


<<institution logo>>	Division of Infectious Diseases and Tropical Medicine, Medical Center of the University of Munich (LMU)	Informed Consent Form	
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INFORMATION AND CONSENT FORM (HHC) - Adult

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

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

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.
- We cannot promise that this research will benefit you. 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 review this consent form carefully. Ask any questions before you make a decision.
- Your choice to participate is voluntary.

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Purpose of the study

We are doing this study to find out if new tests can diagnose tuberculosis (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 the TB could be treated earlier, before people become very ill and suffer lasting consequences of the disease, or even die if 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 you 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 assess 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 test 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. We may also ask you to cough and analyse your cough sounds. Some people may be asked to cough into a chamber to sample the air and see if there is any 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 stay healthy. We seek your permission to look for such differences among your blood cells and in all 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 your incidental findings of these 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 keep these data strictly confidential.

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

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

Procedures and duration

If you participate, we will ask you questions about your health and medical history, and you will have a chest x-ray at each visit. If you have any symptoms or your chest x-ray shows signs which could be TB, we will investigate your sputum sample to find out if you have TB. We will also ask you for some blood samples (about 3-4 tablespoons), spontaneous and induced sputum samples and urine samples. We will test you for HIV. You may be asked to cough so the sounds can be analysed. We may ask you to cough into a chamber so we can sample the air and look for TB bacilli. You will do, spirometry at baseline to check your lung function, measure your blood pressure at each visit to assess your heart

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function, and look into your 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 you in our study clinic every 6 months for 18-24 months. If you are not able to come to the study clinic, our clinic staff may come to your home. When we see you, we will repeat the chest X-ray ask for symptoms and take additional samples (as described above). At one of the follow-up visits most likely at 6 months we will test your sputum once for TB regardless whether or not you have symptoms. If you feel unwell, develop a cough or fever, or lose weight without trying to do so, please do come 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 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 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. Your 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 you. A list of those research institutions is provided below.

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.

Risks and discomforts

The blood test may cause some discomfort or a small bruise, as with any other blood test. If a participant 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 may feel less anxious after knowing your HIV status. If you know you are HIV positive, it may reduce the concern that comes with the uncertainty of not knowing. You 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 cope with such a situation.

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

By participating in this 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. We cannot guarantee or promise that you will receive any direct 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

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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 my 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. A list of these is provided below. 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).

Your 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 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 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 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 are free to withdraw your consent and discontinue participation at any time without penalty.

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 pseudonymized (coded) samples (blood, urine, sputum) or pseudonymized (coded) data, including X-ray (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

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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
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

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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

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

Roche Diagnostics GmbH
Nonnenwald 2
D - 82377 Penzberg
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.

Entities outside the European Union will only receive
data if permitted by the data protection regulation
applicable in Germany.

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 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.

Mandatory for study participation:

I agree to participate in this study YES ☐ NO ☐

I agree with the study team to calling me 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 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 participant:

Name of Participant (Print)

Signature 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

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Sample Donation Form for Future Studies

As participant of the ERASE-TB study, I voluntarily donate all samples 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 my 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.

If I decide later that I do not want my samples to be used for future research or product development, I have the right to tell the study staff at any time and they will destroy them.

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 samples and data 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 participant:

Name of Participant (Print)

Signature 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

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>>