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A Phase 1 Randomized Study to Evaluate the Safety, Tolerability, and Immunogenicity of Ranging Doses of ALFQ Adjuvant in a Candidate HIV Vaccine Containing A244 and B.65321

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MAIN INFORMATION AND CONSENT FORM

Protocol: RV 575

Protocol Title:	A Phase 1 Randomized Study to Evaluate the Safety, Tolerability, and Immunogenicity of Ranging Doses of ALFQ Adjuvant in a Candidate HIV Vaccine Containing A244 and B.63521
Sponsor:	The Surgeon General, Department of the Army
Funding Source:	Division of AIDS
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IND Number:	28352

Thank you for your interest in this exploratory research study. This study will take place at the Walter Reed Army Institute of Research (WRAIR) Clinical Trials Center (CTC). This study is supported by the United States Department of Defense (U.S. DoD). The box below tells you important things you should think about before deciding to join the study. We will provide more detailed information below the box. Please ask questions about any of the information before you decide whether to participate. You may also wish to talk to others (i.e., your family, friends, or your doctor) about this study, before agreeing to join. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information for You to Consider
• **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to join or if after you join, you decide to quit. • **Purpose**. We are doing this research to test how safe and well-tolerated the investigational product (vaccine we are testing), A244/B.63521 is when mixed with ALFQ. B.63521 has not been tested in humans prior to this study, and its safety is not yet fully known. ALFQ is an adjuvant. An adjuvant is a substance that acts to increase the immune response to vaccines. In addition, we are testing which of three doses of ALFQ will best increase the amount and types of antibodies your body makes. • **Duration.** Your part of the study will last 14 months. You will be asked to complete at least 11 clinic visits. You will undergo a brief medical exam and blood collection for testing at every visit. Additionally, you will be contacted by phone, each month for two months after your last clinic visit to discuss any changes you may have experienced after the first 12 months of being in the study. • **Procedures and Activities.** We will ask you to receive 3 doses of the experimental vaccine and monitor your blood and symptoms after each vaccine. • **Risks.** Most studies have some possible harms that could happen to you if you join. In this study, there may be risks associated with blood draws, the vaccine, or from the possibility of false-positive HIV test results due to the immune response to the vaccine. The most serious risk is the possibility of an allergic or (rare) autoimmune reaction (your immune system mistakenly attacking your body) to the vaccine. The clinic has emergency medical equipment in place to handle allergic reactions if they should occur. • **Benefits**. There are no direct benefits for your participation in this study, however the knowledge gained from this study may be beneficial to others in the prevention and or cure of HIV disease in the future. • **Alternatives.** Participation in this study is voluntary and the only alternative is to not participate.

1. WHY IS THIS RESEARCH STUDY BEING DONE?

Researchers are doing this study to test an experimental vaccine for HIV. A vaccine is a medical product given to prevent certain infectious diseases, most often caused by a virus or bacteria (germs). A vaccine may teach the human body to form a defensive response to try to prevent the disease from beginning or taking hold of the body. This defensive response is called the immune response, and it is the body's way to fight infections. The study also tests a combination of adjuvants. An adjuvant is a substance added to vaccines that can help to make the vaccine more effective by improving the immune response or causing the immune response to last longer than without the adjuvant.

You are being asked to take part in this research study because you are a healthy adult. Your participation will help researchers find out whether the experimental vaccine with adjuvant, used in this study is safe, whether it causes mild side effects that are common, "expected" symptoms, like fever, or sore arm at injection site, and if the experimental vaccine causes unexpected reactions. The data we record from the symptoms you experience help tell us if it is safe enough for other people. We also want to gather information about if and how humans respond (develop immune responses) to the experimental vaccine, and how long the effects last; we can learn that from your blood samples.

The main purpose of this study is to test how safe and well-tolerated the A244/B.63521 vaccine is when mixed with ALFQ at different doses. ALFQ is an adjuvant. In addition, we are testing which of three doses of ALFQ will best increase the amount and types of antibodies your body makes.

A244 is a protein that mimics the outer shell, or envelope of the HIV virus. A similar product to the A244 we are using in this clinical trial has been used in previous clinical trials. A very small modification was made to the previous product (a small piece of it was removed) to make the current product. This modified product is being used for the first time in an ongoing clinical trial.

B.63521 is also a protein that mimics the envelope of the HIV virus. This trial will be the first time this product will be used in humans, but very similar products have been tested in humans and are generally well-tolerated.

ALFQ is Army Liposomal Formulation type Q. It contains cholesterol and soap-molecules and a molecule from tree bark (Q). This adjuvant has been tested with other non-HIV vaccines in humans in people before, at the 200 microgram and 100 microgram doses, and did not cause more than moderate reaction including fever and redness at the injection site.

The products being given in this study are not obtained by collecting them from a person. They are artificial products manufactured under controlled, clean conditions used for drug manufacturing.

These vaccines are not generated from HIV virus; **therefore, you will not be infected with HIV virus from receiving these vaccines.** Additionally, these vaccines have not been approved or cleared by the US FDA, however they have allowed the use of the vaccines in this research study to learn more about its safety and efficacy.

2. HOW DO I JOIN THIS STUDY?

If you agree to participate, you will have a screening visit, which includes some lab tests, a review of your health history, and a physical exam. After your test results are available, the researchers will review the results to determine if you meet the eligibility requirements to join this study. You may take this consent form home and discuss the study with your family or friends to help you decide if this is right for you. If you are found eligible, ask the study staff about the study schedule to plan on a time to return to enroll.

At the screening visit you will:

- Attend a briefing to learn about the study and provide your contact information
- Sign the informed consent forms
- Take a short test to check if you understand the study. *To be eligible, you must*

answer 8 out of 10 questions correctly but you can take the test 2 times

- Meet with a doctor to review your medical history
- Have a physical exam including vital signs
- Have blood drawn (23 ml which is a little less than 1.5 Tablespoons) to test for HIV, Hepatitis B, Hepatitis C, and assess your general health
- For women: provide a urine sample for a pregnancy test

You may be allowed to participate in this study if you:

- Are a healthy adult between the ages 18-55 years (inclusive)
- Have signed the consent
- Have completed the screening process
- Have successfully answered the Test of Understanding (TOU)
- Are able and willing to comply with all research requirements
- Weigh at least 110 pounds
- Are free from HIV and low-risk for HIV infection
- Refrain from blood donation during the course of the study
- Are free of significant medical problems
- Are not pregnant and are willing to take precautions to prevent pregnancy
- Do not plan to travel outside the Washington DC metro area (DC, Maryland, and Virginia) that would prevent compliance with planned study visits

Military personnel, regardless of leave status, will be excluded from participation in this study.

You will not be asked to join in this study if you have a history of HIV, or certain other medical conditions, other medical or mental illness that may interfere with your ability to understand the study and give consent to be part of the study, if you have certain other medical conditions such as hepatitis, or if you are pregnant or breast-feeding. Blood will be collected to verify that you are eligible to participate in the study. If you are a woman, urine will be collected to check for pregnancy.

You may not be eligible to take part in this study if the results of the screening indicate that you have health problems. A study staff will explain all the details to you including where you can get assistance and treatment. If you have a reproductive system infection or a positive HIV test result, the study staff will provide you with counseling and referral for medical treatment. You must not have a fever on the day of vaccine administration in order to receive the vaccine.

3. HOW MANY PARTICIPANTS WILL JOIN THIS STUDY?

Researchers will enroll approximately 60 eligible people in this study.

4. WHAT WILL I BE ASKED TO DO IF I JOIN THIS RESEARCH STUDY?

Each time you visit the clinic, you will go through study procedures as detailed on your participant visit schedule, which you will receive at this visit.

If you decide to participate in this study, you will be assigned randomly (like drawing straws) to one of three (3) groups (arms) in the study. The experimental vaccine (A244/ B.63521) will be mixed with the adjuvant (ALFQ), and injected into the deltoid muscle.

Each of the 3 groups will have 20 participants. Each group will receive the same dose of the experimental vaccine (300mcg of each protein), but a different dose of the adjuvant. Arm 1 will receive 200 micrograms (µg) of ALFQ. Arm 2 will receive 100 µg of ALFQ. Arm 3 will receive 50 µg of ALFQ.

Enrollment into the groups will be done in a step-by-step manner for safety reasons. Four participants will be enrolled into Arm 1, one participant will be enrolled into Arm 2, and one participant will be enrolled into Arm 3. After these six participants receive their first injection, enrollment will stop for about a week to allow the researchers to look at the data, and see if it is safe to give the remaining participants their vaccines.

This research study is a blinded study, which means that neither you nor the research team will know which dose of the adjuvant you are receiving. In the event of an emergency, there is a way to find out which one you are receiving.

	Number of participants	**Month 0**	**Month 1**	**Month 2**
Arm 1	20	A244/B.63521 ALFQ-200	A244/B.63521 ALFQ-200	A244/B.63521 ALFQ-200
Arm 2	20	A244/B.63521 ALFQ-100	A244/B.63521 ALFQ-100	A244/B.63521 ALFQ-100
Arm 3	20	A244/B.63521 ALFQ-50	A244/B.63521 ALFQ-50	A244/B.63521 ALFQ-50

After the vaccination, the study staff will observe your symptoms for at least 30 minutes. Also, we will examine your vital signs such as blood pressure and heart rate before you go back home. The investigators will ask you to record how you feel in a diary card (for example, if you have fever, headache, pain, chills, redness, or other symptoms) in the evening after the injection and then every day for the next 14 days after each vaccination. The study staff will give you a thermometer to measure body temperature and a ruler to measure the size of any reactions at the vaccination area.

5. HOW LONG WILL I BE IN THIS STUDY?

Participation in this study will require one screening visit, three vaccination visits, and seven follow-up visits, over the course of 14 months for safety and study of your immune response. Please note that you may be asked to come to the clinic for an unplanned visit if you experience side effects that are of concern. The first two vaccination visits will be followed by a follow-up visit 14 days post-vaccination.

The third vaccination visit will be followed by visits 1 to 2 days, 7 days, and 14 days post-vaccination, the remaining two visits will occur at 6 months and 12 months from your first vaccination. There will be an additional visit after all participants have completed the study at which the study doctor/staff will inform you about the study results and which dose of ALFQ you received. In addition to your visits to the clinic, you will be contacted by phone once per month for 2 months, to discuss any changes you may have experienced after the first 12 months of being in the study. Vaccination visits will take 2-3 hours and follow-up visits will take about an hour.

Please refer to the participant visit schedule given to you to keep track of what can be expected from you at each visit.

6. WHAT ARE MY RESPONSIBILITIES DURING THIS STUDY?

If you take part in this study, you will be asked to:

- Provide proof of your identity.
- Provide complete and accurate information about your medical history, medication use, and any symptoms or illnesses you have during the study.
- Follow the study staff's instructions and complete your diary card.
- Attend all study appointments and be available for telephone calls from the study staff. If you cannot keep an appointment, contact the study clinic immediately to reschedule.
- If female, avoid pregnancy by not having sex or using appropriate birth control methods (male condoms, hormonal contraception or birth control pills, intrauterine device or IUD, hormonal injections, diaphragms or male partners who have undergone a vasectomy are acceptable methods) for at least 30 days prior to vaccination and for at least 3 months after vaccination. Please inform the study doctor/staff immediately if you do become pregnant during the study.
- Inform the study doctor/staff of any change in your health status, side effects, visits to another doctor/hospital and any changes in your plans or ability to participate in the study.
- Not enroll in ANY other clinical research study while you are in this study.

It is important that you know that this product will not protect you from getting or transmitting HIV to others if you become infected with HIV through sexual intercourse or through exposure to blood (example: sharing needles for drug use). The study staff will provide you with risk reduction counseling at each visit.

7. WHY MIGHT RESEARCHERS ASK ME TO LEAVE THE STUDY BEFORE IT ENDS?

Researchers may ask you to leave the study if the sponsor cancels the study or if the medical staff decides it is not good for your health to continue participating in the study. Researchers may ask you to leave for repeated failure to comply with protocol requirements. If you are incarcerated, you will have your study visits suspended. Upon release from jail, and upon discretion of the PI, you may be able to resume your study visits.

8. WHAT IF I WANT TO LEAVE THE STUDY BEFORE IT ENDS?

If you decide to stop taking part in the study for any reason, we will ask you to make a final study visit. At this visit, researchers may ask to:

- Give you a physical exam
- Ask about any side effects or health problems since your last visit
- Draw a blood sample
- Provide a urine sample

9. WHAT SAMPLES WILL YOU TAKE FROM ME DURING THIS STUDY?

The total amount of blood drawn over the entire study is approximately 825.5ml (a little less than 3.5 cups). The amount of blood drawn at your visits will range from 19.5ml (a little less than 1.5 tablespoons to 111.5ml (about a ½ cup). However, within an 8-week period, the cumulative blood draw amount will be 483 ml (about 2 cups), which is within the U.S. Blood Bank donation policy.

We will collect urine, at some visits, for pregnancy tests for the female participants.

10. WHAT WILL HAPPEN TO MY SAMPLES AND DATA?

HIV vaccine studies are done to learn how experimental vaccines affect your immune system and how your body responds. To better understand this, at each visit, the study doctors take blood samples to assess your heath and for research testing. Clinical information that may be beneficial to your health will be shared with you but your results from the research testing will not be shared with you. You may be asked to give more blood, if needed, to assess your health.

Some of your blood will be used to check for Hepatitis B and C, and Human Immunodeficiency Virus (HIV). The study doctor will be required by law to report any positive results of these tests to the local health authorities. The test results reported to local health authorities will contain your name, contact information, including address and telephone numbers, and the typed of testing that was done on you. Genetic testing may be conducted on your samples during this study and in the future. For example, researchers may do "genetic variations" research. They may look at genes that affect how you fight infections. Your genes are passed to you from your birth parents. Genes are the basic "instruction book" for the cells that make up our bodies. The differences in people's genes can help explain why some people get a disease while others do not. We will not notify you of the results of any genetic test. The genetic research tests we plan to conduct are not currently used in medical practice. The results of such tests have not been approved for use in making health care decisions and the results will not be shared with you. To protect your identity, your genetic testing results will not be linked to your name and will not independently identify you as an individual. The research for this study will not include mapping of all your genes (called "whole genome sequencing").

HLA and genetic tests: If you have consented to genetic testing, part of the blood taken for the study will be taken to analyze your DNA gene sequences. We will not notify you with the results of these tests, as they are not part of a normal medical test and the test results will not be used for treatment purposes.

To protect your identity, genetic test results will be assigned a number rather than your name and will not be sufficient to independently identify you as an individual as whole genome sequencing will not be performed on your samples. No one in the laboratory will know any personal information about you.

The samples will be stored at the US Military HIV Research Program in the Maryland. Specimens will be kept and labeled with your study number (in addition to a barcode, and information about the visit number and date, and the type of sample and volume of that sample collected. None of the information on the label is able to identify you, and your name will not be included on the label.

If you withdraw from this study, your specimens and information collected until the withdrawal date will be used to study your immune response to the vaccines.

After the study closes, if granted permission, your remaining specimens will be stored in a secure storage site for future research. We may share study information and or samples to research collaborators outside of WRAIR and MHRP without asking for your permission and there is no time limit on how long your data and samples will be stored for future use. All future research that uses stored samples, must also be reviewed and approved by the responsible organizations and the WRAIR IRB.

Documents, (including this form), notes from your visits, and photographs, if any, will be stored securely and then destroyed by authorized individuals when these records are no longer needed. You have the option to allow your specimens to be used for future research, and you can also choose to allow or decline genetic research at the end of this form. If you agree now and decide later that you do not want us to use your samples for future research, please tell us. We will ask the storage facility to destroy any remaining samples that still have your study ID on them so that they cannot be used for future research. Samples that are "coded", meaning they do not have your study ID on them, will not be withdrawn from storage because, without your ID, there is no way for the researchers to find your samples.

The overall results and findings from this study will not be shared with you.

11. WHAT ARE THE RISKS OF PARTICIPATING IN THIS STUDY?

Blood draws: There is the possibility of pain, bleeding, swelling, or bruising, where the needle enters the arm. There is a rare chance that a local infection can happen where blood was drawn. Rarely, some people can have dizziness or fainting after having blood collected. To minimize risk, blood will be drawn by trained health care providers. Changes at the needle puncture site will be tracked with the diary card and will be examined at the follow up visit. Participants with evidence of severe bruising or infection will be referred for appropriate medical care.

Vaccine injection: The most common side effects occurring after vaccination are pain, redness, hardness or swelling, limitation of arm movement, irritation at the site of injection, and skin infections at vaccination area (very rare). These side effects will be monitored but are generally short-term and do not require treatment.

Risks of study products: A244 and B.63521 are the two study products which make up the vaccine in this study. A244 and B.63521 have not been tested in humans and safety is not yet fully known. However, similar products (HIV-1 gp120s) have been given to participants in many studies, either alone as part of regimens containing other substances that can create an immune response. The most common side effects seen in these studies are fever, shivering, tiredness or feeling unwell, rash, muscle

pain, joint pain, headache, or nausea. These symptoms are similar to those that people have after receiving other preventive vaccinations and should last for only 1-2 days.

ALFQ is being used in 4 clinical trials which test the safety of study vaccines for malaria, COVID, and HIV. The data available from these studies has shown the ALFQ has been safe for participants. Side effects which may occur include bleeding at the site of injection, irritation and/or infection. Fever and tiredness may also occur. The formulation of ALFQ includes an adjuvant or agent that helps boost the body's immune response. Experimental vaccines or adjuvants could uncover or worsen an immune-related disease or syndrome. An immune-related disease occurs when your immune system, which normally fights off infections, attacks your body by mistake. These attacks can occur anywhere in your body, resulting in the weakening of your bodily function. A variety of experimental HIV vaccine components, like those in this study, have been extensively evaluated in humans and have not caused immune-related immune diseases. However, study participants will be closely monitored for immune-related diseases.

As with any Investigational New Drug (IND) product administration and no matter what precautions are taken, there is always the risk of a serious, or even life-threatening, allergic reaction. Medical emergency equipment is located at each study clinic. This is available to handle emergencies, such as anaphylaxis (severe allergic reaction) and cardiac arrest.

Overall, you may feel fatigue from the procedures being done as part of this study.

Pregnancy and breastfeeding:

Researchers do not know if the vaccines may harm unborn babies. You should not become pregnant during this study. If you are having sex that can possibly make you pregnant, you must agree to practice highly effective contraception at least 30 days before enrollment, and through 3 months post-last vaccination. One of the following methods may be used: condoms (male or female) with spermicide, diaphragm, or cervical cap with spermicide, IUD, contraceptive pills, patch, injection, intravaginal ring or other FDA-approved contraceptive method; male partner has previously undergone a vasectomy; or abstinence.

You must also agree not to breastfeed during, and for 2 months following your participation in this study.

VISP: The vaccines may cause "vaccine-induced sero-positivity" or "VISP". After receiving the study vaccine, you may test HIV positive when you really do not have HIV. This clinic's HIV test can tell the difference between real HIV infection and VISP. For this reason, you should avoid all HIV testing not done at this clinic. You will be tested for HIV regularly during this study. After this, if you would like HIV testing, we encourage that you return to this clinic for testing. Researchers do not know how long you may have VISP. At your request, you will be provided with a letter explaining your participation in the study and the possibility of testing positive for HIV antibody. If you have problems because of VISP, with your written permission, the study staff will assist you with any unfair treatment you may experience by being in this study. Should you move out of the D.C. metro area, please call 301-500-3810 and ask to be connected to an MHRP study physician. They will be able to advise you on what to do if you need to receive HIV testing.

This includes talking to insurance companies, employers, and others to verify your study participation or advocate on your behalf.

Also, if you become pregnant and have the baby while you have VISP, your baby may have VISP too. VISP is a laboratory abnormality that is generally temporary and is not harmful to your infant. This clinic's HIV test can tell the difference between real HIV infection and VISP in your baby as well.

If you have VISP, you cannot donate blood and you must not donate blood during your participation in this research study for other reasons as well. If you wish to donate blood after you have completed participation in this study, blood donation options will be explained at the final study visit, however you may be excluded in the future from donating blood when you reveal that you participated in an HIV vaccine study. For the same reason, you may also be excluded from participation in other research studies.

It remains unknown whether the A244/B.63521 vaccine can prevent HIV infection. Therefore, you should try to avoid behaviors that may put you at risk for HIV infection.

Social issues:

You may face personal problems because of being in this study. Family, friends, and others may worry, get upset, or treat you unfairly. People may think that you have HIV or are likely to get it. You could lose your job because your employer thinks that you have HIV, or because you take too much time away from work to be in this study, but it is unlikely.

You may feel embarrassed when answering personal questions about sex or having a physical exam. You may feel anxious when waiting for your HIV test results. If you have these feelings, please tell the study staff so that they can find a way to help you.

Researchers and study staff try hard to protect your privacy. Your friends and family could find out about your participation in the study. You may be treated unfairly because family, friends, co- workers or others learn you are in this study and assume that you have HIV/AIDS or that you are at risk of HIV/AIDS due to your sexual behavior or drug use. People might refuse to give you medical or dental care, employment, insurance, a visa, or entry into the military.

In addition to the potential risk of social harms resulting from an HIV diagnosis, becoming aware of a positive test results for Hepatitis B and or C, or the discovery of incidental findings may might also result in a negative similar emotional effects to those one might experience after becoming aware of a positive test. Researchers have ways to reduce these social risks. Some of these ways include: limiting access to your study records, having your study visits in private, and using codes to identify you and your samples. If you have any of these problems, please talk to the study staff, so that they can try to help you.

Guillain–Barré Syndrome:

Guillain-Barré syndrome (GBS) is a disorder in which the body's immune system attacks part of the peripheral nervous system. It afflicts only about one person in 100,000, and in rare instances vaccinations may increase the risk of GBS. The first symptoms of this disorder include varying degrees of weakness or tingling sensations in the legs. These symptoms can increase in intensity until certain

muscles cannot be used at all. Most individuals recover from even the most severe cases of GBS, although some continue to have a certain degree of weakness. If you develop GBS, you will receive appropriate medical treatment here at the study clinic or you will be referred to a qualified medical facility for further treatment and care.

Genetic testing:

The greatest risk associated with genetic testing is to your privacy. Genetic testing is described in section 10.

Loss of confidentiality

Researchers work hard to protect your confidentiality. You are assigned a number and all information about your involvement in this study is linked to that number instead of your name. Only researchers involved in the study are able to access this information. Still, there is the possibility that information on your participation in the HIV vaccine trial or other information collected during this study could be accidentally disclosed to others not involved in this study. This may result in discrimination by your family, employers and community. The researchers take these risks seriously, and, depending on the situation, the clinic staff will provide appropriate assistance if preventive measures have failed.

Unknown Risks

There may be risks with the use of these study products that are not yet known or that cannot be foreseen based on current information, which includes late-onset effects. Sometimes new facts could become known during the study. It is possible that this information might make you change your mind about being in the study. If new information is discovered, your study doctor will tell you about it right away.

12. CAN I HAVE SEX WHILE I AM IN THIS STUDY?

You can have sex while you are in this study and you should continue to maintain safe sex practices (such as using a condom or being in a monogamous relationship). The vaccination you may receive is not known to be protective against HIV transmission.

13. WHAT WILL HAPPEN IF I BECOME PREGNANT?

Please tell your doctor immediately if you feel you may be pregnant.

If you become pregnant during this study, you will stop getting the study injections but will remain in the study for observation, that will include small blood draws, only to check your health. Study staff will help you find out about available care for you and your baby. This study will not pay for this care. Knowing the results of your pregnancy is important. Study staff may ask you to come back for visits or may call you. Additionally, you should not breastfeed while in this study because researchers do not know if the vaccine may pass through breast-milk and may harm your baby. The study team will follow your pregnancy until your baby is born.

14. WHAT IS THE BENEFIT FROM PARTICIPATING IN THIS STUDY?

You should not expect any direct benefit from participating in this study. The knowledge gained from this study may be beneficial to others in the prevention and or cure of HIV disease.

15. DO I HAVE OTHER OPTIONS?

You may decide not to take part in this study.

16. CAN I CHANGE MY MIND ABOUT PARTICIPATING IN THIS STUDY?

Yes, you can change your mind at any time. Your participation in this study is completely voluntary. Tell the study staff if you are thinking about leaving or have decided to leave this study. Again, any care that you get at this clinic outside of this study will not change.

Study staff may want you to do some follow up visits and testing before you leave this study.

17. HOW WILL RESEARCHERS PROTECT THE PRIVACY OF MY INFORMATION?

Researchers will make every effort to keep your personal information confidential. A code, that will be known only to study personnel, will be used instead of your name on study records in this study. The code will be stored in a locked place. Only the researchers, medical staff, the Sponsor, and the institutional review board involved in the study can access your private information.

Researchers will keep all study information confidential to the extent that is permitted by applicable law. Researchers will not give information to anyone without your written permission, except as mentioned above. For study purposes, you must be willing to have results published or shared with other interested parties (such as local and federal scientists) as long as you are not personally identified.

After the study ends, researchers will keep all the data collected in a secured place. The principal investigator of the study will be responsible for keeping this information secure. If you leave the study, researchers will not collect any new data. Researchers will store the data that was already collected along with the other data from individuals that have completed the study. Data collected from this study will be stored indefinitely.

Study approval and oversight

Several committees monitor this study. These committees make sure that the study is performed ethically and with scientific merit. These committees also make sure that participants are not being hurt by participating in the study and that participants receive medical care if serious problems develop during the study. The study complies with all U.S. regulations and international guidelines on the conduct of medical research.

The WRAIR IRB has reviewed this study. The WRAIR IRB will follow the study as it progresses to ensure continued compliance with ethical standards. This means that WRAIR and U.S. government representatives may review research records as part of their responsibility to protect human participants. The sponsor, WRAIR IRB, US FDA, and the United States Army Medical Research and Development Command (USAMRDC) Office of Research Protection (ORP) Human Research Protections Office (HRPO) representatives may review the study records and access the confidential information about you.

Clinical Trial Information

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

18. WILL I HAVE TO PAY ANYTHING TO PARTICIPATE IN THIS STUDY?

You will not have to pay for medical visits, hospitalizations, physical examinations, medical procedures or blood tests related to this study.

19. WILL I RECEIVE ANY PAYMENT FOR MY PARTICIPATION IN THIS STUDY?

You will receive compensation for your time and effort to be in this study. If you are not a government employee, you may receive up to $1,910 for the entire study. As a civilian government employee, if your study visits occur during off duty hours or when you are on leave, you will be compensated at the non-government employee rate for each visit. However, if study visits occur when a civilian government employee is not on leave/during off-duty hours, you may receive up to $900 for the entire study.

You will receive:

- $200 for each scheduled vaccination visit
- $130 for other follow-up visits
- $50 for each screening visit.
- Unscheduled visits may be compensated $100 each, if the principal investigator deems appropriate.
- $350 bonus completion fee

Payments are made as the visit occurs, and not provided in advance, nor held until the end of the study. If you are a civilian government employee, your compensation is for blood draws only, at $50 per blood draw, unless the visit occurs during off-duty hours, or when you are on leave. Those visits may be compensated at the same rate as civilian non-government subjects.

You will receive $50 for each referred person who then attends a screening session and meets all inclusion and none of the exclusion criteria.

Other than medical care that may be provided and other payment specifically stated in this consent form, there is no other compensation available for your participation in this research study.

Your specimens (even if identifiers are removed), may be used for commercial profit, however you will not share in this commercial profit.

20. WHAT WILL HAPPEN IF I AM INJURED?

If you get sick or injured from taking part in the study, please contact the study team immediately. We will give you an emergency contact card with the phone numbers you should call. You will receive appropriate medical treatment here at the study clinic, or you will be referred to a qualified medical facility for further treatment and care. However, you will not get any other compensation. There is no compensation for research-related injury provided by the NIH.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g.military spouse, dependent of active duty military, retiree), you are entitled to medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes but is not limited to free medical care at DoD hospitals or clinics.

If you are injured because of your participation in this research, and you are not a DoD healthcare beneficiary, you are entitled to care for your injury at an Army hospital or clinic; medical care charges for care at an Army hospital or clinic will be waived for your research-related injury. You are also entitled to care for your injury at other DoD (non-Army) hospitals, but such care for your injury at other DoD (non-Army) hospitals or clinics may be time-limited, and your insurance may be billed. It cannot be determined in advance in which Army or DoD hospital or clinic will provide care. If you obtain care for research-related injuries outside of an Army or DoD hospital or clinic, you or your insurance are responsible for medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided, except in emergencies or if a non-DoD healthcare beneficiary requires a military escort for access to the DoD medical facility.

You should discuss this thoroughly with the Principal Investigator or site clinicians before making a decision to participate in this study. If you have any questions about study-related sickness or injury, you can contact the following person: **Paul Adjei, MD, MS** 301-500-3799**.**

21. WHAT IF THE RESEARCHERS LEARN NEW INFORMATION DURING THIS STUDY?

Result of this study or other scientific research may affect your willingness to continue to take part in this study. During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

We may contact you after the study ends if we have other information related to this research.

22. COVID-19 Information

In light of the circulating severe acute respiratory syndrome Coronavirus-2 (SARS-CoV-2) and the associated coronavirus disease (COVID-19) pandemic, we want you to know that coming to the clinic and being around other people can increase your exposure to SARS-CoV-2.

In order to reduce your risk of contracting the virus, the WRAIR CTC is practicing COVID-19 control measures like social distancing, handwashing, wearing masks and taking temperatures of all persons entering the institution at the entrance.

In the event that there is an increase in infections, that would prompt the need to modify study visits to reduce the risk of transmission, the site may institute the following modifications.

- Visit windows may be extended in order to conduct study visits early or late within the window
- Ability to conduct study visits – in full or in part – off-site if permitted by applicable

government, health authority, and institutional policies
- Certain study procedures may be prioritized during a particular visit so that the participant does not have to be present for the full duration of the scheduled study visit.

Other modifications may be undertaken that are not listed above. However, any proposed modifications put in place are to safeguard the health and well-being of participants. The modifications provide flexibility for conducting study visits and procedures when needed to monitor your safety.

These modifications are expected to be time-limited in relation to the COVID-19 pandemic. In consultation with the Sponsor and MHRP, the study team will determine when, in the future, the guidance is no longer applicable. WRAIR will be notified when such a determination is made.

23. WHAT IF I HAVE ADDITIONAL QUESTIONS?

If you have any questions about this study, how to behave as a participant in this study, or if you have any problems or questions regarding the study staff, you can ask your site Principal Investigator: Paul Adjei, MD, MS 301-500-3799 .

24. WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?

You have the right to leave this study at any time and for any reason. The study staff will continue to treat you the same no matter what you decide. You will not give up your legal rights by signing this informed consent form. You also have the right to know about any new information from this study or other studies. This information may affect your health, welfare, or decision to stay in this study.

If you have questions about your rights as a study participant, contact:

Walter Reed Army Institute of Research IRB, 503 Robert Grant Dr., Silver Spring, MD 20910- 7500; phone: (301) 319-9940, e-mail at usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil

25. HOW DO I CONFIRM MY DECISION TO BE IN THIS STUDY?

My signature below confirms:

- that I voluntarily decided to participate in this study
- that I had the opportunity to read this form
- that this form was explained to me
- that I had the opportunity to ask questions
- that I had the opportunity to discuss my study participation with others

If there is any portion of this document that you do not understand, ask the study staff before signing the form. Signing this form means that you consent to participate in this research, at this time. A signed and dated copy of this document will be given to you.

26. YOUR CHOICES ABOUT WHETHER YOU WANT TO BE PHOTOGRAPHED

A photograph may be helpful to document an unusual or unexpected finding after the experimental vaccination is given. No one will be able to determine your identity from these pictures.

By signing below, you give study doctors permission to take and use photos taken of you during the study.

Refusing to give consent for use of your photos will not affect your participation in this study. If you give consent today, you can withdraw your consent at any time without consequences.

☐___Yes, I agree. ☐___No, I do not agree.
initials initials

27. YOUR CHOICES ABOUT HOW YOUR BIOLOGICAL SAMPLES MAY BE USED

Future Research:

Researchers may store and use my biological samples and data to find new ways to detect, treat, prevent, and cure health problems. Refusing to give consent for future use of your samples and data will not affect your participation in this study.

☐___Yes, I agree. ☐___No, I do not agree.
Initials initials

Genetic Testing:

Researchers may store and use my biological samples and data now and in future research to learn about how genes play a part in diseases. Refusing to give consent for genetic testing of your samples will not affect your participation in this study.

☐_____Yes, I agree. ☐_____No, I do not agree.
Initials Initials

SIGNATURE OF PARTICIPANT

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT

(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date