

pseudonymised (coded) study samples/data study data may be carried out in different countries, and at institutions outside your/your child's country.

Some of these institutions are listed in the main ERASE-TB informed consent form that you have received, but samples/data may also be sent to other entities, e.g. hospitals, scientific centers or data bases, for analyses if the relevant ethical committees permit. For transfer of pseudonymized (coded) data to entities located outside the EU/the European Economic Area (EAA):

These countries may less keenly protect data than the EU does. We however will set up contracts with such institutions to ensure good data protection. Nevertheless, there is a small risk that governmental or private bodies e.g. in the USA, may access your/your child's data in a way that would not be permitted in the EU.

4. Legal basis for processing your personal data

You/your child may only participate in this study, if you allow us to process your/your child's data according to the EU law. Please read the following declaration of consent carefully, your consent to the study and to processing your/your child's data is voluntary. You can withdraw your consent at any time. Data relating to you/your child will be stored in accordance with the rules at the test center and the sponsor for a period of at least 25 years after the end of the study. Longer storage may be permitted by the competent ethics committees only.

5. Passing on your/your child's pseudonymised data

The data collected by the test center will be sent to the following recipients in pseudonymized form if necessary:

- to the sponsor for the purpose of quality control, data analysis, scientific evaluation and publication.
- to inspectors of regulatory authorities, ethics committees, study monitors, and auditors for reviewing purposes to ensure study quality, such as the Medical Research Council of Zimbabwe and the Research Council of Zimbabwe.
- to other hospitals, scientific centers or companies for scientific purposes, collaborations and research databases.

By signing the below consent, you allow to access your/your child's medical information, and to check, transfer and process it for the study.

6. Risks associated to the use of your data

The collection, processing and transmission of your/your child's samples/data carries the small risk that someone might be able to identify you/your child, using other information, e.g. from the internet (social networks), which may lead to discrimination. Genetic data for instance allow to identify you/your child in principle, especially if you post health or genetic/heritage information about yourself/your child on the internet. However, the risk of this is very small.

7. Your /Your child's rights

In accordance with the statutory provisions, you have the right:

- to request information about personal data processed by us and information related to its processing (Art. 15 GDPR), and you have the right to receive a copy of your/your child's data free of charge.
- to request a correction and, if necessary, completion of your/your child's data (Art. 16 GDPR) in the event that your/your child's personal data is no longer correct or incomplete.
- to request the deletion of your/your child's personal data (Art. 17 GDPR) or the restriction of the processing of your/your child's data (Art. 18 GDPR) if the legal requirements are met. However, you cannot claim such eradication if the data are required for scientific reasons to reach study objectives, or if this would seriously limit the overall scientific value. Such a final decision will not be made by your doctor or nurse, but by an independent third party, e.g. ethics committee.
- to finally object to the processing of your/your child's personal data by us at any time (Art. 21 GDPR) for reasons that arise from your/your child's particular situation. If the legal requirements are met, we will no longer process your/your child's personal data.

For all questions related to the protection of your/your child's 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, e-mail: datenschutz@med.uni-muenchen.de

Since the study database will be located in Munich, Germany, you also have the right to submit complaints to the supervisory authority. Their 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

Consent to the processing of my/my child's personal data and release from medical confidentiality

I am aware that:

i) Participation in the study and consent to processing my/my child's personal data are voluntary and I can revoke my consent in whole or in part at any time without giving reasons and without incurring any disadvantages. I know that my revocation can only affect future research but does not affect research and processing of data that have already been carried out.

ii) My/My child's answers will be treated strictly confidential, and the data obtained in the course of the study are intended and used exclusively for scientific purposes.

iii) My/My child's data and samples generated in the course of the study, in pseudonymized form, can also be used for collaborations and research databases. This can also include forwarding them for research projects outside the European Union/the EEA, and to countries that may not guarantee the protection of your/your child's data as the EU does, e.g. the USA. Under these circumstances, there is no guarantee that the processing of your/your child's data can be controlled by independent legal bodies, and that rights and legal means are in place to be enforced for you/your child. However, we will put agreements in place to assure best data protection. In addition, governmental and/or private bodies may make use of their rights to access your/your child's data, but, again, we will put measures in place to best protect your/your child's data, and to avoid any personal disadvantages to you/your child, though this will be unlikely anyhow. **Your/Your child's pseudonymised data can only be passed on to these countries if you have given your written consent. You/Your child cannot participate in this clinical trial without your written consent to the transfer of your/your child's data to countries without an adequacy decision and suitable guarantees.**

I, hereby, agree that my/my child's data will be recorded and passed on in pseudonymized/coded form as set out on the DATA PROTECTION AND CONSENT FORM (adults ≥ 18 year; parent/guardian or pediatric participants ≥ 10 to < 18 years). I also agree that an authorized representative of the ethics committee, who is bound to secrecy, can inspect my/my child's personal data held by the investigators, insofar as this is necessary. For this measure, I release the investigators from their obligation to maintain confidentiality.

Name of participant/child (print)

Signature of participant
(thumbprint if illiterate)

Date

Consent from parent/guardian of participant (if participant is a child):

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, add the name of the person who witnessed the consent here including signature and date:

	Division of Infectious Diseases and Tropical Medicine, Medical Center of the University of Munich (LMU)	Informed Consent Form	
	ERASE_TB_Data Protection_ICF_V1.0 Dated 07.06.2021	Page 4 of 4	

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 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 Medical Research Council of Zimbabwe (MRCZ), Cnr. J. Tongogara & Mazowe Street, P.O. Box CY 573, Causeway, Harare 791792/791193 and 078495612.