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 (or ask a friend or a family member to read it to you) before you decide to take part. 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 TB, 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 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 test can be done in mobile services and at community sites so that samples don't need to be sent and results are available within 2 hours at the service where the person is being assessed for TB. 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 attending TB services that are provided by or supported by Zero TB Yogyakarta mobile case finding services.

Participant Involvement

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

You have been invited to take part in this study because your screening results for TB suggest that it's possible that you have TB. If you choose to take part in this study, you will be asked to provide two sputum samples. This involves coughing to produce sputum (phlegm) and then spitting the sputum into a plastic cup. These samples will be tested for TB in one of two ways and the type of testing that is done will depend on the day that you are tested:

1. **We will follow the current standard and send the samples to be tested at a central laboratory**. We will contact you by phone to inform you of the test result and advise you on what action you should take based on the result. If your result is positive we will usually contact you within two days. If your result is negative, this can sometimes take up to a month.

2. **We will test one of your samples onsite using the Truenat TB test and send the second sample to be tested at a central laboratory.** You will have the choice about how you receive the result. You can wait while we do the test. Or, you can provide contact details and then leave and return when the test is complete. Or, you can provide contact details and advise that you wish to be contacted by phone with the result. When you are given your result we will advise you on the action you should take based on the result. Sometimes, the result from testing at the central laboratory can differ from the Truenat test. In that situation we will notify you and provide advice on any further action you should take. We will contact you again within 2 weeks of your Truenat result to find out whether you have accessed any follow up care that is recommended.

We will record information relating to these samples, the tests performed, the results of these test and your follow up care. We will use this information together with the personal and health information that was collected when you were screened.

The Truenat TB test is an experimental diagnostic. This means that it is not yet approved for diagnosis of TB in Indonesia. If you are tested with Truenat, we will also test one of your samples following standard procedures.

Location and Duration

A safe, private area will be available for you to provide the sputum samples and you can immediately give these to a health care worker. If you are tested with Truenat this test will take about 2 hours. If the Truenat result is positive then a second test to see whether the TB you have is drug resistant will also be done and this will take another two hours. Test results from central laboratory testing are usually available within 1–3 days from when you provided the sample.

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.
- Sputum collection: In providing the sputum to use for the tests, you are at very low risk of any harm.
- Diagnosis: If you are diagnosed with TB disease you may be emotionally affected. If you do receive a positive diagnosis, you will receive education and counselling from the nurse and counsellor when you get your diagnosis and you will be able to ask any questions you may have. You will be referred to the nearest health centre or hospital or provided a referral for another health facility of your choice.

What are the benefits in taking part in the study?

The direct individual health benefits of participating in this research includes the possibility of receiving a test result more quickly if you are tested with the Truenat test. For some people, reducing the wait time for a result will be more convenient and could reduce the period where they are uncertain if they have TB. Reduced time to result will also allow people to act more quickly based on the result.

Outside of the individual benefits, by diagnosing TB disease more rapidly, the study could help to decrease the possibility of germ spread amongst your friends, family, and 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 patent 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. All tests and treatment (if appropriate) related to this screening will be free of charge whether you choose to participate or not.

Will I be compensated for participating in the study?

As this is a free service, you will not receive any financial, food or transport related compensation or any other form of compensation for volunteering for this study. Whether you participate in the study or not, you will receive diagnosis for TB and may receive free-of-charge treatment services using the current care offered by the Indonesian health services if you are diagnosed with TB.

Voluntary Participation & Withdrawal

Participation in this study is voluntary. If you do not want to participate in this study, you do not need to give any reason, or have any fear that it will impact your care at the Puskesmas. If your TB screening shows you should be tested for TB but you do not wish to participate in the study, you can still choose to provide a sputum sample for testing at a central laboratory as this is what would usually be done. Answering the questions in the interview is also voluntary. You do not have to answer all questions if you do not wish to.

You may also withdraw from the project at any time without telling us why, until the data is prepared for write up. If you choose to withdraw from the project, you will not need to provide an explanation and there will be no negative consequences. If you choose to withdraw, your information will not be used in the results, but it will be stored securely at UGM for seven years and then archived. To withdraw at the visit when you join the study or at a follow up visit, you can tell a member of the study team that you wish to withdraw. If you wish to withdraw outside of a visit, you can contact Dr Rina Triasih who is responsible for the study and tell her you would like to withdraw (Email: rina_triasih@yahoo.com, Phone Number: +62 813 9276 4269).

What rights do participants have?

Your participation is entirely your choice. You may choose not to participate. If you do choose to join, you may leave the study at any time without losing any benefits or services. 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.

Alternatives to study participation

If you do not want to volunteer for the study, you may still have testing for TB at the case finding service with testing of your samples performed at a central laboratory. If you prefer not to be seen by the Zero TB Yogyakarta case finding service, you can choose to be seen by Puskesmas health care workers for TB screening and diagnosis.

Confidentiality

Your confidentiality is important to the study and study team. Personal information will be collected as part of the screening and diagnosis services provided by the Zero TB active case finding service. This data will be used to provide care and to reach you for follow up. The research study will use parts of that information but the data used for the study will have only a unique identifier, rather than your name and other personal information. Data collected by the service and the resulting data used for this study will be stored in a secure database on a secure server belonging to the Centre of Tropical Medicine, Universitas Gadjah Mada. If you agree, your data from this study may be used for future studies. All samples taken for testing will only be used for the tests discussed in this information sheet and discussed with you during your screening consult, after the tests they will be destroyed safety. The data that is collected by the Zero TB active case finding service may be used for future studies that have ethics approval to use this data.

Only you will be provided with the results of your TB tests so that your disease status remains confidential. If you are diagnosed with active TB disease, the health facility where you choose to start treatment (if appropriate) will be told of your diagnosis to support you through your treatment and care. As required by the Indonesian National Department of Health, positive TB results will be reported to the relevant National Programme and authorized medical staff. All test results are handled privately by medical staff. Test results can never be revealed to outside parties. The only

other people who may look at the research records are people who review studies to make sure they are safe and protect your rights. This could include:

- Relevant representatives from the National Department of Health, Indonesia.
- Members of the study team from UGM and Burnet Institute
- A sponsor, the Foundation for Innovative New Diagnostics (FIND)

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 (in Australia). 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 (TB Diagnostic Testing)- Adult providing own consent or for child (guardian)

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 give permission for my doctors, other health professionals, hospitals, or laboratories to release information to the Universitas Gadjah Mada and the Burnet Institute concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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

☐ I / my child freely agrees to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

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

☐ I agree that my data can be used for future studies (you can choose not to agree to this and still participate in the study)

Name of Participant (please print) _____

Name of parent / guardian if child or unable to sign _____

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 (TB Diagnostic Testing)

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 and future studies

☐ Wishes to withdraw but to allow data contributed so far to be used for this study **and** future studies

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

☐ 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 (dd/mm/yyyy): __ / __ / _____

Name of study team member to whom withdrawal was requested _____

Signature of study team member _____