

**Attachment 2C - Objectives 1 and 2 ACASI and Objective 3 Clinical Follow-up Clinical Questionnaires
Justification**

**Incident HIV/ Hepatitis B virus infections in South African blood donors:
Behavioral risk factors, genotypes and biological characterization of early infection
OMB Number: 0925-XXXX**

REDS III-INTERNATIONAL

Questions relating to survey objectives

Objective 1 ACASI Questionnaire

The purpose of the audio computer assisted self interview (ACASI) questions is to collect information regarding behavioral risk factors associated with HIV and HBV acquisition among blood donors in South Africa by comparing data reported by HIV, HBV, HCV and syphilis-negative controls with cases having incident HIV and/or HBV infection. The interview data on HIV and HBV risk behaviors among blood donors will be used 1) to understand predominant risk behaviors associated with HIV and HBV positive blood donation in South Africa, for instance unprotected vaginal or anal intercourse, having multiple heterosexual partners, and other behaviors such as tattooing or scarification; and 2) to identify potential modifications to current operational donor screening questionnaires in ways that can decrease risk and improve blood safety.

Content from this survey was originally based on US Centers for Disease Control studies of blood donors and includes expanded interview questions based on two previously OMB-approved blood donor studies; Transfusion-transmitted retrovirus and hepatitis virus rates and risk factors: Improving the safety of the US blood supply through hemovigilance, OMB Control Number: 0925-0630, and The Prevalence and Incidence of HIV Molecular Variants and Their Correlation with Risk Behaviors and HIV Treatment in Brazilian Blood Donors, OMB Control Number 0925-0597.

Section A - Study Data

Objective: Section A will be completed by trained research staff. The following questionnaire items are related to the general profile of respondents (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, as well as for obtaining general demographic information from study subjects.

- Q.A1. Subject ID
- Q.A2. Subject Donor ID
- Q.A8. Study subject is able to read

The following questionnaire items are related to general technical profile of blood bank staff and time and place for the interview.

- Q.A6. Research Assistant Initials
- Q.A3. Blood collection site

- Q.A4. Month of interview
- Q.A5. Year of interview
- Q.A7. Type 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 use of computer key board, mouse, or touch screen for answering questions.

Objective: to obtain demographic data for general risk stratification based on the background of the subjects.

- Q.B1. What is your gender?
- Q.B2. What is your birth year?
- Q.B3. What is your birth month?
- Q.B4. What is your birth day?
- Q.B5a. What is your country of birth?
- Q.B5b. Please specify your country of birth
- Q.B6. What is your race/ ethnic origin?
- QB7. What is the primary language that you speak at home?
- Q.B8. What is your current marital status?
- Qb9. Is your primary sexual partner? (gender of primary partner)
- Q.B9a. If you are married or living with someone, is your spouse/cohabitating partner
- Q.B10. What is the highest level of education you have completed?
- QB11. What is your religion or affiliation?
- QB12a. Do you have medical aid (insurance)?
- QB12b. Do you self-fund access (pay out of pocket) to private hospital?
- Q.B13c. Are you currently working?
- QB13. What type of work are you doing?
- Q13b. If Other, What is your occupation?
- Q.B.14a. In the last 6 months have you spent a total of four weeks or more away from your primary residence (home)?
- Q.B.14b. What was the primary purpose for being away during this period?
- Q.B.15a. How many nights did you sleep at your primary residence (home) in the past six months?
- Q.B.15b. How long has your pattern of sleeping at your primary residence (home) been the same as it has been in the past six months?

Section C - Previous donation and HIV testing

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

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 regarding blood donor eligibility.

- Q.C1. Before your recent donation, have you ever donated blood?
- Q.C2. Before your recent donation, how many times have you donated blood?
- Q.C3. At the time of your donation, were you 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 to ascertain if the donor has actively sought HIV testing before.

- Q.C4. Do you know of places in your community (called HIV Counseling and Testing Centres?) where you can be tested free of charge for HIV?
- Q.C5. Not including HIV testing conducted as part of blood donation, have you ever been tested for HIV?
- Q.C6. Not including HIV testing conducted as part of blood donation, how many times have you been tested for HIV?
- C7a. Not including HIV testing conducted as part of blood donation, what was the primary reason for the most recent HIV test?
- C7b. Please specify the other reason for the HIV test
- C8a. Not including getting an HIV test at a blood center, where else have you been tested for HIV?
- C8b. Please specify the other test site.

Section D - Incentives and Motivations for Donating

Objective: to determine if the donor exhibits altruistic behaviors in their daily life. We want to correlate their daily behavioral answers to assess altruistic reasons for donating blood. It is already known that donors tend to give a socially acceptable response as a reason to donate which may or may not be their only reason for donating. To assess altruism as a potential donor characteristic and motivating factor, it is important to measure the degree to which donors report engaging in different altruistic behaviors.

- Q.D1. Apart from your involvement in blood donation, do you do any volunteer work for any clubs, groups, societies or church in your community?

Objective: to determine motivational factors and their frequency, that lead participants to donate blood. Respondents are asked to respond using *the following scale to indicate how much the factors influenced their decision to donate blood.* 1- Not at all, 2 - Very little, 3 - Somewhat, 4 - Very much

My decision to donate was influenced by...

- Q.D6a. my desire to anonymously help someone else who needs blood.
- Q.D6b. my desire to help a friend or relative who is sick or needs blood.
- Q.D6c. a campaign on TV or radio.
- Q.D6d. a telephone call or text message (SMS) from the blood bank asking me to donate.
- Q.D6e. a belief that it is important to give blood.
- Q.D6f. a desire to get test results for my blood.
- Q.D6g. my belief that my blood type is in high demand.
- Q.D6h. my belief that I am doing something important for society.
- Q.D6i. my belief that I may need blood myself someday.
- Q.D6j. my belief that blood donation is good for my health.
- Q.D6k. my desire to know about my health and blood donation is a good way to find out.
- Q.D6l. someone offering me money for donating.
- Q.D6m. my belief that blood banks always need blood and so donating is the right thing to do.
- Q.D6n. pressure to donate that I received from other people (such as friends, family, colleagues, fellow students, church or temple members).
- Q.D6.O. Is there another reason that best explains why you came to donate?
- Q.D6.P. What is the reason that best explains why you came to donate?

Objective: to determine if the donor was asked to donate, and if the participant was influenced by others.

- Q.D7. 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?

Objective: to determine donor's intention to get HIV testing through blood donation, to ascertain donors intentions, hidden or not at the time donation, to come to the blood center in order to get tested for HIV. Blood bank testing may provide a magnet effect to the participants who do not wish to attend voluntary counseling and testing locations.

- Q.D8. Do you believe that the blood center uses better HIV tests than are available at other places?
- Q.D9. Did you donate blood mainly because you wanted to be tested for HIV?
- Q.D10. What were all the factors that contributed to your decision to come to the blood center to be tested for HIV? Please check all the boxes that apply to your answer. When you have selected all of your answers, please touch the "Next Question" box.
- Q.D10b. Please specify other reason

Objective: to ascertain donors intentions, hidden or not at the time of donation, to come to the blood center in order to get tested for Hepatitis.

- Q.D11. Did you donate blood because you wanted to be tested for hepatitis?
- Q.D12a. Please check all the boxes for the factors that contributed to your decision to come to the blood center to be tested for hepatitis.
- Q.D12b. Please specify other reason

Objective: to determine whether health care providers influenced donors to donate blood to get tested. Health professionals may play an important role in leading persons to donate blood in order to get tested.

- Q. D13. Did a health worker such as a doctor, nurse, or someone from a clinic suggest that you go to the blood center for a blood test for HIV, hepatitis, or for some other reason?
- Q.D14. 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 and HBV.

- D15. 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
- 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. You can donate blood even if you engage in risk behaviors for HIV/AIDS as long as you use condoms.
- D.18. The blood test for HIV identifies everyone who is infected with the virus.
- D.19. The blood test for hepatitis identifies everyone who is infected with a hepatitis 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 South African participants and whether these patterns may or may not be correlated to incident HIV or HBV. A better understanding of epidemiological patterns may allow us to build more accurate questions to improve donor qualification while minimizing unnecessary donor loss.

Objective: to ascertain respondents self-defined sexual orientation. In many cultures, for instance, men do not consider themselves as homosexual as long as, they only have insertive anal sex or oral sex. Nonetheless, specific behaviors confer higher risk of HIV or HBV acquisition and understanding the role of self-defined sexual identity may be important.

- E1. (What) do you consider yourself to be?

Objective: to ascertain an overall indication of sexual history in males.

- E2a. (Ask of Men Only) How many different women have you had sex with since you first began having sex?
- E2a1. If you Don't Know, can you give an approximate answer?
- E.2b. (Ask of Men Only) How old were you when you had sex with a woman for the first time?
- E3a. (Ask of Men Only) How many different men have you had sex with since you first began having sex?
- E3a1. If you Don't Know, can you give an approximate answer?
- E3b. (Ask of Men Only) How old were you when you had sex with a man for the first time?

Objective: to ascertain an overall indication of sexual history in females.

- E2a. (Ask of Women Only) How many different men have you had sex with since you first began having sex?
- E.2a.1. If you Don't Know, can you give an approximate answer?
- E.2b. (Ask of Woman Only) How old were you when you had sex with a man for the first time?
- E.3a. (Ask of Women Only) How many different women have you had sex with since you first began having sex?
- E3a1. If you Don't Know, can you give an approximate answer?
- E3b (Ask of Women Only) How old were you when you had sex with a woman for the first time?

Objective: to determine whether the respondent has ever or recently experienced physical violence from a sexual partner or sexual violence from anyone or an intimate sexual partner. Globally, South Africa has one of the highest rates of physical and sexual violence, and these factors have been associated with HIV risk.

- E4a. Have you ever been physically abused, physically assaulted, or beaten by a sexual partner?
- E4b. In the six months before your donation were you physically abused, physically assaulted or beaten by a sexual partner?
- E5a. Have you ever been sexually abused, sexually assaulted or forced to have any kind of sex when you did not want to?
- E5b. In the six months before your donation were you sexually abused, sexually assaulted or forced to have any kind of sex when you did not want to?

- E5c. In the six months before your donation were you sexually abused, sexually assaulted or forced to have any kind of sex when you did not want to with someone you consider to be an intimate partner, such as a spouse, husband, wife, boyfriend or girlfriend?

Section F - Social/ Sexual Matrix

This part of the questionnaire was designed to capture sexual information for the five most recent sexual partners in the six months before the last blood donation. Both HIV and HBV are sexually transmitted diseases that can be diagnosed within less than 6 months of acquisition. In addition, persons tend to maintain a sexual pattern in their lifetime (MSM, bisexual, heterosexual) as well some other sexual particularities that are relevant to identify riskier behavior for sexually transmitted disease. We assume therefore, asking about more than 5 sexual partners will not provide any supplemental information. We also expect that a small proportion of persons will have more than 1 or 2 sexual partners, if any, in the 6 months before blood donation.

Objective: to ascertain the blood donor sexual history in the preceding year before the last blood donation is necessary to determine whether the number of sexual partners, sexual habits, or behaviors would provide better questions to prevent a riskier person from blood donation.

- F1. How many people did you have sex with in the 12 months before your blood donation?
- F2. How many people did you have sex within the 6 months before your blood donation?

Objective: to ascertain some demographic data are necessary about the participant's network of relationships to understand the epidemiology of incident HIV and HBV infection in South African blood donors.

- F3, G19, G36, G53, G70. What is Partner 1,2,3,4 and 5's gender?
- F4, G20, G37, G54, G71. How old is partner 1,2,3,4 and 5?
- F8, G22, G39, G56, G73. How would you describe partner 1,2,3,4 and 5's race or ethnicity?
- F8a. What country is partner 1 from?
- F9b. (If South Africa) Which province in South Africa is partner 1 from?
- F9c. (If not South Africa) Please specify which country partner 1 is from?

Objective: to ascertain the participant's network of relationships, as well as knowledge of their sexual partner's HIV and HBV status. These questions were designed to evaluate whether the social environment and social network, or knowledge of partners' disease status have influence on sexual behavior activity and HIV or HBV acquisition.

- F5, F22, F39, F56, F73. When did your relationship with partner 1 start? We recognize that you may not remember the exact date and so we are asking that you try to recall the month and the year.
- F6a. Are you currently still in a relationship with partner 1?
- F6b. When did your relationship with partner 1 end? We recognize that you may not remember the exact date and so we are asking that you try to recall the month and the year.

- F7. What type of partner is partner 1,2,3,4, and 5?
- F16, F33, F50, F67, F84. Where did you first meet partner 1,2,3,4, and 5?
- F16a, F33a, F50a, F67a, F84a. Specify where you met partner 1,2,3,4, and 5?
- F12, F29, F46, F63, F80. What is partner 1,2,3,4 and 5's HIV status?
- F13a. Does partner 1 take HIV medications?
- F14. Does partner 1 have hepatitis?
- F15. Did you become sexually involved with partner 1 because you thought that he/she would provide you with some material benefit that you wanted or needed, such as food, shelter, transport, school fees, etc.?
- F15A. If yes, can you tell us what you wanted or needed? It could be food, clothes, transport, school fees, residence, fees, somewhere to stay or sleep, alcohol, drugs, cash or something else.

Objective: to ascertain other risk factors not specifically sexual, but related to HIV transmission, including risk from work-related migration – a well documented risk factor in South Africa.

- F10a. Do you live with partner 1?
- F10b. How many nights did you sleep at your primary residence (home) in the past six months?
- F10c. Is partner 1 currently working (Choose one)?
- F10d. What type of work is partner 1 doing?
- F10e. If Other, What is partner 1's occupation?

Objective: to assess unprotected sexual behaviors, which are very strong predictors of acquisition of HIV or HBV.

- F17, F34, F51, F68, and F85. Number of times you had vaginal sex with partner 1,2,3,4 and 5 in past 6 months.
- F18, F35, F52, F69, F86. When you had vaginal sex, how frequently did you use condoms?
- F19, F36, F53, F70, F87. Number of times you had anal sex with partner 1 in past 6 months.
- F20, F37, F54, F71, F88. When you had anal sex, how frequently did you use condoms?
- F21, F38, F55, F72, F89. Number of times you had insertive anal intercourse (inserted penis in partner 1's anus) with partner 1 in past 6 months.
- F22, F39, F55, F73, F90. When you had insertive anal sex, how frequently did you use condoms?
- F23, F40, F57, F74, F91. Number of times you had receptive anal intercourse with partner 1 (partner 1 inserted penis into your anus) in past 6 months.
- F24, F41, F58, F75, F94. When you had receptive anal sex, how frequently did you use condoms?
- F25. Number of times you had oral sex with partner 1 in past 6 months

Section G - Sexual partners risks

The following section is related to general risks factor for blood borne disease which the participants may had in their lifetime. These questions will be useful in those cases in which the respondent says he or she had no partners in the 6 months before blood donation. (Section F)

Objective: To determine the general risk factors for the participants partners, related to blood borne disease.

- G1a. To the best of your knowledge, have you ever had sex with anyone who was an injection drug user?
- G1b. In the 6 months before your last donation, have you had sex with anyone who was an injection drug user?
- G2a. To the best of your knowledge, have you ever had sex with anyone who tested positive for HIV?
- G2b. In the 6 months before your last donation, have you had sex with anyone who tested positive for HIV?
- G4a. To the best of your knowledge, have you ever had sex with a man who has had sex with another man?
- G4b. In the 6 months before your last donation, have you had sex with a man who has had sex with another man?
- G5a. To the best of your knowledge, have you ever had sex with anyone who received a blood transfusion?
- G5b. In the 6 months before your last donation, have you had sex with anyone who received blood transfusion?
- G6a. To the best of your knowledge, have you ever had sex with a person with haemophilia?
- G6b. In the 6 months before your last donation, have you had sex with a person with haemophilia?
- G7a. To the best of your knowledge, have you ever had sex with anyone who has spent three or more nights in jail, prison, or a detention center?
- G7b. In the 6 months before your last donation, have you had sex with anyone who has spent three or more nights in jail, prison, or a detention center?
- G8a. To the best of your knowledge, have you ever had sex with anyone who had a job that involved exposure to blood or other body fluids?
- G8b. In the 6 months before your last donation,, have you had sex with anyone who had a job that involved exposure to blood or other body fluids?

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. Alcohol and drug use are known to enable risk behavior taking.

Objective: to ascertain alcohol use frequency and quantity per day.

- H1. How often do you drink beer, wine, liquor, or mixed drinks?
- H2. On average how many drinks do you have each time you drink? Number of drinks

Objective: to ascertain non-injected illegal drugs use and frequency, including prevalence of a newly documented drug called “whoonga” or “nyaope” that is reported in some cases to include crushed-up HIV antiretrovirals.

- H3a. Have you ever used dagga, marijuana, or hashish? (Choose one)
- H3b. When was the first year you used dagga, marijuana or hashish?
- H3c. When was the last year you used dagga, marijuana or hashish?
- H4a. Have you ever used whoonga which is also known as nyaope?
- H4b. When was the first year you used whoonga or nyaope?
- H4c. When was the last year you used whoonga or nyaope?

Objective: to ascertain other illegal drugs use and frequency.

- H5a. Have you ever used any non-injected drugs (drugs that are smoked, snorted or taken orally), examples include tik, mandrax, “glue”, cocaine (crack), methamphetamines (crystal), ecstasy (“E”) and LSD?
- H5b. When was the first year you used non-injected drugs?
- H5c. When was the last year you used non-injected drugs?
- H6. If you have smoked or snorted drugs, did you share pipes or straws with another person?

Objective: to ascertain injected illegal drugs use and frequency.

- H7a. Have you ever used injection drugs (examples include heroin, cocaine, and amphetamines)?
- H7b. When was the first year you used injected drugs?
- H7c. When was the last year you used injected drugs?

Objective: to ascertain injected non-prescription substance use and frequency, which could also be routes of infection acquisition for either HIV or HBV through needle sharing.

- H8a. Have you ever injected yourself with any substances including vitamins, steroids, or hormones which were not prescribed by a doctor or nurse?
- H8b. Have you ever shared needles or syringes with another person to inject yourself with any substance including drugs, vitamins, steroids or hormones which were not prescribed by a doctor?

Section I - Medical History

Objective: to obtain data related to general medical procedure exposures known to be routes of HIV and HBV acquisition.

- I1. Have you ever had a blood transfusion?
- I2. How many transfusion episodes have you had?
- I3. When was the first year you received a transfusion?
- I4. When was the last year you received a transfusion?

- 15. Have you ever had minor or major surgery in a hospital, doctor's room, or dentist's office?
- 16. In the 6 months before your donation, have you had minor or major medical surgery in hospital?
- 17. In the 6 months before your donation, have you had any surgical procedures in your doctor's room or office?
- 18. In the 6 months before your donation, have you had any tooth extractions or another dental procedure at a dentist's office?
- 19. 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)?
- 110. In the 6 months before your donation, have you had endoscopy or colonoscopy?
- 111. Have you ever been immunized / vaccinated against Hepatitis B?
- 111b. If yes, can you tell us your age when you were immunized/vaccinated against Hepatitis B?
- 112. In the 6 months before your donation, did you receive an injection from a traditional healer for any reason?

Section J - Other Potential Risk Factors

Objective: to obtain data related to a wide range of other risk exposures that are less common routes of transmission for HIV, but may be common for HBV. Some of the additional questions will focus on personal behaviors that can cause damage to mucosal surfaces or skin that might permit easier transmission of HIV or HBV infection, and other will assess presence of insects that could transmit HBV infection in rare circumstances.

- J1. In the 6 months before your donation have you spent three or more nights in jail, prison, or a detention center?
- J2. In the 6 months before your donation have you had acupuncture treatments?
- J3. Who performed the acupuncture treatments?
- J4. In the 6 months before your donation how many times have you had acupuncture treatments?
- J5. How many tattoos do you have on your body?
- J6. In the 6 months before your donation, have you had a new tattoo or had one re-applied?
- J7. Where did you get your most recent tattoo?
- J8. How many ear or body piercing do you have?
- J9. In the 6 months before your donation, have you had new ear or body piercing?
- J10. Where did you get your most recent piercing?
- J11. Have you ever had a manicure or pedicure at a beauty salon or had a shave at a barbershop?
- J12. How many times have you had manicures or pedicures or shaves at a barbershop?
- J13. In the 6 months before your donation, have you had a manicure or pedicure or had a shave at a barber shop?
- J14a. Have you been circumcised?
- J15b. At what age were you circumcised?
- J15c. Was your circumcision performed in the 6 months before your donation?
- J15d. Was the circumcision performed in hospital?
- J15e. Who performed the circumcision performed?
- J16a. In the 6 months before your donation, how often have you used anything to dry, clean, or tighten your vagina before or after having sex?
- J16b. Please check all the things that you have used to dry, clean or tighten your vagina.

- J17a. In the 6 months before your donation, how often have you used anything to dry, clean, or tighten your anus before or after having sex?
- J17b. Please check all the things that you have used to dry, clean or tighten your anus before having sex.
- J18a. In the 6 months before your donation, have you had Raatib, ritual scarring, ritual piercing, ritual circumcision, blood sharing or been stabbed?
- J18b. Can you please tell us which activity?
- J19. What was the reason for the activity?
- J20. In the 6 months before your donation, did you visit a traditional healer and receive traditional medicine other than cuts and/or scarification?
- J21. In the 6 months before your donation, did you live in an environment where you were frequently bitten by mosquitos?
- J22. In the 6 months prior to your last donation, did you live in an environment where you were frequently bitten by bed bugs or lice?
- J23. In the 6 months prior to your last donation, did you have an injury such as a knife or stab wound or were you in an accident where you lost blood from a cut or injury?

Objective: to obtain data related potential exposure to HIV or HBV through non-sexual interpersonal relationships.

- J31. How many people do you personally know who currently have AIDS or have died of AIDS?
- J32. How many people do you personally know who do NOT have AIDS, but have tested positive for HIV, the virus that causes AIDS?
- J33. How many people do you personally know who have hepatitis? (Choose one)
- J34. How many people do you personally know who have died of hepatitis? (Choose one)
- J35. In the 6 months have you been in close contact with anybody who had Hepatitis (yellow jaundice), e.g. people you live or work with?

Section K - Work Place Exposures

Objective: to obtain data related potential exposure to HIV or HBV through working in environments that could include exposure to blood or other human body fluids.

- K1. Do you work where you are exposed to human bodily fluids (e.g. blood, urine, feces, saliva)?
- K2. In the 6 months before your donation, in your professional work have you had a needle stick injury (accidentally been stuck by a needle or other sharp instrument used for providing medical care to someone else)?
- K3. In the 6 months before your donation, did you in your professional work have 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 questions that will be asked at the end of the interviews related on topics that are unique for persons who have either HIV or HBV.

Objective: to ascertain the blood donor HIV knowledge and use of antiretroviral treatment and ascertain knowledge of HBV status. In South Africa, HAART is available in the public sector for individuals meeting

National Standards, and in the private sector. These questions will be useful to analyze drug resistance, cases with low viral load level, among others.

- L1. (Ask of HIV Cases Only) Did you know your HIV status before your donation?
- L2. (Ask of HIV Cases Only) How do you think you may have become infected with HIV?
- L3. (Ask of HIV Cases Only) When do you think you may have been infected with HIV? (Year)
- L4. (Ask of HIV Cases Only) When do you think you may have been infected with HIV?
- L5. (Ask of HIV Cases Only) Are you currently taking antiretroviral medicines, also called ARVs?
- L6. (Ask of HIV Cases Only) Have you taken antiretrovirals (ARVs) in the past?
- L7. (Ask of HIV Cases Only and Women Only) If Female: Did you know you were HIV-positive prior to or during your most recent pregnancy?
- L8. (Ask of Women Only) Did you take antiretrovirals during your most recent pregnancy to try to prevent HIV transmission to your baby?
- L9. (Ask of HBV Cases Only) How do you think you may have become infected with HBV?

Justification for Objective 3 – Follow Up Clinical Questionnaire

For those persons who participate in Objective 3 we will collect information on medical care, treatment and conditions that may have occurred since the last visit in the prospective cohort study.

Objective: Section A will be completed by trained research staff. The following questionnaire items are related to the general profile of respondents (study subjects) and will be used for de-identified administrative record keeping.

- A1. Subject ID
- A2. Subject Donor Number
- A3. Location of Study Visit?
- A4. Date of Study Visit (DD/MM/YYYY)
- A5. Research Staff Initials?

Section B - Current Medical Status

Objective: to assess presence of conditions requiring medical attention, the use of antiretrovirals and other remedies, and provision of other health services that can impact the immune system and so have the potential to influence HIV disease progression. In addition, women will be asked about pregnancy because pregnancy causes changes to the immune system that could also influence the biomarkers we will test for in the blood samples we collect from each participant. Participants will complete this information in private.

- B1. Since your last visit for participation in this study have you gone to your doctor or sought medical care at a clinic or hospital?
- B1a. If yes, what was the reason for seeking medical care?
- B2. Since your last visit for participation in this study have you gone to a traditional healer?
- B2a. If yes, what was the reason for seeing the traditional healer?
- B3. Since your last study visit have you had a cold, flu, or any other infection?
- B3a. If yes, what symptoms did you have? Please list all the symptoms you can think of such as headache, fever, body pain, chills, vomiting, diarrhea, or any other symptom that you may have had.
- B4. Since your last study visit have you started taking antiretroviral medicines, also known as ARVs?
- B4a. What are the names of the antiretroviral (ARV) medicines you are currently taking?
- B5. If yes, have you had any side effects from taking your current antiretroviral (ARV) medicines?
- B5a. If yes, what side effects did you have? Please list all the side effect you can think of, such as nausea, loss of appetite, vomiting, diarrhea, or any other symptom that you may have had.
- B5b. Did you miss taking some or all of the doses of your current antiretroviral (ARV) medicines because of the side effects you experienced?
- B6. Are you currently taking anything else for your health such as vitamins, herbs, supplements or natural medicines?
- B6a. If yes, please list the name(s) of each vitamin, herb, supplement you are taking?
- B7. Since your last study visit have you started taking traditional medicines that were recommended or provided by a traditional healer?
- B7a. If yes, please list the names of traditional medicines you are taking?
- B7b. If yes, have you had any side effects from taking these traditional medicines?
- B7c. If yes, what side effects did you have? Please list all the side effect you can think of, such as nausea, loss of appetite, vomiting, diarrhea, or any other symptom that you may have had.
- B8. (Ask of Women Only) Are you currently pregnant?