


<<institution logo>>	Division of Infectious Diseases and Tropical Medicine, Medical Center of the University of Munich (LMU)	Informed Consent Form	
	ERASE_TB_Master_ICF_HHC_Guardian_V6.0 Dated 12.07.2022	Page 1 of 10	

## PARENT/GUARDIAN INFORMATION AND CONSENT FORM (HHC)

**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  
D-80802 Munich  
Germany

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

**Dear Parent or Guardian,**

Your child/the child you are legal guardian for ("the child") is living in a household with a person who has been diagnosed with tuberculosis (TB), a disease that can cause bad chest infections or serious illness.

Persons like the child who are in contact with an infectious TB case may become infected themselves. Among those who are infected, most will stay healthy but some will develop TB themselves.

These people would benefit from preventive treatment, which would also stop TB from being spread to other persons.


The problem currently is that it is impossible to determine with certainty who would require preventive treatment, and who will remain healthy.

This is why we are doing this study. We would like to invite you and the child to participate in our study.

### 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.



<<institution logo>>	Division of Infectious Diseases and Tropical Medicine, Medical Center of the University of Munich (LMU)	Informed Consent Form	
	ERASE_TB_Master_ICF_HHC_Guardian_V6.0 Dated 12.07.2022	Page 2 of 10	

- We cannot promise that this research will benefit the child. 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 and the child have the right to refuse to allow to take part, or agree to take part now and change your mind later.
- Please review this consent form carefully. Ask any questions before you make a decision.
- Your and the child's choice to participate is voluntary.

### **Purpose of the study**

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.

Such tests would be beneficial, since TB could be treated earlier, before people become very ill and suffer lasting consequences of the disease, or even die untreated. Also, early treatment will prevent the disease being spread to more people. Researchers have developed a number of new tests, and this study is being done to find out how well they work.

### **Which tests will be the subject of this research?**


Altogether, there are currently at least eight new tests to be evaluated in the study, for which the child will need to provide blood, sputum (mucus), and urine as described below. For most of those there is already some indication that they might work better than existing tests. Two tests will look at how the blood cells of the child 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. One test we may use will analyse the sound of coughing, so we will ask your child to cough. Also we may ask your child to cough into a aerosol chamber which detects TB bacilli in the air. Finally, we will look at how the body uses its inherited information (gene transcription signature) among those that remain healthy versus those that develop TB. Some of these tests may be conducted on your samples or with your data abroad.

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 child's blood cells and in their genes – looking at all their 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 you and/or your child 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 throughout. We will only carry out genetic tests for research purposes and will keep these data strictly confidential.

We would like to invite the child to take part in this study because they are living in a household with a person who has been diagnosed with TB, and therefore they have a higher risk of developing TB themselves.

The study will be carried out in Mozambique, Tanzania and Zimbabwe and the research team is made up of doctors, nurses, counsellors and scientists from the Instituto Nacional de Saúde (INS), Mozambique, the Mbeya Medical Research Centre (NIMR), Tanzania, the Biomedical Research and Training Institute (BRTI), Zimbabwe, the Medical Center of the University of Munich, Germany, the London School of Hygiene and Tropical Medicine, UK, the Karolinska



<<institution logo>>	Division of Infectious Diseases and Tropical Medicine, Medical Center of the University of Munich (LMU)	Informed Consent Form	
	ERASE_TB_Master_ICF_HHC_Guardian_V6.0 Dated 12.07.2022	Page 3 of 10	

Institute, Sweden. The research is funded by the European and Developing Countries Clinical Trials Partnership (EDCTP).

### **Procedures and duration**

If the child participates, we will ask them questions about their health and medical history, and they will have a chest x-ray. If the child has any symptoms or their chest x-ray shows signs which could be TB, we will investigate the child's sputum sample to find out if they have TB. We will also ask the child for some blood samples (about 3-4 tablespoons), spontaneous and induced sputum samples and urine samples. We will test for HIV. Your child may be asked to undergo cough acoustic analysis at every visit, spirometry at baseline to check their lung function, we will measure your child's blood pressure at each visit to assess the heart function, and look into your child's blood sugar level (HbA1c) at least at baseline and subsequent visits as needed. Some of the obtained samples and data will be stored for future studies.

We will see the child in our study clinic every 6 months for 18-24 months. If your child is not able to come to the study clinic, our clinic staff may come to your home. When we see the child we will repeat the chest X-ray, ask for symptoms and take additional samples (as described above). Once during follow-up (most likely at the month 6 visit) we will test your child's sputum for TB regardless of symptoms. If the child feels unwell, develops a cough or fever, or loses weight without trying to do so, please do take them to our clinic for 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 child's 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 the scheduled visits, we may call you and the child again by phone, to assess whether any symptoms suggestive of TB have occurred, or whether a TB diagnosis has been made or treatment initiated. Additional checks may be done by the study doctor, e.g. repeating the spirometry if it was abnormal at the first visit.

The child's samples and some of the data may be shipped to approved researchers who work outside of the country and again they will not be given any other information that identifies the child. A list of those research institutions is provided below.

If we find out that the child has TB, we will ask the child for additional sputum samples to make sure that the diagnosis is correct. We will refer them for treatment to their nearest TB clinic.

### **Risks and discomforts**


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

**HIV testing:** If the test is negative, you and the child may feel less anxious after knowing their HIV status. If you know they are HIV positive, it may reduce the concern that comes with the uncertainty of not knowing. The child can take advantage of treating HIV early – effective treatment for HIV is available at no cost at the government care and treatment centre in the next hospital. You will also know whether or not you can infect others and what to do to prevent this from happening.

The disadvantages of taking an HIV test (especially if its result is positive) are possible rejection and discrimination by friends, family and colleagues, emotional problems, increased stress levels and an uncertainty about the future. Counselling is available to help you and the child cope with such a situation.

The spirometry is a non-invasive exam, although it does require some effort on the part of participant, your child 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.



<<institution logo>>	Division of Infectious Diseases and Tropical Medicine, Medical Center of the University of Munich (LMU)	Informed Consent Form	
	ERASE_TB_Master_ICF_HHC_Guardian_V6.0 Dated 12.07.2022	Page 4 of 10	

Blood pressure is a non-invasive examination. It may cause some discomfort to your child 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**

By participating in this study, the child 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 the child to your primary health care clinic or a specialist. If the sputum test is positive for TB we will refer the child to their preferred TB clinic for treatment. We do not know if the new test will be able to diagnose TB earlier. We cannot guarantee or promise that the child 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 nor the child anything and all the tests will be done free of charge. We will not pay you to take part in the study but we will refund

<< local wording and amount>>.

### **What will happen to the child's samples?**

If you agree, samples that are not used for immediate testing will be pseudonymised (coded) and may be stored in a "biorepository" in (country of trial site). Some of these stored samples may be used for tests at institutions collaborating in this study and others doing research on new tests for TB or other infectious diseases. 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. Children have the right to request that their samples be destroyed when they become legal adults (over the age of 18 years).

The child's samples may be sent to entities in other countries. A list of these is provided below.

For the long-term sample storage, additional details and a separate consent form is provided below, which requires an additional signature. You may choose to have your samples stored or not.

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 below. Data will be stored for up to 25 years. If longer storage is required, permission will be sought from the competent ethics committee.


### **Confidentiality**

If you indicate your willingness to let the child participate in this study by signing this document, all information obtained will be stored anonymously in safe paper and computer files. The computer will be password protected. No one will be able to access the information about the child except for the research team and no one will be able to identify them from the information we collect. Under some circumstances the <<local EC and regulatory authority>> may need to review participant records for compliance audits.

### **Voluntary participation**

Participation in this study is voluntary. If you or the child decide not to participate in this study, your decision will not affect your future relations with this clinic, associated hospitals and its personnel or with the institutions working on this study. If you decide to participate, you or the child are free to withdraw your consent and discontinue participation at any time without penalty.



<<institution logo>>	Division of Infectious Diseases and Tropical Medicine, Medical Center of the University of Munich (LMU)	Informed Consent Form	
	ERASE_TB_Master_ICF_HHC_Guardian_V6.0 Dated 12.07.2022	Page 5 of 10	

## **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: **XXX**

The following regulatory agencies/research institutions/companies may receive your child's pseudonymized (coded) samples (blood, urine, sputum) or pseudonymized (coded) data, including X-ray. We will transfer your child's data and/or samples only if in accordance with the strict data protection laws of Germany (more details in data protection sheet):

World Health Organization  
Geneva  
Switzerland

European Medicines Agency  
Amsterdam  
The Netherlands

Food and Drugs Administration  
Rockville, MD  
United States

NIMR - Mbeya Medical Research Centre  
P. O. Box 2410, Mbeya,  
Tanzania

Biomedical Research & Training Institute (BRTI)  
10 Seagrave Road  
Avondale, Harare  
P. O. Box CY1753, Causeway, Harare, Zimbabwe

Instituto Nacional de Saúde (INS)  
Centro de Investigação e Treino em Saúde da Polana  
Caniço  
Rua da Costa do Sol, 178, Polana Caniço B  
Mozambique

Department of Medicine Solna, Karolinska Institute  
17177 Stockholm, Sweden

Immunology Research Group of the Division of  
Molecular Biology and Human Genetics, Stellenbosch  
University Tygerberg Hospital, Cape Town, 7505,  
South Africa

Beckman Coulter Inc.  
50B, II Phase, Peenya Industrial Area, Bangalore-  
560058, India

With offices in:

- Miami:

11800 SW 147th Ave, Miami, FL 33196  
United States

- Krefeld:

Europark Fichtenhain B 13, 47807 Krefeld  
Germany

Cepheid Sweden  
Cirkusgränd 4, 17236, Sundbyberg,  
Sweden

Cepheid USA  
904 Caribbean Drive  
Sunnyvale, CA 94089  
United States

BioMérieux SA  
69280 Marcy l'Étoile  
France


Qure.ai  
Level 6, Oberoi Commerz II  
Goregaon East, Mumbai 400063, India

SD Biosensor  
C-4&5 Floor, 16, Deogyong-daero 1556beon-gil,  
Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690  
Republic of Korea

Delft Imaging Systems  
Waterstraat 20  
5211 JD 's-Hertogenbosch  
The Netherlands

Salus Discovery, LLC  
110 East Main St., Suite 822



<<institution logo>>	Division of Infectious Diseases and Tropical Medicine, Medical Center of the University of Munich (LMU)	Informed Consent Form	
	ERASE_TB_Master_ICF_HHC_Guardian_V6.0 Dated 12.07.2022	Page 6 of 10	

Madison, WI 53703  
United States  
Norwegian Institute of Public Health  
Division of Infection Control and Environmental  
Health  
PO Box 222 Skøyen, N-0213 Oslo, Norway

Clinical Research Department  
London School of Hygiene and Tropical Medicine  
Keppel Street, London WC1E 7HT, United Kingdom

German Center for Infection Research (DZIF)  
Division of Infectious Diseases and Tropical Medicine  
University Hospital, LMU Munich  
Leopoldstrasse 5  
80802 Munich  
Germany

Infection and Immunity Division  
Walter and Eliza Hall institute of Medical Research  
1G Royal Pde, Parkville, Vic, 3050  
Australia

University of Cape Town  
Wellcome Center for Clinical Research in Africa  
Institute for Infectious Diseases and Molecular  
Medicine  
Faculty of Health Sciences, Observatory 7925  
South Africa

University College London  
Medical Research Council Clinical Trials Unit  
90 High Holborn, London WC1V 6LJ, United Kingdom

FIND  
Campus Biotech, Chemin des Mines 9, 1202 Geneva,  
Switzerland

Malawi Liverpool Wellcome Trust Clinical Research  
Programme  
Queen Elizabeth Central Hospital, College of Medicine  
PO Box 30096, Chichiri, Blantyre, Malawi

LifeArc  
Lynton House  
7-12 Tavistock Square  
London WC1H 9LT UK

Roche Diagnostics GmbH  
Nonnenwald 2  
D - 82377 Penzberg  
Germany

Fraunhofer IIP Immunology Infection and Pandemic  
Research  
Tuerkenstr 87  
80802 Munich  
Germany

Genetic examinations from blood may be done at:

Institute of Clinical Molecular Biology  
Christian-Albrechts-University of Kiel  
University Hospital Schleswig Holstein · Campus Kiel  
Rosalind-Franklin-Str. 12 · 24105 Kiel, Germany

Institute of Translational Genomics  
Helmholtz Zentrum München  
Ingolstädter Landstraße 1 · D-85764 Neuherberg,  
Germany

Infection and Immunity Division  
Walter and Eliza Hall institute of Medical Research  
1G Royal Pde, Parkville, Vic, 3050  
Australia


Roche Diagnostics GmbH  
Nonnenwald 2  
D - 82377 Penzberg  
Germany

Fraunhofer IIP Immunology Infection and Pandemic  
Research  
Tuerkenstr 87  
80802 Munich  
Germany

Pseudonymized (coded) samples/data may be sent to  
other entities (e.g. hospitals, scientific centers or data  
bases) for analysis if the relevant ethics committees  
permit.

For transfer of pseudonymized (coded) data to  
entities located outside the EU/the EEA, please



<<institution logo>>	Division of Infectious Diseases and Tropical Medicine, Medical Center of the University of Munich (LMU)	Informed Consent Form	
	ERASE_TB_Master_ICF_HHC_Guardian_V6.0 Dated 12.07.2022	Page 7 of 10	

compare our information in the data protection  
information.



## Early risk assessment in TB contacts by new diagnostic tests

### 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 the child and what will happen to them if they take part in it
- I understand that at any time we may withdraw from this study without giving a reason and without affecting their normal care and management.

#### Mandatory for study participation:

I agree for the child to participate in this study YES ☐ NO ☐

I agree with the study team to calling us and to ask questions about his/her health, or about studies that he/she may be eligible for, or to visit our home if they cannot otherwise contact us.

YES ☐ NO ☐

I agree that my child's samples and/or data will be used for investigations, in one of the entities abroad listed above

YES ☐ NO ☐

#### Optional:

I agree that genetic testing may be done on stored samples, in one of the entities abroad listed above

YES ☐ NO ☐

#### **Consent from parent/guardian of participant:**

Name of Parent/Guardian of Participant  
(Print)

Signature of Parent Guardian of  
Participant (thumbprint if illiterate)

Date

Name of Research Staff (Print)

Signature of Research Staff

Date

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


Name of Witness (Print)

Signature of Witness

Date






<<institution logo>>	Division of Infectious Diseases and Tropical Medicine, Medical Center of the University of Munich (LMU)	Informed Consent Form	
	ERASE_TB_Master_ICF_HHC_Guardian_V6.0 Dated 12.07.2022	Page 9 of 10	

### YOU WILL BE GIVEN A COPY OF THIS CONSENT 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>>



<<institution logo>>	Division of Infectious Diseases and Tropical Medicine, Medical Center of the University of Munich (LMU)	Informed Consent Form	
	ERASE_TB_Master_ICF_HHC_Guardian_V6.0 Dated 12.07.2022	Page 10 of 10	

### Sample Donation Form for Future Studies

As parent/guardian of a child participating in the ERASE-TB study, I voluntarily donate all samples from the child to be used in future studies; in addition to the tests described in the main form. These samples will be stored in freezers in a safe and secured facility in <<trial site country>> for up to 25 years.

None of the child's personal information will be directly linked to any of the samples or study outcomes. The samples will belong to the researchers that conduct the ERASE-TB study, and will be used to develop or evaluate new tests to diagnose TB. Other researchers from around the world may also like to use these samples to study and help develop cures for other diseases. I herewith agree that the samples collected can be used also for other diagnostic evaluations indicating the risk of a TB infection or other infectious diseases.

The study team will not notify me in case of future use of the stored samples nor will I receive any compensation. I donate all blood, urine, sputum and other biological samples collected during the study to the researchers and hereby give up all rights to these samples and materials obtained from them.

I agree to allow my child's samples to be stored and used for future research outside of the main study for 25 years.  
If longer storage is required, permission will be sought from the competent ethics committee:

YES ☐ NO ☐

### Consent from the child's legal representative/guardian:

Name of Parent/Guardian of Participant  
(Print)

Signature of Parent Guardian of  
Participant (thumbprint if illiterate)

Date

Name of Research Staff (Print)

Signature of Research Staff

Date

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

Name of Witness (Print)

Signature of Witness

Date

