ATTACHMENT 4

ATTACHMENT 4.1

Informed Consent

You are asked to participate in a research study, called the **REDS Donor Iron Study**, which is being conducted at the _____ Blood Center under the supervision of Dr. _____. 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. The **REDS Donor Iron 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.

Introduction

For a number of years, blood donation has been known to lower body iron stores, although usually not to levels that are believed to be of major health significance. This is because iron in the body is primarily found in the red cells of the blood (actually in the main oxygen carrying protein, hemoglobin, within the red cells). You can lose iron for reasons other than blood donation. For example, before menopause, women lose blood during their menses; pregnant women need to provide iron to their developing child; and some people may lose blood due to health conditions such as intestinal bleeding.

Blood donors who do not have enough iron in their body may have a low hemoglobin level in their blood, a condition called anemia. When you have anemia, you may be tired, have problems exercising, and may have other health problems. It is for this reason that blood centers routinely screen for anemia in persons who try to donate and require all donors to have a minimum hemoglobin level in their blood before they can donate blood.

Whether there is health significance for persons with a low level of iron in their body if this level is not low enough to cause anemia is uncertain. Some research suggests that a slightly low iron level can cause mild problems, such as being tired and difficulty concentrating while other research suggests that having a slightly low iron level may be beneficial and decrease heart and blood vessel disease.

Overview of the Study

Why was I asked to participate?

We are asking for your participation in this study because: [One box below to be checked by Research staff]

_____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.

_____You are new to blood donation or have not donated blood in the last two years, and have a hemoglobin level today that is not high enough for you to give blood.

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 as frequently as you can over the next <u>two years</u> (you are eligible to donate blood every 8 weeks or double red cells, using a special blood collection method, every 16 weeks). It is also important that you do NOT donate to another blood center during the two year study. You will be given instructions about how you can schedule donations but the donations should be made at the site where you enrolled or another site which is participating in the research. You will also receive reminders from the research staff at _____ Blood Center 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 (double red cell donations count as two donations): [Research staff to check the appropriate box below]

_____ If you are new to blood donation and have never donated blood, 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)

If your hemoglobin level is NOT high enough today for you to donate, we are asking for you to participate in this study only today so your iron levels and personal characteristics can be assessed once.

What you can expect if you participate in this study

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

If you are eligible, you will then donate blood as normal. When samples are taken from your donation for routine blood testing, an additional three teaspoons (15 ccs) of blood will be taken to check your iron and hemoglobin levels. At the donations between the first and last, only two teaspoons (10ccs) of blood will be taken. The samples between the first and last donations may be used to check on your iron levels later, but the decision on whether these will be tested will be made at the end of the study. The iron tests that will be done on the blood samples you provide today when you enroll in the study will include checking your genetic material (your DNA) for genes that may make you likely to have too little iron or too much body iron. (No other genetic tests other than those related to iron or hemoglobin will be done on your DNA). At today's donation and at the end of the study, we will also check your count of red blood cells, white blood cells and platelets (the different cells in your blood).

At today's donation, you will be asked to complete a 10 minute survey about your blood donation history, your diet, your use of iron supplements and aspirin, your smoking history, and, for women, your pregnancy and menstrual history. You will also be asked to complete a shorter survey (5 minutes) at the end of the study to check if there have been any changes in your use of vitamins and iron supplements, your smoking habits, and, for women, your 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 they be answered fully and accurately for you to participate in the study.

If you are told you cannot donate blood

If you are told you cannot donate blood today because your hemoglobin level is too low, we will ask you to provide three teaspoons of blood for the research tests and to complete the 5-10 minutes survey. However, you will not be asked to participate in the follow-up study for the next two years. You should ask the Blood Center staff when you can next try to donate blood.

If you can give blood today but cannot at some point in the next two years because your hemoglobin level is too low, we will ask you at that time to provide three teaspoons of blood for the research tests. You should ask the Blood Center staff when you can next attempt to donate blood. You are still being asked to continue to participate in the study until it ends.

If you cannot donate blood for a reason other than 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 survey one last time. The regular Blood Center staff will provide you further information on why you cannot donate blood at that time, whether you can donate blood in the future and whether this means anything for your health.

Your blood test results

In general, the iron research test results will not be available until late in the study. Since iron loss is a known effect of blood donation in many donors and the _____Blood Center will routinely let you know if your hemoglobin level is too low when you donate, we do not plan to share with you the results of any research test that may show this expected iron loss, although, upon request we will share these results with you and your physician (if you identify one) when they are available.

Certain research test results however may be important to your health. You (and your physician if you identify one) will be notified if these test results are abnormal and may be of potential medical concern

Sample Repository

If you agree to participate in this study, samples of your blood will be frozen and saved indefinitely in a repository for future research on iron stores. Future testing on these saved samples will be done only to check body iron and hemoglobin levels and may include additional tests of your genetic material if new genes are identified that tell us how your body absorbs and keeps iron or sets hemoglobin levels. No other genetic tests other than those related to iron or hemoglobin will be done on your DNA. The testing may be done at other laboratories, but your identity (name, address) will remain coded and only be known to the research staff at the _____ Blood Center. All proposed testing on saved samples will be subject to review and approval by the Blood Center's Institutional Review Board, which has the responsibility to protect the rights of

research study subjects, the REDS-II study, and representatives of the National Institutes of Health.

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

Risks: Other than the known risks of blood donation (*Insert individual Center's "What You Must Know" that describe these risks to blood donors)* the only additional risks of participation in this research study are:

1) If extra blood draws are needed: 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 I request my results or am notified of a serious health implication from the testing, this information could be upsetting, although it could also represent a benefit to me.
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 me will be handled as confidentially as possible by the investigators. My name and address information will be kept locked in a locked file at my local blood center, and other study data will have a code number instead of my name. Representatives from the funding agency, the National Institutes of Health, may review information about me to check on the study. My name will not be used in any published report about this study.

While we will make every attempt to keep the results of this study confidential, confidentiality cannot be guaranteed. To provide additional protection of your privacy, the blood center has obtained a Certificate of Confidentiality in accordance with Section 301(d) of the Public Health Service Act. This certificate will prevent study staff from being forced to disclose information that may identify you by court order or other legal action. This protection lasts forever (even after death) for all study participants. Any results of the study, such as scientific publications, will be reported as summaries that will not reveal your identity.

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 develop donor-specific guidelines on how often one can safely donate blood. You will not be paid to participate in the study.

Non Consent/Withdrawal from the study

Whether you choose to participate or not in this study will not affect your opportunity to donate blood today nor any rights or privileges you may have with the _____ Blood Center. If you decide to participate in the **REDS Donor Iron 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. You may also request to have your samples withdrawn from the sample repository. Withdrawal from the research study will not affect your relationship with _____ Blood Center or your previous or future blood donations.

Subjects' Rights

Your decision whether or not to take part in this study is voluntary. It will not change your future relationship with _____Blood Center in any way. You are free to end your participation at any time without harm to your rights or your future relationship with _____Blood Center.

If you are injured

[Each Center to insert their own wording- One example given below]

In the event that you suffer physical injury as a direct result of your participation in this research activity, the _____Blood Center 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 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. _____at_____ who will be happy to answer them. If you have questions about your rights as a research subject, call_____(local IRB). If you decide to participate, you will be given a copy of this form to keep.

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**

ATTACHMENT 4.2

Targeted mailing for Interim Visits

*Fe*eling like you need to donate?

Dear Donor,

Thank you for donating blood for patients in your community, and also for agreeing to participate in the REDS-II Donor Iron Study. This study monitors Iron levels in donors over a 2 year period. If you've donated recently, thank you very much! If you haven't donated recently, would you please seriously consider doing so, both for patients that need blood products and researchers that need data from your donation?
You may schedule a convenient donation time by calling <Phone number>, or simply stop by any of our permanent collection sites.

Thank You!

ATTACHMENT 4.3

Targeted mailing for Final Visit

*Fe*eling like you need to donate?

Dear Donor, thank you for donating blood for patients in your community, and also for agreeing to participate in the REDS-II Donor Iron Study. This study monitors Iron levels in donors over a 2 year period. The two year period is nearing the end, and we would like you to schedule a final research donation. Since an extra tube of blood needs to be collected at this final research donation, a research coordinator needs to be present at your donation. You may schedule a convenient donation time by calling <Phone number>, or simply stop by any of our permanent collection sites.
Thank You!