

INFORMATION SHEET & INFORMED CONSENT FORM

Insight-ScHot: Gaining community insights into societal causes of and solutions for schistosomiasis transmission hotspots

You are being invited to take part in a research study run by Vector Control Division – Ministry of Health, in collaboration with Makerere University, and the University of Cambridge. The study has received Ethical Approval by the Vector Control Division – Ministry of Health and University of Cambridge Human Biology Research Ethics Committee. Before deciding whether to take part, you need to understand why this research is being done and what it involves. Please take time to read/listen to the following information carefully and talk to others about the study if you wish. Please ask us if anything is not clear or if you would like more information.

What is the purpose of the study?

Schistosomes are worm infections that can cause liver damage. We have seen evidence of this liver damage in Hoima District. Currently your community is provided with the drug praziquantel once per year to control this infection. We want to identify non-drug based methods of preventing the disease that could be successfully implemented within your community alongside this annual drug treatment and need members of your community to help us identify these methods.

We plan to include 72 participants from Hoima District. Participation in this study is completely voluntary. If you decide to participate you will be asked to sign/finger-print an Informed Consent Form, however you are still free to change your mind and leave the study at any time without giving a reason. If you chose not to participate or to leave the study, your future treatment for schistosomes will not be affected in any way. The study team may choose to withdraw you from the study if they feel it is in your best interest. The Ugandan research authorities or the study team may decide to stop the study at any time. If that happens we will tell you why.

What will happen if you do take part?

Sometimes we don't know the best way of controlling infections due to societal differences in uptake of health interventions, so we need help to identify methods that may work within your community. We would like to hear the opinions of people representing differing groups so that we can identify methods that might help control this worm infection across your community, or other methods that might work best for groups who are at a particularly high risk of infection. You have been identified as an individual who can represent one of these particular groups of people whose opinions we would like to hear.

In the first instance we would like to interview you, and your peers who are also identified to represent your group, away from the other study participants. After which we would like you to join the other groups of people for a wider discussion on how the infection can be reduced within your community. Participation will involve two-days of your time.

Due to the nature of the worm's transmission, which involves open defecation and the necessity for water contact, you may find some topics of discussion distressing to talk about in front of others. You will be under no obligation to participate in any discussion that does make you feel distressed.

The study team will take written notes of observations that they make during these meetings. They will also audio record the discussions with your consent.

Authorised staff who work for the Vector Control Division Research Ethics Committee or the Uganda National Council College of Science of Technology (UNCST) may require access to your personal information and study records to verify the data for this study and ensure that it is being conducted in accordance with Ugandan law. All information collected about yourself as a result of your participation will be kept strictly confidential. The results will be anonymous and you will not

be identifiable from any of the data produced. Anonymous datasets from the study will be made available to other researchers.

What are the possible benefits of taking part?

There is no guarantee that there will be a benefit from taking part in this study. However information collected as part of your participation may be used by the Ugandan Government to improve schistosome treatment programmes in the future. You will receive 30,000UGX compensation for each half day you participate in this study, you will also receive compensation for your transport costs to and from the study venue and a meal and refreshments on the days you participate.

What if there is a problem?

Any complaint about the way you have been dealt with during the study will be addressed. If you have any concerns about any aspect of this study you should speak to the study manager who will do their best to answer your questions. You are also able to contact the chair of the Research Ethics Committee who reviewed the trial procedure. The telephone numbers required are available at the end of this information sheet.

Contact details:

Dr Edridah Tukahebwa
Vector Control Division Ministry of Health
[Redacted telephone number]

Other telephone contacts:
The chair
Vector Control Division Ministry of Health
Review Ethics Committee
+256-414-251927

In any correspondence on this subject please quote: VCD-REC/.....

INFORMED CONSENT FORM – STUDY PARTICIPATION

Study Title: *Insight-ScHot: Gaining community insights into societal causes of and solutions for schistosomiasis transmission hotspots*

Principal Investigator: Dr Edridah Tukahebwa (Ug)
Dr Shona Wilson (UK)

Participant Number: _____

Anthropological Lead: Prof Stella Neema (Ug)

If you agree with each sentence below, please initial the box

INITIALS

1	I have read, or have been read, and understood the Participant Information Sheet version 1.0, dated 10/03/2021 for the above study and I confirm that I understand what will be required of me if I take part in this study.	
2	I understand that my participation in this study is voluntary and that I am free to withdraw at any time, without giving a reason and without affecting my normal medical care and management.	
3	I understand that my personal information will be collected on the study documentation, but that this information will be kept in the strictest confidence and none of my personal data will be published.	
4	I understand that information related directly to my participation in this study may be looked at by responsible individuals from the regulatory authorities and research personnel where it is relevant to them taking part in research and that they will keep my personal information confidential.	
5	I understand that during this study my opinions will be audio recorded by the study team.	
6	I have read and understood the compensation arrangements for this trial as specified in the Information Sheet.	
7	I understand that the investigators in charge of this study may close the study, or stop my participation in it at any time without my consent.	

I agree to my participation in this study:

Name of participant

Signature/Finger print

Date

Name of person taking consent

Signature

Date

Name of witness
(only when required)

Signature

Date

1 copy for the patient, 1 copy for the study team.