MAKERERE UNIVERSITY

COLLEGE OF VETERINARY MEDICINE, ANIMAL RESOURCES & BIOSECURITY

P.O. Box 7062 Kampala, Uganda
Fax: +256-414-554685/534336
Email: sbls@covab.mak.ac.ug

SCHOOL OF BIOSECURITY, BIOTECHNICAL AND LABORATORY SCIENCES

PARTICIPANT ASSENT FORM (10-15 years)

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

What is this study about?
Dr. Enock Matovu of Makerere University is leading a study to understand why different people are affected differently by Bilharzia. Some people suffer severe disease while others are able to tolerate and have mild disease. Understanding the causes of these differences may be useful to develop new ways of fighting Bilharzia. Because this diseases are present in this area, we are asking if you want to participate in this study.

How many people will take part in this study?
About 2000 children will be included in this study.

What will happen if you decide you might want to be in this research study?
First, your parents/Guardians have been asked to give their permission for you to be in this study and they have agreed. If you agree to be in the study, the following will happen:

1. The study clinician will examine you and ask you about how you are feeling and if you have any symptoms like fever, abdominal pain, blood in stool or in urine .
2. An equivalent of 2 teaspoonfuls of blood, 2 sponfuls of urine and stool will be taken from you to examine for Bilharzia.
3. You will be given treatment for Bilharzia.

What will happen to the remaining samples after testing?
If you decide to take part in this study, your blood, urine an dstool samples will be stored in freezers in a secured facility at Makerere University for up to 5 or more years. They will be used to gain more knowledge about Bilharzia. If you do not want your samples to be used for future research, you can tell us at any time and we will destroy them.
All information that you provide will be considered confidential. No names will be attached to your samples, which will be assigned a participant number that cannot be used by anyone outside the study to link these samples with you.

Will any parts of this study hurt or have other risks?
Blood drawing may hurt when the needle is put into and taken out of your arm. 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 experience any discomfort, pain or have any other concerns. There will b eno harm or rist from stool and usine sample collection.

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

Are there any benefits from this study?
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 participation will therefore go a long way towards reducing the suffering and death of our populations from Bilharzia.

What about costs related to this study?
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). Your parent/guardian will also be given a transport refund of Shs 10,000 (Ten thousands only)

Is your participation voluntary? What are your available choices?
You can be in this study only if you want to. Nobody will compel you to participate if you do not want. If you do not want to be in the study, your medical care will continue as normal. If you decide to participate, you may withdraw from the study at any time without giving any reason and without any penalty.

Shall results of this study be made available?
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 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.

Do you have 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 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).
If you do not want to be in this study, just say so, and do not sign this form. If you want to be in this study, please sign your name below. If you sign here, it means you agree to participate in this study. We shall give you a copy of this form to keep.

Participant's Name and Signature	Date	Age
Name and Signature of Person Seeking Assent	Date	