Tuberculosis Reduction through expanded antiretroviral therapy and TB screening (TREATS)

Prevalence Survey (≥18years old)-Information and Consent Form

Participant Information Sheet
Please ask the study staff to explain any words or procedures that you do not clearly understand.

This form gives you information about the research study you are being asked to join. The form describes the purpose, procedures, benefits, and risks of the research study. Please read this Information and Consent Form and ask as many questions as needed. You should not sign this form if you have any questions that have not been answered to your satisfaction. If you choose to sign this form you are giving permission to be included in this research study.

This study is being funded by the European and Developing Countries Clinical Trials Partnership (EDCTP)

Your participation is voluntary
You do not have to take part in this study if you do not want to. Access to health care from the health centres in your community will not be affected if you choose not to participate in the study. You are also free to withdraw from the study at any stage, without consequences to you or your family.

What is tuberculosis (TB)?
TB is an infectious airborne disease caused by bacteria (germs) which are spread through droplets from coughing or sneezing which are inhaled in into the lungs. The TB germ mainly affects the lungs but it can also affect other parts of the body. When the TB germ enters your lungs, we say you have **TB infection.** When you have TB infection, you are usually healthy and do not feel sick at all. You may have TB infection for some time which can be for some weeks up to years. Some people may have TB infection and may never feel unwell. If you start to feel unwell because of the TB germs in your lungs, we say you have **TB disease.**

Purpose of this study
The TREATS study is made up of 4 studies that will look whether the PopART study that has been carried out in 21 communities, 12 in Zambia and 9 in South Africa, reduced the chance of getting TB infection or developing TB disease. The PopART intervention involved HIV testing and treatment as well as screening for the symptoms that suggest you might have TB.

This particular study is called the "Prevalence Survey". In ***[insert the name of the country]*** this study aims to recruit a total of ***[insert number of participants recruited in each site]*** people 15 years and older from this community to measure how much TB disease there is in this community. You have been selected to be one of the people from your community who we are asking to take part in this study.

What will happen during this study?
If you take part in this study, we will ask you some questions about you, your family and your health, as well as about risk factors for TB disease. We will then ask you to have a chest X-ray taken at our mobile X-ray machine. This is a very simple procedure and it is very quick, it takes around 5-10 minutes and you will not be charged. The chest X-ray picture of your lungs will

be seen on a computer and this can tell us if there might be a chance you have TB disease. If you have signs and symptoms of TB or your chest X-ray does not look normal we will ask you to produce ***[insert number of samples needed depending on site requirements]*** sputum sample (s) to test for TB. Your sputum sample (s) will be tested on the spot for TB and the result will be available in 1 or 2 days. In addition we may ask for additional sputum samples to be sent to the laboratory for additional testing for TB. This test can take up to 8 weeks and so if this is the case we will tell you and will come to find you or contact you over the telephone to give you the results when they are ready.

If you are found to have TB, we will contact you and notify your local health facility and refer you there for treatment. If you do not have TB but your chest X-ray shows that you could have other disease we will ask a clinician to discuss this with you and provide you with a referral to a health facility for further investigation or treatment.

We will also request a blood sample of up to 10mls of blood (2 teaspoons) from some individuals to use for new tests to detect TB.

If you agree, we will perform an on-the-spot HIV test. **[*Insert whether a separate informed consent needs to be signed for HIV testing*].** We will provide counselling before and after being tested by qualified counsellors .

If you know that you have HIV, or we test you and find that you have HIV, we will ask for a small sample of blood to be taken using a finger-prick so that we can look at the HIV virus to see if any treatment you are taking has reduced the amount of virus in your blood.We will look at the different types of virus found in blood samples of different people in the community who are living with HIV. In science we call this Phylogenetics. This kind of research will help the PopART research team to understand better how the trial affected the spread of HIV and other viruses in your community

If you are found to have TB or HIV we will provide counselling by qualified counsellors and medical staff and refer you to the clinic for further assessment and care.

What are the possible risks or discomforts?
You may become embarrassed, worried or anxious when learning your HIV or TB infection status. A trained staff member will help you deal with any feelings or questions you have.

Risks associated with chest X-ray are minimal as the radiation exposure from these new machines is very low, and the x-rays are directed at the chest. However, if you are pregnant or have any concerns about the effects that the X-ray may have on your health or on that of your unborn baby please discuss it in detail with the radiographer and make sure all your questions are answered. You can still continue to take part in the study even if you choose not to have the chest X-ray.

Risks associated with blood sampling may be that you will have a small bruise on the site of the blood draw. Occasionally some people may feel a bit faint when blood is drawn but we will try to avoid this by drawing blood when you are sitting comfortably.

What are the potential benefits?
During the study you will learn whether you have TB disease and if so will be linked to care to cure the TB disease. Also you will learn more about the signs and symptoms of TB disease and have an X-ray of your lungs taken free of charge. You will have the opportunity to learn your HIV status and be provided with information on where to receive treatment and care services if needed. You will also be able to ask questions about your health.

In addition, the results will help design better programs to control TB and HIV and promote better health for you and your family as well as helping with acceptance of TB as a community-wide health problem.

Are there any alternatives to participation?
If you decide not to take part in this study, we will refer you to other places where you can be screened for TB disease or receive an HIV test.

How will my confidentiality and privacy be protected?
We will do everything possible to protect your confidentiality if you join this study.
To protect your privacy, you will meet with the researcher in a private area.

What kind of information will be collected from you?
During this study we will collect general information such as your gender, age, home address and employment status. You will also be asked to provide information about the type of house you live in, tobacco and alcohol intake. You will also be asked questions about TB and HIV. No one will be able to recognise you in all of the data that will be collected. A barcode ID with your study number will be allocated to you and will be used instead of your name.

[Insert any other site-specific regulations that need to be included in this section, i.e. refer to national Protection of Personal Information Act].

How will data be recorded?
Some of the information that you give us will be recorded on paper for example the consent form that you will sign, and test results. Other information like the questionnaire will be recorded electronically and will be recorded on a hand-held device. The hand-held device is securely protected by a password only known by the Research Assistant. All this information will be assigned a barcode ID so that your confidentiality is maintained.

How will it be stored?
All paper copies that will have your information will be kept securely in a locked cabinet in a locked room that will only be accessed by assigned study staff. All information that is recorded in hand-held devices is accessed only by the Research Assistant. All electronic data will be stored on a server and will be encrypted and password protected and will only be accessible by the data manager.

All the information collected will be stored for approximately 7 years after the study has ended after which, data will be destroyed.

Who will the information be shared with?
We may share it with people who check that the study is done properly (like the independent ethics committee or review boards). The data that we collect, but not your name or anything else that can identify you will be shared with other researchers working on the TREATS study.

These include researchers working at Zambart in Zambia, health Systems Trust in South Africa, the London School of Hygiene and Tropical Medicine, London School of Economics, University of Oxford, Imperial College and the University of Sheffield in the UK and KNCV in the Netherlands. We will publish study results in medical journals, for meetings and on the internet for other researchers to use. Your name or personal information will not appear in any publication.

After the study is complete copies of the data, without any details that could identify you, will be made publicly available via the internet for other researchers to use. To make sure you can never be identified we will remove information such as your name, where you live, your date of birth, the name of your community and any other data that may lead to someone being able to identify you.Some members of the study team may revisit you in the future to ask some follow up questions about the results of the tests you had, the treatment that you received or about other information provided to us in the course of this study.

What happens if I am injured by participating in this study?
It is very unlikely that you could be injured because of taking part in this study. However, if you are injured while taking part in this study, you will be given immediate treatment for your injuries and referred to the health facility. You will be compensated if an injury occurs during any of the study procedures. You will not be giving up any of your legal rights by signing this Information and Consent Form.

All principal investigators and sites are covered by the LSHTM sponsorship insurance and have Medical Malpractice Insurance to cover claims.

What are some reasons why I may be withdrawn from this study without my consent?
You may be withdrawn from the study without your consent for the following reasons:

- The research study, or this part of the study is stopped or cancelled
- The study staff feels that completing the study or this part of the study would be harmful to you or others

Persons to Contact for Problems or Questions
If you have any questions about taking part in this research study, your rights as a research participant, or if you feel that you have experienced a research-related injury, contact:

Principle investigator's Name: ***[Insert name PI]***

Research Site Address (es): ***[Insert PI's address]***

Daytime telephone number (s): ***[Insert PI's telephone number]***

If you have any other questions or concerns about your rights as a research participant or want to discuss a problem, get information or offer input, you may contact:

Independent Review Board/Ethics Committee: ***[Insert IRB and/or Ethics Committee]***

Address of Independent Review Board: ***[Insert IRB and/or Ethics Committee's address]***

Daytime Telephone Number: ***[Insert IRB and/or Ethics Committee's telephone number]***

[Insert any other required authorities to be contacted for each site]

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STATEMENT OF CONSENT

I have been given sufficient time to consider whether to take part in this study.

My taking part in this research study is voluntary. I understand that I may decide not to take part or can withdraw at any time from the study without penalty or loss of benefits or treatment to which I am entitled.
I understand the research study may be stopped at any time without my consent.

I have been informed of the procedures and tests that may be performed during the research study, as well as of the possible risks and benefits. I have had an opportunity to ask questions about this research study and my questions have been answered to my satisfaction.

I understand that the information I have given will be published in reports and papers, but that confidentiality will be maintained and it will not be possible to identify me from any publications.

I have been informed that my data will be shared with the partners and organisations that are working ***[insert name of the site]*** on this study.

I understand that I do not give up my legal rights by signing this form.

I understand that I will receive a signed and dated copy of this Participant Information and Consent Form.

If you have either read or have heard the information in this Participant Information and Consent Form, if all your questions have been answered, and if you agree to take part in the study, please print and sign your name and write the date on the line below.

I voluntarily agree to take part in this research study

_____	_____
Participant's Name (print)	**Participant's Signature/Thumbprint**

Date: _____

I certify that the information provided was given in a language that was understandable to the participant.

_____	_____
Name of Study Staff Conducting Consent Discussion (print)	**Study Staff Signature**

Date: _____

_____	_____
Witness' Name (print) (As appropriate) Date	**Witness' Signature**

Date: _____

FIX BARCODE HERE

STUDY COMMUNITY: _____