MDH ID:					-					TOV3 ID:	8				

Name of Participant: _____

A Trial of Vitamins and HAART in HIV Disease Progression

Study Consent Form

Written informed consent will be obtained in the local language, Kiswahili.

Consent to Participate in *A Trial of Vitamins and HAART in HIV Disease Progression*

Greetings! My name is Sr…….and I am a nurse working on a research project. The research is trying to see the effect of vitamin supplements on the general health and the progression of HIV disease for people who are taking anti-retroviral drugs. This discussion is to tell you about this research and ask your consent for you to take part in the research study.

Purpose of the Study

We are enrolling men and women who are HIV positive and have begun or are ready to begin anti-retroviral therapy for the treatment of HIV disease. The purpose of the study is to see if taking different doses of multivitamins has any effect on the general health and progression of HIV disease for people who are taking antiretroviral drugs.

If you agree to join the study, you will be put into one of two groups. In one group, participants will receive multivitamins that contain the recommended levels of vitamins B, C, and E. In another group, participants will receive multivitamins that contain higher than the recommended levels of vitamins B, C, and E. Participants will be put into one of the two groups by chance, and no one, including the participants, researchers, doctors and nurses in the study will be able to know which group the participant belongs to until the study is finished. Participants will be asked to stay in the study until it is completed, for at least 24 months.

What Participation Involves

If you agree to join this study, we will give you a bottle containing a one-month supply of multivitamin tablets. We will ask that you take one tablet each day. You will be asked to visit the research nurse at this clinic once each month. At each clinic visit, we will ask that you bring in the used bottle of vitamins with the remaining tablets, and we will give you a new bottle for the next month.

At the monthly clinic visits, we will collect information from you using written questionnaires, laboratory tests, medical records, and other study forms. At each visit, you will be asked questions about your health since the last visit. At some visits, you will be asked questions about what foods you eat, about your household, occupation and education, and about your general health. During each monthly study clinic visits, the nurse and doctor will give you a general physical exam. We will also measure your state of nutrition by measuring your weight, height, and arm size.

We will ask your permission to allow us to take your blood (about 2 teaspoonfuls) four times during the study to allow us to measure your state of nutrition and blood level for some vitamins. Some of the blood may be

stored for later studies on infectious diseases or other health concerns. You can say no to allowing us to store you blood and still participate in the study.

You will be treated for illnesses you may have according to the doctor's examination or results of the laboratory tests, as may be available and following the Ministry of Health's policies. Doctors may prescribe medicines that can be purchased locally. If you cannot afford to buy the medicines, you will be able to get them from the clinic free of charge.

We would like to ask your permission to allow a nurse from the study clinic to escort you home in order to register your address, and to visit you at home if you miss a scheduled clinic visit. The nurse will be dressed in non-hospital clothes and will not be obvious to your neighbours. During the visits, she will ask you questions and check your health as would be done at a clinic visit. If you move out of Dar-es-Salaam, your neighbour or relative may be asked for information about how you are doing.

We would like to perform an additional test on the blood taken from a small sample of participants. This test will measure the level of anti-retroviral drugs in the blood, and will be done at three times during the study. You will not need to make an additional clinic visit for this test. On the days that we will take your blood for this test, we will ask you to come to the clinic in the morning, before taking your dose of anti-retroviral drug for that day. On such days, we ask you to arrive early at the clinic to enable us to collect the specimen early, for you to be able to take your morning medication dose without delay. A nurse will take your blood, and then ask you to take your dose of anti-retroviral drug for that day. You will then have your regular study clinic visit. We will take a second sample of blood after your clinic visit. You can say no to participating in this additional test on your blood and still be able to participate in the study.

Confidentiality

Your name will be written on one form that is used to create a study identification number, using the initials of your three names. Only this number, and not your full name, will be used on all clinic forms we use to collect information. All information we collect on forms will be entered into computers with only the study identification number. All study forms will be stored in a locked room, and only the study supervisor will have access to this room.

All blood samples that we take from you for the research study will be stored in tubes with a study identification number. Only laboratory staff who work on this research project will test these samples. Most samples that we take from you will be tested at a lab at Muhimbili University College of Health Sciences. Some samples will be sent for testing at labs in the United States that are connected with this research study.

Risks

Though we do not expect that any harm will happen to you as a result of joining this study, we do not know how the combination of multivitamins B, C and E with anti-retroviral drugs will affect your general health or the progression of your HIV disease infection.

You may experience slight discomfort or some dizziness from giving blood, and sometimes, a small bruise may occur at the needle site.

We will not tell anyone who is not part of the study about your HIV status. It is your choice whether you tell anyone about your HIV status. If others find out your HIV status, you may have problems with your family and community. To make this choice for yourself, you should think about the potential reactions of people in your family or community. You should also think about the potential benefits of being able to talk openly about your HIV status with someone who is important to you.

Rights to Withdraw and Alternatives

Taking part in this study is completely your choice. If you choose not to take part in the study, or if you later decide to stop taking part in the study, you will continue to receive all services that you would normally get from this hospital.

You can stop taking part in this study at any time, even if you have already given your consent. If you miss some visits for any reason but wish to come back into the study, we will be ready to accept you and continue giving you our services as usual. Refusal to take part or withdraw from the study will not involve penalty or loss of any benefits to which you are otherwise entitled.

People who check on research studies to make sure they are being done right will check the results of this study. We will tell you about any new information from this or other studies that may affect your health, welfare, or willingness to stay in the study.

Benefits

If you agree to take part in this study, you may or may not benefit from the supplement in your group. You may benefit from seeing a physician regularly and being followed closely by our nurses to make sure that you are getting the best available treatment. We hope that the information we learn from this study will benefit other people who have HIV disease.

Money Matters

We will reimburse you the cost of public transport to the clinic on your appointment days. If you become ill and the doctor prescribes medicine, and you cannot afford to buy it, you will be able to get it from the clinic free of charge based on the Tanzanian Ministry of Health guidelines. We do not expect that any additional costs to you will result from taking part in this study. There are no plans to give you money for taking part in this study.

In Case of Injury

We do not anticipate that any harm will happen to you as a result of taking part in this study. However, if any physical injury resulting from taking part in this research should occur, we will provide you with medical treatment according to the current standard of care in Tanzania.

Who to Contact

If you ever have questions about this study, or if you are injured as a result of coming to this clinic, you should contact:

> Prof. Ferdinand Mugusi, Principal Investigator, Muhimbili University College of Health Sciences, Department of Internal Medicine, PO Box 65001, Dar es Salaam. Tel: 784 613 354.

If you ever have questions about your rights as a participant in this study, you should contact:

> Prof. Eligius Lyamuya, Director of the College Research and Publications Committee, Muhimbili University College of Health Sciences, P.O. Box 65001, Dar es Salaam. Tel: 2151489.

MDH ID:					-					TOV3 ID:	8				

Signatures

1. Do you agree that a research assistant will escort you home to register your address?
   Participant agrees_____ Participant does NOT agree_____

2. In case you move out of Dar-es-Salaam during the study period, do you agree that a research assistant can contact your neighbours or relatives to learn about your health?
   Participant agrees_____ Participant does NOT agree_____

3. Do you agree to allow us to perform an additional test of your blood to check for the levels of anti-retroviral drugs in the blood?
   Participant agrees_____ Participant does NOT agree_____

4. Do you agree to allow us to store your blood to use in later research studies?
   Participant agrees_____ Participant does NOT agree_____

I, _____ have read the contents in this form. My questions have been answered. I agree to participate in this study.

Name of Participant:_____

Signature of Participant:_____

Name of Witness:_____

Signature of Witness (if participant cannot read):_____

Name of Research Assistant:_____

Signature of Research Assistant:_____

Date of informed consent (dd/mm/yyyy): | | | / | | | / | | | | |
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