UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

GlaxoSmithKline (GSK) Biologicals S.A.: TH-HIV-011 (114083) Amendment 2.0, 2/6/12
Long-term follow-up of participants from studies evaluating the HIV vaccine 732462

CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND RESEARCH SUBJECT HIPAA AUTHORIZATION

Your contacts for this study at the Hospital of the University of Pennsylvania [HUP] are:

Principal Investigator:	Ian Frank, MD	(215) 349-8092
Coordinator:	Joseph Quinn, RN	

Site address: 502 Johnson Pavilion Philadelphia PA 19104
24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call

What is "Consent"?

You are being asked to join this study because you have participated in the TH-HIV-008 GSK vaccine study. This study is a long term follow up study for persons that received the 732462 vaccine. It is up to you to decide if you want to take part in this research study.

If you decide to join, you will need to sign the pages at the end of this form to show that you voluntarily agree to participate in this study. This is called "giving consent".You will be given a copy of this form.

You should make your decision only after:

1. a study staff person has explained the study to you
2. you know the purpose of the study and the risks, and
3. you are willing to do what is asked of you while participating in this research study.

Talk with your family, friends, and your doctor/health care provider to help you make your decision. You can take as much time as you like to make this decision.

You may change your mind at any time during the study. You may leave the study at any time, even if you have signed this form. You do not have to give a reason.

The study doctor and the institution are paid to conduct this research study by GSK. GSK may use the results of this study to get patents / publications, or sell the vaccine in the future or make profits. There is no plan to contact any participant now or in future about such commercial benefits.

The information and the materials given to you in the study are confidential, belonging to GSK, and should be kept private. You can discuss this information in confidence with your family doctor or friends and family to decide about taking part in this study and talking about your healthcare.

Why Is This Study Being Done?

Scientists at GlaxoSmithKline Biologicals have been working on a HIV vaccine which we hope may be able to prolong the symptom free period before treatment with anti-retroviral medication (medications against HIV) is needed and have a beneficial effect on the progress of the disease in HIV infected persons already receiving anti-retroviral medication.

It is likely that some of the effects of the vaccine on HIV disease will not be seen shortly after vaccination. This study is being done to gather information about the longer term effects of the vaccine on HIV-infected persons.

This study will also look at how long the immune response to the HIV vaccine lasts.

How Many People Will Join This Study?

Only persons who previously took part in a study to evaluate the investigational HIV vaccine developed by GlaxoSmithKline (GSK) Biologicals may join this study; this is about 200 people. Because you were enrolled in the HIV-008 study entitled: "Study to evaluate the efficacy and safety of HIV Vaccine 732462 in ART-naïve HIV-1 infected persons", you are eligible to participate. It doesn't matter if you received the active vaccine or placebo a (mild salt solution that contains no other components). Three persons who were enrolled at the University of Pennsylvania in the HIV-008 study will be offered participation in this long term follow up study.

What Do I Have To Do If I Am In This Study?

The study started in 2010 and will end in 2017. Once a year, for a maximum of 6 years, we will ask your physician to provide the following:

- Data that were collected in the previous year during your regular HIV control visits.
- The CD4 cell counts, viral loads and basic information on your HIV status from your routine visits.
- Information regarding your general health obtained from your records and by asking you.
- Information regarding whether you have started or changed antiretroviral therapy.

At approximately yearly intervals, and if you agree, you will be asked to provide blood for additional testing of your body's immune system (part of the body that fights against infection) at this, or another, routine visit.

Each year, you can choose to allow:

- both collection of your information and a blood sample
- or just collection of your information

If you consent, you will not be asked to book specific study visits. Your health status information and blood samples will be collected during your routine visits to your physician.

In this study you will not receive any treatments or vaccines.

You are also entirely free to participate in any other study. If you decide to participate in any other study, we would still like to continue to collect data on your health status, unless you prefer to withdraw from this long-term follow-up study.

What Will Happen to Samples Taken in This Study?

Samples will not be labeled with information that directly identifies you but will be coded with an identification number.

Collected samples may be transferred to GSK Biologicals and other laboratories working for GSK Biologicals.

By agreeing to take part in this study you will be allowing GSK Biologicals to use your samples for the following purposes:

- ✓ Testing to see how long your body's immune response to the investigational vaccine will last.
- ✓ To assure that the tests used in this study remain of high quality and can be repeated or compared with the results from other studies.

- ✓ To assess, improve or develop tests related to the disease(s) or the vaccine under study that will allow more reliable measurement of the response to the vaccine. This excludes testing related to your genes' hereditary characteristics.
- ✓ If any findings from this study and/or related studies require further investigation into the effects of the HIV vaccine or for further research into HIV infection and AIDS, additional testing on your collected samples may be performed. This excludes testing related to your genes' hereditary characteristics.

Samples collected specifically for this study will be stored for up to 15 years.
In addition, if you agree, your biological sample(s) may be used by GSK Biologicals for further research that is NOT RELATED to the disease(s) or the vaccine under study. This will be done on an anonymous basis (meaning that any identification linking you to the sample is destroyed). Testing on your genes' hereditary characteristics will not be done.. This testing is optional and does not affect your participation in the study.

Check as appropriate

I agree that my biological sample(s) may be used by GSK Biologicals for further research that is NOT RELATED to the disease(s) or vaccine(s) product(s) under study. This testing will be done on an anonymous basis (meaning that any identification linking me to the sample is destroyed). Testing on my genes' hereditary characteristics or testing for HIV will not be done. I understand that if I select "No", it will not affect my participation in the study.

☐ **Yes** ☐ **No**

What Side Effects or Risks Can You Expect in the Study?
If you agree, additional blood (approximately 38 mL) will be taken at the same time as your blood is taken for routine HIV testing. This way, you will not need a second needle stick. When you give blood, you may feel faint, or experience mild pain, bruising, irritation or redness at the site where blood was taken.

Are There Benefits to Taking Part in This Study?
Taking part in this study may not have a direct benefit for you. Information collected during the study may increase knowledge about HIV disease and any long term effects that the HIV vaccine may have. Information that we gain from this study may help to make a better HIV vaccine.

Do I Have To Stay In The Study?
You may choose to stop being in the study at any time, without giving a reason. Your decision will not affect the medical care you receive outside of the study.

GSK (the study sponsor) may choose to stop the study or the study doctor may choose to stop taking part in the study at any time. We will give you the reason at that time.

We will share with you or your legally authorized representative any new information that might affect your choice to stay in the study as soon as possible.

If you decide to leave the study, all the information you gave us before you left the study will still be used for the study. This includes any data from samples taken before you left the study. Any relevant safety information reported after you leave the study will also be collected.

What About Confidentiality?

Who will have access to your personal information?

If you decide to take part in the study, the study doctor and staff will collect medical and personal information about you during the study. People who work for or with GSK, and others like the ethics committee or the review board for the study or regulatory authorities responsible for approving vaccines, will have access to this information in order to check that the study is done properly. GSK staff who see this information will keep it confidential to the extent permitted by applicable laws and regulations.

The study site will transfer some of the information it collects to GSK, in a coded form. The information transferred will not include your name, initials, address, or other direct identifiers. It will have a code number that only the site can connect with your name.

Your permission to the study doctor and staff to use this information or share it with GSK and others as described below for the study doesn't automatically end at a particular time.

Medical information about you may be produced as part of the research or study procedures. If at the time of the study, this information is known to be relevant to your medical care it will be given to the study doctor who should share it with you or your doctor.

While you are in the study, the study site will not share certain new medical information about you that is created as part of the study (such as the results of certain tests) unless the study doctor decides it is medically important to do so. This is done to stop the study results from being distorted. Once the study is over, you will be given access to medical information about you that you are entitled to see.

You will be told if any of this medical information requires confirmation using a clinical test. This is important because some research results are for research purposes and may have only limited relevance for clinical diagnosis or treatment. At any time, you may ask the study doctor to let you see your personal information, e.g. name and address and to correct it if necessary.

What will GSK do with the study information?

The coded information collected by the study doctor will be sent to GSK, who may:

- ✓ Keep it and analyze it by computer to find out what this study is telling us.
- ✓ Share it with the FDA and/or other agencies that approve new vaccines/products/medicines, or with groups that check that research is done properly.
- ✓ Write up the study results for medical journals (this will not include any information that directly identifies you).
- ✓ Share it with other companies or universities to better understand the disease or develop this vaccine. If the information is sent to another country, GSK will apply the same level of protection to your information, to the extent permitted by local law.
- ✓ Use it to plan new studies, other types of research or other medical purposes.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You may withdraw or take away your permission to use and disclose your personal and medical information at any time. You must do so in writing to the Principal Investigator. Even if you withdraw

your permission, your information that was collected before you withdrew your permission will still be used and disclosed, as necessary for the study. If you withdraw your permission, you will not be able to stay in this study.

If you decide not to give permission to use and disclose your personal and medical information, then you will not be able to be in this study.

HIPAA AUTHORIZATION
The authorization part of the consent gives more detailed information about how your personal health information may be used and disclosed by the University of Pennsylvania Health System (UPHS), the School of Medicine and the individual Principal Investigator, subject to University of Pennsylvania procedures.

What personal health information is collected and used in this study and might also be disclosed?
The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, date of birth
- Personal and family medical history
- Current and past medications or therapies
- Results of tests you will undergo during this research study

Why is your personal contact and health information being used?
Your personal contact information is important for the research team to contact you during the study. Your personal health information and results of tests and procedures are being collected as part of this research study. In some situations, your personal health information might be used to help guide your medical treatment.

Which of our personnel may use or disclose your personal health information?
The following individuals may use or disclose your personal health information for this research study:

- The Principal Investigator and the Investigator's study team
- Authorized members of the workforce of the University of Pennsylvania Health System and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

Who, outside of UPHS and the School of Medicine, might receive your personal health information?
As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures. This information may be disclosed to those listed below:

Individuals or organizations responsible for administering the study:

- Contract Research Organization : Monitors that are hired by the sponsor will visit the site to review data and correct mistakes before the data are sent for analysis.
- Government Agencies: Data from this study will be made available to the Food and Drug Administration for them to evaluate the safety and efficacy of the treatments being used in this study.

Regulatory and safety oversight organizations

- The Food and Drug Administration

- The Office of Human Research Protections

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. Data are reported to the sponsor on Case Report Forms that identify you by your unique study number and not your name, date of birth, address, social security number or medical record number. Information regarding your health, such as side effects of the study drug you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may UPHS and the School of Medicine be able to use or disclose your personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. You will also be given the UPHS and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your personal health information.

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

Will I Receive Any Payment?
You will be compensated $50 to come in for the annual visit. This compensation is to help cover your travel and parking expenses, as well as, your time.

Please note that if you receive more than $600.00 compensation in one year for participation in research studies at the University of Pennsylvania, you must provide an Individual Tax Identification number or Social Security Number for tax purposes.

Will There Be Any Cost/Expenses In The Study?
All study procedures will be performed at no cost to you.

What Happens If I Am Injured?
GSK will help pay for care if you are hurt by a procedure done to you as part of the study. GSK will pay for reasonable and necessary care for the injury. GSK will not pay for any other expenses. To pay these medical expenses, GSK will need to know some information about you like your name, date of birth, and social security number. This is because GSK has to check to see if you receive Medicare, and, if you do, report the payment it makes to Medicare. GSK will not use this information for any other purpose.

There is no program for compensation either through the University of Pennsylvania or the sponsor. You will not be giving up any of your legal rights by signing this consent form. If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researchers' names and phone numbers are on page 1 of this consent form.

What Are My Rights As a Research Subject?
Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. Your healthcare provider will treat you the same no matter what you decide.

We will tell you about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you want to be informed of the results of the study at the conclusion of the study, let the study staff know.

What Do I Do If I Have Questions Or Problems?

For questions about this study or a research-related injury, contact:

- Ian Frank, MD (215-349-8092)
- Clinical Trials Unit (215 349-8092)

For questions about your rights as a research subject, contact:

- Director of Regulatory Affairs at the University of Pennsylvania by phoning (215) 898-2614

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Long-term follow-up of HIV vaccine 732462

When you sign this form, you are agreeing to take part in this investigational research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you. You will also be given the University of Pennsylvania Health System and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your health information.

- ✓ confirm that I have read the written information (or have had the information read to me) for study TH HIV-011 (114083) PENN IC V3 2 JUN 2012/ GSK Model V2 5 MAR 2012 and the study procedures have been explained to me by study staff during the consent process for this study.
- ✓ confirm that I have had the opportunity to ask questions about this study and I am satisfied with the answers and explanations that have been provided.
- ✓ understand that I grant access to data about me to authorised persons described in this informed consent form.
- ✓ have been given time and opportunity to consider taking part in this study.

Check as appropriate (this decision will not affect your ability to enter the study):

I agree that my doctor/health care provider will be notified of my participation in this study.

☐ **Yes** ☐ **No**

I agree to have additional blood samples taken once yearly at the same time as routine HIV and/or HIV treatment monitoring.

☐ **Yes** ☐ **No**

I agree to take part in this study.

Signature of Subject _____ Date: _____ dd/ mmm/ yyyy

Printed Name of Person conducting Consent _____

Signature of Person conducting Consent _____ Date: _____ dd/ mmm/ yyyy

I confirm that I am independent of the study, that I attended the informed consent process and that I have read the written information for the study.

*Printed name of Witness _____

Signature of Witness _____ Date: _____ dd/ mmm/ yyyy

* Witness is only required if the subject is unable to read.