Attachment 2: Informed Consent for Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil

OMB Number: 0925-0597
Expiration Date: XX/XX/XXXX

PROJECT "REDS III: RECIPIENT EPIDEMIOLOGY AND DONOR EVALUATION STUDY-III-INTERNATIONAL"

INFORMED CONSENT

INFORMED CONSENT TERM ACCORDING TO THE POLICY OF RESOLUTION CNS 196/96 FOR THE SUB-PROJECT: "PREVALENCE, INCIDENCE, EPIDEMIOLOGY AND MOLECULAR VARIANTS OF HIV IN BLOOD DONORS IN BRAZIL"

The study entitled **"Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil"** is part of a multicenter project entitled "REDS (Recipient Epidemiology and Donor Evaluation Study)-IIII" under the overall direction of Dra. Ester Sabino, and taking place at Fundação Hemominas (Minas Gerais), Fundação Pró-Sangue (São Paulo), Fundação Hemope (Pernambuco) and HemoRio (Rio de Janeiro). The purpose of REDS III-International is to do research on blood safety regarding HIV and other blood borne infections in Brazil.

The first research **objective** of this study is to evaluate HIV seropositive donors that were found in the four participating blood centers and to identify behavioral risk factors for HIV infection in Brazilian blood donors. The second research objective is to find out how many donors were recently infected with HIV, and whether they are infected with a genetic type of the virus that may be resistant to medication used to treat AIDS.

We are asking you to participate because you have recently had a positive test for HIV at the blood center.

Procedures: If you agree to participate, your participation in this study will consist of the following steps:

1 – Answering a questionnaire using a computer in a private consulting room to investigate

the presence of risk factors for infection by HIV. This questionnaire will have questions related to possible risk factors for infection including sexual practices, your knowledge about HIV/AIDS, and about motivations for donating blood.

2 – Collection of 30 ml of blood from your vein to conduct genotype testing and evaluate using a 1st generation HIV antibody assay, known as an enzyme-linked immunosorbent assay (ELISA), to test whether the HIV infection was recent (less than 6 months ago) or not (more than 6 months ago). The HIV genotype test will allow us to determine the HIV subtypes and their resistance to medications used to treat AIDS. These results will be mailed to you, so that you can show them to your physician. The 1st generation ELISA test will help us estimate the percentage of people who were infected in the last 6 months before blood donation. The result of this test does not have any clinical implication and this result will not be sent to you. The samples will be kept in case these tests need to be repeated and shall be sent to the Project's Central Laboratory, located in San Francisco, California, in the United States. These special tests are outside of routine blood bank procedures. The blood sample you provide may be used in the development of other epidemiology blood donor studies in Brazil.

3 – The project will pay you R$ 15.00 to compensate you for the cost of transportation to the study center.

Risks:

1- Blood drawing may cause a small amount of pain when the needle is inserted into the vein, but should not cause long-term pain. After blood is taken, sometimes there can be a small bruise or soreness at the site. Collection of blood may sometimes cause bruising, discomfort, and rarely infection. The blood bank will give you the same assistance given to blood donors in case anything happens to you.

2- There is a small chance that your personal information may not be kept confidential. However, we will work hard to keep your results from this study secret. The questionnaire, as well as the blood sample, will be identified by unique numbers and not your name.

Benefits:

You are not required to participate in this study and at any time you may withdraw your consent to participate. The personal benefit in participating in this study is having your blood tested for HIV genotype and drug resistance which may optimize your therapy as an individual patient.

Questions:

Any questions that you have about the study will be answered by the responsible investigator at the blood center where you donated or research staff before, during, and after the research.

Results:

The results of the study will be kept confidential, only you will be informed of specific results that apply to you. The research group will report summary results for all study participants, which will not include individual identification of study participants. You have the guarantee of research confidentiality by the study team and investigators, before, during and after the study.

Consent:

I agree to respond freely to the topics covered in the computer interview, even those that I consider to be confidential, and I authorize the disclosure of data needed for research. I agree that my blood sample will be tested as described above and stored for possible use in future research projects. I authorize also that material collected will be saved by the institution and possibly sent to other institutions, including ones in other countries, provided that such research is approved of by the Ethics Committee (CEP) at the institution where the samples will be stored and, where appropriate, by the National Commission on Ethics in Research (CONEP).

_____Yes, I allow my sample to be kept for possible use in other studies, if approved by the Ethics Committee.

_____No, I do not allow my sample to be kept for possible use in other studies.

I DECLARE THAT I HAVE READ AND UNDERSTOOD ALL THE INFORMATION AND I AGREE TO PARTICIPATE IN THE ABOVE RESEARCH. I AM FREE TO WITHDRAW FROM THE STUDY IN ANY PHASE OF THE RESEARCH STUDY IF I DO NOT WANT TO CONTINUE PARTICIPATING, WITHOUT CAUSING ANY DAMAGE TO MY RELATIONSHIP WITH THE BLOOD CENTER.

Name: _____

Signature: _____

Date: _____/_____/_____

_____

Investigator

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