

endTB-Q Clinical Trial

Research Screening Parental Consent Form

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SUBJECT IDENTIFICATION

Protocol Title: endTB-Q (Evaluating Newly Approved Drugs in Combination Regimens for Multidrug-Resistant TB with Fluoroquinolone Resistance)

Sponsor: Médecins Sans Frontières (Doctors Without Borders) – France

Principal Investigators: Carole Mitnick, Sc.D. and Lorenzo Guglielmetti, M.D.

Site Principal Investigator: [Insert PI Name]

Research Center: [Insert Research Center Name]

Participant Name (please print): _____

Study Subject ID: _____

About this consent form

Your child has been diagnosed with multidrug-resistant tuberculosis (MDR-TB) with fluoroquinolone (FQ) resistance. We are conducting a study, called endTB-Q, to see if we can find a better treatment for MDR-TB with FQ resistance. We would like to ask if you agree for your child to be interviewed and examined to see whether he/she could be in our study.

This research screening parental consent form is written to help you understand this screening and decide whether you want your child to participate. A member of our study team will talk to you and your child about what it means to do the study screening. There may be words that you do not understand or information that is unclear or confusing. Please ask us questions so we can help you understand better. You may take some time to think about and discuss your child's participation with others.

Even after signing this form, you or your child can decide that he/she will not be in this screening.

If you are not able to sign the consent form, but you would like your child to take part in the screening, you can choose someone you know to sign for you and you can make a thumbprint to show that you understand and would like your child to be screened.

Introduction

TB is a disease caused by bacterium (or germ) that usually affects the lungs. It is passed from person to person through the air by droplets that come from the lungs of a person who is sick with TB. When the sick person coughs, sings, shouts or spits, the TB bacteria can make others sick. Most people with TB can be treated and cured, if they complete all their treatment. Some types of TB bacteria can't be treated with drugs that are commonly used to treat TB, rifampin and fluoroquinolones. This is known as multi-drug resistant tuberculosis (MDR-TB) with fluoroquinolone (FQ) resistance. People sick with MDR-TB with FQ resistance need different drugs for their treatment.

Around 650 people with TB in 6 countries will be screened for this study. We expect that about [number to be adapted locally] people will be screened at [Research Center Name].

This study has been approved by the [Research Center Ethics Committee] [and the applicable national regulatory authority].

Médecins Sans Frontières (Doctors Without Borders) – France is the sponsor of this study.



Because your child is less than [18] years of age (a minor), we will need permission from both you (by signing this consent form) and your child (by signing an assent form) before having your child screened for this study. Taking part in the study screening is completely up to you and your child; your child does not have to be screened if you or your child do not want to. After you have had time to ask questions and think about your child's participation, we will ask you to sign this form if you agree that your child may participate. We will give you a signed copy of this research screening parental consent form to keep. We will also give your child the same information and ask for his/her permission to screening. Your child will be free to refuse even if you give permission for him/her to be screened. You cannot force him/her to participate.

Screening is the first step. If you agree that your child may be screened and he/she is eligible to be in the study, we will give you more information about the study and ask you to sign another form if you agree that your child may be in the study.

Why is this study being done?

Current treatment for MDR-TB with FQ resistance includes 5-9 drugs taken every day for 20 to 24 months. Treatment may be oral or include daily shots. This treatment may cause many mild and some serious side effects, for example: feeling sick to the stomach, throwing up, hearing loss, numbness/tingling in fingers and toes, kidney damage, mental illness/feeling sad, etc. Two new drugs (delamanid and bedaquiline) have recently become available. New treatments with these drugs may be shorter and/or simpler (no injection). Such treatments must be tested to see if they are safe and work well for people with multidrug-resistant TB with FQ resistance. The endTB-Q study will compare new shorter, injection-free treatments to the current treatment for MDR-TB with FQ resistance.

How long will the screening process take?

The complete screening process for this study could take 4 to 5 hours. It is possible that this will take more than one visit. All visits should be done within 2 weeks.

What will happen during screening?

We will ask you and your child to come to [Research Center Name]. We will ask you to sign a consent form before your child starts the study screening. Then, we will do some tests and procedures to see if your child is eligible to take part in the study. The study doctor will review the results of these tests and procedures. If your child cannot participate, the study doctor will tell you why and might ask if you would like your child to participate in another study.

Specifically, during screening, we will:

1. Answer all your questions and get your and your child's permission for screening.
2. Ask for your child's full name, contact information, sex, and age.
3. Review your child's medical history, including past or present illnesses, and information on drugs he/she is currently taking.

The treatment your child will receive for TB may interact with some of the drugs that he/she is currently taking. The study doctor may review with you and your child if some of his/her drugs need to be stopped or changed prior to receiving any MDR-TB treatment.

4. Perform a complete check-up and ask about your child's TB symptoms.

5. Collect 2 tablespoons of your child's blood for laboratory testing to check if his/her body is functioning well.
6. Unless recent results are available, we will also ask to use the collected blood from your child to test for viruses like hepatitis B and C, which affect his/her liver and HIV, which affects his/her body's ability to fight infection. These might affect your child's treatment for TB.

All test results will remain confidential. You and your child will have the right to refuse these tests. Refusing a test will not affect your child's participation in the study or any access to usual treatments that do not depend on knowledge of the test result. If the test result(s) is (are) positive, your child will be referred to appropriate care. If your child has HIV infection, we will test his/her CD4 count and HIV viral load to see if the disease is well controlled.

7. Ask your child to cough up 3 sputum (phlegm) samples. These will be used to test whether the TB bacteria can be treated with regular drugs and/or drugs in the study treatment. This is called testing for drug resistance.
8. Do a test, called an electrocardiogram, to check if your child's heart works normally.
9. Because we don't know if some of these medicines are safe in pregnancy:
 - The study doctor will discuss birth control to avoid pregnancy (for your child or his/her partner) if your child is eligible and you and your child agree to his/her participation in the study.
 - Pregnant patients cannot enter the study. So, if your child is a girl who can get pregnant, we will collect a urine or blood sample for a pregnancy test. The study doctor will refer your child for TB treatment outside of the study if the test shows she is pregnant.

Depending on your child's test results:

- the study doctor may prescribe medicines, for example to balance the level of salts in his/her blood, when possible;
- some of these tests may need to be repeated within the 2-week period; the study doctor will let you know which ones.

Managing Samples and Health Information in the Study

To keep all your child's information private, we will label all your child's samples and health information with a code instead of his/her name. The study team will keep a key that connects your child's name to the code. The study doctor will keep the key to the code in a password-protected computer and/or locked file.

In a special lab in Belgium, sputum samples and TB bugs from your child's sputum might be tested to see if drugs work against the bug.

What are the risks and possible discomforts from being screened for this study?

Risks of Blood Draws

Your child may have a bruise (a black and blue mark) or pain where we take the blood samples. There is also a small risk of infection, light-headedness, and/or fainting.

What are the possible benefits from being screened for this study?

This screening evaluation has not been planned to give your child direct benefits but it may help your child to get treatment within the study, or get other appropriate treatment more quickly. Others with MDR-TB with FQ resistance may benefit in the future from what we learn in this study.

Can my child still receive TB treatment if he/she does not take part in this screening?

Yes. Your child will receive treatment through [local TB care provider/entity] if he/she does not take part in this screening. Taking part in this screening is up to you and your child. You and your child can decide not to take part. You and your child will not lose any benefits you have the right to receive.

What should I do if we want to stop taking part in this screening?

If you or your child decide you want to stop your child's screening, we will talk to you about follow-up care your child might need.

Information collected during your child's screening will be used to help answer study questions. When your child leaves the screening, his/her information may still be used and stored for the study. If you and/or your child do not want this information to be used, and you want it to be destroyed, please contact the study doctor or the email address endTB.clinicaltrial@paris.msf.org.

Will we be paid to be in this screening?

You or your child will not be paid to be in this screening. We will pay transportation costs for visiting the research center(s). We will pay or you will be reimbursed [local currency] _____ for transportation to and from the screening visit.

What will we have to pay for if my child takes part in this screening?

All screening procedures will be free of charge to your child.

What happens if my child is injured as a result of taking part in this screening?

If your child suffers injury from the screening, [] will give him/her immediate medical treatment.

The sponsor will not pay to treat a medical condition or disease your child had before screening or expenses for injury, treatment, or hospitalization that are not the result of your child's participation in the screening.

You do not waive any of your legal rights by signing this consent form.

Who can I speak to if I have questions, concerns or complaints?

If you have questions about this screening, you can contact [PI Name and title] at [PI telephone number]. You can also call [Clinical Investigator] at [CI number] with questions. If you have questions about the scheduling of appointments or study visits, call [Study Coordinator] at [SC number].

For medical emergencies outside business hours, please contact [Must include 24/7 phone number of licensed site physician investigator here].

If you want to speak with someone not directly involved in the screening or study, please contact the [Research Center IRB] office. You can call them at [Research Center IRB number].

If my child takes part in this screening, how will you protect our privacy?

We are careful to protect the identities of people who are screened in this study to the extent permitted by law. We will also keep your child's information secure and confidential. Study information kept on a computer will be password-protected, and paper files will be stored in a locked office at [Research site]. Your child's screening records will be kept at the clinic/hospital for [XX] years [*to be adapted locally*] following the study completion. As needed to monitor the study quality, your child's screening records may be looked at by institutions responsible for quality and privacy, such as the sponsor, Ethics Committee and other Authorities.

For the screening, we will store some non-medical information about your child, such as his/her date of birth and city of residence. You can ask us to access, modify, complete, update, or delete this information. If you have any complaints about the protection of your data, you could contact your local/national Data Protection Authority [*Name and contact to be adapted locally*].

The information collected for screening will be used:

- For the purpose of this study: the sponsor, the study doctor, or other doctors involved in the study may share reports on the screening with scientific groups. After the study ends, you may see your child's records, and you may be told the study results.
- To make new recommendations about treatment of MDR-TB with FQ resistance: your coded information may be used and shared with other institutions, during and after completion of the study, notably with the World Health Organization.

In all cases your child's identity will never be disclosed.

If your child's coded information will be sent electronically to other researchers or institutions, it will be encrypted (scrambled so it cannot be read by unconcerned people) and will be protected according to European Economic Area standards.

endTB-Q Screening Parental Informed Consent and Authorization

Your signature on this document means the following:

I have read this parental consent form. The screening process has been explained to me, including risks and possible benefits, other possible treatments or procedures, and other important things about the study. I have had the opportunity to ask questions. I understand the information given to me. I recognize that my child's participation is voluntary and that I can refuse or end my child's participation at any time, without any loss of benefits that we would otherwise have.

I recognize that by signing this document, I do not lose any of my legal rights as parent/guardian of the patient. I will receive a complete, signed, dated copy of this research screening parental consent form.

By signing below, I give my permission to let my child take part in the screening.

Signature or thumbprint of parent/guardian of the participant Date (DD/MMM/YYYY) and Time

Name of parent/guardian of the participant, printed in capital letters

If applicable, Signature of witness

Date (DD/MMM/YYYY) and Time

Name of witness, printed in capital letters**Study representative who obtained informed consent:**

I have explained this study to the parent/guardian of the participant and have answered all of his/her questions. He/she understands the information described in this document and accepts voluntary participation of his/her child in the screening.

Signature of study representative

Date (DD/MMM/YYYY) and Time

Name of study representative, printed in capital letters

**endTB-Q Screening Parental Informed Consent Form Addendum
Storing Isolates (strains) and Health Information Future Use**

Your child's health information and bacteria isolates (TB bug) collected during the screening can be useful for other research in TB. We are asking permission to store your child's health information and bacteria isolates for future use in research on better treatment and diagnosis of TB, for up to 20 years after the study ends. The endTB-Q study sponsor will control access to this information and will share it only for research on better TB treatment or diagnosis. We do not know yet what these studies will be but they will be on better TB treatment or diagnosis (including resistance). Your child's coded health information will be handled according to the European regulation for the protection of personal data.

Your child's health information contains a code instead of your child's name. To further protect your child's privacy, we will change this code before your child's information is shared for other research.

Your child's bacteria isolates and health information will not be sold for profit.

Your child can be in the endTB-Q screening if you do not agree to store your child's bacteria isolates or health information for future use.

Any use of your child's coded health information or bacteria isolates in your child's country or in other countries for other research will be reviewed by an Ethics Committee in your child's country.

Results from this future TB research can be made public. Your child's identity will never be shared. No one will share individual findings with you or anyone else about your child and his/her health.

Even after signing this consent addendum for future use of bacteria isolates and health information, you have the right to change your mind. Anytime during the storage period of your child's bacteria isolates and health information, you can contact the study doctor or send an email to endTB.clinicaltrial@paris.msf.org to request any information regarding the use, storage and location of your child's coded health information and bacteria isolates and/or their destruction.

Informed Consent and Authorization - Storing Isolates (strains) and Health Information Future Use

Your signature on this document means the following:

I have read this consent form. The purpose of the future use of my child's health information and bacteria isolates has been explained to me.

I understand that this future use is separate from the endTB-Q screening and my decision to allow future use of this information will not affect his/her participation in endTB-Q.

I have had the opportunity to ask questions. I understand the information given to me. I recognize that my child's participation is voluntary and that I can refuse or end the storage of my child's health information and bacteria isolates for future use at any time, without any loss of benefits that we would otherwise have.

I agree to have my child's health information and bacteria isolates stored for future use:

Yes No

I recognize that by signing this document, I do not lose any of my legal rights as parent/guardian of the patient. I will receive a complete, signed, dated copy of this future use of health information and bacteria isolates consent form.

Signature or thumbprint of parent/guardian of the participant Date (DD/MMM/YYYY) and Time

Name of parent/guardian of the participant, printed in capital letters

If applicable, Signature of witness

Date (DD/MMM/YYYY) and Time

Name of witness, printed in capital letters**Study representative who obtained informed consent/assent:**

I have explained the future use of bacteria isolates and health information to the parent/guardian of the participant and have answered all of his/her questions. He/she understands the information described in this document and accepts voluntary participation of his/her child.

Signature of study representative

Date (DD/MMM/YYYY) and Time

Name of study representative, printed in capital letters