INFORMED CONSENT FORM
(FOR CONTROLS)

Protocol Title: Retrovirus Epidemiology Donor Study-II HIV Risk Factor Study

Application No.: NA_00017119

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

Johns Hopkins
Principal Investigator: Hua Shan, MD, PhD

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Researchers at the _____Red Cross Blood Center, Institute of Blood Transfusion (of Chinese Academy of Medical Sciences), Johns Hopkins School of Medicine, United States National Institute of Health and local Center for Disease Control (CDC) Office are interested in learning about the risk factors for HIV infection in Chinese blood donors. The results of this study will lead to improved blood safety.

This study needs healthy HIV negative (not infected with HIV) donors to serve as a comparison group. You are being asked to take part in this study because your blood sample had a NEGATIVE test for HIV at the blood center.

The selection of healthy donors like you is done randomly (by chance) using a computer program. You and other healthy donors will serve as “Controls” in this study.

Please read this consent form carefully and take as much time as you need.

Please ask questions at any time about anything you do not understand.

Procedures

If you agree to join this study:

A trained staff member from the local CDC (or the blood center) will ask you questions related to your sexual practices, your knowledge about HIV and about the reasons you donate blood. It is important that your answers are accurate and truthful.

It will take about 20 minutes to complete these questions.

You will not be paid to take part in this study.

Benefits

There is no direct benefit to you from taking part in this study. However, the information collected in this study will help to improve the safety of the nation's blood supply in the future.

Risks

Some of the questions are personal and sensitive. The questions may make you feel uncomfortable or upset you.

Voluntariness

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. During the interview, you may refuse to answer any question that is asked. 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 and local CDC.

Confidentiality

We will protect your privacy to the extent allowable by law. This consent form is the only paperwork that has your name on it. This form will be separated from the rest of the study packet once it is handed in. In order to protect the confidentiality of the information that you give us, a study number will be used to distinguish you from other participants and their records. Your interview will be treated as confidential. Your answers and your test results will be identified by your study number only, not by any of your personal information. Your personal information (like name, address and phone number) will be stored only in the blood center. Access to your personal information is restricted to the blood center staff. 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.

Release of Data

Some of your information that you provide in this study will be sent to the study investigators in the United States.

There is a law in the United States that protects health information. The law says that medical information about you may only be used and given out to others with your permission.

We are asking you to let us use and give out information about your health as described in the study consent form. The study team will see the details about your

health but will only see your study number, not your personal information, such as your name, address or phone number. Also, some U.S. government offices (such as the Food and Drug Administration) or other companies that provided money to do the study and must review the study results may see the information about your health.

We will try to make sure that all study investigators who see your information uses it only as described in the consent form – but we cannot guarantee this.

You do not have to agree to allow us to release your data to the investigators in the United States**.** But if you do not agree, you may not join this research study.

If you do agree to let us use and give out information about your health, you can change your mind at any time.

If you change your mind, you need to tell us in writing or ask the study team to write this decision for you that you have changed your mind about releasing your health information. From that date on, we will not collect new information about your health.

Please sign this form (or make your mark) if you agree to let us use and give out details about your health.

Signature Date

Persons to Contact

If you have any questions about this study, please contact the Blood Center at:_____.

If you have any questions, concerns or comments about your rights as a participant in research, please call the Institutional Review Board in the Chinese Academy of Medical Sciences at (010) 6510 5183.

Consent

Your signature on this Consent Form indicates that you understand the information given to you about the study. By signing the form it means that you agree to participate in this study.

_____ _____

Signature of Participant Date

_____ _____

Signature of Investigator Date