INFORMATION ABOUT THE RESEARCH

What you should know about this research study:

- This information sheet is so that you can read about the purpose, risks and benefits of this research study.
- Taking part is voluntary, and you have the right to refuse.
- If you agree to take part now, you can change your mind at any time in the future.
- Please read this information sheet carefully, and ask any questions before you make a decision.

What is the study for?

HIV is the virus that causes AIDS, and we know HIV increases the chances of you developing tuberculosis (TB). TB can be very difficult to diagnose in people living with HIV. We are doing a research study to see if using a new test for TB (done on a urine sample) on all people admitted to hospital who are living with HIV can help us diagnose and treat TB more quickly and help improve patients' health. A study has shown one urine TB test (called TB-LAM) improved health when it was used in patients with HIV admitted to hospital and who were suspected of having TB.

The research is taking place in South Africa and Malawi. The research team is from Malawi-Liverpool-Wellcome Trust Research Centre in Blantyre, Dignitas International NGO in Zomba, Malawi, Edendale Hospital in KwaZulu-Natal, South Africa and London School of Hygiene & Tropical Medicine.

Why have I been asked to take part?

You have been asked to take part because you need admission to hospital, and are HIV-positive. If you do take part, you will be one of 2,600 people in this study.

Who can't take part?

If you are less than 18 years old, if you have taken TB treatment in the last year or you live outside the study area you will not be able to take part.

What do I have to do if I take part?

If you do take part, you will be asked to provide a urine sample, a sample of sputum (if possible), and about 3-4 teaspoons (15-20mls) of blood. It will be decided by chance (like tossing a coin) whether your urine is tested for TB or not. Half of the patients will have urine tests done and half will not.

Sputum and urine test results will be given to the doctors and nurses looking after you. They will decide whether to treat you for TB or not, and will provide all your medical care. We will need to see you again in 2 months to find out about your health.

Part of the urine and blood samples you give will be tested immediately, with the rest stored for a period of up to 5 years in a secure laboratory storage facility to be tested later as part of this study. After this time they will be destroyed.

What are the benefits?

If you do have TB, then by participating in this research you may be able to start treatment more quickly, but we cannot guarantee that you will receive any benefits from this study. Taking part will not cost you anything and all the tests will be done free of charge. There is no payment for you to take part in the study but we will provide a small, healthy food parcel for you and we will refund your costs for attending the follow-up appointment in 2 months' time.

What are the risks?

The blood test may cause discomfort or a small bruise. The study is unlikely to lead to any harm. Occasionally laboratory tests for TB can give a wrong positive results (less than 1 in 100 tests). This could lead you to starting TB treatment that is not needed, or a combination of drugs that is not the ideal choice for you.

What information will be collected, and will it be kept private?

Details about your health, your home situation and your hospital stay will be written down.

All information collected is kept private and the records will not include your name. Only approved study staff or people regulating the study will have access to your information, which will be stored electronically. The study results may be published in a medical journal so that others can learn from them, but your personal information will not be included and there is no way you can be identified from it. The study data may be made available to other researchers so that it can be used to improve care, but your personal information will not be included and there is no way you can be identified form it.

Do I have to take part?

You do not have to take part, it is up to you to decide. You can change your mind about taking part at any time, you just need to let your doctor know. If you don't want to take part, or decide to pull out of the study, your doctors and nurses will still care for you and give you the best treatment they can.

Who has approved the study?

The organisations conducting the studies and at least 2 independent groups of people looking after your interests (Research Ethics Committees) have checked the study and agreed it is safe for you to participate.

Who to contact with questions or problems?

You can talk to your study nurse or doctor about the study. You can also speak to _____ who is in charge of the study at your hospital. You are encouraged to ask any questions you wish before, during or after the study. You may also use the following telephone numbers if you still need more information.

Research Nurse _____

Tel no_____

Study doctor _____

Tel no_____

College of Medicine Research Ethics Committee (COMREC) Secretariat
P/Bag 360
Blantyre
Tel: 0111 937 629

What if something goes wrong?

The London School of Hygiene and Tropical Medicine holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that the School is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of the study then you should immediately inform the local Investigator, _____.

CONSENT FORM FOR PATIENT/REPRESENTATIVE

Local PI and contact details:

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.

- I have read and understood the participant information sheet [or have understood the verbal explanation] and had the chance to consider the information, ask questions and have had these answered
- I understand that it is my choice to take part in this study, and that I am free to pull out at any time, without giving reason, and without my medical care or rights being affected
- I understand my medical notes may be looked at by responsible individuals involved in the study, from the London School of Hygiene & Tropical Medicine or from regulatory authorities. I give permission for this.
- I give my permission for data collected about me in this study to be used for future research (with all my personal information removed)
- I agree to participate in the STAMP trial, and for data and samples to be stored and tested later as part of this study.

Participant Consent:

Name of Participant (Print) _____

Signature (or thumbprint/mark) of Participant_____

Date_____

Name of Person Obtaining Consent (Print)_____

Signature of Person Obtaining Consent_____

Date_____

If the participant is unable to sign.

As an impartial witness, I confirm that all the information about the study was given and the participant consented to taking part.

Impartial Witness Name: _____

Impartial Witness Signature: _____

Date_____

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