



# MBARARA UNIVERSITY OF SCIENCE AND TECHNOLOGY

## RESEARCH ETHICS COMMITTEE

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E-mail: irc@must.ac.ug, mustirb@gmail.com

### INFORMED CONSENT FORM

This document outlines the research study and expectations for potential participants. It should be written in layman terms and typed on MUST-REC letterhead.

#### Instructions

1. The wording of this document should be directed to the potential participant not MUST-REC.
2. If a technical term must be used, then define it the first time it is used and any acronyms or abbreviations used should be spelled out the first time they are used.
3. All the sections of this document must be completed without any editing or deletions.
4. Please use a typing font that is easily distinguishable from the questions of this form. Preferably the font size should be 12.

**Study title** – This should be the same as on all other documents related to the study.

Piloting testing of point-of-care diagnostics to improve diagnosis of microbial keratitis in Uganda

#### Principal Investigator(s)

Dr Simon Arunga

#### Introduction

What you should know about this study:

1. You are being asked to join a research study.
2. This consent form explains the research study and your part in the study.
3. Please read it carefully and take as much time as you need.
4. You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will be no penalty if you decide to quit the study.

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REC OFFICE USE ONLY:

APPROVAL DATE: 26/07/2023

APPROVED CONSENT IRB VERSION NUMBER: JULY 2023

PI NAME: SIMON ARUNGA

IRB NO: MUST-2022-592

### Brief background to the study

Infection of the cornea (the clear part of the eye) is an important cause of blindness, especially in low and middle-income countries.

These infections of the cornea are caused by different types of germs (microorganisms). These germs are treated by different types of medicines. Therefore, a good outcome depends on correctly identifying the cause of the infection so that appropriate treatment can be administered.

Unfortunately, most health centers in our country lack services that can be able to correctly identify the cause of this infection. This is partly because some of these equipment that are needed to identify the causative germs are very expensive.

In this study we are trying to see how effective some new tests are at identifying the cause of corneal infections by comparing them with the standard ones we are currently using. These tests can then be used in many other health facilities.

By identifying new ways of identifying these causative germs, we can be able to improve diagnosis of corneal infections in Uganda and help reduce the number of people who become blind because of these corneal infections.

### Purpose of the research project

Include a statement that the study involves research, estimated number of participants, an explanation of the purpose(s) of the research procedure and the expected duration of the subject's participation.

The purpose of this research is to determine new ways of identifying the germs causing infections on the clear part of the eye called the cornea. These will be easier and cheaper ways compared to those currently available and that can be used in all health facilities so that patients get the right treatment for the infections much earlier and hence prevent them from either becoming blind or losing the eye because of severe infection.

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This research involves examining the patient's eye on a special microscope to grade the severity of the disease to aid in the treatment.

It also involves picking some samples from the eyes of patients with infections on the cornea so that we can examine these samples in the laboratory to identify the cause of the disease.

We aim to recruit 300 people with infections in the cornea.

We expect to spend about 25 minutes examining each person who accepts to participate in this study. We will use about 5 minutes asking you a few questions; then about 10 minutes examining the eye on a special microscope, and lastly about 10 minutes picking the samples from the cornea. After you will wait for the laboratory results and for the doctor to prescribe the medicine according to the results.

### **Why you are being asked to participate?**

Explain why you have selected the individual to participate in the study.

You are being asked to take part because you have an infection on the clear part of the eye, which is called the cornea.

### **Procedures**

Provide a description of the procedures to be followed and identification of any procedures that are experimental, clinical etc. If there is need for storage of biological (body) specimens, explain why, and include a statement requesting for consent to store the specimens and state the duration of storage.

### **Baseline assessment**

- The health worker has already carefully examined your eyes and thinks you are eligible to join the study.
- If you accept to be part of this study, we will ask you a few questions. This will include basic contact information, a short history of your current eye problem, and the treatment you have been using before arriving at the hospital.
- We shall again examine the eye using a special microscope.

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- We shall then apply some eye drops in the eye to numb the eye so that there is no pain as we remove samples from the eye. After, we shall collect samples from the eye to test in the laboratory to identify what is causing the infection on your cornea.
- We shall use a special camera to take photographs of your eye so that we have a clear record of the disease. These pictures shall not capture any features of your face that may make you recognisable. As part of this form, we are seeking for your permission to take these photographs.

### Treatment

- Once the initial results of the tests for infection are available, the eye doctor will prescribe treatment according to our hospital guidelines.
- If your infection is severe, we advise that you stay in the hospital for daily review for at least two weeks. Severe diseases are associated with complications like the cornea (the clear part of the eye) developing a hole, or the infection can spread from the cornea to other parts of the eye. These need constant monitoring for immediate intervention as soon as they occur. We shall also be monitoring the eye to see if there is an improvement to see if we may need to change or add any more drugs to the ones you will be using. The duration of admission depends on the severity of the disease.

### Risks or discomforts

Describe any reasonably foreseeable risks or discomforts-physical, psychological, social, legal or other associated with the procedure, and include information about their likelihood and seriousness. Discuss the procedures for protecting against or minimizing any potential risks to the subject. Discuss the risks in relation to the anticipated benefits to the subjects and to society.

The special machine we will be using makes things bigger so that we can see the eye very well to be able to know what disease is in the eye. The machine works by shining some light in the eye. This light sometimes causes some mild discomfort in the eye of some patients. Apart from this discomfort, the light does not in any way damage the eye. This discomfort usually resolves in

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less than 1 minute after the examination on this machine. We shall however minimize the discomfort caused by the light by using the lowest light intensity we need to examine the eye.

We shall also collect samples from the eye for examination in the laboratory so that we know what germs are causing the disease in your eye. To collect these samples, we use a needle. It is a safe procedure and is routinely done for all patients with this disease. There is however a risk of developing a hole on the cornea (the clear part of the eye). To minimize this risk, only properly trained health workers collect these samples, and we do not collect samples from corneas that have a high risk of developing a hole. We also make sure that there is completely no pain in the eye before we start collecting the samples.

### **Benefits**

Describe any benefits to the subject or other benefits that may reasonably be expected from the research. If the subject is not likely to benefit personally from the experimental protocol note this in the statement of benefits.

The study will involve tests to determine the type of germs that have infected the eye. This will help the doctor treating you to choose the best type of treatment for your eyes. These tests are usually not available for patients in Uganda.

### **Incentives or rewards for participating**

It is assumed that there are no costs to subjects enrolled in research protocols. Any payments to be made to the subject, e.g., travel expenses, token of appreciation for time spent, must also be stated, including when the payment will be made.

The clinical examinations and waiting for the laboratory results sometimes may take up to an hour depending on the number of patients we have at that time. We will therefore provide you with water or a refreshment like juice or soda of your choice as you wait to either be attended to or as you wait for your laboratory results.

### **Protecting data confidentiality**

Provide a statement describing the extent, if any, to which confidentiality or records identifying the subjects will be maintained. If data is in form of tape recordings, oigraphs, movies or videotapes, researcher should describe period of time they will be retained before destruction. Showing or playing of such data must be disclosed, including instructional purposes.

The information collected about you will be kept confidential in a controlled place. All your information will be identified by a participant number and not your name.

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|                                         | NAME: SIMON ARUNGA                             |
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**Protecting subject privacy during data collection**

Describe how the privacy of the participant will be ensured during the process of data collection.

The interview and examinations will be conducted in a quiet private room free from interference. In this room, you will be the only patient being examined in the presence of your preferred attendant. You may also choose to be alone as your attendant waits outside the room.

**Right to refuse or withdraw**

Include a statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.

The study is completely voluntary, and you are completely free to decline to participate or withdraw from the study at any time. Should you decline to participate in this study, you will not be penalized in any way and will still have access to all benefits the hospital is able to offer.

**What happens if you leave the study?**

Include a statement that the subject may discontinue participation at any time without penalty or loss of benefits.

You are also free to discontinue your participation in the study at any time without any penalty; and if you do so, you will still receive all hospital services without any loss of benefits.

**Who do I ask/call if I have questions or a problem?**

Include contact for the researcher and Chairperson, MUST-REC.

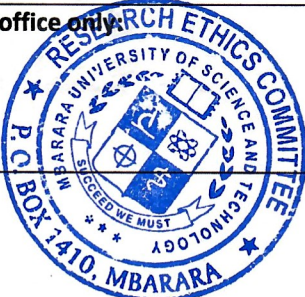
In case you have any questions about the study, you can ask me now, or you can contact the principal investigator of the study called Dr Simon Arunga whose contacts are written below.

**Dr Simon Arunga**

**Department of Ophthalmology**

**Mbarara University of Science and Technology**

**Tel: +256701546684**

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|                                                                                     | IRB NO: MUST-2022-592                          |

The permission to conduct this study was given by the Mbarara University of Science and Technology Research Ethics Committee. This committee reviews the documents of the planned research to ensure that no harm comes to you for participating in the research. You can therefore contact them in case you have any more questions about the study. You can also contact them if you have experienced any unfair or unethical treatment by the research team. All these complaints to the committee shall be handled with confidentiality. The chairperson of the committee is called Assoc. Prof. Paul Alele and his contacts are written below.

**Assoc. Prof. Paul Alele**  
**Chairman, MUST-REC**  
**P.O. Box 1410 Mbarara**  
**Tel: 0773 573372**

**What does your signature or thumbprint on this consent form mean?**

Your signature on this form means

- You have been informed about this study's purpose, procedures, possible benefits and risks
- You have been given the chance to ask questions before you sign
- You have voluntarily agreed to be in this study
- You have voluntarily agreed to have your eye photographed

|                                           |                                                                              |               |
|-------------------------------------------|------------------------------------------------------------------------------|---------------|
| -----<br>Name of adult participant        | -----<br>Signature/Thumbprint of participant/<br>Parent/Guardian/Next of Kin | -----<br>Date |
| -----<br>Name of person obtaining consent | -----<br>Signature                                                           | -----<br>Date |
| -----<br>Print Name of witness            | -----<br>Signature or thumbprint or mark                                     | -----<br>Date |

|                                                                       |                                                                                                                                                              |
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