Guidance for Industry

Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components

DRAFT GUIDANCE

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Additional copies of this draft guidance are available from the Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or from the Internet at http://www.fda.gov/cber/guidelines.htm.

For questions on the content of this guidance, contact Judy Ellen Ciaraldi in the Division of Blood Applications, OBRR, CBER, at 301-827-3543.

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Contains Nonbinding Recommendations

Draft – Not for Implementation

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate FDA staff. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

The Food and Drug Administration (FDA) is recognizing that the full-length donor history questionnaire and accompanying materials (Version No. 1, dated April 2004) prepared by the Interorganizational Uniform Donor History Questionnaire Task Force is an acceptable mechanism to collect the donor information required by manufacturers that collect human blood and blood components (referred to as "manufacturers" or "you"). The April 2004 Task Force's full-length donor history questionnaire and its accompanying materials are referred to as "DHQ documents" in this guidance. They provide a specific process for administering questions to donors of human blood and blood components (referred to as "donors") to determine their eligibility to donate consistent with FDA requirements and recommendations. The FDA, Center for Biologics Evaluation and Research (CBER) (referred to as "we"), believes that the DHQ documents will assist licensed and unlicensed manufacturers, in complying with the donor suitability requirements in 21 CFR Part 640.

This guidance also advises licensed manufacturers how to report the change to implement the DHQ documents described in this guidance to FDA under 21 CFR 601.12, "Changes to an Approved Application," and what information they should submit. Unlicensed registered manufacturers implementing the use of the DHQ documents described in this guidance do not need to report this change to FDA.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidelines describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A donor's eligibility to donate blood and blood components is determined in part by a physical assessment and medical history interview to determine whether the donor is free of any disease transmissible by blood transfusion (§§ 640.3 and 640.63). The first formal uniform donor screening questionnaire was developed in 1953 (Ref. 1). Since then, the number of questions and the amount of information captured during the questioning process has increased in order to capture information related to newly recognized risks of disease transmission, resulting in an increasingly complex and time-consuming process.

The primary purposes of questioning the donor are to ensure that the donation process is safe for the donor and to identify risk factors for diseases transmissible by blood and blood components. The donor interview is especially important to identify risks for diseases and conditions for which there are no laboratory tests, for which tests are not sensitive enough to detect infectious disease agents and for which tests are unable to identify early stage or window period infections.

Donor questionnaires play an important role in identifying most ineligible donors, but we are aware that the donor questionnaire processes currently in place at U.S. blood collection establishments do not prevent all ineligible donors from donating. This is evidenced by the numerous biological product deviation reports submitted to CBER each year related to errors in capturing information and identifying ineligible donors during the donor questioning process (Ref. 2).

In 2000, the American Association of Blood Banks (AABB) convened a multi-organizational task force to address several issues related to the donor questionnaire process. Goals of the task force included reducing the complexity of the questionnaire and the educational materials to assure that donors will better comprehend the information and provide more accurate responses. The task force consisted of representatives from the blood and plasma industry and professional trade organizations. The task force also included an ethicist, statistician, experts in survey design and cognitive methods, and liaisons from the Center for Disease Control and Prevention and FDA. In October 2000, FDA and AABB also co-sponsored a workshop on "Streamlining the Blood Donor History Questionnaire" to discuss specific methods to streamline the donor screening process. Topics discussed included more effective wording and validation of the questions.

The task force revised and redesigned the pre-existing AABB UDHQ and developed a new process for interviewing donors. The new process includes use of the following methods and materials to obtain information about a donor. The materials are intended to be used in their entirety.

- Full-Length Donor History Questionnaire – contains all donor screening questions.
- User Brochure for the full-length questionnaire, including a glossary, flow charts and references – describes how questions should be administered and contains follow-up questions to further evaluate a potential donor's response to capture questions.

("Capture" questions ask a general question about a donor's history or behavior and are followed up by more specific questions if needed.)

- Medication Deferral List – companion document to the questionnaire that contains a list of medications that may serve as a basis for donor deferral.
- Blood Donor Educational Materials – educates the donor about the donation process and risks and conditions that are the basis for deferrals.

The task force developed and evaluated new questions to determine if donors could comprehend them and provide correct information. Focus group studies showed that questions should be simple and focus on one behavior rather than ask about several different behaviors, and that some terms required clarification in order to enhance donor comprehension (Ref. 3). Cognitive interview studies provided information on recall, suggested that questions be reasonably specific, and indicated that individuals tended to answer the questions conservatively, even if they did not always interpret the questions uniformly. The results of the tests showed that there is a need to educate donors about why certain behaviors put them at risk to transmit diseases to recipients. Blood donor interviewers in several blood collection establishments also evaluated the final questioning process. The blood collection establishments stated that the new process for asking questions and for providing information to the donors was an effective, easy-to-use tool (Ref. 4).

We discussed the new donor questionnaire process during several Blood Product Advisory Committee (BPAC) meetings. Informational presentations were given during the BPAC meeting held on June 14, 2001. These presentations described the task force activities, the new questionnaire process developed by the task force, and the focus group study design (Ref. 5). The progress of the task force's activities and the results of the cognitive studies were presented during the BPAC meeting held on June 13, 2002 (Ref. 6). The BPAC unanimously supported the task force's efforts at each meeting.

III. FDA REVIEW AND CONCLUSIONS

We believe that adherence to the following DHQ procedures prepared by the task force, Version No. 1 (v.DHQ-1) (Appendices 1 – 7), would provide adequate measures to meet FDA requirements related to donor eligibility.

- Full-Length Donor History Questionnaire
- Donor History Questionnaire User Brochure, including:
  - Glossary
  - Flow Charts
  - References
- Medication Deferral List
- Blood Donor Educational Materials

These DHQ documents contain questions related to the following issues for which we currently do not have requirements or recommendations: cancer; organ, tissue, or bone marrow transplant;

bone or skin graft; and pregnancy. By recognizing that use of the DHQ documents is one way to satisfy regulatory requirements, we are not requiring or recommending that donors be screened or deferred for these issues. Manufacturers are free to use another alternate questionnaire, which does not include questions related to these additional issues, or to eliminate these questions from their DHQ documents.

While we recognize that the DHQ documents (Version No. 1) provide an effective tool for screening donors, we do not require manufacturers to implement these DHQ documents. Licensed manufacturers may continue to use their previously approved full-length questionnaire and accompanying materials. This would include previously approved alternative procedures and wording.

IV. IMPLEMENTATION OF DONOR HISTORY QUESTIONNAIRES AND ACCOMPANYING MATERIALS

A. Implementation of DHQ Documents (Version No. 1)

For licensed manufacturers that decide to implement the DHQ documents (Version No. 1) described in this guidance, implementation of the DHQ documents would be a manufacturing change reportable to FDA under § 601.12.

1. We believe that if the DHQ documents are implemented without modifications and in their entirety as a complete process for administering medical history and high-risk questions to donors, this change would be a minor change. We recommend that you report such change in your Annual Report under § 601.12(d), noting the date the process was implemented. If donors will be allowed to self-administer the DHQ documents, see section IV.B.

2. We believe that if the DHQ documents are implemented in their entirely, and modified only by adding additional, more restrictive selection criteria that are specific to your blood establishment, or by omitting questions related to the following issues for which we currently do not have requirements or recommendations: cancer; organ, tissue, or bone marrow transplant; bone or skin graft; and pregnancy, this change would be a minor change. We recommend that you report such changes in your Annual Report under § 601.12(d), noting the date the process was implemented and describing the additional criteria or questions that were omitted from your questionnaire.

3. Because donor screening is so important to the safety of blood and blood components, we cannot conclude at this time that DHQ documents which are modified other than as specifically described in IV.A.2, will still be a minor change. Therefore, we recommend that you report such changes as a Prior Approval Supplement (PAS) under § 601.12(b) and include the following in the submission:

a. FDA Form 356h "Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use."
b. A cover letter describing the request and the contents of the submission.
c. A written SOP describing the donor questions and questionnaire process. Please highlight the modifications.
d. The full-length questionnaire and accompanying document(s).

For assistance in preparing the supplement, see FDA's "Guidance for Industry for the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and for the Completion of the Form FDA 356h 'Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use, '" May 1999 (Ref. 7).

B. Implementing the Self-Administration of the DHQ Documents

The task force prepared the DHQ documents so that they may be self-administered by the donor if the manufacturer has chosen this method. Licensed manufacturers that want donors to self-administer the DHQ documents (Version No. 1) should report this change to FDA as follows:

1. We believe that if a manufacturer chooses to implement the written form or audio/visual presentation methods, this change is a minor change. We recommend that you report such change in your Annual Report under § 601.12(d), noting the date the process was implemented.

2. We believe that if a manufacturer chooses to implement the computer-assisted interactive interview procedure, this change is a moderate change. This change presents a slightly higher level of risk because of concerns that the presentation of the questions and information may not be easily readable in all conditions and by all potential users. Additionally, implementation for the first time of a computer-assisted interactive interview procedure may raise new issues that should be evaluated, such as the management of electronic records. Accordingly, we recommend that you report such change as a Changes Being Effective in 30 Days supplement (CBE30) under § 601.12(c).

For assistance in implementing self-administered donor questionnaires and preparing the supplement for the computer-assisted interactive interview procedure, see FDA's "Guidance for Industry: Streamlining the Donor Questioning Process: Self-Administered Questionnaires," dated July 3, 2003 (Ref. 8).

V. IMPLEMENTATION OF UPDATED DHQ DOCUMENTS

In the future, we may issue guidance documents containing new donor deferral recommendations when we identify new infectious diseases, medical conditions, or medications that have the potential to affect the donor's safety or the safety, purity, and potency of human blood and blood components. Implementation of new safeguards may involve amending the DHQ documents (Version No. 1) referred to in this guidance, or if you do not use the DHQ documents, your own questionnaire. We anticipate that, in the event FDA recommends a new donor deferral criterion, the Agency will, in the same guidance, provide recommendations concerning reporting any associated manufacturing changes to FDA. In addition, we may update or revise this guidance to recognize future versions of the DHQ documents.

We recommend that you have a mechanism in place for implementing the updated donor questionnaire materials in all your facilities.

VI. FOR MORE INFORMATION

If you have questions regarding the full-length questionnaire materials, call the Division of Blood Applications, OBRR, CBER, at 301-827-3543 or fax at 301-827-3534.

You may obtain the DHQ documents (Version No. 1) at:

http://www.fda.gov/cber/guidelines.htm

VII. REFERENCES

1. Technical Methods and Procedures. American Association of Blood Banks. 1953:3-5.

2. CBER Biological Product Deviation Reports, FY02 Summary, April 23, 2003. (http://www.fda.gov/cber/biodev/bpdrfy02.htm)

3. Orton S, Virvos V, Williams A. Validation of selected donor-screening questions: structure, content and comprehension. Transfusion 2000; 40:1407-1413.

4. AABB Task Force UDHQ Submission dated March 25, 2002.

5. Blood Product Advisory Committee Transcripts – June 14, 2001. (http://www.fda.gov/ohrms/dockets/ac/cber01/htm#Blood%20Products)

6. Blood Product Advisory Committee Transcripts – June 13, 2002. (http://www.fda.gov/ohrms/dockets/ac/cber02/htm#BloodProducts)

7. FDA "Guidance for Industry for the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and for the Completion of the Form FDA 356h 'Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use,'" May 10, 1999. (http://www.fda.gov/cber/guidelines.htm)

8. FDA "Guidance for Industry: Streamlining the Donor Questioning Process: Self-Administered Questionnaires," July 3, 2003. (http://www.fda.gov/cber/guidelines.htm)

APPENDIX 1: Full-Length Donor History Questionnaire

	Yes	No	
Are you			
1. Feeling healthy and well today?	❑	❑	
2. Currently taking an antibiotic?	❑	❑	
3. Currently taking any other medication for an infection?	❑	❑	
Please read the Medication Deferral List.			
4. Are you now taking or have you ever taken any medications on the Medication Deferral List?	❑	❑	
5. Have you read the educational materials and had your questions answered?	❑	❑	
In the past **48 hours**			
6. Have you taken aspirin or anything that has aspirin in it?	❑	❑	
In the past **week**			
7. Have you had a headache and fever at the same time?	❑	❑	
In the past **6 weeks**			
8. Female donors: Have you been pregnant or are you pregnant now? (Males: check "I am male.")	❑	❑	❑ I am male
In the past **8 weeks have you**			
9. Donated blood, platelets or plasma?	❑	❑	
10. Had any vaccinations or other shots?	❑	❑	
11. Had contact with someone who had a smallpox vaccination?	❑	❑	
In the past **16 weeks**			
12. Have you donated a double unit of red cells using an apheresis machine?	❑	❑	
In the past **12 months have you**			
13. Had a blood transfusion?	❑	❑	
14. Had a transplant such as organ, tissue, or bone marrow?	❑	❑	
15. Had a graft such as bone or skin?	❑	❑	
16. Come into contact with someone else's blood?	❑	❑	
17. Had an accidental needle-stick?	❑	❑	
18. Had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?	❑	❑	
19. Had sexual contact with a prostitute or anyone else who takes money or drugs or other payment for sex?	❑	❑	

20. Had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything not prescribed by their doctor?	❑	❑	
21. Had sexual contact with anyone who has hemophilia or has used clotting factor concentrates?	❑	❑	
22. Female donors: Had sexual contact with a male who has ever had sexual contact with another male? (Males: check "I am male.")	❑	❑	❑ I am male
	Yes	No	
23. Had sexual contact with a person who has hepatitis?	❑	❑	
24. Lived with a person who has hepatitis?	❑	❑	
25. Had a tattoo?	❑	❑	
26. Had ear or body piercing?	❑	❑	
27. Had or been treated for syphilis or gonorrhea?	❑	❑	
28. Been in juvenile detention, lockup, jail, or prison for more than 72 hours?	❑	❑	
In the past **three years** have you			
29. Been outside the United States or Canada?	❑	❑	
From **1980 through 1996**,			
30. Did you spend time that adds up to three (3) months or more in the United Kingdom? (Review list of countries in the UK)	❑	❑	
31. 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			
32. Spend time that adds up to five (5) years or more in Europe? (Review list of countries in Europe.)	❑	❑	
33. Receive a blood transfusion in the United Kingdom ? (Review list of countries in the UK.)	❑	❑	
From **1977 to the present**, have you			
34. Received money, drugs, or other payment for sex?	❑	❑	
35. Male donors: had sexual contact with another male, even once? (Females: check "I am female.")	❑	❑	❑ I am female
Have you **EVER**			
36. Had a positive test for the HIV/AIDS virus?	❑	❑	
37. Used needles to take drugs, steroids, or anything not prescribed by your doctor?	❑	❑	
38. Used clotting factor concentrates?	❑	❑	
39. Had hepatitis?	❑	❑	
40. Had malaria?	❑	❑	
41. Had Chagas' disease?	❑	❑	
42. Had babesiosis?	❑	❑	
43. Received a dura mater (or brain covering) graft?	❑	❑	
44. Had any type of cancer, including leukemia?	❑	❑	

45. Had any problems with your heart or lungs?	❑	❑
46. Had a bleeding condition or a blood disease?	❑	❑
47. Had sexual contact with anyone who was born in or lived in Africa?	❑	❑
48. Been in Africa?	❑	❑
49. Have any of your relatives had Creutzfeldt-Jakob disease?	❑	❑

Additional Questions	Yes	No

APPENDIX 2: Donor History Questionnaire User Brochure

Purpose: The User Brochure was designed to aid the donor historian in determining if a prospective donor is eligible to donate. Each blood center must have a standard operating procedure (SOP) related to donor suitability to be used in conjunction with the User Brochure. The User Brochure does not replace an SOP for determining donor suitability. Both the User Brochure and the SOP must be available to staff performing health histories. Alternately, the User Brochure contents may be transcribed into the SOP.

Introduction: The Donor History Questionnaire (DHQ) must be administered on the date of donation. All prospective donors must read the Donor Educational Materials prior to completing the DHQ. They also must be given the Medication Deferral List, and a list of BSE countries to be used with the DHQ. As an alternative, one or all of the lists can be prominently displayed at the donation site for the donors' use while they are completing the DHQ. The DHQ was designed for self-administration by the donor, with follow-up review by a trained donor historian. All donors should be instructed to complete all questions on the questionnaire. A knowledgeable donor historian should be available to the prospective donor to answer any questions concerning eligibility or the donation process. Alternatively, the DHQ may be administered by a donor historian. The method of administration of the DHQ should be in accordance with the blood center's SOP. Blood collection facilities are reminded that donor screening is an active process involving open communication between donors and trained donor historians, and that donors should be encouraged to voice questions and concerns at any time during the screening and donation process.

Collection facilities using these screening materials should be aware that these materials were tested in English-speaking donor and non-donor groups and due to practical limitations could not be tested in all possible settings, including with non-English speaking donors.

DHQ Format: The DHQ questions were composed for ease of understanding by the prospective donor. The questionnaire, documents and procedure for use were designed, formatted and evaluated collectively and are intended to be used together. The DHQ was evaluated in its current form for comprehension; therefore, the wording and the order and text of the questions should not be changed. A collection facility may make minor changes to the timeframe of a question on the DHQ only if the revision makes the screening criteria more restrictive (for instance, increasing the deferral for aspirin from 48 hours to 72 hours to meet State regulations). Blood centers may choose to add local questions to the end of the DHQ. If a collection facility chooses to add "local" questions it is suggested they be grouped at the end of the DHQ in an area designated "Additional Questions." Facilities may also use this area to incorporate new questions required by FDA until such questions can be formally incorporated into the DHQ by AABB. The Educational Material and Medication Deferral List also must be used unabridged except for local additions. The questions are grouped by time period beginning with a question about "today" and ending with questions relating to "have you ever." When administered by manual/paper self-administration, the entire DHQ should be completed before eligibility is determined.

Questions to detect donors at risk for HIV group O: Questions number 47 and 48 are recommended by FDA to identify donors who may be at risk for HIV group O infections. Blood collection agencies utilizing an HIV antibody test that has been approved by FDA to include a claim for detection of group O viruses may delete questions 47 and 48 from their screening questionnaire and may renumber the remainder of the questions (and related documents such as flow charts). All other centers must continue to use these questions as formatted.

Capture Questions: The DHQ uses **capture questions** that may require donor historian intervention or follow-up. Capture questions are questions that cover a broad topic, and when an affirmative answer is given, additional follow-up questions to elicit additional information are asked by the donor historian. Some follow-up questions are included in the User Brochure, but since specific donor eligibility criteria may vary from one blood center to another, an affirmative response to some questions may require consultation with the blood center's SOP. Blood centers may implement more restrictive deferral policies than described in the User Brochure per their local SOP.

Attention Questions: Additionally, in order to assure that donors who self-administer a paper DHQ maintain focus, several "**attention" questions are included**. An example of one of the attention questions is listed below.

> In the past 6 weeks, have you been pregnant or are you pregnant now? (Males check "I am male")

An inappropriate answer to the question would be a male answering "yes" or "no." Each blood center must define the action of the donor historian when a donor inappropriately answers the attention questions. Attention questions may not be necessary when using other techniques to assure donor focus, such as an audio-visual assisted computer assisted self-interviewing system (CASI) or oral screening by a donor historian.

Documentation: Information impacting donor suitability obtained during follow-up questioning should be meticulously documented on the DHQ. If a donor is determined to be ineligible during follow-up questioning, the reason for deferral should be documented in a designated area on the DHQ. If a donor is determined to be eligible during follow-up questioning for an affirmative response to a question(s), a detailed explanation for each question must be documented in sufficient detail in a designated area on the DHQ.

Example 1: A donor answers "yes" to DHQ Q2, "Are you currently taking an antibiotic?"
Sample documentation: "Donor taking tetracycline daily for acne prophylaxis: OK per SOP."

Example 2: A donor answers "yes" to DHQ Q39, "Have you ever had hepatitis?"
Sample documentation: "Donor had hepatitis A at 7 years old; OK per SOP."

Example 3: A donor answers "yes" to DHQ Q29, "In the past three years have you been outside the United States or Canada?"

Sample documentation: "Donor traveled to rural area in Quintana Roo, Mexico 6 weeks ago; malaria risk; 12 months deferral."

User Brochure Format: The User Brochure is modular and uses flow-charting to guide the donor historian through the donor questionnaire process. Each question is a complete section that begins on a new page, so that changes to the DHQ can be easily modified in the User Brochure. Each section contains the following information:

Question: Question number and the question.
Donor Eligibility: This section provides additional information to the donor historian on donor eligibility requirements for each question.
Note: Optional field; additional relevant information relating to the donor question.
Flow Chart: Each question is flow-charted using standard flow-charting symbols.
Square -- Statement
Diamond -- Question/decision point
Oval -- Action
Arrow -- Move to the next question

Each question ends with an ARROW that indicates to "move to the next question;" however, blood centers must follow their established policies concerning whether or not the donor suitability process is terminated when it is known that the donor will be deferred.

Change Control: Periodically the Donor History Questionnaire, the accompanying documents or the procedure for use will be updated or revised by the AABB DHQ Task Force as required for compliance with regulatory and accrediting agencies. AABB Institutions will be notified of the changes and timeline for implementation in existing publications and on the public area of the AABB website, and all updated documents will be made available on the website. It is the responsibility of collecting facilities to make changes in their forms, procedures and processes to incorporate these revisions within the specified time.

Donor Deferrals: For some questions, a "yes" answer calls for a required deferral, either indefinitely or for a specified period of time. A required deferral is designated in the flow chart by the Action "***Defer donor.***" The donor historian may need to refer to the blood center's SOP to determine if and when the donor may be eligible to return.

For other questions, a "yes" answer may not require a deferral; rather, it may trigger a line of questioning to determine if the donor is eligible. The donor historian will need to refer to the blood center's SOP for follow-up questions to determine suitability. This type of deferral is designated in the flow chart by the Action " ***Defer donor per SOP***." For example, if a donor answers "yes" to the question "Are you currently taking an antibiotic?" A blood center may ask additional questions to ascertain the name of antibiotic and specific indication for use by the donor. Some blood centers may allow donors taking antibiotics for certain indications such as

prophylaxis for acne to donate, as defined in their SOP. Other centers may, for simplicity, defer all donors taking antibiotics, regardless of the indication.

Each blood center's SOP must define how the donor responses to the follow-up questions will be documented on the DHQ. Responses should be documented with sufficient detail to determine the reason for donor acceptance or deferral. (See Documentation Section).

References: A list of references concerning donor eligibility is included at the end of the questions.

APPENDIX 3: Glossary

The following terms are defined in the context of their use in the Donor History Questionnaire.

QUESTIONNAIRE TERMS

Attention Question – Questions in the Donor History Questionnaire that are designed to test if the donor is paying attention. EXAMPLE: In the past six weeks, have you been pregnant or are you pregnant now? (Males check: "I am Male")

Capture Question – A question that covers a broad topic. When an affirmative answer is given, additional follow-up questions to elicit additional information are asked by the donor historian. EXAMPLE: Have you ever been to Africa? If the donor answers yes, additional questions must be asked.

Self-administered Questionnaire – A questionnaire that the donor completes on his/her own, followed by donor health historian review.

TYPES OF CONTACT

Contact with Blood – (1) a needlestick or other sharps injury from an instrument that has been used on any individual or patient; (2) exposure to non-intact skin (e.g., skin that is chapped, abraded, or afflicted with dermatitis); (3) a human bite that breaks the skin; (4) exposure to eye, nose, or mouth i.e., the mucous membranes.

Sexual Contact – The meaning of the words "sexual contact with" and "sex" are identical, and apply 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).

Contact with a person who has had smallpox vaccination – Touching the vaccination area or the scab that forms on the skin, including the bandages covering the vaccination area or scab; touching/handling materials that might have come into contact with an unbandaged vaccination area or scab including clothing, towels, and bedding.

Contact with person who has or may have SARS—participating in activities that have a high likelihood of producing contact with the respiratory secretions and/or body fluids of a patient known to have SARS. These activities could occur either during the period the person was clinically ill or in the 10 days following the resolution of symptoms. Specific examples of close contact activities include:

- living with a person with SARS;
- providing care for a person with SARS;
- kissing, embracing, or sharing eating or drinking utensils with a person with SARS;
- standing within 3 feet of a person with SARS; or

- performing physical examination or any other manner of physical touching a person with SARS.

This does NOT include walking by a person with SARS or briefly sitting across a room from the person.

Note: There currently are no questions in the Donor History Questionnaire that cover SARS. This information is for future reference.

Lived With – Residing in the same dwelling. EXAMPLES: house, dormitory, apartment.

TYPES OF DEFERRAL

Indefinite Deferral – Prospective donor is unable to donate blood for someone else for an unspecified period of time due to current regulatory requirements. EXAMPLE: A prospective donor who states that they lived in England for 1 year in 1989 would be deferred indefinitely. This donor would not be able to donate blood until the current requirement changes. These donors may be eligible to donate autologous blood.

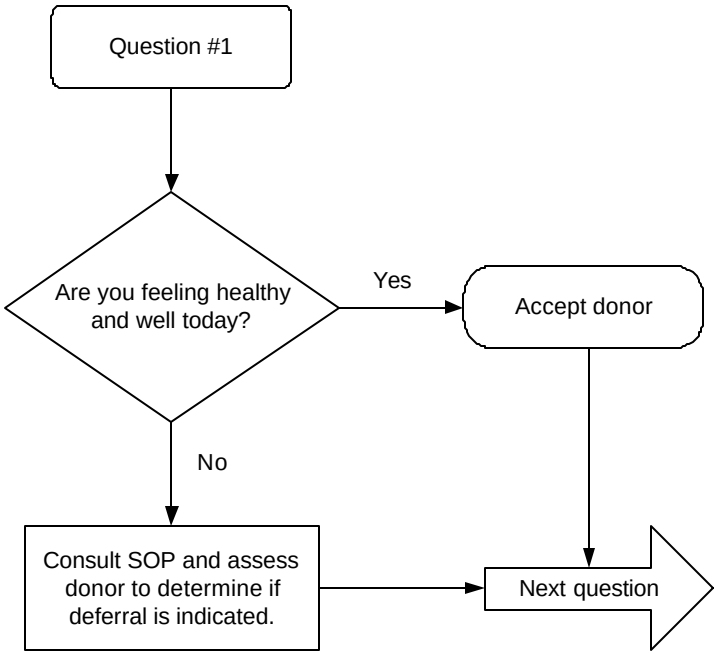
Permanent Deferral – Prospective donor will never be eligible to donate blood for someone else. EXAMPLE: A prospective donor states that he/she has Hepatitis C. Additionally, some permanent deferrals may result from the testing performed on a previous donation. These donors may be eligible to donate autologous blood.

Temporary Deferral – Prospective donor is unable to donate blood for a limited period of time. EXAMPLE: A prospective donor who discloses that he/she received a tattoo is temporarily deferred for 12 months after he/she received the tattoo.

APPENDIX 4: Flow Charts

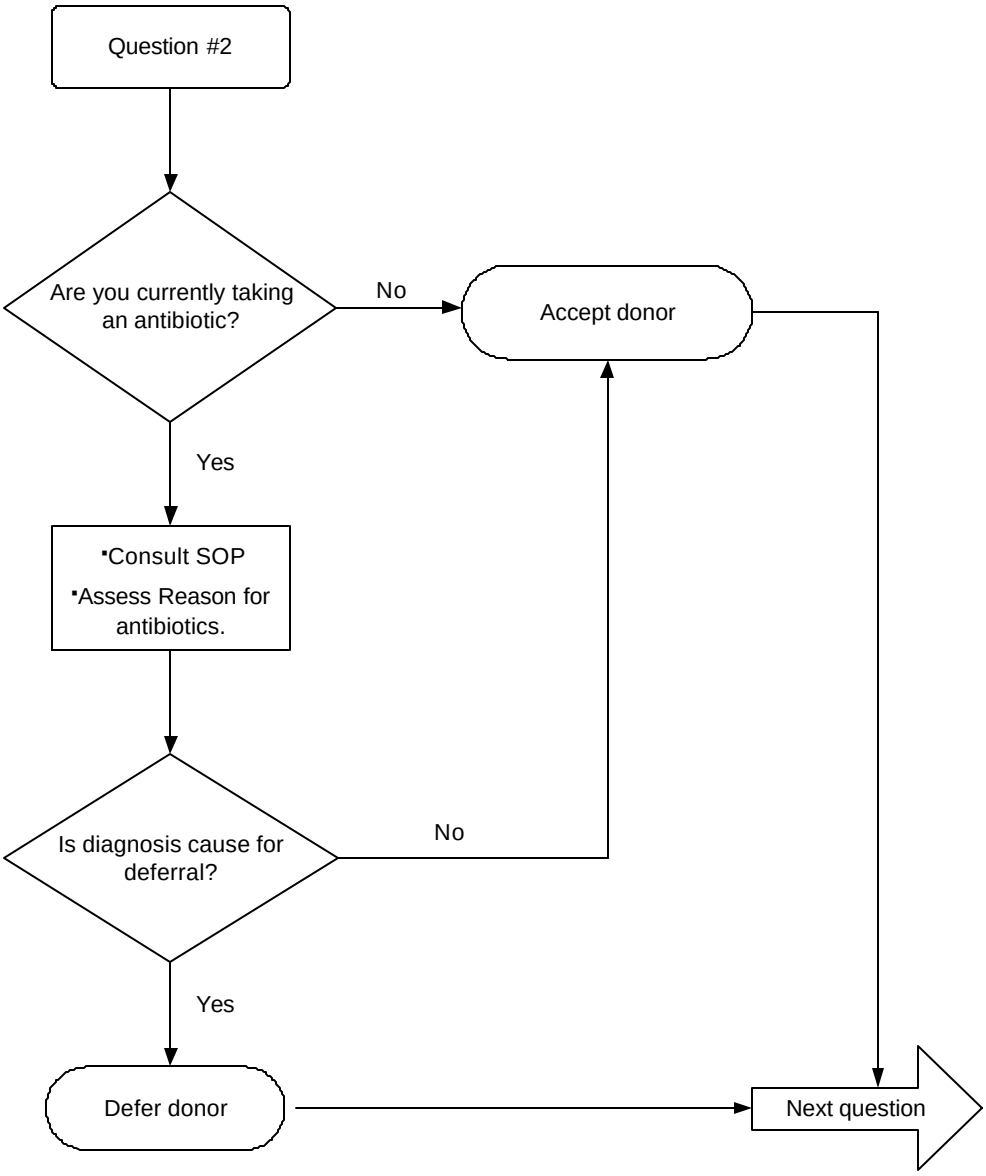
Question: 1. Are you feeling healthy and well today?

Donor Eligibility: A donor should be free of infectious diseases and colds on the day of donation. Donors who are not in good health should not donate until it is determined that the underlying condition is not cause for deferral.



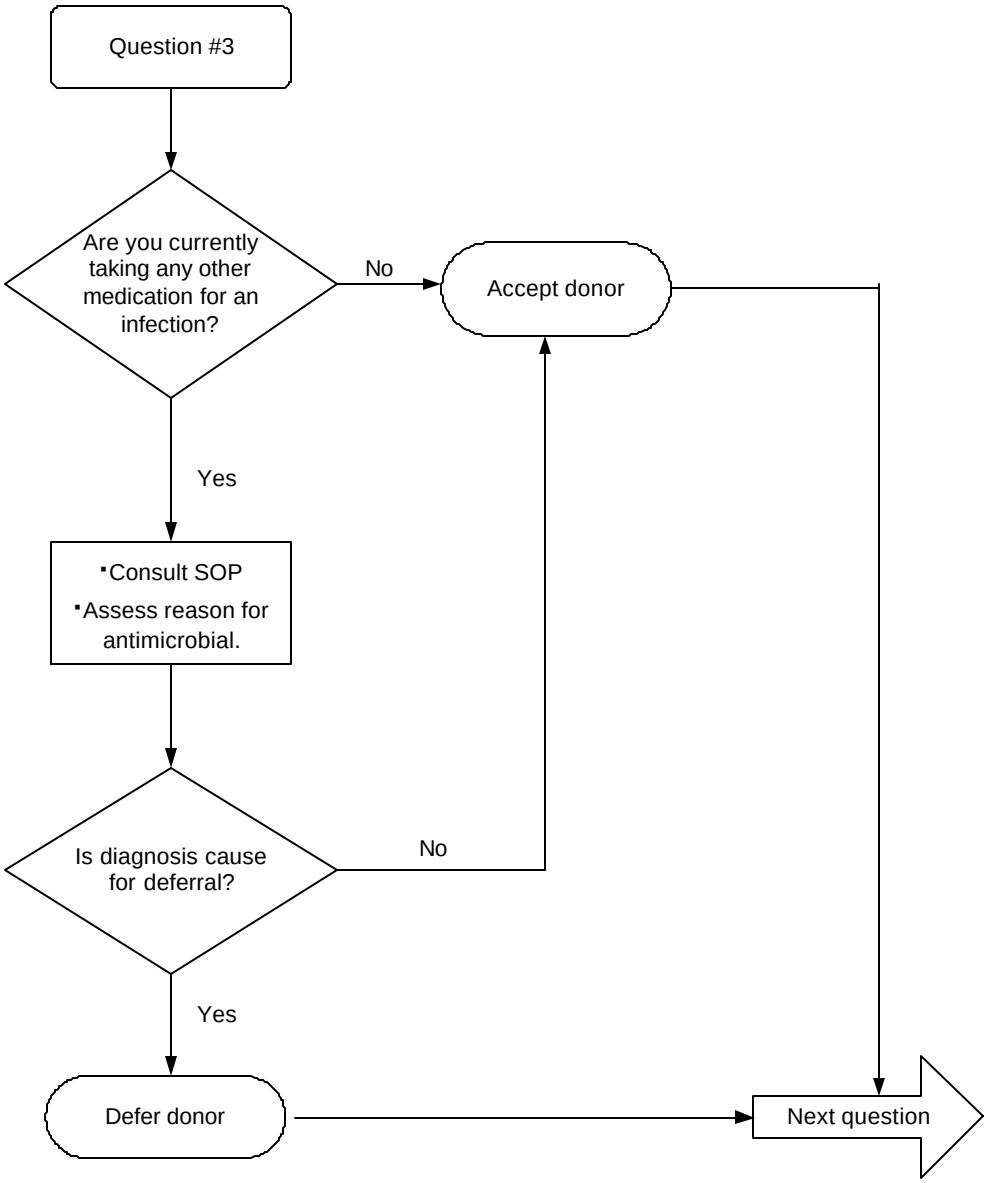
Question: 2. Are you currently taking an antibiotic?

Donor Eligibility: A donor with an infection should not donate. The reason for antibiotic use must be evaluated to determine if the donor has a bacterial infection that could be transmissible by blood.



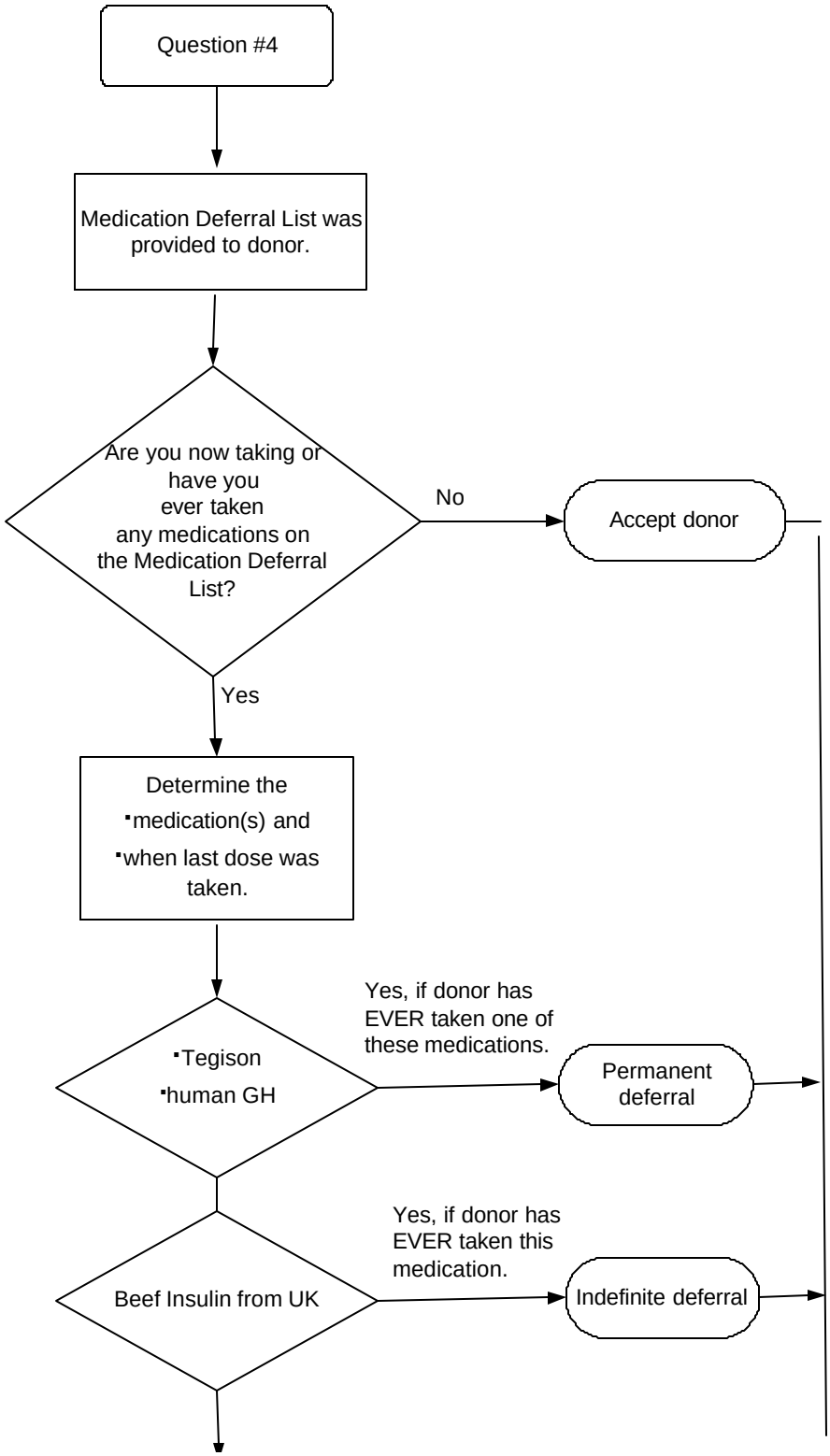
Question: 3. Are you currently taking any other medication for an infection?

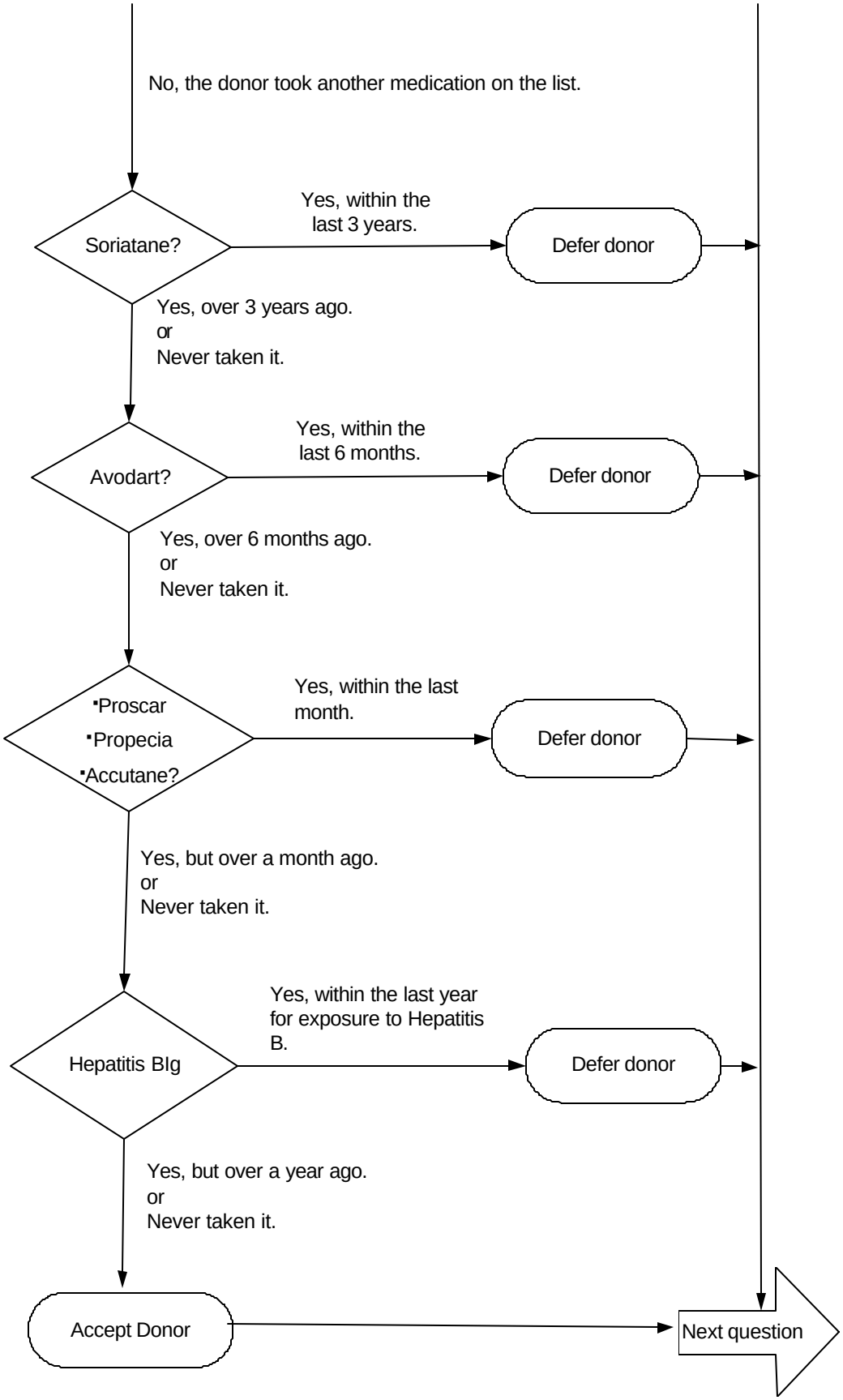
Donor Eligibility: A donor with an infection should not donate. The reason for use of any medication for an infection must be evaluated to determine if the donor has a viral, fungal, parasitic or other infection transmissible by blood.



Question: 4. Are you now taking or have you ever taken any medications on the Medication Deferral List?

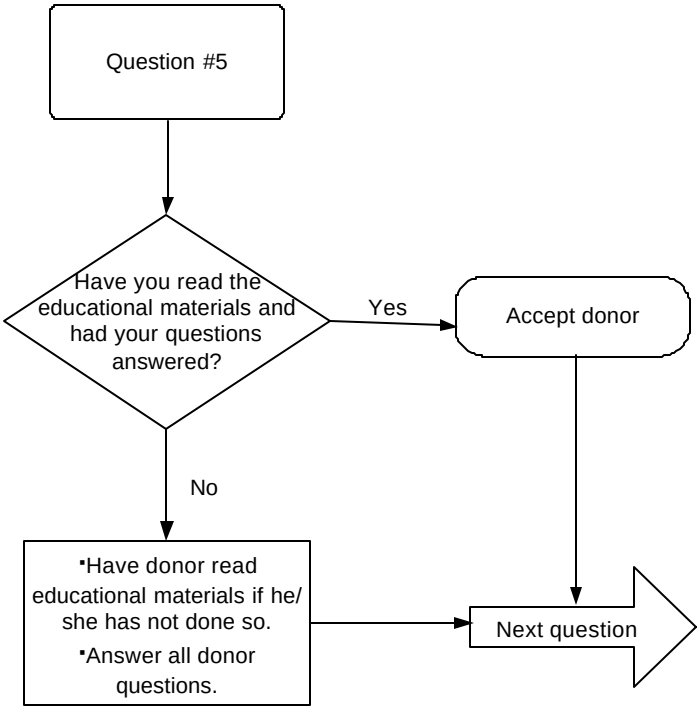
Donor Eligibility: Donors taking certain designated medications, currently or in the past, must not donate blood.




No, the donor took another medication on the list.
Soriatane?
Yes, within the last 3 years.
Defer donor
Yes, over 3 years ago. or Never taken it.
Avodart?
Yes, within the last 6 months.
Defer donor
Yes, over 6 months ago. or Never taken it.
▪Proscar ▪Propecia ▪Accutane?
Yes, within the last month.
Defer donor
Yes, but over a month ago. or Never taken it.
Hepatitis BIg
Yes, within the last year for exposure to Hepatitis B.
Defer donor
Yes, but over a year ago. or Never taken it.
Accept Donor
Next question

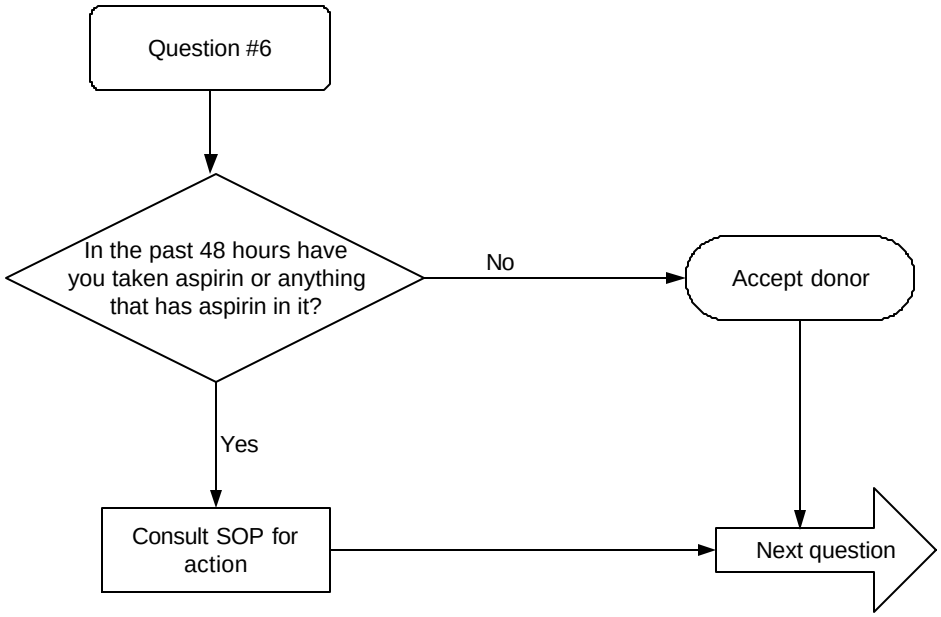
Question: 5. Have you read the educational materials and had your questions answered?

Donor Eligibility: Donors must read the educational materials prior to donating and have an opportunity to have their questions answered.



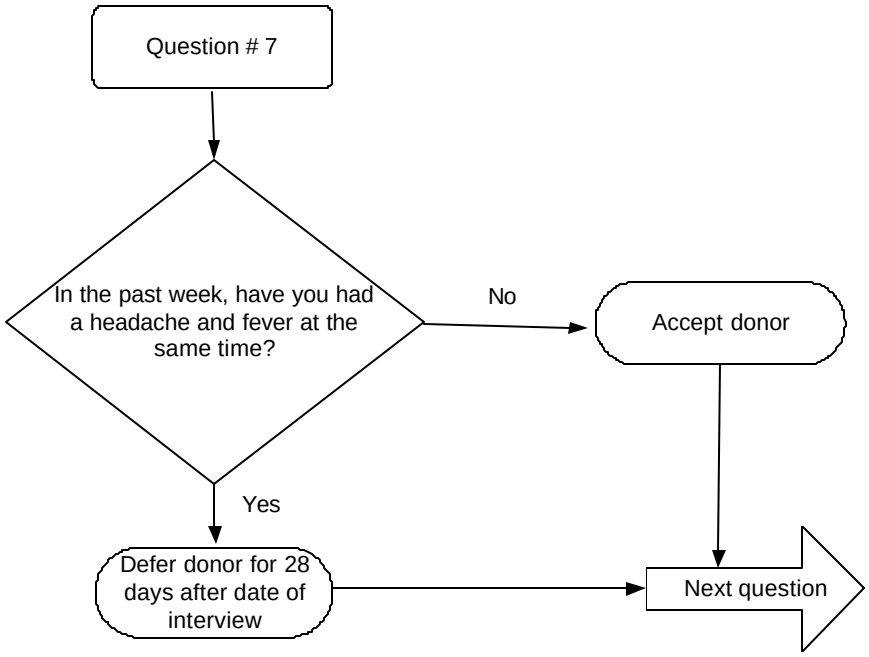
Question: 6. In the past 48 hours have you taken aspirin or anything that has aspirin in it?

Donor Eligibility: Aspirin irreversibly inactivates platelet function. Donors who are taking aspirin or any aspirin containing medication should not be the sole source of platelets.



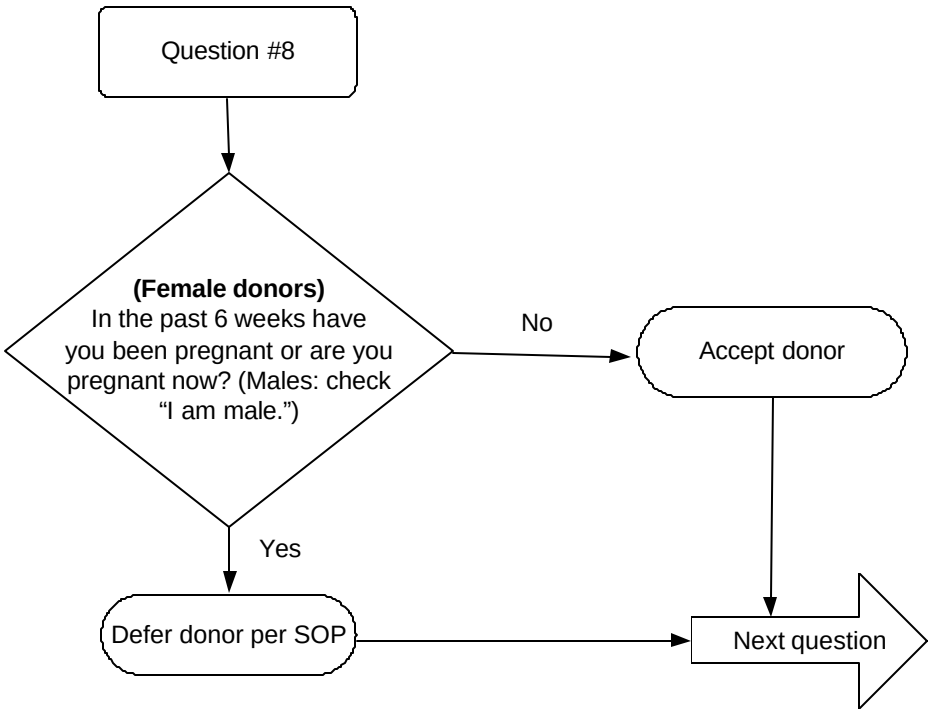
Question: 7. In the past week, have you had a headache and fever at the same time?

Donor Eligibility: Symptoms of West Nile virus (WNV) include fever with headache in the past 7 days. Donors with both of these should not donate blood for 7 days after resolution



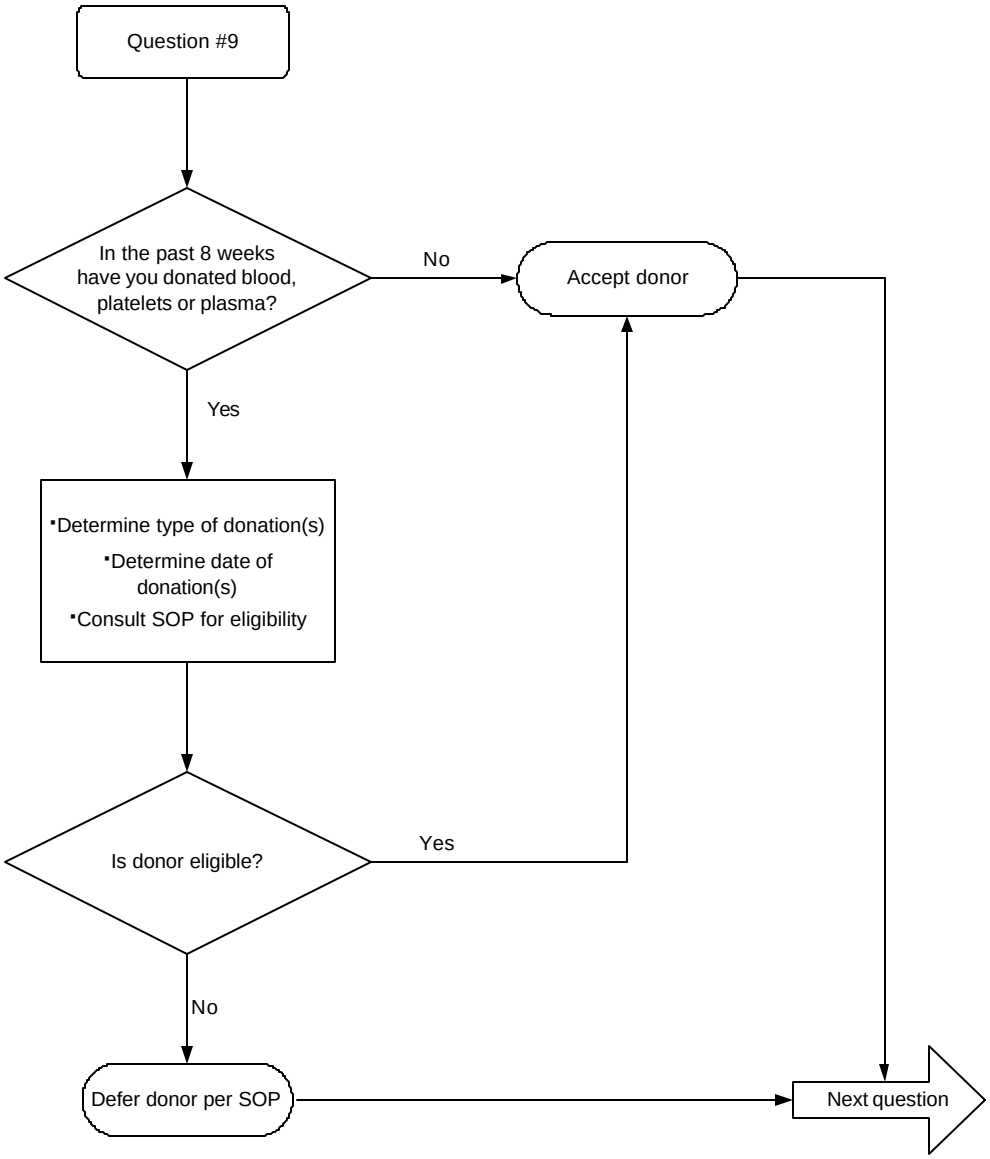
Question: 8. Female donors: In the past 6 weeks, have you been pregnant or are you pregnant now? (Males: check "I am male.")

Donor Eligibility: A female with a known pregnancy or who has been pregnant in the last 6 weeks should not donate blood.



Question: 9. In the past 8 weeks have you donated blood, platelets or plasma?

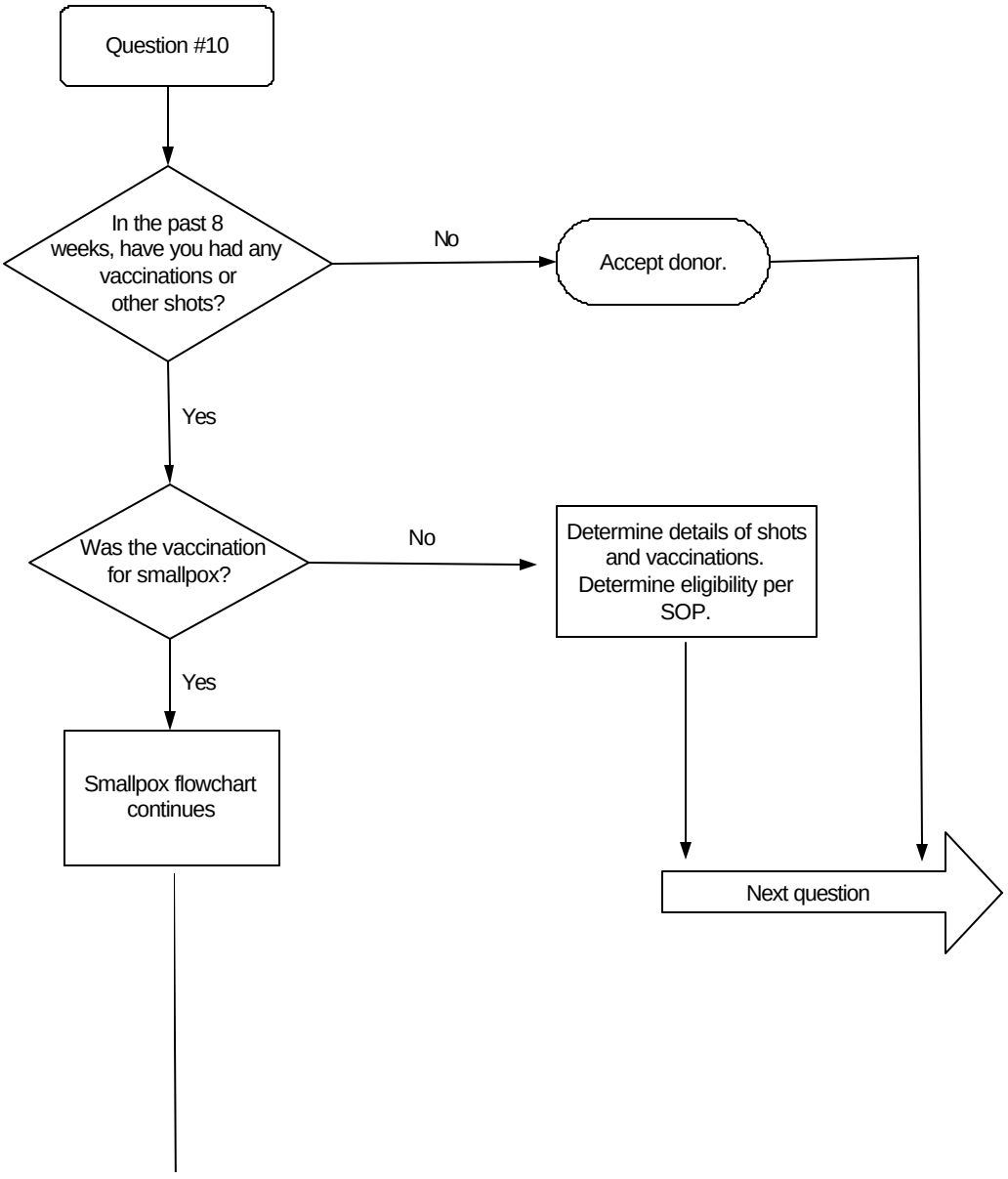
Donor Eligibility: Frequency of whole blood donation is a minimum of every 8 weeks; plasma, platelets or leukapheresis is a minimum of every 2 days.

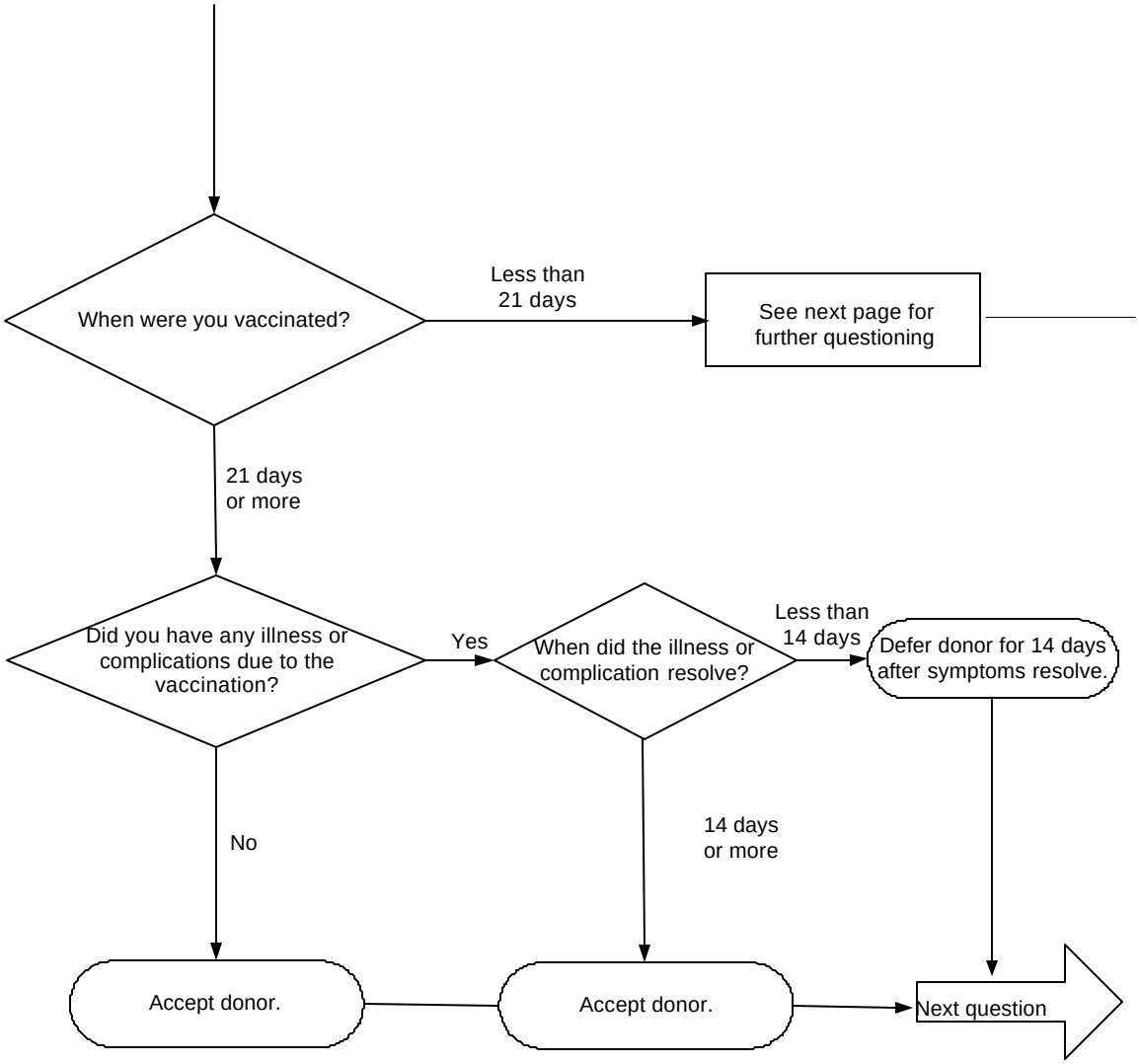


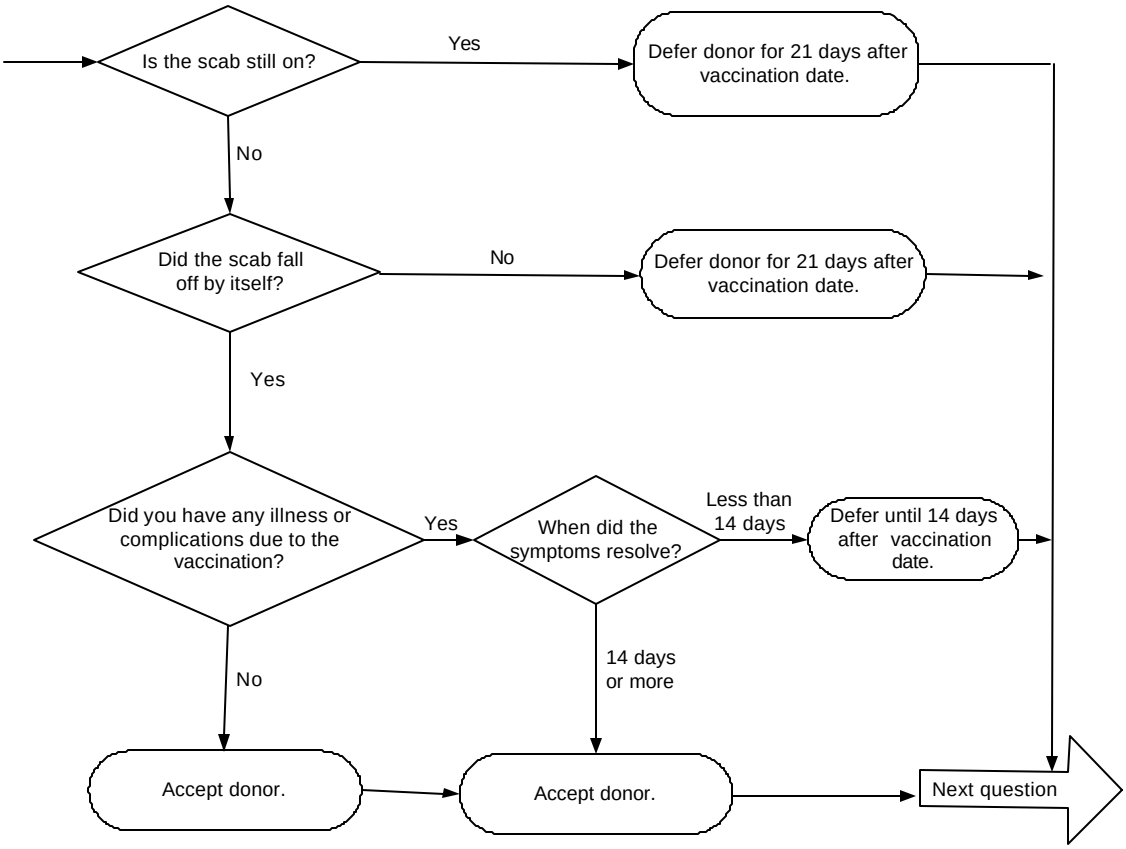
Question: 10. In the past 8 weeks, have you had any vaccinations or other shots?

Note on 10alt Flow Chart: Some blood centers may choose to use a simpler but stricter deferral scheme in which all donors who receive the smallpox vaccination are deferred for 56 days regardless of when the scab fell off or was removed. Blood centers using these stricter criteria should use Alternative Flow Chart 10alt.

Donor Eligibility: Certain vaccinations may contain live viruses. A donor who has been exposed to a live virus via vaccination should not serve as a donor. For other shots, refer to SOP.

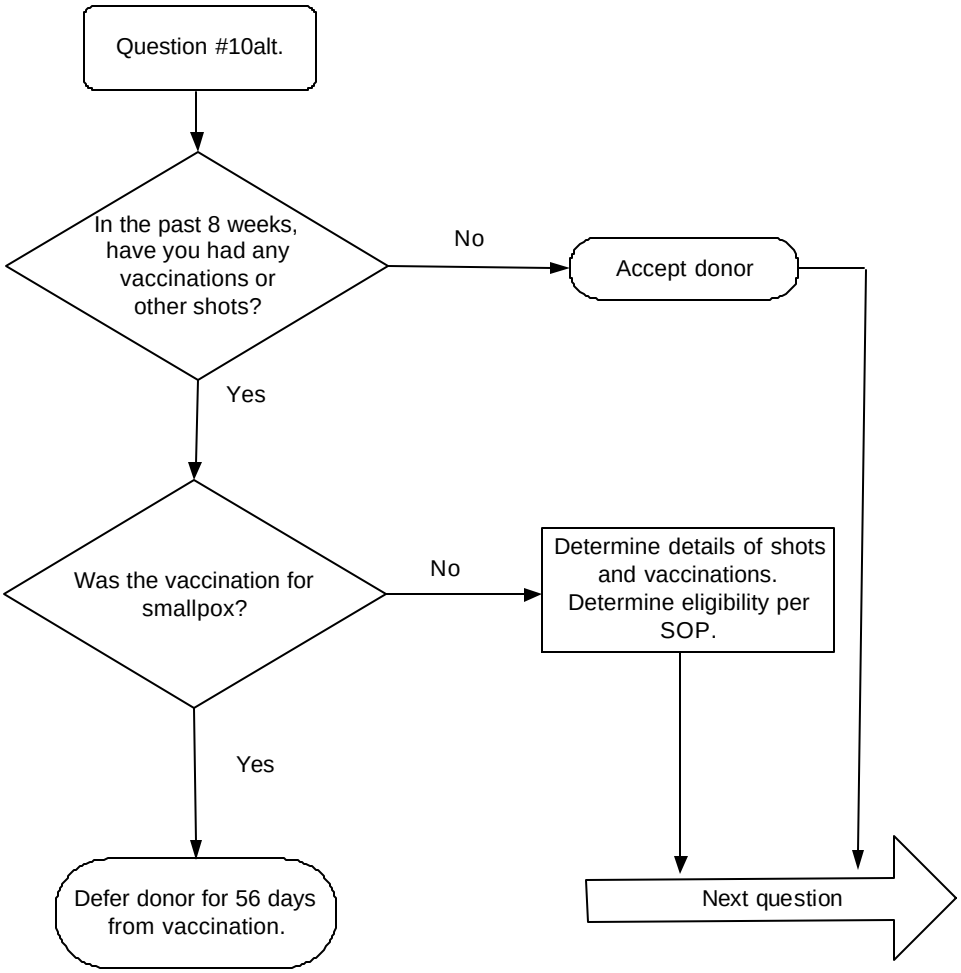



When were you vaccinated?
Less than 21 days
See next page for further questioning
21 days or more
Did you have any illness or complications due to the vaccination?
Yes
When did the illness or complication resolve?
Less than 14 days
Defer donor for 14 days after symptoms resolve.
No
14 days or more
Accept donor.
Accept donor.
Next question


Is the scab still on?
Yes
Defer donor for 21 days after vaccination date.
No
Did the scab fall off by itself?
No
Defer donor for 21 days after vaccination date.
Yes
Did you have any illness or complications due to the vaccination?
Yes
When did the symptoms resolve?
Less than 14 days
Defer until 14 days after vaccination date.
No
14 days or more
Accept donor.
Accept donor.
Next question

Question: 10alt. In the past 8 weeks, have you had any vaccinations or other shots?

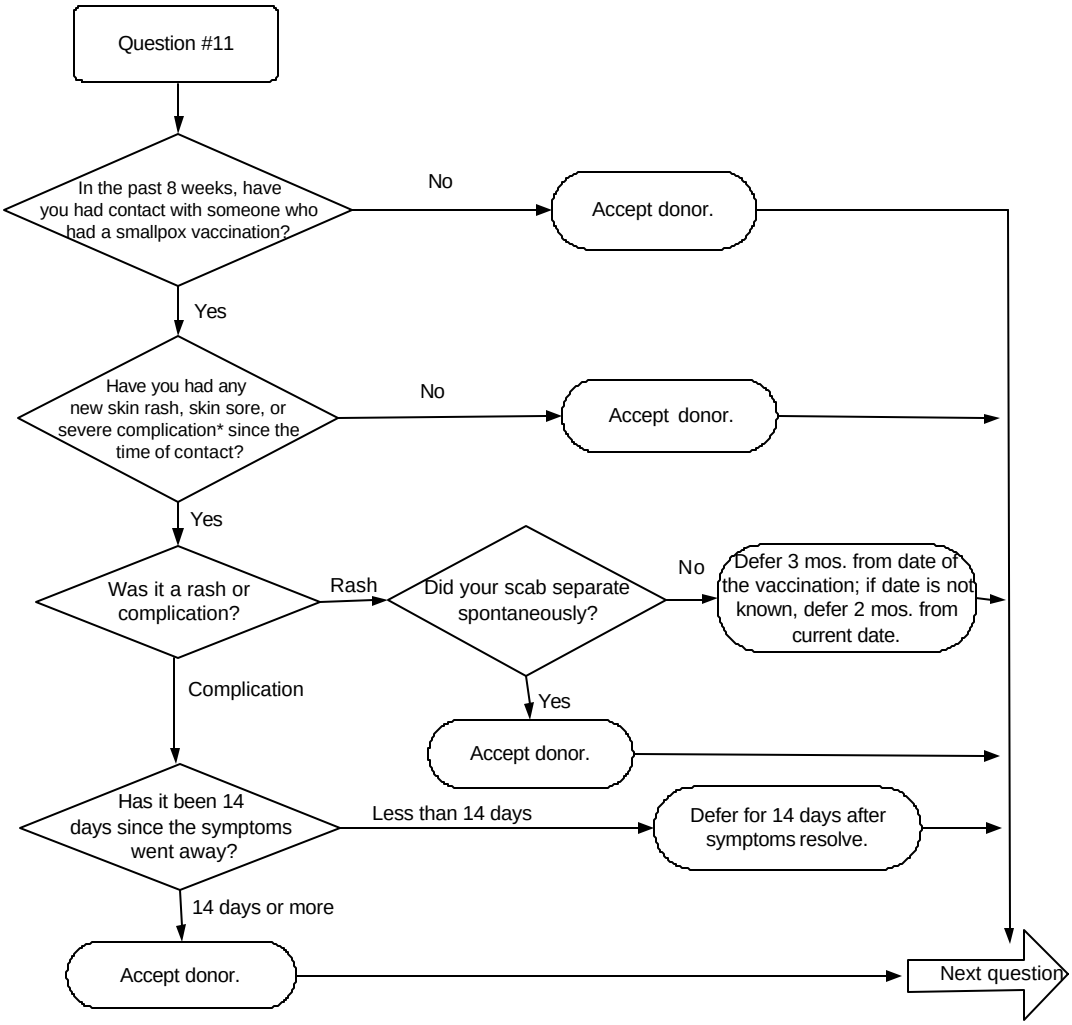
Donor Eligibility: Certain vaccinations may contain live viruses. A donor who has been exposed to a live virus via vaccination should not serve as a donor. For other shots, refer to SOP.



Question: 11. In the past 8 weeks, have you had contact with someone who had a smallpox vaccination?

Note on 11alt Flow Chart: Some blood centers may choose to use a simpler but stricter deferral scheme in which all donors who have been in contact with a person who received the smallpox vaccination are deferred for 56 days if they developed any subsequent complication, skin rash or sore, regardless of when the rash or sore resolved. Blood centers using these criteria should use Alternative Flow Chart 11alt.

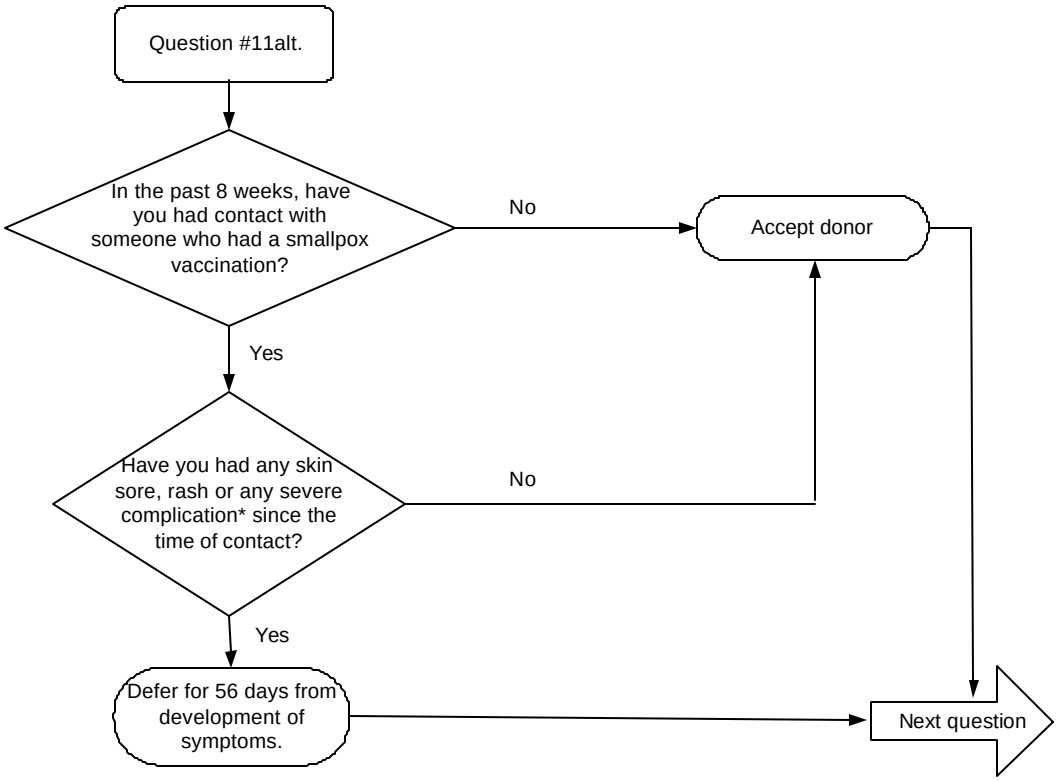
Donor Eligibility: Certain vaccinations may contain live viruses. A donor who has had close contact with the vaccination site, bandages covering the vaccination site or materials that might have come into contact with an unbandaged vaccination site, including clothing, may be exposed to the live virus and should not serve as a donor. See Glossary for specifics.



*Severe complications include the following: rash (resembling blisters) covering a small or large area of the body; necrosis (tissue death) in the area of exposure; encephalitis (inflammation of the brain); infection of the cornea (eye); and localized or systemic skin reaction in someone with eczema or other chronic skin condition.

Question: 11alt. In the past 8 weeks, have you had contact with someone who had a smallpox vaccination?

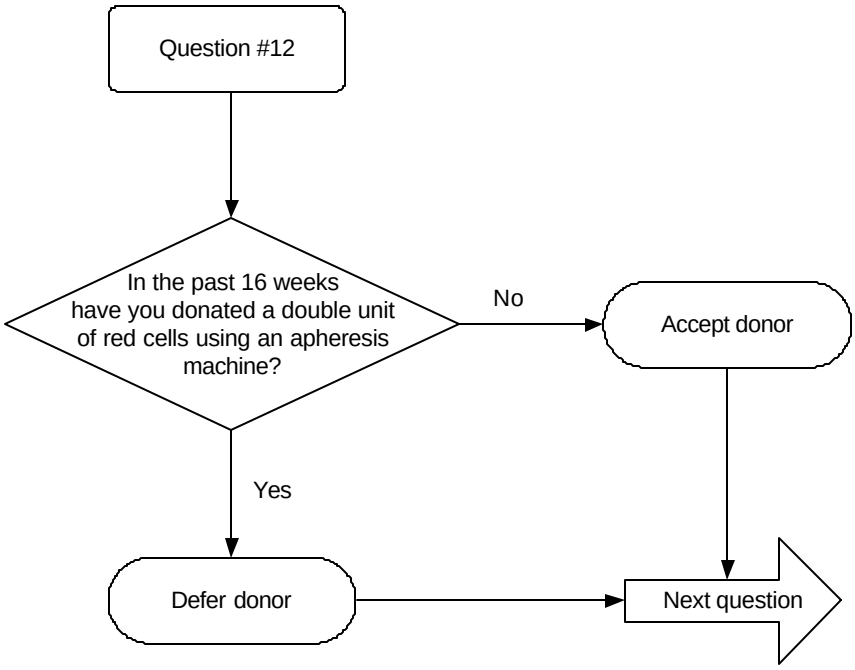
Donor Eligibility: Certain vaccinations may contain live viruses. A donor who has had close contact with the vaccination site, bandages covering the vaccination site or materials that might have come into contact with an unbandaged vaccination site, including clothing, may be exposed to the live virus and should not serve as a donor. See Glossary for specifics.



*Severe complications include the following: rash (resembling blisters) covering a small or large area of the body; necrosis (tissue death) in the area of exposure; encephalitis (inflammation of the brain); infection of the cornea (eye); and localized or systemic skin reaction in someone with eczema or other chronic skin condition.

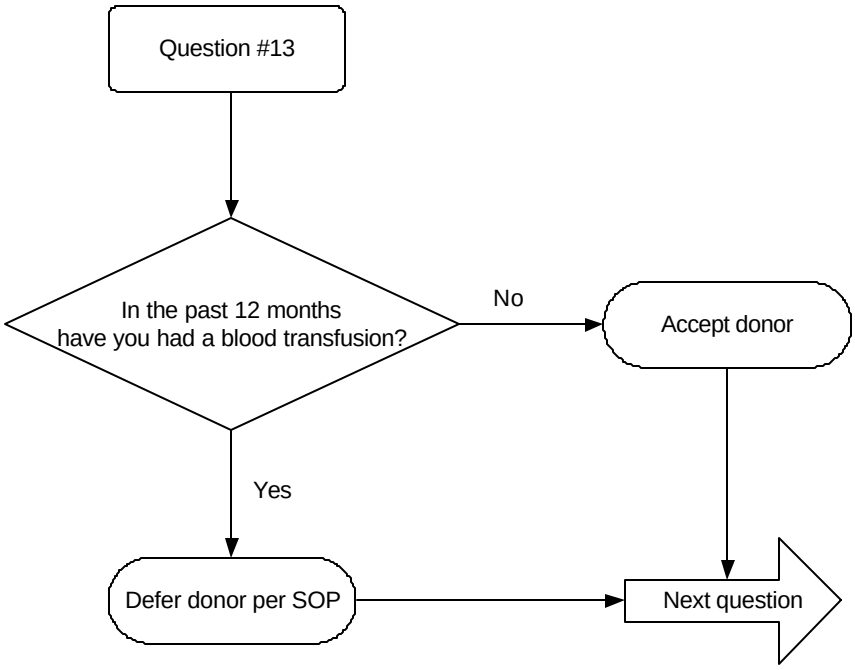
Question: 12. In the past 16 weeks have you donated a double unit of red cells using an apheresis machine?

Donor Eligibility: A donor should not donate double red cells by apheresis more frequently than every 16 weeks.



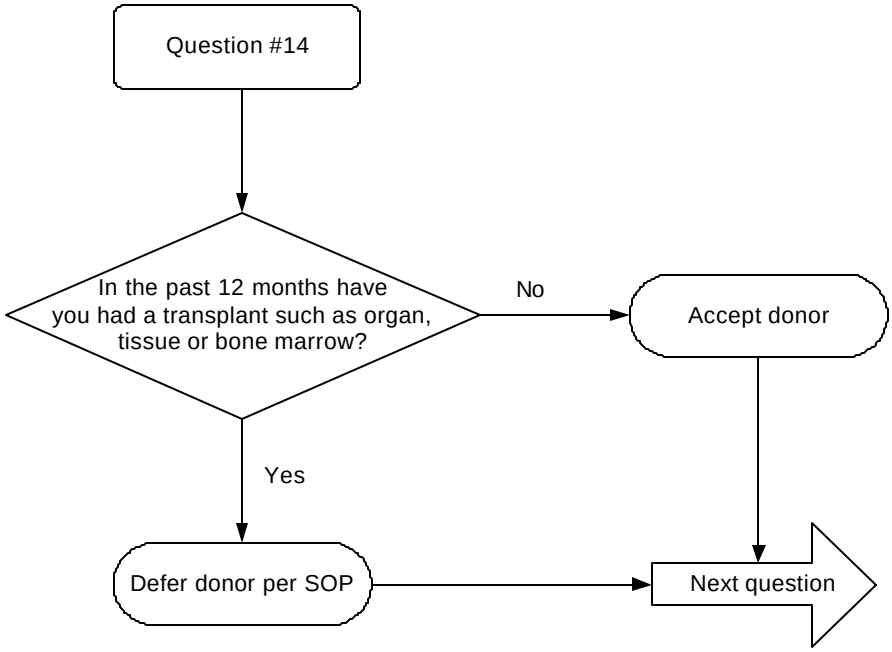
Question: 13. In the past 12 months have you had a blood transfusion?

Donor Eligibility: A donor who has received an allogeneic transfusion of blood, platelets, plasma or other blood component should not donate blood for 12 months following the transfusion, due to possible transmissibility of infectious disease.



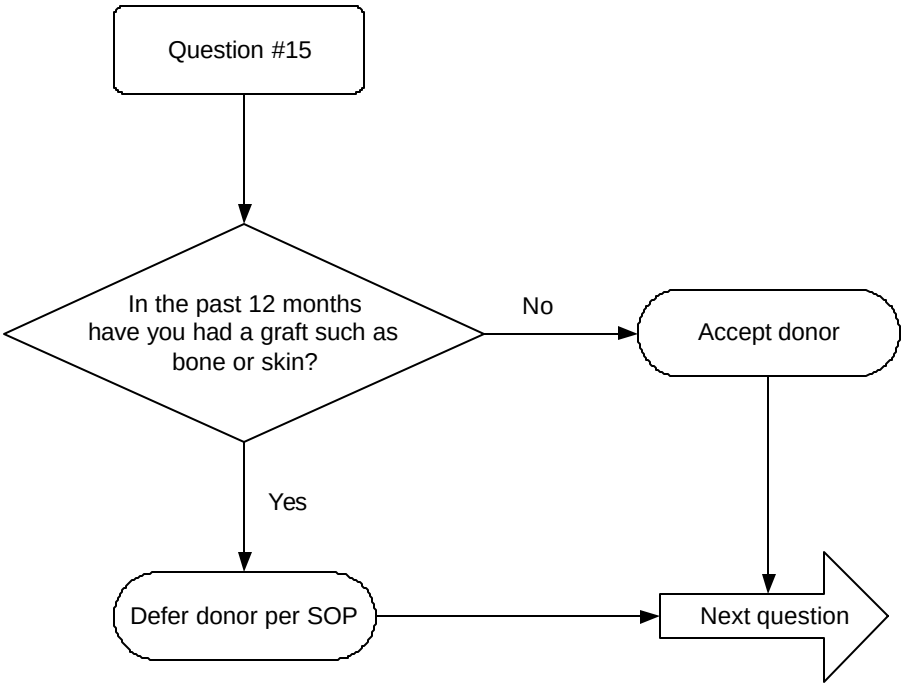
Question: 14. In the past 12 months have you had a transplant such as organ, tissue or bone marrow?

Donor Eligibility: A donor who has been exposed to allogeneic tissues through transplant should not dona blood for 12 months following exposure, due to possible transmissibility of infectious disease.



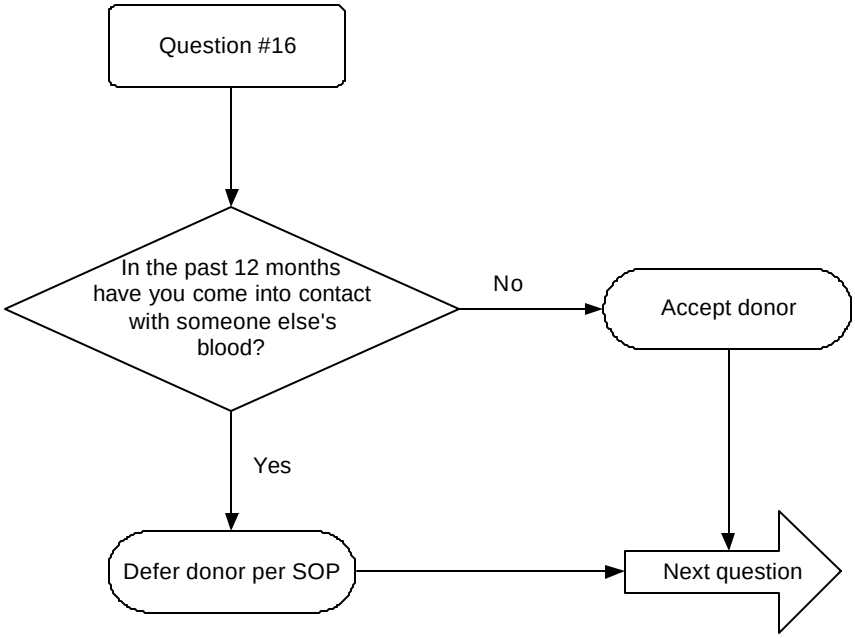
Question: 15. In the past 12 months have you had a graft such as bone or skin?

Donor Eligibility: A donor who has been exposed to allogeneic tissues through grafting should not donate blood for 12 months following exposure, due to possible transmissibility of infectious disease.



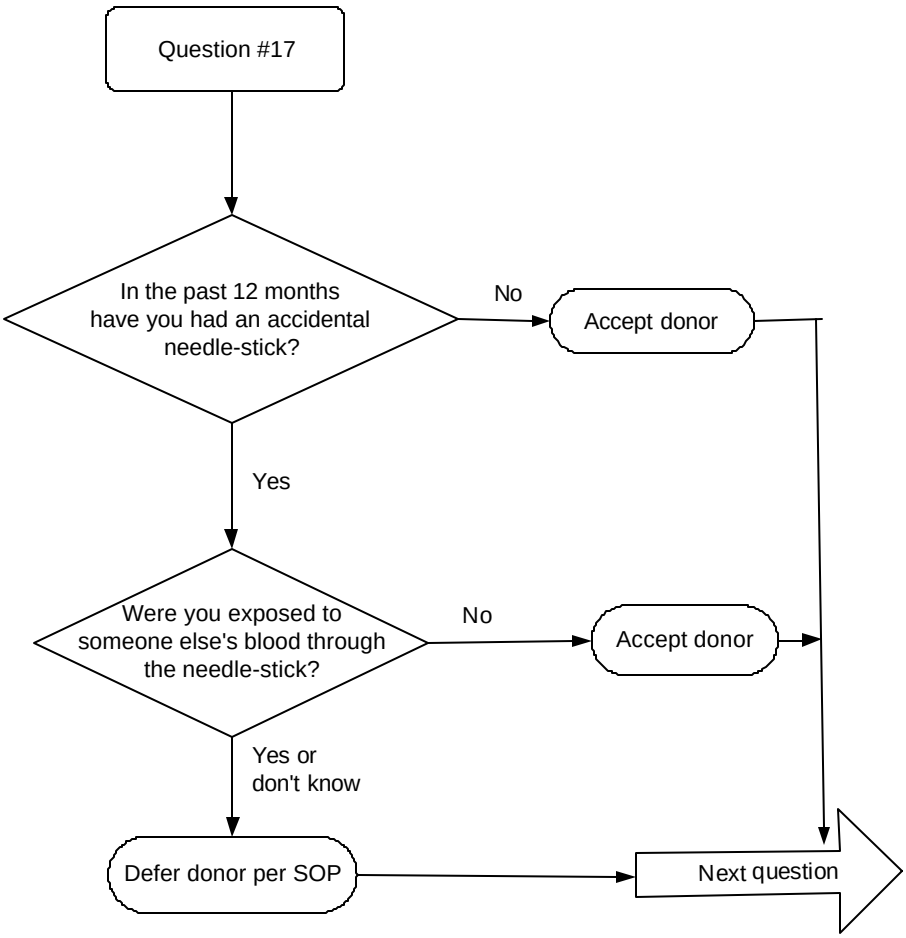
Question: 16. In the past 12 months have you come in contact with someone else's blood?

Donor Eligibility: Persons who have had one of the following during the preceding 12 months: 1) contact of an open wound, non-intact skin or mucous membrane with the blood of a person, or 2) a needle-stick or other sharps injury from an instrument that has been used on a person, are deferred for 12 months from the date of exposure. Infectious diseases may be spread through contact with blood.



Question: 17. In the past 12 months have you had an accidental needle-stick?

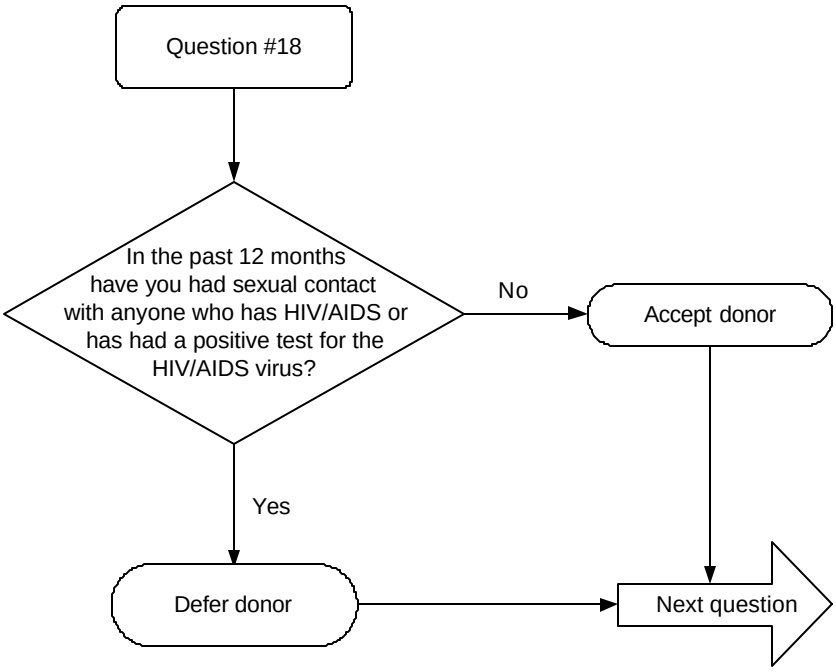
Donor Eligibility: A donor who has been exposed to someone else's blood through a needle-stick should not donate blood for 12 months following exposure, due to possible transmissibility of infectious disease.



Question: 18. In the past 12 months have you had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?

Donor Eligibility: Persons who have had sexual contact with persons with clinical or laboratory evidence of HIV infection are deferred for 12 months from the date of last contact. HIV may be transmitted through sexual contact with an infected person.

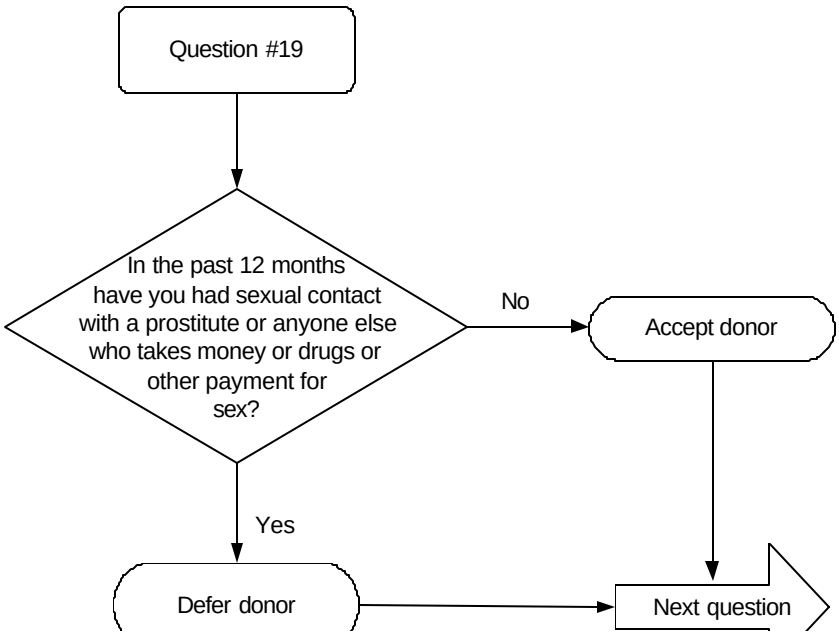
Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.



Question: 19. In the past 12 months have you had sexual contact with a prostitute or anyone else who takes money or drugs or other payment for sex?

Donor Eligibility: Persons who have given money or drugs in exchange for sex (sexual contact) are deferred for 12 months from the date of the last sexual contact. HIV and other diseases may be transmitted through sexual contact.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.

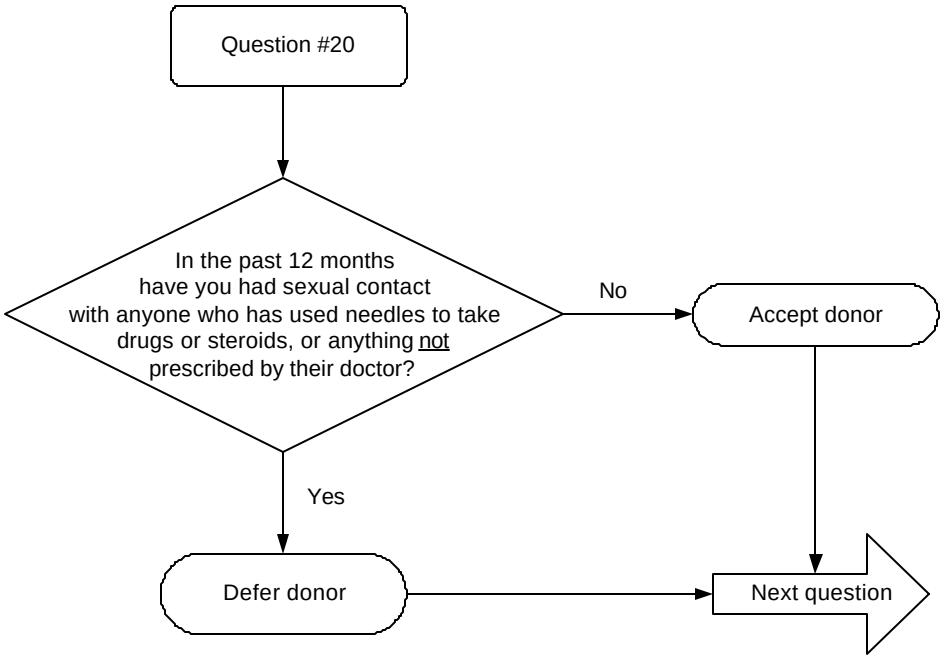


Question: 20. In the past 12 months have you had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything not prescribed by their doctor?

Donor Eligibility: Persons who have had sexual contact with persons who, in the past or present, have used needles to take drugs, steroids, or anything not prescribed by their doctor are deferred for 12 months from the date of the last sexual contact. HIV and other diseases may be transmitted through sexual contact.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.

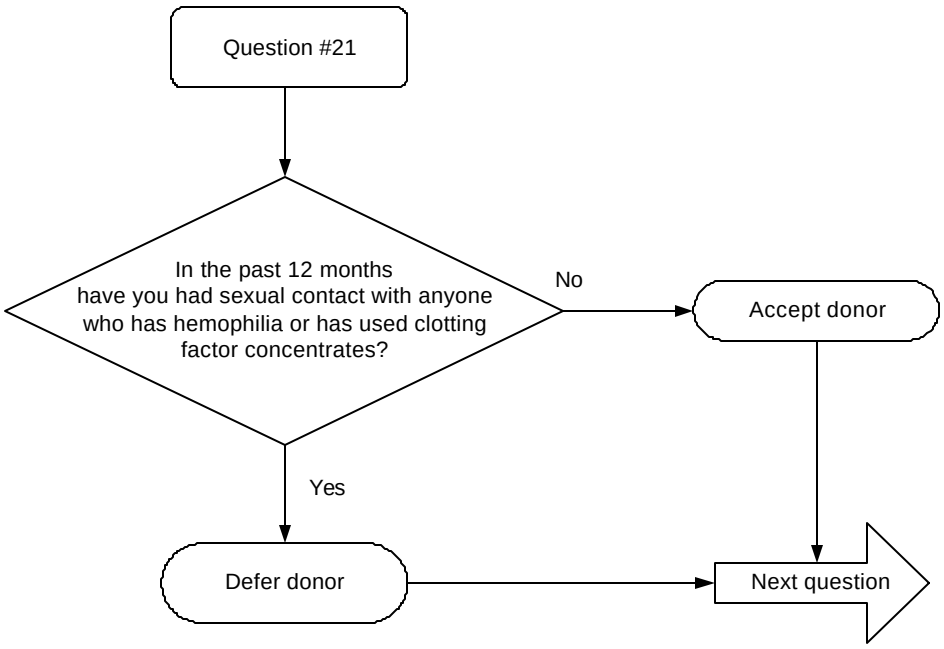
Note: The phrase "use of a needle" includes intravenous use, "skin popping" (injection under the skin), "mainlining" (arterial injection) and any other use of a needle to administer drugs, steroids or anything else not prescribed by their doctor.



Question: 21. In the past 12 months have you had sexual contact with anyone who has hemophilia or has used clotting factor concentrates?

Donor Eligibility: Persons who have had sexual contact with one of the following: 1) any person with hemophilia or related clotting disorders; or 2) any person who has received clotting factor concentrates is deferred for 12 months. HIV and other diseases may be transmitted through sexual contact.

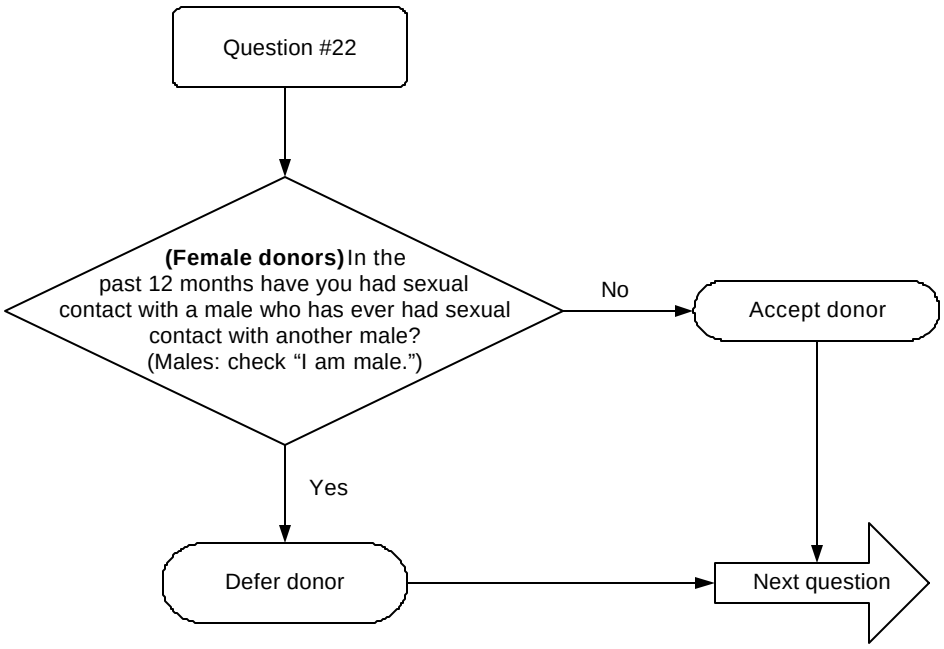
Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.



Question: 22. Female donors: In the past 12 months have you had sexual contact with a male who has ever had sexual contact with another male? (Males: check "I am male.")

Donor Eligibility: Women who have had sexual contact with men who have had sexual contact with another man even one time since 1977 are deferred for 12 months from the date of last sexual contact. HIV and other diseases may be transmitted through sexual contact.

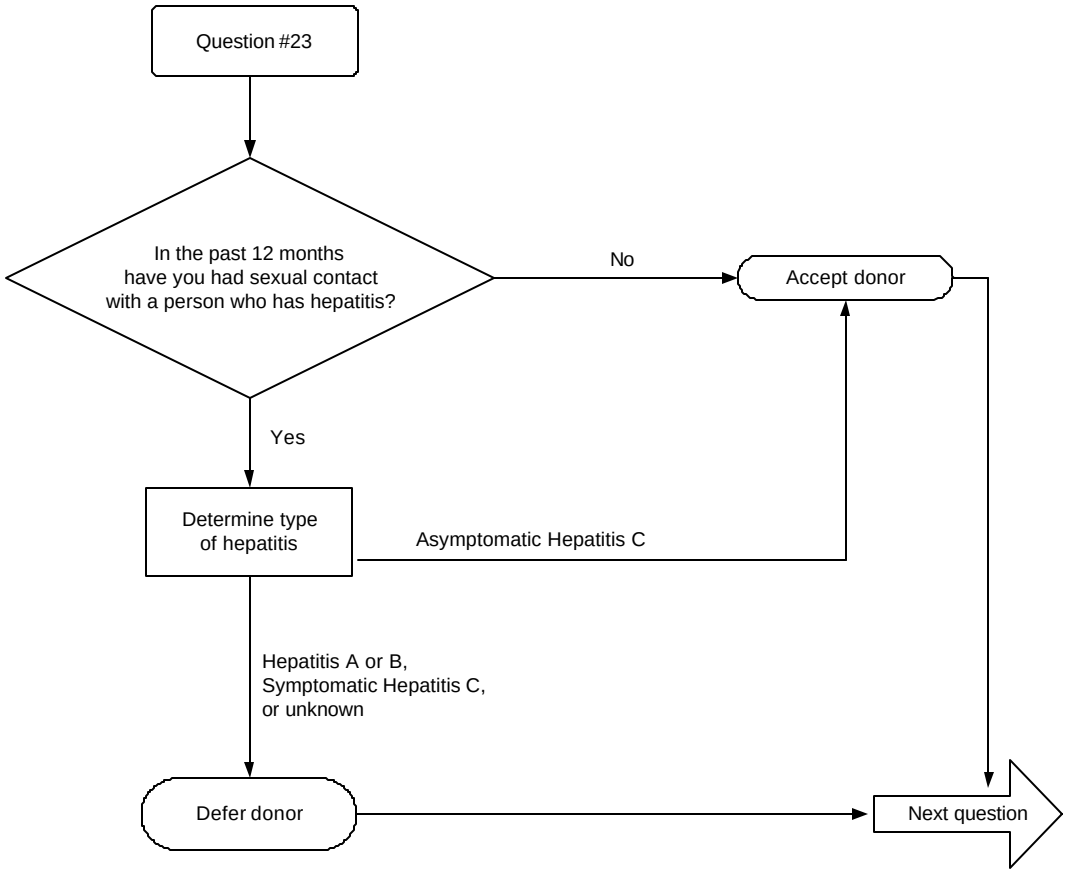
Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.



Question: 23. In the past 12 months have you had sexual contact with a person who has hepatitis?

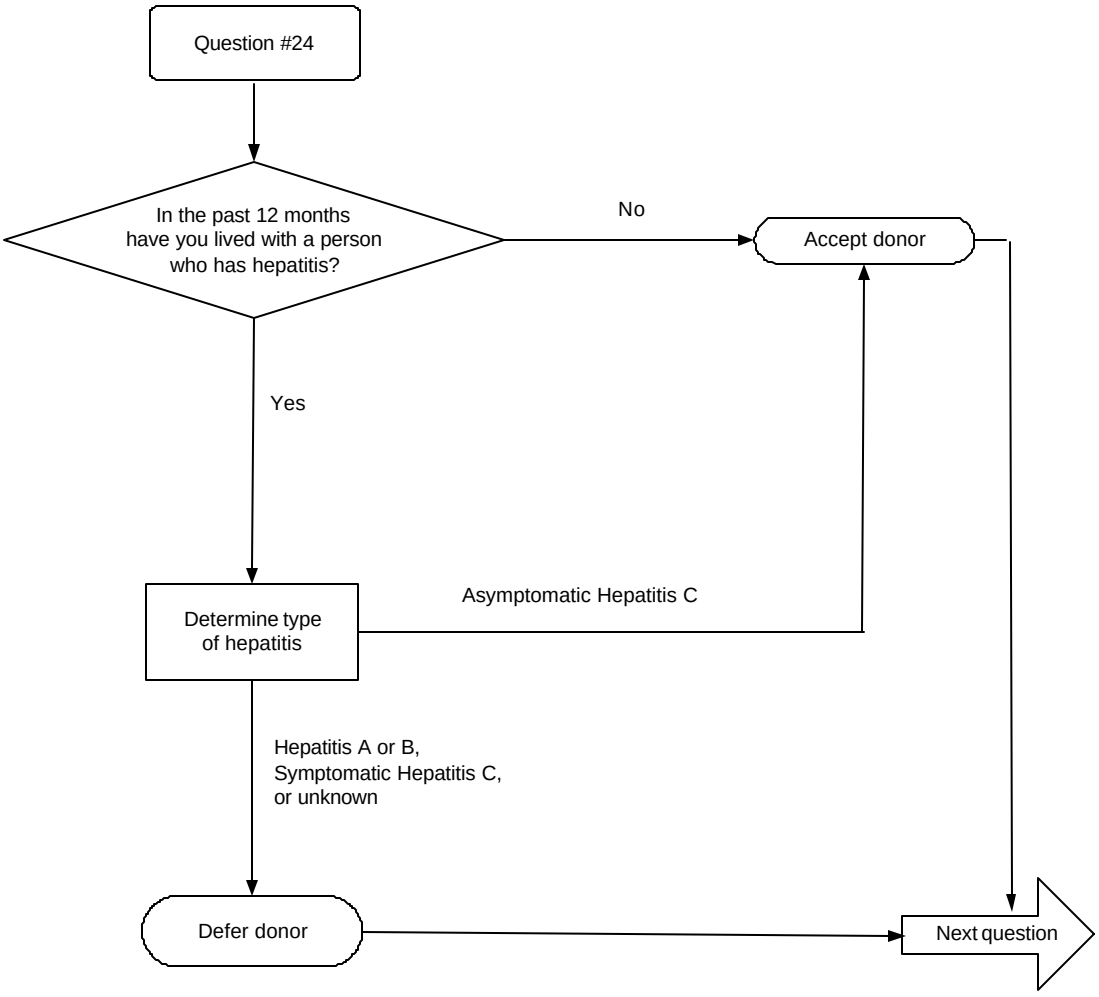
Donor Eligibility: Persons who report having had sexual contact with a person who has hepatitis are to be deferred for 12 months from the time of last exposure. Hepatitis, particularly hepatitis A and B, may be spread through sexual contact.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.



Question: 24. In the past 12 months have you lived with a person who has hepatitis?

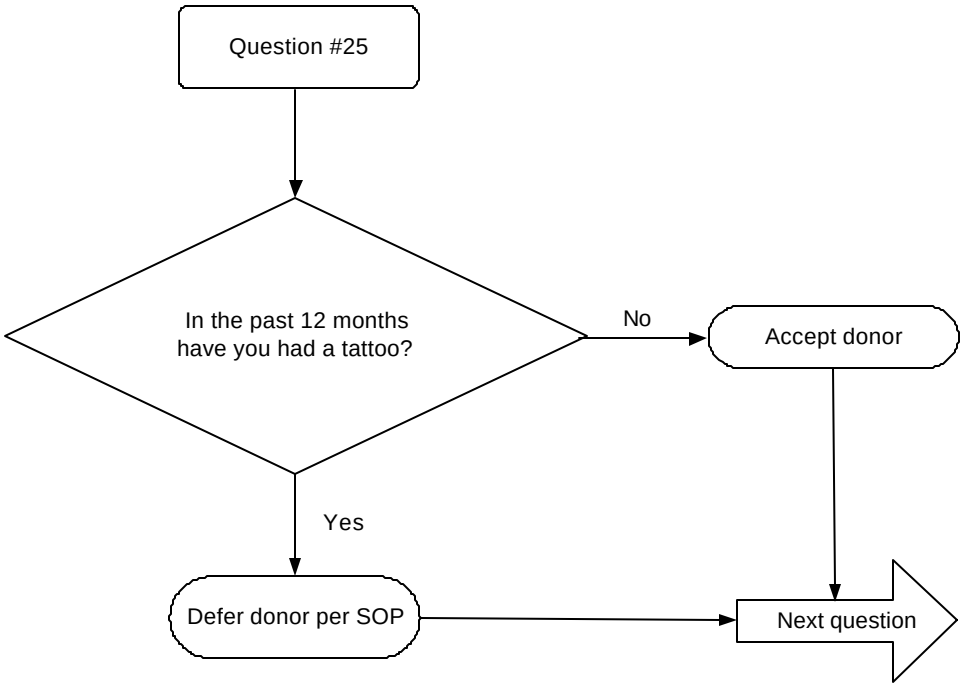
Donor Eligibility: In certain cases, living with a person with hepatitis puts the donor at risk for acquiring hepatitis as well.



Question: 25. In the past 12 months have you had a tattoo?

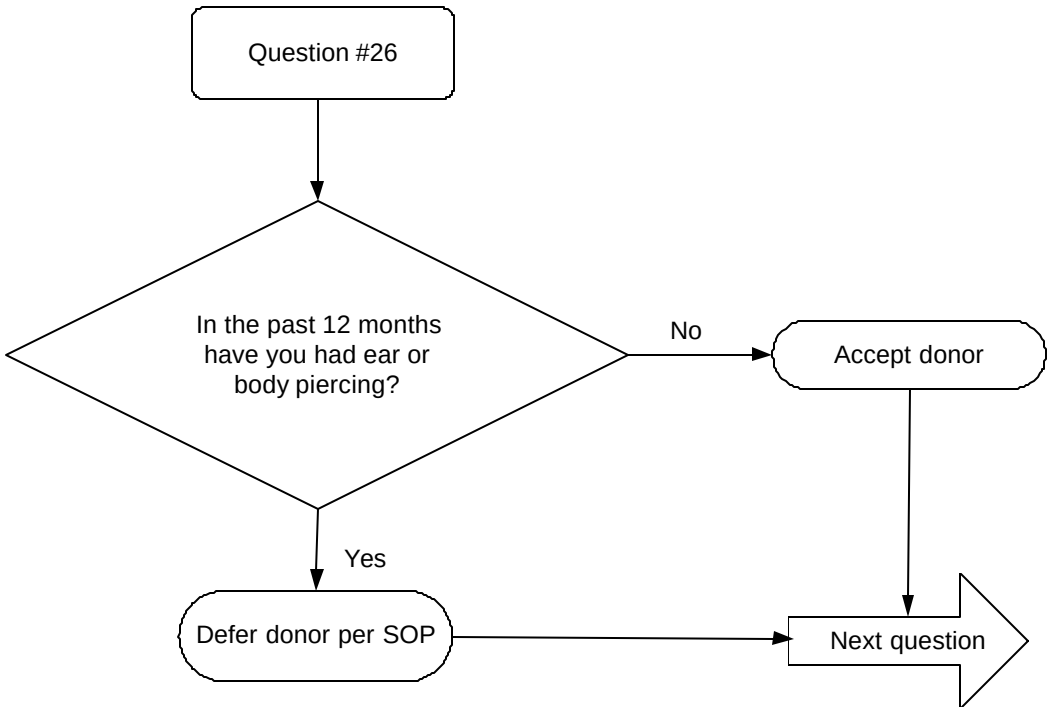
Donor Eligibility: Persons who have had a tattoo in the previous 12 months are deferred for 12 months from the date of the tattoo application. Unless tattoos have been applied using single-use needles and single-use ink, there may be a risk of transmission of infectious diseases.

Note: Tattoos include tattoo "touch ups", tattoos applied by oneself, and those applied by others.



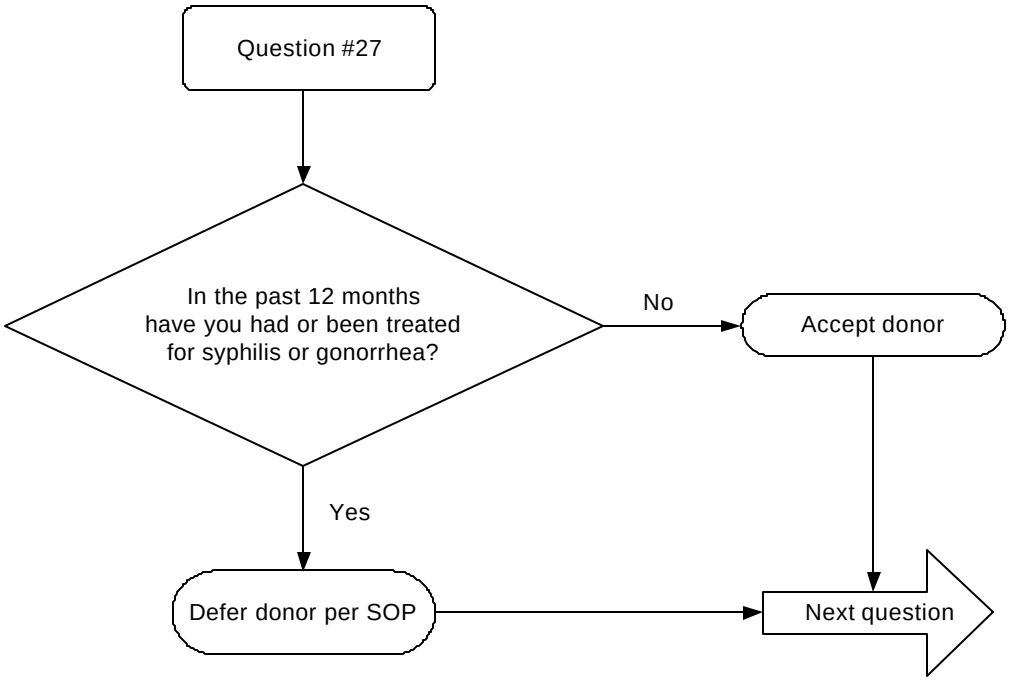
Question: 26. In the past 12 months have you had ear or body piercing?

Donor Eligibility: Persons who have had ear or body piercing during the previous 12 months are usually deferred for 12 months from the date of procedure. Unless ear or body piercing has been done using single-use equipment, there may be a risk of transmission of infectious diseases.



Question: 27. In the past 12 months have you had or been treated for syphilis or gonorrhea?

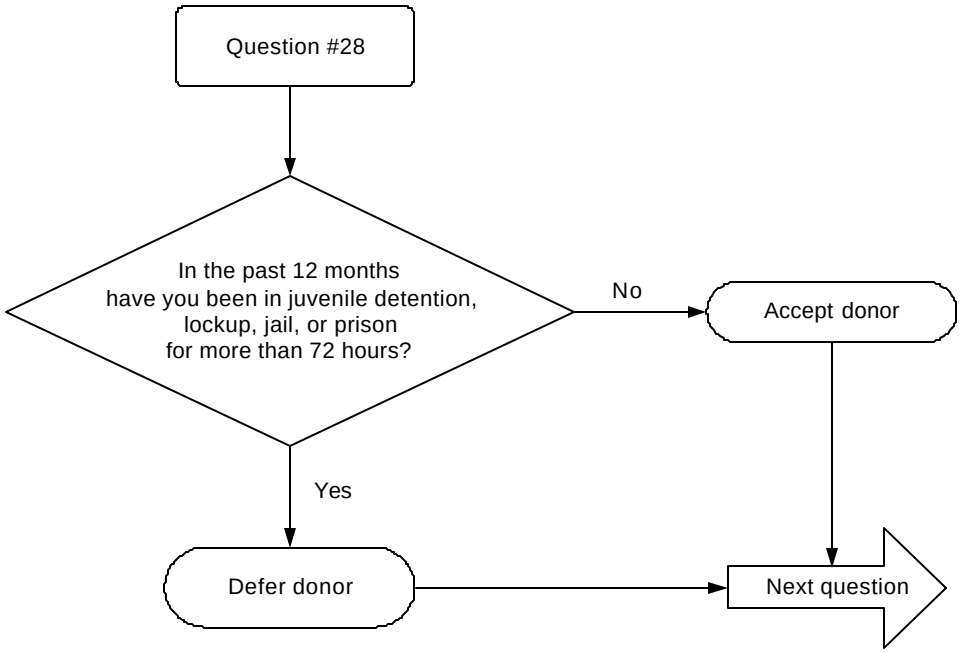
Donor Eligibility: Persons who have had syphilis or gonorrhea, treatment for either, or a confirmed react screening test for syphilis are deferred for 12 months from the date that treatment is completed.



Question: 28. In the past 12 months have you been in juvenile detention, lockup, jail, or prison for more than 72 hours?

Donor Eligibility: Persons who have been detained or incarcerated in a facility (juvenile detention, lockup, jail, or prison) for more than 72 consecutive hours (3 days) are deferred for 12 months from the date of occurrence. These persons are at higher risk for exposure to infectious diseases.

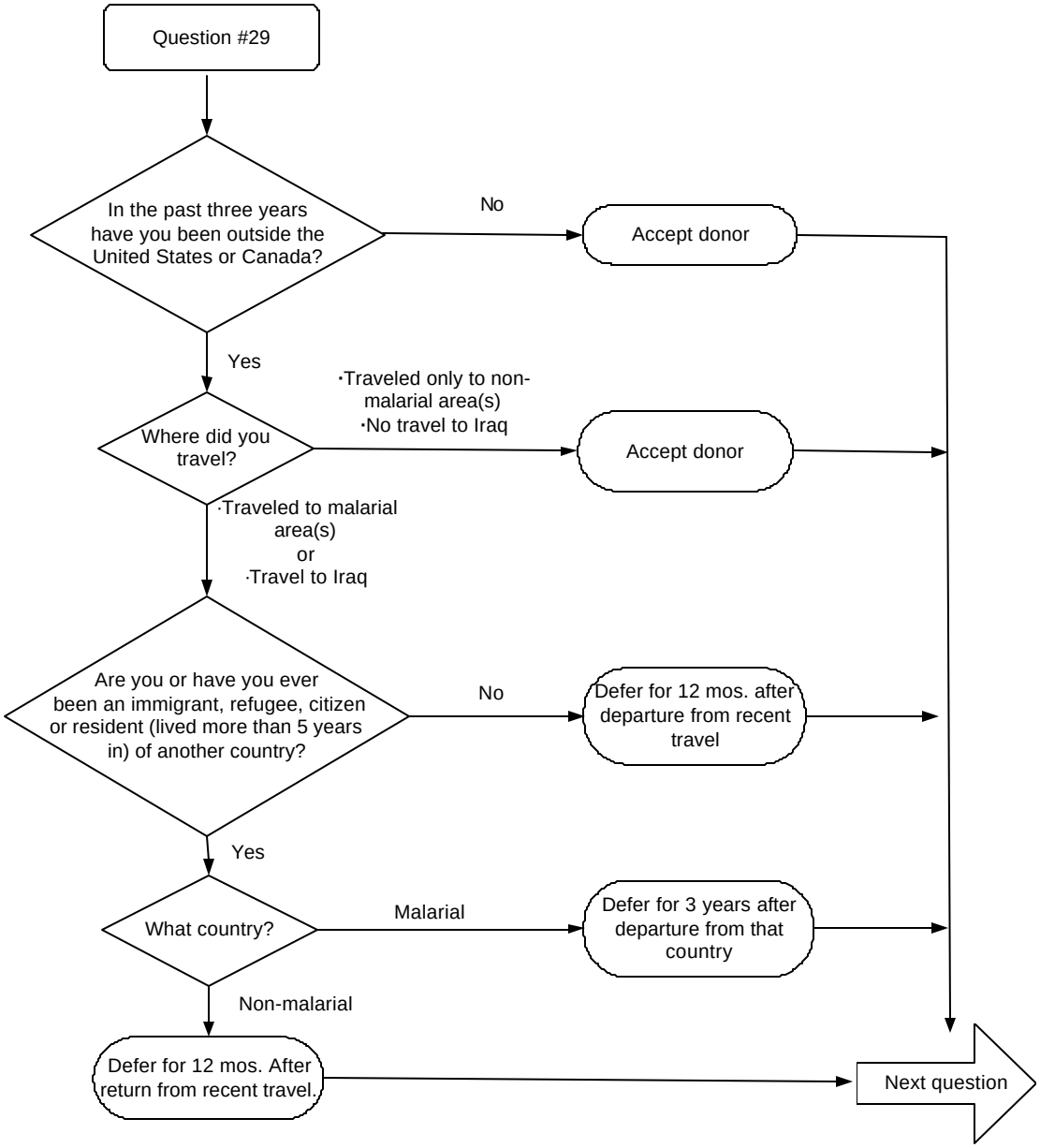
Note: The reason for incarceration (e.g. white-collar crimes, child support) does not change the deferral.



Question: 29. In the past three years have you been outside the United States or Canada?

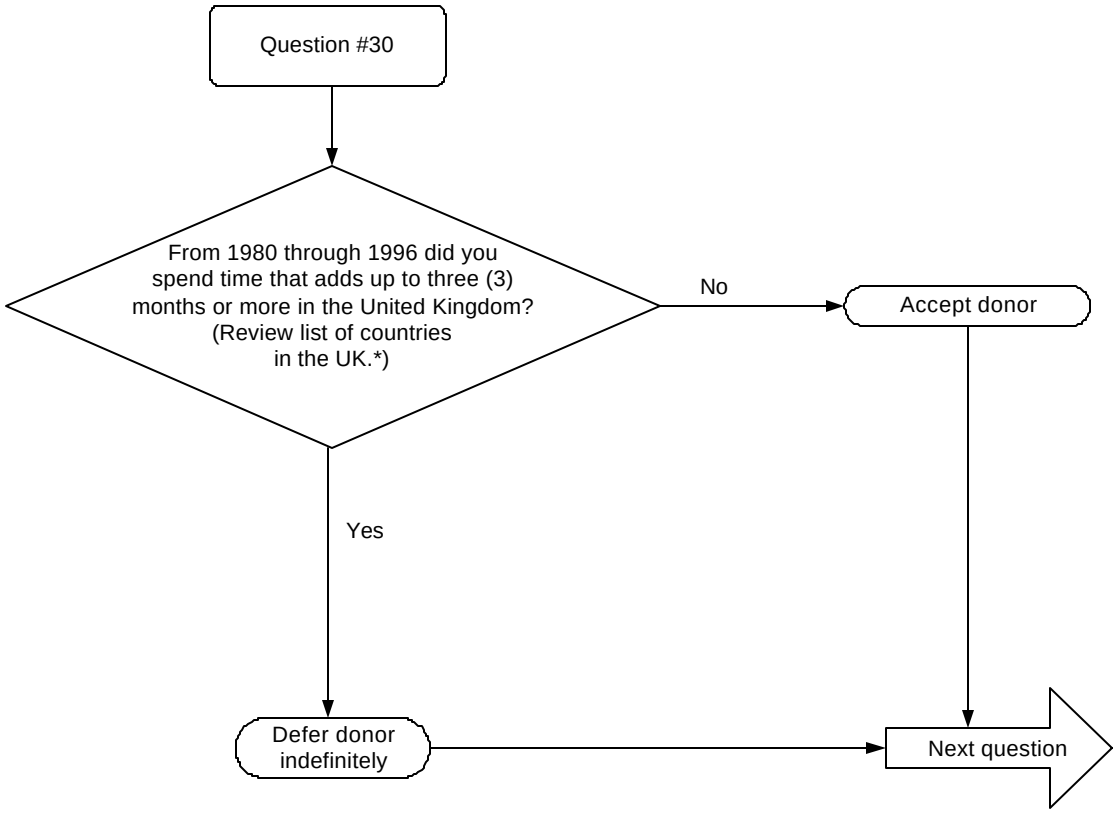
Donor Eligibility: Immigrants, refugees, or citizens coming from a country in which malaria is considered endemic will be deferred for 3 years after departure from the area if they have been free from unexplained symptoms suggestive of malaria. Donors who have traveled to an area where malaria is considered endemic will be deferred for 12 months after departure from that area regardless of whether or not they took anti-malaria prophylaxis. Malaria may be transmitted through blood transfusion. The donors shall be accepted or deferred based on the Malaria Risk Countries as designated by your institution.

Donors who have traveled to Iraq may have been exposed to Leishmaniasis; such donors should be deferred for 12 months after departure from Iraq.



Question: 30. From 1980 through 1996 did you spend time that adds up to three (3) months or more in the United Kingdom? (Review list of countries in the UK.) http://www.fda.gov/cber/gdlns/cjdvcjd.htm

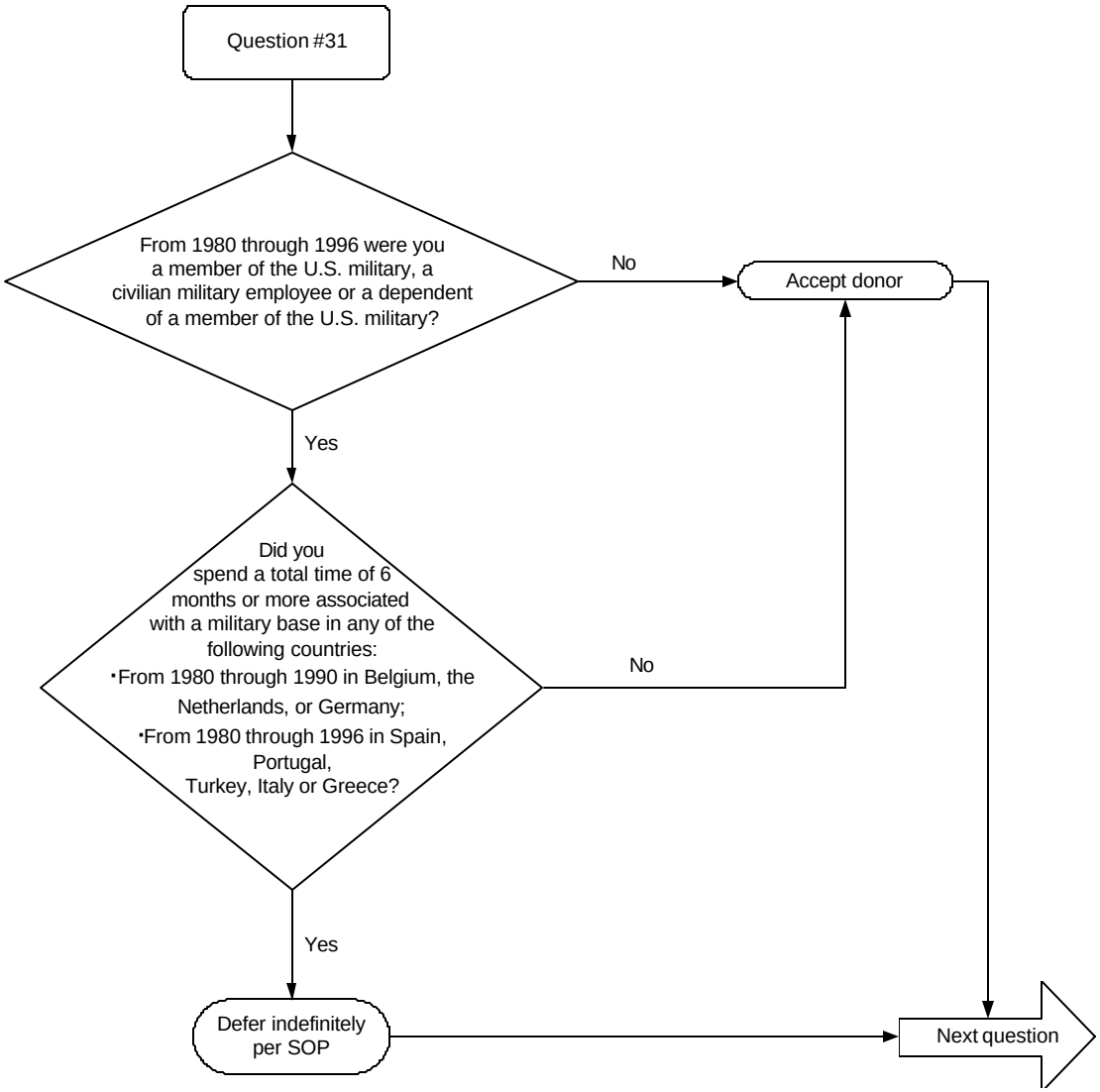
Donor Eligibility: Donors who have spent time that adds up to three (3) months or more in the United Kingdom from 1980 through 1996 are indefinitely deferred. Donors may be at theoretical risk of developing vCJD from eating beef from the UK. There may be a theoretical risk of transmitting vCJD through blood transfusion.



* See FDA "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Ceutzfeldt-Jakob Disease vCJD) by Blood and Blood Products." *http://www.fda.gov/cber/gdlns/cjdvcjd.htm*

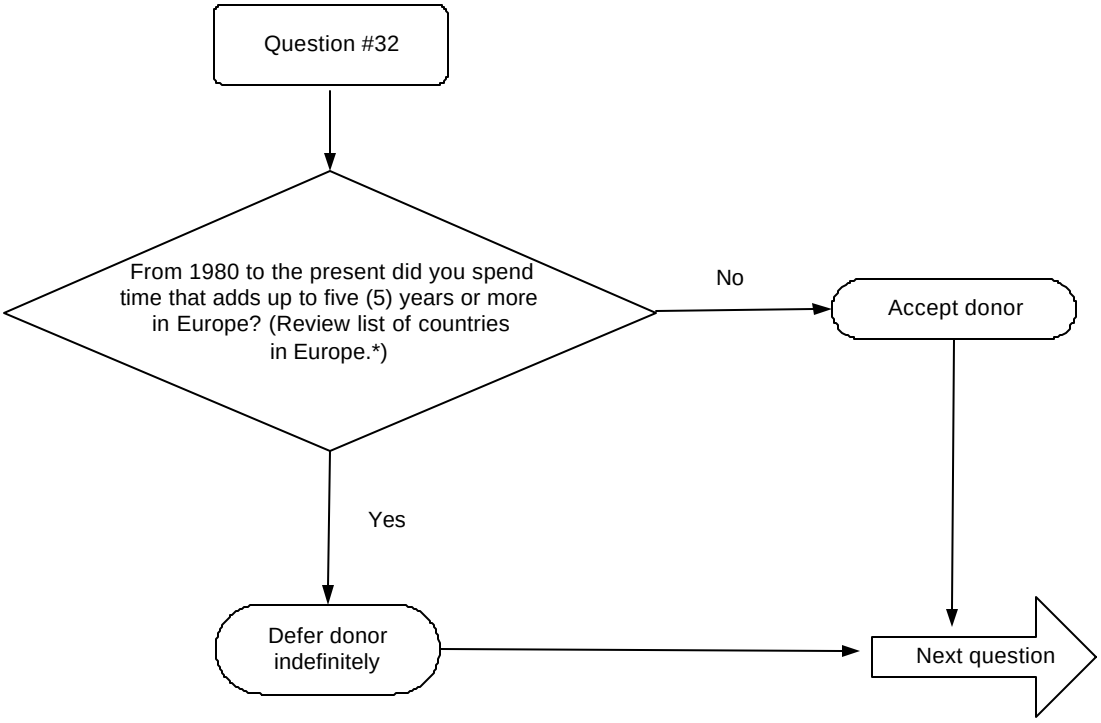
Question: 31. From 1980 through 1996 were you a member of the U.S. military, a civilian military employee or a dependent of a member of the U.S. military?

Donor Eligibility: Members of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military are indefinitely deferred if they spent a total of 6 months or more associated with a military base in any of the following countries: From 1980 through 1990 in Belgium, the Netherlands, or Germany; From 1980 through 1996 in Spain, Portugal, Turkey, Italy or Greece. Donors may be at theoretical risk of developing vCJD from eating beef from the UK. There may be a theoretical risk of transmitting vCJD through blood transfusion.



Question: 32. From 1980 to the present did you spend time that adds up to five (5) years or more in Europe? (Review list of countries in Europe.)

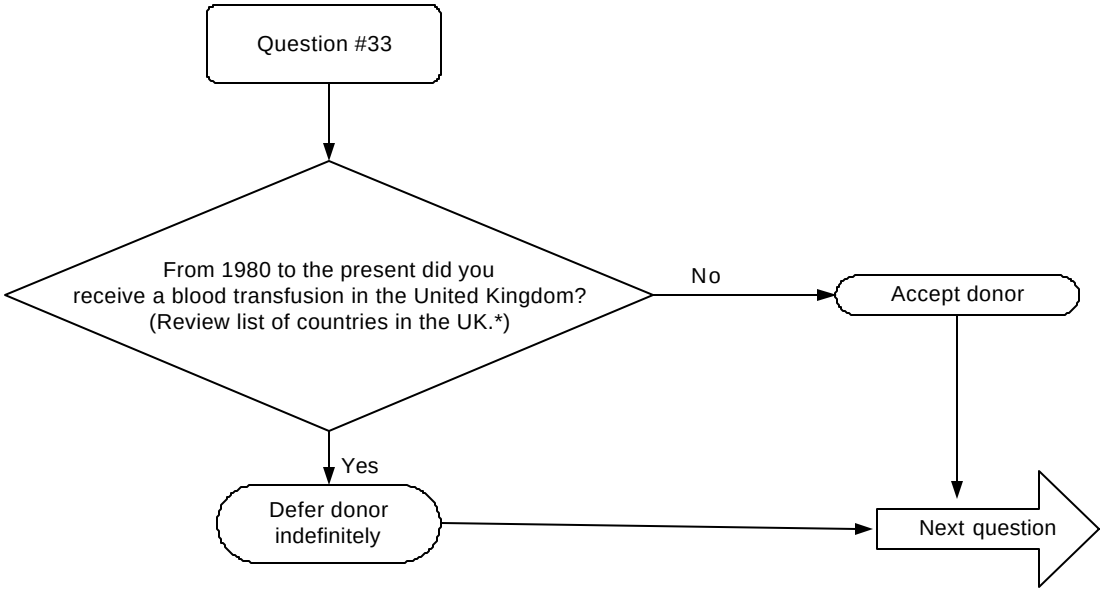
Donor Eligibility: Donors who have spent time that adds up to five (5) years or more in Europe from 1980 to the present are indefinitely deferred. Donors may be at theoretical risk of developing vCJD from eating beef in Europe. There may be a theoretical risk of transmitting vCJD through blood transfusion.



* See FDA "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Ceutzfeldt-Jakob Disease vCJD) by Blood and Blood Products." *http://www.fda.gov/cber/gdlns/cjdvcjd.htm*

Question: 33. From 1980 to the present did you receive a blood transfusion in the United Kingdom? (Review list of countries in the UK.)

Donor Eligibility: Donors who received a transfusion of blood, platelets, plasma, cryoprecipitate, or granulocytes in the UK from 1980 to the present are indefinitely deferred. Donors may be at theoretical risk of developing vCJD through transfusion. There may be a theoretical risk of transmitting vCJD through blood transfusion.

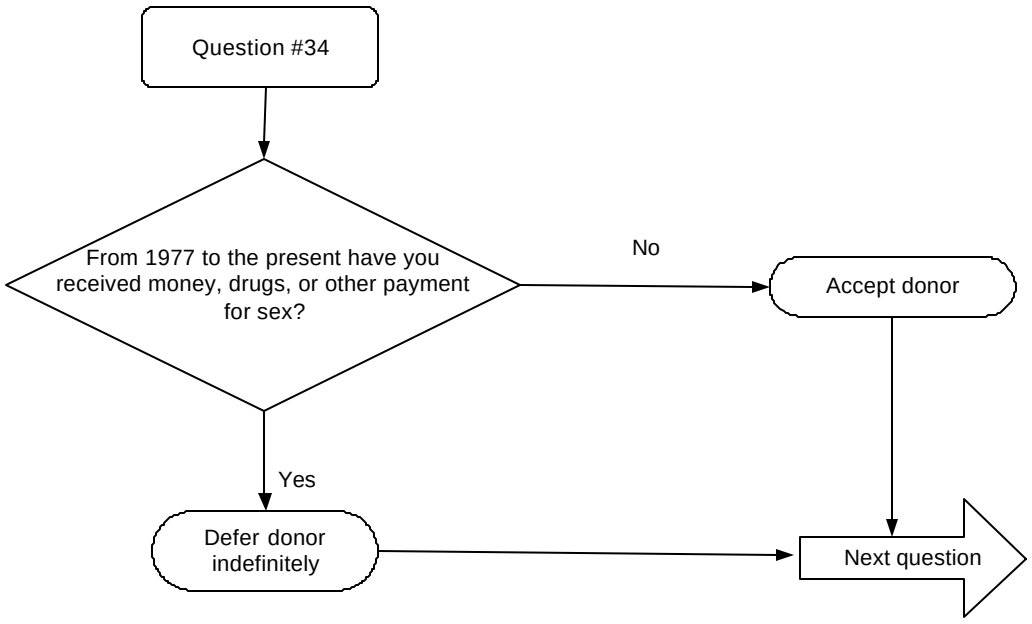


* See FDA "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Ceutzfeldt-Jakob Disease vCJD) by Blood Blood Products." *http://www.fda.gov/cber/gdlns/cjdvcjd.htm*

Question: 34. From 1977 to the present have you received money, drugs, or other payment for sex?

Donor Eligibility: Donors who received money, drugs, or other payment for sex are indefinitely deferred. HIV and other diseases may be transmitted by sexual contact.

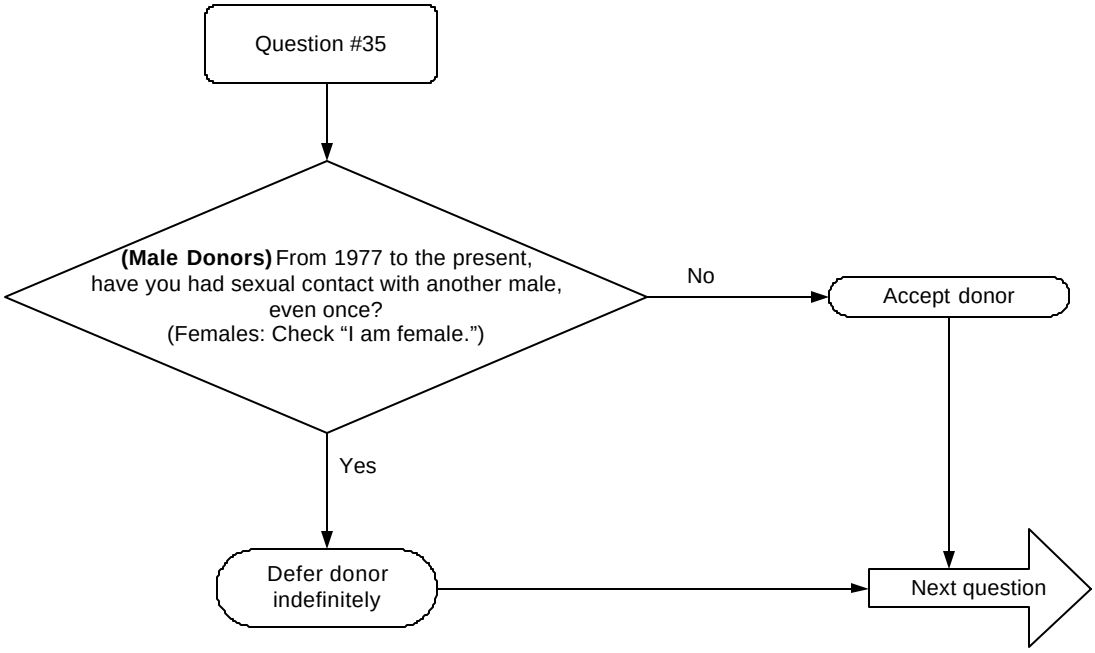
Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.



Question: 35. (Male Donors) From 1977 to the present, have you had sexual contact with another male, even once? (Females: Check "I am female.")

Donor Eligibility: Male donors who have had sexual contact with another male, even once, since 1977 are indefinitely deferred. Males who have had sex, even once, with males may be at risk of transmitting infectious diseases. HIV and other diseases may be transmitted through sexual contact.

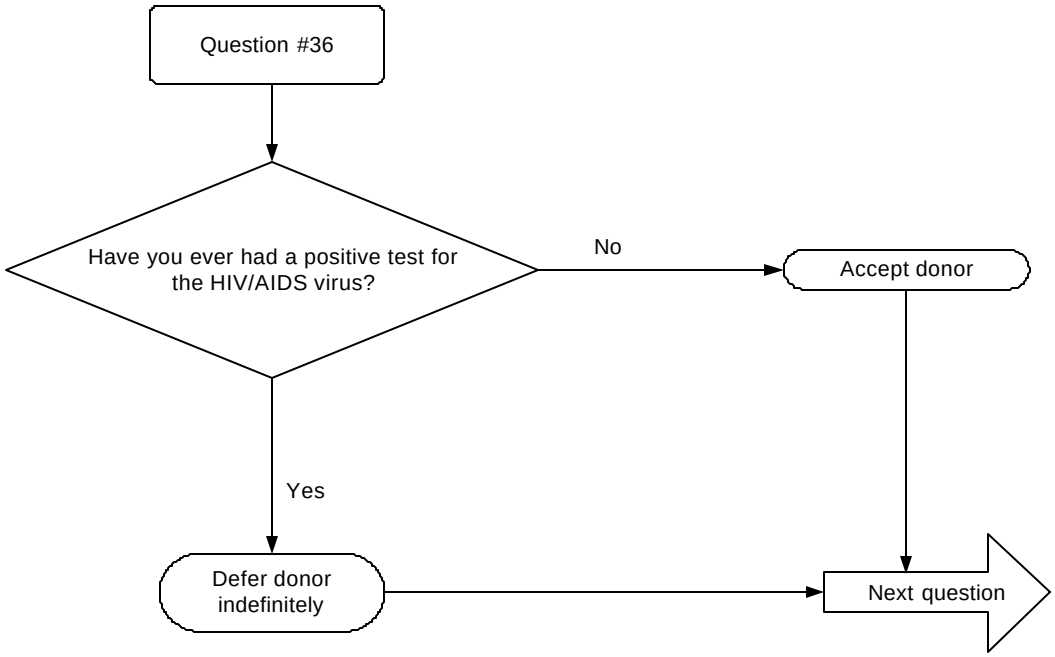
Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.



Question: 36. Have you ever had a positive test for the HIV/AIDS virus?

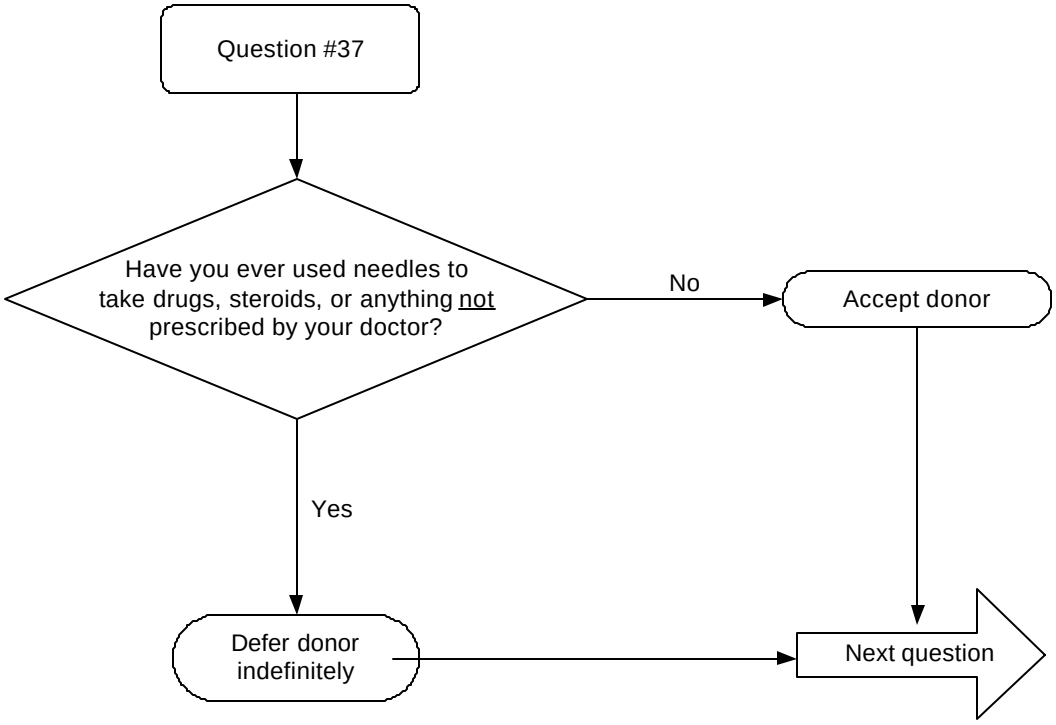
Donor Eligibility: Donors with clinical or laboratory evidence of HIV/AIDS are indefinitely deferred. HIV and other diseases may be transmitted through sexual contact.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.



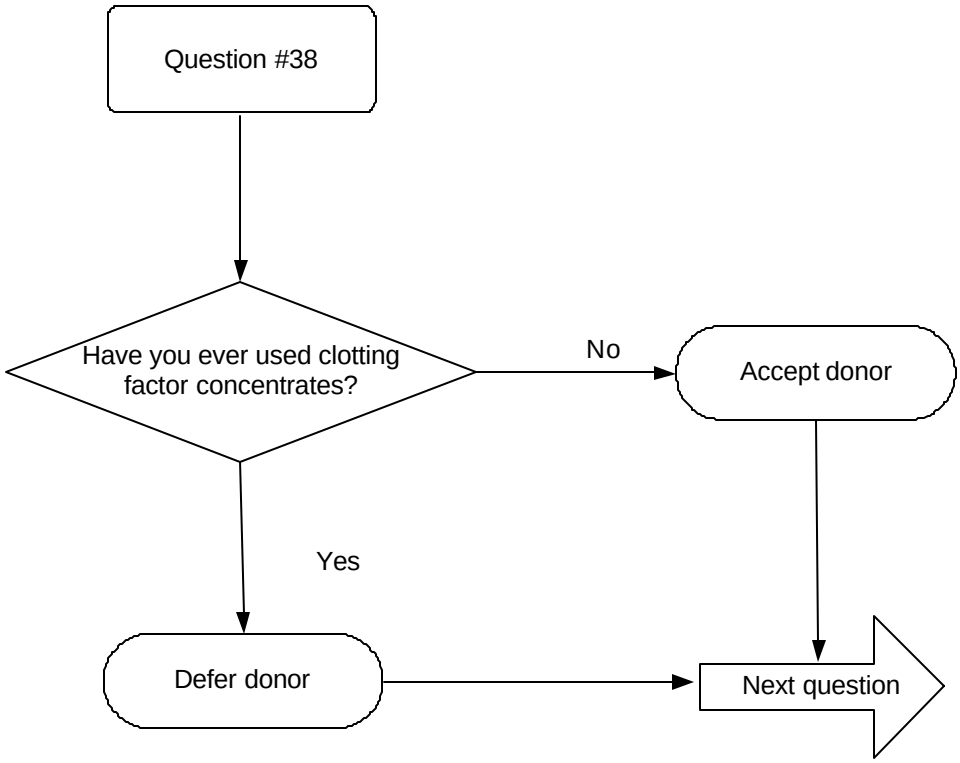
Question: 37. Have you ever used needles to take drugs, steroids, or anything not prescribed by your doctor?

Donor Eligibility: Donors who are past or present needle-using drug users are indefinitely deferred due to potential transmission of infectious diseases.



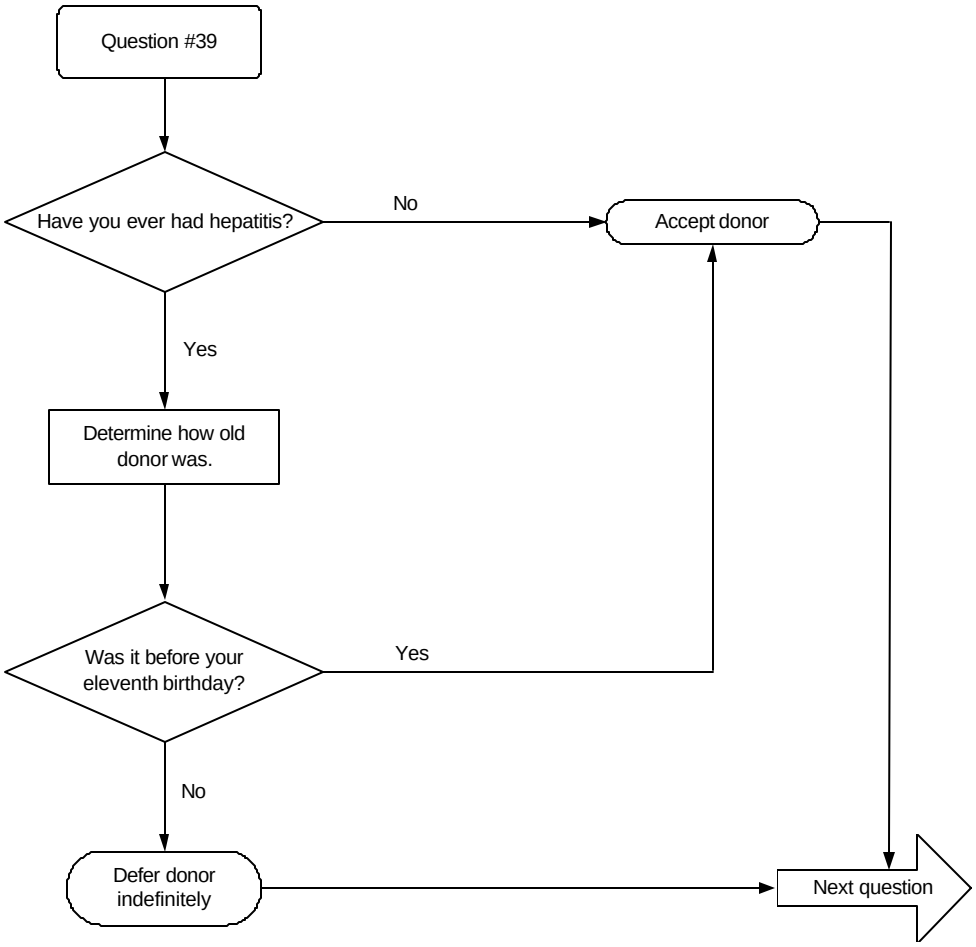
Question: 38. Have you ever used clotting factor concentrates?

Donor Eligibility: A donor who has been exposed to clotting factor concentrates should not donate blood due to possible transmissibility of infectious disease.



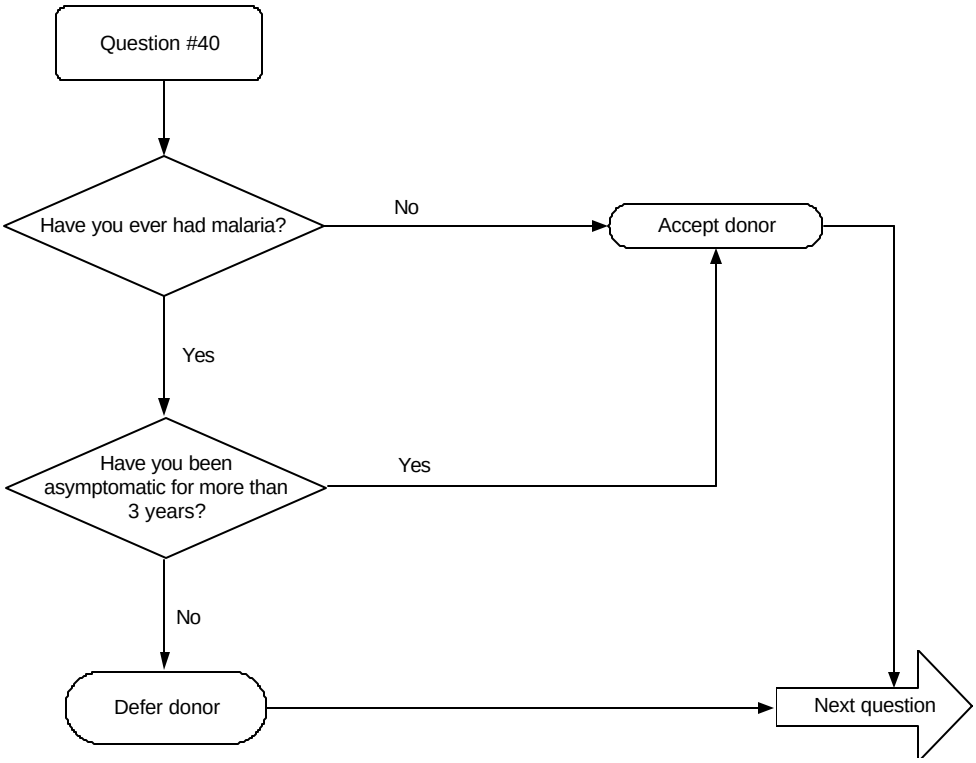
Question: 39. Have you ever had hepatitis?

Donor Eligibility: Donors who have a history of viral hepatitis after their eleventh birthday are indefinitely deferred.



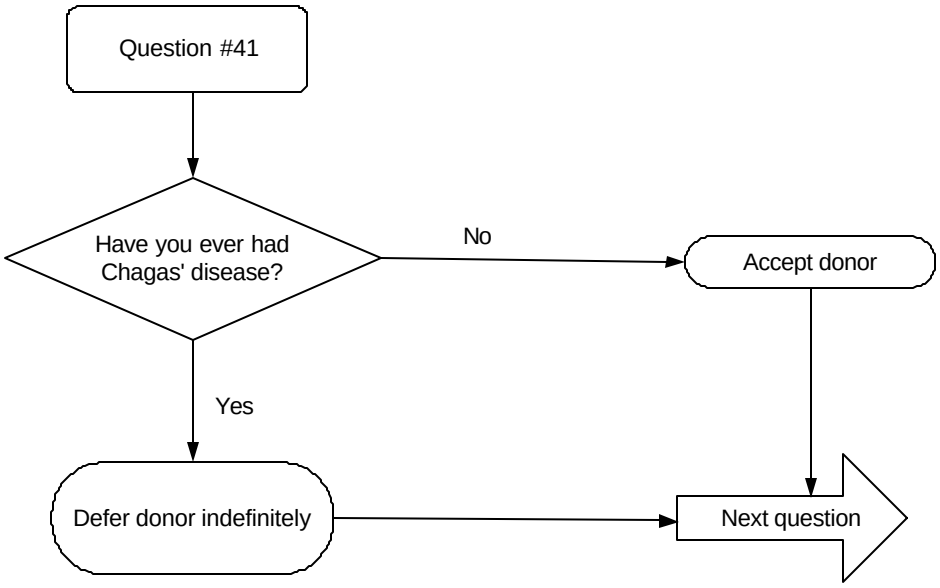
Question: 40. Have you ever had malaria?

Donor Eligibility: Prospective donors who have had malaria and received an appropriate treatment should be deferred for three years after becoming asymptomatic. Malaria can be transmitted by blood.



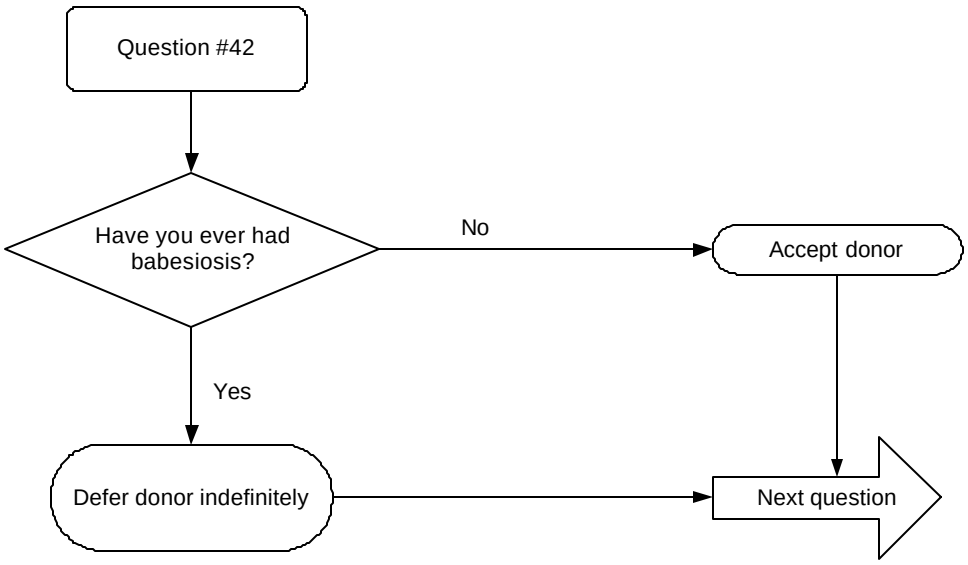
Question: 41. Have you ever had Chagas' disease?

Donor Eligibility: Donors who have had Chagas' disease are indefinitely deferred. Chagas' disease can be transmitted by blood.



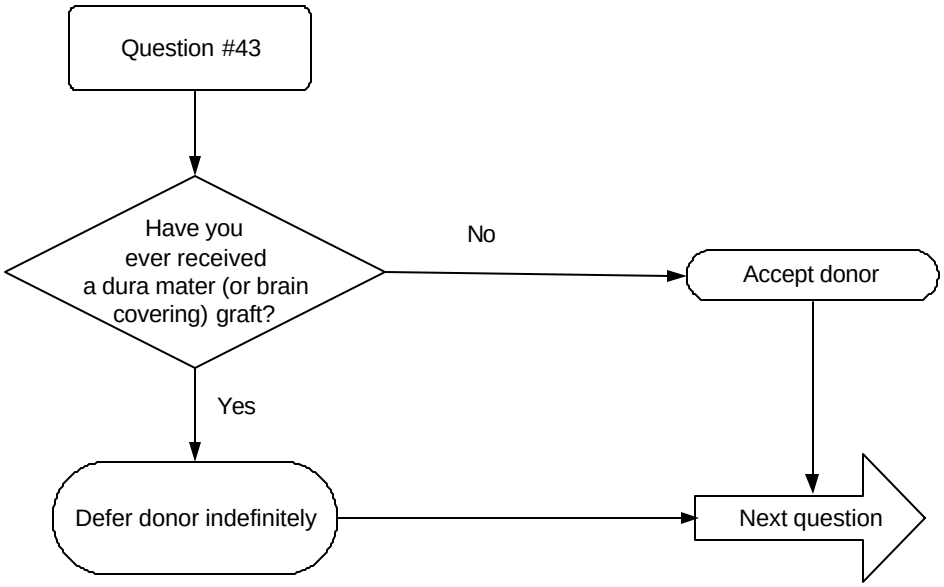
Question: 42. Have you ever had babesiosis?

Donor Eligibility: Donors who have had babesiosis are indefinitely deferred. Babesiosis can be transmitted by blood.



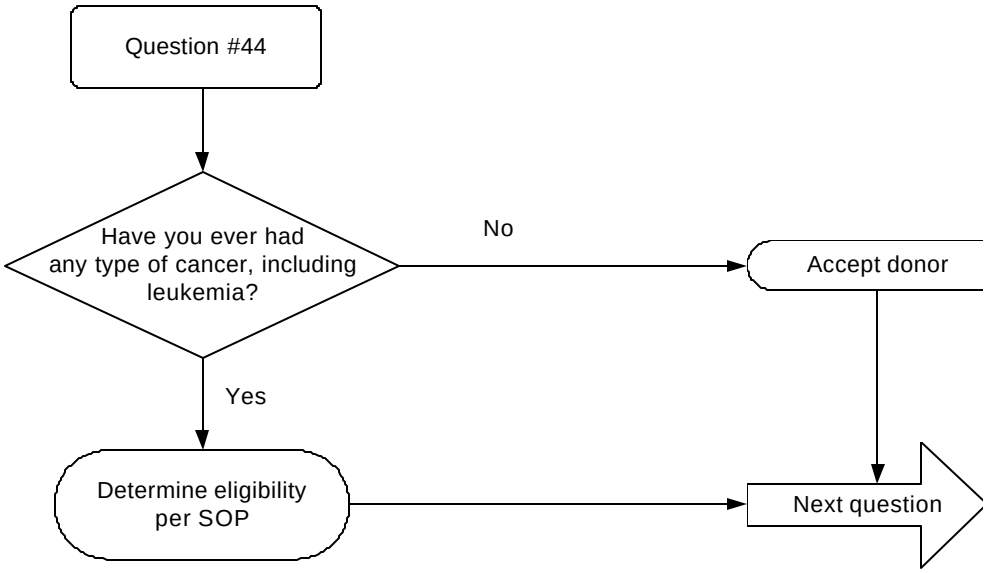
Question: 43. Have you ever received a dura mater (or brain covering) graft?

Donor Eligibility: Donors who have received a dura mater transplant or graft may be at risk for Creutzfeldt-Jakob disease and are indefinitely deferred.



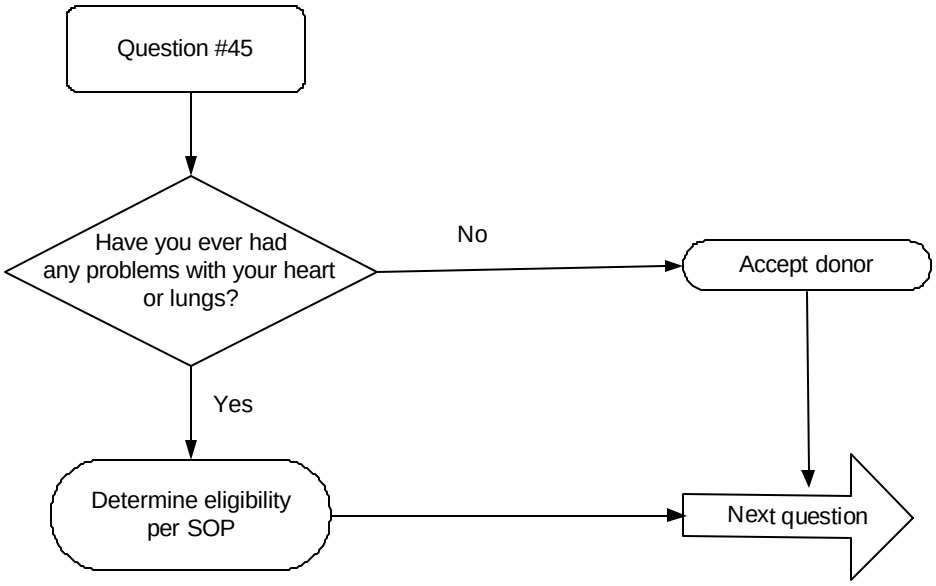
Question: 44. Have you ever had any type of cancer, including leukemia?

Donor Eligibility: Donors with a history of cancer must be evaluated and deemed eligibile to donate. Refer to SOP.



Question: 45. Have you ever had any problems with your heart or lungs?

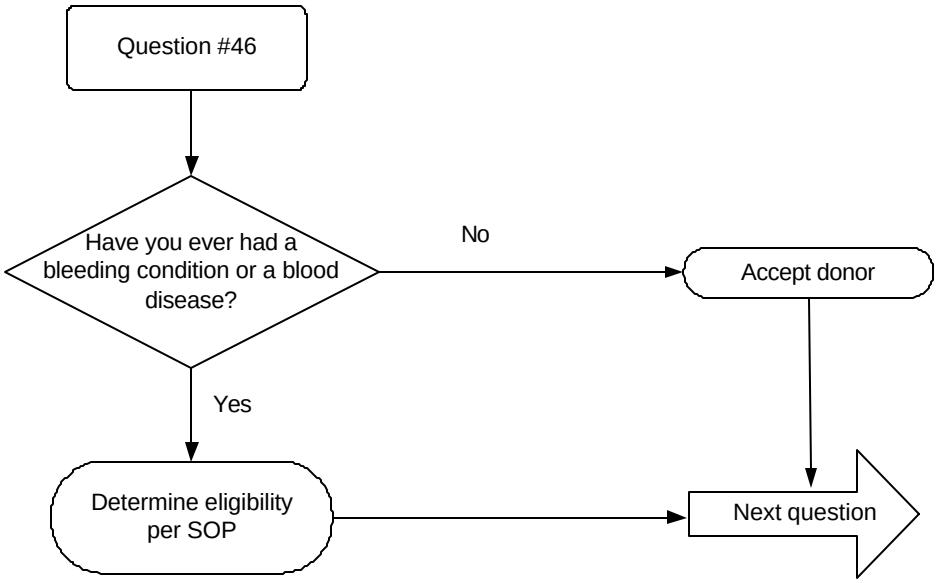
Donor Eligibility: Donors must be free of acute respiratory disease. Donors with a history of diseases of the heart and lungs, including acute lung diseases or colds, must be evaluated. Refer to SOP.



Question: 46. Have you ever had a bleeding condition or a blood disease?

Donor Eligibility: Donors with a history of bleeding problems should be evaluated. Refer to SOP.

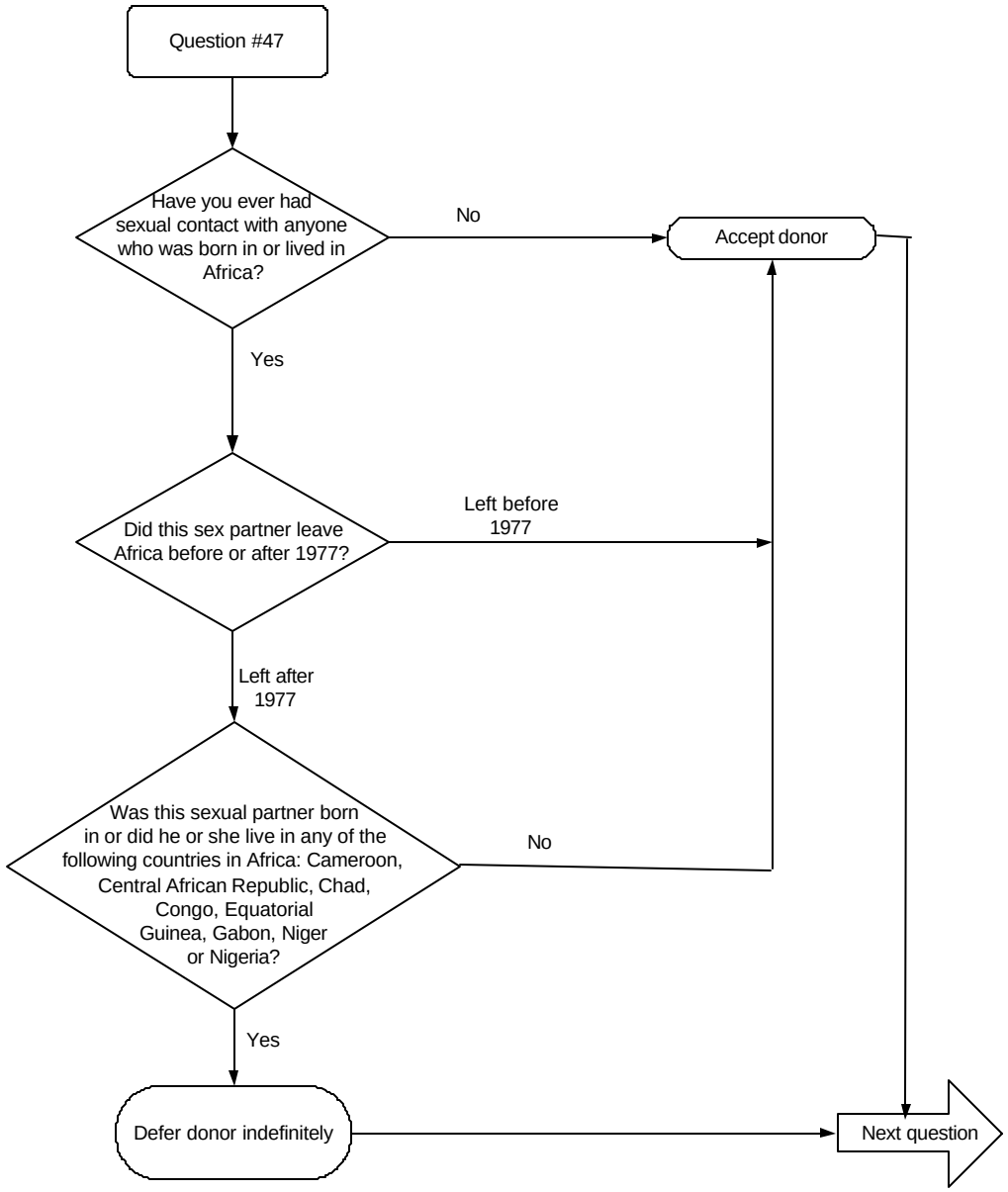
Note: Donors who have been receiving clotting factor concentrates are deferred indefinitely.



Question: 47. Have you ever had sexual contact with anyone who was born in or lived in Africa?

Donor Eligibility: If the donor had a sex partner who was born in or lived in certain countries in Africa (see list below) after 1977, the donor is indefinitely deferred. Donors who have had sexual contact may have been exposed to rare strains of HIV that are not consistently detected by all current test methods. **

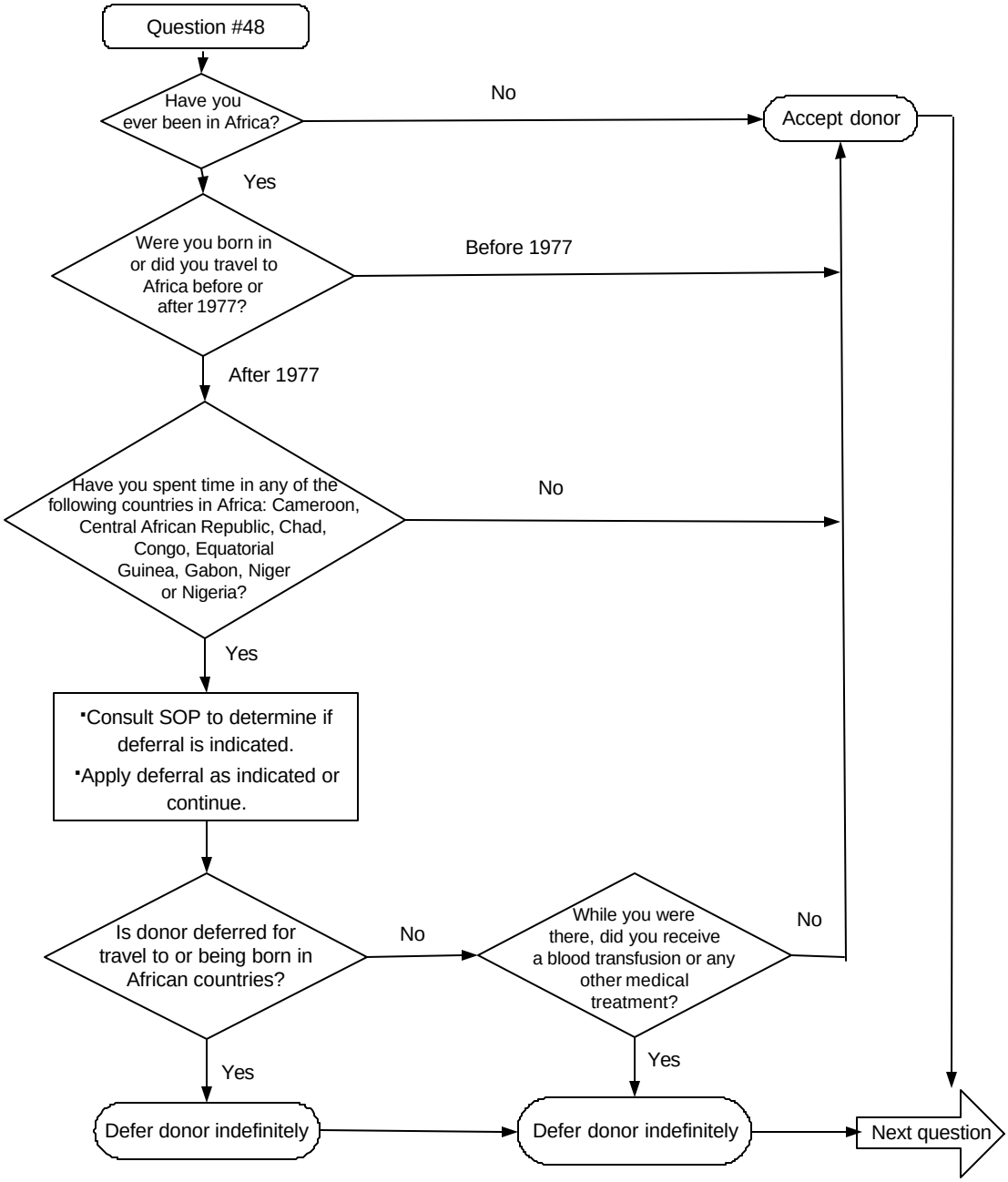
Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.



** Blood collection agencies using an HIV antibody test that has been approved by FDA to include a claim for detection of group O viruses may eliminate this question during screening.

Question: 48. Have you ever been in Africa?

Donor Eligibility: Donors who were born in or have lived in certain countries in Africa since 1977 (see list below) are indefinitely deferred. Donors who have received a blood transfusion or any other medical treatment in Africa are indefinitely deferred. Donors may have been exposed to rare strains of HIV that are not consistently detected by all current test methods. **

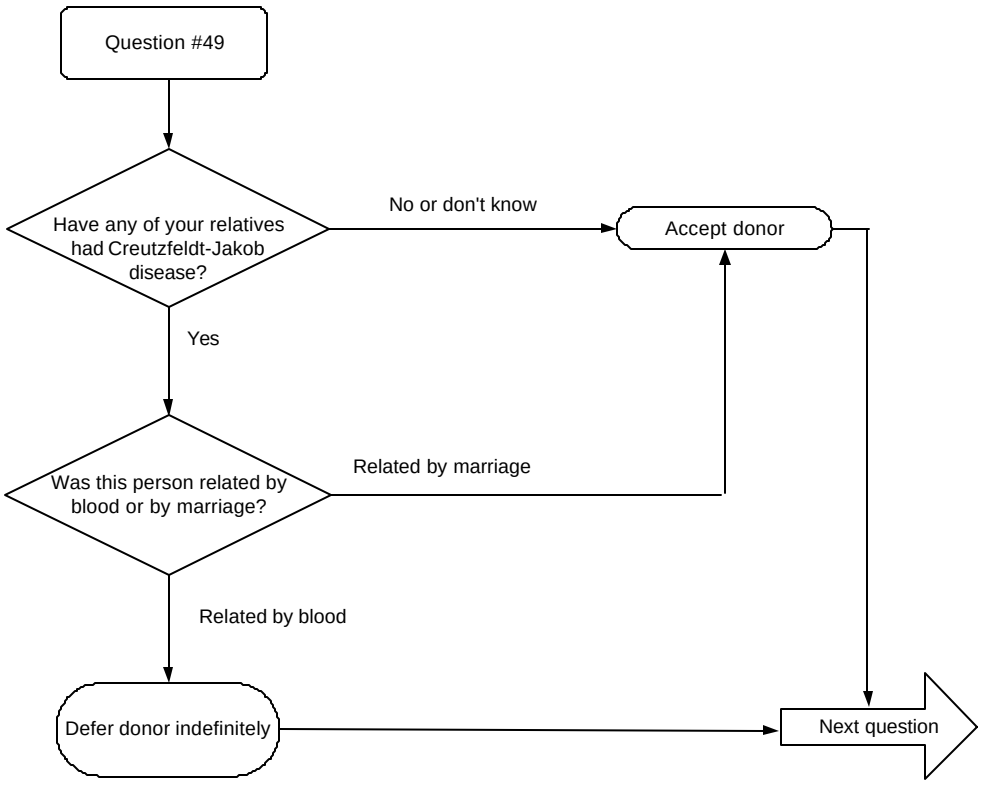


** Blood collection agencies using an HIV antibody test that has been approved by FDA to include a claim for detection of group O viruses may eliminate this question during screening.

Question: 49. Have any of your relatives had Creutzfeldt-Jakob disease?

Donor Eligibility: Donors with a blood relative with Creutzfeldt-Jakob disease are indefinitely deferred.

Note: If laboratory testing (gene sequencing) shows that the donor does not have a mutation associated with familial CJD, the donor is eligible.



APPENDIX 5: References

Donor qualification requirements are located in 21 CFR 640.3 and AABB Standards for Blood Banks and Transfusion Services (Standard 5.4; 5.5; and 5.4.1A in the 21st Edition).

Additional donor qualification requirements may be found in FDA memoranda and guidance:

FDA Memorandum October 7, 1988: Revised Guidelines for the Collection of Platelets, Pheresis.

FDA Memorandum, December 12, 1991: Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing.

FDA Memorandum, April 23, 1992: Revised Recommendations for the Prevention of HIV Transmission by Blood and Blood Products.

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) in Blood Establishments.

FDA Memorandum, July 28, 1993: Deferral of Blood and Plasma Donors Based on Medications.

FDA Memorandum December 22, 1993: Donor Suitability Related to Laboratory Testing For Viral Hepatitis and a History of Viral Hepatitis.

FDA Memorandum July 26, 1994: Recommendation for Deferral of Donors for Malaria Risk.

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.

FDA Memorandum, March 10, 1995: Revision of FDA Memorandum of August 27, 1982: Requirements for Infrequent Plasma Donors.

FDA Memorandum, December 14, 1995: Donor Deferral Due to Red Blood Cell Loss During Collection of Source Plasma.

FDA Memorandum December 11, 1996: Interim Recommendations for Deferral of Donors at Increased Risk for HIV-1 Group O Infections.

Blood Products Advisory Committee Meeting June 16, 2000: Update on Sexual Transmission of HCV.

FDA Guidance, February 2001: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods.

FDA Guidance, January 9, 2002: Revised Preventive Measures to Reduce the Possible Risk of Recent Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products.

Avodart Consumer Information, January 14, 2003: www.fda.gov/cder/consumerinfo/druginfo/avodart.htm.

AABB Pulse Points No. 555, January 14, 2003: Association Bulletin #30-02: Donor Deferral Related to Use of AVODART™ (dutasteride).

FDA Guidance, December 2002: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients.

FDA Guidance, February 4, 2003 (corrected): Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients.

FDA Guidance, May 1, 2003: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection.

FDA Guidance, July 3, 2003: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires.

FDA Guidance, September 16, 2003: Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS.

APPENDIX 6: Medication Deferral List

Please tell us if you are now taking or if you have <u>EVER</u> taken any of these medications:

- **Proscar© (finasteride)** - usually given for prostate gland enlargement
- **Avodart© (dutasteride)** - usually given for prostate enlargement
- **Propecia© (finasteride)** - usually given for baldness
- **Accutane© (isotretinoin)** - usually given for severe acne
- **Soriatane© (acitretin) –** usually given for severe psoriasis
- **Tegison© (etretinate) –** usually given for severe psoriasis
- **Growth Hormone from Human Pituitary Glands** - used only until 1985, usually for children with delayed or impaired growth
- **Insulin from Cows (Bovine, or Beef, Insulin)** - used to treat diabetes
- **Hepatitis B Immune Globulin –** given following an exposure to hepatitis B.
  NOTE: This is different from the hepatitis B vaccine which is a series of 3 injections given over a 6 month period to prevent future infection from exposures to hepatitis B.

IF YOU WOULD LIKE TO KNOW WHY THESE MEDICINES AFFECT YOU AS A BLOOD DONOR, PLEASE KEEP READING:

- If you have taken or are taking **<u>Proscar, Avodart, Propecia, Accutane, Soriatane, or Tegison</u>**, these medications can cause birth defects. Your donated blood could contain high enough levels to damage the unborn baby if transfused to a pregnant woman. Once the medication has been cleared from your blood, you may donate again. Following the last dose, the deferral period is one month Proscar, Propecia and Accutane, six months for Avodart and three years for Soriatane. Tegison is an indefinite deferral.

- **<u>Growth hormone from human pituitary glands</u>** was prescribed until 1985 for children with delayed or impaired growth. The hormone was obtained from human pituitary glands, which are found in the brain. Some people who took this hormone developed a rare nervous system condition called Creutzfeldt-Jakob Disease (CJD, for short). CJD has not been associated with growth hormone preparations available since 1985.

- **Insulin from cows (bovine, or beef, insulin)** is an injected material used to treat diabetes. If this insulin was imported into the US from countries in which "Mad Cow Disease" has been found, it could contain material from infected cattle. There is concern that "Mad Cow Disease" may be transmitted by transfusion.

- **Hepatitis B Immune Globulin (HBIG)** is an injected material used to prevent infection following an exposure to hepatitis B. HBIG does not prevent hepatitis B infection in every case, therefore persons who have received HBIG must wait 12 months to donate blood to be sure they were not infected since hepatitis B can be transmitted through transfusion to a patient.

APPENDIX 7: Blood Donor Educational Materials
MAKING YOUR BLOOD DONATION SAFE

Thank you for coming in today! This information sheet explains how **YOU** can help us make the donation process safe for yourself and patients who might receive your blood. **PLEASE READ THIS INFORMATION BEFORE YOU DONATE! If you have any questions now or anytime during the screening process, please ask blood center staff.**

ACCURACY AND HONESTY ARE ESSENTIAL!

Your **complete honesty** in answering all questions is very important for the safety of patients who receive your blood. **All information you provide is confidential**.

DONATION PROCESS:

To determine if you are eligible to donate we will:

-Ask questions about health, travel, and medicines
-Ask questions to see if you might be at risk for hepatitis, HIV, or AIDs
- Take your blood pressure, temperature and pulse
- Take a small blood sample to make sure you are not anemic

If you are able to donate we will:

- Cleanse your arm with an antiseptic. **(If you are allergic to Iodine, please tell us!)**
-Use a new, sterile, disposable needle to collect your blood

DONOR ELIGIBILITY – SPECIFIC INFORMATION

Why we ask questions about sexual contact:

Sexual contact may cause contagious diseases like HIV to get into the bloodstream and be spread through transfusions to someone else.

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)

HIV/AIDS RISK BEHAVIORS AND SYMPTOMS

AIDS is caused by HIV. HIV is spread mainly through sexual contact with an infected person OR by sharing needles or syringes used for injecting drugs.

DO NOT DONATE IF YOU:

- **-Have AIDS or have ever had a positive HIV test**
- -Have ever used needles to take drugs, steroids, or anything not prescribed by your doctor
- - Are a male who has had sexual contact with another male, even once, since 1977
- - Have ever taken money, drugs or other payment for sex since 1977
- - Have had sexual contact in the past 12 months with anyone described above
- - Have had syphilis or gonorrhea in the past 12 months
- - In the last 12 months have been in juvenile detention, lockup, jail or prison for more than 72 hours
- -Have any of the following conditions that can be signs or symptoms of HIV/AIDS:
  - •Unexplained weight loss or night sweats
  - •Blue or purple spots in your mouth or skin
  - •Swollen lymph nodes for more than one month
  - •White spots or unusual sores in your mouth
  - •Cough that won't go away or shortness of breath
  - •Diarrhea that won't go away
  - •Fever of more than 100.5 ^{o}F for more than 10 days

Remember that you CAN give HIV to someone else through blood transfusions even if you feel well and have a negative HIV test. This is because tests cannot detect infections for a period of time after a person is exposed to HIV. **If you think you may be at risk for HIV/AIDS or want an HIV/AIDS test, please ask for information about other testing facilities.** ***PLEASE DO NOT DONATE TO GET AN HIV TEST!***

Travel to or birth in other countries

Blood donor tests may not be available for some contagious diseases that are found only in certain countries. If you were born in, have lived in, or visited certain countries, you may not be eligible to donate.

What happens after your donation:

To protect patients, your blood is tested for hepatitis B and C, HIV, certain other viruses, and syphilis. If your blood tests positive it will not be given to a patient. You will be notified about test results that may disqualify you from donating in the future. **Please do not donate to get tested for HIV, hepatitis, or any other infections!**

Thank you for donating blood today!
(Donor Center Name)
(Telephone Number)