

## Research Study Invitation

We want to invite you to participate in a research study with the Blood Systems Inc. The study can be done in person or over the telephone and takes less than 30 minutes of your time. The following is a description of the research study.

If you choose to participate you will receive \$35 for your time this will be mailed to your home address after you complete the study.

This study is being conducted at the three largest U.S. blood centers: the American Red Cross (ARC), Blood Systems, Inc. (BSI), and New York Blood Center (NYBC) in order to obtain a nationwide understanding of risk factors for donating virus positive blood. The goal of the study is to identify self-reported risks factors for donations that test positive for one of four possible viruses, human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), and/or human T-cell lymphotropic virus (HTLV). We will also be comparing responses from donors who tested confirmed positive to donors, *like you*, who tested unconfirmed (false positive) to find out if risk factors are different for these two groups of donors. The study protects your identity because the information submitted to the coordinating center will not include your name or other personally identifying information.

### What will happen with the answers I give during the interview?

You will be asked about known risk factors for HIV, HBV, HCV and/or HTLV. Each virus is spread in different ways and you may not have had any of the risk factors that we ask about. Your responses will be grouped with other donors who complete the interview. The study will determine how common different risk factors are and will report summary measures on patterns of risk factors in all of the donors that tested positive for the same virus compared to donors who tested false positive.

If you tell us something during the interview that would have made you ineligible to donate, we will have to add this to your donor record and this may lead to deferral from future blood donation. However there will be no other repercussions if the answers you give now are different than those you gave when you donated.

### How will the privacy of your responses be protected?

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health.

### What is a Certificate of Confidentiality?

With a Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an

insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under specific circumstances. For example, we will voluntarily disclose information about incidents such as an intent to hurt yourself or others.

**Who can answer my questions about the study?**

Your participation in the study is voluntary and you may decide you do not want your interview responses included. If you have questions about the study or you want to have your interview responses excluded at any time, you may call Dr. Brian Custer at Blood Systems Research Institute at (415) 901-0756.

If you have any questions about the testing results from you blood donation please call Donor Counseling and Notification Services at (800) 289-4925 or Dr. Hany Kamel at Blood Systems headquarters at (480) 675-5659

If you have any questions about your rights as a research participant in this study, please call the University of California San Francisco, Committee on Human Research which is also known as an Institutional Review Board (a group of people who review the research to protect your rights) at 415-476-1814.

**How do I join the study?**

Simply call (800) 289-4925 and one of our specially trained clinicians will be happy to enroll you in the study. If we do not hear from you we will likely give you a call to give you a chance to enroll.