# MAKERERE UNIVERSITY

## COLLEGE OF VETERINARY MEDICINE, ANIMAL RESOURCES & BIOSECURITY

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## SCHOOL OF BIOSECURITY, BIOTECHNICAL AND LABORATORY SCIENCES


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## PARENT/GUARDIAN INFORMED CONSENT

## I. INFORMATION SHEET (Bilharzia Study)

**Study name: TrypanoGEN$^{+}$: the Genetic Determinants of two Neglected Tropical Diseases**


**Principal Investigator:** Dr. Enock Matovu, College of Veterinary Medicine, Animal Resources and Biosecurity, Makerere University, P. O. Box 7062 Kampala, Uganda, Email: matovue@covab.mak.ac.ug, Tel. +256 414-533002


### Introduction

I am _____, a Doctor/Clinical Officer at _____..... I would like to invite you to allow your child to participate in a study. Before allowing your child to take part in the study, we request you read this document, and then we will go through it with you. This document describes the purpose of the study, the risks, benefits and your alternatives to participating in the study. You can ask Dr. Matovu, or any other member of the study team, any question you might have about this study at any time.

Your child/dependant's participation is completely voluntary and you have the right to refuse to participate. Even if you agree to take part, you are free to get your child out of the study at any time without giving any reason. Your refusal to take part in the study will not affect your or your child/dependant's access to medical care; you will be given the same treatment as those participating.

### Purpose of the study

Bilharzia is an important disease that is transmitted when we come into contact with waterbodies infested with snails in which the worm that causes this disease proliferates. The snails themselves get this worm when infected people defeacate or urinate in or near water bodies. Bilharzia can be deadly if left untreated and manifests as fever, abdominal pain, diarrhea, skin rash, blood in stool or urine. It may lead to distended abdomens in some individuals

Bilharzia affects different people to varying degrees of severity; in some it manifests as a mild disease while in others it can be severe and life threatening. It is believed that some individuals have natural defense factors that could protect them from severe disease when they get exposed to the worms. By examining the natural make up of such individuals in comparison to those that get severe disease, it may be possible to identify new avenues for treatment of this disease. One way would be by providing new drugs or food supplements that would empower our bodies to counteract the worm's effects and protect the patient.

Your district has been selected for execution of this research. Modern methods will be used to screen all people and identify those affected, who will be offered free treatment from the ministry of health. About 2000 volunteers including persons found to be suffereing from Bilharzia as well as those free from it will be requested to participate in this research.

The study was approved by the Research ethics Committee of the Vector Control Division (Ministry of Health), and by the Uganda National Council for Science and Technology; and sponsored by the Alliance for Accelerating Excellence in Science in Africa (AESA) in collaboration with the Wellcome Trust.


VECTOR CONTROL DIVISION (MOH)
APPROVED
VALID UNTIL
31 DEC 2020
RESEARCH & ETHICS COMMITTEE
P. O. BOX 1661, KAMPALA

**Specimens that your child/dependant will provide**
If you allow your child/dependant to take part in this study, he/she will be examined and asked about any symptoms such as fever, abdominal pain or bloody stool. The equivalent of 2 teaspoonfuls of blood will be taken from your child/dependant for this study. We shall also collect a stool sample and urine for further testing. The samples will be stored frozen at Makerere University in Kampala as the related tests will undertaken. All children will be treated during the on-going mass drug administration by the ministry of health.

**Storage of samples**
If you allow your child/dependant to take part in this study, the collected blood, urine and stool samples will be stored in freezers in a secured facility at Makerere University for 5 years or more, depending on what permission you will give. None of your child/dependant's personal information will be linked to the samples and no one will be able to tell they belong tohim/her, except the study team. If you decide that you do not want your child samples to be used for future research, you can tell us at any time and we shall remove them from the storage facility.

**Risks and discomforts**
There will be only minor uneasiness and risks when your child/dependant participates in this study. Collection of a blood sample may cause discomfort or a small bruise as with any other blood test. The medical team will do everything possible to minimize any potential discomfort or harm. Blood collection will be done by experts and any complications that may arise will be professionally addressed. A new needle will be used for each participant to prevent transmitting any infection. Please tell the medical team in case you child/dependant experience any discomfort, pain or have any other concerns. There will be no rists or disconforts from stool or urine collection.

**Benefits**
By participating in this study, you provide the opportunity to gain more understanding of this disease. This may provide avenues for new drugs or diagnostic tests that will be vital to control or even eliminate it from your area. Your child/dependant's participation will therefore go a long way towards reducing the suffering and death of our populations from Bilharzia.

**Costs**
Taking part in the study will not cost you anything. You will however be provided a transport refund of Shs 10,000 (Ten thousands only)

**Compensation**
There will be no reward for taking part in the study. You or your child/dependant will not receive money from us or any other person as a result of the use of the samples in medical research or testing. It is unlikely that your child/dependant will suffer any physical harm caused by one of our sample collection procedures. Should this ever occur, you he/she be treated and fairly compensated for it according to local laws and any insurance policy in effect. You are allowing your child/dependant to give away, for free, any property rights over the samples and any medical, scientific or commercial products such as drugs or diagnostics or other inventions created through the study or use of those samples. Your child/dependant's participation in this study is a free gift in the spirit of human kindness to help future generations fight Bilharzia and remain healthy.

**Confidentiality**
All information that we shall collect will be considered confidential. No names will be attached to your child/dependant's samples, which will be assigned a participant number that cannot be used by anyone outside the study to link these samples with their source. Study personnel will refer only to the participant number when conducting research. Some people responsible for the quality and oversight of the study, including monitors, auditors and inspectors will have access to the medical records. No mention of your child/dependant's name will appear in any publication in connection with this study. No persons other than the local staff overseeing your care will be able to link your name to the participant number.

**Sharing the results**

We will publish the results of this study in journals and might present it in seminars. The anonymised data will be stored in public archives where other researchers may see it, but it will not bear your child/dependant's names or even location where it was collected. A comprehensive report will also be made. At the end of the study, feed back on the results will be made to you in a meeting involving all participants and local leaders.

**Voluntary participation and withdrawal**
Your child/dependant's participation is voluntary. If you do not want to participate in this study, your medical care will continue as normal. If you allow your child/dependant to participate, you may withdraw him or her from the study at any time without giving any reason and without any penalty.

**Questions**
You have the right to ask any questions you may have about this study. If you have any further question or you want to withdraw your child from the study, you can contact Dr. Matovu (Tel: 0772550226), or any member of the study team, at any time.
This study was approved by the Vector control Division's research and ethics committee. If you have questions regarding your rights, please contact the chairman of that committee, Dr. Abbas Kakembo (Tel: 0771828378).

## II. PARENT/GUARDIAN CONSENT FORM

I have read the Participant Information Sheet concerning this study (or have understood the verbal explanation) and I understand what will be required of my child/dependant if he/she takes part in this study.
I have had the opportunity to ask questions about the study and they have been answered by..... My signing this consent form indicates that I am voluntarily allowing my child/dependant to participate. I understand that I have the right to withdraw my child/dependant from the study and that this does not in any way affect my or my dependants access to the medical care available at any healthcare facility presently or in the future.

Participant (Child/dependant) name:.....

Parent/Guardian's name: .....

Parent/Guardian's signature: .....

Date: ...../...../20..... (dd/mm/yyyy)

Parent/Guardian thumbprint here

*If the parent/Guardian is unable to read, the person who witnessed the consent must sign and date below:*
I have impartially witnessed the consent process for this parent/guardian and attest that the information was accurately explained to, and apparently understood. I confirm that the parent/Guardian has freely given consent.
Witness name: .....
Witness signature: ..... Date: ...../...../20.....

*Investigator/Researcher (or designee) obtaining informed consent:*
I have explained this study to the parent/guardian and have given adequate time to decide if he/she wants the child/dependant to participate or not. I confirm that the parent/guardian has freely given consent and that a copy of this informed consent has been provided to the parent/guardian.
Name of Investigator (or designee) obtaining informed consent: .....
Signature: ..... Date:...../...../20.....

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