

Uganda Virus Research Institute

The Urban Survey of Allergies and Metabolic Outcomes

Information for children

We are inviting you to take part in a health-related research study, Urban Survey. The Urban Survey is finding out about asthma and other allergic diseases and diseases like diabetes in the people living in Entebbe, Uganda.

A lot of people in the world have asthma, eczema and atopy. The number of people suffering from these conditions is reported to be increasing especially in the cities.

Worm infections can reduce the strength of blood in a person's body. They can damage parts of the body, especially the liver. However, worm infections are also believed to somehow protect against allergies and related diseases such as asthma and against diabetes. This might help to explain why asthma, eczema and allergies are often commoner in cities than in rural communities.

What are asthma, eczema and allergies?

Asthma is a disease that affects the lungs. People with asthma have attacks of difficulty in breathing which come and go. Different things can trigger asthma attacks – such as exercise, cold weather, and “flu”. When someone has an asthma attack their breathing makes a whistling noise called wheezing.

Eczema is an itchy skin rash which comes and goes. Usually the rash occurs around the eyes, around the neck, inside the elbows or behind the knees.

Allergies are a reaction to substances in the environment which should not normally cause any problem. Allergic reactions are sometimes triggered by foods or insect bites, and sometimes by substances in dusts and in the environment. When a person gets into contact with the substance they are allergic to, they may have diarrhoea (if it is a food) or may start itching, sneezing or wheezing.

Allergy-related conditions are becoming commoner in countries like Uganda. It is thought that living in clean, modern environments may increase the risk of allergies and related conditions.

Urban Survey Information and assent form

Version 3.0_8 March 2016_English



Page 1 of 6

What is diabetes?

Diabetes is a disease in which the blood sugar levels are poorly controlled and a person develops high blood sugar. This can lead to complications such as poor resistance to infections, eye disease and heart disease. Diabetes is often associated with abnormal levels of fats (lipids) in the blood. Blood tests can detect diabetes, or a tendency towards diabetes, by measuring blood sugar levels, and the levels of insulin, which controls blood sugar.

What are worms?

Worms are parasites such as hookworm and round worm which infect humans through eating food contaminated with faeces, or walking on bare-foot in places contaminated with faeces. Worms live in the human gut and eggs are passed out in faeces.

Why is this study being done?

We want to find out the different types of asthma, eczema and allergies in Entebbe, and about blood sugar and related abnormalities among people in Entebbe. We also want to find out about why some people suffer these diseases.

We also want to find out how worms and other infections protect against these conditions. If we can find this out, we may be able to develop better ways of preventing or of treating such diseases.

The study will help the Ministry of Health to plan their worm treatment campaigns, and to plan for better ways of treating people with asthma, eczema and allergies and diabetes.

Why have I and my household been chosen to take part in this study?

Your household is among the 420 households in Entebbe that have been selected to part in the study. People living in the selected households (altogether 1500 people) will provide information and samples in order to find out about the different types of allergic conditions and about blood sugar levels, and whether worms protect against them. Households to give samples are chosen using a computer. To make it fair, the process of choosing households is like the choice of a number in a lottery.

What will happen if I take part?

If you agree to take part in this study, this is what will happen:

- You will be asked to sign or thumb-print the consent form that accompanies this information sheet
- The researchers will ask some questions about your health.

Urban Survey Information and assent form

Version 3.0_8 March 2016_English



Page 2 of 6



UGANDA VIRUS RESEARCH INSTITUTE

MRC

**MRC/UVRI Uganda
Research Unit on AIDS**

- You will undergo a physical examination including measurement of height, weight, waist circumference, hip circumference blood pressure and for visible skin allergies.
- Your lung function will be tested. For this you will be asked to blow into a small, hand-held instrument called a spirometer
- You will be tested for reaction to substances that commonly cause allergies, by skin prick testing
- A blood sample (20 ml, four teaspoons, if you are aged 13 to 17; 12 ml, two-and-a-half teaspoons if you are aged 5-12 years; 10ml, two teaspoons, if you are aged one to four years) will be taken from you
- You will be asked to provide one stool sample and one urine sample
- The researchers will map the location of your home, and take note of the type of environment in which you live
- You will receive a soft drink after completion of the procedures above, and if you are invited to the study clinic for any reason, a transport refund of 10,000 Ushs will be provided.

What will the stool, urine and blood samples be used for?

Stool samples will be used to test for worms and other intestinal infections. Urine samples will also be used to test for worm infections, as well as for sugar levels and protein levels. For girls who have started having periods urine will also be used for a pregnancy test. Blood samples will be used for tests for anaemia, malaria, and other infections, and for allergy tests, tests of blood sugar and of fat levels. Among infections, counselling and testing for HIV infection will be included if you 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. Some of the stored samples may be used for genetic studies. All the information collected, and the results of tests, will be completely confidential.

What are genetic studies?

Genetic studies find out whether inherited differences between individuals and families have an effect on a person's resistance to infections or diseases. If you agree we will store some of your blood for future genetic studies.

Will this cause any problems to me?

Taking the blood sample will hurt a bit. Skin prick testing involves placing about five drops of liquid, containing the substances to be tested, on the skin, and gently scratching through the liquid. Sometimes there is an itchy reaction, like the reaction to a mosquito bite. Very rarely a person may over-react to a skin prick test and may need urgent treatment. The research team is ready to treat such a reaction, but it is very unlikely to happen.

Urban Survey Information and assent form

Version 3.0_8 March 2016_English



Page 3 of 6

Your right to refuse or withdraw from the research study.

Taking part in the study is voluntary. This means that you or the people who look after you can say that you do not want to be involved. You can change your mind about taking part in the study at any time.

You can find out more about the study at any time by asking any members of the research team. You may also contact Dr Elliott (telephone: 0417 704000) who is in charge of the study, or the Ethics Committee Chairman from Uganda Virus Research Institute on 0414 320631.



Urban Survey Information and assent form

Version 3.0_8 March 2016_English

Page 4 of 6

Uganda Virus Research Institute
The Urban Survey of Allergies and Metabolic Outcomes

Child Assent form

**Sub-ward
name**

Participant ID number

Child

*Initial or thumbprint
each box*

1. I have read and understood (or been read to and understand) the information sheet for this study. My questions have been answered. I understand that taking part in the study is voluntary and I agree to participate in this study.

2. I agree to the skin prick tests that will show my response to substances that cause allergy.

Name of child

Signature or thumb print

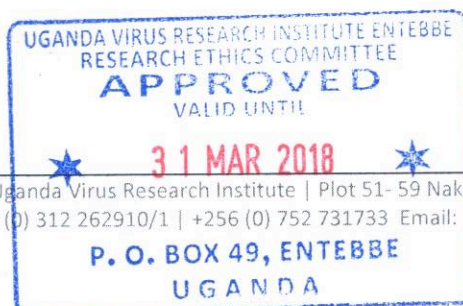
Date

Urban Survey Information and assent form

Version 3.0_8 March 2016_English

Page 5 of 6

MRC/ UVRI Uganda Research Unit on AIDS | C/O Uganda Virus Research Institute | Plot 51- 59 Nakiwogo Road - Entebbe | P.O Box 49 Entebbe | Tel: +256 (0) 417 704000 | +256 (0) 312 262910/1 | +256 (0) 752 731733 Email: mrc@mrcuganda.org | Website: www.mrcuganda.org



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.



Urban Survey Information and assent form

Version 3.0_8 March 2016_English

Page 6 of 6