Partnership for Research on Ebola VACcinnation (PREVAC)

Informed Consent Form
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CONSENT TO PARTICIPATE IN STUDY

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Sites:
Liberia, West Africa
Guinea, West Africa
Sierra Leone, West Africa
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WHAT IS A VACCINE CLINICAL RESEARCH STUDY?

Vaccines are medicines that are used to prevent people from getting certain diseases. Many people get vaccines to prevent diseases like flu, measles, polio, and tetanus. A vaccine helps your body to fight off a particular germ if you come in contact with it.

A clinical research study helps doctors understand new ways to prevent or treat a disease. One way to do this is by studying vaccines. In a study, the vaccines are

'experimental,' which means they are still being studied. That is why studies are needed to find out if vaccines are safe and work in people.

WHAT IS THIS STUDY ABOUT?

You are here today to hear about a vaccine clinical research study that we are inviting you to participate in. Right now, there are no approved vaccines to stop people from getting sick with Ebola. In this study, we will test 3 experimental vaccines to see if they are safe and if they can get the body to make antibodies against Ebola. Antibodies are what the body makes to fight off infection.

In the rest of this consent document, 'you' can mean you or your child if you are thinking about allowing your child to be in the study.

WHAT VACCINES ARE BEING STUDIED?

We are studying 3 different kinds of vaccines (rVSVΔG-ZEBOV, Ad26.ZEBOV, and MVA-BN-Filo) used in different combinations. Each participant will receive 1 injection followed by another injection 56 days later. Each of the vaccines has a very small portion of the Ebola virus. But you cannot get Ebola from the vaccines. These vaccines have been given to many adults and some children around the world.

Some people on this study will get placebo and others will get 1 or 2 of the vaccines. The placebo is an injection of salt water, which contains no vaccine and has no effect on the body. This is done to find out how well the vaccines work.

If there is an Ebola outbreak in the area where the study is being conducted, participants that are within the "ring of contacts" identified by local health officials may be offered the opportunity to receive the rVSVΔG-ZEBOV vaccine.

WILL I GET A VACCINE OR SALT WATER?

There are 5 study groups. If you join the study, you will be randomly put into 1 of these groups. This happens by chance. Out of every 7 people on this study, 5 will be in a vaccine group and 2 will be in a salt water group.

You and the study staff will not know what group you are in or if you are getting vaccine or salt water. This is done to prevent study participants and the study staff from forming opinions about the study drugs that could affect the outcome of the study.

YOU CAN SAY "YES" OR "NO" TO TAKE PART IN THIS STUDY.

To be in this study, you must be older than one year of age and plan to continue to live in the study area for at least the next year and are willing to follow the protocol requirements needed to take part in this study. The decision on when children will be enrolled will be made by an independent data and safety monitoring board. You cannot be in this study if you are an Ebola survivor or if you have ever received an

Ebola vaccine. Pregnant women and breastfeeding mothers are not allowed to take part in the study.

Additionally, children will have laboratory tests done to determine if they have HIV. Children who are HIV positive will not be able to take part in this study.

If you think you may want to join this study, we will describe the study and answer any questions you may have. You can also talk to your friends and family about the study. We will also give you written information about the study.

You do not have to join this study if you don't want to. If you agree to be in the study, we will ask you to sign this consent form.

WHAT HAPPENS IF I AGREE TO BE IN THIS STUDY?

When you sign your name or put your mark on the consent form, it means that you agree to be in the study. You can change your mind at any time and leave the study. If you decide not to join the study or to leave the study later, you will not lose any regular health care services you already are getting. About 5,000 people will be taking part in this study in West Africa.

We will ask you some questions and take your temperature to see if you qualify to be in this study. It is important for you to tell the truth so the study team can make sure it is safe for you to be in the study.

WHAT DOES THE STUDY INVOLVE?

If you qualify for the study and decide to join, you will come back to the clinic 8 or 9 times over the next year. After the first year, we may ask you to come back for 1 study visit once a year, for 4 more years. During the clinic visits, we will ask how you are feeling and if you have been sick, take your temperature and weight, and check your blood for research purposes. You will receive an inconvenience allowance for your time after each study visit at the site.

During 2 of the clinic visits you will get an injection into your upper arm, or thigh for younger children. This injection will be a study vaccine or salt water. Getting the injection might hurt a little. You will feel a pinch with the needle. We will watch you closely for 30 minutes after the injection. We will give you an ID card with a phone number of who to contact in case you feel sick at any time after your visit. For children, we will contact you every day for 7 days after each injection to find out how you are doing.

We will collect a saliva sample from a small group of children (up to 17 years old) during 7 of the clinic visits. We will collect the saliva by asking the child to spit into a cup. We will store the samples for research testing. They will be labeled with a code and not with a name.

WHAT COULD BE THE SIDE EFFECTS FROM THE INJECTIONS?

These vaccines have been given to people in other research studies, and some of these people had side effects. Some of the side effects you may have after the injections are:

- you may have pain, swelling, itchiness, redness, or warmth where you got the shot, and you may have a small sore on your arm just like any other vaccine;
- your arm may be sore and harder to move;
- the glands under your arms or in your neck may swell;
- you may get a fever or headache, feel tired, or have chills, rash, nausea, change in appetite, vomiting, diarrhea, dizziness, muscle, joint or belly aches, mouth sores, or body pains.

Some people will have some side effects after the injection. One person experienced itchiness across the body several days after vaccination. Other people may have no side effects. These side effects are temporary and should only last a few days but may last for a few weeks for some people.

ARE THERE ANY OTHER RISKS OF VACCINATION?

The immune system is the part of your body that fights infections. Vaccines work by getting the immune system ready to do this. Rarely, a vaccine can cause the immune system to attack parts of your own body. This type of side effect can sometimes be serious.

People can have allergic reactions to vaccines, including hives, trouble breathing, or other allergic responses. This is very rare, but is also a possible effect of any vaccine. Vaccines may cause temporary changes in some blood test results. Some people have had mild tingling of the hands and feet or mild muscle weakness after vaccination. These have lasted as little as one day in some people and up to several weeks in other people, but usually go away on their own. One person developed a moderately severe case of these symptoms that has been ongoing for several months. These symptoms interfere with some of their daily activities. There may be other side effects of vaccination that may be severe or life-threatening.

Recently, one person in a study of one of the MVA-BN-Filo vaccines had double vision, pain when moving the eye, and difficulty keeping balance when walking. This happened about a week after a common cold with fever and a month after vaccination. We do not know if the person received MVA-BN-Filo or placebo at their vaccination. This person had to go to the hospital for therapy and has recovered. These symptoms were most likely caused by the cold with fever. However, we cannot say for sure that this was not related to the vaccination. The risk of this happening in this study is not known, but is very low.

A recent study of the rVSVΔG-ZEBOV vaccine was suspended after 3 of 9 volunteers reported signs of knee arthritis (with pain and stiffness) of unknown origin. The reason for this is not known. This effect was also seen in an earlier study of the vaccine in Europe. During the course of the study, whatever the trial product used,

the medical team will pay close attention to signs that may suggest arthritis.

Since these are new vaccines, they may cause other changes that could hurt or bother you that we do not know about. Short-term medical care can be provided if there are side effects from the injections. It is important that you always tell the study staff if you have any problems and always keep in touch with them.

WHAT INSTRUCTIONS DO I NEED TO FOLLOW?

One of the study vaccines is made from the VSV virus, which normally affects animals and does not normally cause any serious disease in humans. This virus can be dangerous for certain groups of people, like very sick people or infants.

It is important to follow instructions to prevent the VSV virus from being passed to others. And since you will not know whether or not you have received this vaccine, everyone needs to do the following: You must try not to expose other people to your blood and body fluids for 6 weeks after each vaccination. To do this, you and your partner should use condoms during any form of sex and you should avoid sharing needles, razors, forks, spoons, cups, toothbrushes, etc, with anyone. You must also avoid open-mouth kissing. If you should develop mouth sores, we may ask you to follow the above directions for a longer time until the sores go away. You should not donate blood for one year after getting the study injections. You should also follow routine precautions to protect yourself from other diseases such as typhoid and malaria. For example, wash commonly consumed leaves with chlorine, drink clean water, and protect yourself from mosquito bites.

WHAT DO I NEED TO KNOW ABOUT PREGNANCY AND/OR BREASTFEEDING DURING THE STUDY?

Women: You cannot be in this study if you are pregnant or breastfeeding. We do not know the effects of the study vaccine in pregnancy or in a nursing baby. If you get pregnant around the time you get the study vaccine, we don't know if there may be effects on you or your baby. Therefore, you must avoid getting pregnant for 3 months after receiving the study vaccine. You will have a pregnancy test done before participating in the study and before each injection. You will need to use birth control, unless you are not able to get pregnant. If you think that you have gotten pregnant during the study, tell the study team right away, and seek medical care for your pregnancy. If you get pregnant during the first 90 days of the study, we will follow you until delivery.

Men: The effect of the vaccine on sperm is not known. Therefore, you should not get a sexual partner pregnant after you get the vaccination. You need to use a latex condom every time you have sex for 3 months after receiving each study vaccine.

HOW WILL MY BLOOD BE TESTED?

Blood will be taken by inserting a new, clean needle into a vein in your arm. You may feel a pinch when the needle goes through your skin. This doesn't last long and we

will put a bandage on your skin once the needle is taken out. A bruise may appear where the needle was put in. This is common and should go away in a couple of days.

Your blood will be tested to know if the vaccines will work to prevent Ebola. We will also test your blood for syphilis and for infection with HIV, which is the virus that causes AIDS. If you have HIV infection or syphilis, you are at least 18 years old, and the investigator determines you are in good health, you can still be in this study. We will tell you what the test results mean for you and how to find care.

WHAT WILL HAPPEN TO MY BLOOD?

After we do our research tests on your blood samples, we will keep your leftover samples for future research that may help us learn more about developing vaccines against Ebola. You will not get any information from this. If you change your mind and decide you do not want us to store your blood samples anymore, please let us know. We will do our best to follow your wishes but cannot promise that we will always be able to destroy all your samples. For example, if your sample was already used, we would not be able to destroy it.

Your blood samples will be labeled with a code and not with your name. Your coded samples might be sent to other scientists, including scientists outside of your home country, for research. Other information, such as your sex, age, or health history might also be shared, but your name will not. Your blood samples will not be sold. You will not be paid for any products that result from this research. The only risk of allowing us to store your samples would be an accidental release of your identity.

WHAT DO I NEED TO DO FOR FOLLOW-UP ON THIS STUDY?

If you feel sick at any time during the study, it is important that you quickly call the study contact number on your ID card. We may ask you to return to the clinic for a medical exam.

We do not know yet if the Ebola vaccines work to protect people against Ebola. If you get one of these vaccines, you may be protected from Ebola, but you may not. If you get the placebo, you will not be protected from Ebola. You must continue to protect yourself from contact with Ebola. We will give you information on how to prevent Ebola. If you experience anything that seems like symptoms of Ebola, such as fever, diarrhea, vomiting, or unexplained bleeding, it is very important that you get medical care as soon as possible, and let the study team know you are sick.

If we find out anything new during this study that may be related to your health or to your decision to continue in the study, we will discuss this new information with you.

WHAT ARE THE BENEFITS OF BEING IN THIS STUDY?

Based on results from previous studies, it was found that those who received one of the experimental vaccines produced antibodies that may potentially protect against

Ebola. We do not know how long those antibodies will last in your body which is one of the reasons we are doing this study. However, if you are in the placebo group, you will not benefit from the vaccine. You will be screened for syphilis and HIV infection and some of your blood tests will show if you have other conditions such as severe anaemia which you may not have been aware of. Your participation in this study is important to learn how people respond to these vaccines. It will help in the development of vaccines to prevent Ebola and may in the future help people all over the world.

WHO WILL BE ABLE TO SEE MY INFORMATION?

We will keep your study information private. All files with information that could identify you will be kept in locked cabinets. Samples of blood that are collected from you will be marked with a number that tells the study team that it is your blood. These samples will not be marked with your name. We may take your fingerprint or a picture of your eyes to help us identify you during the study. We will keep a copy of your fingerprint or eye picture in a secure computer file.

The monitor(s), the auditor(s) of the sponsors and collaborators, the IRB/IEC, and the regulatory authority(ies) will be granted direct access to your original medical records for verification of clinical trial procedures and/or data, without violating your confidentiality, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, you or your legally acceptable representative is authorizing such access.

WHO IS WATCHING OVER THIS STUDY?

A Data and Safety Monitoring Board (DSMB) will be looking at the study information very often. The DSMB is made up of doctors and other people who are not directly involved in the study and who have a good understanding of Ebola and vaccine studies. The DSMB may decide to stop the study earlier than planned if they think it is not safe anymore or will not be able to find out if these vaccines work.

WHAT ELSE SHOULD I KNOW ABOUT THIS STUDY?

A description of this study will be on the internet at http://www.ClinicalTrials.gov. This website will not include information about you. At most, the website will include a summary of the results. You can search this website at any time.

The United States National Institutes of Health (NIH) researchers must tell the NIH at least yearly about any stock they own in the companies that make the study vaccines. All study investigators are also asked to do this. If you would like to get more information, you may ask your study team.

WHO CAN I TALK TO ABOUT THIS STUDY?

If you want to talk to anyone about this research study because you think you have been hurt by being part of the study, or if you have any questions about the study,

you should tell the study team: Day time phone numbers xxxx-xxx-xxx or xxxx-xxx-xxx, Night time phone numbers xxxx-xxx-xxx or xxxx-xxx-xxx.

Also, you can contact Gloria Mason coordinator of the National Research Ethics Board (Tel: +xxx-xxx-xxx-xxx/+xxx-xxx-xxx-xxx) to answer questions you may have about being part of this study and your rights as someone who is in a study.

If you have any questions at any time about this research study, you may ask someone on the study team.

Your participation in this study should not change your attitude toward public safety measures to prevent the spread of Ebola virus. In case of a new Ebola outbreak, you should continue to practice Ebola prevention behaviors.

The “Comité d'Evaluation Ethique de l'Inserm” (Inserm IRB; IRB00003888 and FWA00005831) approved this study on March 20th, 2018.

I agree to the storage of my blood samples for future research testing (after the end of the study) about infectious diseases in African countries.

☐ By checking this box, I do **NOT** allow the storage of my blood samples for future research testing (after the end of the study) about infectious diseases in African countries.

If you agree to be in this study, please sign or put your fingerprint on the next page.

_____ Date:____/____/____

Signature or fingerprint of volunteer or guardian *dd mon yyyy*

_____

Printed name of volunteer

_____ Date:____/____/____

Signature of investigator *dd mon yyyy*

_____

Printed name of investigator

Complete if participant is illiterate:

Witness to Consent Interview

On the date given next to my signature, I witnessed the consent interview for the research study named above in this document. I attest that the information in this consent form was explained to the subject, and the subject indicated that his/her questions and concerns were adequately addressed.

_____ Date:____/____/____

Signature of witness *dd mon yyyy*

_____

Printed name of witness

Attach PID bar-code label if not printed on the form: