

INFORMATION AND CONSENT FORM

For Adults Aged 18 and Older
Additional Facility Sites

Program Title: Expanded Access IND Program to Provide Stamaril® Vaccine to Persons in the United States for Vaccination Against Yellow Fever

Program #: STA00011

Sponsor: Sanofi Pasteur

Program Health Care Provider: Kimberly W. McDonald MD

Wake County by and through Wake County Human Services
10 Sunnybrook Rd.
Raleigh, NC 27610

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Sponsor's Primary Investigator:

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Sanofi Pasteur

1 Discovery Dr., Ste. 391T, Swiftwater, PA 18370

You are invited to take part in an Expanded Access Program of Stamaril vaccine. Stamaril vaccine helps protect against yellow fever virus. This document explains why this program is being carried out. It will help you decide whether you wish to take part. Taking part in this program is completely voluntary.

If anything in this document is unclear, or if you have any questions about this program, please ask one of the program team members.

If you experience any health problems after you receive the Stamaril vaccine, please contact the program health care provider.

If you agree to take part in the program, you will have to sign the informed consent form. You will be given a signed copy to keep.

Sanofi Pasteur is the company that makes Stamaril vaccine and is providing the vaccine and paying for this program.

The program health care provider will inject Stamaril vaccine as part of this program. The program health care provider is responsible for determining if you can receive Stamaril vaccine as part of this program.

Although Stamaril vaccine is not currently licensed in the United States (US), internationally, this vaccine has been approved for use in over 100 countries, including 28 countries in Europe.

Stamaril vaccine is considered to be an “investigational drug.” That means it is not approved for sale in the United States by the US Food and Drug Administration (FDA).

Because Stamaril vaccine has been used outside the United States for 30 years, the US FDA has approved its use under this Expanded Access Program until a stable supply of the currently licensed yellow fever vaccine (YF-VAX®) becomes available. Stamaril and YF-VAX are vaccines that help prevent yellow fever, and their benefits and risks are expected to be similar. Both vaccines are manufactured by Sanofi Pasteur.

While you are in the program, you must:

- Follow the instructions you are given.
- Tell the program health care provider about any changes in your health or the way you feel.
- Tell the program health care provider if you want to stop being in the program at any time.

What is yellow fever?

Yellow fever is a mosquito-borne disease that is caused by a virus. The virus causes a wide range of health problems, from mild symptoms to severe illness and death. Yellow fever is widespread in sub-Saharan Africa and tropical South America and continues to be a significant health problem to residents of countries where yellow fever is regularly found and non-vaccinated travelers entering these countries.

Are there other vaccines, medications, or treatments available to prevent or treat yellow fever?

The only yellow fever vaccine licensed in the United States is YF-VAX manufactured by Sanofi Pasteur. YF-VAX is temporarily not available.

Like YF-VAX, Stamaril vaccine contains a live but weakened yellow fever virus. Stamaril vaccine, like YF-VAX, should not be administered to persons who have an allergy to vaccine ingredients, to eggs or to chicken proteins, a poor or weakened immune system, and a medical history of problems with the thymus gland, including removal of the thymus gland for any reason.

Stamaril vaccine has been licensed in other countries since 1986; over 400 million doses have been distributed worldwide. The benefits and risks of Stamaril vaccine and YF-VAX are expected to be similar.

There is no specific treatment for yellow fever; however medicines can be used to help reduce the symptoms in seriously ill people.

You should discuss your alternatives to participating in this program with the program health care provider. In addition, you may discuss your options with your regular health care provider.

Why is the Program Health Care Provider suggesting to give you Stamaril vaccine instead of YF-VAX?

In agreement with the US FDA, during the non-availability of YF-VAX, an alternative yellow fever vaccine, Stamaril, manufactured by Sanofi Pasteur but not licensed in the United States, can be used within this Expanded Access program.

How will this program be done?

During the period when YF-VAX is unavailable, it is estimated that approximately 100,000 persons might receive Stamaril vaccine as part of this program.

Persons in the United States who are at high risk for yellow fever infection, including researchers, laboratory workers, vaccine production staff, and those traveling within 30 days to a region where yellow fever is found or to a country requiring proof of yellow fever vaccination under International Health Regulations will be offered Stamaril vaccine in this program.

The program health care provider who will vaccinate you will check, as part of routine practice before vaccination, that it is okay for you to receive Stamaril vaccine. No other procedures or tests will be performed as part of this program.

Your participation in this program consists only of administration of the vaccine according to routine practice during a single visit at the program health care provider's office/clinic.

What will happen after the end of the program?

There are no planned procedures after the end of the program (that is, after you receive vaccine). However, after receiving Stamaril vaccine, you will be asked to report to the program health care provider, who is identified on the first page of this form, any health problems that you experience after vaccination.

What are the risks and possible side effects of vaccination with Stamaril vaccine?

Ask the program health care provider if you have questions about the signs or symptoms of any side effects that you read about in this consent form.

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

The most frequently reported reactions include:

- **headache**
- **tiredness or weakness**
- **injection site reactions (such as pain, tenderness, redness, swelling)**
- **muscle pains**

Other common symptoms include fever, problems with your stomach, and joint pain. Young children may experience irritability, crying that does not stop with comforting, appetite loss, and drowsiness. These reactions **usually occur within the first 3 days following vaccination** (except fever, which is likely to occur between the 4th and the 14th day after vaccination), and usually last for not more than 3 days.

Other reported reactions include an abnormal sensation, typically tingling or pricking (“pins and needles”) and flu-like illness.

As with any vaccination, there is a **possibility of an allergic reaction**, such as:

- a rash
- itching or hives on the skin
- swelling of the lips or face
- swelling of the throat
- a fast pulse
- sweating
- a feeling of dread
- difficulty breathing
- a sudden drop in blood pressure (making you feel dizzy or lightheaded)
- inability to breathe without assistance

If such a reaction occurs, it is usually almost **immediately after the vaccination**. This is why you should remain under observation for 20 minutes after vaccination so that the health care provider can provide immediate medical attention, if needed. In addition, fainting can occur following, or even before, any needle injection.

You should get medical help and contact the program health care provider if you have any of these or any other side effects during the program.

The most serious adverse reactions that may happen after vaccination with a yellow fever vaccine, including Stamaril vaccine, are the occurrence of:

- **Yellow Fever Vaccine-Associated Acute Viscerotropic Disease (YEL-AVD) affecting vital organs similarly to yellow fever infection**
- **Yellow Fever Vaccine-Associated Acute Neurotropic Disease (YEL-AND) affecting the brain and nerves**

These reactions occur very rarely and may have a fatal outcome. The risk appears to be higher in those aged 60 years and over, although cases have also been reported in younger people.

- **YEL-AVD** has been reported to occur **within 10 days of the vaccination**. The reaction can resemble an infection with the yellow fever virus. It generally begins with feeling tired, fever, headache, muscle pain, and sometimes low blood pressure. It may then go on to a severe muscle and liver disorder with yellow color of your skin or eyes, drops in the number of certain types of blood cells resulting in unusual bruising or bleeding and increased risk of infections, and loss of normal functioning of the kidneys and lungs. Half of the people who suffered from this disease died and the other half recovered.

- **YEL-AND** has been reported to occur **within 1 month of the vaccination**. It generally begins with high fever with headache, confusion, and stiff neck. Inflammation of brain and nerve tissues may also cause seizures or loss of movement or feeling in part or all of the body. Most of people who suffered from this disease have recovered.

Note: If you develop any symptom suggestive of YEL-AVD or YEL-AND within 6 weeks after vaccination, you should inform your treating physician that you had received yellow fever vaccine and also notify the program health care provider who administered the Stamaril vaccine.

This is not a complete list of possible side effects. You may experience other possible side effects. The program health care provider who will inject the Stamaril vaccine may provide further information about possible side effects.

What to do if you experience health problems after the vaccination.

It is very important that you tell the program health care provider who vaccinated you with Stamaril vaccine about any health problems you experience after vaccination that in your opinion may be related to the vaccine.

If a serious health problem occurs – for example, one that requires you to go to the hospital or is an important medical event or illness – you, or a family member must tell the program health care provider as soon as possible, even if you think it was not caused by the vaccine, especially if the event occurs within 6 weeks of vaccination.

Contact information for your program health care provider is provided on the first page of this information sheet.

Pregnancy and Breastfeeding Risks

Pregnant women and breastfeeding women should review the risks and benefits of vaccination with the program health care provider. The vaccine may be dangerous to an embryo or fetus or to a breastfed infant.

If you are a woman and after receiving the vaccine you discover that you were pregnant at the moment of vaccination, or if you become pregnant within 30 days after vaccination, you must inform the program health care provider who vaccinated you as soon as possible. The program health care provider will keep in touch with you until the end of your pregnancy to check on your health and that of your baby. The program health care provider may ask for information about the pregnancy and the child's health at birth and may share this information with the sponsor.

If you are breastfeeding, you cannot receive the vaccine unless you stop breastfeeding for 14 days after vaccination.

If you accidentally breastfeed your infant/child less than 14 days after vaccination, inform the program health care provider right away. The program health care provider will keep in touch with you to check on your health and the health of your breastfed infant/child for at least 30 days

after vaccination. This includes women who are vaccinated during the final 2 weeks of pregnancy and breastfeeding less than 14 days after vaccination.

Other Risks

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the program health care provider if you would like to know more about how your information will be protected while you are in this program.

If the program health care provider staff learns any new information that might change your mind about continuing in the program, they will tell you about it.

What are the possible benefits for you?

Stamaril vaccine has been shown to help prevent yellow fever virus infection. However, vaccination does not protect 100% of individuals. As a result, there is no promise or guarantee that you will get any benefit from the yellow fever vaccine administered as part of this program.

What will happen if you choose not to take part in the program, if you change your mind after you agreed, or if you are removed from the program?

You are free to refuse to take part in the program. If you agree to take part but later change your mind, you will be able to stop at any time. You will not have to give any reason to explain your decision. There will be no penalty to you, and you won't lose any benefits.

Whatever you decide, the medical care you have the right to receive will continue.

If you leave the program, the program health care provider will still be able to use your information that they have already collected.

Will you have to pay for anything?

Your program health care provider will discuss any charges with you.

Your health-care payer/insurer might not cover the cost of the vaccine or costs related to vaccine administration.

You should contact your health-care payer/insurer to see if your plan will cover the costs of vaccination.

What if you get hurt or sick while you are in this program?

If you develop any serious medical problems after receiving Stamaril vaccine and if it was caused by the vaccine, you will be paid back all medical costs that are directly related to the medical problems.

Sanofi Pasteur has an insurance to cover any possible risk/event related to your participation.

You do not give up any of your legal rights by signing this form.

Be aware that your health care payer/insurer might not cover the costs of program-related injuries or illnesses.

Who will see your medical and personal information?

The information on the health problems you experience during the program will be given to Sanofi Pasteur. This information may also be given to other companies and health authorities. To protect your privacy, these records will not be identified with your name, but with your birth date and initials. Only the program health care provider and the program staff at the site who are involved in the program will know your name and other identifying information that can link you to these records.

Any records in the program health care provider's offices that are connected to this program, including your medical records and health history, may be looked at by the US FDA or someone authorized by Sanofi Pasteur or Quorum Review, a group of people who review research studies (or programs, such as the one in which you are being offered to participate in) to protect the rights and welfare of research/program participants. Therefore, we cannot guarantee complete confidentiality of your records.

If you are hospitalized after vaccination, the program health care provider who provided Stamaril vaccine will ask to have access to the medical records of the hospital(s) where you have been admitted.

Participant-level information may also be shared for the purposes of scientific and medical research (e.g., with researchers, to allow public access to program information, or in publications). To safeguard your privacy, all information that could re-identify you will be removed before the data are released.

WHO CAN I TALK TO ABOUT THIS PROGRAM?

In the event of an emergency, dial 911 immediately.

If you require emergency care, be sure to tell the emergency care provider about your participation in this program. Contact the program health care provider as soon as possible.

You can ask questions about the program at any time. You can call the program health care provider at any time if you have any concerns or complaints. You should call the program health care provider at the phone number listed on page 1 of this form if you have questions about the program procedures, program costs (if any), program payment (if any), or if you get hurt or sick during the program.

Quorum Review reviewed this program. Quorum Review is a group of people who review research studies (or programs, such as the one in which you are being offered to participate in) to protect the rights and welfare of research/program participants. Review by Quorum Review does not mean that the program is without risks. If you have questions about your rights as a

research participant, if you are not able to resolve your concerns with the program health care provider, if you have a complaint, or if you have general questions about what it means to be in a research program, you can call Quorum Review or visit the Quorum Review website at www.QuorumReview.com.

Quorum Review is located in Seattle, Washington.
Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.
Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

Who will see your medical and personal information?

This section explains who will use and share your health information if you agree to be in this program. You must authorize this use and sharing of your information by signing this form or you cannot be in the program.

The program health care provider will collect, use, and share health information about you, including any information needed to do the program and other identifying information about you, such as your name, address, phone number, or social security number.

The information used and shared will include:

- information from your medical records
- information collected about you during the program

Your information may be used and shared with these people for the following purposes:

- The program health care provider to conduct this program.
- The sponsor, Sanofi Pasteur, people who work with or for the sponsor; and other program healthcare providers involved in this program. These people will use your information to review the program, and to check the safety and results of the program.
- Others required by law to review the quality and safety of this program, including the US FDA, Department of Health and Human Services, Office for Human Research Protections, other government agencies in the United States and other countries, and Quorum Review.

After your information is shared with the people and companies listed above, the law may not require them to protect the privacy of your information. To maintain the integrity of this program, you might not have access to any health information developed as part of this program until it is completed. At that point, you generally would have access to your health information.

You can cancel your authorization to use and share your information at any time by writing a letter to the program health care provider. If you cancel your authorization, you will not be able to continue in the program.

If you cancel your authorization, the program health care provider will still be able to use and share your information that they have already collected.

This authorization to use and share your information expires in 50 years.

INFORMED CONSENT FORM

By signing this form, I certify to all of the following:

- I confirm that I have read the entire consent form (or had the information read to me) and that I understand it. I received explanations regarding what will be done to me and what I am being asked to do. I have had the opportunity to ask questions and received satisfactory answers. I understand that I may ask questions about this program at any time.
- I understand that my confidential personal information can be reviewed by Sanofi Pasteur or its representative, by any health authorities (such as the US FDA), or by Quorum Review, as described above.
- I understand that my coded information may be archived and sent to another country.
- I voluntarily consent to receive Stamaril yellow fever vaccine, instead of YF-VAX.
- By signing this form, I do not give up any of my legal rights.
- I will get a signed copy of this consent form.

Printed Name of Participant

Signature of Participant

Date

I attest that the individual providing consent had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participation in this program.

Printed Name of Person Explaining Consent

Signature of Person Explaining Consent

Date