Project Title:
Localised mobile active case finding with Truenat molecular testing for the effective diagnosis of tuberculosis (LOCATE-TB) in Yogyakarta, Indonesia

Lead Researchers: Dr Rina Triasih (Universitas Gadjah Mada) & Dr Philipp du Cros (Burnet Institute)

Institutions involved: This research study is a part of a wider Tuberculosis Elimination program being conducted under the 'Zero TB Initiative Yogyakarta' (ZTBY), a collaborative program lead by the Universitas Gadjah Mada in Indonesia and the Burnet Institute (from Australia), in collaboration with the Yogyakarta government, Yogyakarta and Kulon Progo District Health Offices, the Yogyakarta Provincial Health Office and the Indonesian National TB program (NTP).

You are invited to take part in this research project that will test whether the Truenat TB test works well and is acceptable to persons seen at TB active case finding services in Sleman district in Yogyakarta Province. Please read this information sheet. Please ask if there is anything that is not clear.

This Information and Consent form has two parts:

1. Participant Information Sheet (For sharing information about the study with you and for you to keep)
2. Participant Consent Form (for your signature if you agree to take part)

Participant Information Sheet

General Outline of the Study

Study Background

You are invited to take part in a research study that will assess whether a new TB test, Truenat Mtb Plus, is reliable, easy to use, and acceptable to patients when diagnosing TB within mobile TB case finding services. The study will help us to understand if using the Truenat test can help patients being screened for TB to get their results more quickly; whether the test equipment is reliable; and whether people are willing to be tested using this test. The Truenat TB test is an experimental diagnostic. This means that it is not yet approved for diagnosis of TB in Indonesia.

The study is taking place in Sleman district, Indonesia at sites where the Zero TB Yogyakarta Project deploys it's mobile TB case finding services. The study will be conducted over a 6 to 9-month period. The study is being conducted by the Universitas Gadjah Mada with the support of the Burnet Institute, which is a non-profit health organization based in Australia. Before you decide to take part, it is important that you understand why the study is being done and what you will be asked to do. If you agree to volunteer for the study, you will be asked to sign a consent form. It is your choice as to whether you participate in the study, and even if you agree to volunteer, you can choose to leave the study at any time.

Why is the study being done?

Tuberculosis (TB) is a disease caused by a germ that spreads through the air when people with TB cough or sneeze. It can affect any part of the body, but it mainly affects the lungs. The signs of sickness from TB include long-term cough, loss of weight, night sweats and fever. TB is usually curable with drugs, but if TB is not treated correctly, it can cause death. TB affects thousands of people in Indonesia every year. It is important to find people with TB and to help those diagnosed with TB to start treatment so they can get better; and so that they do not spread TB to friends, family and other people.

When a person needs to be tested for TB, making it easier and faster to get tested and get their result could help that person seek care for TB and start treatment promptly if they are diagnosed with TB. Currently, people who are tested for TB at health facilities need to have a sample sent to a laboratory for testing. This adds to the amount of time needed to conduct the test and give the patient the result and this typically takes several days. The Truenat TB test is a battery-operated

rapid molecular diagnostic test that can test for TB and rifampicin resistance from sputum samples. As a battery-operated device the test can be used outside of dedicated laboratories, including sites where there is intermittent or no electricity. Specifically, it can be used in mobile services and at community sites so that samples don't need to be sent to a central laboratory. The tests usually take about 2 hours to run allowing that the test can be conducted and results reported to the patient on the same day at the same site where the patient is seen. This study will examine whether the Truenat test works well in mobile services and whether using it results in patients getting their results more quickly.

You are being asked to take part in this study because you are involved in the provision of services for diagnosing TB using rapid molecular diagnostic tests by screening patients for testing collecting samples for testing, performing rapid molecular diagnostic tests or reporting results to patients and linking them to treatment initiation; and have been trained on how to conduct testing for TB using Truenat.

Participant Involvement

What do I have to do if I agree to take part in this study?

If you choose to take part in this study, we will assess whether the training you received on how to perform the Truenat tests was effective in giving you the skills need to perform the Truenat tests correctly. We will do this by observing you as you perform the tests and by asking you questions about how the device works and its correct use. These assessments will be done immediately after the training as well as one month after the study has started testing people using the Truenat tests.

Location and Duration

Post-training assessment for Truenat testing will be done immediately after the training; and one-month after the study has started testing people using Truenat. The assessment is expected to take no more than two hours each time.

What are the risks in participating?

- Germ spread: To limit the risk of spread of COVID-19 and TB, all participants and staff will wear personal protective equipment, social distancing measures will be in place, consumables for hand hygiene made available and the van and high contact surfaces will be regularly cleaned and disinfected.

- Sample handling and transportation: There is a limited risk of spills and contamination during handling and transportation of sputum specimens. Staff will be trained on safe transportation and handling procedures. In addition, staff will be trained on spill procedures and equipment will be provided for safe handling of spills.
- Sample preparation and testing: There is limited risk of the sputum samples being reaerosolised during sample preparation and testing. To limit this risk, environmental controls will be implemented to reduce the risk of infection and safe standard operating procedures will be developed for staff to follow. In addition, appropriate PPE will be worn when preparing and testing specimens.

What are the benefits in taking part in the study?

By diagnosing TB disease more rapidly, the study could help to decrease the possibility of TB transmission in the community. The study will also provide information that can be used by policy makers and TB services to decide whether using the Truenat TB test can help provide better patient care; on how to use the Truenat TB test; and on how to improve training on the Truenat TB test for laboratory staff and health care workers.

What is the cost of participating in the study?

There is no cost to participate in this study for lab staff and health care workers.

Will I be compensated for participating in the study?

Lab staff and health care workers who participate in the study will be able to undertake observation and assessment on Truenat as part of their work hours. No additional compensation is provided to them for participating in the study.

Voluntary Participation & Withdrawal

Participation in this study is voluntary. Observation and assessment of your proficiency in conducting the Truenat test is beneficial to assure the quality of care and accuracy of testing using the Truenat test. However, you may opt to not have your results included in the study.

If you wish to withdraw from the study at the time that your proficiency assessment is being done please tell the member of the study team who is performing your assessment. If you wish to

withdraw at any other time prior to the completion of both proficiency tests, you can contact Dr Rina Triasih whose contact details are listed below (under "Queries and Concerns").

What rights do participants have?

Your participation is entirely your choice. You have the right to ask any questions concerning the study at any time. A team member will always be available to answer your questions willingly. You do not have to say why you left the study. If you choose not to participate in the study and don't contribute your proficiency assessment results; or if you withdraw from the study this will not impact your employment.

Confidentiality

Your confidentiality is important to the study and study team. For data on observation and assessment of Truenat testing, your name will be collected and recorded in a database and then removed from the database once data collection is complete.

Data collected for this study will be stored in a secure database on a secure server belonging to the Centre of Tropical Medicine, Universitas Gadjah Mada. The data used for this study will not be used for any other purposes, including other studies. Once the study is finished the data will be archived at the University and will not be used for any future studies.

Analysis and reporting on the post-training will be anonymous and aggregated such that it will not be possible to know any individual persons' results

Queries and Concerns

You have the right to ask any questions you may have about this study. If you have any questions concerning this study or want to withdraw from the trial, you can contact:

- Dr Rina Triasih
    - Email: rina_triasih@yahoo.com
    - Phone Number: +62 813 9276 4269

Ethical Committees Clearance

The ethical aspects of this research have been approved by the Medical Health Research Ethics Committee at the Universitas Gadjah Mada and The Alfred Hospital Ethics Committee. The

ethical committee may review your research records, as they relate only to this study. These reviews would be done to check on the quality of the research. No one is allowed to share your private information with anyone else. If you have any concerns or complaints about how this research has been conducted, please contact:

Ethics Manager
Medical Human Research Ethics Committee
Universitas Gadjah Mada
Telephone: +62 811-2666-869
Email: mhrec_fmugm@ugm.ac.id

Complaints Officer, Office of Ethics & Research Governance, Alfred Health – Australia
Email: research@alfred.org.au
Please quote the following project number: 440/22

Participant Number:

Consent Form (Post-Training Proficiency Assessment)

Study Title	Localised mobile active case finding with Truenat molecular testing for the effective diagnosis of tuberculosis (LOCATE-TB) in Yogyakarta, Indonesia
Principal Investigators	Dr. Rina Triasih, M. Med(Paed), Ph. D, Sp. A(K) Dr Philipp du Cros (Burnet Institute)

Declaration by Participant

☐ I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

☐ I understand the purposes, procedures and risks of the study described in the project.

☐ I have had an opportunity to ask questions and I am satisfied with the answers I have received.

☐ I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study

☐ I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study team member / researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of study team member (please print) _____

Signature _____ Date _____

† A member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Withdrawal Form (Post-Training Proficiency Assessment)

To be completed by member of study team to whom the request to withdraw was made

☐ The participant has requested to withdraw from further involvement in the study.:

The participant has been asked and has indicated that he/she (choose one based on what the participant has reported):

☐ Wishes to withdraw all of their data from this study

☐ Wishes to withdraw but to allow data contributed so far to be used for this study

☐ Did not state whether they wish to allow data contributed so far to be used

Name of Participant (please print) _____

Participant number

Date withdrawal was requested

Name of study team member to whom withdrawal was requested

Signature of study team member