

endTB-Q Clinical Trial
Research Parental Consent Form

Version 4.3 Version Date: 05 Jul 2022

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 is being asked to participate in a study, called endTB-Q. This research parental consent form is written to help you understand this study and decide whether you want your child to participate. A member of our study team will talk to you and your child about being in this study. 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. Being in the study is completely up to you and your child; your child does not have to be in the study if you or your child does not want to. After you have had time to ask questions and think about your child’s participation, we will ask you to sign the consent form if you agree that your child may be in the study. We will give you a signed copy of this research parental consent form to keep. We will also give your child the same information and ask for his/her permission to be in the study, by signing an assent form. Your child will be free to refuse to be in the study even if you give permission for him/her to participate. You cannot force him/her to participate.

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

If you are not able to sign the consent form, but you would like your child to participate, you can ask someone you know to sign for you and you can make a thumbprint to show that you understand the study and would like your child to take part.

Introduction

Your child has been asked to join a study called endTB-Q clinical trial because your child has a type of tuberculosis (TB) that 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. Researchers want to know what combinations of drugs work well for people who have MDR-TB with FQ resistance. We do not know which combination of drugs is the best. The new combination of drugs used in this study is called “experimental”; all the drugs have been used before but we do not know how well they work together.

Around 350 people with MDR-TB with FQ resistance in 6 countries will participate in this study. About [number to be locally adapted] people will take part 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.



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Why is this study being done?

Current treatment for MDR-TB with FQ resistance has 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 my child be in this study?

Your child will be in this study for 1.5-2 years (73 to 104 weeks). During this time, we will ask your child to make 26 to 30 study visits to [Research Center Name].

What will happen in this study?

If your child chooses to be in this study, we will ask your child to sign an assent form and you to sign a parental consent form before your child starts the study. If your child is currently taking any medicines that can't be taken with his/her study drugs, he/she may need to stop these medicines before starting the study drugs. Your child's doctor may give new drugs to your child instead of his/her current medicines. If this makes your child feel bad, please tell the study doctor. If your child's medicines cannot be replaced by other treatment or need to be stopped for more than 2 weeks before taking study drugs your child may not be able to be in this study.

At the beginning of the study, patients will be assigned by chance (like rolling dice) to one of the 2 treatment groups described below. Two patients out of 3 will get the experimental treatment. One out of 3 will get the regular treatment for MDR-TB with FQ resistance. Nobody can choose your child's study treatment group.

If your child is assigned to the experimental treatment, he/she will get 4 study drugs that will be taken by mouth. Your child will be assigned to take the study drugs for 24 weeks (6 months) or 39 weeks (9 months). The duration of the experimental treatment that your child will receive will depend on the severity of his/her TB. This will be based on exam results before your child starts the study treatment and on exams performed during the first weeks of study treatment.

The experimental treatment includes the MDR-TB drug linezolid. The amount of linezolid your child receives will be changed after about 4 months of treatment or even earlier if your child is experiencing some particular side effects. We are looking at two ways to lower the total dose of linezolid: reduce the amount given every day or give it less often (3 times/week). This study will help us to know if one way is better than the other. The way your child takes less linezolid will be assigned to him/her by chance (like rolling dice): about half of participants receiving the experimental treatment will receive the daily dose and about half will receive the 3 times/week dose. Nobody can choose how linezolid dose will be reduced.

If your child is assigned to the control treatment, he/she will get the treatment used for MDR-TB with FQ resistance in your country according to international guidelines from World Health

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Organization. Your child will receive study drugs by mouth and maybe by needle shots. The treatment will last for about 20 to 24 months.

Your child's study doctor will tell you and your child how many pills of each drug he/she will have to take. Study staff will teach you and your child how, when and where your child should take his/her study drugs and for how long. Your child must follow these instructions carefully.

Your child will also have scheduled study visits (described below).

If your child misses doses or a study visit, a study worker may call you or go to your home to check if your child is well. He/she might discuss ways to help your child take all his/her study drugs and go to all his/her study visits. *[to be adapted locally based on the site set-up]*

With your agreement, the study doctor will inform your child's regular doctor or other medical doctors who may be treating him/her, of his/her participation in the study.

Your child will go to the *[Research site name]* for study visits until at least 73 weeks (17 months) and possibly as long as 104 weeks (24 months) after your child starts his/her study treatment. The exact time your child will spend in the study will depend on the overall progress of the study. If your child is still on treatment at the end of the study, we will help you and your child talk to the regular TB doctors to make sure your child can finish his/her treatment.

Visit procedures

All participants have the same visits and the same procedures. All procedures are part of normal care for people with MDR-TB with FQ resistance. In the study, we do them more often to see how your child is doing, learn about any side effects, and to understand how the treatment is working. What happens at each visit is explained here:

Visit before starting treatment

At this visit, we will:

- Answer all your and your child's questions and get your consent and your child's assent to be in the study.
- Ask about your child's job and schooling, smoking or alcohol use.
- Ask about any changes in your child's medical history or medicines since the screening visit, perform a brief exam and ask about TB symptoms and daily activities.
- The study doctor might change some of the medicines your child is already taking and will recommend birth control so your child/your child's partner can avoid pregnancy while taking study treatment.
- Check your child's vision, hearing, movement and feeling in toes, mental health status.
- If your child is a girl who can get pregnant, collect about ½ tablespoon of blood for a pregnancy test. This test will be repeated if the study drugs are started a few days after this blood draw.
- Do an electrocardiogram to check if his/her heart is working normally.
- Unless recent results are available, we might also:
 - Collect up to 2 tablespoons of blood to test for viruses like hepatitis B and C, which affect your liver, and HIV, which affects your body's ability to fight infection.

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These might affect your treatment for TB. All test results will remain confidential. You have the right to refuse these tests. Refusing a test will not affect your 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, you will be referred to appropriate care. If you have HIV infection, we will test CD4 count and HIV viral load to see if the disease is well controlled.

- Collect ½ tablespoon of blood for laboratory testing.
- Ask your child to cough up sputum (phlegm). This 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.
- Perform a chest X-ray.

Follow-up Visits (Week 1 to Week 73/Week 104)

After your child starts taking the study drugs, he/she will return to [Research site name] for the follow-up visits every week during the first 3 months, then approximately every month until the end of your child's study participation. Each visit takes about 1 ½ hours including waiting time.

At each visit, we will:

- Take your child's medical history; perform a brief exam, ask about TB symptoms, how he/she is feeling, whether he/she is taking study drugs correctly, and which other medicines he/she is taking; and answer all your questions. The study doctor may change some of your child's prescriptions if he/she is taking medicines that can have interactions with drugs in his/her TB regimen.
- If your child is a girl who can get pregnant, we will ask her about her last menstrual period and use of birth control. The study doctor might do a pregnancy test.
- The study doctor will recommend birth control so your child/your child's can avoid pregnancy while taking study drugs.

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Times of visits and study activities at each visit are in the table below:

Visit	Medical exam and interview ¹	1 tbsp. Blood Collection (for adverse events)	½ tbsp. Blood Collection for tests for people with HIV ²	½ tbsp. Blood Collection for Blood Sugar Level ³	Sputum Collection	Test of your heart ⁴	Chest X-Ray	Check vision, hearing, movement and feeling in toes	Mental Health assessment	ECOG Performance status ⁵	Pregnancy test ⁶
Week 1	X					X					(X)
Week 2	X				X	X					(X)
Week 3	X					X					(X)
Month 1	X	X			X	X		X			(X)
Weeks 5, 6, and 7	X					X					(X)
Month 2	X	X			X	X	X	X			(X)
Weeks 9, 10, and 11	X					X					(X)
Month 3	X	X			X	X		X			(X)
Months 4 and 5	X	X			X	X		X			(X)
Month 6 (Week 24)	X	X	(X)	(X)	X	X	X	X		X	(X)
Months 6.5, 7, and 8	X	X			X	X		X			(X)
Month 9 (Week 39)	X	X			X	X	X	X		X	(X)
Month 10	X	X			X	X		X			(X)
Month 11	X	X	(X)	(X)	X	X		X			(X)
Month 12	X				X	X					(X)
Months 13.5 and 15	X				X						(X)
Month 17 (Week 73)	X		(X)	(X)	X	X	X	X	X	X	(X)
Months 19, 20, and 22 ⁷	(X)				(X)						(X)
Month 24 ⁷	(X)	(X)			(X)		(X)	(X)	(X)	(X)	(X)

¹Medical exam and interview includes: talking about your child's medical history, discussing any (change in) medicines he/she is taking, physical exam; asking about TB symptoms and about taking your child's treatment.

²CD4 and viral load counts: these are tests that explain how well controlled disease is.

³If patient had abnormal blood sugar level at baseline.

⁴This is called an electrocardiogram and will tell if there is anything abnormal about the way your child's heart is working.

⁵The doctor or nurse will ask you/your child questions about which of your child's activities he/she can do and whether he/she needs help.

⁶For women who might be pregnant.

⁷Exams after Month 17 will be done only if your child's study follow-up is still on-going.

If your child has other diseases, for example hepatitis C, we might collect the exam results that his/her doctor orders according to clinical routine practice.

If needed, your child's study doctor might call you/your child for additional examinations.

Stopping or leaving the study early

If you or your child decide you want to stop your child being in the study, you should tell us. We will ask your child to have a study visit and will make sure that your child leaves the study safely. We will talk to you and your child about follow-up care you might need.

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The study doctor might also decide to take your child out of the study early. This may happen because:

- Your child becomes pregnant.
- The study doctor thinks it is best for your child to stop taking the study drug(s).
- Your child can't make the required study visits.
- We stop the study.

If this happens, the study doctor will explain why. We will ask your child to come in for a study visit as described above. We will also help arrange other care your child might need.

And, depending on when your child stops, we may ask your child to make one or two more visits.

At this/these visit(s), we will do the following:

Visit	Medical exam and interview ¹	2 tbsp. Blood Collection (for adverse events)	½ tbsp. Blood Collection for tests for people with HIV ²	½ tbsp. Blood Collection for Blood Sugar Level ³	Sputum Collection	Test of your heart ⁴	Chest X-Ray	Check vision, hearing, movement and feeling in toes	Mental Health assessment	ECOG Performance status ⁵	Pregnancy test ⁶
Early termination	X	X			X	X	(X)	X	X	X	(X)
Week 39 (Month 9)	X		(X)	(X)	X		(X)			X	
Week 73 (Month 17)*	X		(X)	(X)	X		(X)			X	

¹Medical exam and interview includes: talking about your child's medical history, discussing any (change in) medicines he/she is taking, physical exam; asking about TB symptoms and about taking your child's treatment.

²CD4 and viral load counts: these are tests that explain how well controlled disease is.

³If patient had abnormal blood sugar level at baseline.

⁴This is called an electrocardiogram and will tell if there is anything abnormal about the way your child's heart is working.

⁵The doctor or nurse will ask you/your child questions about which of your child's activities he/she can do and whether he/she need help.

⁶For women who might be pregnant.

*If your child leaves the study early, his/her last visit will be at or before the Week 73 follow-up visit.

What will happen to your child after the end of the study?

Once your child completes his/her participation in the study, any follow-up of his/her TB will be done by his/her regular doctor.

If your child still has side effect(s) when he/she ends the study, the study doctor may stay in touch with your child until the side effect gets better or stops getting worse. The study doctor may also contact your child if he/she experiences a new side effect.

You may refuse to be contacted and you and your child do not have to provide any information if you don't want to.

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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 and to see if the bug is the same as the one that was in your child's sputum at the beginning of the study.

Will anything bad happen to my child from being in this study?

Risks of Taking Study Drugs:

Your child will take several MDR-TB drugs when he/she is in this study. The drugs used in the control are the standard MDR-TB medicines used in your child's country according to international guidelines from the World Health Organization. Experimental treatments will use the following 4 drugs: bedaquiline, delamanid, clofazimine and linezolid.

Medicines for MDR-TB have different side effects. The study doctor will tell you and your child the most common side effects that he/she may have while taking study treatment and you will be given a paper ("leaflet") that describes the main side effects. There may be other risks that are not known yet. We will do frequent clinical, laboratory and other examinations in order to find and promptly treat possible side effects. Your child's doctor will explain in detail when you or your child should get in touch with him/her.

As with any drug, an **allergic reaction** can happen. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. Sometimes allergic reactions can be more serious, and even result in death.

Some of the drugs may have an unknown, harmful effect on an embryo or fetus (developing baby still in the womb), or on a breastfeeding infant. Because of these unknown risks, women cannot start this study if they are known to be pregnant, trying to become pregnant, or unwilling or unable to stop breastfeeding an infant.

For women who are able to get pregnant, we will require negative pregnancy tests before starting the study drugs.

If your child is sexually active while taking his/her study drugs (and possibly after), we will require use acceptable forms of birth control. Acceptable birth control may be achieved by using a single "highly effective" method or by using a combination of other methods.

Acceptable "highly effective" birth control methods for use in this study are:

- Hormonal methods,
- Intrauterine device (IUD).

An acceptable combination birth control method for use in this study is:

Condom (male or female)ⁱ used with or without a spermicideⁱⁱ AND one of the following used with a spermicideⁱⁱ: diaphragm, cap, or sponge.

ⁱ Male and female condom should not be used together.

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These options are also summarized in the table below:

Method	Use alone or in combination. ^{i,iii}
Hormonal method: birth control pills, patches, injections, vaginal rings, or implants.	Highly effective alone; needs no combination.
Intrauterine device (IUD).	Highly effective alone; needs no combination.
Condom (male) used with or without a spermicide. ^{i,ii}	To be used in combination with one of the following: diaphragm, cap, or sponge AND spermicide. ⁱⁱ
Condom (female) used with or without a spermicide. ^{i,ii}	To be used in combination with one of the following: diaphragm, cap, or sponge AND spermicide. ⁱⁱ
Diaphragm, cap, or sponge used with a spermicide. ⁱⁱ	To be used in combination with male or female condom ⁱ , with or without spermicide.

The study doctor will explain these to you and your child so you understand the options available.

For female participants, if your child misses a period or thinks she might be pregnant during the study, you/your child must tell the study doctor right away. If your child becomes pregnant, her treatment might be changed and she might stop taking part in the study.

Male participants do not have to stop taking the study drugs or stop taking part in the study if their partner becomes pregnant. You or your child should let us know immediately if your child's partner becomes pregnant.

In both cases, the study doctor will ask for permission to collect information about the outcome of the pregnancy of your child/your child's partner and the condition of the newborn.

Risks of Taking the Study Drugs with Other Medicines

Some drugs are not safe to be taken with the study medicines, or may not work when taken with the study medicines. Please tell and consult with the study doctor if, at any time during the study, your child's doctor prescribe or your child begins using any other medicines.

For your child's safety during this study, talk to the study doctor BEFORE your child takes any:

- new medicines prescribed by another doctor;
- other medicines sold over-the-counter without a prescription;
- dietary or herbal supplements.

ⁱⁱ Spermicide: a foam cream or gel that kills sperm.

ⁱⁱⁱ Withdrawal (coitus interruptus) and/or periodic abstinence during fertile times are unacceptable on their own but may be used in combination with any highly effective method or acceptable combination.

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Risks of Blood Draws and Administration of Medicine through Veins

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. Bleeding and nerve injury are possible with repeated injections.

If your child's treatment plan requires frequent needle pricks for medicine administration or blood draws, your child's doctor might recommend inserting CVAD (Central Venous Access device). It is a small tube inserted in your vein (mostly arm) which will be used for giving medications and collecting blood. The tube can safely stay in your arm for a few days at a time or up to a few months. CVAD can help avoid the pain of frequent needle sticks and reduce the risk of irritation to the smaller veins. It is possible that bleeding, blood clots, irregular heartbeat, pneumothorax (air outside of the lung), nerve injury or infection could happen. It is also possible that the tube could get blocked, or break, and would have to be replaced.

What are the possible benefits from being in this study?

By participating in the study, the child's treatment may be all-oral and shorter than the current treatment recommended for MDR-TB with FQ resistance. We do not know if these shorter treatments work better than the currently available standard treatment. Some patients will need their treatment to be changed; if your child participates in the study, the study doctor will have more information about how best to change your child's treatment. The study doctors can also take care of your child's side effects sooner and better by having extra tests in the study.

Your child will receive more treatment support in the study than you would outside the study. Others with MDR-TB with FQ resistance may benefit in the future from what we learn in this study.

What other treatments or procedures are available for my child's condition?

Your child does not have to be in this study to get treatment for MDR-TB with FQ resistance. Other treatment is available in your country through [local TB care provider/entity]. This treatment is similar to that in the control arm in the study. Talk with the study doctor if you or your child have questions about the other treatment.

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

Yes. Taking part in this study is completely up to you and your child. Your child can decide not to take part. Your child will receive treatment through [local TB care provider/entity] if your child does not take part in this study. You and your child will not lose any benefits you have the right to receive. Treatment outside the study is also free of charge.

What should we do if we want to stop being in the study?

If you or your child decide to stop being in the study, we will make sure that your child stops the study safely.

We will talk to you about follow-up care your child might need, and your child will be encouraged to come back at least for one additional study visit.

And, we will tell you and your child if we learn any new information that could make you or your child change your mind and choose to leave the study.

Information collected while your child is in the study will be used to help answer study questions. When your child leaves the study, his/her information may still be used for the study.

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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 study?

You and your child will not be paid to be in this study. We will pay transportation costs for study visits. You or your child will also receive [local arrangement for monthly food supplements] when your child takes part in the study. In sum, you or your child will be reimbursed [local currency] _____ for transportation for the baseline visit, [local currency] _____ for each follow-up visit, [local currency] _____ for any unscheduled visits and [local currency] _____ for your child's final visit.

What will we have to pay for if my child takes is in in this study?

You and your child will not have to pay to be in this study. You and your child will also will not have to pay for the study drugs, or for any study-related procedures, and visits.

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

If your child suffers injury as a direct result of participation in this study, the sponsor has made insurance arrangements to pay for any injury your child may suffer. If this happens, please inform your doctor and seek medical attention right away. The sponsor will ensure that your child receives appropriate medical treatment.

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

In an emergency, the sponsor has made plans to pay for a specialist visit, related treatment, and/or a hospital stay. For non-urgent situations, the sponsor may pay for your child to see a specialist. The study team will review your child's situation and decide whether the sponsor will pay for the resulting treatment if your child's condition is not the result of his/her participation in the study. You and your child do not waive any of your legal rights by signing this consent form.

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

If you have questions about this study, you can contact [PI Name and title] at [PI telephone number]. You or your child can also call [Clinical Investigator] at [CI number] with questions about this study. If you or your child 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 site licensed physician investigator here].

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

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

We are careful to protect the identity of people 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

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[*Research site*]. Your child's study 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 records may be looked at by institutions responsible for quality and privacy, such as the sponsor, Ethics Committee and other Authorities.

For the study, 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 the study 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 study 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 resistance to FQ: your child's 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.

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endTB-Q Research Parental Informed Consent and Authorization

Your child completed the screening process of this study and is eligible to take part, or he/she completed the screening process for another study (endTB) and was found to be eligible for this study (endTB-Q). In the second case, you agree that your child's data and personal information collected during endTB screening will be used for the endTB-Q study.

Your signature on this document means the following:

I have read this consent form. This study 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 a parent/guardian of the patient. I will receive a complete, signed, dated copy of this research parental consent form.

By signing below, I give my permission to let my child take part in this study.

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 study.

Signature of study representative Date (DD/MMM/YYYY) and Time

Name of study representative, printed in capital letters

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endTB-Q Research Adult Consent/Assent Form Addendum
Storing Isolates (strains) and Health Information Future Use

Your child's health information and bacteria isolates (TB bug) collected during the study 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 study 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.

endTB-Q Clinical Trial
Research Parental Consent Form

Version 4.3 Version Date: 05 Jul 2022

SUBJECT IDENTIFICATION

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 my child's participation in the endTB-Q study 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 a 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.

Signature of study representative

Date (DD/MMM/YYYY) and Time

Name of study representative, printed in capital letters