

Attachment 5.2

REDS III-INTERNATIONAL HIV Risk Factor Study in Blood Donors from Five Chinese Regions

Questions relating to survey objectives

We have developed a Risk Factor Questionnaire (RFQ) that will be used for assessing the risk factors for HIV infection. The questionnaire will collect general demographic and risk factor information pertinent to HIV infection. The questionnaire has been developed based on a thorough review of the current international and Chinese literature. Efforts have been made to ensure that our questionnaire is comprehensive and culturally appropriate.

For all five regular REDS-III blood centers, blood centers will mail a study enrollment packet to all donors selected as potential Cases and Controls. Telephone calls will be made before sending out packets to confirm the correspondence address. Cases and Controls will receive the same Risk Factor Survey study packet which includes an informed consent document explaining the voluntary nature, the benefit and risk of this study, a Risk Factor Questionnaire and an envelope with paid postage for a donor to mail their completed questionnaire back to the blood center. The donor can also complete the survey at the study website. Donors are not asked to sign the consent form because of the anonymous design of this study. By sending back the completed questionnaire, a donor indicates his/her consent for this study.

Cover page- Study Data

- **Date:** This question captures information on the administration of the questionnaire. The surveyed subject will fill out the date when the survey is taken.
- **Study identification number:** This will be completed by trained research staff. The study ID number will be used for de-identified administrative record keeping, such as linking interview responses to the HIV testing results and the donor/donation profile of the study subjects.

Body of the Questionnaire

All the following questions in the questionnaire will be completed by study subject in privacy.

Please note: The questions are presented in this justification document grouped according to their subject matter rather than consecutively presented as they appear to the respondent in the questionnaire.

Your Background

Objective: The following questionnaire items are related to the general demographic information of the study subjects.

1. When were you born?
2. What is your gender?
3. What is your place of birth?
4. What is your ethnicity?
5. What is your current occupation?
6. What is the highest level of education you have received?
7. What is your marital status?

Attachment 5.2

History of Blood Donation & Infection Risks – History of Blood Donations

Objective: The following questionnaire items are used to obtain data related to the frequency of previous donation and the year and type of each blood donation.

8. How many times have you donated blood?
- 8a. Most recent donation
- 8b. Next most recent donation
- 8c. Next most recent donation

History of Blood Donation & Infection Risks - Incentives and motivation

Objective: To determine motivational factors that lead participants to donate blood. The following questions help understand the donor's intention to get HIV testing through blood donation (test seeking). Blood bank serology testing may be a magnet that attracts people wishing to be tested for HIV. We intend to ascertain donor's perceptions/confidence related to HIV serology performed by the blood bank as well as whether the blood screening serology testing was a contributing factor in donating.

- 9 How much do you agree or disagree with each of the statements (9a-9c) below:
- 9a It's important that I received blood test results from blood donation.
- 9b I think blood donation is a good, fast, anonymous way to get my blood test.
- 9c One of my reasons for donating blood is to find out if I have HIV and/or hepatitis infection.

History of Blood Donation & Infection Risks - Health Condition History

Objective: To obtain data related to general medical history exposures that could lead to HIV transmission, including acupuncture, medical injection, medical surgery, cosmetic surgery, dental cleaning, dental surgery, endoscopies.

10. Have you ever been told that you are at risk for spreading diseases through your blood?
- 10a. What kind of diseases? (Mark all that apply)
- 10b. When was the last time you were told so?
14. Have you ever received acupuncture treatment?
- 14a. In the past 6 months, did you have acupuncture?
15. In the past 6 months, did you have any injection (including intravenous [IV] and intramuscular [IM] injections)?
- 15a. How many times did you have injection(s)?
16. Have you had any finger sticks (excluding the one prior to making a donation)?
- 16a. In the past 6 months, did you have finger sticks (other than the one prior to making a donation)?
17. When you had acupuncture, finger sticks, or injections, were needles and syringes used disposable?
- 17a. Acupuncture
- 17b. Finger sticks
- 17c. Injections
18. In the past 6 months, have you ever visited the following medical facilities?(Mark all that apply)
- 18a. What kind of treatment did you receive from the above medical facilities?(Mark all that apply)
19. Have you ever had in-patient medical surgery?
- 19a. In the past 6 months, did you have in-patient medical surgery?
20. Have you ever had out-patient medical surgery?
- 20a. In the past 6 months, did you have out-patient medical surgery?
21. Have you ever had cosmetic surgery (e.g. laser, eye/lip surgery, collagen injection, dermal abrasion)?

Attachment 5.2

- 21a. In the past 6 months, did you have cosmetic surgery?
- 23. Have you ever had any dental cleaning?
- 23a. In the past 6 months, did you have dental cleaning?
- 24. Have you ever had any dental surgery, such as root canal treatment or tooth extraction?
- 24a. In the past 6 months, did you have dental surgeries?
- 25. Have you ever had any endoscopy (such as gastroscopy and colonoscopy)?
- 25a. In the past 6 months, did you have endoscopies?

History of transfusion

Objective: Due to the unsanitary illegal blood collection and transfusion practices in China in the early to middle 1990s, the history of blood transfusion in the 1990s has been identified by several studies as a major risk factor for HIV infection. So the following questions ask about the year and frequency of previous transfusion.

- 22. Have you ever received a blood transfusion?
- 22a. How many times did you have blood transfusions?
- 22b. Year of your first time of blood transfusion?
- 22c. Year of your last time of blood transfusion?

Previous deferral

Objective: To ascertain if the blood donor has been deferred at the time of the blood donation and the reason for deferral. In China, the blood centers are building up the information system for deferred donors so next time when these donors come to donate, they will be automatically identified. These questions will be useful for understanding the effectiveness of deferral system and the donors' information of deferral.

- 12. Before your most recent donation, had you ever been permanently deferred as a blood donor?
- 12a. For what reason were you permanently deferred?(Mark all that apply)
- 13. Before your most recent donation, had you ever been temporarily deferred as a blood donor?
- 13a. For what ineligibility were you temporarily deferred?(Mark all that apply)

Health Condition History - Previous diagnosis of hepatitis, HIV and STD

Objective: Previous infection of hepatitis, or STD or history of exposure to these and HIV infections may be associated with HIV infection. The following questions ask about the donor's previous diagnosis of hepatitis, HIV and STD as well as the infectious status of their family members for hepatitis, HIV and STD.

- 26. Have you ever been previously diagnosed with hepatitis?
- 26a. What type(s) of hepatitis did you have (please choose all that apply)?
- 27. Have you ever been previously diagnosed with syphilis, gonorrhea, or any other sexually transmitted disease?
- 28. Have any of your family members had hepatitis?
- 29. Have any of your family members had HIV/AIDS?
- 30. Have you ever had household contact with someone with HIV/AIDS?
- 30a. In the past 6 months, did you have household contact with someone with HIV/AIDS?

Attachment 5.2

Drug use History

Objective: For the following questions we intend to evaluate the influence of illicit drug use on HIV infection. The questions include injected and non-injected illegal drugs use and frequency. To ascertain if illegal drugs use included sharing the drug delivery device, which could lead to disease transmission, we also ask the questions about sharing injected drug delivery device

- 31. Have you ever used needles to shoot (or take) street drugs?
 - 31a. How long have you shot (or taken) street drugs?
 - 31b. How many times per month did you shoot (or take) street drugs?
 - 31c. Have you ever shared needles or syringes with others to inject street drugs?
 - 31d. In the past 6 months, did you ever use needles to shoot (or take) street drugs?
- 32. Have you ever used illegal oral or intranasal drugs without doctor's prescription?
 - 32a. In the past 6 months, did you use illegal oral or intranasal drugs without doctor's prescription

Objective: The following questions intent to identify illicit drug use among the donor's cohabitants lifetime and during the past 12 months, as well as among their family members.

- 33. Have you ever lived with a person who was an intravenous drug user?
- 33a. In the past 6 months, did you live with a person who was an intravenous drug user?
- 34. Are any of your close friends or family members intravenous drug users?

Sexual History

Objective: The following questionnaire items are used to obtain data related to sexual lifestyle, including the number of sexual partners during the lifetime, which increases the odds of having a sexual transmitted disease, as well as its spread. The sexual history will allow us to determine the most prevalent sexual patterns for the Chinese blood donors and whether this pattern may or may not be correlated to specific serologic markers. A better understanding of sexual risk factors for HIV may allow us to build more accurate questions to improve the donor qualification process.

- 5a. Have you ever provided special services at entertainment business (including night clubs, private clubs, night bar, Karaoke clubs)?
- 35. Have you had more than 2 concurrent sexual partners of the opposite sex?
 - 35a1. In your lifetime, how many heterosexual partners did you have?
 - 35a2. In the past 6 months, how many heterosexual partners did you have?
 - 35b1. How often do you or your sex partner use a condom when you have sex with your heterosexual partner?
 - 35b2. In the past 6 months, how often do you or your sex partner use a condom when you have sex with your heterosexual partner?
- 36. (FOR MALE RESPONDENTS ONLY) In your lifetime, have you ever had sex with another male?
 - 36a1. In your lifetime, how many times did you have sex with males?
 - 36a2. In your lifetime, how many male partners have you had sex with?
 - 36a3. In your lifetime, how often do you or your sex partner use a condom when you have sex with male partner?
 - 36b1. In the past 6 months, how many times did you have sex with males?
 - 36b2. In the past 6 months, how many male partners have you had sex with?
 - 36b3. In the past 6 months, how often do you or your sex partner use a condom when you have sex with male partner?
- 37. Have you ever paid or received money or other forms of remuneration for having sex?

Attachment 5.2

37a. In the past 6 months, have you paid or received money or other forms of remuneration for having sex?

Sexual History - Sexual Partners

Objective: The following questions are related to known risks factors for blood borne disease in the donor's sexual partners in their lifetime.

- 38. Have you ever had a sex partner who was an intravenous drug user?
- 38a. In the past 6 months, did you have a sex partner who was an intravenous drug user?
- 39. In your lifetime, have you ever had a sex partner who had a positive test for syphilis, gonorrhea, or any other sexually transmitted disease?
- 39a. In the past 6 months, did you have a sex partner who had a positive test for syphilis, gonorrhea, or any other sexually transmitted disease?
- 40. In your lifetime, have you ever had a sex partner who had been diagnosed with HIV/AIDS?
- 40a. In the past 6 months, did you have a sex partner who had been diagnosed with HIV/AIDS?
- 41. In your lifetime, have you had sexual contact with anyone who received blood transfusion?
- 41a. In the past 6 months, did you have sexual contact with anyone who received blood transfusion?

Other Risk Factors - Work Place Exposures

Objective: Donors who work in a health care profession or other social setting that could lead to exposure to blood or other body fluids could be at higher risk for HIV acquisition.

- 42. Have you ever had contact with human blood and other human body fluids in your workplace?
- 42a. In the past 6 months did you ever have contact with human blood and other human body fluids in your workplace?

Other Risk Factors - Other Potential Risk Factors

Objective: To obtain data related to rare risk factors for HIV infection such as body piercing and tattoo, we ask about ever exposure and also exposure in the year before blood donation.

- 43. Have you ever had a tattoo?
- 43a. In the past 6 months, did you have a tattoo?
- 44. Have you ever had your ears or other body parts pierced?
- 44a. In the past 6 months, did you have your ears or other body parts pierced?

History of Blood Donation & Infection Risks - Notification and Adherence

Objective: The following questions are used to determine the notification service provided by the blood center and whether or not the donor is willing to adhere to the advice for further testing and health care. This helps us understand if the notification is effective.

- 11. Did you ever receive notification from blood center about your infection status?
- 11a. Before your most recent donation, had you ever received notification from blood center about your infection status (excluding any such notification after your most recent blood donation)?
- 11b. Had you sought further testing or health care according to the instruction of the notification (excluding any such notification after your most recent blood donation)?

Attachment 5.2

11c. Are you planning to seek further testing or health care according to the instruction of the notification?