ATTACHMENT 3

Invitation to Participate Brochure

As a blood donor you already know the vital role that your blood donation plays in saving the lives of others. By participating in the REDS Donor Iron Study, you can also play a vital role in the research that helps keep frequent blood donors healthy. The information contained in this brochure can help you decide if you would like to participate in this important study.

The Donor Iron Study is designed to answer questions about how iron and hemoglobin levels change in blood donors over time. Iron is a necessary part of hemoglobin which is the part of the red blood cell that carries oxygen from your lungs to other parts of the body. This study is designed to look at how blood donation and personal characteristics may affect levels of iron and hemoglobin in a person's blood. Information from the study will also help us evaluate which laboratory tests are best for monitoring donor's iron levels, the best frequency for blood donation, and how genetic factors may influence iron and hemoglobin levels.

Who is being asked to participate in the REDS Donor Iron Study?

Two groups of donors are being asked to participate in the study for 1 ½-2 years. One group consists of frequent donors who have given blood at this center regularly in the past year. The other group includes donors who either have never given blood before or have not done so in the past 2 years but who, we hope, will now agree to give regularly.

A third group of donors who are deferred because of low hemoglobin at their first donation will also be asked to participate by completing only the initial assessment.

We need to study all three types of donors in order to understand how blood donation influences iron and hemoglobin levels.

What will be required of me if I decide to enroll in the REDS Donor Iron Study?

First you will be required to read and sign a consent form to participate in the study. This consent form will explain in greater detail than this brochure what the study requirements are. It will also contain information on your rights as a study participant and how your privacy is protected. You should read the consent form carefully before enrolling in the study and only sign it if you meet the study requirements, want to participate and have all your questions answered by the study staff.

The main requirement of the study will be to continue donating blood during the next two years. Most people involved in the study will be asked to donate twice a year for the next two years. Men who were frequent donors before enrolling will be asked to donate 3 times per year. This will be explained again in the consent form for the study. Because of the study requirements, you can only donate blood during this study at a limited number of sites, preferably at the donation site where you enroll in the study.

After enrolling, you will be asked to fill out a brief questionnaire about yourself that should take no more than 10 minutes to complete. The questionnaire will ask you about your previous blood donations, dietary habits, whether you take iron supplements or vitamins with iron, and your smoking habits. Women will also be asked about their menstrual cycle and blood loss during menstruation and their history of pregnancy. You will then be asked to donate blood as you normally would. At the time of your donation today and until your final visit, when samples are taken from your donation for routine blood testing, an additional 2 teaspoons of your blood may be taken to be used for laboratory tests that measure your iron stores.

After approximately a year and a half you will be recruited by the research staff to give a final set of blood samples which will be used to check your iron levels and complete another survey. You can donate blood at the same time, but the final visit will need to be specially scheduled. The final visit will need to be scheduled within 2-3 months of your receiving a reminder notification letter.

Before you leave, you will be given a membership card identifying you as a participant in the REDS Donor Iron Study. You can use the contact information on this card to arrange for your next donation. The card will also let you know where you can donate while you are enrolled in the study and remind you (if you already made an appointment) when you agreed to next donate blood. But, first of all, you should show this card to the blood center staff when you come in to donate so they are reminded that you are a study participant!

Please note, that if at any time after you are enrolled and successfully donate, you are asked not to donate blood because your hemoglobin level becomes too low, you are still asked to continue participating in the study. Although you will not be able to donate that day, you will be asked to provide blood samples to check your iron levels on the day you are deferred. The blood center will give you advice on how quickly you can return to donate.

What tests will be performed on my blood sample for the research study?

Your blood samples will be tested for several indicators of your body's iron stores. Your blood will be analyzed using newer testing designed to detect early iron deficiency. Some people, depending on how their body uses available iron, may be more likely to have too little iron while others may be more likely to have too much. Because of this we will also analyze your genes related to iron metabolism to find out how your body uses iron.

A small portion of the blood collected on your first visit will be frozen and stored for possible later use. The samples will only be used if other tests for iron status or iron genetic markers are developed. The researchers will not use your blood for any other purpose without your written consent.

Will anyone be able to link my survey answers or blood test results back to me?

Your information will be kept confidential. Details of how we keep your information private are in the consent form.

Who are the REDS Donor Iron Study researchers?

The REDS Donor Iron Study researchers are part of a larger group of researchers participating in the REDS-II study, sponsored by the National Institutes of Health, National Heart, Lung and Blood Institute. If you have not already received information about the REDS-II study we will be happy to provide it to you now.

Who do I contact if I have questions about the study?

<INSERT BLOOD CENTER NAME AND CONTACT INFORMATION>