**Attachment 2.2: Objective 2 Consent Form for the Study “Characterization of risk of HIV and HIV outcomes in the Brazilian Sickle Cell Disease (SCD) population and comparison of SCD outcomes between HIV sero-positive and negative SCD patients”**

|  |
| --- |
| Public reporting burden for this collection of information is estimated to average 15 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-NEW). Do not return the completed form to this address. |

**OMB Number: 0925-XXXX**

**Expiration Date: XX/XX/XXXX**

**“Characterization of risk of HIV and HIV outcomes in the Brazilian Sickle Cell Disease (SCD) population and comparison of SCD outcomes between HIV sero-positive and negative SCD patients” a RECIPIENT EPIDEMIOLOGY AND DONOR EVALUATION STUDY (REDS) III INTERNATIONAL study**

**INFORMED CONSENT**

**INFORMED CONSENT TERMS ACCORDING TO THE POLICY OF RESOLUTION CNS 196/96 FOR THE OBJECTIVE 2 “Comparison of Sickle Cell Disease Outcomes between HIV Positive and Negative Sickle Cell Patients”**

This study is part of an international multicenter project called the Recipient Epidemiology and Donor Evaluation Study-III (REDS-III) under the overall direction of Dr. Ester Sabino in Brazil. The purpose of REDS-III is to do research on blood safety related to the HIV virus, and this project will study the relationship between Sickle Cell Disease and HIV in Brazil.

*Who is conducting this study?*

This study is being conducted by Fundação Hemominas (Minas Gerais), 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. Researchers at the Hemocenters developed this study with the researchers at the US research institutes. This scientific study 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 national ethics committees in Brazil (CONEP), the \_\_\_\_\_\_\_\_\_\_\_\_\_ (insert Hemocenter name) CEP and ethical committees in the United States.

*What is the purpose of this study?*

We are doing this study to understand the risk of HIV in patients with sickle cell disease and also to better understand how HIV affects patients with sickle cell disease. We will review the medical record of people who have both HIV and sickle cell disease to understand the types of HIV complications that happen in people with sickle cell disease. Another part of the research is to understand the risk of HIV in sickle cell disease.

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

We are asking you to participate because you have sickle cell disease and HIV.

*How many people will be part of the research?*

Approximately 300 patients will participate in this research to answer questions about the risk of HIV in sickle cell disease. Another 30-40 people with sickle cell disease and HIV will be included to understand how HIV affects patients with sickle cell disease.

*What will happen to me if I participate in this study?*

If you agree to participate, we will review your medical record to collect information about your sickle cell disease and your HIV infection. There is another part of this research that you can choose to participate in or not: an interview. The reason for the interview is to understand the risk of HIV in patients with sickle cell disease. If you agree to be in this part of the project you will answer questions about your lifestyle, sexual behavior, drug use, and other HIV risk factors. We understand these are personal questions. You will be alone with the computer so no one will hear the questions or see your answers. However, the study research assistant will be available to answer any questions you have. The questions will take no more than 40 minutes to answer. You can decide to only give permission for the review of your medical record, but not participate in the interview if you prefer.

If you participate in the interview, a trained doctor will be available if you have any questions. If you want to talk to the doctor, just tell the research assistant and you will be taken to a private room to talk to the doctor.

You can choose to participate in the interview and give permission to review your medical records, or only give permission to review your medical records.

We will also collect a little of your blood (total of 12 milliliters) to test your blood for the levels of HIV, the type of HIV, the response of the HIV to different medications and measure the white blood cell count. You will be asked if your leftover blood (after the HIV testing is complete) can be saved for future research. If you agree, the blood would be saved in the University of Sao Paulo and the University would have control of the future use of the blood for research.  This would not be part of the REDS-III study or be paid for by the US National Heart Lung and Blood Institute, National Institutes of Health.  This option will be explained in a separate consent.

*Will I be paid for my participation in this study?*

For your participation in the project, we will pay R$ 60.00 to compensate you for a meal and for your transportation to the study center.

*Do I have to pay for anything to be part of this study?*

No, you do not have to pay anything to be part of this study.

*Are there any risks to participating in this study?*

There is a small chance that your personal information may not be kept confidential. However, we emphasize that we have developed a detailed plan to protect your privacy. If you choose to participate in the interview, the questionnaire that records the answers to your questions will be identified by unique numbers and not your name. When we analyze the results of the study, all the participants’ answers will be grouped together and the datasets used for analysis will never contain your name or other information that can personally identify you. The researchers in Brazil will not tell anyone your individual responses to any question. The researchers in the United States will not know your name. The information from your medical record that is stored in the research database will also be linked to a number, not your name.

When your blood is collected there may be some bruising and pain, but usually these symptoms go away in a few days or weeks. In very rare situations there can be infection where the needle was inserted in the skin.

*Are there benefits to participating in this study?*

There are no direct benefits to you for participating in this study. Your participation may help blood centers to better understand how HIV affects people with sickle cell disease.

*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 about you that has not already been analyzed. We will not be able to remove your information from any research if analysis has already been completed but we will not include your information in any future analysis after we receive your notification.

*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. (insert Hemocenter information)

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. I UNDERSTAND THAT SIGNING THIS CONSENT GIVES MY PERMISSION TO REVIEW MY MEDICAL RECORD TO COLLECT INFORMATION ABOUT MY SICKLE CELL DISEASE AND HIV INFECTION AND TO HAVE 12 ML OF BLOOD COLLECTED. I ALSO UNDERSTAND THAT MY BLOOD WILL BE TESTED FOR LEVELS OF HIV. IF I WOULD LIKE TO GIVE THE RESEARCHERS PERMISSION TO SAVE ANY BLOOD LEFTOVER AFTER THIS TESTING, A SEPARATE CONSENT WILL BE GIVEN TO ME TO EXPLAIN HOW THIS WILL WORK.**

**Name and signature of the study participant:**

**Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator

**IN ADDITION TO GIVING CONSENT TO REVIEW MY MEDICAL RECORD, I ALSO AGREE TO PARTICIPATE IN THE INTERVIEW. I UNDERSTAND THIS MEANS I WILL ANSWER QUESTIONS ON A COMPUTER ABOUT MY HIV.**

\_\_\_\_ YES \_\_\_\_ NO

Dra. Ester C. Sabino : (011) 3061 8702

**Faculty of Medicine, University of São Paulo (USP)**