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 before you decide to take part. Please seek more information from the study contact listed 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.

Participant Involvement

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

If you agree to take part, we will ask you to complete a written survey to obtain your views on the feasibility and acceptability of the Truenat TB test. The survey will be anonymous and you can complete it online. Because the survey is anonymous it means that no one will know who has responded and what they said.

Location and Duration

Filling in the survey is anticipated to take no more than 1 hour.

What are the risks in participating?

Due to the fact that the survey is anonymous, it's not expected that there are risks in participating. Your employer has given agreement for employees to participate in the survey and to do so during work hours.

What are the benefits in taking part in the study?

The main direct individual benefits is having the opportunity to provide (anonymously) your views on issues and challenges in TB services that affect your work and your ability to provide patient care.

Outside of the individual benefits, 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; and on how to use the Truenat TB test.

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?

Your employer has given agreement for employees to participate in the survey and to do so during work hours. No additional compensation is provided for participating in the study.

Voluntary Participation & Withdrawal

Participation in this study is voluntary. The survey is voluntary and you do not have to respond to the survey or answer any questions on the survey that you do not wish to.

You can also discontinue answering the survey at any time and for any reason, even if you have not answered all questions. On the final page of the survey, before submitting the survey there is a final opportunity to indicate if you have changed your mind and would not like your response to the survey to be included in the study.

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 be available to answer your questions willingly. You do not have to say why you left the study. If you choose not to participate, or you withdraw from the study, this will not impact your employment.

Confidentiality

The survey on feasibility and acceptability is anonymous and you will be prompted to record information about your role but no other identifying information.

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. Your data from 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 feasibility and acceptability survey results will be anonymous such that it will not be possible for your assessment/responses to be associated with you.

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 (User Feasability and Acceptability Survey)

Study Title	Localised mobile active case 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

☐ 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 emailed signed copy of this document to an email address of my choosing

Name of Participant (please print) _____

Signature _____ Date _____

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