RV306

The Main Information Sheet for Study Participants

Study Title

Randomized, Double Blind Evaluation of Different One-Year Boosts after Sanofi Pasteur Live Recombinant ALVAC-HIV (vCP1521) and Global Solutions for Infectious Diseases (GSID) gp120 B/E (AIDSVAX® B/E) Prime-Boost Regimen in HIV-uninfected Thai Adults

Short Title: Prime and Multiple Boost HIV Experimental Vaccine Project

We would like you to thoroughly read and understand this document before signing the consent form.

Attention All Study Participants

You are being invited to participate in this study because you are a healthy person who meets the criteria for this study, listed later in section 3.

Before deciding to participate in this study, please read this document thoroughly. In doing so, you will acknowledge the purpose and details of this study. If you have any further questions, please feel free to ask the study team or investigator doctors or nurses at all times. The investigators will answer and make clarification of any matter.

You are also able to ask for any suggestions on participation in this study from your family, friends, or your personal doctor. You have enough time to make a decision freely until the targeted number of volunteers has been enrolled. If you finally decide to participate in this study, please sign the consent form. You will receive a copy of the document.

1. Purpose and Background

This research study is funded by the U.S Army and the U.S. National Institutes of Health. Participation in this research study will create better understanding of the effect of these HIV vaccines on the human immune system. The HIV vaccines used in this trial have been studied in over 8,000 Thai volunteers (RV144 study). The previous study results have shown that these vaccines are safe, capable to activate human immune system and can reduce HIV infection by 31%

in comparison with ones who received placebo. However, this preventive effect may be short-lasting. This study will perform a vaccine trial using the previously studied vaccines by applying additional doses in order to evaluate how they affect the human immune system to defend HIV virus.

The Principal Investigator of this study is Dr. Punnee Pitisutthithum, the Vaccine Trial Center, Faculty of Tropical Medicine, Mahidol University. This study will be conducted at:

- The Vaccine Trial Center, Faculty of Tropical Medicine, Mahidol University, Bangkok
- The Armed Forces Research Institute of Medical Sciences, the Royal Thai Army Medical Department, Bangkok
- The Research Institute for Health Sciences, Chiang Mai University, Chiang Mai
- The Thai Red Cross AIDS Research Centre, Bangkok
- The King Chulalongkorn Memorial Hospital, Bangkok
- Hospital of Tropical Diseases, Mahidol University

Scientists from several countries have worked together in order to develop an HIV vaccine especially in Thailand, where there is the spread of HIV B-type and E-type. There are two types of experimental vaccines used in this study; ALVAC-HIV and AIDSVAX B/E vaccines.

ALVAC-HIV vaccine is generated by inserting genetic synthesized parts of the HIV virus B-type and E-type in a virus that is not harmful. AIDSVAX B/E vaccine is generated from proteins identical to outside surface proteins of HIV virus B-type and E-type. Both vaccines can primarily activate human immunity in blood. However, we do not yet know if these vaccines are capable of activating the immune system in other parts of human body such as vagina or sigmoid (the lower part of your intestine) or semen.

These vaccines are not generated from HIV virus; **therefore, you will not be infected with HIV virus from receiving these vaccines.**

These vaccines are not yet registered as commercial vaccines either in America or Thailand. However, they are approved for use in human trials by the US and Thai Food and Drug Administration, the Ethical Committees, and the Institutional Review Boards.

The important information you should know as follows;

1) Study participation is freely decided and **truly voluntary.**

2) You may choose not to participate in and withdraw from the study at any time without any negative consequences to you.

2. Study Objectives

Results of large previous studies of the same HIV vaccines study have found that levels of immune responses to vaccine decrease with time. The objectives of this study are as follows:

- To evaluate whether or not adding additional vaccinations can improve the quality and the duration of the immune responses and to further evaluate the safety and tolerability of the vaccines.
- To better understand mechanisms and results of immune system activation in other parts of the human body (for example blood, bodily fluid such as semen, mucosal secretions from cervical, vaginal and rectal, mucosal tissue of cervical and large intestine, and bone marrow).
- To examine if there is any difference in the immune response following receipt of two vaccines and one vaccine by comparing between the 4 study groups.

3. Study Participation

The total number of volunteers in this study is 360 volunteers, 60 volunteers will be enrolled in Chiang Mai site and 300 will be enrolled in Bangkok sites. They are divided into 4 groups: 27 vaccine recipients and 3 placebo recipients in group I, 100 vaccine recipients and 10 placebo recipients each from groups II, III and IV for a total of 327 vaccine recipients and 33 placebo recipients. Group IV will be further divided into IVa and IVb with 50 vaccine recipients and 5 placebo participants in each subgroup.

On the enrollment date, you will be randomly grouped by a computer, which will determine whether you will receive vaccine or placebo, and whether you are in one of four different vaccine groups listed in the Table below. However, neither you nor the study staff will know if you receive vaccines or placebo.

Placebo is the investigational solution that looks similar to the vaccine but contains no active ingredients. The study team will inform if you receive vaccines or placebo after you complete the study.

Vaccination Schedule:

Vaccination Schedule						
Group	**No. of volunteers/Vaccine or Placebo**	**Week No.**				
		0	**4**	**12**	**24**	**48**
1	**27**	**ALVAC**	**ALVAC**	**ALVAC + AIDSVAX**	**ALVAC + AIDSVAX**	
	3	**Placebo**	**Placebo**	**Placebo**	**Placebo**	
2	**100**	**ALVAC**	**ALVAC**	**ALVAC + AIDSVAX**	**ALVAC + AIDSVAX**	**ALVAC + AIDSVAX**
	10	**Placebo**	**Placebo**	**Placebo**	**Placebo**	**Placebo**
3	**100**	**ALVAC**	**ALVAC**	**ALVAC + AIDSVAX**	**ALVAC + AIDSVAX**	**AIDSVAX**
	10	**Placebo**	**Placebo**	**Placebo**	**Placebo**	**Placebo**
		0	**4**	**12**	**24**	**60**
4a	**50**	**ALVAC**	**ALVAC**	**ALVAC + AIDSVAX**	**ALVAC + AIDSVAX**	**ALVAC + AIDSVAX**
	5	**Placebo**	**Placebo**	**Placebo**	**Placebo**	**Placebo**
		0	**4**	**12**	**24**	**72**
4b	**50**	**ALVAC**	**ALVAC**	**ALVAC + AIDSVAX**	**ALVAC + AIDSVAX**	**ALVAC + AIDSVAX**
	5	**Placebo**	**Placebo**	**Placebo**	**Placebo**	**Placebo**

ALVAC vaccine or Placebo will be injected in left deltoid (shoulder) muscle

AIDSVAX vaccine or Placebo will be injected in right deltoid (shoulder) muscle

The qualifications to be participated in the study are as follows;

- Thai nationality with Thai ID card, age between 20 – 40 years old, weighing over 45 kilograms and capable of coming for follow up for two years (24 months).
- Pass the evaluation criteria of having low risk of HIV infection.
- Capable of reading Thai and must understand and complete the informed consent process.
- Pass the Test of Understanding of the study
- Healthy, no history of severe sickness, and normal blood and urine tests during screening.
- Blood test shows not infected with HIV within 45 days prior to participate in the study.
- For female volunteers, pregnancy test must be negative at the screening, at each vaccination and before the additional specimens procedures
- Female volunteers must use effective birth control within 45 days before the first vaccination and continue to use it for at least 3 months after the last vaccination. The contraceptive methods are as follows;
    - Contraceptive medications delivered orally, intramuscularly, vaginally, or skin-implanted
    - Surgery (removal of uterus, female sterilization)
    - Using condoms
    - Vaginal diaphragm or medical device placed through the uterus.
    - Refrain from having sexual intercourse

You are unable to participate in the study if you have the following conditions:

- Have physical and mental problems which in the opinion of the medical investigator that it may interfere with the conduct of the study.
- Do not allow disclosure of your medical history or refuse a medical examination and blood draw.
- Currently breastfeeding, pregnant, or plan to become pregnant during study participation and until 3 months after the last vaccination
- Take medicines routinely that may affect immune response
- Received blood or blood components within 120 days prior to participating in the study
- Received immunoglobulin within 30 days prior to participating in the study

- Received other licensed vaccines within 14 days prior to receiving the first vaccination
- Used to have other HIV experimental vaccines
- Have an allergy to any known part of the vaccines used in this study, including eggs, egg products, streptomycin, or neomycin
- Received study agents or vaccines within 30 days prior to participating in the study
- Received tuberculosis treatment and prevention drugs within 90 days prior to participating in the project
- Is staff of this study

4. Study Duration

Your participation will take 96 weeks (approximately two years or 24 months) from the time of enrollment. There will be up to 18 study visits and 1 to 2 screening visits (in order to provide adequate time for the informed consent process and completing screening procedures), there will be 4-5 visits for vaccination (according to study group) and approximately 12-13 visits for follow-up. Each vaccination will take approximately 3-4 hours. Other appointments will take approximately 1-2 hours. However, these do not include additional appointments if you have any side effects and if the study team requests you to come to the clinic.

If you are willing to participate in a special procedure such as sigmoid biopsy, cervical biopsy, special process of white cell collection or bone marrow aspiration, it may take longer than the usual visit or you may be asked to come to the clinic for more than one visit. Informed consent for mucosal biopsies, bone marrow aspiration and white blood cell collection may be administered at a later time during the study but prior to the procedure.

You have right to withdraw from the study by any reason at anytime; but please inform the study staff.

Clinic visits may occur following the final visit for the purpose of providing unblinding or other information, if needed.

5. Study Procedures

How to enroll in the study?

After thoroughly reading and understanding the details in the information sheet, and if you are willing to participate, you must sign this consent form. You must complete the entire screening

process. Moreover, you will be asked to provide your contact information and to show proof of identification which are the Thai identification card.

What you have to do during each visit?

You will receive details of the activity schedule of each appointment in order to make you understand what will happen at each appointment.

Screening Process

After signing the consent form, the study staff will ask you to complete the test of understanding of the study. This test will let us know how much you understand the study and what is necessary for participation in this study. To pass the test, you must answer correctly to at least 8 questions out of 10. You can do the test not more than 3 times, at least 30 minutes apart. After you have passed the test, the study staff will ask about your health history and the doctor will perform a medical examination as well as collect urine and blood specimens; approximately 1 table spoon (16 cc) for laboratory tests including HIV, Syphilis, pregnancy test (for women).

Your screening results may demonstrate that you are unable to be enrolled in the study. The study staff will explain the results to you and recommend a treatment location if you require additional medical evaluation or treatment.

If there is confirmed or clinical suspicion for genital infections found during the screening process or during the study participation, the investigator will assist in referral to the institutional network hospital for diagnosis and treatment without cost to you, and with your permission, provide all medical test results to the referral physician.

Data and specimens collected during the screening process are part of this study and will be used to determine if you are healthy and able to participate in this study.

If you qualify for this study, the investigators will make an appointment for group randomization. The first vaccination must be given not later than 45 days after the screening date.

General Appointment Activity

General appointments will take approximately 1-2 hours. For each appointment, the study staff will ask if there are any symptoms that have occurred since the last appointment as well as and medications taken. Additional urine and blood specimens may be collected for laboratory analyses per schedule of each appointment.

In addition, you will be given information regarding additional specimen collections in order to evaluate the immune response in other parts of the body. You can choose to participate or

refuse. You will be asked for additional consent for each procedure in a separate document. The additional specimen collections are as follows:

The mucosal secretion collections are as follows;

- Vaginal and cervical secretion collection in female volunteers
- Semen and/or rectal secretion collection in male volunteers

You may only participate in one of the following procedures for additional specimen collection;

- Cervical biopsy in female volunteers which this procedure will be performed at Thai Red Cross AIDS Research Centre
- For both sexes
    - Special process of white blood cell collection (leukapheresis) in male and female which will be performed at Chulalongkorn hospital.
    - Bone marrow aspiration will be performed at Chulalongkorn hospital and Hospital for Tropical Diseases (only for volunteers in group 2).
    - Sigmoid biopsy will be performed at Chulalongkorn Hospital

Participation in this study and in these specimen collections are voluntary without coercion. For cervical and sigmoid biopsy, white blood cell collection, and bone marrow aspiration, the study team will arrange your travel and accommodation without any cost to you. Accommodation will be offered for volunteer's convenience and not for medical need as all procedures are done as outpatient procedure. In addition, the study staff will accompany you from the study location to place which these specimen collection take place.

The study team will inform you of the results from your lab tests and medical examination in the next study visit. In cases where an abnormality is found, the investigators will notify you immediately. If abnormality is detected, you will be referred for appropriate testing, treatment and care.

You will not become infected by HIV by receiving this vaccine. After you have received the vaccine from the study, we cannot guarantee that the vaccine will protect you from becoming infected with HIV. Therefore, you have to be careful with your risk behavior. For example, use condoms and do not share needles for drug users. The study staff will provide counseling on this issue periodically to reduce your risk behavior.

If you get HIV infected during the study because of your own risk behavior, the investigator will pay for the diagnostic tests. Apart from having the regular test, we will confirm the infection by using specific tests that will identify whether you have a false positive from the vaccine or a natural infection. We will conduct risk assessment and HIV counseling. We will also perform CD4 and viral load tests for the benefit of further treatment as well as helping with counseling.

The study will be responsible for coordinating with the institutional network hospital in order for the participant to receive care and treatment according to the treatment of HIV infected individuals and AIDS patients according to Thailand national guidelines. We will also follow up with you regarding safety issues according to the study visit schedule without cost to you.

On Vaccination Day

You will be given the following vaccines regardless of what group you are in among the four groups;

- Four vaccinations with ALVAC vaccine or placebo on the first date of participating in the study, and in the 4^{th}, 12^{th}, and 24^{th} week.
- Two vaccinations with AIDSVAX vaccine or placebo on the 12^{th} and 24^{th} week.
- Then, there will be additional vaccinations by group as follows:
    - Group 1: No additional vaccination.
    - Group 2: You will be given both vaccines or both placebos at the 48th week
    - Group 3: You will be given AIDSVAX vaccine or placebo at the 48th week.
    - Group 4a: You will be given both vaccines or both placebos at the 60th week.
    - Group 4b: You will be given both vaccines or both placebos at the 72nd week.

Before every vaccination, the study staff will ask about your symptoms and medications taken. For female volunteers, you will be tested for pregnancy. The result must be negative before each vaccination.

The study team will evaluate HIV infection risk. There will be a blood screening test as well as counseling provided. An appointment for vaccination will take approximately 3-4 hours.

Vaccine will be injected using needle and syringe. After each vaccination, the study staff will observe your symptoms for at least 30 minutes to 1 hour. Also, we will examine your vital signs before you go back home. The investigators will ask you to record how you feel in the

reactogenicity diary card 6 hours after vaccination and everyday for 3 days. You will get a thermometer to measure body temperature and a ruler to measure the size of any reactions in the vaccination area.

If you have any side effects, please inform the doctors or nurses immediately. You may need to come to the clinic for medical examination if necessary. The study team may make an appointment for additional tests, even if your scheduled appointment has not arrived yet. Also, please pay attention to follow all instructions given by the investigators.

If you experience a serious side effect, the investigator doctors may decide to stop the remaining vaccinations. However, the study team will ask you to come per the appointment schedule. If it is found that you are infected with HIV or pregnant during participation in the study, you will not receive any further vaccinations, but you will continue your study visits for the duration of your study participation.

6. Your specimens during the study

Blood and urine specimens: The investigators may utilize part of your blood to test for any possible side effects as well as evaluate the immune response to vaccine. Urine collect at study visits, where no vaccine is administered, will be used for pregnancy tests for female volunteers in addition to any other laboratory tests

HLA and genetic tests: Part of the blood specimen of the study will be taken to analyze for HLA type. HLA is a protein with an important role in the immune response to foreign organisms. For this study, an HLA test is used to examine related factors contributing to the response to vaccine, disease progression, or other conditions. An HLA type test is therefore important for the study. We will not notify you with the results of this test unless there is any medical requirement. The HLA test for this study is not a normal medical test and the test result will not be used for treatment purpose.

Amount of each blood draw ranges from approximately 1 tablespoon (16 cc) to approximately 11 table spoons (166.5 cc) depending on the requirement at each visit and each group. Total blood drawn in 2 years (24 months) of study participation is approximately 4 measuring cup and 15 tablespoons (1171 cc) for Groups 1, 2 and 3, approximately 4 measuring cup and 11 tablespoon (1132 cc) for Group 4a, and approximately 4 measuring cup and 8 tablespoon (1061cc) for Group 4b. However, within a 12-week period, blood drawn amount will

range approximately 11 tablespoons (167 cc) to 1 cup and 6 tablespoons (339 cc) within the Thai National Blood Donation recommendation. In addition, we will collect urine for some visits. If there is any abnormality found, the study team will inform you immediately.

Other specimens: including bodily fluids such as semen, rectal secretions, and vaginal and cervical secretions, bone marrow aspiration, sigmoid biopsy, and vaginal biopsy, will be sent for analyses inside or outside of Thailand.

Before signing your name to store your specimen for future use, you will have an opportunity to review, ask, and discuss regarding information in the informed consent form. You can ask to limit the use of your specimens or your study data in the future, which may not be indicated in this document. After study closer, your remaining specimens will be stored for 5 years. If there are needed to be kept longer than that, the reseach team will inform and ask for approval from the responsible organizations and the Institutional Review Board

7. Specimen Storage

Leftover blood and other specimens will be frozen and kept at the HIV Vaccine Research Center of Excellence (HVRC), Royal Thai Army Medical Department, Thailand, to analyze your body's immune response to the vaccines. These specimens may be sent outside Thailand. During ongoing study, the investigators outside Thailand will use these frozen specimens for analyses in support of the study objectives. Your personal information will not be disclosed with these specimens. An electronic system is used to store and follow up the specimen data.

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.

8. Specimen labeling

Specimens will be kept and labeled using a numeric barcode without your name attached. Only the investigator team is able to connect those numeric codes and your name. Personal identification Information will be kept confidentially according to the laws.

9. Future Study

If you are willing, specimens collected during this study participation will be stored up to 5 years for future use in laboratory tests in accordance with this study's objectives. Other

investigators inside and outside of Thailand may want to study these specimens. Specimens will be kept in numeric code without personal information attached. These researchers may request some information such as gender, age, health history; however, we will not give them your personal information. Any study of these stored specimens must be reviewed by the Ethical Committee and/or Institutional Review Board before starting the study. These committees may approve storage of the sample for more than 5 years if necessary in the future. These committees are responsible for overseeing the medical study in order to protect rights and welfare of human study volunteers.

The study team may ask to study genetic characteristics of your stored specimens for better understanding of your immune response to vaccine.

These specimens will be used for study purpose only. They will not be sold or purchased.

Result of your specimens may bring about new product development in the future; however, you will not receive any additional compensation.

In this step, the study team will ask if you are willing to let us store your blood or others specimens for future use. You can withdraw to store your specimens at anytime by contacting the study staff. If you do not allow permission for future storage, your specimens will be destroyed upon completion of the study according to the local guidelines.

Whenever possible, a subset of samples will be divided and kept for the National Serum Bank, Department of Medical Sciences, Thai Ministry of Public Health after all protocol objectives have been fulfilled.

10. Possible risks of this study participation

Risks or hazards or discomfort due to study participation

The most common side effects occurring after vaccination with either vaccine or placebo are pain, redness or swelling, limitation of arms movement, and infected at vaccination area (very rare). You may experience shivering, fever, rash, pain and ache, or fatigue. These symptoms are similar to other preventive vaccinations and should last for only 1-2 days. Although these side effects may occur, there has been no report of any serious side effects for study vaccines used in this study. However, since these vaccines are experimental vaccines, the study team will inform you if there are any other side effects which occur in the future. While this vaccine combination

has been extensively tested in over 8000 people, there may be unforeseeable risks that we have not identified.

Blood drawing from the arm may cause pain and bruising when the needle pierces the skin. Someone may have dizziness, and fainting or infection at blood drawing area. However, these symptoms are very rare.

If you have any of these symptoms mentioned as above, the study team will provide appropriate treatment and refer for follow up.

Social risks due to vaccination and contact by the study staff

For volunteers who have received vaccine, results of a general HIV test may show false positive. This false positivity may not last long and return to normal after a while (approximately 6 months, but might last for several years). However, results from previous HIV vaccine studies have shown that other HIV blood tests can prove that you are not infected with HIV, and that the false positive result is simply a result of the immune response to the vaccine. Thus, you should refrain from having any HIV tests outside of the study clinic. If you want or have to do the HIV test outside of the study clinic, we would like you to discuss this with the investigators before doing the test in order to prevent possible problems if the test is false positive.

If your HIV test result is false positive from an immune response to the vaccine, the study team will perform additional blood tests free of charge, even if study has finished. The investigators will do everything carefully such as using numeric system instead of your name in order to protect your confidentiality.

Due to the above false positive reason, the study team will ask you to stop blood donation during study participation. If you would like to donate blood, the study staff will provide you additional information on the last visit by monitoring the duration of false positive until it disappears.

However, it is possible that you will be refused for blood donation because of participation in HIV vaccine trial and false HIV positive result.

Your friends and family may know about your study participation from a contact by the study staff. You may be treated differently by family, friends, colleagues, or other persons since they may think that you have HIV infection/AIDS or are at risk due to your risky sexual behavior or using drugs. You may be refused of medical or dental services, employment, insurance, visa, or to be enrolled as a soldier.

After you have given your written permission, the study staff will assist you with any unfair treatment as a result of study participation. The study team will provide counseling and education to family members, friends and others to reduce any potential negative social impact which may occur (if you required). You will be transferred for treatment and care in the same type of treatment and care provided for other illnesses that may occur during the course of study participation. This includes discussion on your behalf with a health insurance company, employer, or other persons to confirm that you have participated in the study. In addition, you may ask for a letter explaining of study participation if needed. You will get counseling and advice on how to answer any questions about your participation in the study, including how to manage problems that may occur.

The study team will follow you, closely through counseling and medical history taking, in order to promptly become aware if any negative events/impacts occur and provide support as quickly as possible. The study team will also inform the Community Advisory Board (who represents the community) about the progress of the study and seek for their opinions. Also a study overview will be presented to the community advisory board at every meeting.

Results from a previous HIV vaccine trial have found that the same vaccines can reduce HIV infection by approximately 31% in comparison with placebo group. However, it is still unclear if these vaccines are capable to prevent from HIV infection. Also, you may either receive vaccine or placebo. **Therefore, you should avoid all risky behaviors for HIV infection.**

Theoretical risks of AIDS vaccine

In general, vaccination can stimulate the human immune response. In some cases, the generated immune response may cause easier infection. However, this situation has not occurred in the vaccines used in this study.

Possible risks to fetus and breastfeeding infants

It is still unclear about effect of vaccine to pregnancy and fetus. Data from the HIV vaccine phase III trial indicated that there is no clear data showing that these vaccines are harmful to pregnant woman and breastfeeding infants. Nevertheless, you should avoid pregnant during vaccination and 3 months after the last vaccination by using effective contraception. If you are pregnant or breastfeeding before the 2nd vaccination, the study team will stop giving you the remaining vaccinations. However, we will follow up for safety aspects until the end of your pregnancy. You and your baby's health status will be recorded.

Possible genetic effect to the offspring of male volunteer

The possible effect of these vaccines to the offspring of male volunteer is unknown.

Risks from genetic and HLA tests

Results of genetic test may indicate information of your susceptibility for some diseases. If this information is used inappropriately, you may be discriminated (for example, health insurance). HLA type can be used to tract of the actual parents. However, your blood specimens from the study will be used to understand the immune system. Results will be shown in numeric code without your name or personal information in order to protect your confidentiality. You and your doctor will not receive results of these tests.

Risk of the special procedures will be described in more detail in the information sheet of each specimen collection.

11. Benefits from the study participation

The results of this study will provide important information on vaccine design for the vaccine specific to the HIV strain found in Thailand (especially subtypes B and E), including possible improvements to future vaccines and timeline for development. Data collected from this study will be used to further develop a vaccine to prevent HIV vaccine in Thailand. If this study vaccine or related vaccines can prevent HIV infection, this could benefit Thailand and the health of the Thai people. During the study, you will be provided with knowledge about HIV, counseling, and knowledge of how to reduce risky behavior in order to prevent HIV infection. In addition, the study team will perform HIV tests for you periodically, free of charge and will inform you the result. Results from this study may be useful for yourself and the others in the future.

12. Compensation for study participation

You will be compensated for your time, travel expenses, and missed wage for travelling as described below:

- 1,000 baht compensation for each regular appointment and screening
- 1,000 baht compensation for each mucosal secretion collection

- 2,000 baht compensation for biopsy
- 2,000 baht compensation for white blood cell collection
- 3,500 baht compensation for bone marrow aspiration

Appointment for other reasons needed for health issues requested by the investigator, the investigator will pay for the transportation and compensation as appropriate. You may also receive a small token of appreciation intended to commemorate your participation in the study.

13. Personal information confidentiality

The investigators and the study staff will maintain and protect your data. We will do everything to protect your confidentiality as stated by the law. You will receive a study number which is known among the study team only and it is used to keep confidentiality of study data. Collected specimens will not display any of your personal information

Clinical trial information will be kept at the database at the National Medical Library in the United States of America/the National Institute of Health of the United States of America on http://www.clinicaltrials.gov as required by U.S. law. This website will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

Clinical and study data may be monitored and audited by the representatives of the following organizations which are responsible to oversee this study:

- U.S. Military HIV Research Program (USMHRP)
- United States Army Medical Research and Materiel Command (USAMRMC)
- The U.S. Food and Drug Administration
- The National Institutes of Allergy and Infection Diseases
- The Health and Human Services (HHS), Office for Human Research Protections (OHRP) Institutional Review Board/Ethical Committee
    - The Ethical Review Committee for Study Human Subjects, Ministry of Public Health, Thailand.
    - The Royal Thai Army Medical Department Institutional Review Board
    - Ethics Committee of the Faculty of Tropical Medicine, Mahidol University
    - Research Institute for Health Sciences Human Experimentation Committee, Chiang Mai

- Walter Reed Army Institute of Research Institutional Review Board
- Institutional Review Board, Faculty of Medicine, Chulalongkorn University

- Other Thai Regulatory Authority

Your general and health information will be considered as importance and kept confidential. The representatives of the above organizations have to follow the restriction in keeping confidential and not revealing the data to others.

Publication or presentation of the data from this study in scientific peers will not disclosed name which can connect to you.

The United States Army Medical Research and Materiel Command (USAMRMC) has a policy to collect data of all volunteers who participate in this study to be placed into a "Volunteer Registry Database". There are two objectives for this data collection; 1) to answer question of volunteers who participate in the study funded by the United States Army Medical Research and Materiel Command (USAMRMC) and 2) to ensure that the study volunteers are informed of risks or new information.

The required information is as follows:

- Name and last name
- ID Number
- Date of birth
- Contact information
- Study title, date participating in the study as well as withdrawal reason
- Serious unexpected adverse reaction and adverse events related to the vaccine occurring during study participation
- Details of study products you received

This database will be stored in Thailand for 75 years under the responsibility of AFRIMS in coordination with Faculty of Tropical Medicine, Mahidol University. However, the information of name-surname and ID number will be stored separately from the USAMRMC volunteer registry database collection.

14. Sickness or injury as a result of study participation and treatment

If you get sick or injured due to the vaccination of this study, you will receive appropriate medical treatment and care as provided with two types of coverage by a limited fund and a clinical trials medical insurance policy that will be obtained by the study sponsor. While we anticipate the combination of the set-aside fund and the insurance policy is more than enough to pay for the costs associated with this study, there is a limit to the amount of coverage available. The study team is responsible for the cost without using any personal health care package which belongs to the volunteer. Costs which do not fall under the deductible for the insurance policy for this study will be submitted to QBE insurance. However, you will not get any other compensation. You should discuss this thoroughly with the Principal Investigator or the Co-Investigators before making a decision to participate in this study. If you have any question about study- related sickness or injury, you can contact the following persons:

Punnee Pitisuttithum, MD
Vaccine Trial Center
Faculty of Tropical Medicine, Mahidol University
420/6 Ratchawithi Road, Bangkok
Tel. 08 1829 4906

LTG. Sorachai Nitayaphan, MD
The Armed Forces Research Institute of Medical Sciences, Thai party
315/6 Ratchawithi Road, Bangkok
Tel. 08 1625 1531

Suwat Chariyalertsak, MD
The Research Institute for Health Sciences
Chiang Mai University
Post Box.80 Chiang Mai University, Chiang Mai Province
Tel. 08 5040-4524 and 0 5394 5055

15. If there is a new finding

The study team will inform you if there is any new information during the study that may affect your willingness to participate in the study.

16. Other options to participate the study

You may decide not to participate in this study or may decide to participate in other study if it is available.

17. Ending study participation

You can choose not to participate or withdraw from the study at anytime without any consequence to you. However, before withdrawing from the participatory, the study team may perform a medical examination, blood and urine tests to evaluate your health status before your participation has come to an end.

If you would like to withdraw of this study, please contact the Principal Investigators or the study staff mentioned previously. You will not lose any legal rights, including the rights for medical treatment and others if you withdraw from this study. Although you are willing to continue in the study, the investigators may stop giving you vaccinations but will continue follow up or the investigators may withdraw you from the study if any of the following situations occur:

1. Study is stopped.
2. Study sponsors or the Institutional Review Board request to terminate the study for unexpected reasons.
3. You are unable to comply with the study requirement.
4. You are not willing to have blood drawn although you are still willing to participate in other processes.
5. You have a medical problem where continuing to be in the study would be harmful to you.
6. Other incidents occurred and may be harmful to you if continue being the study volunteer.

18. If you need more information or have additional questions

If you have any question about this study, how to behave as being the volunteer in this study, or if you have any problems or questions regarding the works of the study staff, you can ask the Principal Investigator or designee;

Punnee Pitisuttithum, MD
Vaccine Trial Center
Faculty of Tropical Medicine, Mahidol University
420/6 Ratchawithi Road, Bangkok
Tel. 0 2245 5919

LTG. Sorachai Nitayaphan, MD
The Armed Forces Research Institute of Medical Sciences
The Royal Thai Army
315/6 Ratchawithi Road, Bangkok
Tel. 08 1625 1531

Suwat Chariyalertsak, MD
The Research Institute for Health Sciences
Chiang Mai University
Post Box.80 Chiang Mai University, Chiang Mai Province
Tel. 0 5394 5055 and 08 5040 4524

If you have any question and need to ask about your right or you do not get appropriate treatment and care for sickness or injury which occur as a direct result of taking part in this study or the investigator does not treat you fairly in accordance with what is described in the information sheet, you may make a complaint to the following bodies:

Ethics Committee of the Faculty of Tropical Medicine, Mahidol University c/o Research and Academic Services
4th Floor, The 60th Anniversary of His Majesty the King's Accession to the Throne

Building
Faculty of Tropical Medicine, Mahidol University
420/6 Ratchawithi Road, Bangkok 10400, Thailand
Tel: 0 2354 9100-19, ext. 1349

Royal Thai Army Medical Department Institutional Review Board
The 5th floor, Phramongkutklao Medical Building
Phramongkutklao College of Medicine
315 Ratchawithi Road,
Bangkok 10400 Thailand
Tel. 0 2354 7600 ext. 94270; 0 2354 9011

Human Experimentation Committee
The Research Institute for Health Sciences, Chiang Mai University
110 Intawaroros Road, Chiang Mai Province
Tel. 0 5394 5055, 0 5394 6148 ext.360

Institutional Review Board,
Faculty of Medicine, Chulalongkorn University
1873 Rama 4 Road, Pathumwan, Bangkok 10330
Tel. 0 2256 4455 ext 14, 15

The Ethical Review Committee of Research in Human Subjects
Ministry of Public Health,
Office of the Secretary, 3rd Floor, Department of Medicine Services Building,
Tiwanon Road, Nonthaburi 11000,
Tel 0 2590 6171-2
Fax 0 2591 8251