Participant Information Sheet and Consent Form: Impact on Patient Costs Project

Substudy within TB Fast Track: a study to evaluate the effect of a point-of-care TB test-and-treat algorithm on early mortality in people with HIV accessing ART, a trial with randomisation at clinic level

Investigators:
London School of Hygiene & Tropical Medicine, UK: Prof. Alison Grant, Dr Katherine Fielding, Dr Anna Vassall, Dr Sophie Candfield
Aurum Institute for Health Research: Dr Salome Charalambous, Dr Mpho Tlali, Dr Chris Hoffmann, Prof. Gavin Churchyard
Foundation for Professional Development: Ms Suzanne Johnson

Hello, my name is [_____]. I am a researcher with the Aurum Institute. We are doing a research study and we would like to invite you to take part. Research is the process to learn the answer to a question. This information sheet explains the study. You are free to decide if you want to take part or not. If you decide to take part, we will ask you to sign or make your mark on a consent form, or give a thumbprint. Signing or marking the form means that you agree to take part in the study, and that you are aware of your right not to take part, and to stop taking part at any time. You can decide not to take part, and this will not affect your right to health care at this clinic.

Why are we doing this study?
You are already enrolled on a study about tuberculosis (TB) in South Africa. TB is known to have a big effect on how well people feel and how much they can work. Sometimes, when people cannot work because of TB, their family has to make changes so that they can still get the things that they need like food. Their family may also need to find extra money to pay for things like transport to hospital or medications for the person.

We will ask about 50 people in Gauteng, North West and Limpopo provinces to take part in this additional study into how being a person who may have TB affects people's personal finances (money). The study is paid for by the UK Department for International Development, the Medical Research Council and the Wellcome Trust.

If you take part in this study, what will happen?
If you agree to take part in this study, with your permission:

- We will ask you some questions about yourself (such as age and where you live) and your health, any treatment you are taking, and whether you have been treated for TB now or in the past.
- This study will take about 45 minutes of your time today
- To help us understand how much it costs people to come to clinic when they are sick, and the effect on their family, we would like to ask you some more detailed questions about your household income, and things you pay for or have in your home; how much it has cost you in money and time to attend pharmacies, clinics and healers about this illness, and how much any tests and treatment have cost you so far; also about any income you have lost if you needed to take time off work because of this illness, or to seek care; or if family members have needed to take time off to look after you or others because of this illness. These questions will take about 45 minutes. We would be very grateful if you are able to take the time to help us by answering these questions.
- We may use some additional information about you from the records that have been made about you for the trial that you are already in.

What are the risks and benefits of taking part in this study?

- There are no direct benefits to you of taking part in this study
- There is a risk of you feeling upset if these issues have been difficult for you. If this is the case you can choose to stop the interview at any time and leave this part of the study.
- This study aims to see how expensive it is for families to have a member with TB, or for individual people to have TB. This is useful information and may help guide health authorities about where to put money
- If this study shows people experience severe money problems relating to the treatment of TB, then this study may be extended to more people from the original study so that we can see whether these problems are made better by treating people's TB early on.

What happens if I do not agree to take part in this study?

- You do not have to take part in this study: if you do not take part, this will not affect the medical care that you receive at this clinic. You can decide to stop taking part in the interview at any time, without giving a reason.
- You can choose not to be in this part of this study and continue to be in the original study.

How will the information collected during this study be kept confidential?

- All information collected during the course of this study will be kept securely and confidentially in a locked cupboard or filing cabinet: Dr Candfield is responsible for this. Your name and contact details will only be available to a restricted group of study staff, and when we store this information on a computer, it will be protected by a password, and kept separate from other information (such as information about your health) that you give us. The health information you give us will be identified on forms and on computer files only by a study number, not your name or contact details. This will be kept for at least five years in case they need to be checked. They will then be destroyed. When the information is analysed, your information will remain private and confidential. Information that we collect as part of the study may be reviewed by the Ethics Committee, the Medicines Control Council and independent monitors, to check that the study procedures were done correctly and the information is correct. Reports about the study and results that may be published in scientific journals will never include any information which allows you to be identified.

What if I have more questions I wish to ask about this study?

- If you have any questions about this study, please ask us now. If you have questions later you can ask study staff, or telephone Dr Candfield/Dr Tlali on 010 590 1514. The committees giving ethical approval for this study are the Research Ethics Committees of the University of the Witwatersrand, South Africa and the London School of Hygiene & Tropical Medicine, UK. If you have any questions concerning your rights as a person taking part in a research study, you may contact Prof. Cleaton-Jones, Chairperson of the University of the Witwatersrand, Human Research Ethics Committee (HREC), which is an independent committee established to help protect the rights of research participants, at 011 717 2301. If the study staff or ethics committee do not provide satisfactory answers to your questions, you can write to: The Registrar, South African Medicines Control Council, Department of Health, Private Bag X828, Pretoria 0001; telephone 012 312 0000; fax 012 312 3105.
- We will give you a copy of this sheet which explains the study to take away with you.
- *(This information sheet will be available in the most common local languages: e.g. Sepedi, isiZulu, Xitsonga, English)*

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- I have read the information sheet about this study (or the information sheet about this study has been read to me) and I understand what will be required of me and what will happen if I take part in the study.
- My questions concerning this study have been answered by:

Research staff name (printed)	Signature	Date

- I understand that I may withdraw from this study at any time without giving a reason and without affecting my normal care and management.
- I agree to take part in the study

Study participant name (printed)	Signature/mark/thumbprint	Date

If the information sheet and consent form were translated or explained to the participant, enter the name of the translator here and their signature:

Translator name (printed)	Signature/mark/thumbprint	Date

If the participant gave verbal consent, enter the name of the person who witnessed the consent here and their signature:

Witness name (printed)	Signature/mark/thumbprint	Date