National Institute for Medical Research (NIMR)
Box 1462, Mwanza, Tanzania. Tel: 028 2503012

PARTICIPANT INFORMATION SHEET

Title: Nutritional support for Africans starting antiretroviral therapy (NUSTART) study

Introduction
My name is ……., am from the National Institute for Medical Research (NIMR). NIMR in collaboration with the department of health, Mwanza City Council, and Bugando Medical Centre, Sekou-Toure and Mwananchi hospitals in Mwanza, and London School of Hygiene and Tropical Medicine and University of Copenhagen is implementing this study in Mwanza, Tanzania. You are being invited to take part in this study because you have been referred for ARV therapy. However, before you decide to take part in this study, it is important you understand why the research is being done and what it will involve. Please take time to read the following information carefully. Before you decide, you may discuss it with relatives, friends or whoever you want to involve in making decision. Ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?
Available information indicates nutrition problems have a big impact on the health of people with HIV infection. In this study we want to find out if a nutritional supplement with high dose vitamins and minerals is better than the normal supplement made out of groundnuts. If you are willing to participate in this study we are going to give you a food supplement made of groundnut paste in a foil packet. This will be in two stages: first in small quantities and then large quantities as you begin to put on weight. You may be given a supplement with high dose vitamins and minerals, or you may receive a regular supplement. No one is going to decide which supplement to give you nor will the staff know which supplement you are receiving: the packets of supplement have already been prepared in France using a computer code so that no one knows what each packet contains. This is important so that we make unbiased assessments of your progress.

What are we asking you to do?
You will continue to be cared for at your local clinic and will be given your antiretroviral drugs from there. Besides the local ART clinic visits we will require you to come for 3 extra visits and two of these visits will be to Sekou-Toure hospital. We will provide transport. When you come to Sekou-Toure we will take detailed body measurements which take 4 to 5 hours. All these tests are completely painless. When you are seen at the local clinic the visit will be for 30 to 60 minutes, including a simple test to measure your appetite by observing how much porridge you eat. During the study we will collect 6 extra samples of blood; most of these will be 7 mls (one and half tea spoons) but on two occasions the amount collected will be 20 mls (4 teaspoons).

What do we do with the samples we take?
The samples we will collect from you will be used initially for the HIV test and for the CD4 count (which is a measure of how HIV is affecting the immune system). Most of the blood samples are required for monitoring the amount of potassium and phosphate in the blood which is simply good practice when giving these minerals, and to ensure safety. The two samples which involve collecting larger volumes of blood will be used to assess changes in iron in the body and to analyse immune cells in a bit more detail. Part of every blood sample will be stored in a big freezer so that we can measure vitamins and minerals and immune cells at a later date. During storage, samples are identifiable with a code so that no-one can see whose samples are being held without referring to our highly confidential register.

Risk and benefits
As part of the study blood will be drawn for various investigations. However, these procedures will be done aseptically to ensure safety of study participants. All the patients will be started on ART therapy following national guidelines, and those found to have very low levels of serum electrolytes at

anytime during the study will be treated accordingly. The nutritional supplements that will be given to study patients are safe and not expected to cause any adverse effects. You will also be reimbursed travel costs and for time spent at the clinic for participating in the study

Consent and confidentiality
You are participation in this study is voluntary and that you are free to withdraw from it at any time, and if you decide to do so you will not be penalized for your decision nor will you be denied routine health care. Information collected from you will be kept confidential and only the study team and trial monitors will be allowed to have access to it whenever necessary.

Contact for further information
If you have any concerns or questions about this study you may ask any of the study team member or Mr John Changalucha, the study principal investigator or Drs George PrayGod and Kidola Jeremiah at the address written at the top of the first page or Dr Mwele Malecela, who is the chairperson of the national ethics committee responsible for approval and monitoring of research to be conducted in Tanzania. Her address is; National Institute for Medical Research, P. O. Box 9653 Dar es Salaam, tel:+255-22-2121400

CONSENT FORM

Title: Nutritional support for Africans starting antiretroviral therapy (NUSTART) study

Study ID:

Participant consent to participate in the study

1. I have read/been read the information sheet that explains the objectives of the study, and all the procedures that I am being asked to participate in.

2. All the questions I had about this study have been answered satisfactorily.

3. I clearly understand what I will be required to do, and what will be done to me, if I agree to participate in this study.

4. I also understand that I have the right to leave the study at any time if I do not want to continue.

5. I am also aware that all the information that I give, and all the laboratory findings will be kept confidential.

6. I agree to take part in this study.

_____	_____	_____
Name of participant	Signature/thumbprint	Date

_____	_____	_____
Name of witness (If participant is illiterate)	Signature	Date

_____	_____	_____
Name of person taking consent	Signature	Date