

INFORMED CONSENT FOR THE STORAGE AND FUTURE USE OF SAMPLES

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

The purpose of this consent form is to ask for your permission to store your samples after this study ends for use in future research. Before consenting to the storage and future use of any biological samples from this study, please ensure that you understand the definition of a “biological sample”. 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.

Please read this document carefully in order to understand the reasons for storing biological samples and the ways that your information will be protected. If you have any questions or concerns, please ask the principal investigator or study team. They will be happy to answer your questions. You can ask for advice about your permission for the storage and future use of your biological samples from family, friends, or your doctor before deciding whether or not to give your permission. You will be given as much time as you need to make this decision. If you decide to give permission for the storage and future use of your biological samples, you will be asked to sign this consent form and will receive a signed copy for your records.

Giving permission for the storage and future use of your biological samples is optional, and you will still be allowed to take part in the study without agreeing to this. If you withdraw your consent to participate in this study, the samples that have already been collected will be used for analysis according to study objectives. You can also withdraw your consent for storage and future use of samples that have not yet been collected at the time that you withdraw consent. If you either do not agree to or withdraw your consent for the storage and future use of your samples, then your samples will be destroyed at the end of the study after they have been analyzed according to study objectives.

How will my samples be used in the future?

Stored biological samples will be used for future testing to learn more about the effects of the study vaccinations. As new methods (or ways) of measuring the body’s immune response to vaccines are made in the laboratory, we would like to test these methods on the samples we have already collected from you. For example, if a new type of immune response to HIV is discovered, we would use the samples already collected from you to test it in the laboratory.

We know that sometimes genes, passed down from your parents, can be important to a person's immune response. Because of this, we may want to do genetic testing on your stored samples. We may use methods that have not been developed yet, so we cannot describe them to you now. We will only use your stored samples to learn more about how the immune system responds to the vaccines and how vaccines can prevent HIV infection. Results from the genetic testing will not be sufficient to independently identify you as an individual as whole genome sequencing will not be performed on your samples. Future genetic testing is optional, and you will still be allowed to take part in the study without agreeing to it. You can indicate your choice of whether to allow or refuse future genetic testing on your samples at the end of this form.

You will not receive the results of future studies or future genetic tests involving your stored samples. This is because the samples will be used only for research purposes and the results of the tests have not been approved for use in making health care decisions.

How will my privacy be protected?

We will protect your privacy with any future research testing of your samples, just like we do with all research information collected from you during the main 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.

Who can access my stored biological samples?

Investigators in Uganda or other countries may wish to study your stored samples. Samples will not be transferred to any sites other than those involved in this study without the approval of the appropriate Institutional Review Boards/Ethics Committees. These committees are responsible for overseeing clinical research in order to protect the rights and welfare of human participants.

What are the benefits of allowing the storage and future use of my biological samples?

There is no direct benefit for allowing your samples to be stored and used in future research. The researchers will not contact you or your health care provider with results from future studies or future genetic tests that use your samples. This is because the samples will be used only for research purposes and the results of 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 the storage and future use of my biological samples?

When tests are done on the stored samples there is a small but possible risk that information about you could accidentally be released to other people not involved in this study, including information about you receiving vaccination for the prevention of HIV. This could result in discrimination by your family, employers, and community. The risk of this happening is extremely low because your results will not be a part of your medical record and will not be given to the clinic. Researchers who have access to details of your identity are required to treat this confidentially under applicable laws.

How long will my biological samples be stored?

The specimens collected during this study will be stored indefinitely in a secure storage site after the study closes.

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 future research, please tell us. We will ask the storage facility to destroy any remaining samples that still have your study code on them at the end of the study so that they cannot be used for future research.

For more information:

If you have questions about the use of your samples for future research, a problem that you think may be related to the use of your samples for future research, 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.

INFORMED CONSENT FORM FOR THE STORAGE AND FUTURE USE OF SAMPLES

“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”

Participant Statement:

The principal investigator, Dr. Grace Mirembe or their representative has explained in detail the purpose for the storage and future use of my biological samples, 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 the storage and future use of my biological samples and all 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 the storage and future use of my biological samples, including any future genetic testing, by marking the applicable box below, writing my initials next to the marked box, and printing and signing my name in the space 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 the storage and future use of my biological samples and future genetic testing now, I have a right to withdraw my consent at any time without losing any rights to which I am entitled. I have been offered a signed copy of this consent form.

 ☐ I allow you to store and use my samples for future testing which may include
initials genetic testing.

 ☐ I allow you to store and use my samples for future testing, but I **do not** allow
initials future genetic testing to be performed on my stored samples.

 ☐ I **do not** allow you to store and use my samples for future testing.
initials

SIGNATURE OF PARTICIPANT

DATE

PRINT NAME OF PARTICIPANT

SIGNATURE OF PERSON ADMINISTERING CONSENT

DATE

PRINT NAME OF PERSON ADMINISTERING CONSENT