

Information and Assent Form
Ages 7-17
Additional Facility Sites
Sanofi Pasteur Inc.
STA00011

INFORMATION AND ASSENT FORM
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Program Name: Expanded Access IND Program to Provide Stamaril® Vaccine to Persons in the United States for Vaccination Against Yellow Fever

Program Number: STA00011

Sponsor: Sanofi Pasteur

Program Health Care Provider: Michael Sauri MD

Travel Advisory and Immunization Clinic
2301 Research Blvd., Ste. 125
Rockville, MD 20850

Telephone Number: (301) 738-6420

After Office Hours: (301) 738-6420

Sponsor's Primary Investigator:

Dr. Riyadh Muhammad
Sanofi Pasteur
1 Discovery Dr., Ste. 391T, Swiftwater, PA 18370

This form tells you why we are doing this program. It is important for you to read all of this form. This form will help you decide whether or not you want to get the yellow fever vaccine we are giving in this program.

If you do not understand anything in this form, please ask your parents or guardian to explain it to you.

You can ask the doctor or nurse questions before you make up your mind. You can ask to read the information the doctor gives your mom or dad about this program.

You do not have to be in the program if you don't want to.

What is this program about?

Yellow fever is caused by the bite of an infected mosquito. Yellow fever is found in parts of Africa and South America.

The only yellow fever vaccine approved in the United States is called YF-VAX®. It is made by Sanofi Pasteur. This vaccine is not available at this time.

In this program, you can get a yellow fever vaccine that is like YF-VAX. This vaccine is called Stamaril™. This vaccine is also made by Sanofi Pasteur. But, Stamaril vaccine is not approved in the United States. Stamaril vaccine is approved in other countries.

The doctor will check that it is okay for you to get the Stamaril vaccine.

This program involves one trip to the doctor's office to have the vaccine injected.

If you do not want to get an injection, you can say you do not want to be in the program.

Can anything bad happen to me in this program?

After the vaccination, these things may happen where the shot is given:

- pain
- redness
- bruising
- swelling (a bump)

These things can also happen:

- You may feel tired or weak and generally not feel well
- You may have a fever (feeling hot)
- You may have problems with your stomach
- You may have pain in your joints or muscles
- You may get a headache
- You may feel tired or not hungry
- You may feel tingling or pricking like "pins and needles"
- You may get a flu-like illness

If these things happen, they usually go away after a few days.

In addition, you may faint after, or even before, any needle injection.

The doctor or nurse will watch you for 20 minutes after you get the injection.

The most serious health problems that may happen after vaccination with a yellow fever vaccine, including the Stamaril vaccine are very rare. These happen mostly in adults 60 years of age and older. These are described below.

- One problem may cause problems with pumping of blood, a lot of muscle pain, yellow color of skin or eyes, and bruising or bleeding. This problem also causes a higher chance of getting sick, and kidneys and lungs not working like they should. This is very serious.
- The other problem starts with high fever with headache, confusion, and stiff neck. It can cause jerking or loss of movement or feeling in the body. Most of the people who had this disease got better.

Sometimes people have an allergy to medicines or shots. This could be very serious. Here are some things that could happen if you have a serious allergy:

- a rash (red or rough skin)
- heart beating fast
- sweating
- a feeling of fear
- swelling near the eyes and/or involving the mouth or throat
- wheezing (whistling) when you breathe
- feeling dizzy or lightheaded
- a hard time breathing

You might also feel other things. While you are in the program, you have to tell the doctor or your mom or dad if you feel sick or if you take any medicines. You or your mom or dad can tell the doctor.

If you are a girl and become pregnant, the vaccine could cause problems for you or your baby. You should talk with your parents and doctor about the risks and benefits of getting the vaccine during pregnancy. After you get the vaccine, you or your parents will be asked to tell the doctor as soon as possible if:

- You find out that you were pregnant at the time you got the vaccine
- You find out you are pregnant within 30 days after you got the vaccine.

If you are breastfeeding and want to get the vaccine, you must stop breastfeeding for at least 14 days after vaccination.

Do I have to get Stamaril vaccine in this program?

Please talk with your parents or guardian before you decide to get the Stamaril vaccine. We will also ask your parents or guardian to give their permission for you to get the vaccine. Even if they say "yes", you can still say "no". If you want to get the vaccine but your parents or guardian say "no", you cannot get the vaccine.

Being in this program is voluntary. Remember, being in the program is up to you and no one will be upset if you do not want to.

You can ask any questions that you have about the program. If you have a question later that you did not think of now, you can call the doctor or nurse.

Will getting this vaccine help me?

Stamaril vaccine helps to stop you from getting yellow fever. But vaccines do not protect all people. So, we cannot promise you that you will get any benefit from the yellow fever vaccine you get.

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WHO CAN I TALK TO ABOUT THE PROGRAM?

You can ask questions about the program at any time. You can call the doctor or nurse at any time. The doctor and nurse's phone number is on the first page.

If you want to ask questions about what it means to be in a research program, you or your mom or dad can call Quorum Review at 1-888-776-9115 (toll free).

If you sign your name at the bottom of this form, it means that you want to get the Stamaril vaccine.

We will give you and your parents or guardian a copy of this form after you sign it.

ASSENT FORM

Please sign below if you want to be in this program, but remember: You don't have to be in this program if you don't want to.

Printed Name of Minor Participant

Signature of Minor Participant

Date

I attest that the minor participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this program.

Printed Name of Person Explaining Assent

Signature of Person Explaining Assent

Date