<BLOOD CENTER LOGO/LETTERHEAD>
Informed Consent Form

REDS-II Causes of Post Donation Information (PDI) Study

You are asked to participate in a research study called the REDS-II Causes of Post Donation Information (PDI) Study, which is being conducted at the <*Blood Center Name*> and Westat, the study's Coordinating Center under the supervision of Dr. <*Name*>. This study is part of a larger program conducting blood safety and availability research called REDS (Retrovirus Epidemiology Donor Study) funded by the National Heart, Lung, and Blood Institute.

Overview of the Study

Obtaining an accurate health-history prior to blood donation is a key step in protecting the safety of the blood supply. For reasons largely unknown or understood, however, the health history process is known to be error-prone. Donors frequently fail to report a risk that would make them ineligible (defer) to donate temporarily or permanently. Then, at a subsequent point that is typically a future donation, this history is often disclosed by the donor. This information shared by the donor at a subsequent donation which may have led to a deferral at the previous blood donation is called post donation information (PDI). This study is designed to find out why PDI error events occur and to gather information on the health-history screening process in general. Data will be collected using a telephone interview that will be conducted by trained staff. Telephone interviews will include accepted donors (donors who were able to give blood), appropriately deferred donors (those donors who could not give blood due a reason that leaves them ineligible to donate), and donors involved in PDI occurrences (donors who failed to report their personal/health history accurately).

Appropriately deferred donors and donors involved in PDI occurrences will be selected from one of five broad categories including

1) Travel (malaria, vCJD);
2) Medical (history of cancer or other diseases including jaundice/hepatitis and medications needed to treat disease including Tegison, Proscar and Accutane);
3) Blood/Disease Exposure (tattoo, piercing, accidental needle stick);
4) High Risk Behavior-Sexual (male-to-male sex (MSM), sex with IV drug-user or test positive individual);
5) High Risk Behavior-Non-Sexual (illegal drug by needle, non-sexual exposure to Hepatitis C or Hepatitis B).

The telephone interviewer will ask you questions regarding the health-history screening process at <Blood Center Name>, your knowledge about this process, experiences during the process and specific questions related to your specific deferral. If you are an accepted donor, the questions will focus on your experiences and your knowledge about the health-history screening process.

Why was I asked to participate?

We will be interviewing donors who belong to one of the following three groups:

1. Accepted Donors (donors who were able to give blood)

2. PDI donors (donors who subsequent to a previous donation, now provide post donation information that results in them being ineligible to donate temporarily or permanently)

3. Deferred donors (donors who are ineligible to donate due to the disclosure of a history included in one of the five broad categories described above and are not PDI donors)

You are being asked to participate because the blood center records show that you may belong to one of the three groups mentioned above.

What do I need to do to participate?

With your consent, your blood donation history and contact information, including name, phone number and address, will be released to Westat. Westat is the Coordinating Center for this study and their staff will be conducting the telephone interviews regarding the health-history screening process. The contact information you provide will only be used by Westat for the purposes of contacting you for the study interview. At the end of the interview, the interviewer will confirm your mailing address and send you the $25 incentive that you will be eligible to receive upon completion of the interview. Westat will destroy all of your personal identifying information that you provide upon completion of the study and none of this information will be linked to your interview responses.

Participation in the telephone interview requires approximately 30 minutes of your time. With your permission, Westat will record this interview for quality control purposes. All personal recordings will be destroyed at the conclusion of the study.

What are the benefits of participating in this study?

There is no direct benefit to you besides the satisfaction of participating in a study that has the potential to help improve the health-history screening process for future blood donors.

What are the risks of participating in this study?

The risks of taking part in this study are minimal.

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 provide additional protection of your privacy, <Blood Center Name> has obtained a Certificate of Confidentiality in accordance with Section 301(d) of the Public Health Service Act. This certificate prevents study staff from being able 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. 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.

What about compensation for study participation?

For completion of the telephone interview, you will receive a check for $25.00.

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 should sign one copy of this consent form and return it in the postage paid envelope to the blood center. You should keep the second copy of this consent form for your own records. 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 PDI Study, but change your mind later you may withdraw at any time or elect not to complete the telephone interview. In the case that you are unwilling to complete the telephone interview 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.

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

I have read this form and understand the purpose of this study, procedures to be followed, and the potential risks and benefits. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I understand that I may withdraw at any time after signing this form. A signed copy of this consent form has been given to me.

[ ] I consent to participate in this study and allow my contact information to be given to Westat, resulting in my participation in a subsequent telephone interview.

_____

Printed or Typed Name

_____ _____

Signature of Participant **Date**