

Date: December 2, 1999

To: AABB Institutional Members

From: Paul Ness, MD Karen Shoos Lipton, JD
 President Chief Executive Officer

Re: New Uniform Donor History Questionnaire Issued

The uniform donor history questionnaire has been prepared by the AABB Blood Bank/Transfusion Service Standards Program Unit of the Standards Program Committee. The AABB Board of Directors has charged this committee to update the questionnaire as needed to be consistent with AABB Standards and Food and Drug Administration (FDA) requirements. This version of the questionnaire supersedes the existing questionnaire, which was issued on June 12, 1998, as Association Bulletin #98-3. It was amended on February 16, 1999, in Association Bulletin #99-5. This revision complies with the 19th edition of *Standards for Blood Banks and Transfusion Services*.

The donor screening process is an important tool that is designed to help safeguard the nation's blood supply. It is imperative that screening be performed consistently to prevent unsuitable donor candidates from donating. The process must be comprehensive, comprehensible and educational.

The questions have been prepared to assist in developing uniform guidelines for blood donor screening nationwide. They have been carefully worded to convey content simply and briefly, and have been reorganized into logical groupings. Changes made since the last version reflect the deliberations and decisions of the Standards Program Committee and recent statements issued by the FDA. New questions have been added, cites have been updated and comments have been revised so it is recommended that blood establishments review this questionnaire in its entirety.

The FDA has reviewed and approved the questionnaire, which is in compliance with the current FDA regulations/recommendations for donor suitability. The FDA further stated that "when distributing this questionnaire to your membership, it would be prudent to remind them to use it *in toto, without modifications*." (Emphasis added by the AABB.)

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Licensed blood establishments need to report changes in the donor history questionnaire in accordance with 21 CFR 601.12 (Changes to an approved application). Implementation of the FDA-approved AABB uniform donor history questionnaire without modification is reported in an establishment's annual report (21 CFR 601.12(d)).

You may be aware that the donor screening process has come under increasing public scrutiny, and has been discussed at recent meetings of the FDA Blood Products Advisory Committee and the Public Health Service's Advisory Committee on Blood Safety and Availability. These discussions have focused on the need for uniform donor screening throughout the country.

Although the questionnaire is not an AABB requirement and is provided as a tool to help members with compliance on donor screening, the AABB strongly recommends that each member institution administer the questions, as written, as part of its donor screening process.

*AABB members may also view this document by going to the AABB Web site: www.aabb.org. In the Member section of the Web page, click on Library and see the Association Bulletin section.

** The first Association Bulletin of each calendar year provides a listing of Association Bulletins. For copies of AABB association policy statements, including the Technical Bulletins and Joint Statements, fax a request to the Executive Secretary in the AABB Executive Office, (301) 907-6895.

Donor History Questions.	American Association of Blood Banks (AABB)	Food and Drug Administration (FDA)	Comments
1. Have you ever donated or attempted to donate blood using a different (or another) name here or anywhere else?	Blood collection facilities shall confirm donor identity and link the donor to existing donor records. (Standard B2.100)	A record shall be available from which unsuitable donors may be identified so those products from such individuals will not be distributed. (21 CFR 606.160(e) April 1999)	
2. In the past 8 weeks, have you given blood, plasma or platelets here or anywhere else?	Frequency of whole blood donation is every eight weeks. (Standard B1.300)	Frequency of blood donation is every 8 weeks unless otherwise approved by the medical director (21 CFR 640.3(f) April 1999)	Infrequent plasma donors can donate every four weeks. (FDA Memos 3/10/95 and 12/14/95)
3. Have you for any reason been deferred or refused as a blood donor or told not to donate blood?	No specific requirement.	No specific requirement.	
4. Are you feeling well and healthy today?	The prospective donor shall appear to be in good health. (Standard B2.000)	Donor must be determined to be in good general health. (21 CFR 640.3(b) April 1999)	Requires "yes" answer that tests donor's attention to question context. Inflates sequence of personal health history questions (4-13).
5. In the past 12 months have you been under a doctor's care or had a major illness or surgery?	No specific requirements.	Persons who have received a transfusion of whole blood or a blood component within the past 12 months should not donate blood or blood components. (FDA Memo 4/23/92)	
6. Have you ever had chest pain, heart disease, recent or severe respiratory disease?	Prospective donors with diseases of the heart or lungs should be excluded unless determined to be suitable to donate by the blood bank medical director. (Standard B1.700)	Donor must be free of acute respiratory disease. (21 CFR 640.3(b)(4) April 1999)	
7. Have you ever had cancer, a blood disease or a bleeding problem?	Prospective donors with a history of cancer or abnormal bleeding tendency shall be excluded unless determined to be suitable to donate by the blood bank medical director. (Standard B1.700)	Persons with hemophilia or related clotting disorders who have received clotting factor concentrates must not donate blood or blood components. (FDA Memo 4/23/92)	
8. Have you ever had yellow jaundice, liver disease, viral hepatitis or a positive test for hepatitis?	Prospective donors with diseases of the liver shall be excluded unless determined to be suitable to donate by a blood bank physician. (Standards B1.700) Donors with a history of hepatitis after their 11 th birthday or a confirmed test for HbsAg or a repeatedly reactive test for anti-HBc are indefinitely deferred. (Standard B2.711)	No individual with a history of hepatitis shall be source of whole blood donation. (21 CFR 640.3(c) April 1999) Exemptions for history of hepatitis before age 11. (FDA Memos 4/23/92 and 12/22/93)	
9. Have you ever had malaria, Chagas' disease or	Prospective donors who have had a diagnosis of	Prospective donors who have had malaria should	

<p>babesiosis?</p>	<p>malaria shall be deferred for 3 years after becoming asymptomatic. (Standard B2.741) A history of babesiosis or Chagas' disease shall be cause for indefinite deferral. (Standard B2.750)</p>	<p>be deferred for 3 years after becoming asymptomatic. (FDA Memo 7/26/94⁵)</p>	
<p>10.</p> <p>A. Have you ever taken etretinate (Tegison) for psoriasis?</p> <p>B. In the past 3 years, have you taken Acitretin (Soriatane)?</p> <p>C. In the past 36 hours, have you taken aspirin, or anything that has aspirin in it?</p> <p>D. In the past month, have you taken isotretinoin (Accutane) or finasteride (Proscar) (Propecia)?</p> <p>E. In the past 4 weeks, have you taken any pills or medications?</p> <p>1. Have you at any time since 1980 injected bovine (beef) insulin?</p>	<p>A. People who have received etretinate shall be deferred indefinitely. (Standard B2.520)</p> <p>B. Donor is to be Deferred for 3 years From date of last use. (Standard B2.520)</p> <p>C. Ingestion within 36 hours of donation of medications known to irreversibly damage platelet function (eg, aspirin-containing medications) or that inhibit platelet function and have a prolonged half-life should preclude the use of donor as the sole source of platelets for a recipient. (Standard B2.510)</p> <p>D. For Accutane, Proscar, or Propecia, donor is to be deferred for 1 month after receipt of last dose. (Standard B2.520)</p> <p>E. Drug therapy shall be evaluated by a qualified person to determine suitability to donate blood. (Standard B1.900)</p>	<p>A. A donor who has taken or is taking Tegison should be permanently deferred. (FDA Memo 7/28/93⁷)</p> <p>B. Donor is to be deferred for 3 years from date of last dose (per manufacturer's insert.)</p> <p>C. No specific requirement for whole blood donation. Donors who have recently taken medication containing aspirin, especially within 36 hours, may not be suitable donors for platelet pheresis. (FDA Guidelines 10/7/88⁶)</p> <p>D. A donor taking Accutane or Proscar should be deferred from donating blood for at least one month after receipt of the last dose. (FDA Memo 7/28/93⁷)</p> <p>A donor taking Propecia should be deferred for one month. (FDA Telephone Communication to AABB, January 1998.)</p> <p>E. Facility medical director to determine donor acceptability or deferral based on medications. (FDA Memo 7/28/93⁷)</p> <p>1. As a precaution, the FDA recommends that blood donors who have injected bovine insulin since 1980 be indefinitely deferred unless it has been established that the</p>	<p>A. Potentially teratogenic; may be present up to 3 years after last use.</p> <p>B. Potentially teratogenic. May be present up to 3 years after last use.</p> <p>C. Preferred time varies. May be mandated by state health and safety code.</p> <p>D. Medication questions grouped.</p> <p>E. Medication questions grouped.</p> <p>If donor answers "yes" to this question, see #1 below.</p> <p>1. If the donor answers "yes" or "don't know" to the question, the FDA recommends that the donor be indefinitely deferred, unless it has been established that the product</p>

		product was not manufactured since 1980 from cattle in the United Kingdom. (FDA Guidance for Industry, 11/23/99 ³)	was not manufactured since 1980 from cattle in the United Kingdom. The FDA recommends that blood establishments review their policies regarding acceptance of insulin dependent diabetic patients as donors and their donor history questions to determine if or at which point in the interview process this question should be asked. The AABB recommends, however, that blood establishments maintain the current order to ensure uniformity of the questionnaire.
11. In the past 4 weeks, have you had any shots or vaccinations?	Donors must be queried about vaccines and immunizations. (Standard B2.600)	No specific requirement.	
12. In the past 12 months, have you been given rabies shots?	Donor is deferred for 12 months after vaccine for rabies if immunization is given after bite or other exposure to a potentially rabid animal. (Standard B2.600)	No specific requirement.	
13. Female donors: In the past 6 weeks, have you been pregnant or are you pregnant now?	Existing pregnancy or pregnancy in the past 6 weeks is cause for deferral. (Standard B1.800)	No specific requirement.	
14 A. In the past 3 years, have you been outside the United States or Canada?	A. Residents of countries in which malaria is not considered endemic but who have been in an area in which malaria is considered endemic may be accepted as regular blood donors one year after return irrespective of the receipt of antimalarial prophylaxis. (Standard B2.743) Immigrants, refugees or citizens coming from a country in which malaria is considered endemic may be accepted as blood donors 3 years after departure. (Standard B2.742)	A. Travelers to an area considered endemic for malaria should not be accepted as donors of whole blood and blood components prior to one year after departure. After one year, donors free of unexplained symptoms suggestive of malaria may be accepted whether or not they have received antimalarial chemoprophylaxis. Immigrants, refugees and citizens of endemic countries should not be accepted as donors prior to 3 years after departure. After 3 years, donors free of unexplained symptoms suggestive of malaria may be accepted. (FDA Memo 7/26/94 ⁶)	A. Initiates sequence of exposure-type questions (14-30).
B. Have you visited or lived in the United		B. The FDA believes that donors who have	B. The FDA recommends that within a facility,

<p>Kingdom (England, Northern Ireland, Scotland, Wales, the Isle of Man or the Channel Islands) from 1980 to 1996? If so, have you spent a total of six months or more from 1980 through 1996?</p>		<p>resided in the United Kingdom (as identified by these questions) may be at risk for acquiring nvCJD. As a precaution, the FDA recommends that donors who answer "yes" to this question be indefinitely deferred. (FDA Guidance for Industry 11/23/99⁶)</p>	<p>current donors need only be questioned once, and new donors questioned at first donation only.</p>
<p>15</p> <p>A. Have you ever received human pituitary-derived hormone?</p> <p>B. Have you received a dura mater (or brain covering) graft?</p> <p>C. Have you or any of your blood relatives ever had Creutzfeldt-Jakob disease or have you ever been told that your family is at an increased risk for Creutzfeldt-Jakob disease?</p>	<p>A. Prospective donors who have a family history of Creutzfeldt-Jakob disease or who have received tissue or tissue derivatives known to be a possible source of Creutzfeldt-Jakob agent (eg, dura mater, pituitary growth hormone of human origin) shall be deferred indefinitely. (Standard B2.410)</p>	<p>A. The FDA recommends that any donor who has received injections of pit-hGH be permanently deferred. (FDA Memo 7/28/93⁷, Guidance for Industry 11/23/99⁸.)</p> <p>B. The FDA recommends that persons who have received transplants of dura mater be permanently deferred from donation. (FDA Guidance for Industry 11/23/99⁸.)</p> <p>C. The FDA recommends that donors at increased risk for CJD be indefinitely deferred and appropriately counseled. The FDA considers that donors who answer "yes" to any of these questions (15 a, b, or c) are at an increased risk for developing CJD. (FDA Guidance for Industry 11/23/99⁸.)</p>	<p>A. If the donor is uncertain about his or her treatment, the following question may be asked: Was the hormone treatment given repeatedly by injection? Donors who answer "yes" should be deferred.</p> <p>C. If the donor is not familiar with the term Creutzfeldt-Jakob disease, this may be taken as a negative response. If the donor is deferred because of family history (one or more family members with CJD), that donor may be re-entered if they meet FDA reentry criteria. (FDA Guidance for Industry 11/23/99⁸)</p>
<p>16. In the past 12 months, have you had close contact with a person with yellow jaundice or viral hepatitis, or have you been given Hepatitis B Immune Globulin (HBIG)?</p>	<p>Close contact with person who has viral hepatitis is a 12 month deferral. (Standard B2.724)</p>	<p>Close contact with person who has viral hepatitis is a 12 month deferral. (FDA Memo 4/23/92¹⁰)</p>	<p>Close contact generally refers to cohabitation. The medical director should establish a policy for these potential donors. The FDA does not recommend deferral of a sexual partner of an HCV antibody positive individual. (FDA Communication to AABB, August 1999)</p>
<p>17. In the past 12 months, have you taken (snorted)</p>	<p>Intranasal use of cocaine is a 12-month deferral.</p>		

cocaine through your nose?	(Standard B2.727)		
18. In the past 12 months, have you received blood or had an organ or tissue transplant or graft?	Prospective donors who during the preceding 12 months received blood, blood components or derivatives, or other human tissue known to be possible sources of blood-borne pathogens, shall be excluded. (Standards B2.420, B2.430)	Persons who have received a transfusion of whole blood or a blood component within the past 12 months should not donate blood or blood components. (FDA Memo 4/23/92)	Includes Immunization with RBCs.
19. In the past 12 months, have you had a tattoo applied, ear or skin piercing, acupuncture, accidental needlestick or come in contact with someone else's blood?	Prospective donors shall be deferred from donating blood or blood components for transfusion who, within the preceding 12 months, have a history of: 1) A tattoo. 2) Mucous membrane exposure to blood. 3) Nonsterile skin penetration with instruments or equipment contaminated with blood or body fluids. 4) Sexual or household contact with an individual with viral hepatitis. 5) Sexual contact with an individual with HIV or at high risk of HIV infection. (Standards B2.721, B2.722, B2.723, B2.724, B2.725)	Persons who have had any contact with blood and body fluids through percutaneous inoculation (such as injury or accidental needlestick) or through contact with an open wound, non-intact skin or mucous membrane during the preceding 12 months should be deferred. (FDA Memo 4/23/92)	
20. A. In the past 12 months, have you had a positive test for syphilis? B. In the past 12 months, have you had or been treated for syphilis or gonorrhea?	A history of syphilis or gonorrhea, treatment for either, or a reactive screening test for syphilis shall be cause for deferral for 12 months after completion of therapy. (Standard B2.340)	Persons who have had, or have been treated for, syphilis or gonorrhea during the preceding 12 months should not donate blood or blood components. Persons with a positive (STS) test should be deferred 12 months. (FDA Memo 12/12/91 ¹¹)	
21. In the past 12 months, have you given money or drugs to anyone to have sex with you?	Donor must be given educational material on AIDS high-risk activity, and such at-risk persons should refrain from donating blood. Donor screening shall include questions intended to identify persons at high risk for HIV infection and high risk for HIV transmission. Such high-risk persons shall be deferred as specified in FDA recommendations. (Standards B3.100, B2.730)	Men and women who have engaged in sex for money or drugs since 1977 and persons who have engaged in sex with such people during the preceding 12 months should not donate blood or blood components. (FDA Memo 4/23/92)	
22. A. At any time since 1977, have you taken money or drugs for sex? B. In the past 12 months, have you had sex, even once, with anyone who has taken money or drugs	Refer to question #21	Men and women who have engaged in sex for money or drugs since 1977 and persons who have engaged in sex with such people during the preceding 12 months should not donate blood or blood components. (FDA Memo 4/23/92)	

for sex?			
<p>23.</p> <p>A. Have you ever used a needle, even once, to take drugs that were not prescribed by a doctor?</p> <p>B. In the past 12 months, have you had sex, even once, with anyone who has used a needle to take drugs not prescribed by a doctor?</p>	<p>A. Stigmata of narcotic habituation is an indefinite deferral. The donor shall not have used a needle even once to take drugs other than those prescribed by his/her physician. (Standard B2.330)</p> <p>B. Refer to question #21.</p>	<p>A. Donor must be free from skin punctures or scars indicative of addiction to self-injected narcotics. (21 CFR 640.3(b)(7) April 1999) Past or present intravenous drug users should not donate blood or blood components. (FDA Memo 4/23/92)</p> <p>B. Persons who have had sex with any person who is a past or present intravenous drug user should not donate blood or blood components for 12 months. (FDA Memo 4/23/92)</p>	
<p>24. Male donors: Have you had sex with another male, even once, since 1977?</p>	<p>Refer to question #21.</p>	<p>Men who have had sex with another man, even one time, since 1977 should not donate blood or blood components permanently. (FDA Memo 4/23/92)</p>	
<p>25. Female donors: In the past 12 months, have you had sex with a male who has had sex, even once, since 1977 with another male?</p>	<p>Refer to question #21.</p>	<p>Females who have had sex with men who have had sex with another man even one time since 1977 should not donate blood or blood components for 12 months. (FDA Memo 4/23/92)</p>	
<p>26.</p> <p>A. Have you ever taken clotting factor concentrates for a bleeding problem, such as hemophilia?</p> <p>B. In the past 12 months, have you had sex, even once, with anyone who has taken clotting factor concentrates for a bleeding problem such as hemophilia?</p>	<p>No specific requirement.</p>	<p>A. Persons with hemophilia or related clotting disorders who have received clotting factor concentrates should not donate blood or blood components. (FDA Memo 4/23/92)</p> <p>B. Persons who have had sex with any person with hemophilia or related clotting disorders who have received clotting factor concentrates should not donate blood or blood components for 12 months. (FDA Memo 4/23/92)</p>	
<p>27.</p> <p>A. Do you have AIDS or have you had a positive test for the AIDS virus?</p>	<p>Refer to question #21.</p>	<p>A. Persons with clinical or laboratory evidence of HIV infection must not donate blood or blood components. (FDA Memo 4/23/92)</p>	

<p>B. In the past 12 months, have you had sex, even once, with anyone who has AIDS or has had a positive test for the AIDS virus?</p>		<p>B. Persons who have had sex with persons with clinical or laboratory evidence of HIV infection should not donate blood for 12 months. (FDA Memo 4/23/92)</p>	
<p>28. Are you giving blood because you want to be tested for HIV or the AIDS virus?</p>	<p>No specific requirement.</p>	<p>No specific requirement.</p>	<p>Direct question to further evaluate donation motive.</p>
<p>29. Do you understand that if you have the AIDS virus, you can give it to someone else even though you may feel well and have a negative AIDS test?</p>	<p>No specific requirement.</p>	<p>Donors should be informed that there is an interval during early infection when the HIV antibody test may be negative although the infection may still be transmitted. (FDA Memo 4/23/92)</p>	<p>Queries donor understanding of "Important Information for Donors."</p>
<p>30. A. Were you born in, have you lived in, or have you traveled to any African country since 1977? C. When you traveled to <country(ies)> did you receive a blood transfusion or any other medical treatment with a product made from blood? D. Have you had sexual contact with anyone who was born in or lived in any African country since 1977?</p> <p>30. Continued</p>	<p>(Association Bulletin #97-5¹³)</p>	<p>(FDA Memo 12/11/96¹⁴)</p>	<p>A. If "no," proceed to the question (question c) about sexual contact.</p> <p>If "yes," the donor should be asked to name the specific country(ies). If the donor identifies an African country not listed in the FDA Memo, proceed to question C. If one or more of the countries listed in the FDA Memo is named by the donor, determine if the donor was born in, lived in, or traveled to the country(ies) named by the donor. If the donor was born in or lived in any of the FDA-identified countries, defer indefinitely; questioning stops here. If travel was the donor's risk, ask question B.</p> <p>The Central African Republic was the Central African Empire in the late 1970s. None of the other countries listed in the FDA Memo have undergone a change in name since 1977.</p> <p>Blood establishments should critically evaluate the potential donor's history and statements; and decide whether the individual could have been in the country long enough to have encountered those local conditions related to risk, such as use of unsterile needles or sexual contact.</p> <p>When donors report demographic HIV-1 Group O risks, no follow-up actions</p>

			<p>regarding previously donated blood are necessary.</p> <p>A. If "no," proceed to Question c.</p> <p>If "yes," defer indefinitely.</p> <p>B. If "no," or the donor names a country not identified in the FDA Memo, no deferral.</p> <p>If "yes," ask the donor to specify which country(ies). If donor names country listed in the FDA Memo, defer indefinitely.</p>
<p>31. In the past 12 months, have you been in jail or prison?</p>	<p>Donors are deferred for 12 months if in the preceding 12 months they have been incarcerated in a correctional institution (jail or prison) for more than 72 consecutive hours. (Standard B2.726)</p>	<p>Individuals who have been incarcerated for more than 72 consecutive hours during the previous 12 months should be deferred as donors for 12 months from the last date of incarceration. (FDA Memo 6/8/95¹⁴)</p>	
<p>32. Have you read and understood all the donor information presented to you, and have all your questions been answered?</p>	<p>No specific requirement.</p>	<p>Information should be written in language that assures that the donor understands the definition of high-risk behavior and the importance of self-exclusion. Donors should not be considered suitable unless information about risks can be communicated in the language appropriate to each donor and is constructed to be culturally sensitive to promote comprehension. (FDA Memo 4/23/92⁵)</p>	

Standards referred to are from the 19th edition of *Standards for Blood Banks and Transfusion Services*, effective June 1, 1999.

1. FDA Memorandum, March 10, 1995; Revision of FDA Memorandum of August 27, 1982: Requirements for Infrequent Plasma Donors.
2. FDA Memorandum, December 14, 1995: Donor Deferral Due to Red Blood Cell Loss During Collection of Source Plasma.
3. FDA Memorandum, April 23, 1992: Revised Recommendations for the Prevention of HIV Transmission by Blood and Blood Products.
4. FDA Memorandum, April 23, 1992: Exemptions to Permit Persons with a History of Viral Hepatitis Before the Age of Eleven Years to Serve as Donors of Whole Blood and Plasma: Alternative Procedures, 21 CFR 640.12D.
5. FDA Memorandum, December 22, 1993: Donor Suitability Related to Laboratory Testing for Viral Hepatitis and a History of Viral Hepatitis.
6. FDA Memorandum, July 26, 1994: Recommendation for Deferral of Donors for Malaria Risk.
7. FDA Memorandum, July 28, 1993: Deferral of Blood and Plasma Donors Based on Medications.
8. FDA Memorandum, October 7, 1988; Revised Guidelines for the Collection of Platelets, Pheresis.
9. Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products. November 23, 1999.
10. FDA Memorandum, April 23, 1992: Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV).

11. FDA Memorandum, December 12, 1991: Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing.
12. FDA Memorandum, December 11, 1996: Interim Recommendations for Deferral of Donors at Increased Risk for HIV-1 Group O Infection.
13. FDA Accepts AABB Changes to HIV-1 Group O Donor Questions, Association Bulletin #97-5, August 1, 1997.
14. FDA Memorandum, June 8, 1995: Recommendations for the Deferral of Current and Recent Inmates of Correctional Institutions as Donors of Whole Blood, Blood Components, Source Leukocytes, and Source Plasma.