

Attachment 2: Informed Consent for the effectiveness of donor notification, HIV counseling, and linkage of HIV positive donors to health care in Brazil

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-XXX). Do not return the completed form to this address.

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

Appendix 2 Informed Consent

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

INFORMED CONSENT

INFORMED CONSENT TERMS ACCORDING TO THE POLICY OF RESOLUTION CNS 196/96 FOR THE SUB-PROJECT: "The effectiveness of donor notification, HIV counseling, and linkage of HIV positive donors to health care in Brazil"

We are inviting you to participate in the sub-project: **The effectiveness of donor notification, HIV counseling, and linkage of HIV positive donors to health care in Brazil.**

This study is part of a multicenter project entitled, "Recipient Epidemiology and Donor Evaluation Study-III (REDS-III)," under the overall direction of Dr. Ester Sabino. The purpose of the REDS-III Brazil International program is to do research on blood safety related to the HIV virus and other infections in Brazil.

Why have we asked you to be a part of this study?

We are asking you to participate because you have participated in a previous HIV research study at this blood bank. This study is a follow-up study to the one in which you previously participated.

Who is conducting this study?

This study is being conducted by Fundação Hemominas (Minas Gerais), Fundação Pró-Sangue (São Paulo), Fundação Hemope (Pernambuco) and HemoRio (Rio de Janeiro) in Brazil, in collaboration with two US research institutes; the Blood Systems Research Institute in San Francisco, California and the Research Triangle Institute in Rockville, Maryland, United States. Principal Investigators at the Blood Systems Research Institute and Research Triangle Institute jointly developed with the Brazilian Investigators, this scientific study protocol to be implemented in four (4) Brazilian blood banks. Furthermore the Research Triangle Institute will develop the informatics software programs that will perform the quality control and analysis of data collected from the study participants. This scientific study protocol is paid for by the National Heart, Lung and Blood Institute (NHLBI), of the National Institutes of Health (NIH) in the United States and has been approved by the respective ethics committees in Brazil and in the United States.

What is the purpose of this study?

For this project we have the following objectives:

1. To evaluate changes in behavior among HIV-positive donors since learning about their HIV status and to

assess whether HIV-positive donors who return to the blood center for notification of test results and counseling subsequently attend referral centers for additional counseling, treatment and follow-up care.

2. To assess ways we can improve donors' disclosure of HIV risk factors during the clinical donor screening interview at the time of blood donation and to investigate the motivating factors that influence people when they make the decision to donate.
3. To compare the responses you give on the study questionnaire to your HIV disease progression and your treatment data that are maintained by the Ministry of Health. If you have not had any treatment or do not consent to allow us to access these data, your Ministry of Health data will not be included in this part of the study.

How many people will be part of the research?

Approximately 275 persons who are between the ages of 18 and 69 years old who have previously participated in similar HIV studies at the four blood centers in Brazil will participate in this study.

What will happen to you if you participate in this study?

If you agree to participate, using a computer in a consulting room, you will answer a questionnaire about what has happened to you since being notified of your HIV infection status at the blood center. This questionnaire will have questions related to access to health care and treatment, risk reduction after the HIV notification, HIV status disclosure to sexual partners, family and friends, stigma and prejudice and, ways you think we can enhance HIV disclosure during the donor eligibility assessment. The questions will take no more than 40 minutes to answer.

For your participation in the project, we will pay \$35 USD (R\$ 75) to compensate you for a meal and for your transportation to the study center.

What else can I expect if I participate in this study?

The questionnaire we will ask you to complete will be administered by computer. You will be able to read the study questions and answer options on a screen, and will also hear the questions and answer choices using headphones. You will then be able to record your answers using a computer keyboard or by touching the computer screen. The interview is intended to be conducted in private. However, the study research assistant will be available to answer any questions you have or address any other concerns.

While you are at the blood center, a trained counselor physician will be on site during and after you answer the questions on the computer. This physician will be available if you would like additional counseling. All you have to do is let the research assistant know you want to talk to the counselor physician and you will be provided a private location for any conversation you wish to have.

Are there any risks to participating in this study?

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Due to the nature of the study, some of the questions are about private and personal matters and may make you feel uncomfortable or embarrassed. Our purpose in asking you these questions is to improve the safety of donated blood. Your participation is voluntary and you may refuse to answer any questions.

There is a small chance that your personal information may not be kept private. The highest risk of loss of privacy will occur when we seek to obtain information on your treatment from the Brazil Ministry of Health because we have to send information including your name, date of birth, and your mother's maiden name to the Ministry of Health. However, we emphasize that, to ensure the privacy of information collected from each participant, the researchers have developed a thorough Data Security Plan. A highly trained IT professional at each blood center will develop an encrypted dataset for each participant containing the following information: a) the participant's name; b) date of birth; c) mother's name; d) blood bank ID, and 5) study ID. Study subjects' encrypted datasets will be sent to the National HIV Treatment and Progression Databases [Brasilia SI-CTA], in order to obtain viral load, CD4 and CD8 information.

At the Brasilia SI-CTA, one of their highly trained IT professionals will merge the blood center dataset with the Brasilia SI-CTA data related to viral load, CD4 and CD8 counts. This new linked dataset will be an encrypted file and may include one or more records per participant, as appropriate. This file will contain the following variables: a) study ID, b) viral load, c) date of viral load, d) CD4 count, e) date of CD4 count, f) CD8 count, and g) date of CD8 count.

Treatment information returned to us from the Ministry of Health will only include the study number that has been assigned to you. The questionnaire will be identified by unique numbers and not your name. The datasets used for analysis will never contain information that can personally identify you. The answers that you provide will be combined with the answers from all other participants who complete the questionnaire. Study investigators will never disclose individual responses to any question. You can be assured of the privacy of the research conducted by the study team and investigators, before, during and after the study to the extent permitted by law.

If you would like more detailed information about our data security plan, please inform the research assistant and you may read the complete Data Security Plan text.

Are there benefits?

There are no direct benefits to you for participating in this study. Your participation may help blood centers to understand if we are successfully linking HIV positive blood donors to treatment in Brazil, or if improvements are necessary. In addition your answers may help us to improve blood donor selection procedures in the future, potentially improving blood safety in Brazil.

If I decide to participate in this study, what are my rights?

You can choose to participate or not in this study. Regardless of your decision, there is no penalty and there will be no impact on your routine medical care. Also, if you choose to participate in the study now and leave the study later, this will not affect your medical care.

If you decide in the future that you do not want your information to be used in this study, you can notify the blood center in writing at any time. As soon as we receive your notification, we will destroy any information which was collected for this research study.

In addition, you may choose to accept or not to accept the collection of the following information:

1. We will ask you to allow us to collect information regarding your HIV viral load and CD4/CD8 counts, which are important indicators of infection progression. These data will be obtained from the central HIV treatment records contained in the Sistema de Informacao–Centro de Testagem e Aconselhamento in Brasilia (Brasilia SI-CTA) kept at the Brazilian Ministry of Health. For that we will need your mother's name, and your date of birth. This information, along with your name, will be compared to records kept by Brasilia SI-CTA. Information the Brasilia SI-CTA has on your treatment will be sent back to us under a code that will not directly identify you by name so that we can include it in our analysis dataset for this study.

HIV Viral Load and CD4/CD8 agreement:

_____ **Yes, I allow the researchers to access my viral load, CD4 and CD8 results from the** Brasilia SI-CTA records.

My mother's complete name (please print):

My date of birth: ____/____/____

City of Birth: _____/ **State:** _____

My current age: _____

R.G: _____

CPF: _____

Unified Health System number: _____

_____ **No, I do not allow the researchers to access my viral load, CD4 and CD8 results from the** Brasilia SI-CTA records.

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Who can answer my questions about the study?

Any questions you have will be answered by researchers at the blood bank before, during and after your visit to the blood bank for this research project: Dr. XXXXXX, address XXXXX, Monday to Friday, business hours XXXXXXX.

You can also speak with Dr. Ester Sabino, Principal Investigator in Brazil, by phone (011) 3061-8702 or e-mail sabinoec@gmail.com

Consent:

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 CHANGE TO MY RELATIONSHIP WITH THE BLOOD CENTER.

Name and signature of the study participant:

Name: _____

Signature: _____

Date: ____/____/____

Investigator

Dra. Ester C. Sabino : (011) 3061 8702
Faculty of Medicine, University of São Paulo (USP)