

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

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You are 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 you. 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 take part, or agree 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 participate is voluntary.

WHY ARE WE DOING THIS STUDY?

The research project will explore the experience of being screened (tested for a disease when you may not have any symptoms) for tuberculosis and selected chronic diseases in Zimbabwe, how such screening may impact people's lives and how it may be used in the Zimbabwean health system. Many health initiatives focus on a single disease, in this project we aim to develop opportunities to bring together testing for different diseases.

WHAT DOES PARTICIPATING IN THE STUDY INVOLVE?

The study is being conducted as part of 'ERASE-TB' a large project which aims to develop new tests which can diagnose TB earlier. You may have also been a participant in that study. If you are, whether you choose to participate in this study will not impact on participation in ERASE-TB.

In this study, we will interview people who have been screened for TB, and/or other chronic diseases, healthcare workers at local polyclinics and hospitals, and people who develop health policies in Zimbabwe. The project will run over 18 months from October 2021. In total we aim to interview around 50 people.

If you do decide to take part in the study, you will be asked to sign a written consent form and take part in an interview or group discussion. Interviews will take place at a private location which is convenient for you (e.g., in the clinic or Biomedical Research and Training Institute offices), and any travel costs will be reimbursed. Interviews will last around an hour. The interview will be in English or in Shona. You will be asked questions about the experience of being tested for medical problems, including about the different types of tests used, and the implications of the results.

POTENTIAL RISKS AND DISCOMFORTS

There may be questions which will be sensitive or difficult to answer, if you do not wish to answer any question you do not have to, we can move on to the next question. If you would like to stop the interview at any point you can do so without any consequences.

POTENTIAL BENEFITS AND/OR COMPENSATION

We do not promise that you will receive any benefits from this study. We hope that this study will benefit other people in the future by helping us to better understand their experiences and learn how to improve their care. We cannot and do not offer any payment for your participation. We can reimburse you for travel

expenses for any travel for the sole purpose of the study. There will be no additional costs to you in participating in this study.

CONFIDENTIALITY AND PROTECTION OF DATA

If you indicate your willingness to participate in this study by signing this document, any information that is obtained in connection with this study that can be identified with you will remain confidential and will be disclosed only with your permission.

When processing your data we will remove any information that could identify you. We will use the information in anonymised form in research outputs, which will include scientific publications and reports. Under some circumstances the information may be reviewed by responsible individuals from Medical Research Council of Zimbabwe and the local Institutional Review Board for monitoring and audit purposes.

AUDIO RECORDING

For the purpose of this study, the conversation will be audio recorded as we will be not be able to take notes of everything we talk about. The audio will be transcribed so that we can read it and make an analysis. If at any time your name is mentioned at the time of transcribing we will change your name to a different name, so there is no way to identify you. We will delete the audio tapes after the project is completed.

PROCESSING OF DATA

The data collected for this study will be stored anonymously, using password protected software and will be used for specific research purposes and for in some cases for audit and quality control purposes. The data will be solely the responsibility of the researchers undertaking this study. Anonymized research data may be shared with other researchers. The study will be written up in a report and a poster with our findings will be displayed at your health clinic.

VOLUNTARY PARTICIPATION

Participation in this study is voluntary. If you decide not to participate in this study, your decision will not affect your future healthcare, at this or any clinic or hospital, or participation in any other study. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without penalty. If you do decide to withdraw, you will have the option to request that any data which identifies you (including voice recordings) are deleted.

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 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 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] and I understand what will be required of me and what will happen to me if I take part in it.
- I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.
- I understand that my participation is voluntary, and I may withdraw from this study without giving a reason and without affecting my normal care and management.
- I understand that audio recordings will be taken during the study.

I agree to participate in this study

☐ YES

☐ NO

I agree to **being audio recorded**

☐ YES

☐ NO

Name of Participant (print)

Signature of Participant

Date

Name of Research Staff (print)

Signature of Research Staff

Date

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

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.