

OMB#0925-XXXX
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DONOR RISK FACTOR QUESTIONNAIRE

SECTION A - INTERVIEW DATA

Blood Unit Number:

Blood Collection Center:

Center Code:

Donation Date: / /

Testing Results:

Donor is: repeat reactive (unconfirmed) OR confirmed positive for which virus and which markers?

Virus: <input type="radio"/> HIV	Markers: <input type="radio"/> Anti HIV-1,-2	<input type="radio"/> HIV NAT	If available: <input type="radio"/> HIV-1	<input type="radio"/> HIV-2
<input type="radio"/> HTLV	<input type="radio"/> Anti-HTLV-I,II		If available: <input type="radio"/> HTLV-I	<input type="radio"/> HTLV-II
<input type="radio"/> HCV	<input type="radio"/> Anti-HCV	<input type="radio"/> HCV NAT		
<input type="radio"/> HBV	<input type="radio"/> HBsAg	<input type="radio"/> Anti-HBc	<input type="radio"/> HBV NAT	
	HBV NAT type: <input type="radio"/> Ultrio	<input type="radio"/> Roche	<input type="radio"/> NGI	

Date of Interview: / /

Interviewer Initials:

Contact/Interview Details (select one) : The donor called I called the donor Interview conducted in person
Interview Language (select one) : English Spanish

Notes to interviewer:

- Administer this survey as early as possible after the date that disease marker testing including confirmation testing is completed for the donation.
- Be sure to properly identify the donor according to standard operational procedures.
- Please complete your part of Questions 13 and 14 before administering the survey.
- When reading the possible answers to the donor, do not say "Don't know" or "Refuse to answer".

Verbal Consent - Please read the following to the donor:

We are asking you to be part of a research investigation about risk factors for infectious diseases in blood donors. The study is being carried out by the New York Blood Center, Blood Systems Research Institute, and the American Red Cross.

For Confirmed Positives: *We are contacting you because a test was positive for a viral infection the last time you donated blood. If you agree to participate, I will ask you questions about possible ways you could have gotten infected.*

For Repeat Reactives (Unconfirmed) (known as False Positives) : *We are contacting you because your recent donation tested unconfirmed or false positive. If you agree to participate, I will ask you questions about risk factors for viral infections so we can compare answers from false positive donors, like you, to answers that true positive donors give on the same questions.*

Some of the questions are about personal and private matters such as sexual experiences and drug use. Our purpose in asking these questions is to improve the safety of donated blood. The interview should take no more than 20 minutes. Your participation is voluntary and you may refuse to answer any question. If you tell us something during the interview that would have made you ineligible to donate, we will have to add this to your donor record and this may lead to deferral from future blood donation. However there will be no other repercussions if the answers you give now are different than those you gave when you donated.

We will keep your responses confidential. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you. The risk of participating in this study is if the information you give is not kept confidential. However no information that identifies you will be entered into the database, only the answers to these questions. There is no direct benefit to you of participation other than the knowledge that you are helping efforts to maintain a safe blood supply by allowing us to understand risks and motivations of blood donors.

If you have any questions, feel free to ask me now. You may also call the Donor Counseling and Notification Services at (800) 289-4923 or Dr. Hany Kamel at Blood Systems headquarters at (480) 675-5659. Do you have any questions for me before we begin?

Do you agree to participate in this study? Yes No **If YES, verbal consent obtained.**

Signature of Interviewer: _____ Date: _____



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SECTION B - DONOR DEMOGRAPHIC DATA

Please read the following: First, I will ask you some questions about your general demographics and donation history. I remind you that your answers will be kept confidential.

1. What is your gender? Male Female Transgender

2. What is your birth date?

 /

 /

3. What is your country of birth?

4. What is the highest level of education you have completed?

- Never been to school
- Elementary school
- Junior high school
- High school
- College or technical school
- Graduate school or professional degree
- (Don't know)
- (Refuse to answer)

5. Do you consider yourself Hispanic?

- Yes
- No
- (Don't know)
- (Refuse to answer)

6. How would you describe your race?

- White
- Black or African American
- Asian, Native Hawaiian or other Pacific Islander
- American Indian or Alaska Native
- (Don't know)
- (Refuse to answer)

7. What is your occupation?

8. What is your current marital status?

- Single, never married → **SKIP TO QUESTION 10**
 - Living together, but not legally married
 - Married
 - Separated or divorced
 - Widowed
 - (Don't know)
 - (Refuse to answer)
- } → **SKIP TO QUESTION 10**



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9. If you are married or living with a partner, what is the gender of this person?

- Female
- Male
- Transgender
- (Don't know)
- (Refuse to answer)

10. Before your most recent donation had you previously donated blood at this or any other blood center or blood drive? (MARK ALL THAT APPLY)

- No
- Yes, at this blood center
- Yes, at another blood center
- (Don't know)
- (Refuse to answer)

11. a) 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. (READ SLOWLY AND MARK ALL THAT APPLY)

- Yes No I wanted to donate blood to help someone in need
- Yes No In response to a TV or radio campaign, or a phone call, or letter from the blood bank
- Yes No I was pressured or encouraged by family, friends, coworkers, or by someone at a blood drive
- Yes No I wanted to get my test results for my blood
- Yes No I wanted to get the incentives for donating that the blood bank was offering

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

- Yes
- No → **SKIP TO QUESTION 12**
- (Don't know)
- (Refuse to answer)

c) Can you please tell me the reason?

12. Did any of the following factors influence your decision to come to the blood center? For each statement, please answer yes or no. (READ SLOWLY AND MARK ALL THAT APPLY)

- Yes No Blood center testing is confidential
- Yes No Blood center testing is more accurate than at other test sites
- Yes No Blood center testing is free
- Yes No I think that the tests would identify any problem with my blood
- Yes No None of these factors influenced my decision



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13. We would like to ask your opinion about blood donation. For each of the statements, please answer yes or no.

- Yes No Do you think the current blood donor selection and screening policies are unfair?
- Yes No Did your opinion about current blood donor selection and screening policies influence your decision to donate blood?

If you think that donor selection and screening policies are unfair, can you tell me what you think is unfair about them?

14. *To the interviewer: please mark whether the donor is* Reactive *or* Confirmed Positive. *Then, fill in the infection (s) before reading the question:*

Is this the first time you have been told about testing reactive or positive for

 ?

(WRITE IN NAME OF INFECTION (S))

- Yes
- No
- (Don't know)
- (Refuse to answer)

(Questions 15 and 16 are for confirmed positive donors only.)

15. How do you think you got infected with

 ?

(WRITE IN NAME OF INFECTION (S))

16. Can you specify the date when you think you got infected?

(ENTER AS MUCH DATE INFORMATION AS THE PERSON CAN PROVIDE)

(Note to interviewer if any risk disclosed in question 15 ask 17, if not skip to 18.)



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17. a) At the time of donation were you aware that the activity you stated in question 15 could place you at a higher risk for infection?

- Yes No

17. b) If no, how did you find out the activity you stated in question 15 could place you at higher risk for infection?

SECTION C - RISK FACTORS ASSESSMENT - Part I

Please read the following: *In this next section, I will ask you some questions about behaviors you may or may not have engaged in that can increase the risk of infection. I am asking you for this information because the data could help improve the safety of the blood supply. I remind you that your answers will be kept confidential.*

For all parts of questions 19 and 20 we would like you to use the following definition of "sexual contact": The words "have sexual contact with" and "sex" are used in some of the questions we will ask you, and apply to any of the activities below, 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)*

18. In the last year I have been monogamous, meaning I am in a committed relationship and have had sexual contact with only one partner.

- Yes No

19. a) How many male sexual partners have you had in your lifetime? Please include both ongoing partners and one-time encounters.

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(IF NONE, SKIP TO QUESTION 20a)

b) In the last 5 years, how many male sexual partners have you had? Please include both ongoing partners and one-time encounters.

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c) In the last 12 months, how many male sexual partners have you had? Please include both ongoing partners and one-time encounters.

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d) Regarding your male sexual partners and one-time encounters in the last 12 months (QUESTION 19c) , if you had vaginal or anal sex how often did you use condoms or protective barriers?

- Never
 Sometimes
 Always
 (Don't know)
 (Refuse to answer)



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e) Before your most recent blood donation, when was your last sexual contact with a male?

/
Month Year

20. a) How many female sexual partners have you had in your lifetime? Please include both ongoing partners and one-time encounters.

(IF NONE, SKIP TO QUESTION 21a)

b) In the last 5 years, how many female sexual partners have you had? Please include both ongoing partners and one-time encounters.

c) In the last 12 months, how many female sexual partners have you had? Please include both ongoing partners and one-time encounters.

d) Regarding your female sexual partners and one-time encounters in the last 12 months (QUESTION 20c) , if you had vaginal or anal sex how often did you use condoms or protective barriers?

- Never
- Sometimes
- Always
- (Don't know)
- (Refuse to answer)

e) Before your most recent blood donation, when was your last sexual contact with a female?

/
Month Year

21. a) Have you ever had a sexually transmitted disease, also known as a STD? Examples of STDs include gonorrhea, chlamydia, syphilis, genital herpes, genital warts.

- Yes
- No → **SKIP TO QUESTION 23a**
- (Don't know)
- (Refuse to answer)

b) Can you tell me which STD (s) ?



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22. a) In the last 12 months, have you had a STD? Examples of STDs include gonorrhea, chlamydia, syphilis, genital herpes, genital warts.

- Yes
- No → **SKIP TO QUESTION 23a**
- (Don't know)
- (Refuse to answer)

b) Can you tell me which STD (s) ?

23. a) Have you ever injected illegal drugs, steroids, or vitamins not prescribed by a doctor?

- Yes
- No → **SKIP TO QUESTION 24a**
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you injected illegal drugs, steroids, or vitamins not prescribed by a doctor?

- Yes
- No
- (Don't know)
- (Refuse to answer)

24. a) Have you ever shared needles or syringes with another person?

- Yes
- No → **SKIP TO QUESTION 25a**
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you shared needles or syringes with another person?

- Yes
- No
- (Don't know)
- (Refuse to answer)

25. a) Have you ever used any illegal 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.

- Yes
- No → **SKIP TO END of SECTION C Part I**
- (Don't know)
- (Refuse to answer)



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b) In the last 12 months, have you ever used any illegal 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.

- Yes
- No
- (Don't know)
- (Refuse to answer)

Interviewer Comments: Please provide any additional comments or impressions about the risk factors disclosed or not disclosed by the donor in Part I.

SECTION C - RISK FACTORS ASSESSMENT - Part II

Please read the following: *Now I am going to ask you about other risk factors or behaviors that can increase the chances of infection. Please answer each question to the best of your knowledge. I am asking you for this information because it could help to improve the safety of the blood supply. I remind you that your answers will be confidential.*

26. a) How many tattoos do you have on your body?

- 0 (No tattoos) → **SKIP TO QUESTION 27a**
- 1
- 2
- 3 or more
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you had a new tattoo or had one re-applied?

- Yes
- No
- (Don't know)
- (Refuse to answer)

c) Where did you go to have your most recent tattoo (s) applied?

- Tattoo parlor
- At home or a friend's house
- At a party or rave
- In jail, prison, or a detention center
- (Don't know)
- (Refuse to answer)



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27. a) In total, how many ear piercings do you have?

- 0 (No piercings) → **SKIP TO QUESTION 28a**
- 1
- 2
- 3 or more
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you had new ear piercings?

- Yes
- No
- (Don't know)
- (Refuse to answer)

28. a) In total, how many body piercings do you have?

- 0 (No piercings) → **SKIP TO QUESTION 29a**
- 1
- 2
- 3 or more
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you had new body piercings?

- Yes
- No
- (Don't know)
- (Refuse to answer)

29. a) Have you ever spent three or more nights in a row in any of the following? (MARK ALL THAT APPLY)

- Jail or Prison
- Detention Center (For example: juvenile detention or inpatient treatment)
- A Shelter or Group Home
- None of the above → **SKIP TO QUESTION 30**
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you spent three or more nights in a row in jail, prison, a detention center, a shelter, or a group home?

- Yes
- No
- (Don't know)
- (Refuse to answer)

c) In total, how long have you spent in jail, prison, a detention center, a shelter, or a group home?

- Less than 1 month
- 1 month to less than 6 months
- 6 months or more
- (Don't know)
- (Refuse to answer)



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For all parts of questions 26-29 we would like you to use the following definition of "sexual contact": The word "sex" is used in the questions we will ask you, and applies to any of the activities below, 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)

30. a) Have you ever given or received money or drugs for sex?

- Yes
- No → **SKIP TO QUESTION 31**
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you given or received money or drugs for sex?

- Yes
- No
- (Don't know)
- (Refuse to answer)

Please read the following: These next questions ask about the health and risk factors of your previous sexual partners. While you may not know their exact medical histories, please answer these questions to the best of your ability.

31. a) Have you had sex with anyone who has injected illegal drugs, steroids or vitamins not prescribed by a doctor?

- Yes
- No
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you had sex with anyone who has injected illegal drugs, steroids or vitamins not prescribed by a doctor?

- Yes
- No
- (Don't know)
- (Refuse to answer)

32. a) Have you ever had sex with a male who has also had sex with another male?

- Yes
- No → **SKIP TO QUESTION 33a**
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you had sex with a male who has also had sex with another male?

- Yes
- No
- (Don't know)
- (Refuse to answer)



33. a) Have you ever had sex with anyone who has tested positive for hepatitis?

- Yes
- No → **SKIP TO QUESTION 34a**
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you had sex with anyone who has tested positive for hepatitis?

- Yes
- No
- (Don't know)
- (Refuse to answer)

34. a) Have you ever had sex or intercourse with anyone who has tested positive for HIV?

- Yes
- No → **SKIP TO QUESTION 35a**
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you had sex or intercourse with anyone who has tested positive for HIV?

- Yes
- No
- (Don't know)
- (Refuse to answer)

35. a) Have you ever had sex or intercourse with anyone who has received a blood transfusion?

- Yes
- No → **SKIP TO QUESTION 36a**
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you had sex or intercourse with anyone who has received a blood transfusion?

- Yes
- No
- (Don't know)
- (Refuse to answer)

Please read the following: *This next set of questions asks about any medical procedures you may have undergone or accidents you may have experienced that could have increased your risk for infection. I once again remind you that your answers are confidential.*

36. a) Have you ever received a blood transfusion?

- Yes
- No → **SKIP TO QUESTION 37**
- (Don't know)
- (Refuse to answer)

b) When was the last time you had a blood transfusion?

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37. Have you ever received a tissue or organ transplant?

- Yes
- No
- (Don't know)
- (Refuse to answer)

38. a) Have you ever had an endoscopy (a medical test where a flexible tube is used to look inside of your throat and digestive system) or a colonoscopy (a medical test where tube is used to look inside your colon/large intestine) ?

- Yes
- No → **SKIP TO QUESTION 39a**
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you had an endoscopy or a colonoscopy?

- Yes
- No
- (Don't know)
- (Refuse to answer)

c) When did you have your last endoscopy or colonoscopy?

Month			/	Year				
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39. a) Have you ever received an intravenous or intramuscular injection such as for anesthesia or for other medical treatment (including for surgery, and diagnostic scans) in any location where health care is provided? For this question, please exclude any dental treatments, vaccinations, and acupuncture you may have had.

- Yes
- No → **SKIP TO QUESTION 40a**
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you received an intravenous or intramuscular injection such as for anesthesia or for other medical treatment (including for surgery, and diagnostic scans) in any location where health care is provided? For this question, please exclude any dental treatments, vaccinations, and acupuncture you may have had.

- Yes
- No
- (Don't know)
- (Refuse to answer)

40. a) Have you ever received injections for dental procedures?

- Yes
- No → **SKIP TO QUESTION 41a**
- (Don't know)
- (Refuse to answer)



b) In the last 12 months, have you received injections for dental procedures?

- Yes
- No
- (Don't know)
- (Refuse to answer)

41. a) Have you ever received acupuncture?

- Yes
- No → **SKIP TO QUESTION 42a**
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you received acupuncture?

- Yes
- No
- (Don't know)
- (Refuse to answer)

42. a) Have you ever had 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) ?

- Yes
- No → **SKIP TO QUESTION 43a**
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you had a needle stick injury?

- Yes
- No
- (Don't know)
- (Refuse to answer)

43. a) Have you ever gotten someone else's blood, body fluids, vomit, or feces splashed into your eyes, mouth, or in an open skin wound?

- Yes
- No → **SKIP TO QUESTION 44a**
- (Don't know)
- (Refuse to answer)

b) In the last 12 months, have you gotten someone else's blood, body fluids, vomit, or feces splashed into your eyes, mouth, or in an open skin wound?

- Yes
- No
- (Don't know)
- (Refuse to answer)



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44. a) To the best of your knowledge, has anyone living in your household (including family or roommates) been infected with Hepatitis B virus or Hepatitis C virus?

- Yes
- No → **SKIP TO QUESTION 45**
- (Don't know)
- (Refuse to answer)

b) Can you tell me which person (s) is / are infected with Hepatitis B or C? (MARK ALL THAT APPLY)

- Mother
- Father
- Sister or brother
- Spouse (husband or wife) or significant other
- Child
- Another relative
- A roommate or close friend
- (Refuse to answer)

45. Is your family from or have they immigrated to the US from any of the following areas?

(MARK ALL THAT APPLY)

- Japan
- Other parts of Asia (Including India, China, Taiwan, Korea etc. and other countries in Asia)
- Africa
- The Caribbean
- South America
- (Don't know)
- (Refuse to answer)

Please read the following:

This is the last part of the questionnaire. In this part I will ask you about your current health and possible medical diagnoses you may have had.



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46. Please indicate which statements best describe your own health state today.
(Note to interviewer: please mark only one answer for each group below.)

a) Mobility

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

b) Self-Care

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

c) Usual Activities (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

d) Pain/Discomfort

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

e) Anxiety/Depression

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

Best imaginable health state

100

90

80

70

60

50

40

30

20

10

0

Worst imaginable health state

47. **READ to the donor:** To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0. Can you picture the thermometer I am describing in your mind? (Pause for the being interviewed to say yes, if the person says no, please re-read text) .

We would like you to indicate on a thermometer-like scale how good or bad your health is today, in your opinion. Please do this by telling me on a scale of 100 representing the best imaginable health state to 0 representing the worst imaginable health state, how good or bad your health state is today. (Interviewer: please mark response on the scale at right and in the box below.)

Your own health state today.

Please enter response:

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48. Have you ever been diagnosed with Chronic Fatigue Syndrome (sometimes called CFS or myalgic encephalopathy) as described here?

Chronic Fatigue Syndrome is characterized by persistent or recurrent fatigue, diffuse muscle and bone pain, sleep disturbances, and subjective cognitive impairment of 6 months duration or longer.

Symptoms are not caused by ongoing exertion; are not relieved by rest; and result in a substantial reduction of previous levels of occupational, educational, social, or personal activities.

Yes No

49. Have you ever been diagnosed with fibromyalgia?

Fibromyalgia is characterized by long-term, body-wide pain and tender points in joints, muscles, tendons, and other soft tissues, resulting in pain without weakness.

Yes No

Thank you for taking the time to complete this questionnaire. If you have any questions or concerns, you may ask me now. You can also contact Donor Counseling and Notification Services for more information at (800) 289-4923.