glasgow. If study results are given to other researchers, you will be identified by a code number, and any information about you will have your name and address removed so that you cannot be recognised from it.

WHAT ABOUT COMPENSATION?

If we ask you to return to the hospital for a second blood sample in 4-6 weeks time, we will provide you with money to cover the cost of your transport for this visit. No other compensation will be provided for your participation in this study.

WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?

Taking part in this study is completely voluntary. You may choose not to take part in this study. Your decision will not affect your ability to take part in other studies or result in the loss of any benefits you are entitled to.

WHO HAS REVIEWED THIS STUDY?

This study has been approved by the Ethics Committees of KCMC, the Tanzanian National Institute of Medical Research (NIMR) and the University of Glasgow.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?

For questions about this study contact: Dr Gabriel Shirima at 0763 973 003 or Dr Venance Maro at 0754 581 444. For questions about this study, to discuss problems, concerns or suggestions related to the study or to ask for information about this study, contact the Kilimanjaro Christian Medical Centre Ethics Committee at 027 275 3909. You can also contact the National Health Research Ethics Committee at 022 212 1400.

THANK YOU!

On behalf of the project team we would like to thank you for agreeing to take part in this study