

I. Justification for Sensitive Questions

Blood donors in the United States are required by AABB (formerly the American Association of Blood Banks) and Food and Drug Administration to answer specific health and personal history questions and to read educational materials related to the signs and symptoms of HIV, transmission of infection by blood donation, withdrawing from blood donation and the importance of giving accurate information. Most blood centers in the United States have adopted the Uniform Donor History Questionnaire (UDHQ) as the format for asking or self-administering the health and personal history questions. A template of the current UDHQ follows as Attachment 5.3.

Post Donation Information (PDI) is directly related to the questions that every blood donor sees at each donation attempt. PDI is an error in the health history screening process that occurs when a donor gives health or personal information that permitted donation, but subsequently provides information that results in donor deferral. Most frequently, this deferral information was known by the donor but not disclosed. The reasons for non-disclosure are unclear. While a donor may reveal deferral history at the next donation, many donors continue to give multiple times before the deferral history is disclosed. Examples of histories that would have resulted in deferral if they had been disclosed include travel to malaria areas, certain medical conditions, medications, men having sex with men, IV drug use, and tattoo and piercing.

We will be asking donors about the specific question that resulted in their PDI and subsequent deferral. These questions will be no different than those already seen by the donor during their previous donations and latest donation attempt that resulted in deferral. We will also be asking questions related to their knowledge, attitudes, behaviors and beliefs relative to why the question is asked, if they read deferral and educational materials related to blood donation, their understanding of these materials and their experiences in the screening process and their interaction with blood center staff. Their responses will be compared with appropriately deferred (not PDI donors) donors who will experience the same type of interview questions and accepted donors. Appropriately deferred and accepted donors have likewise seen the health and personal history questions and educational materials during each and every donation event.

While Attachment 5.3 shows the required questions for donor qualification, we have further broken these questions into five broad categories. These categories of questions include Medical, Blood/Disease Exposure, Travel, High Risk Behavior-Sexual and High Risk Behavior-Non Sexual. This will facilitate analysis across the three groups of donors and allow us to identify differences based upon the kind of deferral history that is at some point finally disclosed.

	Question	Categories
Are you		
1	Feeling healthy and well today?	Medical
2	Currently taking an antibiotic?	

3	Currently taking any other medication for an infection?	
4	Are you now taking or have you ever taken any medications on the Medication Deferral List?	
In the past 48 hours		
6	Have you taken aspirin or anything that has aspirin in it?	
In the past 6 weeks		
7	Female donors: Have you been pregnant or are you pregnant now? (Males: check "I am male.")	
In the past 8 weeks have you		
8	Donated blood, platelets or plasma?	
9	Had any vaccinations or other shots?	
10	Had contact with someone who had a smallpox vaccination?	
In the past 16 weeks		
11	Have you donated a double unit of red cells using an apheresis machine?	
In the past 12 months have you		
12	Had a blood transfusion?	
13	Had a transplant such as organ, tissue, or bone marrow?	
14	Had a graft such as bone or skin?	
15	Come into contact with someone else's blood?	Blood/Disease Exposure
16	Had an accidental needle-stick?	
17	Had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?	High Risk behavior - Sexual
18	Had sexual contact with a prostitute or anyone else who takes money or drugs or other payment for sex?	
19	Had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything not prescribed by their doctor?	
20	Had sexual contact with anyone who has hemophilia or has used clotting factor concentrates?	
21	Female donors: Had sexual contact with a male who has ever had sexual contact with another male? (Males: check "I am male.")	
22	Had sexual contact with a person who has hepatitis?	
23	Lived with a person who has hepatitis?	High Risk Behavior – Non Sexual
24	Had a tattoo?	Blood/Disease Exposure
25	Had ear or body piercing?	
26	Had or been treated for syphilis or gonorrhea?	Medical
27	Been in juvenile detention, lockup, jail, or prison for more than 72 hours?	High Risk Behavior – Non Sexual
In the past three years have you		
28	Been outside the United States or Canada?	Travel
From 1980 through 1996,		
29	Did you spend time that adds up to three (3) months or more in the United Kingdom? (Review list of countries in the UK)	
30	Were you a member of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military?	
From 1980 to the present, did you		

31	Spend time that adds up to five (5) years or more in Europe? (Review list of countries in Europe.)	
32	Receive a blood transfusion in the United Kingdom or France? (Review list of countries in the UK.)	Blood/Disease Exposure
From 1977 to the present, have you		
33	Received money, drugs, or other payment for sex?	High Risk behavior - Sexual
34	Male donors: had sexual contact with another male, even once? (Females: check "I am female.")	
35	Had a positive test for the HIV/AIDS virus?	
36	Used needles to take drugs, steroids, or anything not prescribed by your doctor?	High Risk Behavior – Non Sexual
37	Used clotting factor concentrates?	Medical
38	Had hepatitis?	
39	Had malaria?	
40	Had Chagas' disease?	
41	Had babesiosis?	
42	Received a dura mater (or brain covering) graft?	
43	Had any type of cancer, including leukemia?	
44	Had any problems with your heart or lungs?	
45	Had a bleeding condition or a blood disease?	
46	Had sexual contact with anyone who was born in or lived in Africa?	High Risk behavior - Sexual
47	Been in Africa?	Travel
48	Have any of your relatives had Creutzfeldt-Jakob disease?	Medical

II. Question By Question Description and Purpose of Each Question Item

Introduction

Section I

Objective: The following questionnaire items are intended to confirm the interviewer has contacted the appropriate donor, confirmed their visit to the blood center, that they did give permission to have Westat contact them, and that they are giving permission to record the interview.

- Q1 Permission to contact verified and confidentiality of discussion stated. Date of donation visit at blood center.
- Q2 Provide opportunity to reschedule interview if needed
- Q3 Permission to record conversation
- Q3a Turning on tape recorder and confirmation of permission to record
- Q3b Continue without recording if permission refused.

Section II: Donation Experience

Objective: To understand the donor's motivation (s) to give blood

- Q4 Reasons for blood donation

Q5 How reasons to donate have changed over time

Q6 Reason for last donation

Section III: Educational Materials

Objective: This series of questions is intended to understand that the donor knew that they would need to meet certain eligibility requirements to donate. This section also seeks to know if they read the required educational materials on signs and symptoms of HIV, transmission of infection by blood donation, withdrawing from blood donation, and the importance of giving accurate information.

Q7 Did donor see eligibility requirements for blood donation?

Q7a When and where did donor see eligibility requirements?

Q7b Did donor read eligibility requirements?

Q8 Experience with reading eligibility requirements and previous donations.

Q8a Perceptions of familiarity with eligibility requirements and ease of understanding during previous donations

Q9 Did donor see educational materials for blood donation?

Q9a Did donor see educational materials regarding signs/symptoms of HIV?

Q9b Did donor see educational materials regarding infection transmission?

Q9c Did donor see educational materials regarding the importance of accurate information?

Q9d Did donor see educational materials regarding withdrawing from blood donation?

Q10 Did donor read and understand educational materials for blood donation?

Q11 Reading experience with educational materials and previous donations

Section IV: Process of taking health and personal histories

Objective: This series of questions is intended to understand the donor's knowledge and experience about the process of taking health and personal history

Q12 Recall the role of the health history screener

Q13 How was it different from previous donation experiences?

Q14 How did the donor feel about the health history screener?

Q15 What could a health history screener have done to make it a better experience?

Q16 What does the donor think about the health history screening questions?

Q17 Does the donor think it is necessary to ask these questions every time blood is donated?

Q18 Does the donor find any of these questions difficult to understand, uncomfortable to answer, inappropriate, or irrelevant?

- Q19 What does the donor do when not sure about the correct way to answer the questions?
- Q20 Why does the donor think donors omit information that could possibly result in a deferral?

Section V: Module questions specific for each reason

Objective: These questions apply to the types of deferrals or PDI errors that fall within the five categories of interest.

- Q21 Asks donor about the reason for their deferral and if there is anything about the question that caused them to answer differently with respect to an earlier donation(s).
- Q22 Additional information that will provide better understanding of blood donation screening experience

Section VI: Information about the donor

Objective: To obtain demographic data of the donors

- Q23 Level of education
- Q24 Occupation