

Integrated multi-disease screening for TB-affected households in Zimbabwe

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Your child is being invited to take part in a research project.

What you should know about this research study:

- We are giving you this information sheet so that you can read about the purpose, risks, and benefits of this research study.
- We cannot promise that this research will benefit your child. The main goal of research studies is to gain knowledge that may help other people in the future.
- You have the right to refuse to allow your child to take part or agree for your child to take part now and change your mind later.
- Please review this consent form carefully. Ask any questions before you make a decision.
- Your choice to allow your child to participate is voluntary.

WHY ARE WE DOING THIS STUDY?

The World Health Organization has placed a high priority on looking for tuberculosis (TB) among people who live with someone who has TB (household contact screening). This research project will evaluate whether people living in TB-affected households have undiagnosed chronic diseases and explore whether looking for these conditions, alongside TB, may be a useful way to improve the health of individuals and communities in Zimbabwe.

We are inviting your child to take part in this study because they live in a household with someone who has been diagnosed with TB. This study is being conducted as part of 'ERASE-TB' a large project which aims to develop new tests which can diagnose TB earlier. Your child may have also been a participant in that study. If they are, whether you choose to allow them to participate in this study will not impact on participation in ERASE-TB. The research team is made up of scientists from the Biomedical Research and Training Institute, the London School of Hygiene and Tropical Medicine, UK, and the University of Munich, Germany.

WHAT DOES PARTICIPATING IN THE STUDY INVOLVE?

If your child participates in the study, you will be asked to sign a written consent form and your child will be asked to sign an assent form. We will ask you/your child some questions about their health and lifestyle. After explaining what the tests are for, we will offer them a number of different screening tests, including tests for HIV (using blood or saliva), over/underweight, vision problems and sexually transmitted infections. Most of these tests are done during the study visit, some will be performed at a laboratory in Harare. All samples taken will be destroyed after the test is complete. Your child will be told the results of the tests performed during the study visit, where possible. If results are not available during the visit we will contact you/your child via phone when the results are available. If your child does not wish to have any of the tests offered, they can decline, without affecting participation in the study.

If your child is a household contact participant in ERASE-TB, we will integrate the screening into the visit for ERASE-TB. In this case participating may extend the visit time by up to 15 minutes. If not, we estimate that the study visit will take around 45 minutes to one hour.

RISKS AND DISCOMFORTS

Blood tests may cause some discomfort or a small bruise, as with any other blood test. Your child may be diagnosed with a medical problem as a result of participating in this study, which can be stressful, however we will support your child with this.

BENEFITS AND/OR COMPENSATION

We do not promise that your child will receive any benefits from this study. Testing for diseases before they cause someone to become sick can help diagnose medical problems earlier. As a result, your child can take treatment and prevent problems in future. We will provide you/your child with information on the different diseases we are testing for in this study, and we will support them with attending for further testing or treatment in the case that the screening is positive.

We hope that this study will benefit other people in the future by helping us to understand the health problems caused by chronic diseases in Zimbabwe and develop ways to support people to be diagnosed, and have treatment for, these diseases.

We cannot and do not offer any payment for your child's participation. We can reimburse you/your child for travel expenses for any travel for the sole purpose of the study. There will be no additional costs to you/your child in participating in this study.

CONFIDENTIALITY AND PROTECTION OF DATA

If you indicate your willingness for your child to participate in this study by signing this document, any information obtained in connection with this study that can identify your child will remain confidential and can only be accessed by the research team. When processing your child's information, we will anonymize it so that your child can no longer be identified. This anonymised information will be used in reports and scientific publications and may be shared with other researchers. Under some circumstances the Medical Research Council of Zimbabwe may review participant records for compliance audits.

VOLUNTARY PARTICIPATION

Participation in this study is voluntary. If you decide not to allow your child to participate in this study, your decision will not affect your/your child's future healthcare, at this or any clinic or hospital, or participation in any other study. If you decide to allow your child to participate, you are free to withdraw your consent and discontinue participation at any time without penalty.

WHO TO CONTACT WITH QUESTIONS OR PROBLEMS:

If you would like more information or have any questions about this study, please ask the study staff. You may also use the following telephone numbers if you still need more information.

Principal Investigator: Dr Claire Calderwood
Telephone number: +263 780981949

Study Co-ordinator: Mr Edson Marambire
Telephone number: +263 772286311

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AUTHORIZATION

You are making a decision whether or not to allow your child to participate in this study. Your signature indicates that you have read and understood the information provided above, have had all your questions answered, and have decided to allow your child to participate.

Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over.

- I have read the information sheet concerning this study [or have understood the verbal explanation]. I understand what will be required of my child and what will happen to them if they take part in it.
- I understand that my child's participation is voluntary, and that my child may withdraw from this study without giving a reason and without affecting their normal care and management.

I agree for my child to participate in this study ☐ YES ☐ NO

I agree with the study team calling me/my child to ask questions about my child's health, or to discuss results of any tests performed as part of this study, or to visit my home if they cannot otherwise contact me. ☐ YES ☐ NO

Consent from parent/guardian/legally authorised representative:

Name (print)	Signature	Date
Relationship to Participant		

Assent from participant (if child aged 13-17 years):

My participation in this research study is voluntary. I have read [or been explained] and understood the information. All my questions have been answered and I agree to take part in this study

Name of Participant (print)	Signature of Participant	Date
Name of Research Staff (print)	Signature of Research Staff	Date

If the participant gave verbal assent, add details of the person who witnessed the assent:

Name of Witness (print)	Signature of Witness	Date

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research participant or research-related injuries; or if you feel that you have been treated unfairly and would like to talk to someone other than a member of the research team, please feel free to contact the Medical Research Council of Zimbabwe on telephone 791792/791193 and 0784956128 or the following address:
Medical Research Council of Zimbabwe, Cnr. J. Tongogara & Mazowe Street, Causeway, Harare.