

endTB-Q Clinical Trial

Pregnant Partner 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): _____

Partner Study Subject ID: _____

About this consent form

You are being asked to provide information for a study, called endTB-Q, because your partner is participating in this study and you are pregnant. This pregnant partner consent form is written to help you understand the endTB-Q study and decide if you agree to provide information on your pregnancy and the birth and health of your baby. A member of our study team will talk to you about 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 participation.

Providing information for this study is completely up to you; you do not have to provide information for this study if you do not want to. After you have had time to ask questions and think about it, we will ask you to sign if you agree to provide information. We will give you a signed copy of this form to keep.

Even after signing this form, you can change your mind.

If you are not able to sign the consent form, but you would like to provide information, you can choose someone you know to sign for you and you can make a thumbprint to show that you understand the study and agree to provide information.

Introduction

Some of the drugs that your partner is taking during his participation in the study endTB-Q may move into the semen. This is why when he started in the study, your partner was asked to use birth control while taking the study drugs. The effects of your partner's study treatment on pregnancy and the developing fetus (baby still in the womb) are currently not known or not fully understood. For this reason, we would like to collect medical information about your pregnancy and the birth and health of your baby. We want to follow your pregnancy and try to find out if the study treatment has any effect on your pregnancy and the health of your baby.

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.

What will happen if I agree to provide information about my pregnancy?

If you agree to sign this consent form, we will review and collect medical information about your pregnancy, the delivery of your baby and the health of your baby at least at 6 and 12 months of age.

Will anything bad happen to me?*Risks of Providing Information about Your Pregnancy:*

We are careful to protect the identity of people in this study to the extent permitted by law. We will also keep your and your baby'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 and your baby's 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 and your baby'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 you and your baby, such as 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 this 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 with scientific groups. After the study ends, you may see your and your baby's records, and you may be told the study results.
- To make new recommendations about treatment of MDR-TB with resistance to FQ: coded information about you and your baby may be used and shared with other institutions, during and after completion of the study, notably with the World Health Organization.

Your identity will never be disclosed.

If coded information about you or your baby 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.

What are the possible benefits?

There are no direct benefits to you or your baby for providing information relating to your pregnancy. However, we hope that the information we gather about your pregnancy will help future patients and their children by helping us understand the potential effects of the study medications on pregnant women and developing babies.

What should I do if I want to stop providing information about my pregnancy?

If you decide to stop providing information to this study or if you change your mind later, you should tell us.

Information collected from you will be used to help answer study questions. When you leave, your information may still be used for the study. If you do not want this information to be used, and you want it to be destroyed, please contact your study doctor or the email address endTB.clinicaltrial@paris.msf.org.

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Will I be paid to provide information about my pregnancy?

This study will not cover any costs related to your pregnancy, delivery or care of your baby.

What will I have to pay for if I provide information about my pregnancy?

The sponsor will cover the costs of collecting medical information on you and your baby. There will be no cost or payment to you.

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

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

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

Informed Consent and Authorization

Your signature on this document means the following:

I have read this consent form. It has been explained to me why it is useful to collect data about pregnancy, delivery, and the health of my baby. I have had the opportunity to ask questions. I understand the information given to me.

I recognize that my participation is voluntary and that I can refuse or stop providing information 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 pregnant woman. I will receive a complete, signed, dated copy of this informed consent form.

By signing below, I agree to provide information about my pregnancy, delivery, and the health of my baby.

Signature or thumbprint of pregnant partner

Date (DD/MMM/YYYY)

Time

Name of pregnant partner, printed in capital letters

If applicable, Signature of witness

Date (DD/MMM/YYYY)

Time

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

I have explained collection of information to the pregnant partner and have answered all of her questions. She understands the information described in this document and accepts voluntarily to provide information about her pregnancy, delivery and health of her baby for the endTB-Q study.

Signature of representative

Date (DD/MMM/YYYY)

Time

Name of study representative, printed in capital letters