

## PATIENT INFORMATION AND ASSENT FORM FOR CHILDREN (AT LEAST 10 YEARS OLD)

(Valid in combination with Parent/Guardian Consent Form)

**Protocol Title:** Early Risk Assessment in TB contacts by new diagnostic tests

**Short Title:** ERASE-TB

**Protocol Code:** LMU-IMPH-AIDA-03

**Sponsor:** University Hospital of Munich (KUM)

Division of Infectious Diseases and Tropical Medicine

Medical Center of the University of Munich (LMU)

Leopoldstrasse 5, 80802 Munich, Germany

<b>Principal Investigator (Study Doctor):</b>	
<b>Institution and address (Clinic/Hospital):</b>	
<b>email:</b>	
<b>Telephone number:</b>	+XX
<b>Participant ID number (as allocated in screening register)</b>	_ _ _ _  ·  _ _ _ _ _

### What you should know about this research study

- We are giving you this information sheet so that you may read about the purpose, risks, and benefits of this research study.
- The main goal of research studies is to gain knowledge that may help other people in the future.
- This research may have side effects.
- You have the right to refuse to allow to take part, or agree to take part now and change your mind later.
- Please ask any questions before you make a decision.
- You do not have to participate.

We would like to invite you to participate in our research study, and ask you to read this information which explains the project. You may ask the study staff or doctor any questions you have about the study.

### Purpose of the study

You are living with a person who is suffering from a disease called tuberculosis (TB). TB is very common and can cause bad chest infections or serious illness. By living with this person, you may become infected and sick as well.


Among those who are infected, most will stay healthy but some will develop TB themselves. These people would benefit from preventive treatment, a treatment received before the disease breaks out. This would also stop TB from

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	ERASE_TB_Master_ICF_Assent_V6.0 Dated: 12.07.2022	Page 2 of 6	

being spread to other persons. The problem currently is that it is still impossible to predict well who would require preventive treatment, and who will remain healthy.

This study will look at and compare a number of new diagnostic tests, to see which of those will be able to predict TB in persons like yourself. These persons in the future would then be able to receive medication to prevent them from getting sick.

We are doing this study to find out if new tests can diagnose TB earlier, before a person gets ill. Current tests can only find TB when someone is sick, or the TB bacilli can be found in their phlegm.

The study will include 2,100 household contacts (700 per country) of infectious TB patients from the age of 10 years in Tanzania, Mozambique, and Zimbabwe.

### **Which new tests will tried?**

Altogether, there are currently at least eight new tests to be evaluated in the study, for which we want to take some blood, sputum (mucus), and urine. For most of those, researchers already think that they might work better than existing tests. Two tests will look at how your blood cells react to TB (so-called TAM-TB and the host response tests; these will be done at your research institution); one will look at whether parts of TB bacilli appear in urine (Urine LAM), and the other will look at whether computers can read X-ray images in a better way than humans. Finally, we will look at how your body uses the genes/information it inherited from your father and mother – this may give a clue on whether you are developing TB. For some of these tests, your samples or your data may be taken to other countries, to specialized researchers who are working there.

Further, this study shall be used to find out more on why some persons who are infected with TB go on to develop the disease, and why others will stay healthy. We seek your permission to look for such differences on your blood cells and in your genes – looking at all your genes (“genome-wide association”), but also at specific genes that others have suspected earlier to have an influence (“locus-specific”). It is not planned to report back to your incidental findings of this genetic investigation that may describe other inherited diseases. In this process, the study and sample data will be encrypted by pseudonymization. We will only carry out genetic tests for research purposes and will keep these data strictly confidential.

### **Procedures and duration**

If you participate in the study, we will see you in our study clinic for a first baseline visit and then every 6 months for 18-24 months. We will also ask you some questions your schooling, university and employment.

Today and every time we see you we will do an X-ray, ask whether you feel ill, and take additional samples (blood of 3-4 tablespoons and urine). We may ask you to cough so we can analyse the sound. We may also ask you to breath into a chamber to see whether we can find TB bacilli in the air. Today you will also undergo a spirometry at baseline to check your lung function, we will measure your blood pressure at each visit to assess your heart function, and look into your blood sugar level (HbA1c) at least at baseline and subsequent visits as needed. If you feel unwell, develop a cough or fever, or lose weight without trying to do so, we will do the same check-up even if this is in between the 6 months visits. In this case, you can also call us and we will evaluate your symptoms and the necessity of an on-site or home visit telephonically. Resolution of symptoms may be reported by telephone as well.

After the end of these visits, we may call you and/or your parents/guardian again by phone, to assess whether any symptoms suggestive of TB have occurred, or whether a TB diagnosis has been made or treatment initiated.

Your samples and some of the data may be taken to other countries for the purpose of doing research in the future.

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ERASE TB



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	ERASE_TB_Master_ICF_Assent_V6.0 Dated: 12.07.2022	Page 3 of 6	

If we find TB in your samples, we will ask you for additional sputum samples to make sure that the diagnosis is correct. We will refer you for treatment to your nearest TB clinic.

This study is conducted by the study doctor at the clinic/hospital where you are being treated, together with clinics and hospitals in other countries, in co-operation with the University Hospital of Munich (KUM) in Germany and some other international researchers. Some of the samples taken from participants like you in the study may be sent to these foreign places for testing.

The study has been approved by the Ethics Committees of the KUM and all participating clinics/hospitals.

### **Risks and discomforts**

The blood test may cause some discomfort or a small bruise, as with any other blood test. If you become pregnant during the study we will not stop the follow-up however we will not do the chest X-rays.

The spirometry is a non-invasive exam, although it does require some effort on the part of participant, you may feel tired, dizzy. To avoid this, the study team will conduct the examination in an appropriate, well-ventilated setting, ensuring air circulation, safety and comfort.

Blood pressure is a non-invasive examination. It may cause some discomfort to the participant during the actual measurement such as light pain from pressure on the upper arm, which immediately vanishes as soon as the cuff of the blood pressure device is removed.

### **Benefits and compensation**

If you volunteer to join the study, you will benefit from regular check-ups for TB and other lung conditions. If the chest X-ray shows any problem which is not TB we will refer you to your primary health care clinic or a specialist. If the sputum test is positive for TB we will refer you to your preferred TB clinic for treatment. We do not know if the new test will be able to diagnose TB earlier, so their results will not be used to decide on your treatment. We cannot guarantee or promise that you will receive any benefits from this study but the study may help people in the future. Taking part in the study will not cost you anything and all the tests will be done free of charge.

We will not pay you to take part in the study but will refund << local wording and amount>> for study visits.

### **What will happen to my samples?**

Your samples may be shipped to approved researchers in other countries and again they will not be given any other information that identifies you. When you become a legal adult, you have the right to tell the study staff you want your samples destroyed.

If you agree, samples that are not used for immediate testing may kept for a longer time in <<country of trial site>>. The samples taken will be stored for up to 25 years. If longer storage is required, permission will be sought from the competent ethics committee.

There may be genetic testing performed at a later date. Any results will remain anonymous.

### **What will happen to my data?**

If you agree, some data (e.g. chest X-ray image, laboratory output) will be pseudonymised (coded) and may be transferred to collaborating research institutions and/or industry partners in other countries for research purposes only. A list of these is provided in the sheet that your parent/guardian receives. Data will be stored for up to 25 years. If longer storage is required, permission will be sought from the competent ethics committee.

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	ERASE_TB_Master_ICF_Assent_V6.0 Dated: 12.07.2022	Page 4 of 6	

### **Voluntary participation**

You do not have to participate in the study. You will receive regular medical care even if you don't participate. If you do decide to participate, you can end your participation without having to give a reason at any time. If you choose not to participate, nobody will be angry with you.

### **Who to contact with questions or problems?**

If you would like more information or have any questions about the ERASE-TB study, please ask the study team or contact the Study Coordinator: <<name of coordinator>>

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	ERASE_TB_Master_ICF_Assent_V6.0 Dated: 12.07.2022	Page 5 of 6	

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### AUTHORIZATION

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, HAVE HAD ALL YOUR QUESTIONS ANSWERED, AND HAVE DECIDED TO PARTICIPATE.

**Before you sign this form, please ask any questions on any aspect of this study that is unclear to you.  
You may take as much time as necessary to think it over.**

- I have read the information sheet concerning this study [or have understood the verbal explanation] and I understand what will be required of me and what will happen to me if I take part in it
- I understand that at any time I may withdraw from this study without giving a reason and without affecting my normal care and management.

### Assent Statement for participation in the study

#### Mandatory for study participation:

I agree to participate in this study YES ☐ NO ☐

I agree with the study team to calling me/my guardian and to ask questions about my health, or about studies that I may be eligible for, or to visit my home if they cannot otherwise contact me. YES ☐ NO ☐

I agree that my samples and/or data will be used for investigations, in one of the entities abroad listed on my guardian's ICF YES ☐ NO ☐

#### Optional:

I agree that genetic testing may be done on stored samples, in one of the entities abroad listed on my guardian's ICF YES ☐ NO ☐

### **Assent from participant:**

Name of Participant (Print)

Signature of Participant  
(thumbprint if illiterate)

Date

Name of Research Staff (Print)

Signature of Research Staff


Date

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	ERASE_TB_Master_ICF_Assent_V6.0 Dated: 12.07.2022	Page 6 of 6	

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

Name of Witness (Print)

Signature of Witness

Date

**To be completed by (authorized) person who obtained assent:**

I have accurately informed the child/adolescent, and to the best of my ability made sure that they understand why the study is being done, what is being asked of the them, how long the study will last and the risks and benefits of their participation in the research.

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked have been answered correctly and to the best of my ability. I confirm that the child has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the child and/or their parent/guardian.

Printed name of person  
obtaining assent

Signature

Date

**Impartial witness (only for illiterate children, or information given by translator):**

By signing the below, I hereby verify that verbal informed assent was obtained from the above child. The child has been informed about the discomforts and the benefits of the research, understands these, and is able to give assent to participate, without coercion, undue influence or inappropriate incentives.

Printed name of witness/translator

Signature of witness/translator

Date

### **YOU WILL BE GIVEN A COPY OF THIS ASSENT FORM TO KEEP**

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research subject or research-related injuries; or if you feel that you have been treated unfairly and would like to talk to someone other than a member of the research team, please feel free to contact the <<local EC and contact details>>

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