Attachment 2.1: Objective 1 Consent Forms 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"

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 TERMS ACCORDING TO THE POLICY OF RESOLUTION CNS 196/96 FOR THE OBJECTIVE 1 "Characterization of HIV Risk Factors in the Brazilian Sickle Cell Disease Population"

Study Population: Persons with sickle cell disease (cases)

INFORMED CONSENT

"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 1 "Characterization of HIV Risk Factors in the Brazilian Sickle Cell Disease Population"

Study Population: Persons with sickle cell disease (cases)

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. We do not believe people with sickle cell disease have a higher risk of HIV than other people. This study will help us better understand what the risk is. We will ask people with sickle cell disease like you and also people without sickle cell disease to be part of the study. We will ask everyone questions about certain things associated with a risk of HIV. We will compare the answers from patients with sickle cell disease to the answers of the same questions from people without sickle cell disease to understand if the risk of HIV is different in sickle cell disease patients compared to other people.

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

We are asking you to participate because you are already enrolled in another REDS study and are older than 18 years. Now we are asking if you want to be part of this study to understand the risk of HIV in sickle cell disease.

How many people will be part of the research?

Approximately 150 people with sickle cell disease and 150 people without sickle cell disease will be invited to be in this study.

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

If you agree to participate, you will answer questions about your lifestyle, sexual behavior, drug use, and other HIV risk factors. We understand these are personal questions. This is why we will use a computer in a private consulting room to ask the 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 or address any other concerns. The questions will take no more than 40 minutes to answer.

While you are at the blood center, a trained doctor will be available if you have any questions. If you want to talk to the doctor, just ask the research assistant and you will be taken to a private room to talk to the doctor.

We will also collect a little of your blood (total of 12mL) to test you for HIV. You can give permission or not to save the leftover blood (after this HIV testing is complete) 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.

You are already tested for HIV as part of your routine clinical care, but the test may have been performed over a year ago. We will repeat the HIV test to confirm if you have HIV or not at the time you participate in the study. We will tell you your results when they become available, usually within 2 weeks after your visit. If your test shows that you have HIV, we will contact you to come back to the Hemocenter and repeat the HIV test. Your sickle cell doctor will meet with you to discuss the results and if the HIV is confirmed, you will be referred to a health center for counseling, follow up and treatment of the HIV in the same way your sickle cell doctors would if your HIV test as part of your routine care was positive.

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 my participation in this study?

No, you do not have to pay 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 have developed a detailed plan to protect your privacy. 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. Researchers in the United States will not know 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?

There are no direct benefits to you for participating in this study. Your participation may help blood centers better understand the risk of HIV in 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 your information that is not already analyzed. We will not be able to remove your information from any analysis that has already been completed, but from the date we receive your notification, your information will not be included in any future analysis.

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 for each Hemocenter)

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 MEANS I WILL ANSWER QUESTIONS ABOUT RISK OF HIV AND HAVE 12ML OF BLOOD COLLECTED. I ALSO UNDERSTAND THAT MY BLOOD WILL BE TESTED FOR HIV AS PART OF THIS RESEARCH. 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

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

"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

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 466/12 FOR THE OBJECTIVE 1 "Characterization of HIV risk factors in the Brazilian Sickle Cell Disease Population"

Study Population: Persons without sickle cell disease (controls)

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. We will ask people with sickle cell disease and also people like you without sickle cell disease to be part of the study. We will ask everyone questions about certain things associated with a risk of HIV. We will compare the answers from patients with sickle cell disease to the answers of the same questions from patients without sickle cell disease to understand if the risk of HIV is different in sickle cell disease patients compared to other people.

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

We are asking you to participate because you do not have sickle cell disease and are the same age as a patient with sickle cell disease patients who is participating in this research. You will be in the group of people who will serve as a comparison group to the people with sickle cell disease.

How many people will be part of the research?

Approximately 150 people with sickle cell disease and 150 people without sickle cell disease will be invited to be in this study.

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

If you agree to participate, you will answer questions about your lifestyle, sexual behavior, drug use, and other HIV risk factors. We understand these are personal questions. This is why we will use a computer in a private consulting room to ask the 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 or address any other concerns. The questions will take no more than 40 minutes to answer.

While you are at the blood center, a trained doctor will be available if you have any questions. If you want to talk to the doctor, just ask the research assistant and you will be taken to a private room to talk to the doctor.

We will also collect a little of your blood (total of 12mL) to test you for HIV and sickle cell. You can give permission or not to save the leftover blood (after this testing is completed) 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.

We will tell you your results when they become available, usually within 2 weeks. All blood donors in Brazil are tested for HIV at Hemocenters, and we will test your blood for HIV in the same way for this research. If your test shows that you have HIV, we will contact you to come back to the Hemocenter and repeat the HIV test again. One of the Hemocenter doctors will meet with you to discuss the results and if the HIV is confirmed on the repeat testing, you will be referred to a health center for counseling, follow up and treatment of the HIV in the same way blood donors are referred when their HIV test is positive.

Your blood will also be tested for sickle cell disease or trait. If your blood tests show that you have either sickle cell disease or sickle cell trait, we will arrange a meeting with one of the Hemocenter doctors who is a sickle cell expert to help explain what the tests mean and refer you for further care if that is necessary.

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. 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. Researchers in the United States will not know 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 the risk of HIV in 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 that is not already analyzed. We will not be able to remove your information from any research if analysis has already been completed, but from the date we receive your notification, your information will not be included in any future analysis.

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 MEANS I WILL ANSWER QUESTIONS ABOUT RISK OF HIV. I ALSO UNDERSTAND THAT MY BLOOD WILL BE TESTED FOR HIV AND SICKLE CELL DISEASE / TRAIT AS PART OF THIS RESEARCH. 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

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