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

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

Addendum

Participant Information Sheet

We are contacting you because you participated in the TREATS TB Prevalence Survey (TBPS). We are now following up participants who submitted sputum samples in the survey.

To be in that survey you completed an informed consent form which we will show you again today. All of the information on that form is still very relevant but these follow-up activities were not described there and so we would like to go through this additional form today. It is up to you whether you choose to take part in these follow-up activities or not.

Purpose of this study

We are coming to see you today because you provided us with a sputum sample in the TBPS as we want to check that you received all of your results and that you have started treatment if you needed to. If you have not started treatment we will check whether you have any symptoms of TB and may ask you to give us another sputum sample if you are still unwell. We will also ask you if you would like to have another chest x-ray to see if the changes we saw in the TBPS, if any, have changed in any way.

What will happen during this study?

If you gave us sputum samples as part of the TREATS TBPS we will ask you some questions about your health and whether you have received any treatment or seen a health worker since you took part in the survey. We will also ask you for permission to look at your clinical TB record at the health facility.

We will offer you a chest X-ray. This is a very simple and quick procedure (5-10 minutes) and you will not be charged. The chest X-ray picture of your lungs will be compared to the one that was taken as part of the TBPS to see whether your x-ray has improved or not.

If you are not taking TB treatment but still have symptoms of TB or an abnormal chest x-ray we will ask you to provide another sputum sample for testing for TB. Your sputum sample will be sent and tested at the laboratory and the result will be available in 1 or 2 days. We will come to find you or contact you over the telephone to give you the results back when they are ready, and if you are found to have TB, we will 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 another disease we will ask a clinician to discuss this with you and refer you to the health clinic.

If you did not test for HIV during the survey or want to know your HIV status we will offer you an HIV test again. If you are found to have HIV we will refer you to the clinic for further treatment.

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.

What are the potential benefits?
We would like to ensure that you have received the treatment that you need, if you have TB or any other disease shown on your X-ray. We would also like to reassure you if any problems we found on your chest X-ray at the time of the survey have got better.

Are there any alternatives to participation?
If you decide not to take part in this study, you can go to your nearest health facility for testing for TB and HIV.

What will we do with the data we collect from you?
While the main purpose of this follow up activity is to ensure that you have received all of the results and care that you need, the data collected from you in this follow up activity may be published in reports and papers but you and your community will not be named and measures will be taken to make sure no-one can recognise you in these reports. These reports will help improve TB and HIV control in Zambia and the world.

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 follow-up activity.

I have asked any questions and had them answered. I also understand that I do not need to take part and that I can stop at any time with no penalty to me.

I understand that I will receive a signed and dated copy of this addendum to add to the consent form from the prevalence survey

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 follow-up activity

_____	_____
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: _____