Attachment 1A: OBJECTIVES 1 AND 2 INFORMED CONSENT –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:

OBJECTIVES 1 AND 2

INFORMED CONSENT – CASE PARTICIPANTS

South African National Blood Service
Consent for Research

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

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 ~~asked~~ 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 the 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-III (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 in the United States (by the data coordinating center for the REDS-III research program, 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 find out how many donors were recently infected by HIV and/or Hepatitis B virus, and what subtype of virus these donors have.
2. The second purpose of this research is to study donors who, following the donation of a unit of blood to SANBS, were found to have been recently infected with HIV and/or Hepatitis B, and to identify behaviors that may have caused them to become infected.

We are asking you to participate because you have recently had a test result indicating possible HIV and/or HBV at the blood center.

What will happen if you participate in this study?

This study consists of two parts, namely:

1. Taking a new sample of your blood.
2. Completing a computer interview.

Procedures:

If you agree to participate, the following will happen:

1. We will collect an additional 48 ml (about 3 tablespoons) of blood from you, which will be used to perform the following tests: measure the stage of infection and amount of virus in your body and determine the genetic make-up of the HIV and/or Hepatitis B virus you have. This will allow us to determine the type of HIV or HBV you have and, if it is HIV, whether it is resistant to some of the antiretroviral medicines used to treat HIV/AIDS.
    a. The results of tests we plan to conduct on your blood samples will not be available at the same time. If you are confirmed positive for infection we will inform you of the results of the tests to measure the amount of virus in your body when you come back to SANBS for test results notification. Also we will inform your doctor if you grant us permission to do so. If you are HIV positive, we will also ask you to return to SANBS in a few months to tell you about the results that indicate whether or not you have an HIV infection resistant to some antiretroviral medicines. The results of tests that will not influence your care for HIV or Hepatitis B virus will not be provided to you.

b. Your blood samples will be kept in case some tests need to be repeated. Some of the samples will be sent to other research laboratories in South Africa, and may be sent to the project's central laboratory, Blood Systems Research Institute, located in San Francisco, United States, for additional testing. These laboratory tests are not part of the routine testing at SANBS. These samples may also be used in other future studies about HIV and/or HBV infection. Your blood samples may be stored indefinitely at SANBS, but any future research not related to HIV and/or HBV research as described in this consent will require additional or new approval by appropriate ethics committees.

2. You will complete a confidential questionnaire using a computer to answer questions about your sexual history, other factors that may be associated with HIV or Hepatitis B virus infection, your knowledge about HIV/AIDS and about the motivations that took you to donate blood. You may skip any questions that you are not comfortable answering.

Please note that we will provide information on local services in your community that can provide counseling and other medical services to you, should you require this. In addition, you should feel free to speak to the research staff from SANBS or physicians from the local SANBS blood centre after the computer interview if you have any questions or need anything to be explained to you again.

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. SANBS 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.
3. The results of the testing we will conduct could influence the types of medical care you may require, such as which medications are prescribed for you. Some of the testing may reveal that, if you are HIV-infected, your HIV infection is resistant to some of the antiretroviral medicines and this could be upsetting to you.

Are there benefits to you for participating in the study?

Benefits:

1. For you personally, participating in this study may result in you learning about the stage of your infection. If you have HIV you will also learn whether it is resistant or not to antiretroviral medicines used in HIV/AIDS treatment. This information will help you and your doctor find the most effective treatment for your HIV infection.
2. Beyond this there is no other specific benefit for you in participating in this study. You will, however, be helping to better the understanding of the HIV and Hepatitis B epidemics in our country.

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 centre following completion of the interview. 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 will not be forced 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.

Questions you may have:

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 form.

Informed Consent Signature Page – CASE PARTICIPANTS

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

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.

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.

Do you consent to allow the researchers to send the results of tests that may influence the care your doctor provides to you for HIV or Hepatitis B infection directly to your doctor or medical care provider's address?

___ Yes **____ No**

Contact information for your doctor or medical care provider:

Name:

Address:

Telephone number (if known):

I DECLARE THAT I HAVE READ AND UNDERSTOOD ALL THE INFORMATION CONTAINED IN THE CONSENT 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: _____/_____/_____

OMB #: 0925-XXXX Expiration Date:

OBJECTIVES 1 AND 2

Informed Consent – Control 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

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 ~~asked~~ 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" **You are being approached to be a control in this study which means that if you have donated before you tested NEGATIVE for HIV and Hepatitis B infection. Blood from your donation today will be tested and we will include you in the study as a comparison donor if your blood tests negative for all of the tests that South Africa National Blood Service uses to test blood donations.**

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 coordinating center for the REDS-III research program, 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. **We are asking you to participate because you just donated blood. Studies like this need donors who are NEGATIVE for HIV and Hepatitis B infections to serve as a comparison group. Your blood will be tested and we will include you in the study as a comparison donor if your blood tests negative for all of the tests that South**

Africa National Blood Service uses to test blood donations. If by chance your donation tests positive for HIV or Hepatitis B virus, Hepatitis C virus or syphilis when it is tested you will be removed from the study as a comparison person. In that case you will be contacted and counseled using standard procedures of the SANBS.

What will happen if you participate in this study?

The study consists of one main activity, namely:

1. Completing a computer interview.

Procedures

If you agree to participate, the following will happen:

1. You will complete a confidential questionnaire using a computer to answer questions about your sexual history, other factors that may be associated with HIV or Hepatitis B infection, your knowledge about HIV/AIDS and about the motivations that took you to donate blood. You may skip any questions that you are not comfortable answering.

Please note that we will provide information on local services in your community that can provide counseling and other medical services to you, should you require this. In addition, you should feel free to speak to the research staff from SANBS or physicians from the local SANBS blood centre after the computer interview if you have any questions or need anything to be explained to you again.

Are there risks to you for participating in the study?

1. 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 from

happening, the study questionnaire will be identified by code numbers and not your name.

Are there benefits to you for participating in the study?

Benefits:

1. There is no personal benefit to you from participating in this study, but you will be helping to improve our understanding of the HIV epidemic, Hepatitis B virus, and ways to keep blood safe in our country.

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 following completion of the interview.

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

You will not be forced 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 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.

Questions you may have:

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 – CONTROL PARTICIPANTS

Incident HIV/ Hepatitis B virus infections in South African blood donors:
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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.

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 THE CONSENT 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: _____/_____/_____