Informed Consent
REDS-II Donor Iron Status Evaluation (RISE) Study

You are asked to participate in a research study, called the REDS-II Donor Iron Status Evaluation (RISE) Study, which is being conducted at the <BLOOD CENTER NAME> under the supervision of Dr. <NAME>. This study is part of a larger network of blood safety research called REDS (Retrovirus Epidemiology Donor Study) funded by the National Heart, Lung and Blood Institute.

Overview of the Study
The RISE Study will assess how blood donation and personal characteristics may affect levels of iron and hemoglobin in a person's blood. Information from the study will help us evaluate which laboratory tests are best for monitoring donors' iron and hemoglobin levels, the best frequency for blood donation, and how some personal characteristics such as your diet, use of mineral supplements, or smoking may influence iron levels and the ability to donate blood. We will also assess in women donors how menstrual periods affect their iron levels and ability to donate blood.

Why was I asked to participate?

We are asking for your participation in this study because: [Research staff to check one box below]

_____You are new to blood donation and have never donated blood.

_____You have not donated blood in the last two years before today.

_____You are a man who has donated at least 3 times in the last 12 months (not including today). Double red cell donations count as two donations.

_____You are a woman who has donated at least 2 times in the last 12 months (not including today). Double red cell donations count as two donations.

What do I need to do to participate?

If your hemoglobin level is high enough today for you to donate**,** we are asking you to participate in this study for approximately 2 years during which time we will assess your hemoglobin and/or iron levels each time you come to donate.

For the study to accomplish its goals, it is important that you understand we would like you to donate blood to the <BLOOD CENTER NAME> as frequently as you can over the next two years. You will receive reminders from the research staff at <BLOOD CENTER NAME> to donate blood while you are enrolled in the study. You will also receive routine recruitment calls from the blood center.

We would like you to donate at least as often as checked below: [Research staff to check one box below]

_____ If you have never donated before today, you agree to donate blood at least twice a year for the next two years (4 more donations after today over the next two years).

_____ If you have not donated blood in the last two years before today, you agree to donate blood at least twice a year for the next two years (4 more donations after today over the next two years).

_____ If you are a man who has donated at least 3 times in the last 12 months (not including today), you agree to continue to donate at least three times a year for the next two years (6 more donations after today over the next two years).

_____ If you are a woman who has donated at least 2 times in the last 12 months (not including today), you agree to continue to donate at least two times a year for the next two years (4 more donations after today over the next two years).

What can I expect if I participate in this study?

At each donation visit, including today, you will be evaluated as usual by blood center staff to determine if you are eligible to donate. This will include a hemoglobin screening test to check for anemia.

As part of your blood donation, an additional three teaspoons (15 ccs) of blood will be taken to check your iron and hemoglobin levels at your first and final study visit. For all other donations between the first and final study visits, only two teaspoons (10ccs) of blood will be taken. Your samples between the first and the final study visits may or may not be used to check your iron levels. The iron tests that will be done on the blood samples you provide today will include checking your genetic material (DNA) for genes that may make you likely to have either too little or too much iron. No other genetic tests other than those related to iron or hemoglobin will be done on your DNA. Also, at today's donation and at your final study visit, we will check your blood cell counts.

Today you will be asked to complete a 10-minute survey about your blood donation history, diet, use of iron supplements and aspirin, smoking history, and, for women, pregnancy and menstrual history. At your final study visit, you will be asked to complete a 5-minute survey to check if there have been any changes in your use of vitamins and iron supplements, smoking habits, and, for women, menstrual history. These are all factors that are expected to influence your body's iron stores. Some of these questions may be sensitive, but it is important for the study that they be answered fully and accurately.

What will happen if I cannot donate blood?

If at some point in the next two years your hemoglobin level is too low to donate on a particular day, we will ask you to provide three teaspoons of blood for the study which may be used for testing your blood iron levels. By providing these samples, you are continuing to participate in the study until it ends.

If you cannot donate blood for a reason other than low hemoglobin during the next two years, your participation in this study will end but you will be asked to provide a final sample of three teaspoons of blood and to complete the 5-minute survey.

Will I receive the results of my blood tests?
The research iron test results, which will not be available until late in the study, will not be medically relevant. The <BLOOD CENTER NAME> routinely informs you if your

hemoglobin level is too low to donate. Therefore, we do not plan to notify you of the results of any research tests that may show expected iron loss, unless you specifically request them.

DNA test results, such as the test for iron overload (hemochromatosis), may be important to your health. You (and your physician, if you identify one) will be notified if these test results are abnormal. These results may be of potential medical concern.

Other test results, including complete blood count, will be shared with you or your physician, if these are medically significant or upon your request.

What are the risks and benefits of participating in this study?

Risks: Other than the known risks of blood donation that you have been informed of upon registering to donate, the only additional risks of participating in this research study are:

1) If a blood draw is necessary for study purposes, you may experience pain, bruising, and rarely infection.
2) Small additional blood loss: Rarely, the extra 2-3 teaspoons of blood drawn for the study at each blood donation could aggravate iron loss.
3) Information risk: If you request your results or are notified of a serious health implication from the testing, this information could be upsetting, although it could also represent a benefit to you.
4) Genetic testing: Knowing that you have a genetic or inherited abnormality in how your body absorbs iron could cause distress to you and your family, although it could also represent a benefit to you or your family.
5) Confidentiality: Participation in research may involve loss of privacy, but information about you will be handled as confidentially as possible by the investigators. Your name and address will be kept in a locked file at the blood center. Other study data will have a code number instead of your name. Your name will not be used in any published report about this study.

To further protect your privacy, the study investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the investigators may not disclose information (for example by court order or subpoena) that may identify you in any federal, state or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes. A Certificate of Confidentiality does not prevent you, however, from voluntarily releasing information about yourself or your involvement in this research.

Benefits: Although you will not directly benefit from participating in this study, this study may benefit other donors like you in the future, by helping <BLOOD CENTER NAME> develop donor-specific guidelines on how often one can safely donate blood. You will not be paid to participate in the study.

What are my rights as a study subject?
Your decision whether or not to take part in this study is voluntary. It will not change your future relationship with <BLOOD CENTER NAME> in any way. If you decide to participate, you will be given a copy of this form to keep. You are free to end your participation at any time without harm to your rights or your future relationship with

<Blood Center name>. If you decide to participate in the RISE Study, but change your mind later you may withdraw at any time or elect not to provide a study blood sample or complete one of the questionnaires. In the case that you are unwilling to provide samples or complete surveys as outlined in this consent, we may decide to withdraw you from the study. Withdrawal from the research study will not affect your relationship with <BLOOD CENTER NAME> or your previous or future blood donations.

In the event that you suffer physical injury as a direct result of your participation in this research activity, the <BLOOD CENTER NAME> will assume responsibility for making immediate medical care available to you. This care will be provided without charge if you notify Dr. <Principal Investigator's or designee's name and telephone number> within fifteen days of the date of the injury or appearance of symptoms, and consent to the care offered. There is no provision for monetary compensation to you at the expense of <BLOOD CENTER NAME> for such things as lost wages, disability, injury or discomfort resulting to you from such physical injury. Further information concerning treatment and payment of medical expenses in the event of an injury may be obtained from <Principal Investigator's or designee's name and telephone number>.

Contact Person

If you have any questions, please ask us now. If you have any additional questions later, contact Dr. <NAME> at <PHONE> who will be happy to answer them. If you have questions about your rights as a research subject, call at <PHONE> (local IRB).

Consent Authorization

My signature indicates that I have read the above explanation of this research project. I have been given the opportunity to ask questions of and my questions have been answered. The potential risks and benefits have been explained to me. Based on this information, I have voluntarily decided to participate in this research study. I understand that I have the option to withdraw from the study without penalty at any time after signing this form.

_____

Printed or Typed Name

_____ _____

Signature of the participant **Date**

_____ _____

Witness Name and Signature **Date**