# **REDS II-INTERNATIONAL HIV CASE CONTROL STUDY Questions relating to survey objectives**

The purpose of the interview questions is to collect donor profile data for comparing risk exposures between prospective blood donors who test HIV positive (cases) and HIV negative (controls). The responses will permit us to determine risk factors associated with HIV infection among volunteer replacement blood donors in Brazil. A case control study will yield interview data on HIV risk behaviors among prospective donors that will be used; 1) to understand predominant risk behaviors associated with in HIV positive blood donation in Brazil, for example: male-to-male sex, having multiple heterosexual partners, and to a lesser extent injection drug use (IDU), 2) the results may also lead to suggestions for modification to current operational donor screening questionnaire in ways that can decrease risk and improve blood safety. The questions for both cases and controls are identical, except for five additional questions that will be asked at the end of the interview on topics that are unique for HIV positive individuals (cases).

The questionnaire is administered using audio computer-administered self interview (ACASI) program. The purpose of using a self-administered instrument is to ensure that potentially stigmatizing behaviors will be reported as honestly as possible without fear or concern that an interviewer would stand in judgment.

# Section A- Study Data

All portions of Section A will be completed by trained research staff with the assistance of the study subject where necessary:

- **Objective**: The following questionnaire items are related to the general profile of the study subjects, and will be used for de-identified administrative record keeping, such as linking interview responses to the HIV strain type and potential drug-resistance profile of the infection in cases, as well as for obtaining general demographic information from the study subjects.
- QA1 Subject ID
- QA2 Subject Type
- **Objective:** to obtain demographic data for general risk stratification based on the background of the subjects.
- QA8 Study subject is able to read
- QA9 What level of education do you have?
- QA10 What is your occupation?

The following questionnaire items capture information on the administration of the questionnaire.

- QA3 Blood collection site
- QA4 Month of interview
- QA5 Year of interview
- QA6 Research Assistant Initials
- QA7a Place of Interview

QA7b Please specify other place of interview

# Section B- Demographic data

Section B will be completed by the study subject with the assistance of the trained research staff. This will allow the subject to become familiar with listening to and/or reading the questions and the computer touch screen for answering the questions.

- **Objective:** to obtain additional demographic data for general risk stratification based on the background of the subjects.
- QB1 What is your gender?
- QB2 What is your birth year?
- QB3 What is your birth month?
- QB4 What is your birth day?
- QB5a What is your country of birth?
- QB5b Please specify your country of birth (if not Brazil)
- QB6 What is your ethnicity?
- QB7 What is your current marital status?
- QB8 If you are married or living with someone, is your spouse/cohabitating partner male or female?

# Section C- Previous donation history and HIV testing

Section C and all remaining sections of the questionnaire will be completed by study subject in privacy.

- **Objective:** to obtain data related to whether a donor has donated blood before and if so the frequency of previous donation and knowledge of information on blood donor eligibility. In Brazil there is no country-wide system such as a deferred donor registry to prevent a donor from attempting to donate at another blood center. A person at risk for HIV infection might donate blood at many blood banks and these questions will capture information on common donating a multiple locations is.
- QC1 Have you ever donated blood at another blood center?
- QC2 How many times have you donated blood at another blood center?
- QC3 At the time of your last donation, do you remember being given information about who should not donate blood?
- **Objective:** to determine if the donor exhibits HIV testing behavior that would suggest knowledge of risk factors for HIV acquisition and indicate if the donor has actively sought HIV testing before.
- QC4 Other than blood donation, have you ever been tested for HIV?
- QC5a What was the reason for the HIV test?
- QC5b Please specify the other reason for test.
- C6a Other than a blood center, where else have you been tested for HIV?
- C7 Excluding HIV testing conducted as part of blood donation, how many times have you been tested for HIV?

#### Section D - Incentives and Motivations for Donating

- **Objective**: To assess a donor's level of altruism by determining if the donor exhibits altruistic behaviors in their daily life. We want to correlate their daily behavioral answers to assess how much of a factor altruism is when donating blood. It is already known that donors will give a socially acceptable response rather than the real reason to donate when asked directly about blood donation. There is a major difference between asking a donor whether altruism is a motivation factor and measuring the degree to which donors report engaging in other altruistic behaviours.
- QD1 Have you helped carry a stranger's belongings?
- QD2 Do you allow someone who is elderly or disabled to go ahead of you in a line?
- QD3 Have you offered to help a handicap or elderly person across a street?
- QD4 Do you give money to charity?
- **Objective:** To determine motivational factors that lead participants to donate blood. Using a scoring system based on responses to all of the questions QD5a QD5p we will classify donors into three categories of motivation; Altruistic, Direct Appeal and Self Interest.
- QD5a To anonymously help someone else who needs blood.
- QD5b To help a friend or relative who is sick or needs blood.
- QD5c In response to a campaign on TV or radio.
- QD5d I received a telephone call or letter from the blood bank asking me to donate.
- QD5e I think that it is important to give blood.
- QD5f I wanted to get test results for my blood.
- QD5g My blood type is in high demand.
- QD5h I think that I am doing something important for society.
- QD5i I may need blood myself someday.
- QD5j I heard that blood donation is good for my health.
- QD5k I like to know about my health and blood donation is a good way to find out.
- QD51. Someone offered me money for donating.
- QD5m Blood banks always need blood and so donating is the right thing to do.
- QD5n Is there another reason that best explains why you came to donate?
- QD5p What is the reason that best explains why you came to donate?

**Objective:** To determine if the donor decided to donate based a specific social influence.

- QD6Some people feel they must donate blood because family, friends, co-workers or other persons in an organization they know donate blood or encourage others to donate. Did this happen to you when you last donated blood?
- **Objective:** To determine 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 whether the blood screening serology testing was contributing factor in donating.
- QD7 Do you believe that the blood center uses better HIV tests than are available at other places?
- QD8 Did you donate blood because you wanted to be tested for HIV?
- QD9a Please checks all the boxes for the factors that contributed to your decision to come to the blood center to be tested for HIV.
- QD9b Please specify other reason
- **Objective:** Similar to HIV, some donors may come to the blood bank to obtain testing for HBV or HCV. To determine 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 hepatitis. We intend to ascertain donor's perceptions/confidence related to hepatitis serology performed by the blood bank as well whether the blood screening serology testing was contributing factor in donating.
- QD10 Did you donate blood because you wanted to be tested for hepatitis?
- QD11a Please checks all the boxes for the factors that contributed to your decision to come to the blood center to be tested for hepatitis.
- QD11b Please specify other reason
- QD12a Did you come to the blood center to be tested for some other reason?
- QD12b Please specify other reason
- **Objective:** to determine whether a health professional had an influence on the donor's decision to donate blood. Health professionals may play an important role leading person to donate blood in order to get tested.
- QD13 Did a health worker such as a doctor, nurse, or someone from a health department suggest that you go to the blood center for a blood test for HIV, hepatitis, or for some other reason?
- QD14 Please tell us who suggested you to come to the blood center.

**Objective:** To determine respondents' knowledge about HIV, risk behaviors and window period for HIV.

QD15 You can donate blood if you have engaged in risk behaviors for HIV or AIDS because the blood center tests all blood and throw away any infected blood

- QD16 You can donate blood even if you engage in risk behaviors for HIV or AIDS as long as you have a negative HIV test.
- QD17 The blood test for HIV identifies everyone who is infected with the virus.

### **Section E - Sexual History**

Sexual lifestyle, including the number of sexual partners during the lifetime increases the odds of having a sexual transmitted disease, as well its spread. The sexual history will allow us to determine the most prevalent sexual patterns for the Brazilian blood donors and whether this pattern may or may not be correlated to specific serologic markers. The path of HIV spread has moved from homosexual to heterosexual patterns in many countries including Brazil. However this pattern has not been clearly demonstrated in blood donors. A better understanding of sexual risk factors for HIV may allow us to build more accurate questions to improve the donor qualification process. It may also help us to avoid potential discrimination and unnecessary loss of donors if the patterns of HIV transmission are not shown to be associated with sexual activity.

In 2004 Brazilian policies were changes to allow men who have sex with men (MSM) to donate blood if the last sexual intercourse occurred 12 months before the blood donation. The HIV prevalence in Brazil is 10 times higher than in USA and nucleic acid testing has not been adopted to identify donors who recently acquired HIV infection. No data on HIV prevalence in blood donors has been published since this new policy was implemented.

- **Objective:** To ascertain the respondent sexual self-reported orientation. For instance, in many Latin American cultures men do not consider themselves as homosexual as long as they only have insertive anal sex or oral sex.
- QE1 What do you consider yourself to be? [What is your sexual orientation?]

**Objective:** To ascertain past sexual history in men. [Questions are not asked of women.]

- QE2 (Ask of Men Only) How many different women have you had sex with since you first began having sex?
- QE3 (Ask of Men Only) How many different men have you had sex with since you first began having sex?

Objective: To ascertain past sexual history in women. [Questions are not asked of men.]

QE2 (Ask of Women Only) How many different men have you had sex with since you first began having sex?

#### **Section F - Sexual partners risks**

The following section is related to known risks factors for blood borne disease in the donor's sexual partners in their lifetime. These questions will be useful for those cases where the respondents says they had 0 (zero) or no sexual partners in the 12 months before blood donation in Section G of the questionnaire.

**Objective:** To determine the known risk factors for the donor's sexual partners.

- QF1a To the best of your knowledge, have you <u>ever</u> had sex with anyone who was an intravenous drug user?
- QF1b In the year before your last donation, have you had sex with anyone who was an intravenous drug user?
- QF2a To the best of your knowledge, have you ever had sex with anyone who tested positive for HIV?
- QF2b In the year before your last donation, have you had sex with anyone who tested positive for HIV?
- QF3a To the best of your knowledge, if your partner tested positive for HIV, was he/she taking HIV medications?
- QF3b In the year before your last donation, if your partner tested positive for HIV, was he/she taking HIV medications?
- QF4a To the best of your knowledge, have you <u>ever</u> had sex with a man who has had sex with another man.
- QF4b In the year before your last donation, have you had sex with a man who has had sex with another man?
- QF5a To the best of your knowledge, have you <u>ever</u> had sex with anyone who received a blood transfusion?
- QF5b In the year before your last donation, have you had sex with anyone who received blood transfusion
- QF6a To the best of your knowledge, have you ever had sex with anyone who was a hemophiliac?
- QF6b In the year before your last donation, have you had sex with anyone who was a hemophiliac?
- QF7a To the best of your knowledge, have you <u>ever</u> had sex with anyone who has spent three or more nights in jail, prison, or a detention center?
- QF7b In the year before your last donation, have you had sex with anyone who has spent three or more nights in jail, prison, or a detention center?
- QF8a To the best of your knowledge, have you <u>ever</u> had sex with anyone who had a job that involved exposure to blood or other body fluids?
- QF8b In the year before your last donation, have you had sex with anyone who had a job that involved exposure to blood or other body fluids?

Section G- Social Matrix

This section of questionnaire was designed to capture detailed sexual information for up to 5 sexual partners in the 12 months before the last blood donation. The reasons for focusing on this period of time is that most blood borne disease and sexual transmitted disease can be diagnosed within less than 12 months period of acquisition; in Brazil having 6 or more sexual partners is the current number of partners leading to deferral for multiple sexual partners; in general persons tend to maintain a standard pattern of sexual behavior in their lifetime (MSM, bisexual, heterosexual) as well as specific sexual practices that are relevant to identify higher risk behaviors for HIV transmission. We assume therefore that asking about more than 5 sexual partners will not provide any supplemental information. Responses from different partners will be combined to determine the frequency that a donor has engaged in higher risk tac an be used to determine if specific sexual practices are associated with testing positive for HIV. We also intend to correlate the HIV incidence and prevalence among repeat and first time blood donors. The following questions will guide future efforts target to develop donor health history questions that will help to avoid accepting donors with high risk.

It must be stressed that only if a donor reports having sexual encounters in the 12 months before donation will the computer program direct the donor to answer these questions. In addition there are built-in skip patterns so that if a person says that he or she has not engaged in a specific behavior with a specific partner, he/she will not be asked the progressively more detailed and sexual explicit questions.

- **Objective:** To ascertain the blood donor sexual history in the past 12 months before the last blood donation. This question is necessary in order for the computer program to determine how many different sexual partners between 0 and 5 the donor should be asked about.
- QG1 How many people did you have sex with in the 12 months before your blood donation?

**Objective**: These demographic data are necessary to help classify the donor's social network.

QG2, G19, G36, G53, G70	What is Partner 1,2,3,4 and 5's gender?
QG3, G20, G37, G54, G71	How old is partner 1,2,3,4 and 5s?
QG5, G22, G39, G56, G73	How would you describe partner 1,2,3,4 and 5's race or ethnicity?

**Objective**: To ascertain how the donor met their sexual partners and what knowledge the donor has regarding his or her sexual contacts in the year before blood donation. These questions where designed to evaluate whether the donor's social network has an influence on testing HIV positive.

QG4, G21, G38, G55, G72	What type of partner is partner 1,2,3,4, and 5?
QG9, G26, G43, G60, G77	Where did you first meet partner 1,2,3,4, and 5?
QG10, G27, G44, G61, G78	Specify where you met partner 1,2,3,4, and 5?
QG7, G24, G41, G58, G75	Is partner 1,2,3,4 and 5 a male who has had sex with other males?
QG8, G25, G42, G59, G76	What is partner 1,2,3,4 and 5's HIV status?

Objective: To ascertain risk factors beyond sexual contact related to HIV transmission.

QG6, G23, G40, G57, G74 Is partner 1,2,3,4 and 5 an injection drug user?

**Objective:** To access unprotected sexual behaviors and correlated the responses specific serologic markers for HIV

QG11, G28, G45, G62, and G79	In Number of times you had vaginal intercourse with partner 1,2,3,4 and 5 in past 12 months.
QG12, G29, G46, G63, G 80	When you had vaginal sex, how frequently did you use condoms?
QG13, G30, G47, G64, G81	Number of times you had anal intercourse with partner 1 in past 12 months.
QG14, G31, G48, G65, G 82	When you had anal sex, how frequently did you use condoms?
QG15, G32, G49, G66, G83	Number of times you had insertive anal intercourse with partner 1 in past 12 months.
QG16, G33, G50, G67, G84	When you had insertive anal sex, how frequently did you use condoms?
QG17, G34, G51, G68, G85	Number of times you had receptive anal intercourse with partner 1 in past 12 months.
QG18, G35, G52, G69, G86	When you had receptive anal sex, how frequently did you use condoms?

## Section H - Alcohol and drug use

For the following section we intend to evaluate the influence of social lifestyle in terms of alcohol and drug use. Use of mood altering substances may be associated with the risk of HIV acquisition. However this has not been clearly demonstrated in Brazilian blood donors. We also intend to evaluate whether specific serologic markers are related to riskier behaviors or illicit drug use.

**Objective**: To ascertain alcohol use frequency and quantity per day.

QH1 How often do you drink beer, wine, liquor, or mixed drinks?

QH2 On average how many drinks do you have each time you drink? Number of drinks

**Objective**: To ascertain the non-injected illegal drugs use and frequency.

- QH3 Have you ever used any non-injected illegal drugs (drugs that are smoked, snorted or taken orally), examples include marijuana (aka pot), hashish, cocaine (aka blow or crack), methamphetamines (aka crystal), ecstasy (aka "e"), mushrooms, and LSD?
- QH4 When was the <u>first year</u> you used non-injected illegal drugs?
- QH5 When was the <u>last year</u> you used non-injected illegal drugs?
- **Objective:** To ascertain if illegal drugs use including sharing the drug delivery device, which could lead to disease transmission.
- QH6 If you have smoked or snorted illegal drugs, did you share pipes or straws with another person?

**Objective**: To ascertain injected illegal drugs use and frequency.

- QH7 Have you ever used or shot up injection drugs (examples include heroin, cocaine, and amphetamines)?
- QH8 When was the <u>first year</u> you used injected drugs?
- QH9 When was the <u>last year</u> you used injected drugs?
- **Objective:** To ascertain if other non-prescription substances use and frequency. These substances may not be or may not be viewed as illegal drugs, but could serve as routes of transmission.
- QH10 Have you ever injected any non-prescription substances including vitamins, anabolic steroids, or hormones?
- QH11 Have you ever shared needles or syringes with another person to inject any non-prescriptions substance including vitamins, anabolic steroids, and hormones?

## **Section I Medical History**

- **Objective**: To obtain data related to general medical history exposures that could lead to HIV transmission. Only if a donor indicates they have no sexual or drug-related risks would we presume that medical exposure could be the route of infection acquisition.
- QI1 Have you ever had a blood transfusion?
- QI2 How many transfusion episodes have you had?
- QI3 When was the <u>first year</u> you received a transfusion?
- QI4 When was the <u>last year</u> you received a transfusion?
- QI5 Have you ever had minor or major medical surgery, tooth extraction or another dental procedure?
- QI6 In the year before your last blood donation, have you had minor or major medical surgery, tooth extraction, or another dental procedure?
- QI7 Have you ever had endoscopy (a medical test where a flexible tube is used to look inside of your throat and digestive system) or colonoscopy (a medical test where tube is used to look inside your colon/large intestine)?
- QI8 In the year before your last blood donation, have you had endoscopy or colonoscopy?

## **Section J- Other Potential Risk Factors**

- **Objective:** To obtain data related to rare risk factors for HIV infection. Only if a donor indicates they have no sexual, drug-related, or medical risks would we presume that any of these exposures could be the route of infection acquisition. In this section we ask about ever exposure and also exposure in the year before blood donation. Through laboratory testing we will know whether HIV positive donors have recently acquired infection or not. We need to determine if both cases and controls have similar exposure levels for these rare potential risk factors.
- QJ1 Have you spent three or more nights in jail, prison, or a detention center?
- QJ2 Have you had acupuncture treatments?
- QJ3 How many times have you had acupuncture treatments?
- QJ4 In the year before your last blood donation, have you had acupuncture treatments?
- QJ5 How many tattoos do you have on your body?
- QJ6 In the year before your last blood donation, have you had a new tattoo or had one re-applied?
- QJ7 Where did you get your most recent tattoo?
- QJ8 How many ear or body piercing do you have?
- QJ9 In the year before your last blood donation, have you had new ear or body piercing?
- QJ10 Where did you get your most recent piercing?
- QJ11 Have you ever had a manicure or pedicure at a beauty salon or had a shave at a barbershop?
- QJ12 How many times have you had manicures or pedicures or shaves at a barbershop?
- QJ13 In the year before your last blood donation, have you had a manicure or pedicure or had a shave at a barber shop?
- QJ14 How many people do you personally know who currently have AIDS or have died of AIDS?
- QJ15 How many people do you personally know who do NOT have AIDS, but have tested positive for HIV, the virus that causes AIDS?

#### Section K - Work Place Exposures

**Objective**: To obtain data related to rare risk factors for HIV infection. Only if a donor indicates they have no sexual, drug-related, or medical risks would we presume that any of these exposures could be the route of infection acquisition. However, 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.

- QK1 In your profession, do you take care of humans or have exposure to their bodily fluids?
- QK2 In your professional work have you ever had a needle stick injury (accidentally been stuck by a needle or other sharp instrument used for providing medical care to someone else)?
- QK3 In your professional work have you ever got someone else's blood, body fluids, or excrement splashed into your eyes, mouth or in an open skin lesion?

## Section L - Exposure and Treatment

The following 5 additional questions will be asked of <u>cases only</u> on topics that are unique for HIV positive individuals and will be asked at the end of the interview.

- **Objective:** To ascertain if the blood donor new of his/her HIV status at the time of blood donation, self-reported route and time of infection, and past or current antiretroviral therapy (ART). In Brazil, ART is a universally available for HIV treatment. These questions will be useful for interpreting possible drug resistance patterns in the molecular surveillance component of the study.
- QL1 Did you know your HIV status before donating?
- QL2 How do you think you may have become infected with HIV?
- QL3 When do you think you may have been infected with HIV?
- QL4 Are you currently taking antiretroviral therapy?
- QL5 Have you taken antiretroviral therapy in the past?

## **Detailed question justifications:**

#### Section A – Study Data

- QA1 Subject ID: *Source: Original; new.* The subject ID is a code number that identifies the blood donor as subject in the study. Through this code we will be able to examine; the blood donor's status for the following factors: type of donor (volunteer or replacement); frequency of blood donation (first time, repeated or lapsed); HIV testing results for the current donation.
- QA2 and A3 Subject Type-Case or Control? Control Type onsite or offsite recruitment? *Source: Original; new.*

Is the study subject a case (HIV +) or a control (HIV -). Case or control status is the main analysis variable. All other questions will be analyzed to determine if the reported risk behavior or exposure is a predictor of being a case (HIV +) or a control (HIV -).

If a control, what type of control is this study subject - recruited onsite or returning donor? Group A Control - Recruited onsite at the time of donation or Group B Control - Recruited offsite by telephone or mail. The two control groups may provide different answers and so we need to collect this information so in data analysis we can determine if the control recruited in different ways have the same risk profile

- QA4 Blood collection site. FPS Sao Paulo; HEMOMINAS Minas Gerais; HEMOPE Pernambuco; HEMORIO-Rio de Janeiro. *Source: Original; new*. The HIV prevalence as well the transmission risk behaviors may vary from city to city. Responses will be correlated to blood donors' status (first-time, repeated or lapsed); Test seeking and No testing seeking, as well, cases and controls for future efforts target at ensuring a safe and adequate blood supply.
- QA5 & A6 Month of interview; Year of interview. *Source: Original; new*. This data is used as part of study administration to capture the interviews responses on a calendar date.
- QA7 Research Assistant Initials: *Source: Original; new.* This question will be used to identify the research assistant. A research assistant or nurse will provide the ACASI laptop (including earphones to be able to listen to the questions confidentially) to each subject at the blood center. The research assistant or nurse will remain available to respond to questions and to provide assistance to the study subject, if necessary. This information is important for follow up interviewer quality control.
- QA8a & A8b Place of Interview: Blood Center; Study Subject's Home; Study Subject's Work; Other; Please, specify other place of interview. *Source: Original; new*. This question will be used to identify the place where the interview took place. We assume that most of interview will be conducted at the blood bank, but we will offer other possible locations to ensure enrollment of as many subjects as we can. It is not intended that data will be analyzed according to location of interview, but this data will be collected in case a problem is identified with any type of interview location.

- QA9 Study subject is able to read. *Source: Original; new*. This question determines whether a study subject will be able to read the questions themselves or will have to rely on the audio recordings to understand what is being asked.
- QA10 What level of education do you have? *Source: Original; new.* This question will classify the blood donor's educational level. The response will be correlated to their answers about attitudes, knowledge, exposures/unsafe behaviors to HIV transmission routes. In Brazil, subjects may be able to read but do not have any formal schooling, this is called adult alphabetizing. In the last decade the HIV epidemic has been disseminating throughout the population, with an increasing impact on women and the poor throughout the country.
- QA11 What is your occupation? *Source: Original; new.* This question will classify the blood donors by occupation. General occupation groups may also be predictive of HIV infection with unskilled labor positions more likely to have lower educational attainment therefore a higher risk of HIV infection. Occupations will be grouped into the categories specified by the Brazil Census.
- QA12 Type of interview. *Source: Original; new.* The HIV case control questionnaire was design to be done in a self-administered audio computer-assisted self-interview (ACASI) format on a laptop computer in order to maximize reporting of stigmatized behaviors. However, the instrument can be used either with an audio or without an audio portion when subjects are able to read and specifically prefer to not to hear the audio portion. The questionnaire can also be administered via a traditional paper method in case of technical failure of the computer equipment. We need to keep track of the type of interview in case responses are different based on the method of administration.

## Section B – Demographic Data

- QB1 What is your gender? *Source: Original; new.* This question will classify the blood donor according gender. In many cites in Brazil, the HIV trends among the general population have been shifted from homosexual men to heterosexuals. At other hand the blood donation in Brazil used to be exclusively from men but has shifted and dropped from 80% to 60% in the past ten years. Response to this question will provide more information about blood gender trends for HIV infection in blood donors in Brazil.
- QB2, B3, B4 What is your birth year? *Source: Original; new*. This question will classify the blood donor according to age. In the past 20 years Brazilian government has take many procedures to stop HIV spread, as such providing educational material, implementing condoms use, and universal HAART treatment to HIV positives. We expected a lower HIV prevalence and incidence among blood donors age 18 to 30 years, and higher among 31 to 50 years.
- QB5a What is your country of birth? B5b If not Brazil, Please specify your country of birth. *Source: Original; new.* This question is designed to assess the subject country of birth. Response to this question will provide more accurate information and may be related to risk of HIV infection.

- QB6 What is your ethnicity? *Source: Original; new*. This question is designed to assess the subject's self-reported ethnicity. Response to this question will provide more accurate information related to HIV risk in different ethnic groups in Brazil.
- QB7 What is your current marital status? *Source: Original; new.* This question is designed to establish the blood donors' marital status. Response to this question will provide information about the role of current marital status regarding HIV transmission routes.
- QB8 If you are married or living with someone, is your spouse/cohabitating partner male or female? *Source: Original; new.* This question is designed to establish if donor has an opposite sex or same sex partner without specifically asking about sexual orientation.

## Section C - Previous Donation and HIV testing

- QC1 Have you ever donated blood at another blood center? *Source: Original; new.* This question establishes the blood donor commitment to one or more blood centers. Brazil doesn't have a national ineligible donor registry. A high risk person might donate blood in many blood banks. Response to this question will be important especially for the HIV cases. If HIV donors are morel likely to donate a multiple locations this data could serve to help build a justification for a national ineligible donor registry.
- QC2 How many times have you donated blood at another blood center? *Source: Original; new*. Related to the question above, this question is designed to ascertain whether the donation frequency is or not related to HIV positivity.
- QC3 At the time of your last donation, do you remember being given information about who should not donate blood? *Source: Original; new*. This question asks donors about any information they might have received regarding reasons for exclusion before their blood donation. Response to this question will guide future tools related to increase blood donor awareness in order to avoid at risk donors.

QC4, C5a, C5b, C6a, C7

C4. Other than blood donation, have you ever been tested for HIV? C5a.What was the reason for the HIV test? C5b. Please specify the other reason for test, C6a. Other than a blood center, where else have you been tested for HIV? C6b. Please specify the other test site. C7. Excluding HIV testing conducted as part of blood donation, how many times have you been tested for HIV? *Source: Original; new.* These questions are designed to ascertain other reasons and frequency for being tested for HIV other than blood donation. In Brazil the HIV test results may take longer when are performed by STD counseling centers compared to blood centers, at other hand in some private laboratories setting, the HIV test is very expensive. Test-seekers usually come to the blood bank in order to get their HIV test results because it is easier, faster, and anonymous than to get it from a STD counseling center.

## Section D - Incentives and Motivations for Donating

QD1, D2, D3, D4

## ATTACHMENT 3.2

D1. Have you helped carry a stranger's belongings? D2. Do you allow someone who is elderly or disabled to go ahead of you in a line? D3. Have you offered to help a handicap or elderly person across a street? D4. Do you give money to charity? *Source: Original; new.* These questions are designed to ascertain altruistic attitudes. In a previous pilot study conducted in Brazil, we found out that altruism scored just as high among test-seekers as no test-seekers, indicating that helping behavior may be driven by egoistic or selfish concerns. Response to these questions will be used to define a general altruism score for general level of altruism. The results will be correlated to the motivations factors listed below and will provide better understanding about intrinsic versus extrinsic factors that leads at risk persons to donate blood.

### QD5a – D5p

D5a. To anonymously help someone else who needs blood. D5b. To help a friend or relative who is sick or needs blood. D5c. In response to a campaign on TV or radio. D5d. I received a telephone call or letter from the blood bank asking me to donate. D5e. I think that it is important to give blood. D5f. I wanted to get test results for my blood. D5g. My blood type is in high demand. D5h. I think that I am doing something important for society. D5i. I may need blood myself someday. D5j. I heard that blood donation is good for my health. D5k. I like to know about my health and blood donation is a good way to find out. D5l. Someone offered me money for donating. D5m. Blood banks always need blood and so donating is the right thing to do. D5n. Is there another reason that best explains why you came to donate? D5p. What is the reason that best explains why you came to donate? Source: Original; new. These questions are designed to ascertain 3 major motivator factors: altruistic, self-interest and direct appeal by asking the donor to indicate how much the factor contributed to a donor's decision to donate on a 4 point scale for each question.

- QD6 Some people feel they must donate blood because family, friends, co-workers or other persons in an organization they know donate blood or encourage others to donate. Did this happen to you when you last donated blood? *Source: Original; new*. This question is designed to identify social influences that may have contributed or encouraged the participant to donate blood. Peer or social pressure may contribute to HIV+ persons attempting to donate.
- QD7 Do you believe that the blood center uses better HIV tests than are available at other places? *Source: Original; new.* This question is designed to evaluate the blood donor confidence at the HIV test performed by the blood center.
- QD8 Did you donate blood because you wanted to be tested for HIV? *Source: Original; new.* This question will assess the magnet effect among blood donors. In some Brazilian blood centers this question is a reason for a clinical deferral. In reality, as many blood donors have already known this deferral criterion, many of them may deny this question during the clinical screening in order to donate blood to get their test results. Response to this question will guide future marketing strategies at general population to reduce this magnet effect.

### QD9a, D9b

D9a. Please check all the boxes for the factors that contributed to your decision to come to the blood center to be tested for HIV. D9b. Please specify other reason. *Source: Original; new*. This question is designed to assess which are the factors that lead the magnet effect to the blood donors.

QD10 Did you donate blood because you wanted to be tested for hepatitis? This question will assess the magnet effect among blood donors. In some Brazilian blood centers this question is a reason for a clinical deferral. In reality, as many blood donors have already known this deferral criterion, many of them may deny this question during the clinical screening in order to donate blood to get their test results. Response to this question will guide future marketing strategies at general population to reduce this magnet effect.

### QD11a, D11b, D12a, D12b

D11a. Please check all the boxes for the factors that contributed to your decision to come to the blood center to be tested for hepatitis. D11b. Please specify other reason. D12a. Did you come to the blood center to be tested for some other reason? D12b. Please specify other reason. *Source: Original; new*. These questions have been formulated to determine other magnet effects besides HIV testing. What are the roles, relevance and prevalence of test seeking for other infections?

### QD13, D14

D13. Did a health worker such as a doctor, nurse, or someone from a health department suggest that you go to the blood center for a blood test for HIV, hepatitis, or for some other reason? D14. Please tell us who suggested you to come to the blood center *Source: Original; new*. This question is designed to identify whether the health workers may have contributed or encouraged the participants to donate blood in order to get their test results. It has been already describe that in some Brazilian settings, the health staff may encourage persons to donate blood to get the test-results. The response to these questions will provide more accurate information which will help us to build special approaches towards health workers in Brazil in order to avoid this potentially risky approach to testing.

#### **Section E-Sexual History**

#### QD15, D16, D17

D15. You can donate blood if you have engaged in risk behaviors for HIV or AIDS because the blood center tests all blood and throws away any infected blood.

D16. You can donate blood even if you engage in risk behaviors for HIV or AIDS as long as you have a negative HIV test.

D17. The blood test for HIV identifies everyone who is infected with the virus.

*Source: Original; new.* These questions are designed to ascertain donor's attitudes and knowledge about risk behavior, AIDS, the HIV window period (the time between infection and the ability of our current tests to correctly identify HIV infection). In a previous pilot study we found out that Brazilian blood donors have a low HIV knowledge and it is even lower among test-seekers. Responses to these questions will be correlated to case and control status in the study and in secondary analyses to other indicators such as first-time, lapsed, repeated donor status, volunteer *versus* replacement, testing seeking *versus* not testing seeking.

QE1 What do you consider yourself to be? *Source: Original; new.* This question is designed to ascertain the subject's self perception of his or her sexuality. In Brazil, as in some Latino American cultures, men do not consider themselves as homosexual, as long as, they only have oral or insertive anal sex with other men. This question will permit us to analyze whether riskier sexual activities are related to a subject's self perception of their sexual orientation. Responses to

these questions will be correlated to case and control status in the study and in secondary analyses to other indicators such as first-time, lapsed, repeated donor status, volunteer *versus* replacement, testing seeking *versus* not testing seeking.

- QE2 (Ask of Men Only) How many different women have you had sex with since you first began having sex? *Source: Original; new.* This question is designed to assess the estimated number of life-time female partners for each male donor, regardless of his self-reported sexual orientation. A high number of partners could be a marker for a person being at higher risk for HIV infection.
- QE2 (Ask of Women Only) How many different men have you had sex with since you first began having sex? *Source: Original; new.* This question is designed to assess the estimated number of life-time male partners for each female donor, regardless of her self-reported sexual orientation. A high number of partners could be a marker for a person being at higher risk for HIV infection.
- QE3 (Ask of Men Only) How many different men have you had sex with since you first began having sex? *Source: Original; new*. This question is designed to assess the estimated number of life-time male partners for each male donor, regardless of his self-reported sexual orientation. A high number of partners could be a marker for a person being at higher risk for HIV infection.

## Section F - Sexual Partners Risks

- QF1a To the best of your knowledge, have you <u>ever</u> had sex with anyone who was an intravenous drug user? *Source: Original; new.* This question is designed to ascertain the blood donor's risk based on having sex with an IDU partner at any time in his or her life. We will correlate this response to HIV infection status based on the results of the HIV testing of the blood donation. For example, a "yes" answer to this question could be route of infection acquisition for a donor who tests HIV positive. Recent risk activity could be reflected in the combination of HIV markers that are positive thus indicating recent HIV acquisition.
- QF1b In the year before your last donation, have you had sex with anyone who was an intravenous drug user? *Source: Original; new.* This question is designed to ascertain the blood donor's risk based on having sex with an IDU in the year before donating, which will reflect a relatively recent risk. We will correlate this response to HIV infection status based on the results of the HIV testing of the blood donation. For example, a "yes" answer to this question could be the route of infection acquisition for a donor who tests HIV positive. Recent risk activity could be reflected in the combination of HIV markers that are positive thus indicating recent HIV acquisition. Responses to this question will be useful for establishing parameters for future deferral criterion.
- QF2a To the best of your knowledge, have you <u>ever</u> had sex with anyone who tested positive for HIV? *Source: Original; new.* This question is designed to ascertain the blood donor's risk based on having sex with an HIV positive partner at any time in his or her life. We will correlate this response to HIV infection status based on the results of the HIV testing of the blood donation. For example, a "yes" answer to this question could be route of infection acquisition for a donor who tests HIV positive. Again, recent exposure would be consider more important and perhaps reflect a failure of the donor health history process, as a donor who responds "yes" to this question likely should have been deferred.
- QF2b In the year before your last donation, have you had sex with anyone who tested positive for HIV? *Source: Original; new.* This question is designed to ascertain the blood donor's risk based on

having sex with an HIV positive partner in the year before donating, which will reflect a relatively recent risk. We will correlate this response to HIV infection status based on the results of the HIV testing of the blood donation. For example, a "yes" answer to this question could be the route of infection acquisition a donor who tests HIV positive. Again, recent exposure would be consider more important and perhaps reflect a failure of the donor health history process, as a donor who responds "yes" to this question likely should have been deferred. Recent risk activity could be reflected in the combination of HIV markers that are positive thus indicating recent HIV acquisition. Responses to this question will be useful for establishing parameters for future deferral criterion.

- QF3a To the best of your knowledge, if your partner tested positive for HIV, was he/she taking HIV medications? *Source: Original; new.* This question is designed to assess the blood donor's risk for having sex with HIV positive who is taking HAART. As part of the study, we also intend to ascertain the HIV drug resistance for those who will be classified as cases. Since HAART has been a universal treatment for HIV positive persons in Brazil, depending on the behaviors of these individuals, transmission of drug resistant strains may occur with increased frequency. The transmission of resistant HIV variants to uninfected individuals raises serious clinical and public health consequences and may dramatically impair the capacity of treating HIV the future.
- QF3b In the year before your last donation, if your partner tested positive for HIV, was he/she taking HIV medications? This question is designed to assess the blood donor's risk for having sex with HIV positive who is taking HAART. As part of the study, we also intend to ascertain the HIV drug resistance for those who will be classified as cases. Since HAART has been a universal treatment for HIV positive persons in Brazil, depending on the behaviors of these individuals, transmission of drug resistant strains may occur with increased frequency. The transmission of resistant HIV variants to uninfected individuals raises serious clinical and public health consequences and may dramatically impair the capacity of treating HIV the future. Recent sexual exposure in blood donors is critical question to ask. Again, recent exposure would be consider more important and perhaps reflect a failure of the donor health history process, as a donor who responds "yes" to this question likely should have been deferred. Recent risk activity could be reflected in the combination of HIV markers that are positive thus indicating recent HIV acquisition.
- QF4a To the best of your knowledge, have you <u>ever</u> had sex with a man who has had sex with another man? *Source: Original; new.* This question is designed to rule-in or rule-out HIV acquisition via sexual contacts with homosexual or bisexual men. Bisexual men may be the more likely to engage in unprotected sex with women and so this is a potentially important route of infection for women.
- QF4b In the year before your last donation, have you had sex with a man who has had sex with another man? *Source: Original; new.* This question is designed to rule-in or rule-out HIV acquisition via sexual contacts with homosexual or bisexual men. Bisexual men may be the more likely to engage in unprotected sex with women and so this is a potentially important route of infection for women with recent exposure (within the last year) of particular interest. Recent risk activity could be reflected in the combination of HIV markers that are positive thus indicating recent HIV acquisition.
- QF5a To the best of your knowledge, have you <u>ever</u> had sex with anyone who received a blood transfusion? *Source: Original; new.* This question is designed to ascertain whether having sex with transfused person could be the route of HIV acquisition. In Brazil blood transfusion used to

be an important route of HIV transmission. Universal screening of blood donors for HIV antibody was instituted in Brazil in 1988. This would be the attributed route of infection if no other risk factor is reported by the HIV positive donors.

- QF5b In the year before your last donation, have you had sex with anyone who received blood transfusion? *Source: Original; new.* This question is designed to ascertain whether having sex with transfused person could be the route of HIV acquisition. In Brazil blood transfusion used to be an important route of HIV transmission. Universal screening of blood donors for HIV antibody was instituted in Brazil in 1988. This would be the attributed route of infection if no other risk factor is reported by the HIV positive donors. Again, recent exposure would be consider more important and perhaps reflect a failure of the donor health history process, as a donor who responds "yes" to this question likely should have been deferred. Recent risk activity could be reflected in the combination of HIV markers that are positive thus indicating recent HIV acquisition.
- QF6a To the best of your knowledge, have you <u>ever</u> had sex with anyone who was a hemophiliac? *Source: Original; new.* This question is designed to evaluate the HIV transmission routes related to sexual activity in persons who have had sex with a hemophiliac. This is expected to be a rare route of infection acquisition and would be attributed as the route of acquisition only if no other risk factor was reported.
- QF6b In the year before your last donation, have you had sex with anyone who was a hemophiliac? *Source: Original; new.* This question is designed to evaluate the HIV transmission routes related to sexual activity in persons who have had sex with a hemophiliac. This is expected to be a rare route of infection acquisition and would be attributed as the route of acquisition only if no other risk factor was reported. Recent risk activity could be reflected in the combination of HIV markers that are positive thus indicating recent HIV acquisition.
- QF7a To the best of your knowledge, have you <u>ever</u> had sex with anyone who has spent three or more nights in jail, prison, or a detention center? *Source: Original; new.* This question is designed to evaluate the risk taken for having sex with person who has been in prison because prison is as recognized word-wide as a site for transmission of blood-borne viruses (BBVs).
- QF7b In the year before your last donation, have you had sex with anyone who has spent three or more nights in jail, prison, or a detention center? *Source: Original; new.* This question is designed to evaluate the risk taken for having sex with person who has been in prison because prison is as recognized word-wide as a site for transmission of blood-borne viruses (BBVs). Recent risk activity could be reflected in the combination of HIV markers that are positive thus indicating recent HIV acquisition.
- QF8a To the best of your knowledge, have you <u>ever</u> had sex with anyone who had a job that involved exposure to blood or other body fluids? *Source: Original; new.* This question is designed to evaluate the risk taken for having sex with person who has been exposed to blood or other body fluids. It has been shown that transmission of HIV, hepatitis B or C can occurs due to needle stick injury and, body fluids splash.
- QF8b In the year before your last donation, have you had sex with anyone who had a job that involved exposure to blood or other body fluids? *Source: Original; new.* This question is designed to evaluate the risk taken for having sex with person who has been exposed to blood or other body fluids. It has been shown that transmission of HIV, hepatitis B or C can occurs due to needle stick

injury and, body fluids splash. Recent risk activity could be reflected in the combination of HIV markers that are positive thus indicating recent HIV acquisition.

#### **Section G - Social Matrix**

The following questions are listed in the manner shown because where indicated each question is the same except for being directed toward a specific recent sexual partner. The results obtained will be used to describe the social circle the HIV cases and controls travel in, respectively. The questions will be used to establish an index of risk based on both the number of partners, where the partners were met, and most importantly the types of sexual activities each blood donor has engaged in. Unprotected vaginal and anal sex represent high risk behaviors. For example a donor who reports having 5 partners in the last year and engaging in unprotected sex with all of them would be classified as having the highest risk index. Stratification into heterosexual and homosexual sex may also be important to assess if the routes of current routes of HIV acquisition have changed in Brazil. When all of this data is analyzed together it may suggest modifications to current deferral approaches and questions.

QG1 How many people did you have sex with in the 12 months before your blood donation? *Source: Original; new.* The odds of acquiring HIV or other sexually transmitted disease is correlated with the number of sexual partners. This question will ascertain the number of sexual partners that the subjects may have had in the 12 months before their last blood donation. In Brazil having 6 or more sexual partners in the last year before the blood donation is a clinical deferral criterion, but few data have been collected to demonstrate the value of this criterion. Response to this question will help us to establish whether donors accurately stated the number of partners in the last 12 months during the health history examination. This question also serves as prompt within the computer program for the number of additional questions the donor receives in section G of the interview.

QG2, G19, G36, G53, G70.

What is Partner 1, 2, 3, 4 and 5's gender? *Source: Original; new.* This question is designed to ascertain the gender of subject's recent sexual partner(s). This question will be used to determine if this partner represented a heterosexual or homosexual contact when analyzed together with study subject's own gender.

QG3, G20, G37, G54, G71.

How old is partner 1, 2, 3, 4 and 5s? *Source: Original; new.* This question is designed to ascertain the age of the subject's recent sexual partner(s). It is important to evaluate the HIV trends by age, as generally people tend to have sexual encounters with people near themselves in age. What is the role of age in HIV transmission among heterosexuals and homosexuals? This question will help the study to assess whether younger subjects engaged in more at risk behaviors than older subjects or *vice versa*, or if subjects with much younger/older partners have higher risk profiles.

QG4, G21, G38, G55, G72.

What type of partner is partner 1, 2, 3, 4 and 5? *Source: Original; new.* This question is designed to assess the subject's relation network. It is already known that some sexual relationships are riskier than others, with more casual or anonymous sexual experiences related to increased STD risk. Response to this question will be correlated to all the remaining questions in section G. These correlations will help us to build a risk matrix to indicate which would be the less and the more risky blood donor profile.

### QG5, G22, G39, G56, G73.

How would you describe partner 1, 2, 3, 4 and 5's race or ethnicity? *Source: Original; new.* This question is designed to assess the subject's sexual partner's ethnicity. Response to this question will provide more accurate information related to HIV within ethnicity network. It is already known that ethnicity network plays a relevant role in the HIV transmission routes. For instance, in Rio de Janeiro and Recife, the ethnicity network is much more mixed than that of Sao Paulo and Belo Horizonte.

QG6, G23, G40, G57, G74.

Is partner 1, 2, 3, 4 and 5 an injection drug user? This question is designed to assess the subject's knowledge of risks other than the risk for sexual transmission of HIV transmission by his/her partner. Response to this question will be correlated to questions related to unsafe sex and other risk factors.

QG7, G24, G41, G58, G75.

Is partner 1, 2, 3, 4 and 5 a male who has had sex with other males? *Source: Original; new.* This question is designed to assess the subject's homosexual network. Since Brazilian policies have allowed blood donation among MSM, responses to this question will provide important information related to HIV transmission among homosexuals, bisexuals, heterosexuals and to those who do not consider themselves as homosexual based on having only insertive anal sex with other men.

QG8, G25, G42, G59, G76.

What is partner 1, 2, 3, 4 and 5's HIV status? *Source: Original; new.* This question is designed to assess the subject's knowledge of risk taken according serological HIV status of his/her sexual partner. This question will be analyzed with the questions on whether the subject had unprotected sex with this partner. If the HIV status is known positive and the sex was unprotected this represents one of the highest risk categories in the proposed risk matrix. How frequently this occurs in Brazilian blood donors has not previously been measured. Responses to this question will be correlated to questions related to unsafe sex and other risk factors.

QG9, G26, G43, G60, G77. & G10, G27, G44, G61, G78

Where did you first meet partner 1, 2, 3, 4 and 5? - Specify where you met partner 1, 2, 3, 4 and 5? *Source: Original; new.* These questions are designed to assess how the subject meets each of his or her recent sexual partners and whether this is associated with the risk of HIV. These questions are also designed to evaluate whether the environment and social network may have influence at risk sexual behavior activity. Responses to these questions will provide useful information's to build a risk matrix that may indicate which would be the less and the more risky blood donor profile.

QG11, G28, G45, G62, and G79.

Number of times you had vaginal intercourse with partner 1, 2, 3, 4 and 5 in past 12 months. *Source: Original; new.* This question is designed to assess the frequency of vaginal intercourse and correlate it to specific serologic markers. It is possible that HIV acquisition may be inversely

correlated to the amount of sexual activity. Responses to this question will also be analyzed with responses to questions on other sexual behaviors.

QG12, G29, G46, G63, G 80.

When you had vaginal sex, how frequently did you use condoms? *Source: Original; new.* This question is designed to assess the frequency of unprotected sexual behaviors and correlate it to specific serologic markers. Responses to this question will also be analyzed with responses to questions on other sexual behaviors.

QG13, G30, G47, G64, G81. Number of times you had anal intercourse with partner 1 in past 12 months *Source: Original; new*. This question is designed to assess the frequency of anal sex and correlated it to specific serologic markers. It is important to highlight that in Brazil, MSM can only donate blood if the last sexual contact was before the 12 months before the blood donation. This rule is not applied to heterosexuals. This question is designed to assess the frequency of anal intercourse and correlate it to specific serologic markers regardless of sexuality. Responses to this question will also be analyzed with responses to questions on other sexual behaviors.

QG14, G31, G48, G65, G82.

When you had anal sex, how frequently did you use condoms? *Source: Original; new.* This question is designed to assess the frequency of unprotected anal sex and correlate it to specific serologic markers. Responses to this question will also be analyzed with responses to questions on other sexual behaviors.

QG15, G32, G49, G66, G83.

Number of times you had insertive anal intercourse with partner 1 in past 12 months. *Source: Original; new.* This question is designed to assess the frequency of insertive anal sex and correlate it to specific serologic markers. Responses to this question will also be analyzed with responses to questions on other sexual behaviors.

QG16, G33, G50, G67, G84.

When you had insertive anal sex, how frequently did you use condoms? *Source: Original; new.* This question is designed to assess the frequency of unprotected insertive anal sex and correlated it to specific serologic markers. Responses to this question will also be analyzed with responses to questions on other sexual behaviors.

QG17, G34, G51, G68, G85.

Number of times you had receptive anal intercourse with partner 1 in past 12 months. *Source: Original; new.* This question is designed to assess the frequency of receptive anal sex. Receptive anal intercourse has long been recognized as major risk factor for HIV transmission. Responses to this question will also be analyzed with responses to questions on other sexual behaviors.

#### QG18, G35, G52, G69, G86.

When you had receptive anal sex, how frequently did you use condoms? *Source: Original; new.* This question is designed to assess the frequency of unprotected receptive anal sex. Response to these questions will help us to build a risk matrix and provide guidance regarding HIV

transmission risk reduction and education strategies to ensure safer blood donation. Responses to this question will also be analyzed with responses to questions on other sexual behaviors.

#### Section H - Alcohol and Drug Use

- QH1 How often do you drink beer, wine, liquor, or mixed drinks? *Source: Original; new.* This question will help us to identify the frequency of alcohol usage because it may be related to unsafe behaviors leading to HIV transmission. Responses to this question will be combined with QH2 to estimate an alcohol consumption index and will be analyzed with responses to questions on sexual behaviors.
- QH2 On average how many drinks do you have each time you drink? Number of drinks *Source: Original; new.* This question will help us to identify the frequency of alcohol usage because it may be related to unsafe behaviors leading to HIV transmission. Responses to this question will be combined with QH1 to estimate an alcohol consumption index and will be analyzed with responses to questions on sexual behaviors.
- QH3 Have you ever used any non-injected illegal drugs (drugs that are smoked, snorted or taken orally), examples include marijuana (also known as pot) hashish, cocaine (also known as blow or crack), methamphetamines (also know as crystal), ecstasy (also known as "e"), mushrooms, and LSD? *Source: Original; new.* Any non-injected illegal drug use has long been recognized as a risk factor for the transmission of HIV and other STDs because of the mood altering properties and risk taking. For instance, there is a significant joint relative hazard for using methamphetamine or crack and HIV infection due to unsafe behaviors. Response to this question will allow for the assessment of an association between drug use and unprotected sex, and may indicate the importance of tailoring risk reduction efforts to address certain drugs and sexual behaviors among blood donors.

#### QH4 & H5

H4. When was the <u>first year</u> you used non-injected illegal drugs? H5. When was the <u>last year</u> you used non-injected illegal drugs? *Source: Original; new.* These questions will help us to evaluate whether the years of usage of non-injected illegal drugs may be correlated to HIV infection in blood donors, and also the how recent the drug use was relative to the blood donation.

- QH6 If you have smoked or snorted illegal drugs, did you share pipes or straws with another person? *Source: Original; new.* HIV virus and hepatitis C virus share the same routes of transmission, and the habit of sharing pipes or straws may be associated with co-infection. This question will evaluate this HIV transmission route among blood donors.
- QH7 Have you ever used or shot up injection drugs (examples include heroin, cocaine, and amphetamines)? *Source: Original; new.* This question will capture the blood donors risk exposure for a known very high risk behavior as well for potential risk behaviors while under influence of injected illegal drugs that are also associated with HIV infection.
- QH8 When was the <u>first year</u> you used injected drugs? H9.When was the <u>last year</u> you used injected drugs? *Source: Original; new.* These questions will help us to evaluate whether the years of usage of injected illegal drugs may be correlated to HIV infection in blood donors, and also the how recent the drug use was relative to the blood donation.

- QH10 Have you ever injected any non-prescription substances including vitamins, anabolic steroids, or hormones? *Source: Original; new.* This question is designed to ascertain the usage of other injected substances that could lead to HIV transmission through the injection process. If these activities are reported by HIV positive donors, the results will be used to expand donor questioning and risk reduction efforts.
- QH11 Have you ever shared needles or syringes with another person to inject any non-prescriptions substance including vitamins, anabolic steroids, and hormones? *Source: Original; new.* This question is designed to ascertain whether needle-sharing occurred during the use of other injected substances, which is a likely route of HIV transmission through the injection process. If these activities are reported by HIV positive donors, the results will be used to expand donor questioning and risk reduction efforts.

### **Section I - Medical History**

Many of the risk factors listed in this section are relatively rare routes of HIV acquisition. However these question link to other proposed studies in REDS II Brazil project. Obtaining responses to these questions in both HIV positive and HIV negative donors will be valuable for interpreting the results of a deferred donor study that will commence once this HIV case control study is completed.

- QI1 Have you ever had a blood transfusion? *Source: Original; new.* This question is designed to ascertain HIV transmission routes related to medical procedures. In Brazil blood transfusion used to be an important route of HIV transmission. Universal screening of blood donors for HIV antibody was instituted in Brazil in 1988 but although technically recommended by the Brazilian Government, HIV nucleic acid testing (NAT) have delayed its implementation. Responses to this question will provide important information on whether HIV is still transmitted via this pathway. We may interpret the route of HIV infection acquisition to be transfusion if donors do not report sexual or drug- related exposures.
- QI2 How many transfusion episodes have you had? *Source: Original; new.* This question will measure the number exposure of blood transfusion, which historically was a marker for the risk of acquiring HIV.

## QI3 & I4

I3. When was the <u>first year</u> you received a transfusion? I4. When was the <u>last year</u> you received a transfusion? *Source: Original; new.* These questions will help us to evaluate whether the years of transfusion may be correlated to HIV infection in blood donors, and also the how recent the transfusion was relative to the blood donation.

- QI5 Have you ever had minor or major medical surgery, tooth extraction or another dental procedure? *Source: Original; new.* This question is designed to ascertain uncommon but possible HIV transmission routes related to medical procedures. Transmission of blood borne viruses, notably hepatitis B virus and HIV may occur during these medical procedures. Responses will aid blood banks in formulating future policies regarding medical procedures.
- QI6 In the year before your last blood donation, have you had minor or major medical surgery, tooth extraction, or another dental procedure? *Source: Original; new.* This question is designed to ascertain uncommon but possible HIV transmission routes related to medical procedures in the year before the blood donation. Transmission of blood borne viruses, notably hepatitis B virus and HIV may occur during these medical procedures. Responses will aid blood banks in formulating future policies regarding medical procedures.
- QI7 Have you ever had endoscopy (a medical test where a flexible tube is used to look inside of your throat and digestive system) or colonoscopy (a medical test where tube is used to look inside your colon/large intestine)? *Source: Original; new Source: Original; new* The risk of blood-borne virus transmission because of inadequately cleaned medical instruments is not well-known in Brazil. Recently, these procedures were removed from being reasons for donor deferral in Brazil. Responses will aid blood banks in formulating future policies regarding medical procedures.
- QI8 In the year before your last blood donation, have you had endoscopy or colonoscopy? *Source: Original; new* The risk of blood-borne virus transmission because of inadequately cleaned medical instruments is not well-known in Brazil. Recently, these procedures were removed from being reasons for donor deferral in Brazil and so it is particularly important to inquire about recent endoscopy or colonoscopy procedures. Responses will aid blood banks in formulating future policies regarding medical procedures.

## **Section J- Other Potential Risk Factors**

The risk factors listed in this section are relatively rare routes of HIV acquisition. However these question link to other proposed studies in REDS II Brazil project. Obtaining responses to these questions in both HIV positive and HIV negative donors will be valuable for interpreting the results of a deferred donor study that will commence once this HIV case control study is completed.

- QJ1 Have you spent three or more nights in jail, prison, or a detention center? *Source: Original; new.* Prisons are recognized worldwide as important sites for transmission of blood-borne viruses (BBVs). This question is designed to evaluate the risk of HIV acquisition from someone who has been in prison because prison is as recognized word-wide as a site for transmission of bloodborne viruses (BBVs).
- QJ2 Have you had acupuncture treatments? *Source: Original; new.* The risk of HIV acquisition from acupuncture is low, but there have been case reports of transmission of HIV and hepatitis from reused, unclean acupuncture needles. Responses will aid blood banks in formulating future policies regarding medical procedures.
- QJ3 How many times have you had acupuncture treatments? *Source: Original; new.* This question is designed to evaluate whether the number of applied acupuncture treatments can be correlated to a

higher risk in blood donors. Responses will aid blood banks in formulating future policies regarding medical procedures.

- QJ4 In the year before your last blood donation, have you had acupuncture treatments? *Source: Original; new.* This question is designed to evaluate whether the number of acupuncture treatments in the last 12 months can be correlated to a higher in blood donors. An incident HIV infection could be attributed to these behaviors, so we will specifically inquire about recent behaviors. Responses will aid blood banks in formulating future policies regarding medical procedures.
- QJ5 How many tattoos do you have on your body *Source: Original; new.* This question is designed to evaluate whether the number of applied tattoos can be correlated to a higher risk in blood donors. Responses will aid blood banks in formulating future policies regarding elective procedures.
- QJ6 In the year before your last blood donation, have you had a new tattoo or had one re-applied? *Source: Original; new.* This question is designed to evaluate whether the number of applied tattoos in the before blood donation can be correlated to a higher risk in blood donors. An incident HIV infection could be attributed to these behaviors, so we will specifically inquire about recent behaviors. Responses will aid blood banks in formulating future policies regarding elective procedures.
- QJ7 Where did you get your most recent tattoo? *Source: Original; new* Very little is known about the association between different categories of tattoo parlors or locations and the risk of viral infection. We predict that non-professionally applied tattoos will confer a higher risk of infection acquisition. Responses will aid blood banks in formulating future policies regarding elective procedures.
- QJ8 How many ear or body piercings do you have? *Source: Original; new.* Body piercing of any kind is a practice that is not free of infection risk and could be the route of HIV acquisition. Responses will aid blood banks in formulating future policies regarding elective procedures.
- QJ9 In the year before your last blood donation, have you had new ear or body piercings? *Source: Original; new.* Body piercing of any kind is a practice that is not free of infection risk and could be the route of HIV acquisition. An incident HIV infection could be attributed to these behaviors, so we will specifically inquire about recent behaviors. Recent piercing will be of more interest in terms of the risk of HIV and responses will aid blood banks in formulating future policies regarding elective procedures.
- QJ10 Where did you get your most recent piercing? *Source: Original; new.* Very little is known about the association between different locations for piercing and the risk of viral infection. We predict that non-professionally performed piercings will confer a higher risk of infection acquisition. Responses will aid blood banks in formulating future policies regarding elective procedures.
- QJ11 Have you ever had a manicure or pedicure at a beauty salon or had a shave at a barbershop? *Source: Original; new* As a rare route of infection acquisition because of the use of poorly cleaned tools, these common practices could lead to HIV acquisition. The prevalence of these behaviors in our blood donors will be assessed and then risk of HIV acquisition based on these activities will be determined when a donor does not report any sexual or drug-related risk behaviors.

- QJ12 How many times have you had manicures or pedicures or shaves at a barbershop? *Source: Original; new* As a rare route of infection acquisition because of the use of poorly cleaned tools, these common practices could lead to HIV acquisition. The frequency of these activities in our blood donors will be assessed and then risk of HIV acquisition based on these activities will be determined when a donor does not report any sexual or drug-related risk behaviors.
- QJ13 In the year before your last blood donation, have you had a manicure or pedicure or had a shave at a barber shop? *Source: Original; new* As a rare route of infection acquisition because of the use of poorly cleaned tools, these common practices could lead to HIV acquisition. An incident HIV infection could be attributed to these behaviors, so we will specifically inquire about recent behaviors. The prevalence of these behaviors in our blood donors will be assessed and then risk of HIV acquisition based on these activities will be determined when a donor does not report any sexual or drug-related risk behaviors.
- QJ14 How many people do you personally know who currently have AIDS or have died of AIDS? *Source: Original; new* This question assesses both the potential for the extremely unlikely inadvertent transmission and also the familiarity a person may have with AIDS. The more familiar a person who is HIV negative is about AIDS through knowing someone with AIDS, the more precautions the person may take in terms of risk behaviors.
- QJ15 How many people do you personally know who do NOT have AIDS, but have tested positive for HIV, the virus that causes AIDS? *Source: Original; new* This question assesses both the potential for the extremely unlikely inadvertent transmission and also the familiarity a person may have with HIV infection. The more familiar a person who is HIV negative is about HIV through knowing someone with HIV infection, the more precautions the person may take in terms of risk behaviors.

#### **Section K - Work Place Exposures**

- QK1 In your profession, do you take care of humans or have exposure to their bodily fluids? *Source: Original; new.* This question is designed to evaluate healthcare and related professions risk for being exposited to blood or other body fluids that may contain HIV infection. It has been shown that transmission of HIV and other viruses can occur through exposure to body fluids in the workplace.
- QK2 In your professional work have you ever had a needle stick injury (accidentally been stuck by a needle or other sharp instrument used for providing medical care to someone else)? *Source: Original; new.* This question is designed to evaluate healthcare and related professions risk for being exposited to HIV infection through needle-stick injuries. It has been shown that transmission of HIV and other viruses can occur through needle-stick injuries in the workplace.
- QK3 In your professional work have you ever got someone else's blood, body fluids, or excrement splashed into your eyes, mouth or in an open skin lesion? *Source: Original; new.* This question is designed to evaluate healthcare and related professions risk for being exposited to blood or other body fluids that may contain HIV infection. It has been shown that transmission of HIV and other viruses can occur through exposure to body fluids through the body's mucous membranes.

### Section L - Exposure and Treatment

The following 5 additional questions will be asked of <u>cases only</u> on topics that are unique for HIV positive individuals and will be asked at the end of the interview.

- QL1. Did you know your HIV status before donating? *Source: Original; new*. This question is designed to ascertain the blood donor HIV status/knowledge before their last blood donation. Response to this question will be correlated to other questions regarding HIV transmission, window period risks, and motivations for donating. Responses will be correlated to test seeking behavior.
- QL2 How do you think you may have become infected with HIV? *Source: Original; new.* This question is designed to ascertain how the blood donor thinks he or she may have become infected with HIV. Response to this question will provide useful information for blood bank policies regarding deferral criteria and questions that could be asked during the health history interview.
- QL3 When do you think you may have been infected with HIV? *Source: Original; new.* This question is designed to ascertain **when** the blood donor may have become HIV infected. Response to this question will provide useful information for blood bank policies regarding incident as opposed to prevalent cases of HIV.
- QL4 Are you currently taking antiretroviral therapy? *Source: Original; new.* This question is designed to evaluate the blood donor's recent HIV treatment history. Response to this question will provide useful information for blood bank policies regarding HIV testing performance and its correlation to low viral load, for instance. In Brazil, ART is a universally available for HIV treatment. This question will be useful for interpreting possible drug resistance patterns in the molecular surveillance component of the study. A donor currently taking ART may have started therapy after testing HIV positive and so we need to distinguish between a yes answer to this question and the one below.
- QL5 Have you taken antiretroviral therapy in the past? *Source: Original; new.* This question is designed to evaluate the blood donor's past HIV treatment history. Response to this question will provide useful information for blood bank policies regarding HIV testing performance and its correlation to low viral load, for instance. In Brazil, ART is a universally available for HIV treatment. This question will be useful for interpreting possible drug resistance patterns in the molecular surveillance component of the study.