

Transfusion-Transmissible Infection Monitoring System (TTIMS)
Laboratory and Risk Factor Coordinating Center (LRCC)

Questions relating to survey objectives

The purpose of the interview questions is to collect donor demographic and behavioral profile data for comparing risk exposures between blood donors who test positive (cases) for HIV (NAT yield and seropositive), HCV (NAT yield), and/or HBV (NAT yield) to persons who test false positive (controls). The responses will allow TTIMS to determine risk factors associated with each of the three viral infections. This case-control study design will yield interview data on risk behaviors among blood donors that will be used to understand predominant risk behaviors associated with HIV, HBV, or HCV infections in US blood donors. Routes and risks factors for infection acquisition are different for each of these three viral infections but may include male-to-male sex, having multiple heterosexual partners, injection drug use (IDU), exchanging money or drugs for sex, and some medical procedures. The only way to collect information on these risk factors is to directly ask participants to self-disclose these behaviors or exposures.

The questionnaire is administered by trained donor counselors over the telephone or by clinicians or trained donor counselors during an in-person interview at the time of notification of the donor that he or she has tested positive for an infectious marker.

SECTION A - DONATION DATA and VERBAL CONSENT

Other than providing verbal informed consent, there is no respondent burden for Section A. This section is completed by the trained donor counselors or clinicians before contacting each donor. This information will be obtained from existing operational records at each blood center that were created when the donor consented to blood donation including infectious disease testing.

The donor counselor (or clinician) will read the verbal consent information, answer any questions the potential participant may have, and then the participant will either agree to or decline participation in the study.

Objective: The following questionnaire items are related to the specific tracking and record keeping information necessary to confirm and cross-check each donor's infectious disease testing results. These data are necessary to confirm case versus control status among other objectives such as determining where there are geographic clusters of infections based on where the donor donated blood.

Donation Identification Number

Donor Identification Number

Blood Collection Center

Center Code

Donation Date

Donor Type: Case or Control

Type of Infection: HIV, HBV, and/or HCV

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

Date of interview

Interviewer initials

Interview language

SECTION B - DONOR DEMOGRAPHIC DATA

Section B and all remaining sections will be completed by the participant. Each question will be asked by the trained counselors or clinicians. All answers given by each participant will be recorded in the secure internet-based Qualtrics electronic questionnaire system by the person conducting the interview.

Factors known to be associated with HIV infection in the US general population include socio-economic status, age, race and gender. We have reworded questions to appropriately reflect the current phrasing used in other government-approved data collection activities, such as the US Census. Questions have been slightly revised to temporally relate to the time of last donation, which would effectively be the last time the donor was eligible to donate because both confirmed positive and false positive infectious disease screening marker results result in donor deferral. These data are critical in order to determine if risk factors in blood donors are similar to those reported for the general population of the country. The data recorded here will be used in multivariable statistical modeling to control for potential confounding by these factors so that we may gain a more accurate understanding of the risk behaviors associated with each of the three viral infections rather than factors that might superficially appear to be related to demographic characteristics.

Objective (Q1-Q12): To obtain demographic data for general risk stratification based on the background of the participants.

- Q1 What sex do you consider yourself to be?
- Q2 What sex were you assigned at birth?
- Q3 What is your birth date?
- Q4 What is your country of birth?
- Q5 At the time of your last blood donation, what was the highest level of education you had completed?
- Q6 Are you of Hispanic, Latino, or Spanish origin?
- Q7 What is your race?
- Q8 At the time of your last blood donation, what was your occupation?
- Q9 At the time of your last blood donation, what was your annual household income from all sources?
- Q10 At the time of your last blood donation, what was your marital status?
- Q11 At the time of your last blood donation, if you were married or living with a partner, what was the gender of this person?
- Q12 Which of the following best represents how you think of yourself?
- Straight/heterosexual
 - Bisexual
 - Gay/lesbian/homosexual
 - Something else
 - (Don't know)
 - (Refuse to answer)

Objective (Q13-Q23): To obtain data on HBV vaccination history and use of pharmacological HIV infection prevention and treatment methods for assessment of risk mitigation behaviors in the participants.

- Q13 Have you ever been vaccinated against hepatitis B virus? If yes, proceed to Q13.1, otherwise skip to Q14.
- Q13.1 Were you vaccinated as an...?
- Infant
 - Child
 - Adult
- Q14 Before your last donation, did you ever take PRE-exposure prophylaxis, or PrEP? [Interviewer, please read the following:] *PrEP is antiviral medication taken daily for months or years to reduce a person's chance of getting HIV.*

- Q15 In the month before your last blood donation, were you taking PRE-exposure prophylaxis, or PrEP?
- Q16 Before your last donation, did you ever take POST-exposure prophylaxis, or PEP? [Interviewer, please read the following:] *PEP is antiviral medication taken daily for 28 days after a person has had a high-risk exposure to HIV.*
- Q17 In the month before your last blood donation, were you taking POST-exposure prophylaxis, or PEP?

Q18 will only be asked of HIV confirmed positive cases:

- Q18 Did you know you were infected with HIV before you donated blood?
- Q19 Before your last donation, did you ever take anti-retroviral therapy for HIV infection?
- Q20 In the month before your blood donation, were you taking anti-retroviral therapy for HIV infection?
- Q21 Before your last blood donation, did you do any activities that you think may have put you at risk for an HIV infection or hepatitis infection? If yes, proceed to Q 21.1
- Q21.1 What was the activity or activities? [Interviewer, please ask as an open-ended question, then select the most applicable option(s) below:]
- Heterosexual contact
 - Homosexual contact
 - Unsafe sexual contact (did not use condoms or other protective barriers)
 - Sexual contact, not specified
 - IDU
 - Medical/Dental procedure
 - Accidental needle stick
 - Tattoo/Piercing
 - Blood transfusion
 - From mother at birth
 - Non-sexual contact (work/family exposure)
 - Travel or living in a foreign country
 - Other (SPECIFY)_____

The next two questions will only be asked of confirmed positive cases:

- Q22 Can you specify the date when you think you might have got infected?
- Q23 At the time of your last donation were you aware that the activity you thought might be the reason for your infection could place you at a higher risk for infection? If yes, proceed to Q 23.1

Q23.1 How did you find out the activity could place you at higher risk for infection? [Interviewer, please ask as an open-ended question, then select the most applicable option below:]

Healthcare provider

Blood center

Internet

Friends

Other (SPECIFY)_____

Objective (Q24-Q30): to obtain data related to whether a donor has donated blood before and has had previous TTI testing outside of blood donation. Motivations for donating and history of previous TTI testing are important so that we may identify the prevalence of persons seeking to have their blood tested for infectious markers. This is known as “test-seeking” behavior.

Q24 Before your last donation had you previously donated blood at this or any other blood or plasma center or blood drive?

Q25a-f Please tell me whether any of the following reasons or factors contributed to your decision to donate blood. For each statement, please answer yes or no.

I wanted to donate blood to help someone in need

I donated in response to a TV or radio campaign, or a phone call, or letter from the blood bank

I was encouraged or pressured by family, friends, coworkers, or by someone at a blood drive

I wanted to get my test results for my blood

I wanted to get the incentives for donating that the blood bank was offering

I donated to help others after a natural or man-made disaster or tragedy occurred

Q26 Is there any other reason why you came to the blood center?

Q27a-d Did any of the following factors influence your decision to come to the blood center? For each statement, please answer yes or no.

Blood center testing is confidential

Blood center testing is more accurate than at other test sites

Blood center testing is free

I think that the tests would identify any problem with my blood

Q28 Outside of blood donation, have you previously been tested for HIV?

Q28.1 If yes, when was the last time you were tested for HIV (Month & Year)?

Q28.2 What was the result of the test? (Positive or Negative)?

Q29 Outside of blood donation, have you previously been tested for HBV? If yes, proceed to Q29.1

Q29.1 When was the last time you were tested for HBV (Month & Year)?

Q29.2 What was the result of the test? (Positive or Negative)?

Q30 Outside of blood donation, have you previously been tested for HCV? If yes, proceed to Q30.1

Q30.1 When was the last time you were tested for HCV (Month & Year)?

Q30.2 What was the result of the test? (Positive or Negative)?

SECTION C – RISK FACTORS ASSESSMENT – PART 1

Section C Part I and all remaining sections of the questionnaire will be completed by respondents. Each set of questions serves an important role because we are seeking to see if we can stratify the infected donor population based on the history of exposure and total number of exposures for known risk factors for infection.

Objective (Q31-Q33): to obtain data related to whether a donor has a single sexual partner in the last year or multiple sexual partners. Increased number of sexual partners is associated with increased risk of sexually transmitted infections.

For the next few questions unless stated otherwise the term “sex” refer to any of the following activities, whether or not a condom or other protection was used:

1. Vaginal Sex (contact between penis and vagina)
2. Oral Sex (mouth or tongue on someone’s vagina, penis, or anus)
3. Anal Sex (contact between penis and anus)

Q31 Using these definitions of sex, in the 12 months before your last donation did you have sex?

Q32 In the 12 months before your last donation did you have sex with only one partner?

Q33 To the best of your knowledge, in the 12 months before your last donation did your partner have sex with only you?

Sexual History

All questions may be asked of men and women, but with built-in skip patterns a respondent will not be asked the entire list of questions if the person reports he or she has not had any sexual contact or has only had same sex or opposite sex contact .

The number of lifetime sexual partners during increases the odds of having a sexual transmitted disease, as well its spread. The sexual history will allow FDA to determine the most prevalent behavioral patterns for US blood donors and whether such patterns may or may not be correlated to specific serologic markers. The routes of sexually transmitted infections continue to be through sexual contact. However, the current patterns for US donors following the change to a 12-month deferral of men who have sex with men (MSM) are not known. A better understanding of sexual risk factors associated with HIV and the other viral infections may allow more accurate questions to be developed to improve the donor qualification process, minimizing donor deferral for behaviors that are actually not associated with increased risk. In addition, it might help facilitate the development donor evaluation approaches based upon individual risk assessment.

Objective (Q34-Q38): To ascertain the respondent's sexual history with male sexual partners. The time spans are relevant with respect to the revised 12-month deferral policy in the US. We are also asking about the frequency of use of condoms or protective barriers as this information is important for distinguishing between higher risk behaviors and behaviors with lower risk regardless of the number of sexual partners.

- Q34 How many male sexual partners have you had in your lifetime? Please include both ongoing partners and one-time encounters with men.
- Q35 In the 5 years before your last blood donation, how many male sexual partners did you have? Please include both ongoing partners and one-time encounters with men.
- Q36 In the 12 months before your last blood donation, how many male sexual partners did you have? Please include both ongoing partners and one-time encounters with men.
- Q37 Regarding your male sexual partners and one-time encounters with men in the 12 months before your last blood donation, if you had vaginal or anal sex how often did you use condoms or protective barriers?
- Q38 Before your last blood donation, when was your last sexual contact with a male?

Objective (Q39-Q45): To ascertain the respondent's sexual history with female sexual partners. The time spans are relevant with respect to potential regulatory decision making by the US FDA. We are also asking about the frequency of use of condoms or protective barriers as this information is important for distinguishing between higher risk behaviors and behaviors with lower risk regardless of the number of sexual partners.

- Q39 How many female sexual partners have you had in your lifetime? Please include both ongoing partners and one-time encounters with women.
- Q40 In the 5 years before your last blood donation, how many female sexual partners did you have? Please include both ongoing partners and one-time encounters with women.
- Q41 In the 12 months before your last blood donation, how many female sexual partners did you have? Please include both ongoing partners and one-time encounters with women.
- Q42 Regarding your female sexual partners and one-time encounters with women in the 12 months before your last blood donation, if you had vaginal or anal sex how often did you use condoms or protective barriers?
- Q43 Before your last blood donation, when was your last sexual contact with a female?

Objective: Previous history of sexually transmitted infections is a strong predictor of sexually transmitted viral infections in the general population. We will determine whether this is the case in the donor population based on the answers to the questions below. Recent history of sexually transmitted infections is expected to be more important than lifetime history.

- Q44 Before your last donation did you ever have a sexually transmitted disease, also known as a STD? Examples of STDs include gonorrhea, Chlamydia, syphilis, genital herpes, genital warts, and HPV.
- Q44.1 Can you tell me which STD(s)?
- Q45 In the 12 months before your last blood donation, did you have a STD? Examples of STDs include gonorrhea, Chlamydia, syphilis, genital herpes, genital warts, and HPV.

Q45.1 Can you tell me which STD(s)?

Drug Use

All questions may be asked of each respondent, but with built-in skip patterns a respondent will not be asked the entire list of questions if the person reports no history of drug use.

Objective (Q46-Q55): to obtain data related to whether a donor has used illegal drugs. Injection drug use is the most important risk factor for viral infection related to drug use. However use of other “hard” drugs (i.e., heroin, methamphetamines, etc.) may also be an indicator of risk behaviors that could lead to infection acquisition. To ascertain the non-injected illegal drugs use and frequency.

- Q46 Before your last donation, did you ever inject drugs, steroids, or vitamins not prescribed by a health care provider?
- Q47 In the 12 months before your last blood donation, did you inject drugs, steroids, or vitamins not prescribed by a health care provider?
- Q47.1 Can you tell me what substance or substances were injected?
- Q48 Before your last donation, did you ever share needles or syringes with another person?
- Q49 In the 12 months before your last blood donation, did you share needles or syringes with another person?
- Q50 Before your last donation, did you ever use any drugs that you did not inject, that is, drugs that are smoked, snorted, inhaled, or taken orally? Please do not include the use of marijuana when answering this question.
- Q51 In the 12 months before your last blood donation, did you use any drugs that you did not inject, that is, drugs that are smoked, snorted, inhaled, or taken orally? Please do not include the use of marijuana when answering this question.
- Q52 Before your last donation, did you ever intentionally engage in sex while “high” or “drunk”?
- Q53 In the 12 months before your last blood donation, did you intentionally engage in sex while “high” or “drunk”?
- Q54 Before your last donation, did you ever give or receive money or drugs for sex?
- Q55 In the 12 months before your last blood donation, did you give or receive money or drugs for sex?

SECTION C – RISK FACTORS ASSESSMENT – Part II

Objective (Q56-Q65): To obtain data related to less common risk factors historically associated with HIV, HBV, and/or HCV 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. We need to determine if both cases and controls have similar exposure levels for these less common potential risk factors. Each of the exposures is known to be route of infection transmission for one or more of the three infections of interest.

- Q56 How many tattoos do you have on your body?
- Q57 In the 12 months before your last blood donation, did you get a new tattoo or had one re-applied?
- Q58 Where did you go to have your most recent tattoo(s) applied?
- Q59 In total, how many ear piercings do you have?
- Q60 In the 12 months before your last blood donation, did you get any new ear piercings?
- Q61 In total, how many body piercings do you have?
- Q62 In the 12 months before your last blood donation, did you get any new body piercings?
- Q63 Before your last donation, did you ever spend three or more nights in a row in any of the following?
- Q64 In the 12 months before your last blood donation, did you spend three or more nights in a row in jail, prison, a detention center, a shelter, or group home?
- Q65 In total, how long did you spend in jail, prison, a detention center, a shelter, or a group home?

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 C Part I of the questionnaire.

Objective (Q66-Q75): To determine the known risk factors for the donors that are rare and to determine potential risks the donor's sexual partners may have.

- Q66 Before your last donation, did you have sex with anyone who has injected illegal drugs, steroids or vitamins not prescribed by a health care provider?
- Q67 In the 12 months before your last blood donation, did you have sex with anyone who has injected illegal drugs, steroids or vitamins not prescribed by a doctor?
- Q68 Before your last donation, did you ever have sex with a male who has had sex with another male?
- Q69 In the 12 months before your last blood donation, did you have sex with a male who has had sex with another male?
- Q70 Before your last donation, did you ever have sex with anyone who has tested positive for hepatitis?
- Q71 In the 12 months before your last blood donation, did you have sex with anyone who has tested positive for hepatitis?
- Q72 Before your last donation, did you ever have sex or intercourse with anyone who has tested positive for HIV?
- Q73 In the 12 months before your last blood donation, did you have sex or intercourse with anyone who has tested positive for HIV?
- Q74 Before your last donation, did you ever have sex or intercourse with anyone who has received a

blood transfusion?

- Q75 In the 12 months before your last blood donation, did you have sex or intercourse with anyone who has received a blood transfusion?

Medical and Family History

Objective (Q76-Q85): To obtain data related to general medical history exposures, medical accidents and family history that could lead to transmission of HIV, HBV, HCV. 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.

- Q76 Before your last donation, did you ever receive a blood transfusion?
- Q76.1 When was the last time you had a blood transfusion?
- Q77 Before your last donation, did you ever receive a tissue or organ transplant?
- Q77.1 What type of organ or tissue?
- Q78 Before your last donation, did you ever receive acupuncture?
- Q79 In the 12 months before your last blood donation, did you receive acupuncture?
- Q80 Before your last donation, did you ever have a needle stick injury (accidentally been stuck by a needle or other sharp instrument after it was used for providing medical care to someone else) or some other unintentional needle stick?
- Q81 In the 12 months before your last blood donation, did you have a needle stick injury?
- Q82 Before your last donation, did you ever get someone else's blood, body fluids, vomit, or feces splashed into your eyes, mouth, or in an open skin wound?
- Q83 In the 12 months before your last donation, did you get someone else's blood, body fluids, vomit, or feces splashed into your eyes, mouth, or in an open skin wound?
- Q84 To the best of your knowledge, before your last donation, was anyone living in your household (including family, friends or roommates) infected with HIV, hepatitis B or hepatitis C?
- Q84.1 Can you tell me which person(s) is/are/were infected?
- Q85 Are you currently taking antiviral therapy?