

**RV306**  
**Information Sheet for Additional**  
**Special Process of White Blood Cell Collection (Leukapheresis)**

**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

**Study Short title:** Prime and Multiple Boost HIV Experimental Vaccine Project

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

**Attention the Study Participants**

**Before deciding to participate in the special process of white blood cell collection, please read this document thoroughly. In doing so, you will acknowledge the rationale and details of this sample collection. 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 clarify any matter.**

**You are also able to ask advice about participation in this sample collection 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**

White blood cells are an essential part of the immune system against pathogens including defense against HIV. Testing for an immune response in white blood cells following vaccination is, therefore, very important for HIV vaccine development in the future. The laboratory investigators need a large amount of white blood cells to use for study analyses which would

require a normal blood draw of 450 ml (30 tablespoons). For this study, we will use special process called “Leukapheresis”. This process will separate the white cells to store and return the rest of blood components to the body. For this process, you will not lose the large amount of blood as you would with the regular blood collection.

## **2. Special process of white blood cell collection**

This process will be done at the blood bank of Chulalongkorn Hospital. The estimated number of volunteers to participate in the special process of white blood cell collection is 29 persons. White blood cell collection will be performed at week 26 (group 1) and week 50 (group 2 and 3)

Before starting the special process of white blood cell collection, the staff will check your weight, body temperature, blood pressure, and pulse.

Before and/or after the procedure, up to 10 mL of blood may be drawn from your arm and/or the end of your finger to test for safety labs depending on the institutional requirement.

For female participants, you will be tested for pregnancy before doing this procedure.

The special process of white blood cell collection will be performed by inserting needle from the vein of either forearm, connected to automatic blood separating machine. This machine will separate the white blood cell into specialized bag. Platelets, plasma, and other blood components will be returned to your body via the vein of the other forearm. Using this method, a volunteer will lose only three tablespoons (50 ml) of red blood cells, which is the residual in the machine. Ten tablespoons (150 ml) of serum will be stored together with the white blood cells.

The special process for white blood cell collection will take approximately two and a half hours. You should sit and recline calmly on the chair while the machine is operating. After the process is over, you can go back home if you have no abnormal symptoms.

For this process, the study staff will make an appointment for you to travel to Blood bank, Chulalongkorn Hospital. We will be responsible for arranging the travel and accommodation. The study staff will also accompany you to the hospital. Accommodation will be offered for volunteer's convenience and not for medical need as this procedure is done as outpatient procedure. There is no cost to you.

### **3. Risks and discomfort from the special process of white blood cell collection**

Severe side effects of the special process of white blood cell collection rarely occur. In general, you may feel pain, swelling, or bruising or have infection at needle piercing area, which happens rarely. Some volunteers may feel dizzy for few minutes and feel uncomfortable from sitting still for a long time.

Since blood anticoagulant is used in this process, you may feel chills or numbness at the lip or fingertips. In addition, there are rare symptoms including nausea and vomiting, fainting, cramps, headache, itchiness, flushing, sneezing, wheezing, or chest tightness. If you have any of these symptoms, the staff may reduce the application rate of blood anticoagulant or may ask you to a chew calcium carbonate as suggested by the hematologist.

In addition, you may be allergic to any substance of the equipment used in the special process. Therefore, we will question you thoroughly regarding your allergy history before initiating this special process.

After completion of the special process of white blood cell collection, you will be advised to drink plenty of water and avoid heavy exercise.

In addition, before doing this process, the study staff will perform a blood test. If it is out of normal range, the study team may ask you to postpone this process.

In order to prevent any the above mentioned problems, the special process to collect white blood cell will be performed by a specialist and will be done under sterile conditions. All equipments to be used are sterile and are disposable. There will be no blood transfusion given to you.

Female volunteers who are pregnant or intend to get pregnant should not participate in this special process and should inform the study staff.

### **4. Your benefits from white blood cell collection**

You may not directly benefit from this special process for white blood cell collection. However, this study data will provide the investigators insight into the human immune system and HIV infection, and will be used for HIV-vaccine development in the future.

## **5. Compensation for the special process of white blood cell collection**

You will be compensated for your time, travel expenses, and missed wages for travelling to each appointment for white blood cells collection in the amount of 2,000 Baht (two thousand Baht only).

## **6. Sample Storage**

Stored plasma and white blood cell samples will be kept and labeled using a barcode with a numeric code; your personal information is not presented. These samples will be sent for laboratory analyses inside or outside of Thailand.

The samples will be frozen and kept at HIV Vaccine Research of Excellence, Royal Thai Army Medical Department, Thailand.

If you withdraw from this study, your white blood cell sample and information collected until the withdrawal date will be used to study your body's immune response to the vaccines.

## **7. Future Study**

If you are willing, white blood cell samples will be stored for future use in laboratory tests which are related to this study's objectives. Investigators inside and outside of the country may request to study these samples. Other future studies required to use these samples must be approved by the Ethical Committee and the Institutional Review Board which oversee the medical study in order to protect rights and welfare of human subjects.

The investigator team may ask to study genetic characteristics of your white blood cell sample. Genetic study is conducted to better understand your immune response to vaccine.

These samples will be used for study purposes only. They will not be sold or purchased.

Result obtained from the study of your sample may bring about new product development in the future. However, you will not receive any additional compensation.

The study team will ask for your permission to store the white blood cell for future use. After study closure, your remaining specimens will be stored for 5 years. If there is a need for it to be kept longer than that, the research team will inform and ask for approval from the responsible organization and the Institutional Review Board/Ethical committees. These committees may approve storage of the sample for more than 5 years if necessary in the future.

You are able to withdraw your permission to store this sample at anytime by contacting

the study staff. If you do not allow storage of this sample, your sample will be destroyed upon completion of the study according to the local guidelines.

#### **8. If you get sick or injured from the special process of white blood cell collection**

If you get sick or injured due to this special process of white blood cell collection, 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. However, you will not get any other compensation apart from this. You should ask the Principal Investigator or the Co-Investigators about this matter completely before making a decision to participate in this white blood cell collection. If you have any question about illness or injury related to this sample collection, you can contact the Principal Investigator or the representative, 1) Punnee Pitisuttithum, MD, Tel: 08 1829 4906. 2) LTG. Sorachai Nitayaphan, Tel 08 1625 1531

#### **9. If you are not willing to participate in this special process for white blood cell sample collection**

You can withdraw from this sample collection at anytime by informing the staff of your decision. A decision to withdraw will not affect study participation as well as not affect rights for treatment and health you are entitled to.

#### **10. Other options to participate in the special process for white blood cell collection**

If you decide not to participate in this special process for white blood cell sample collection), you may still decide to participate in other sample collections.

#### **11. If you need more information or have additional questions**

If you would like to ask how to behave as being the volunteer of 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, Thai party  
315/6 Ratchawithi Road, Bangkok  
Tel. 08 1625 153

If you do not receive proper treatment for any injury or illness resulting directly from the study or you are not treated as stated in the information sheet for study participants or if you have any question regarding your rights, you can complain at

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 5<sup>th</sup> floor, Phramongkutklao Medical Building  
Phramongkutklao College of Medicine  
315 Ratchawithi Road,  
Bangkok 10400 Thailand  
Tel. 0 2354 7600 ext. 94270; 0 2354 9011

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