

**ATTACHMENT 1**  
**Simplified Blood Donor Screening Questions**

Current Question	Proposed Revision	Rationale for Changes
2. In the past 8 weeks have you given blood, plasma, or platelets here or anywhere else?	A. In the past 8 weeks have you given blood, platelets, or plasma? B. In the past 16 weeks have you given double red cells?	"..here or anywhere else" wording dropped - proposed wording should capture recent donation activity. <i>Part B added to capture donors who have donated dual red cells by apheresis - if added to part A, would become too complex</i>
4. Are you feeling well and healthy today?	Are you feeling well today?	Eliminate redundancy
<u>General medical questions</u> 5. In the past 12 months have you been under a doctor's care or had a major illness or surgery? 6. Have you had chest pain, heart disease, recent or severe respiratory disease? 7. Have you ever had cancer, a blood disease, or a bleeding problem?	Have you ever had any type of cancer, including leukemia? <i>Have you ever had any problem with your heart and/or lungs?</i> Have you ever had a bleeding condition or a blood disease? <i>Have you had any medical conditions listed on the Medical Deferral list?</i>	Question 5 was an AABB-derived question to capture history of transfusion in past twelve months; a specific question to address recent transfusions will be included. <i>Avoid multi-item format and group conditions together more appropriately</i> Focus on specific disease conditions required by AABB Standards or FDA documents <i>"Medical Deferral List" optional; to include conditions of interest to local medical director that are not already listed on questionnaire.</i>
8. Have you ever had yellow jaundice, liver disease, viral hepatitis, or a positive test for hepatitis?	Have you ever had hepatitis?	Gets directly to the heart of regulatory intent: to identify prospective donors with history of hepatitis. Per 12/22/93 FDA memorandum, donors are not deferred at time of screening if they give a history of reactive hepatitis tests but <del>never had a clinical diagnosis of hepatitis</del>
9. Have you ever had malaria, Chagas' disease, or babesiosis?	Have you ever had malaria? Have you ever had a) Chagas' disease? B) Babesiosis?	Simplification
10. Parts A-E ask collectively about Tegison, Soriatane, aspirin in past 36 hours, Accutane, Proscar, Propecia, medications taken in past 4 weeks (with a specific inquiry about bovine insulin for insulin-dependent diabetics)	<u>At the time of screening, donors will be given a list of FDA-deferrable meds and asked:</u> "Are you taking any medications on the medication list?" <u>Also will be asked:</u> "Are you currently taking an antibiotic or any other medication for an infection?" "In the past 36 hours have you taken aspirin or anything that has aspirin in it?"	Shortens the 5 part, multi-item question to a more simplified form. Use of a medication list will obviate the need to add new items to the questionnaire itself, while meeting any new regulatory requirements. The medication list will incorporate educational information about the medications, the reason for the deferral, and deferral periods. <i>Specific question about anti-microbials important for identifying potentially bacterially infected donors.</i> ASA question retained
11. In the past four weeks have you had any shots or vaccinations?	No changes recommended	

13. Female donors: In the past 6 weeks have you been pregnant or are you pregnant now?	Female donors: Are you pregnant?	Simplification (please see Attachment 2 for rationale)
14A. In the past 3 years have you been outside the United States or Canada? 14B. Have you visited or lived in the United Kingdom <names of countries> from 1980-1996? If so, have you spent a total of six months or more from 1980-1996?	14A. No changes recommended 14B. Between 1980 through 1996, did you spend time in the United Kingdom that adds up to six months or more? <names of countries>	14B: Simplification
<u>CJD</u> 15A. Have you ever received human pituitary derived growth hormone? 15B. Have you ever received a dura mater (or brain covering) graft? 15C. Have you or any of your blood relatives ever had [CJD] or have you ever been told that your family is at increased risk for [CJD]	15A. Will be added to the medication list and removed from the card proper (along with bovine insulin). 15B. No change recommended 15C. Have any of your relatives ever had [CJD]?	15C. The crux of this question is family history or risk of CJD, and the wording is revised to reflect that. It is highly unlikely that a person with CJD would present to donate, and, since clinical symptomatology is the basis for a diagnosis, symptoms would be likely be evident at the time of presentation, leading to a deferral.
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?)	<u>Split:</u> A. In the past twelve months have you come into contact with blood or saliva from, or had sexual contact with, a person who has hepatitis? B. In the past 12 months have you been given hepatitis immune globulin (HBIG) (NOTE: This is not the same as the hepatitis B vaccine)	According to the Fall 2000 AABB Survey of Blood Centers, the original apples-and-oranges compound question confused donors; survey respondents and Focus Groups suggested splitting the HBIG portion from the contact portion. <i>Part A was expanded to enumerate activities that constitute "close contact"</i>
18. In the past 12 months have you received blood or had an organ or a tissue transplant or graft?	<u>Split:</u> A. In the past 12 months have you had a blood transfusion or received clotting factor concentrates? B. In the past 12 months have you had a transplant such as organ, tissue, or bone marrow? C. In the past 12 months, have you had a graft such as bone or skin?	Numerous kinds of exposures possible. Broken up to simplify. The 12 month clotting factor deferral is consistent with CFR changes that limit the deferral period for possible exposure to hepatitis through clotting factor concentrates to 12 months. Whole blood and source plasma donors now undergo HIV antigen and NAT testing; source plasma undergoes chemical and other viral inactivation processes.
19. In the past 12 months have you had a tattoo applied, ear or skin piercing, acupuncture, accidental needlestick, or come into contact with someone else's blood?	<u>Split:</u> A. In the past 12 months have you had a tattoo applied or ear or skin piercing (including acupuncture?) B. In the past 12 months have you had an accidental needlestick or come into contact with someone else's blood?	Simplification from compound question into its elements

<p>20A. In the past twelve months have you had a positive test for syphilis?</p> <p>20B. In the past 12 months have you had or been treated for syphilis or gonorrhea?</p>	<p>A. Eliminate</p> <p>B. No changes recommended</p>	<p>Part A: Please see Attachment 2 for rationale</p>
<p><u>Money-sex exchange:</u></p> <p>21. In the past 12 months have you given money or drugs to anyone to have sex with you?</p> <p>22A. At any time since 1977 have you taken money or drugs for sex?</p> <p>22B. In the past 12 months have you had sex, even once, with anyone who has taken money or drugs for sex?</p>	<p><u>Rearrange, reword, and combine into two questions:</u></p> <p>A. In the past 12 months have you had sex with a prostitute or anyone who takes money, drugs, or other payment for sex?</p> <p>B. Since 1977 have you ever received money, drugs, or other payments for sex?</p>	<p>Simplifies while simultaneously addressing giving and receiving of money for sex.</p> <p><i>While recognizing that use of the word "prostitute" constitutes a label rather than behavior (although behavior is addressed in the question), Task Force survey design experts believe that "prostitute" is understood by most people and would be more likely to trigger a positive response from the target group.</i></p>
<p>23A. Have you ever used a needle, even once to take drugs that were not prescribed by a doctor?</p> <p>23B. In the past twelve 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. Have you ever used needles to take drugs, steroids, or anything else not prescribed by your doctor?</p> <p>B. In the past 12 months, have you had sex with anyone who has ever used needles to take drugs, steroids, or anything else not prescribed by their doctor?</p>	<p>Expands the spectrum of non-prescribed injected substances</p>
<p>24. Male donors: Have you had sex with another male, even once, since 1977?</p>	<p>Male donors: Since 1977 have you ever had sex with another male?</p>	<p>Puts focus on the timeframe; "even once" redundant when "ever" is used, and thus has been removed.</p>
<p>25. Female donors: In the past 12 months, have you had sex with another male who has had sex, even once, since 1977 with another male?</p>	<p>Female donors: In the past 12 months have you had sex with a male who has ever had sex with another male?</p>	<p>Simplified, and will capture the "since 1977" cohort of at-risk male partners.</p>
<p>26A. Have you ever taken clotting factor concentrates for a bleeding problem such as hemophilia?</p> <p>26B. 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>A. Covered in revised question 18</p> <p>B. In the past 12 months have you had sex with anyone who has hemophilia or has used clotting factor concentrates?</p>	<p>26B. Simplifies the current version.</p>
<p>27A. Do you have AIDS, or have you had a positive test for the AIDS virus?</p> <p>27B. 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>A. Have you ever had a positive test for the HIV/AIDS virus?</p> <p>B. In the past 12 months, have you had sex with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?</p>	<p>Reference to the clinical diagnosis "AIDS" removed, because a positive test would suggest HIV infection</p>

<p><u>Africa</u></p> <p>30A. Were you born in, have you lived in, or have you traveled to any African country since 1977?</p> <p>30B. (If "yes" to A).When you traveled to &lt;country&gt; did you receive a blood transfusion or any other medical treatment with a product made from blood?</p> <p>C. Have you had sexual contact with anyone who was born in or lived in any African country since 1977?</p>	<p>A. (Capture question). Have you ever been in Africa?</p> <p>B. (If "yes" to A). While you were there, did you receive a blood transfusion or have any other exposure to blood?</p> <p>C. Have you ever had sex with anyone who was born in or lived in Africa?</p>	<p>A. Simplification.</p> <p>B. Focus Group feedback indicated that meaning of the original wording was lost on participants.</p> <p>C. Simplification</p> <p>NOTE: Affirmative responses to A and/or C would be followed up with additional questions, which would be described in SOPs. (Instructions to ask follow-up questions will appear in the "User's Pamphlet.")</p>
<p>31. In the past 12 months have you been in jail or prison?</p>	<p>In the past 12 months have you been in juvenile hall, lock-up, jail, or prison?</p>	<p>Per Focus Groups, covers a broader spectrum of incarceration scenarios</p>

UDHQTFSummary forJayEpstein1(4.24.01)