INFORMED CONSENT FORM

Title of Research: Retrovirus Epidemiology Donor Study-II International Program

Domestic Principal Investigator: Dr. Jingxing Wang, Professor, Chinese Academy of Medical Sciences

Johns Hopkins Principal Investigator: Hua Shan, MD, PhD

Application No.: NA_00010304:

Thanks for coming to donate blood today. The Blood Center is currently conducting an international collaborative research study with the Chinese Academy of Medical Sciences and the Johns Hopkins School of Medicine. The research has been approved by the Chinese Ministry of Health (document number [2007] 483). The Chinese Academy of Medical Sciences Institute of Blood Transfusion, the Beijing Red Cross NAT Laboratory, and five blood centers in Chengdu (Sichuan), Luoyang (Henan), Kunming (Yunnan), Liuzhou (Guangxi), and Urumqi (Xinjiang) are participating in the study. The purposes of this study are to examine risk factors associated with transfusion transmitted infectious diseases among Chinese donors, to improve the donor screening process and testing techniques, and to provide scientific data for developing policies in reducing transfusion transmitted diseases, therefore improving safety of blood supply in China. We invite you to take part in this study. Below we explain some of the important information that you might want to know about the study. Please read this consent form carefully and ask the study assistant to explain any words or information that you do not clearly understand.

Procedures

You are being asked to take part in this study because according to the rapid testing results, you have an abnormal test result of Hepatitis B surface antigen or amino alaninetransferase (ALT) which disqualifies you from donating blood. We would like to collect an additional two 3 ml blood samples from you for our research study with the purpose of improving the quality of donor testing. The REDS-II Study will not send results of additional testing to you. You may contact your blood center if you have questions.

Benefits

You will not receive money to participate in this study. However we believe that your participation in the study helps to increase the safety of the nation’s blood supply.

Risks

Collection of a small amount of blood is safe, but a small number of people may feel lightheaded or faint at the sight of blood. Some may have bruising, pain, or infection caused by the needlestick, and some people may have an allergic reaction to the arm scrub or tape.

Voluntariness and Confidentiality

Participation in this study is entirely voluntary and at no cost of you. You may refuse to participate now, or at any time during the process. Refusal to participate in the study or

withdrawing from the study will involve no penalty, and will not change your future relationship with the blood center.

We will protect your privacy to the extent allowable by law. Your personally identifiable information such as name, address and phone number will be stored only in the blood center. Access to this information is restricted to the blood center staff. In the study database your blood samples and testing results will be labeled by a study number and will not show your personal identifying information. Consequently, your identity will not be known to the persons analyzing data or preparing materials for publication. While study results may be published, your name and other identifying information will not be revealed.

This study has been carefully reviewed and approved by research ethics committees at the Chinese Academy of Medical Sciences and Johns Hopkins School of Medicine to ensure your rights are strictly protected.

Persons to Contact

If you have any questions about this study, please contact the Blood Center number listed below:_____. If you have any concern about rights as a participant in research, please call the Institutional Review Board in Chinese Academy of Medical Sciences at (010) 6510 5183.

Consent

Your signature on this Consent Form will indicate your consent to participate in this study.

_____ _____

Signature of Participant Date

_____ _____

Signature of Investigator Date