Uganda Virus Research Institute

Lake Victoria Island Intervention Trial on Worms and Allergies, LaVIISWA

Information for parents/ guardians of child household members: main surveys

We are inviting your child to take part in a survey that is part of the research study, LaVIISWA. LaVIISWA is investigating the effects of worms on health, and the advantages and disadvantages of regular treatment of the whole community for worm infections.

The worm infection called schistosomiasis (Bilharzia) is still a problem among fishing communities. Worm infections can cause health problems such as anaemia (which is often described as having little blood). They can damage parts of the body, especially the liver and gut. It is possible that they can also reduce the body's defences against other infections. On the other hand, it is possible that worm infections somehow protect against allergies and diabetes but that is not certain. That might explain why such diseases are often more common in cities than in rural communities.

What are worm infections?

Bilharzia is a disease caused by worms called schistosomes. Adult worms live in humans and their eggs pass out in the faeces. The eggs hatch in the lake water and the worms live for a while in snails in the lake. Then the worms are released from the snails into the water. The worms infect people again through the skin when the people are in contact with lake water. People who are infected with schistosomes (Bilharzia) may suffer from anaemia, diarrhoea with blood, and liver disease.

Other worms that occur in fishing villages include hookworm and roundworm. These both live in the human gut and eggs are passed out in faeces. People become infected with hookworm by walking bare-foot in places contaminated by faeces. Hookworm causes anaemia. People become infected with roundworm by eating food contaminated with faeces.

What is diabetes?

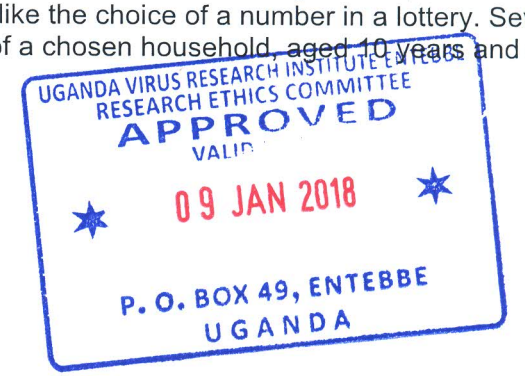
Diabetes is a disease that makes a person develop high blood sugar. This happens when the body poorly controls the levels of sugar in blood. This can lead to complications such as poor resistance to infections, eye disease, heart disease and kidney disease. Diabetes often coexists with abnormal levels of fats (lipids) in the blood and high blood pressure. Blood tests can detect diabetes or a tendency towards diabetes, by measuring blood sugar levels and the levels of insulin, which controls blood sugar.

Why is this study being done?

We want to find out the advantages and disadvantages of mass treatment against worm infections for general health outcomes and for diabetes. We also want to find out how worms and other infections protect against diabetes. If we can find this out, we may be able to develop better ways of preventing or of treating diabetes. The study will help the Ministry of Health to plan their worm treatment campaigns, and to plan for improved services to sufferers from diabetes.

Why has my child been chosen to take part in this study?

There are 27 villages taking part in the study, and samples are needed from people in each village, in order to find out what the effects of mass treatment for worms are. Households to give samples are chosen using a computer. The process of choosing households is like the choice of a number in a lottery. Seventy households are selected in every village. Members of a chosen household, aged 10 years and above, are being asked to take part.



What will happen if I take part?

If you agree for your child to take part, this is what will happen:

- You will be asked to sign or thumb-print the consent forms that accompany this information sheet
- Your child will also be asked to sign or thumb-print an "assent" form to show that he or she agrees to take part
- The researchers will ask some questions about your child's health
- Your child will undergo a physical examination including measurement of height, weight, waist and hip circumference and blood pressure.
- Your child will be asked to fast overnight before blood samples are taken
- A blood sample (at most 20 ml; just under four teaspoons) will be taken
- Your child will be asked to provide one stool sample
- The researchers will map the location of your home

What will my child's stool and blood samples be used for?

Stool samples will be used to test for worms. Blood samples will be used for tests for the level of glucose, insulin and fats (lipids). Counselling and testing for HIV infection will be included if you or your child wish it. Some blood will be used for tests of immunity (the body's defence system against infections). Part of each sample may be stored for other tests in future including genetic studies. All the information collected, and the results of tests, will be completely confidential. We will contact you with the results if they are abnormal and important for your health. We will not contact you with results from stool samples, because everyone will be offered treatment for worms as soon as the survey ends.

Are there any risks or disadvantages to me of taking part?

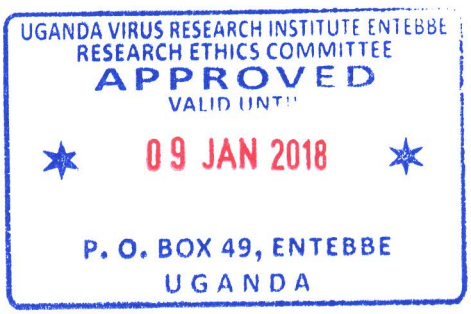
Taking part in the study is not expected to cause any problems for your child, apart from the discomfort of fasting overnight and having blood samples taken.

Are there any benefits to me of taking part?

There are no direct benefits to your child of taking part, but your child, and all the members of your village will continue to benefit from the regular provision of treatment for worm infections by the study. From the measurements taken, you will be able to know your weight, blood pressure and blood sugar level. If found to have a condition that needs treatment, this will be provided whenever possible, or you will be advised as to how to obtain the treatment that you need. Your child will be provided with a soft drink when procedures have been completed. Your child will also be provided with a piece of bathing soap as a token of appreciation.

What happens if I refuse to participate?

Taking part is voluntary. You are free to refuse for your child to participate or to withdraw your child at any time. This will not affect your right to the provision of treatment for worms within the study. It will not affect your right to health care provided by the government services. Your child is free to participate in the study even if you decline to have his/her samples stored for future use.



Who will have access to information from this research?

All our research records are stored securely in rooms with restricted access and on password protected computers. Only research staff trained to keep the information confidential will have access to the records. The names of individual participants will not appear on any reports on this research. After all your child's samples have been collected, his/ her name will be removed from the records, so no-one will be able to find out information about him/ her from our records. The information collected may be used to support other research in the future, and may be shared anonymously with other researchers.

Who has allowed this research to take place?

An independent national committee (the Uganda National Council for Science and Technology) and a committee at the Uganda Virus Research Institute have looked carefully at this work and agreed that the research is important, that it will be conducted properly, and that participants' safety and rights have been respected.

What if I have any questions?

If you have any questions about your child's participation in this study, please feel free to ask any member of the research team at any time. If you prefer, you may speak to Dr Richard Sanya – telephone: 0417 704000 or Professor Alison Elliott – telephone: 0417 704000.

What if I want to ask someone independent about anything on this research, or have any questions about my rights as a research participant, who shall I contact?

You may speak with the Ethics Committee Chairman from Uganda Virus Research Institute on 0414 321962.

Uganda Virus Research Institute

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Consent form for child household members; main surveys

Village name ..... **Participant ID number** .....

Child's name .....

Parent or guardian

I have read and/or been fully explained the information sheet concerning my child's participation in this study and I understand what will be required if he or she takes part. I understand that my child's participation is voluntary. My questions concerning this study have been answered. I understand that at any time, I may withdraw my child from this study without giving a reason and without affecting his or her entitlement to government health care. I agree for my child to take part in this study.

.....	.....	.....
Name of parent or guardian	**Signature or thumb print**	**Date**

Relationship to child (mother, father, guardian) .....

Witness:

.....	.....	.....
Witness name	**Signature**	**Date**

Witness required only for those using a thumb print instead of the final signature, or unable to read the information and consent form, or if the person taking consent does not speak the participant's language. The witness must not be a member of the research staff or a study participant. The witness must be present for the whole consent process.

Person taking the consent:

.....	.....	.....
Researcher name	**Signature**	**Date**

Form to be completed and signed in duplicate. Give one copy to the participant; retain one copy for the study file.

UGANDA VIRUS RESEARCH INSTITUTE ENTEBBE
RESEARCH ETHICS COMMITTEE
APPROVED
VALID UNTIL
09 JAN 2018
P. O. BOX 49, ENTEBBE
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