Attachment 1B: Objective 3 Clinical Follow-up Consent Form for Incident HIV/ Hepatitis B virus infections in South African blood donors: Behavioral risk factors, genotypes and biological characterization of early infection

OMB #: 0925-XXXX Expiration Date:

OBJECTIVE 3

Informed Consent – Clinical Follow-up Participants

South African National Blood Service
Consent for Research

Incident HIV/ Hepatitis B virus infections in South African blood donors:
Behavioral risk factors, genotypes and biological characterization of early infection

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Dear Blood Donor,

Thank you for taking the time to review the information below before considering whether you are willing to participate in this research project. You are being invited– to take part in a research study titled, "Incident HIV / Hepatitis B virus infections in South African blood donors: Behavioral risk factors, genotypes and biological characterization of early infection"

The person in charge of this study in South Africa is Dr. Charlotte Ingram from South African National Blood Service. Before you decide if you want to join this study, we want you to learn about the study. The study staff will talk with you about the study and answer your questions.

Before you agree to join this study please read this consent form carefully. Take your time in deciding if you wish to join this study. This consent form might contain some words that are not familiar to you. Please ask questions about anything you do not understand.

Who is conducting this research study?

The study is part of an international project known as the "Recipient Epidemiology and Donor Evaluation Study (REDS-III)". The **South Africa National Blood Service (SANBS)** is leading this study in collaboration with researchers from the University of California San Francisco and Blood Systems Research Institute in the United States. The data collected for this study will be analyzed in South Africa and the United States (by the data coordinating center for REDS-III, Research Triangle Institute, Inc. located in Rockville, Maryland, US) and results reported in medical journals. The results of the study may be used to improve blood safety in South Africa and other countries in Africa. The study is supported financially by the National Heart, Lung, and Blood Institute of the U.S. National Institutes of Health.

What is the purpose of this research study?

1. The first purpose is to study donors with very recent HIV infection in order to find out how the HIV virus begins to reproduce and how the body's natural defenses (immune system) reacts to the HIV virus over the first few months of infection.
2. The second purpose is to study donors who have HIV infection but whose immune systems seem to have controlled the virus without treatment so that it is difficult to

detect any HIV virus in the body. Finding out how these people control the virus could help develop new treatments or vaccines against HIV.

You are being ~~asked~~invited to participate in this research study because you have already participated as a case participant in the larger research study, and you have either (1) recently become infected with HIV or (2) have an HIV infection but with a very low or undetectable amount of HIV virus in your body.

What will happen if you participate in this study?

There are two main study activities that will happen to you on four different visits to SANBS, namely:

1. A new sample of your blood will be taken at four different dates over the next ~6 months.
2. You will complete a brief questionnaire each time a blood sample is collected.

Procedures

If you agree to participate, the following will happen:

We will ask you to agree to participate in a 6-month long follow-up study in which we will ask you to attend research study visits at the blood center a total of 4 times (today, in 1 month, in 2 months, and in about 5 months from now.)

1. At each visit we will collect 6 tubes of blood totaling 48 ml (3 tablespoons) from your vein.
2. We will use these samples to conduct special tests that measure the type of HIV infection you have and you body's immune response to that infection. The results of this project will not be sent to you because they are research tests and will not influence the healthcare you receive. Please note that results from the larger research study will be given to you when you come back to SANBS to participate in

this part of the study. The results that will be given to you have been described in the INFORMED CONSENT – CASE PARTICIPANTS document you already signed. For this part of the study some of the samples will be sent to the Project's Central Laboratory, Blood Systems Research Institute, located in San Francisco, United States for additional testing. These tests are not part of the routine testing at the blood service.

3. The sample you give to us may be used in future studies to understand how people's bodies respond differently to HIV infection. Your specimens may be stored indefinitely at SANBS or Blood Systems Research Institute in San Francisco, US, but additional approval by Ethical Committees will be necessary for future research use outside of HIV research consent you are providing for this study.
4. At each follow-up visit, you will be ~~asked~~ invited to complete a short paper questionnaire on your current medical status, including questions about visits to health care providers, any medications you may have started taking, and symptoms you may have experienced since your last study visit.
5. Our research nurses will stay in contact with you to schedule your follow-up visits. We will stay in contact with you using telephone calls, text messages and emails. We would like to call you every month just to check-in with you.

Are there risks to you for participating in the study?

Risks:

1. There is a small risk, such as bruising or a little pain, when collecting a blood specimen. A trained nurse or other health care professional will collect the blood samples. The blood service will provide you the same assistance given to all blood donors in case this happens to you.
2. There is a small chance that your personal information may become public because of an unintentional or accidental data security breach. However, to avoid this, the questionnaire as well as the samples will be identified by code numbers and not your name.

Will I be paid and are there any costs to the research?

You will be paid 80 Rand to compensate you for your transportation to the study center after each follow-up visit. All of the research tests will be done free of charge.

What if I don't want to participate after I have completed the study?

You do not have to participate in this study and you may retract your consent for participating at any time by contacting the investigator listed on this consent form. If you decide to remove yourself from the study, your blood samples will be destroyed and your questionnaire responses will be deleted from the study databases. However, if the data have already been analyzed and reported in medical journals we will not be able to remove you from the study. Your decision to remove yourself from the study will not affect your relationship with SANBS in any way.

<u>Questions you may have</u>:

You can have any questions you may have answered by the responsible investigator, before and during the research. If you have questions right now please ask them before signing this consent.

Informed Consent Signature Page – LONGITUDINAL FOLLOW-UP PARTICIPANTS

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If you have any questions about this research study, your blood donation test results, or if you are injured as a result of the research you may contact the following at any time:

South African National Blood Service Contact Person

Name: TBN

Telephone Number: TBD

You may also contact the Secretariat of the Ethics Committee of SANBS, at telephone number (TBD) if you have questions about your rights as a research ~~subject~~participant~~s~~.~~.~~

Your participation in this research is voluntary, and you will not be penalized or lose benefits in anyway if you refuse to participate or decide to stop participating.

If you agree to participate, you will be given a signed copy of this entire informed consent document, which provides you with a written summary of the research.

I DECLARE THAT I HAVE READ AND UNDERSTOOD ALL THE INFORMATION CONTAINED IN THECONSENT DOCUMENT AND I AGREE TO PARTICIPATE IN THIS RESEARCH STUDY. I AM FREE TO RETRACT MY CONSENT IN ANY PART OF THE RESEARCH IF I DECIDE THAT I DO NOT WANT TO CONTINUE PARTICIPATING.

Name: _____

Signature: _____

Date: _____/_____/_____

Signature of study staff taking consent:
I declare that the above participant has been fully informed about the nature, conduct and risks of the above study.

Name: _____

Signature: _____

Date: _____/_____/_____