



## MUHIMBILI UNIVERSITY COLLEGE OF HEALTH SCIENCES

### INFORMED CONSENT FORM

#### STUDY TITLE

The Sickle cell disease (SCD) Study

#### THE RESEARCHERS

Our research team consists of researchers from Muhimbili University College of health sciences and Muhimbili National Hospital. This includes doctors, nurses, laboratory technologists etc. We also work with researchers from other universities and hospitals from all over the world including the London School of Hygiene and Tropical Medicine, UK and Kenya.

#### PURPOSE OF STUDY

Sickle cell disease (SCD) is an inherited condition that affects many people in Tanzania. As you know some people become very ill with frequent complications and risk of death while others remain relatively healthy despite the fact that both have SCD. We need to find out why this is so. If we can discover how some people do not have severe disease we may be able to use information to make a medicine that we can give to everyone or to develop ways to prevent them from developing severe complications of SCD.

The aim of the study is to describe the spectrum of clinical disease in patients with SCD attending and/or admitted to Muhimbili National Hospital (MNH). This will be the first step in trying to understand the causes of illness in SCD in Muhimbili and will focus on some areas which are relevant in determining treatment guidelines: malaria, infections, nutrition and stroke.

#### WHO WILL BE IN THE STUDY

All patients with proven or suspected SCD who attend the outpatient clinic or who are admitted to the paediatric or medical wards at MNH will be told about the study and given the option to participate in the study. We will also be asking relatives or people without SCD to participate in the study.

#### WHAT PARTICIPATION INVOLVES

For patients with SCD, we will ask you to attend the Haematology clinic every 3 months where a doctor will ask you questions regarding the symptoms of SCD that you have had that may or may not have brought you to hospital to seek medical attention. You will also

be asked questions about medical problems in the past, demographic, family history etc. This is because it is thought that SCD is thought to present with various problems in different people and levels of severity is determined by various factors. You will then be examined to determine and document any physical signs and investigations will be taken. A blood will also be collected – which is a normal practice for SCD patients attending the haematology clinics. In addition, we will also collect a urine sample at each clinic.

For patients/relatives who are not initially known to have SCD, the same procedures will be taken and you will be informed of the results of the tests. If you do not have SCD you will not need to attend the haematology clinics.

#### **WHAT WILL HAPPEN TO THE SAMPLE**

We will take a sample of blood and urine from you or your child to do the tests that should be done on all patients attending the hospital, whether or not you are participating in the study. These tests will be done in the laboratory at Muhimbili. In addition, there will be some special tests that will be done which were not previously done because of lack of resources.

There will be some tests that will also be done as part of the research to improve our understanding of SCD. Some of these tests will be done immediately in Muhimbili while others will be done in a laboratory outside Tanzania.

We will also study the genetic material that is in the blood sample, and we would like to explain to you what that genetic material is. The genetic material is what makes everyone different from birth - in our height, in our looks, and in many other ways, including why people have different complications of SCD. We are studying the genetic material from some children who are very ill with SCD, and other children who are not ill with SCD, to try to discover what part of the genetic material is responsible for this difference.

There will be some tests that take many years to develop. Therefore we are asking your permission to store samples, including genetic material, so that we can perform other tests in the future. We are also asking for permission to perform tests on samples which had been stored from your previous visits to hospital since your enrolment to the SCD study.

#### **BENEFITS OF THE STUDY**

There will be no direct benefit, financial or otherwise that you will get from this study. Your participation in the study will mean that questions about SCD, will help to provide answers about SCD. This information will therefore be of use in understanding this condition and help to develop medicines and better ways of looking after patients with SCD in order to prevent complications, in Tanzania and other places in the world.

#### **POTENTIAL RISKS OF THE STUDY**

There will be slight pain and discomfort at the site of blood collection. For the blood collection we will use equipment that is free of germs and that is made to reduce pain during pricking. There will be no new or special drug or treatment that you will receive.

If your child has any evidence that suggests increase risk of developing a complication, we will discuss the situation with you and we will offer increased frequency of follow up to try to prevent this causing any problem in the future. As new ways are developed to prevent these problems they will be discussed with you and offered to your child

### **FREEDOM TO PARTICIPATE IN THE STUDY**

We would like to stress that your participation in this study is strictly voluntary - it is your decision. Should you decide not to participate; it will not affect the treatment or management that you will receive from the hospital. In addition, at any time point during the study, decide that you do not wish to participate any further; you are free to end your participation, effective immediately. Any such decision will be respected and will not influence the quality of health care we will give you or your child.

If you miss some visits for any reason, but wish to come back into the study or attend the clinic, we will be ready to accept you back.

### **CONFIDENTIALITY**

All the information that you provide will be confidential. You will be given a code number and we will be very careful with the information that we have collected. We will make absolutely sure that when we tell people about our findings on the genetic material, no-one will be able to discover that this genetic material came from you or your child. Only the principal researcher or somebody authorized by him or her will be able to link the sample back to each participant.

**Please feel free to ask any questions about the information you have just been given or anything else to do with SCD and the care of your child.**

**There is more information in the form of leaflets, published papers that is available for you to learn more about SCD. Please feel free to take this home with you and you can contact us or ask us during your next visit for more information.**

**For the study, we will ask you to sign this paper to confirm that you have received this information and that you consent to participate in this study.**

**In case there is any further information that you require with regard to the study please ask to speak to Dr J Makani, Department of Haematology and Blood Transfusion, Muhimbili University College of Health Sciences. Tel: 0787 7680688 or any of the other investigators. If you ever have questions about your rights as a participant, you may call the chairman of the college research and Publications Committee, P. O. Box 65001. Tel: 2150302.**

**Informed consent for participants:**

I have read or I have been read the attached information regarding the SCD study in English / Swahili (please circle one), a language I speak fluently. I have also had an opportunity to discuss the study with the investigators and I am satisfied that I understand what the study involves.

I agree to participate in this study or allow my child / children (listed below) to take part in this study:

- (1) \_\_\_\_\_
- (2) \_\_\_\_\_
- (3) \_\_\_\_\_
- (4) \_\_\_\_\_
- (5) \_\_\_\_\_
- (6) \_\_\_\_\_

**Patients/ Parent / Guardian's**

**Signature or thumb print** \_\_\_\_\_ **Date** \_\_\_\_\_

**Parent / Guardian's Name:** \_\_\_\_\_

*(Please print name)*

**Witness**

**Signature (if caretaker cannot read)** \_\_\_\_\_ **Date** \_\_\_\_\_

**Witness' Name:** \_\_\_\_\_

*(Please print name)*

**I certify that the above was explained verbally to the parent/guardian, and that s/he understands the nature and the purpose of the study and consents to the participation in the study of the above patients.**

I have given them the opportunity to ask questions which have been answered satisfactorily.

**Research Officer**

**Signature** \_\_\_\_\_ **Date** \_\_\_\_\_

**Research Officer Name:** \_\_\_\_\_

*(Please print name)*