

INFORMED CONSENT FOR GENETIC TESTING

Title of Protocol: A Phase I, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of an Ad26.Mos4.HIV and CH505 TF chTrimer (Env) Combination to Mimic Acute HIV Viral Replication Kinetics in Healthy Adults

Sponsor: The Surgeon General, Department of the Army

Principal Investigator: Grace Mirembe, MBChB, MMed

Introduction

As we told you in the main informed consent form for this study and in the consent form for the storage of samples for future use, we will do some testing on the biological samples that we collect from you. Some of the testing that we will do on your biological samples will be genetic testing. As a reminder, the biological samples that we will collect from you for this study includes any blood, blood components such as plasma and serum, and lymph nodes if you decide to undergo the optional lymph node biopsy. This consent form tells you everything we know now about genetic testing using your biological samples.

You can decide whether or not to let us use your biological samples for genetic tests. Your decision does not affect your participation in the study or any care you receive at this clinic. If you decide to allow us to use your biological samples for genetic tests, we will ask you to sign this form. You will get a signed copy of the form to keep.

Why is genetic testing done on my biological samples?

Researchers are able to measure how the immune system responds by looking at biological samples. We know that sometimes genes, passed down from your parents, can be important to a person's immune response. Because of this, we would like to do genetic testing on your biological samples to try to understand how the study vaccines affect your immune response, if the immune response is different in some people, and why immune responses may be different. We will only perform genetic testing to learn more about how the immune system responds to the study vaccines.

Part of the blood samples that we collect from you for this study will be used for a test called HLA type. HLA stands for 'Human Leukocyte Antigen', a group of proteins present on the surface of all cells on the human body and help the body's immune system respond to foreign, harmful substances. For research, HLA testing is used to try to identify factors associated with response to a vaccine, progression of a disease or related conditions. Determining HLA type is necessary to be able to perform certain research studies.

In addition to HLA typing, other genetic testing may be performed to look for "genetic variations" and other factors that affect your immune response.

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 and have not been approved for use in making health care decisions.

Your Samples Used For Genetic Testing May Be Shipped to the USA

In order to complete the genetic testing on your blood samples, they may be shipped and stored in the United States. There is no time limit on how long your samples will be stored.

How will my privacy be protected?

We will protect your privacy with any genetic testing of your samples, just like we do with all research information collected from you during the study. The samples will not be labeled with any personal information, such as your name. Instead, they will have your study code. The link between your personal information and your study code will be kept secure with access limited to only those who need the information to conduct the study. After this study ends, when the samples are requested for future research, the study code stays with them, or in some cases, it is removed before the samples are sent to be used, if this information is not necessary for the study.

What are the benefits of allowing genetic testing on my biological samples?

The researchers will not contact you or your health care provider with results from the genetic testing using your samples. This is because the use of the samples is for research and the tests have not been approved for use in making health care decisions.

There is a chance that the biological samples you are donating under this study may be used in other research studies and found to have some commercial value. Your samples will be used only for research and will not be sold. Should your donated sample(s) lead to the development of a commercial product, the study sponsor and inventor will own it and may take action to patent and license the product. Neither the sponsor nor the inventor intends to provide you with any compensation for the samples you provide in this study, nor for any future value that the sample you have given may be found to have.

Are there any risks related to genetic testing on my biological samples?

Risk of genetic tests and HLA testing: The greatest risk associated with genetic testing is to your privacy. Genetic test results can be used to provide information about how susceptible you are to certain diseases. Used inappropriately, this information could be discriminatory (for example, by insurance companies). HLA typing can also be used to determine who the true parent of a child is (if compared to the child's HLA type). However, the risk of this happening is extremely low because your results will not be part of your medical records and will not be provided to the clinic.

The samples that you provide will only be used to provide study investigators information about your immune system. We will not look at your full set of genes. The results will be coded to protect your identity. Your HLA and other genetic test results can only be connected to you by the coded study number and not by your name or other personal information. Neither you nor your doctor will be given the results of the tests as they are for research purposes only and not used to make health-related decisions.

If I agree now, can I change my mind later?

If you agree now but decide later that you do not want us to use your samples for genetic testing, please tell us. We ensure that no further genetic testing is performed on your samples, however any results from genetic testing that has already been completed will be retained and used in this study.

For More Information:

If you have questions about the use of your samples for genetic testing, a problem that you think may be related to the use of your samples for genetic testing, or if you want to withdraw your consent, you can contact Dr. Grace Mirembe by telephone at 0312-330400, 0800-200058, or 0772-577768; or you can contact the study coordinator, Dr. Job Kasule by telephone at 0312-330400, 0800-200058, or 0701-772291.

If you have questions about your rights as a research participant, problems or concerns about how you are being treated in this study, or feel that you have not received the appropriate care and treatment for a sickness or injury that occurred as a direct result of taking part in this study, you may contact Dr. Joseph Kagaayi at the Research and Ethics Committee, Makerere University School of Public Health, Mulago Hospital Complex by telephone at 0773-785333 or you may contact The Executive Secretary at the Uganda National Council for Science and Technology by telephone at 0414-705500.

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Participant Statement:

The principal investigator, Dr. Grace Mirembe or their representative has explained in detail the purpose of genetic testing, how my privacy will be protected, and the risks and benefits that may arise. I have been informed that by signing this form, I am not giving up any legal rights. I have been given a chance to ask questions about genetic testing and all of my questions were answered to my satisfaction. If I have other questions about this study, I can contact Dr. Grace Mirembe, by telephone at 0312-330400, 0800-200058, or 0772-577768; or I can contact the study coordinator, Dr. Job Kasule by telephone at 0312-330400, 0800-200058, or 0701-772291.

I am indicating my decision of whether to allow genetic testing on my biological samples by marking the applicable box below, writing my initials next to the marked box, and printing and signing my name in the spaces provided below. I will do my best to follow the recommendations of the study team, and I will report all problems occurring from this study to the study team. It has been explained to me that even if I agree to allow genetic testing now, I have a right to withdraw my consent at any time and without losing any rights to which I am entitled. I have been offered a signed copy of this consent form.

____ ☐ I allow you to use my samples for genetic testing.
initials

____ ☐ I **do not** allow you to do genetic testing on my samples.
initials

SIGNATURE OF PARTICIPANT

DATE

PRINT NAME OF PARTICIPANT

SIGNATURE OF PERSON ADMINISTERING CONSENT

DATE

PRINT NAME OF PERSON ADMINISTERING CONSENT