

endTB Clinical Trial
Research Parental Consent Form

Version 3.3 Version Date: 14 February 2019

Subject Identification

Protocol Title: endTB (Evaluating Newly approved Drugs for multidrug-resistant TB)

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

Please read this form, called research parental consent form, carefully. It tells you important information about this study, called endTB. A member of our research team will also talk to you and your child about taking part in this study. People who agree to be in the study are called “participants” in this consent form. Recruitment of participants for this study has been approved by the [Research Center Ethics Committee] [and the applicable national regulatory authority].

You have the option of having your child join a study. If you have any questions about the research or about this form, please ask us. Taking part in this study is 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.

If you decide to let your child take part in this study, we will ask that you sign this form to confirm that you want him/her to take part. 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 take part in the study, by signing an assent form. Your child will be free to refuse to take part in the study even after you give permission for him/her to participate. His/her decision not to take part cannot be over-ridden by your decision. Your child can also decide to stop taking part in this study at any time if you or your child does not want to, even after signing this form.

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.

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Introduction

Your child has been asked to join a study called endTB clinical trial. Researchers want to know what combinations of drugs work better for people who have multi-drug resistant tuberculosis (MDR-TB). Drugs work differently in different people, and it is not clear what combination of drugs is best for any one person. The new combinations of drugs used in this study are called “experimental”; they have been used before but we do not know how well they work together.

We are asking your child to take part in this study because he/she is at least 15 years old and has tuberculosis that is affecting his/her lungs. Your child completed the screening process of this study and is eligible to take part. During the study, we will do some more tests to make sure that your child may safely take part. 750 participants in 7 countries will participate in this study. About [number to be locally adapted] participants will take part at [Research Center Name].

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

Why is this study being done?

Current treatment for MDR-TB has 5-9 drugs taken daily for 18 to 24 months. During at least six months, treatment includes a daily needle shot. 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 containing at least one of these drugs may be shorter for example, 9 months and/or simpler (without injection). Such treatments must be tested to see if they are safe and work well for people with MDR-TB. We are asking you to take part in this study to compare new experimental treatment regimens to the current treatment for MDR-TB.

How long will my child take part in this study?

It will take your child between 1.5 to 2 years (73 to 104 weeks) to complete this study. During this time, we will ask you and your child to make 26 to 30 study visits to [Research Center Name]. All study visits will take place at [Research Center Name].

What will happen in this study?

If your child chooses to take part in this study, we will ask your child to sign the assent form and you to sign this parental consent form before we start the study with you. If your child is currently taking any medications that can't be taken with your study drugs, s/he may need to stop these medications before starting the study drugs. Your child's doctor may prescribe new drugs instead of your child's current medications. This could make your child feel bad. If this happens, please tell the study doctor. If your child's medications 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 take part in this study.

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At the beginning of the study, patients will be assigned by chance (like rolling a dice) to one of 6 treatment groups described below. Most patients will get one of the experimental treatments. A smaller number will get the regular treatment for MDR-TB. We don't know exactly how many patients will get each treatment because, as we learn how the different treatments are performing, more patients will be assigned to the treatments that are helping more patients. You, your child and the study doctor cannot choose your child's study treatment group.

If your child is assigned to an experimental treatment, he/she will get 4 or 5 study drugs that will be taken by mouth. Your child will take the study drugs for 39 weeks (9 months).

If your child is assigned to the control treatment, he/she will get the treatment used for MDR-TB according to current practice in your country and to international guidelines from World Health Organization. Your child will receive medications by mouth and by needle shots. The treatment will last for [18 to 24 months *to be adapted if short regimen accepted*].

If your child is receiving an experimental regimen with linezolid, one of the drugs used for MDR-TB, we will change his/her linezolid dose after about 4 months of treatment or earlier if s/he is having important side effects that might be caused by linezolid. We are looking at two ways to lower the total dose of linezolid: in one, we reduce the daily dosage (dose still daily but lower - for example, 1 pill instead of 2 pills every day) or by giving it less often (same dose but not every day; for example, 2 pills every 2 days instead of 2 pills every day). We do not know if one way is better than the other.

If your child is receiving an experimental regimen with linezolid, one of the ways of lowering the linezolid dose will be assigned to him/her by chance. You, your child and the study doctor cannot choose how linezolid dose will be reduced.

For all your child's study drugs at all times during treatment, your child's study doctor will tell you how many pills of each drug he/she will take. Study staff will teach you and your child how, how often and where your child should take his/her medications and for how long. Your child must follow these instructions carefully and should not stop taking the study drugs without telling the study workers. A study worker [*to be adapted locally based on the setting for DOT/treatment support*] will be with your child every time he/she takes his/her study drugs and bring all the unused study drugs back to the [Research Center].

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 and, if needed, discuss ways to help your child keep taking his/her study drugs and go to 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 doctors who may be treating him/her, of his/her participation in the study.

You and your child will go to the [Research site name] for study visits until at least 73 weeks (17 months) and possibly as late as 104 weeks (24 months) after your child start his/her study treatment. The exact time your child will spend in the study will depend on the overall progress

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of the study. Your child might still be on treatment at the end of the study; if so, 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. 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 take part in the study.
- Ask about your child's job and schooling.
- Ask about any changes in your child's medical history or medicines being taken since the screening visit. The study doctor might change some of your child's medications and will discuss and recommend birth control methods so your child can avoid pregnancy (himself/herself or his/her partner) while taking study medications.
- Ask about your child's smoking or alcohol use. *[to be moved to screening parental consent if applicable]*
- Perform a brief exam and ask about TB symptoms.
- Check your child's vision, hearing, movement, mental health status, and ask about his/her daily activities.
- Collect ½ tablespoon of blood for laboratory testing (we might not do some of these s/he has had these tests recently); and for a pregnancy test if your child is a woman who can get pregnant. The pregnancy test might be repeated if the study medications are started a few days after the first test.
- Do an electrocardiogram to check if his/her heart is working normally;
- Depending on what tests your child has had recently, we might:
 - Collect ½ tablespoon of blood for CD4 and HIV viral load testing if your child is HIV-infected.
 - Ask your child to cough up a sputum specimen if he/she does not already have one test result from the study laboratory to show the TB germ is resistant to rifampin and susceptible to fluoroquinolone.
 - Perform a chest X-ray.

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

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. At each visit, our study worker will schedule the next visit and write the date on your child's study identification card. If your child needs to change a visit date, please let the study worker know as early as possible. Each visit will take about 1 ½ hours including waiting time.

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

Doctor's exams:

At each visit, we will:

- Ask about any changes in your child's medical history and any change in medicines he/she is taking since the last visit. The study doctor may change some of your child's prescriptions if s/he is taking medicines that can have interactions with drugs in his/her TB regimen.
- Perform a brief exam and ask your child about TB symptoms and how he/she is feeling.
- Check if your child is taking his/her study medications correctly and answer all your questions.
- If your child is a woman who can get pregnant, we will ask her about her last menstrual period and use of birth control methods. The study doctor might do a pregnancy test.
- The study doctor will discuss and recommend birth control methods so she can avoid pregnancy (herself or her partner) while taking study medications.
- If s/he is affected by other diseases, for example hepatitis C, we might collect the exam results that his/her doctor will prescribe according to clinical routine practice.

Other special exams

- Electrocardiograms will be done to check your child's heart at every visit until Month 12, then once again at Month 17 (25 times).
- Your child's vision, hearing, and movement status will be checked every 4 weeks until Month 8, then at Months 9, 10, 11, 17, and 24* (up to 15 times).
- Your child's ability to carry out his/her daily activities will be reviewed at Months 9, 17, and 24*.

* Exams after Month 17 will be conducted only if your child study follow-up is still ongoing.

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- Your child's mental health status will be checked at Months 17 and 24*.
- A chest X-ray will be done at Months 2, 9, 17 and 24*.

Collecting your child's sputum samples

- Your child will provide 2 sputum samples to our study workers every 2 weeks for the first month for the study, then at Month 2, and then at every visit after Month 3 until study completion.
- Your child must follow our study workers' instructions on how to collect and pack his/her samples properly.

Collecting your child's blood samples

- One tablespoon of blood will be collected at the clinic to check for possible side effects approximately every 4 weeks until Month 11.
- 1/2 tablespoon of blood will be collected for CD4 and HIV viral load at Months 6, 11 and 17 if your child is HIV-infected.
- 1/2 tablespoon of blood will be collected to check blood sugar at Months 6, 11, and 17 if your child has abnormal blood sugar level at screening/baseline visit.

Stopping or withdrawing from the study early

If your child starts the study and decides he/she wants to stop, you should tell us. We will make sure that your child stops the study safely. We will ask your child to make a termination visit. At this visit, we will:

- Ask your child about changes in his/her medical history and in medicines he/she is taking since the last visit.
- Perform a brief body exam and ask your child about TB-related symptoms and how he/she is feeling.
- Check your child's vision, hearing, movement, functional and mental health status.
- Obtain 2 tablespoons of blood for laboratory testing.
- If your child is a woman who can get pregnant we will ask her about her last menstrual period and use of birth control methods. The study doctor might prescribe her a pregnancy test.
- Collect 2 sputum specimens.
- Do an electrocardiogram to check your child's heart.
- Do a chest X-ray (unless recent results are available).

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We will talk to you and your child about follow-up care, if needed.

Also, the study doctor might decide to take your child out of the study before he/she finishes it. This might happen because:

- Your child is a female participant and become pregnant.
- The study doctor thinks it is best for your child to stop taking the study drug.
- Your child can't make the required study visits.
- We stop doing the study for any reason.

If this happens, the study doctor will explain why your child needs to stop taking part in the study. We will invite you and your child to come in for the termination visit as described above. We will also help arrange other care for your child, if needed.

If your child's study termination occurs before Week 39 (Month 9) or before Week 73 (Month 17), we will ask you and your child to come back for follow-up visits at the time of Week 39 and Week 73.

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

- Ask about changes in your child's medical history and in medicines s/he is taking since the last visit.
- Perform a brief body exam and ask about TB-related symptoms and how you s/he is feeling.
- Collect 2 sputum specimens.
- Unless recent results are available, we will:
 - Do a chest X-ray,
 - Collect up to 1/2 tablespoon of blood sample to measure his/her sugar level if it was abnormal when your child started the study,
 - Collect up to 1/2 tablespoon of blood sample for CD4 and HIV viral load testing if your child is HIV-infected.

The termination visit or the Week 73 follow-up visit will be his/her last visit for the study.

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 disease will be done by his/her regular doctor.

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If your child completes the study with side effect(s) that are not yet resolved, the study doctor may contact you and your child until the side effect goes away or is stable.

If you or your child decide to leave the study or if your child is taken out of the study early, and s/he still has ongoing side effect(s) at this time, your study doctor may contact you and your child until the side effect goes away or is stable. You might also be contacted by your study doctor if your child experiences a new side effect.

Please let your study doctor know if you do not want you and your child to be contacted even for updates on the ongoing side effects. You and your child do not have to give any information that you don't want to.

Managing Samples and Health Information in the Study

We will label all your child's samples and health information with a code instead of his/her name to keep all your child's information private. The key to the code connects your child's name to his/her samples and health information.

The bacteria isolates from your sputum samples might be tested for drug resistance confirmation and further analyses on the bacteria in a specialized laboratory in Belgium.

Storing Isolates (strains) and Health Information for Future Research

We would like to store some of the bacteria isolates (TB bug) and your child's health information for future research related to TB, which will be collected during this study. All your child's health information and bacteria isolates will be handled in a way to keep all his/her information private. Any use of stored bacteria isolates and your child's health information for other research inside your country or in other countries will be approved by the ethics committee of your country.

This future research is independent from your child's participation in the endTB- study and your decision to let your child participate in the future research will not affect your child's participation in the study.

The bacteria isolates found in his/her sputum samples and his/her health information may be stored for up to 20 years in a special place (bank or repository) created to safely store them. The stored isolates and your child's health information will be used only to help future research in TB and to improve diagnosis (including resistance testing) and treatment of TB. During your child's participation in the endTB study, and the following storage period of 20 years after completion of the study, you can contact the study doctor or the email address endTB.clinicaltrial@paris.msf.org to request any information regarding the use, storage and location of your child's health information and bacteria isolates.

Do you agree that your child's health information and the bacteria isolates collected from his/her sputum samples may be stored for 20 years and used only for future TB research? You are free to

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refuse such storage and further use for TB research of your child's health information and bacteria isolates and still have your child taking part in the study.

☐ Yes ☐ No [Initials or signature, to be adapted locally]_____

You and your child have the right to change your mind and to later want your child's health information and/or bacteria isolates destroyed. In that case, during your child participation in the endTB study, and the following storage period of 20 years after completion of the study, you can contact your child's study doctor or the email address endTB.clinicaltrial@paris.msf.org to request any information regarding the use, storage and location of your child's health information and bacteria isolates and/or their destruction.

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

Risks of Taking Study Drugs:

Your child will take a combination of MDR-TB drugs when he/she is on this study, whether your child gets an experimental treatment or the control treatment. The drugs used in the control are the nation's standard MDR-TB medications, according to international guidelines from World Health Organization. Experimental treatments will use together 4 or 5 of the following drugs: bedaquiline, delamanid, clofazimine, linezolid, moxifloxacin, levofloxacin, and pyrazinamide.

Medications for MDR-TB have different side effects. We do not know which of the combinations is the easiest to take. Your child's 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 document entitled "participant information leaflet" that summarizes the main side effects. There may be other risks of the study drugs that are not known yet. Your child will be closely followed through clinical, laboratory and other examinations (hearing test, heart test) in order to detect and treat promptly possible side effects. Your child's doctor will explain more in detail when you or your child should get in touch with him/her.

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

Some of the drugs may have an effect on an embryo or fetus (developing baby still in the womb), or on a breastfeeding infant. It is possible that this effect is unknown and may be harmful. Because of these unknown risks, women cannot start this study if they are:

- known to be pregnant;
- trying to become pregnant;
- unwilling or unable to stop breastfeeding an infant.

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If your child is female and has had any well-documented method of surgical sterilization, she will not need to have a pregnancy test. Methods of surgical sterilization include having had a hysterectomy (removal of the uterus), bilateral oophorectomy (removal of both ovaries), a tubal ligation (having your tubes tied), and transvaginal occlusion (plugging the opening of the tubes with a coil). All other women must have a negative pregnancy test before starting the study drugs.

Regardless of your child's sex, if he/she is sexually active and able to become pregnant or father a child, your child must agree to abstain from sex (have no sex) or to use two of the birth control methods listed below while taking study drugs. Your doctor may also discuss with you and your child the use of birth control after your child finishes taking his/her study drugs.

Acceptable female birth control methods for use in this study are:

- Hormonal methods, such as birth control pills, patches, injections, vaginal rings, or implants.
- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm).
- Intrauterine device (IUD).

Acceptable male birth control methods for use in this study are:

- condoms with spermicide (a foam, cream, or gel that kills sperm).

For female participants, if your child misses a period or thinks she might be pregnant during the study, you must tell the study doctor immediately. *[to be adapted locally]* If your child becomes pregnant, her treatment might be changed and she might stop taking part in the study. The study doctor will ask for permission to collect information about the outcome of her pregnancy and the condition of her newborn.

For male participants, if a female partner becomes pregnant, we would like to follow the outcome of the pregnancy. You or your child should let us know immediately if your child's partner becomes pregnant. Your child will not have to stop taking the study drugs or stop taking part in the study if his partner becomes pregnant.

In both cases, the study doctor will ask for permission to collect information about the outcome of the pregnancy and the condition of the newborn.

Risks of Taking the Study Drugs with Other Medications

Some drugs are not safe to be taken together with the study medications, or may not work when taken with the study medications. Please inform and consult your study doctor if, at any time of the study, your child is prescribed or begin using any other medications.

For your child's safety during this study, call your study doctor BEFORE your child takes any:

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

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 in this study?

By participating in the study, your child may receive a shorter all-oral treatment compared to the current treatment recommended for MDR-TB. There is no guarantee that any of these shorter treatments will work better than the current [18 to 24 – to be adapted if short regimen available] months standard treatment. During this study, we will learn more about the treatments and use the information to assign more patients to treatments that are helping other patients. When your child receives the study drugs, we expect his/her medical condition/symptoms to improve. It is also possible that the TB bacteria are or become too strong to be killed by the study drugs he/she receives. If that happens, the study doctor will change your child's treatment. Your child will have more tests that allow the doctors to know what kind of anti-TB drugs cannot fight the TB bacteria in his/her body, so the doctors will know if your child need any special treatment. The study doctors can also take care of your child's side effects sooner and better by having those extra tests. However, it may be harder for your child to be cured if very few drugs work against his/her TB bacteria.

Your child will receive greater treatment support from the study team throughout the study than during regular MDR-TB treatment. Others with MDR-TB 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 take part in this research study to be treated for MDR-TB. Other treatment is available to treat MDR-TB in your country through [local TB care provider/entity]. This treatment is similar to that in the control arm in the study [18-24 months to be adapted if short regimen accepted] of combination therapy, including about 6 months of a daily shot). 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 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. There will be no penalty, and you will not lose any benefits you receive now or have a right to receive. The treatment outside the study is also free of charge.

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

If your child takes part in this study and decides that he/she wants to stop, you or your child should tell us. We will make sure that your child stops the study safely.

Also, it is possible that we will have to ask your child to leave the study before he/she finishes it. If this happens, we will tell you and your child why.

We will tell you and your child if we learn any new information that could make you or your child decide that your child will leave the study.

If any of these happens, we will talk to you about follow-up care, if needed, and you will be encouraged to come back at least for one additional visit (“termination visit”).

Information collected during your child’s participation will be used to help answer study questions. When your child leaves the study, his/her health information, and information obtained from sputum samples and bacteria isolates previously collected may still be used and stored for 20 years for the study and future TB research. However, if you and your child prefer this information is not used and that it is destroyed, you can contact your child’s study doctor or the email address endTB.clinicaltrial@paris.msf.org.

Will we be paid to take part in this study?

You and your child will not be paid to take part in this study. We will pay the 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 part in this study?

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

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

The sponsor has made insurance arrangements to pay for an injury your child suffers due to his/her participation in the study.

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If your child suffers physical injury from this study please inform your doctor and seek medical attention right away, _____ will ensure that your child receives appropriate medical treatment.

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

In an emergency, the study sponsor has made plans to pay for your child's visit to a specialist, the related treatment, and/or your child's stay in the hospital. For non-urgent situations, the sponsor may pay for your child's visit to see a specialist. The study team will review you and your child's situation and decide whether the sponsor will pay for the resulting treatment if your condition is not the result of your participation in the study.

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

You or your child can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you or your child want.

[PI Name and title] is the person in charge of this study. You or your child can call him/her 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 the people in this study to the extent permitted by law. We also keep your child's information secure and confidential. Electronic study information will be password-protected, and paper files will be stored in a locked office at [Research site]. Your child's study records will be kept at the clinic/hospital for XX years [to be adapted locally] following the completion of the study. If needed to monitor the study quality, your child's study information may be looked at by institutions responsible for quality and privacy such as the sponsor, Ethics Committee and Competent 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].

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The information collected for the study will be used for the following purposes:

- For the purposes of this study. The sponsor, the study doctor, or other doctors involved in the study may publish reports or articles on the study or present screening findings to scientific groups. After the study is completed, you may see your child's records, and you may be told the results of the study.
- Secondary use for TB research; your child's coded information may be used and shared with other institutions only for the purpose of further TB research during and after completion of the study and notably with the World Health Organization.

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

Your child's coded information may be sent electronically to other researchers or institutions. If sent, it will be encrypted (scrambled so it can't be read by people who shouldn't see it).

We guarantee that, when we send your coded information, it will be protected according to European Economic Area standards.

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Informed Consent and Authorization

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 I 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 participant. 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 of Parent/Guardian of the Participant

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

Witness (if applicable):

Signature of witness

Date (DD/MMM/YYYY) and Time

Name of witness, printed in capital letters

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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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Subject Identification

Schedule of Visits

Visit	Consent	Doctors' Exam	Nurses' Interview	Blood Collection	Sputum Collection	ECG	Chest X-ray
Baseline	✓	✓	✓	(✓)	(✓)	✓	(✓)
Week 1		✓	✓			✓	
Week 2		✓	✓		✓	✓	
Week 3		✓	✓			✓	
Month 1		✓	✓	✓	✓	✓	
Week 5, 6, 7		✓	✓			✓	
Month 2		✓	✓	✓	✓	✓	✓
Week 9, 10, 11		✓	✓			✓	
Month 3, 4, 5, 6, 6.5, 7, 8		✓	✓	✓	✓	✓	
Month 9		✓	✓	✓	✓	✓	✓
Month 10, 11		✓	✓	✓	✓	✓	
Month 12		✓	✓		✓	✓	
Month 13.5, 15		✓	✓		✓		
Month 17		✓	✓	(✓)	✓	✓	✓
Month 19, 20, 22*		✓	✓		✓		
Month 24*		✓	✓	✓	✓		✓