INFORMED CONSENT FORM ACCORDING TO THE POLICY OF RESOLUTION CNS 196/96 FOR THE SUB-PROJECT:

"Does pre-donation behavioral deferral increase the safety of the blood supply?"

The study entitled **"Does pre-donation behavioral deferral increase the safety of the blood supply?"** is part of a multicenter project entitled "REDS – Retrovirus Epidemiology Donor Study-II-International" under the overall direction of Dra. Ester Sabino. The study is being conducted at Fundação Hemominas (Minas Gerais), Fundação Pró-Sangue (São Paulo), Fundação Hemope (Pernambuco) and HemoRio (Rio de Janeiro). The purpose of this study is to learn about infectious disease rates in donors who are deferred for higher risk sexual and drug use behavior. Infectious disease rates in deferred donors will be compared to those observed in individuals who donated blood.

We are asking you to participate in this study because you <u>were deferred as a blood donor today</u>.

<u>Procedures:</u> Your participation in this study will have the following steps:

1- A total of 24 ml (2 tablespoons) of blood will be collected from your vein for the performance of following tests: HIV, Hepatitis C, Hepatitis B, HTLV, syphilis, and *Trypanosoma cruzi* (the parasite that causes Chagas Disease) using the same laboratory tests and procedures that are used to screen all blood donations.

2- You will be answering a questionnaire in a private room in the blood center. This questionnaire will be completed using an audio-computer assisted interview (ACASI), which provides extra privacy. We will provide you with headphones for you to [hear the questions and you will mark your answers using the computer. You will be asked questions about your reasons for wanting to donate blood, and about other lifestyle behaviors.

3- As soon as the blood tests mentioned above are completed, and if they are negative, we will mail the results to you. If you prefer, you may come to pick them up at the blood

center. If the any test results are positive and or uncertain, we will a send a letter to you asking you to come back to the blood center for further analyses.

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 protect your privacy. 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 in participating. The personal benefit in participating in this study is having your blood tested for a variety of infectious diseases at highly qualified institutions and with highly qualified professionals.

Questions:

Any questions that you have about the study will be answered by the responsible investigator or research staff before and during 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.

<u>Consent</u>: I agree to respond freely to issues contained in this form, even those that I consider to be confidential, and I authorize the disclosure of data needed for research. I agree that my donated blood sample will be stored for 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 depository institution 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 Ethical 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 RETRACT MY CONSENT 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

Investigator’s Contact Phone:

Dra. Ester Cerdeira Sabino : (011) 3061 5544 ramal 399

Fundação Pró-Sangue