



INFORMATION AND CONSENT FORM (INDEX CASE)

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.

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, which happened in your case.

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 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 six new tests to be evaluated in the study. Samples for those tests will be collected from your household contacts who might have contracted TB from you.

For most of those tests there is already some indication that they might work better than existing tests. Two tests will look at how 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 the body uses its inherited information (gene transcription signature) while someone is healthy and while someone develops TB. Some of these tests may be conducted on your samples or with your data abroad. We would like to invite you to take part in this study because you have been found to have TB and are living in a household with other persons who therefore 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 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, access to health care and income/employment. We will also ask you about the people, who are living in your house. If you are the head of household we may ask you some additional questions related to your living arrangement.



We will further ask you for two samples of phlegm, to measure the amount of TB bacilli (germs that cause the disease) in. In case you can provide a digital chest X-ray, we will upload it. Some of the obtained samples and data will be stored for future studies.

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. The shipment and storage of specimens will be done according to the <<locally applicable guidelines>>. A list of those research institutions is provided below.

If needed, we will refer you for treatment to your nearest TB clinic.

Risks and discomforts

There are no risks or discomforts associated with submitting phlegm samples.

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Benefits and compensation

By participating in this study, members of your household will benefit from regular check-ups for TB and other lung conditions, and if TB is found, this will most likely be early.

We do not know if the new test will be able to diagnose TB earlier, therefore their results will not be used to make decisions. 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 <<enter local wording and amount>> for study visits.

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. The samples taken will be stored for up to 20 years. If longer storage is required, permission will be sought from the competent ethics committee.

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.

What will happen to my data?

If you agree, your chest X-ray image 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 20 years. If longer storage is required, permission will be sought from the competent ethics committee.

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.

Data protection
<p>Data protection guidelines and medical confidentiality are strictly adhered to throughout the study. You may access your medical information as allowed by national/European Union (EU) law.</p> <p>Your personal data and findings will be collected, stored and given a code number, instead of using your name. Neither your name nor the date of birth appear in the code number. You will remain anonymous in any publication of study results.</p> <p>Only coded data will be entered into the database and analysed.</p> <p>The records of this study may be reviewed by inspectors of regulatory authorities, ethics committees, study monitors, and auditors who ensure the quality of the study and maintaining the confidentiality of your data, such</p>



as the <<local ethics committee>>. By signing the consent form, you are allowing such access, and that your medical information to be checked, transferred and processed for the study.

You have the right to obtain access to the personal data collected from you and to receive a copy of these data free of charge.

You are free to withdraw from this study at any time.

On your request you may ask the sponsor to rectify or erase personal data. However you cannot claim such eradication if the data are required for scientific reasons to reach the objectives of the research, or if this would seriously limit the scientific value. The final decision in such a situation will not be made by your doctor or nurse, but by an independent third party, e.g. ethics committee.

As part of the study, investigations using study data may be carried out in different countries; it is also possible that the pseudonymised (coded) data will be analysed at below mentioned sites.

These countries may have a lower level of data protection than the EU. The sponsor assures, as far as legally possible, to comply with the EU data protection level and to contractually oblige its research partners to do the same. Nevertheless, there is a risk that governmental or private bodies may access your data, although this would not be permitted under European data protection law. Therefore, it cannot be ruled out with certainty that, for example, potential employers or insurers will obtain knowledge of this data. The criteria and review of ethical principles for conducting clinical studies may also differ from the regulations applicable in this country. In addition, you may have fewer or less enforceable rights as a data subject and there may be no independent supervisory authority to assist you in exercising your rights. A transfer of your data/samples to these countries can only take place if you have expressly agreed to this. You can check the appropriate box in the declaration of consent.

For all questions related to the protection of your personal data and privacy you may ask the study team and your doctor or nurse for help. If they cannot help you, you may also ask the data protection officer of the institution responsible for the conduct of the study. Their contact details are:

Official Data Protection Officer

LMU Klinikum

Pettenkoferstr. 8, 80336 Munich, Germany

email: datenschutz@med.uni-muenchen.de

Since the study database will be located in Munich you also have the right to submit complaints to the supervisory authority concerned, whose contact details are:

Bavarian State Commissioner for Data Protection (BayLfd)

Postal: P.O. Box 22 12 19, 80502 Munich, Germany



Address: Wagnmüllerstr. 1, 80538 Munich, Germany

Tel.: +49-89 212672-0; Fax: +49-89 212672-50

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: <<local staff member>>

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

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World Health Organization
Geneva
Switzerland

Cepheid USA
904 Caribbean Drive
Sunnyvale, CA 94089, United States

European Medicines Agency
Amsterdam
The Netherlands

BioMérieux SA
69280 Marcy l'Étoile
France

Food and Drugs Administration
Rockville, MD
United States

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

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

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

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

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

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

Salus Discovery, LLC
110 East Main St., Suite 822
Madison, WI 53703
United States

Department of Clinical Science and Education,
Karolinska Institute
17177 Stockholm
Sweden

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

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



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

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

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

Cepheid Sweden
Cirkusgränd 4, 17236, Sundbyberg,
Sweden

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

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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

Samples/data may be sent to other entities 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.

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 ·

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 contact details>>

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 <<country of trial site>> for up to 20 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.

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 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 20 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