PROJECT "REDS: RETROVIRUS EPIDEMIOLOGY DONOR STUDY-II-INTERNATIONAL"

INFORMED CONSENT

HIV POSITIVES

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

The study entitled **"Prevalence, incidence, epidemiology and molecular variants of HIV virus in blood donors in Brazil"** is part of a multicenter project entitled "REDS – Retrovirus Epidemiology Donor Study-II-International" under the overall direction of Dra. Ester Sabino, abd taking place at Fundação Hemominas (Minas Gerais), Fundação Pró-Sangue (São Paulo), Fundação Hemope (Pernambuco) and HemoRio (Rio de Janeiro). The purpose of REDS Inernational is to do research on blood safety regarding HIV virus and other 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 by 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 consulting room to investigate the presence of risk factors for infection by HIV. This questionnaire will have questions related to your sexual practices, your knowledge about HIV/AIDS and about the motivations that took you to donate blood.

2 **–** Collection of 30 ml of blood from your vein to perform the following tests: HIV virus genotype test and 1st generation ELISA test. The HIV virus genotype test will allow us to determine the HIV sub types and their resistance to the used medication in AIDS treatment. This result will be sent to you, so that you can show to your physician. The 1st generation ELISA test will help us indicate the percentage of people that were infected in the last 6

months. The result of this test does not have any clinical implication and the error rate in individual basis is too high, therefore this result will not be sent to you. The samples will be kept in the case of need to repeat these exams and shall be sent to the Project's Central Laboratory, located in San Francisco, United States. These exams do not make part of the blood bank routine. We still inform that these samples may be used in the development of other epidemiology blood donor studies.

3 - The project will pay R$ 12,00 to compensate you for your transportation to the study center.

Risks:

1- There is a small risk in blood collection such as hematoma and pain. A trained person will make the blood collection. The blood bank will give you the same assistance given to blood donors in case this 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 the results of this study secret. The questionnaire, as well as the samples, will be identified by code numbers and not your name.

Benefits:

You are not forced to participate of this study and at any moment you may retract your consent in participating. The personal benefit in participating in this study is to have the genotype test performed, and beyond that, you will be helping to make the understanding of HIV virus epidemic better in our country.

Questions:

You will have any questions answered by the responsible investigator, before and during the research.

Consent:

____ **Yes, I allow my sample to be shipped to USA for analysis.**

____ **Yes, I allow my sample to be kept for possible usage in other studies, if approved by the Ethic Committee.**

I DECLARE THAT I HAVE READ AND UNDERSTOOD ALL THE INFORMATIONS AND I AGREE TO PARTICIPATE IN THE ABOVE RESEARCH. I AM FREE TO RETREAT MY CONSENT IN ANY PHASE OF THE RESEARCH IF BY ANY CHANCE I DON´T WANT TO

CONTINUE PARTICIPATING, WITHOUT CAUSING ANY DAMAGE TO FUNDAÇÃO PRÓ SANGUE.

Name: _____

Signature: _____

Date: _____/_____/_____

_____

Investigator

_____

Investigator's Contact Phone:

Dra. Ester Cerdeira Sabino: (11) 3061-5544 ramal 399

IC 1.2 - Sub-project 1

PROJECT "REDS: RETROVIRUS EPIDEMIOLOGY DONOR STUDY-II-INTERNATIONAL"

INFORMED CONSENT
NEGATIVE CONTROLS

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

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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 by HIV, and whether they are infected with a genetic type of the virus that may be resistant to medication used to treat AIDS.

Studies like this need healthy, HIV negative donors to serve as a comparison group. We are asking you to participate because you have recently had a NEGATIVE 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 consulting room to investigate the presence of behavioral factors that may or may not be linked to HIV/AIDS. This questionnaire will have questions related to your sexual practices, your knowledge about HIV/AIDS and about the motivations that took you to donate blood.

2 – The project will pay R$ 12,00 to compensate you for your transportation to the study center.

Risks:

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

Benefits:

You are not forced to participate of this study and at any moment you may retract your consent in participating. There is no personal benefit to you from participating in this study, but you will be helping to improve understanding of HIV virus epidemic and ways to keep blood safe in our country.

Questions:

You will have any questions answered by the responsible investigator, before and during the research.

Consent:

I DECLARE THAT I HAVE READ AND UNDERSTOOD ALL THE INFORMATIONS AND I AGREE TO PARTICIPATE IN THE ABOVE RESEARCH. I AM FREE TO RETREAT MY CONSENT IN ANY PHASE OF THE RESEARCH IF BY ANY CHANCE I DON´T WANT TO CONTINUE PARTICIPATING, WITHOUT CAUSING ANY DAMAGE TO FUNDAÇÃO PRÓ SANGUE.

Name: _____

Signature: _____

Date: _____/_____/_____

_____

Investigator

_____

Investigator's Contact Phone:

Dra. Ester Cerdeira Sabino: (11) 3061-5544 ramal 399

Ethic Committee for