

This document is one component of the full-length PPTA donor history questionnaire documents. This full length directions for use contains information for all source plasma organization regardless of HIV-1 Group O testing capabilities. The full length PPTA Donor History Questionnaire Documents must be used collectively.

## **Source Plasma Full-Length PPTA Donor History Questionnaire Directions for Use**

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## Source Plasma Full-Length PPTA Donor History Questionnaire Directions for Use

**Purpose:** The PPTA Donor History Questionnaire (PPTA DHQ) Directions for Use is a guideline designed as an aid for the plasma sourcing organizations to use in the development of specific company policies and training materials related to donor eligibility. The PPTA DHQ Directions for Use does not replace the company policy for determining donor suitability. Each source plasma collection organization must have a standard operating procedure (SOP) related to donor suitability to be used in conjunction with the Directions for Use. The Directions for Use does not replace an SOP for determining donor suitability. Both the Directions for Use and the SOP must be available to staff performing health histories. Alternately, the Directions for Use contents may be transcribed into the SOP.

**Introduction:** The following documents are included in this package: Two Full-Length PPTA Donor History Questionnaires (PPTA DHQ<sup>1</sup>), two Risk Posters, two Travel Posters<sup>1</sup>, and a Medication List. The PPTA DHQ must be administered on the date of donation as per Title 21, Code of Federal Regulations, Part 640.63(b). The plasmapheresis center staff must provide to the prospective donor the Risk Poster, the Travel Poster, and the Medication List, and any other material that the plasmapheresis center's company policy requires to be used with the PPTA DHQ. These documents should be incorporated into the company's donor eligibility process, which includes the physical examination and informed consent (each having its own educational information), in a manner that conveys the importance of the donor history questions in protecting the donor's health and the safety of the plasma supply and the responsibility of the donor to provide accurate information. The Risk Poster was designed to replace the "AIDS Bulletin" which is currently used by plasmapheresis centers to educate donors about HIV infection and AIDS. Also, for additional donor education, the Risk Poster, the Travel Poster, and the Medication List may be prominently displayed in designated areas.

**Methods of Administration:** The method of administration of the PPTA DHQ should be in accordance with the plasmapheresis center's company policy.

The questionnaires were designed to be used by a health historian in direct donor questioning or by self-administration, with follow-up review (if necessary) by a trained donor historian. A trained historian should be available to the prospective donor to answer any questions concerning eligibility or the donation process. Donor screening is an active process involving open communication between donors and trained donor historians. Donors should be encouraged to voice questions and concerns at any time during the screening and donation process. Company policies should require that donors be asked if they have questions and if they have had their questions answered. This does not need to be a specific question on the questionnaire, but may be

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<sup>1</sup> The questionnaire, risk poster or travel poster used is dependent on whether the plasma sourcing organization uses a test to detect HIV-1 Group O.

incorporated into the donor eligibility process, including the physical examination, and/or put into the informed consent.

Self-administration may occur in a computer-assisted self interview (CASI) process. With CASI administration, the Risk Poster, Travel Poster and Medication List can be provided in hard-copy form or in an electronic format. Formatting can be adjusted as long as the order, content and wording are unchanged. Questions directed at one sex can be omitted from sex-specific questionnaires. As stated above, a trained historian should be available to a prospective donor to answer any questions concerning eligibility or the donation process. For further instructions, refer to the CASI manufacturer's instructions and operator's manual.

If questionnaire is administered by a health historian in direct donor questioning, the heading before each section should be stated along with the question to ensure the specific timeframe or instruction is clear.

Deferral decisions can be made any time during the administration of the questionnaire. Individual company policies will dictate whether an eligibility decision can be made prior to completing the entire questionnaire. However, it is recommended that the questionnaire be completed before making a determination of eligibility since some deferrals are temporary, but others are indefinite/permanent. Depending on the sequence of questions, a donor could be deferred temporarily, only to return at a later date and discover that he/she is permanently deferred due to the answer to another question that was not answered on the previous visit.

**Full-Length PPTA DHQ Format:** The Full-Length PPTA DHQ questions were composed for ease of understanding by the prospective plasma donor. The PPTA DHQ questions are grouped by time period beginning with a question about "today" and ending with questions relating to "have you ever". The questions are therefore grouped under headings. Depending on the method of administration, e.g., oral administration by a health historian, the heading may need to be repeated with each question. The PPTA DHQ questions and format were evaluated for comprehension; therefore, the wording and the order of the questions should not be changed.

**Additional Questions:** Plasma sourcing organizations may choose to add "local" additional questions to the end of the PPTA DHQ. If a collection facility chooses to add "local" questions they should be grouped at the end of the DHQ in the area designated for additional questions. Facilities should also use this area to incorporate new questions that are necessary due to new policies recommended by FDA and/or PPTA. This area should be used until such questions can be formally incorporated into the DHQ materials by PPTA. The questions will remain in the additional questions section until a revised strategy for incorporation is approved by FDA. If the new question(s) result from FDA guidance, incorporation and implementation of the new question(s) should be consistent with the current thinking in the FDA guidance document that discussed the new question(s) or deferral. In order to delineate the proper order of the questions PPTA will renumber the questions as needed when questions are added or deleted. Plasma sourcing organizations may choose to use a different numbering system, but the order of the questions should not be changed.

Plasma sourcing organizations should use the Medication List, as is, to elicit whether a donor is currently taking or has taken the medications on the list. Information on other medications may be provided as an appendage or separate document, as appropriate.

**Questions to detect donors at risk for HIV Group O:** The questions related to Africa are recommended by FDA to identify donors who may be at risk for HIV Group O infections. Plasma sourcing organizations utilizing an HIV test that has been approved by FDA for donor screening to include a claim for detection of group O viruses may delete these questions from their screening questionnaire and may renumber the remainder of the questions (and related documents such as flow charts). All other plasma collection centers must continue to use these questions as formatted. To assist in the ease of administration and questioning of the questions related to Africa, PPTA created two sets of documents: (I) to be used by those who use a test approved to detect HIV-1 Group O and (II) those that do not. Therefore, there are two Risk Posters available and two Travel Posters available. The posters that may be used are dependent on whether the source plasma organization uses an approved test for detection of HIV-1 Group O. The appropriate version of the risk and travel poster that is chosen should be used in its entirety.

**Capture Questions:** The PPTA DHQ uses “capture questions” that may require donor historian intervention or follow up. Capture questions are general questions that when answered “yes” require additional questions or information to determine donor suitability. Some follow-up questions are included in the PPTA DHQ Directions for Use but since specific donor eligibility criteria may vary from one plasma sourcing organization to another, an affirmative response to some questions may require consultation with the plasmapheresis center’s company policy.

**Attention Questions:** In order to assure that donors who self-administer a paper PPTA DHQ maintain focus, several “attention” questions are included. An example of an attention question is: “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 plasma sourcing organization 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 CASI or oral screening by a donor historian.

**Full-Length PPTA DHQ Administration Frequency:** The Full-Length PPTA DHQ was designed as a stand alone questionnaire that may be used at each donation. It may also be used in conjunction with an abbreviated form for frequent donors. Use of the full-length questionnaire in conjunction with the abbreviated questionnaire is discussed in the PPTA Abbreviated Donor History Questionnaire Directions for Use.

**PPTA DHQ Directions for Use Flow Chart Format:** The PPTA DHQ Directions for Use is modular and uses flow-charting to guide organizations through the donor questionnaire process. Each question is a complete section that begins on a new page so that changes to the PPTA DHQ and the Abbreviated PPTA DHQ can be easily

modified in the PPTA DHQ Directions for Use. Each section contains the following information:

Question: Question number and the question

Donor Eligibility: This section provides additional information to the donor historian donor eligibility requirements for each question.

Note: Optional field that provides 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, plasmapheresis centers must follow their established policies to determine if the donor suitability process is completed when it is known that the donor will be deferred.

**Donor Deferrals:** For some questions, a “yes” answer calls for a required donor deferral either indefinitely or for a specified period of time. A required deferral is designated in the flow chart by the Action “Defer donor” followed by “indefinitely” or with the time period established by FDA regulations/recommendations or “per company policy”. For the latter, the organizations will use their established policies and procedures to determine if and when the donor may be eligible to return. In some cases, such as a donor’s providing a history of having had cancer, company policy will dictate the follow-up questions that are required to determine donor eligibility. Evaluation “per company policy” may deem the donor eligible to donate without a period of deferral. Additionally, when a question provides information that the donor may be deferred “per company policy”, per company policy cannot be less restrictive what is clearly delineated in FDA policy.

**Documentation:** Answers to the questions that are cause for donor deferral must be documented according to the plasmapheresis center’s company policy. Each plasmapheresis center’s company policy must define how the donor responses to the follow up questions will be documented.

**Maintenance/Change Control:** The Plasma Protein Therapeutics Association (PPTA) is responsible for the maintenance of the PPTA Donor History Questionnaire project documents. Documents are posted on the PPTA website. Periodically the PPTA Donor

History Questionnaire, the accompanying documents or the procedure for use will be updated or revised by the PPTA DHQ task force as required for compliance with regulatory and accrediting agencies. PPTA member companies will be notified of the changes and timeline for implementation in existing publications and on the PPTA website, and all updated documents will be made available on the website. It is the responsibility of plasmapheresis centers to make change in their forms, procedures and processes to incorporate these revisions within the specified time.

## GLOSSARY

The following terms are defined in the context of their use in the PPTA 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.

**CASI** – Computer-assisted Self-interviewing system. Most often the system consists of an interactive computer screen. Questions are asked in written format, with or without graphics and audio.

### 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).

**Close Contact with Smallpox Vaccination Site** – Touching the vaccination site, including the bandages covering the vaccination site; touching/handling materials that might have come into contact with an unbandaged vaccination site including clothing, towels, and bedding.

**Lived With** – Residing in the same dwelling in which kitchen and bathroom facilities are shared. Donors that have the same address would not be considered under the term “lived with” unless kitchen and bathroom facilities are shared.

## 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.

**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.

**Temporary Deferral** – Prospective donor is unable to donate blood for a limited period of time. **EXAMPLE:** A prospective donor who has received a transfusion within the last 12 months would be deferred for 12 months from the date of the transfusion.

## References

Donor qualification requirements are located in Title 21, Code of Federal Regulations, Subpart G—Source Plasma, and in PPTA voluntary standards in its International Quality Plasma Program (IQPP).

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

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, 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, 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, May 2010: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products.

Avodart Consumer Information, January 14, 2003:

[www.fda.gov/cder/consumerinfo/druginfo/avodart.htm](http://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, 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.

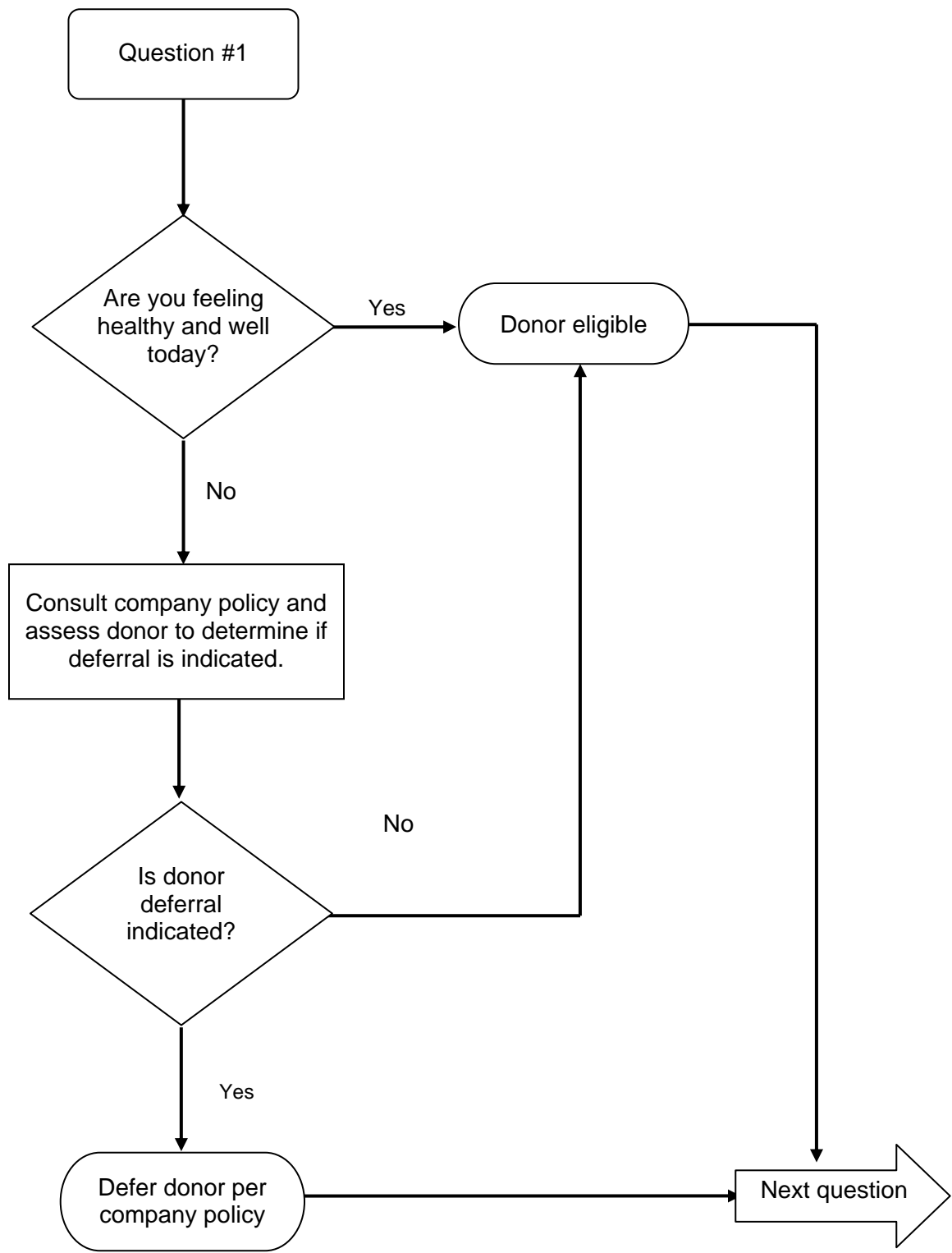
FDA Draft Guidance, August 8, 2006: Amendment (Donor Deferral for Transfusion in France Since 1980) to "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products"

FDA Guidance, October 27, 2006: Implementation of Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Donors of Blood and Blood Components.

FDA Guidance, June 20, 2007: Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs.

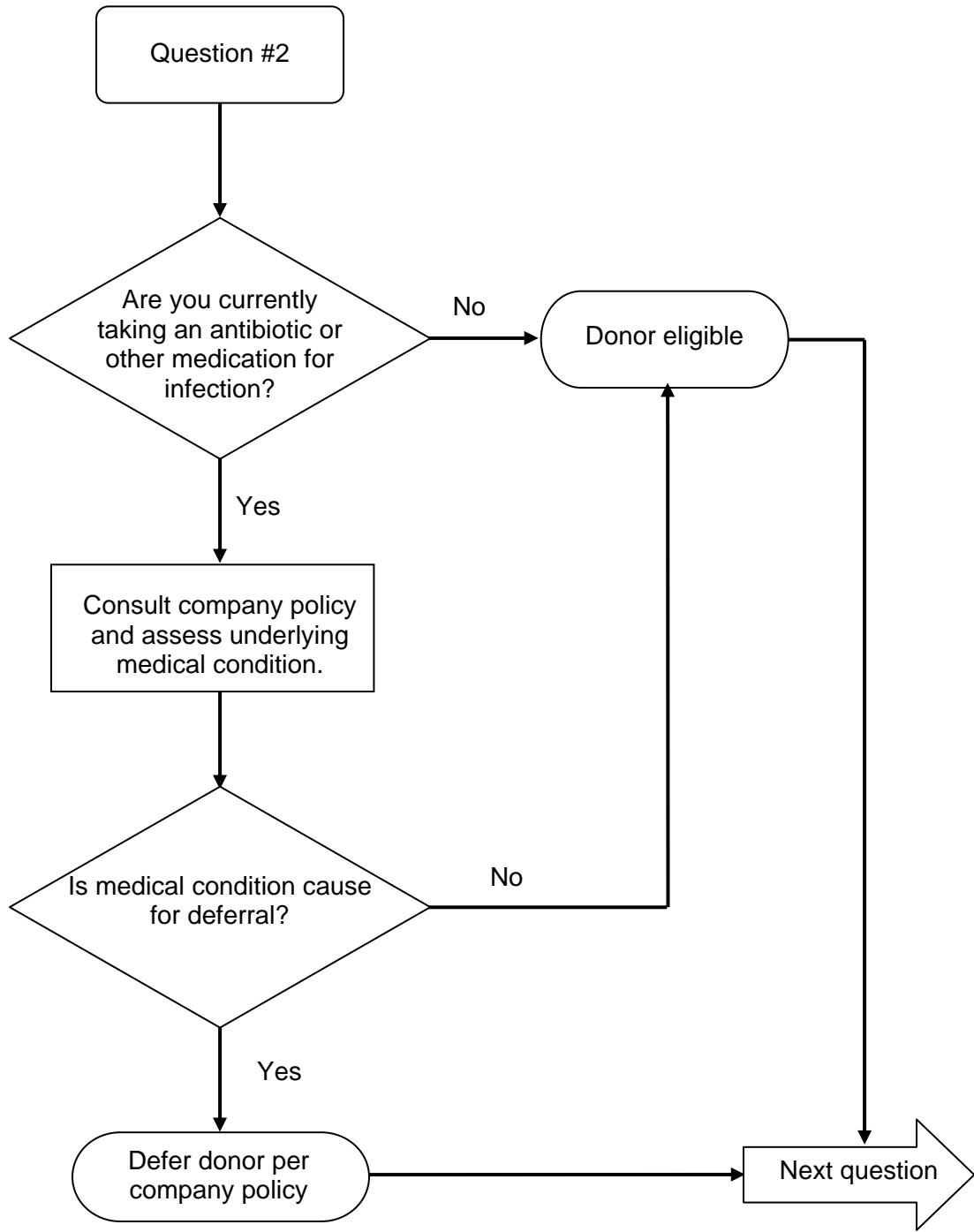
**Question #1:** Are you feeling healthy and well today?

**Donor Eligibility:** A donor should be free of infectious diseases 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.



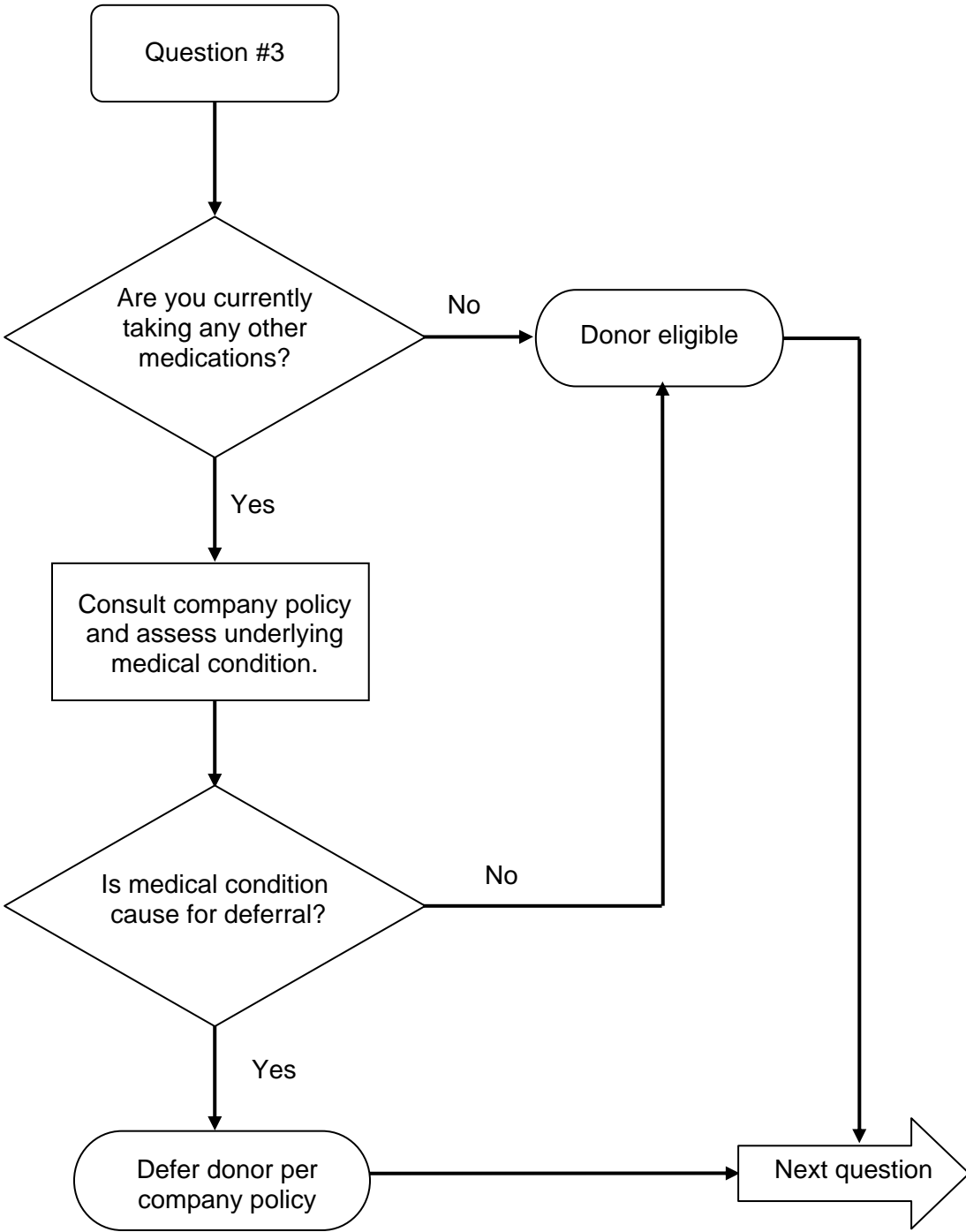
**Question #2:** Are you currently taking an antibiotic or other medication for infection?

**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.



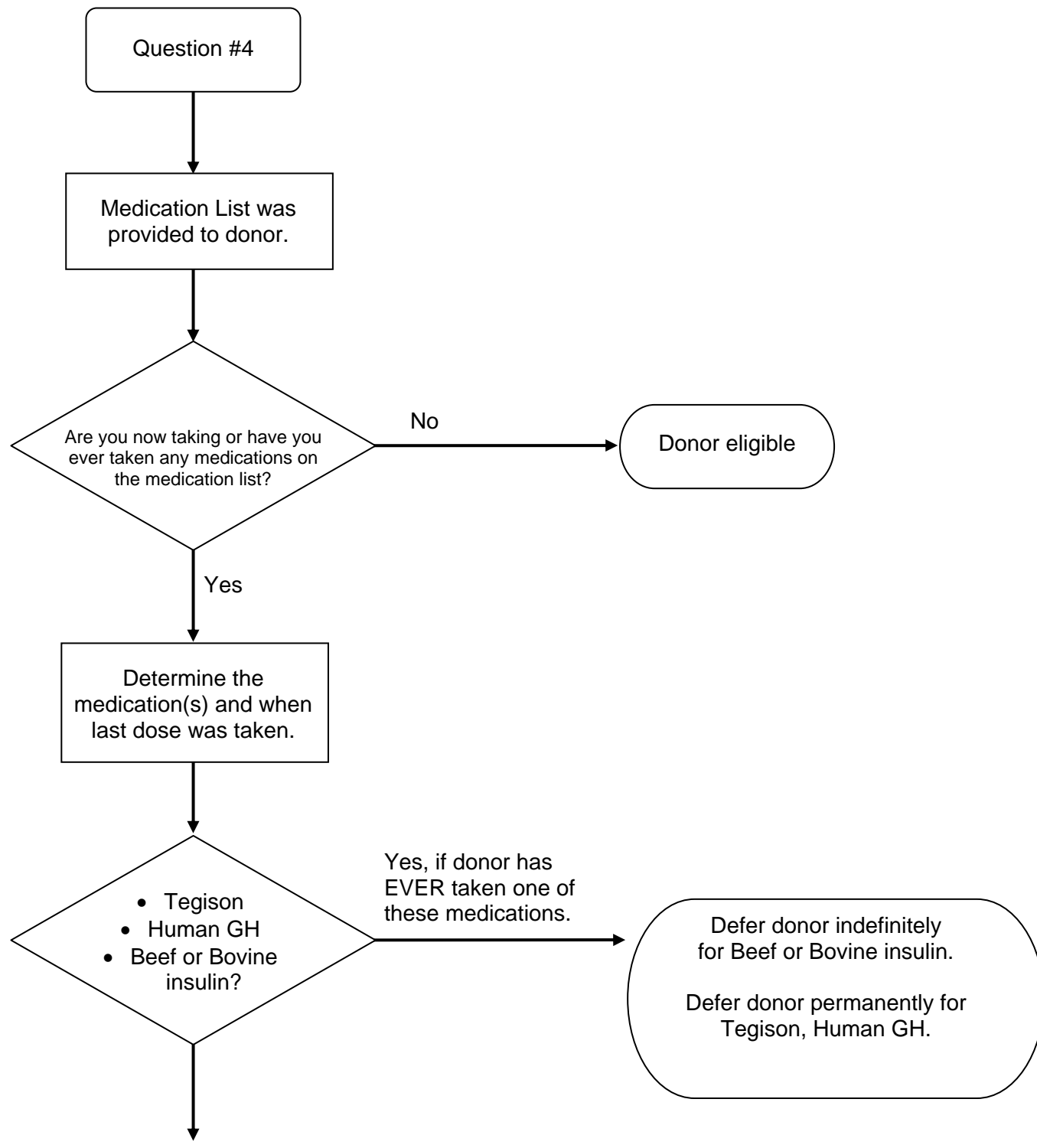
**Question #3:** Are you currently taking any other medications?

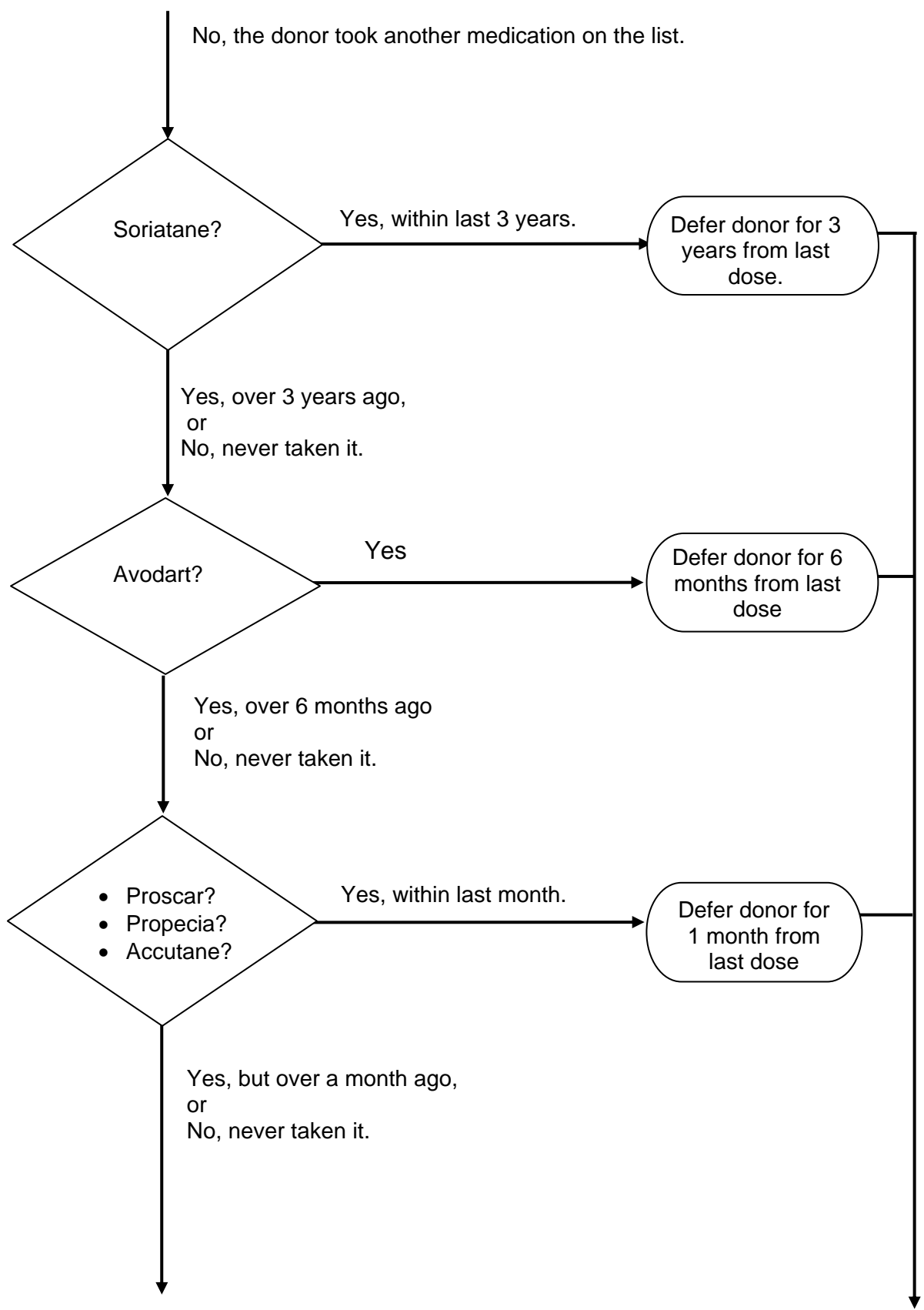
**Donor Eligibility:** The reason for use of a medication to treat a medical condition must be evaluated (follow company policy).

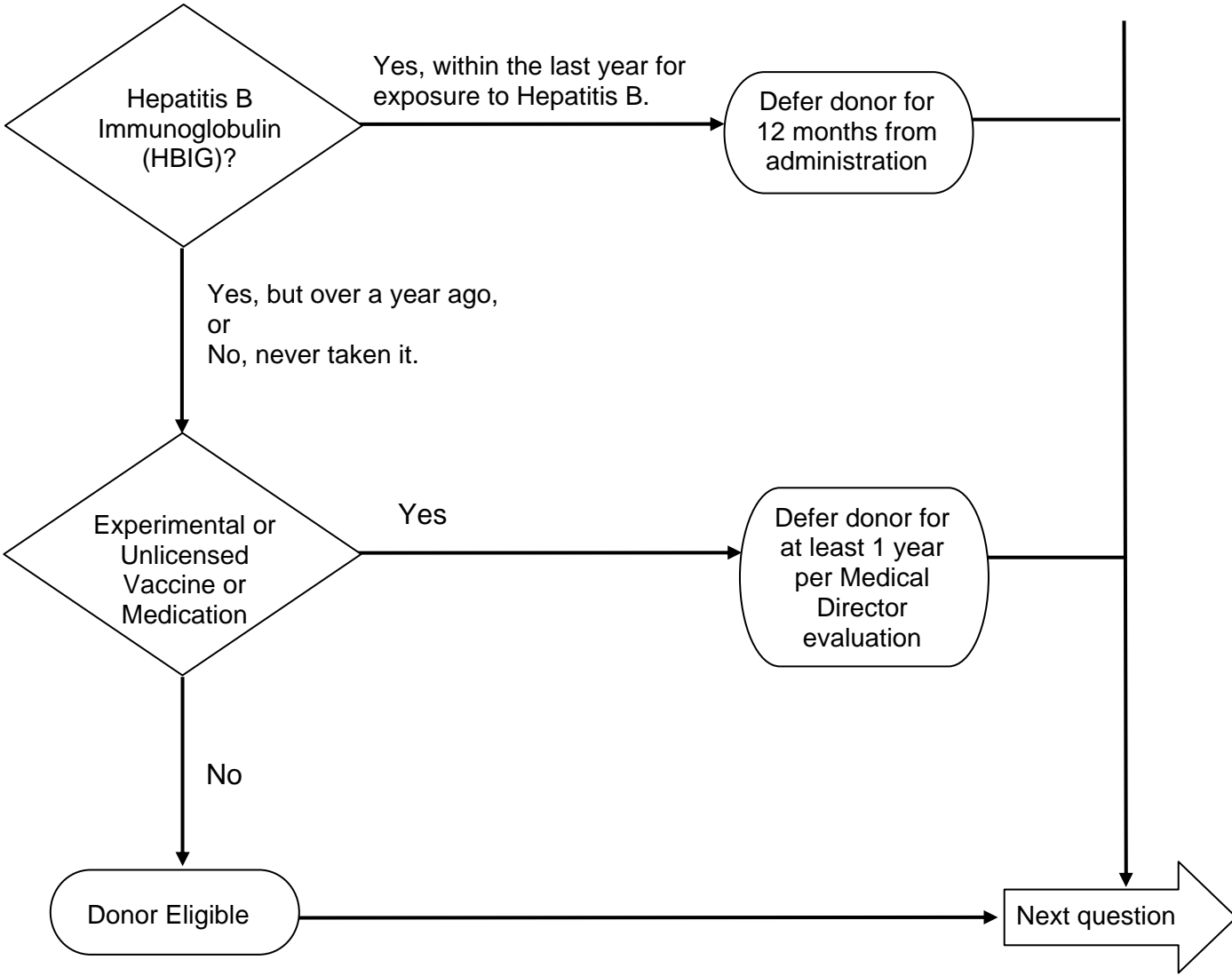


**Question #4:** Are you now taking or have you ever taken any medications on the medication list?

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

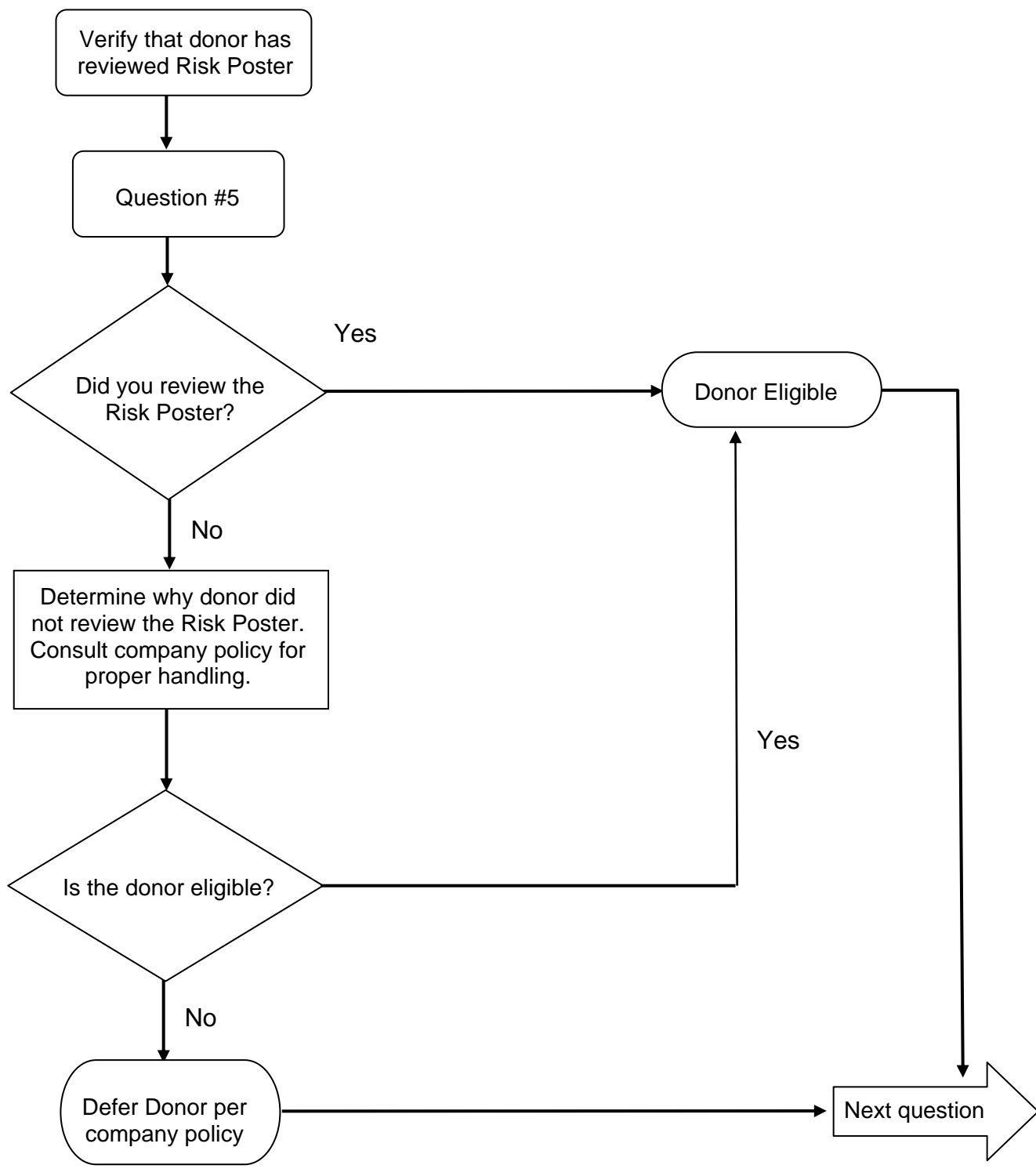






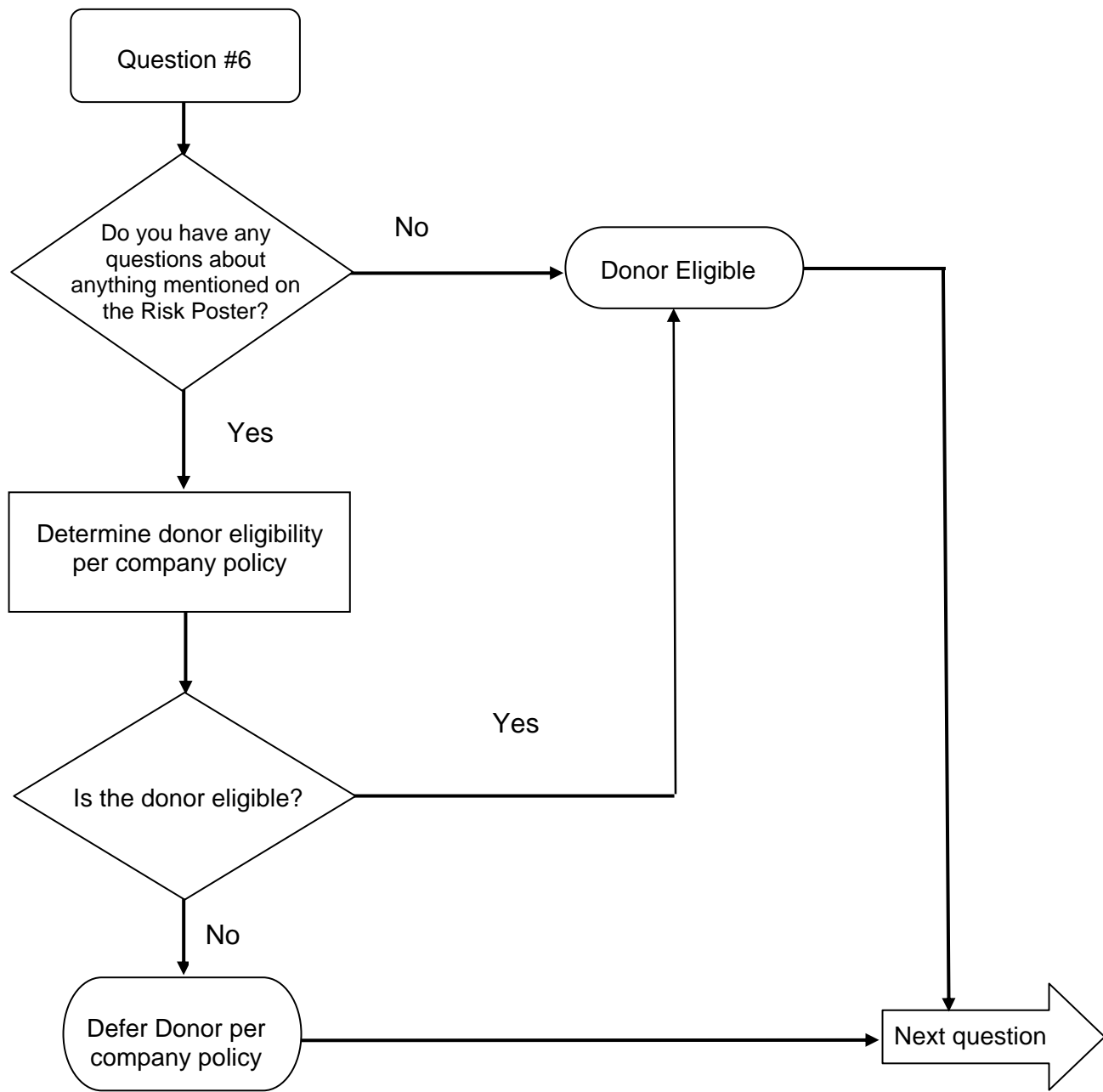
**Question #5:** Did you review the Risk Poster?

**Donor Eligibility:** The Risk Poster includes information on risk activities for HIV/AIDS, viral hepatitis, and other infectious diseases that may be transmitted through blood. Therefore, potential plasma donors must read the Risk Poster information provided during the donor interview to determine if they are at risk of transmitting infectious diseases.



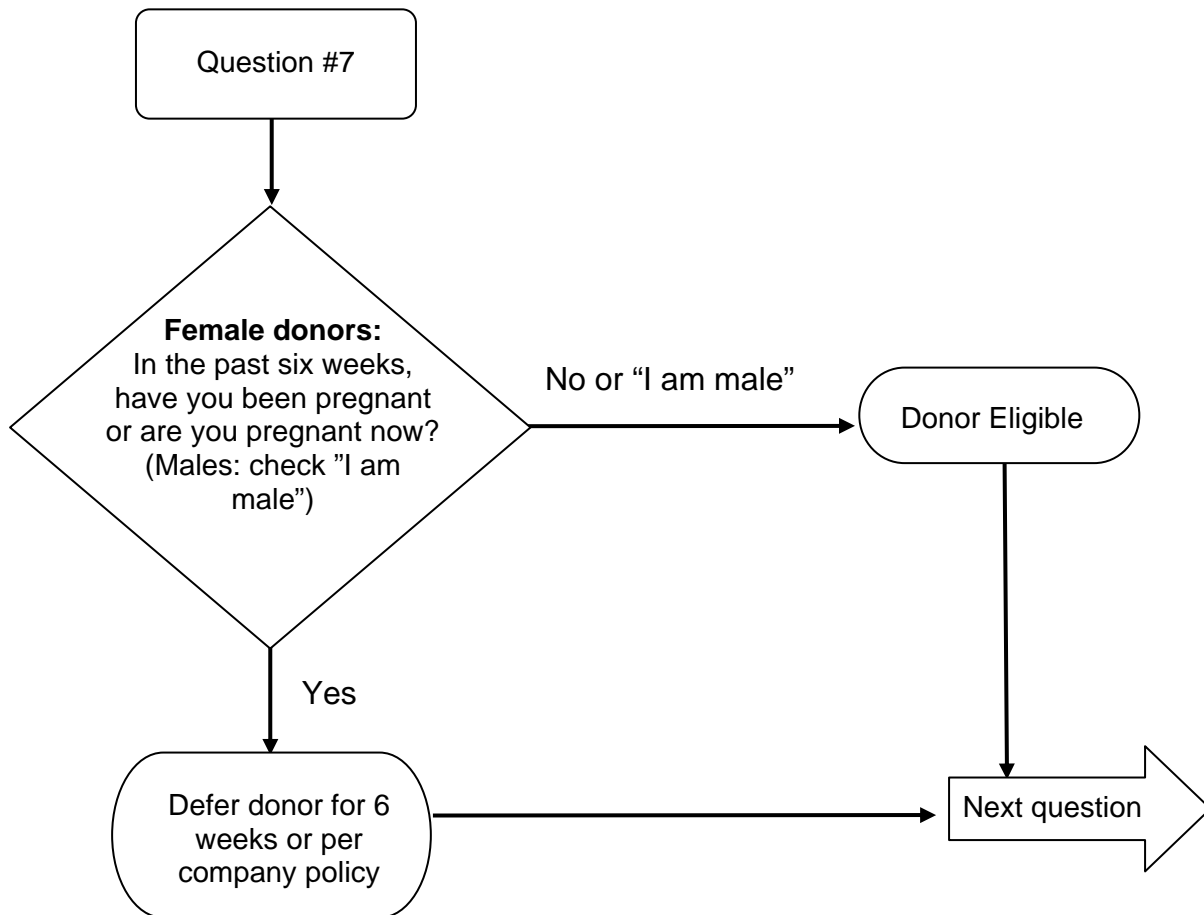
**Question #6:** Do you have any questions about anything mentioned on the Risk Poster?

**Donor Eligibility:** The Risk Poster includes information on risk activities for HIV/AIDS, viral hepatitis, and other infectious diseases that may be transmitted through blood. Donors should be encouraged to ask questions if material is not understood. For donor deferral follow company policy.



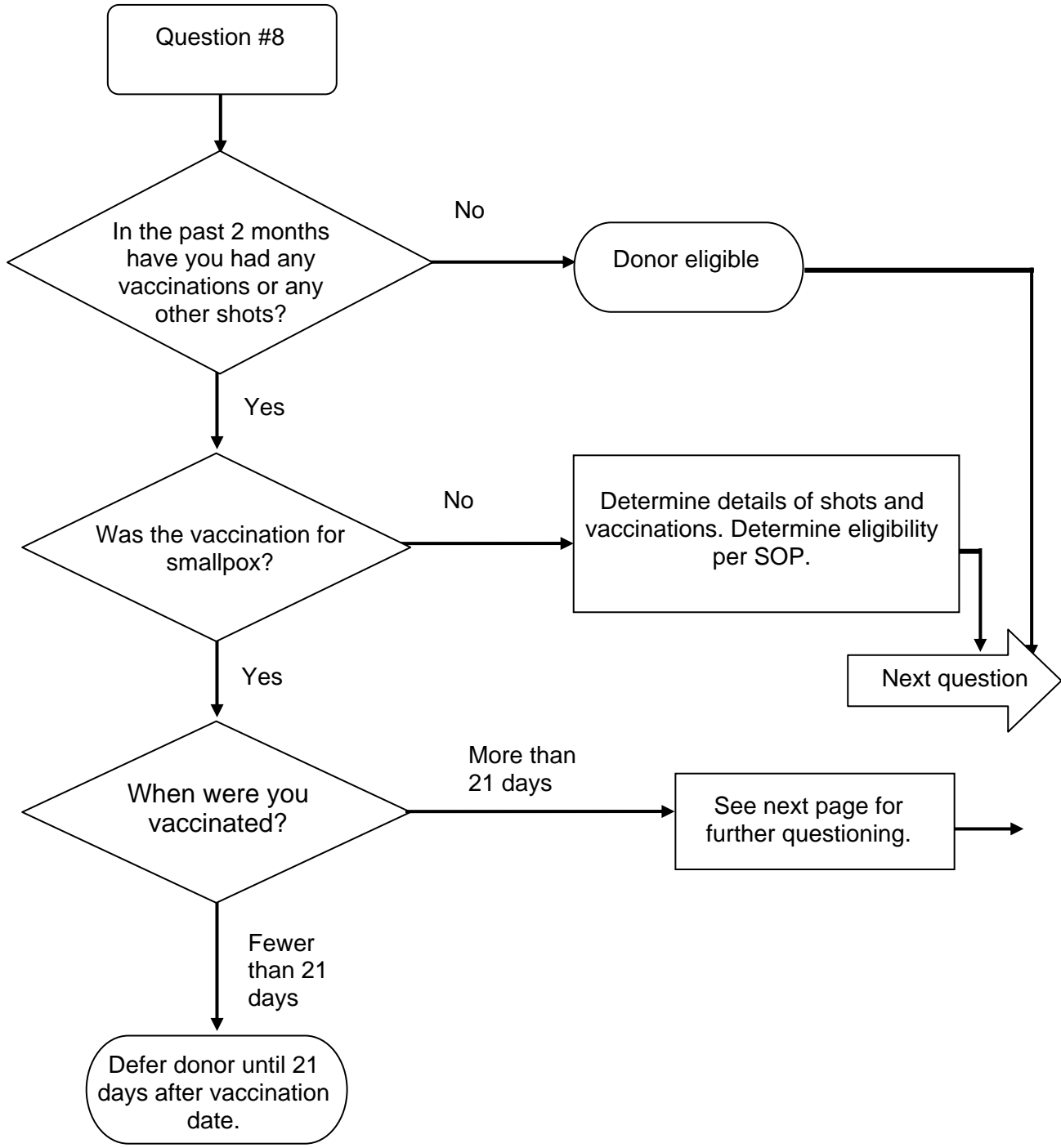
**Question #7:** Female donors: In the past six weeks, have you been pregnant or are you pregnant now? (Males: check "I am male")

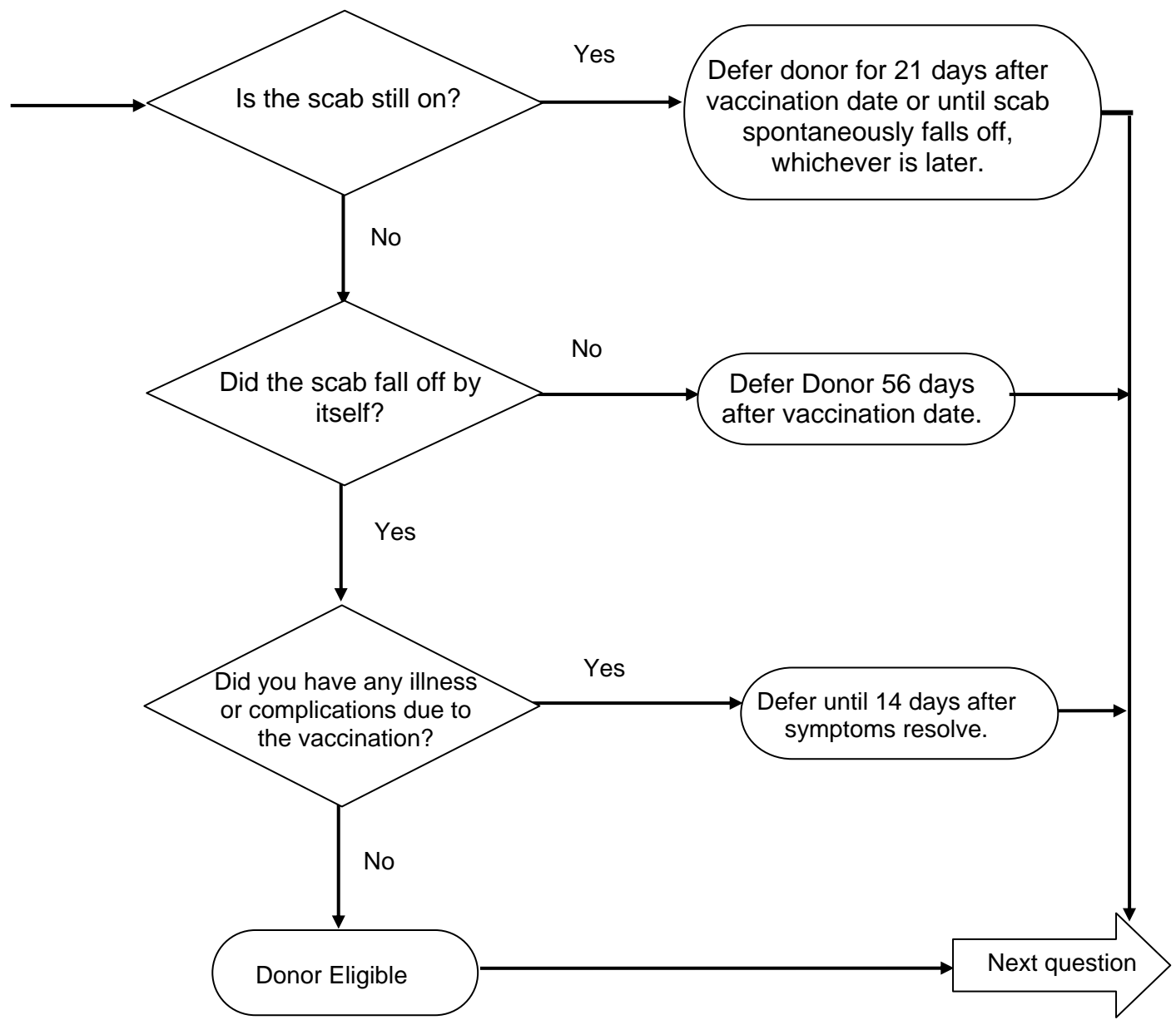
**Donor Eligibility:** A female with a known pregnancy or who has been pregnant in the last six weeks should not donate blood or plasma.



**Question #8:** In the past 2 months have you had any vaccinations or other shots?

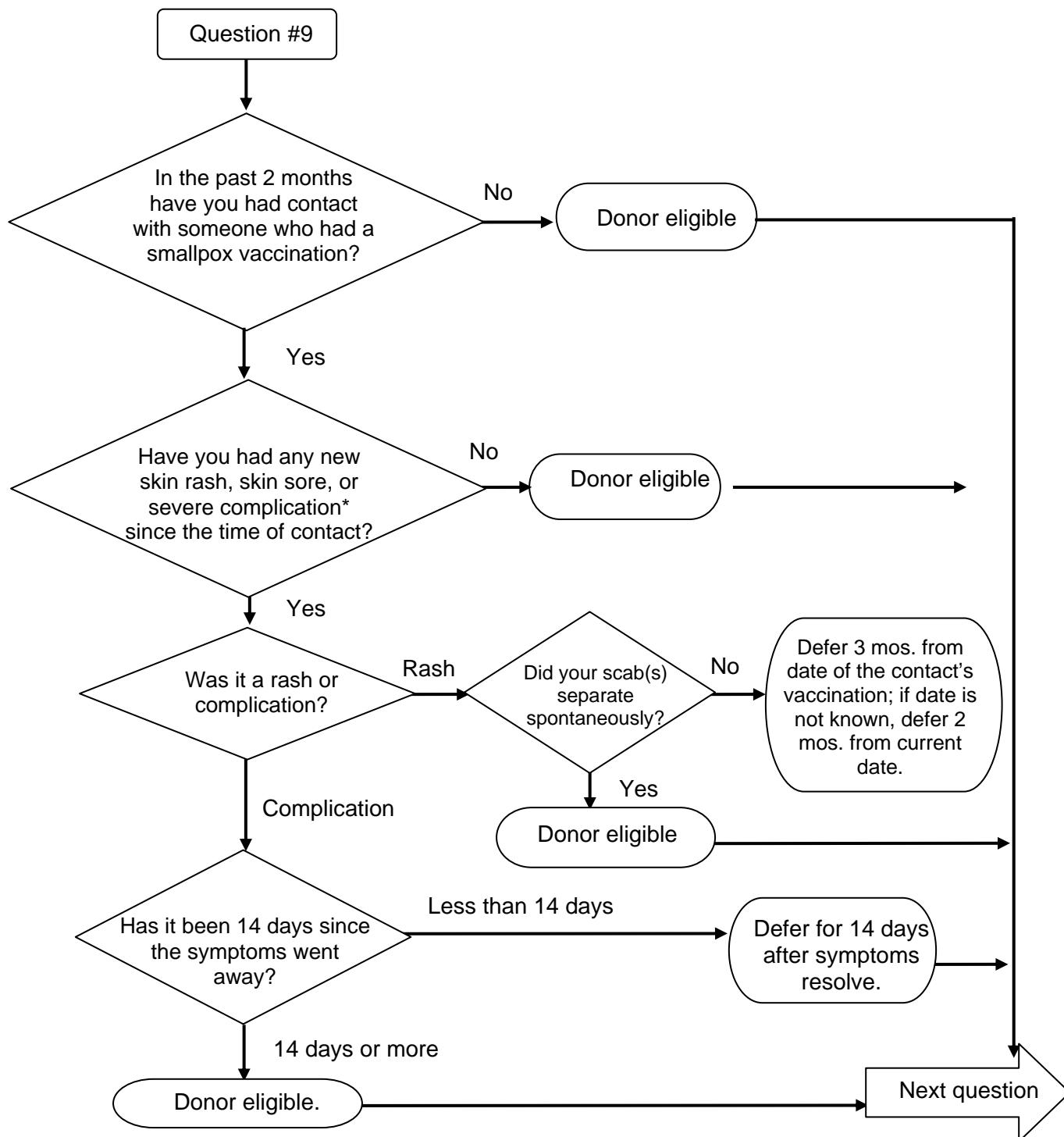
**Donor Eligibility:** Certain vaccinations may contain a live virus. A donor who has been exposed to a live virus via vaccination should not serve as a donor. For other shots, consult company policy to determine eligibility.





**Question #9:** In the past 2 months have you had contact with someone who had a smallpox vaccination?

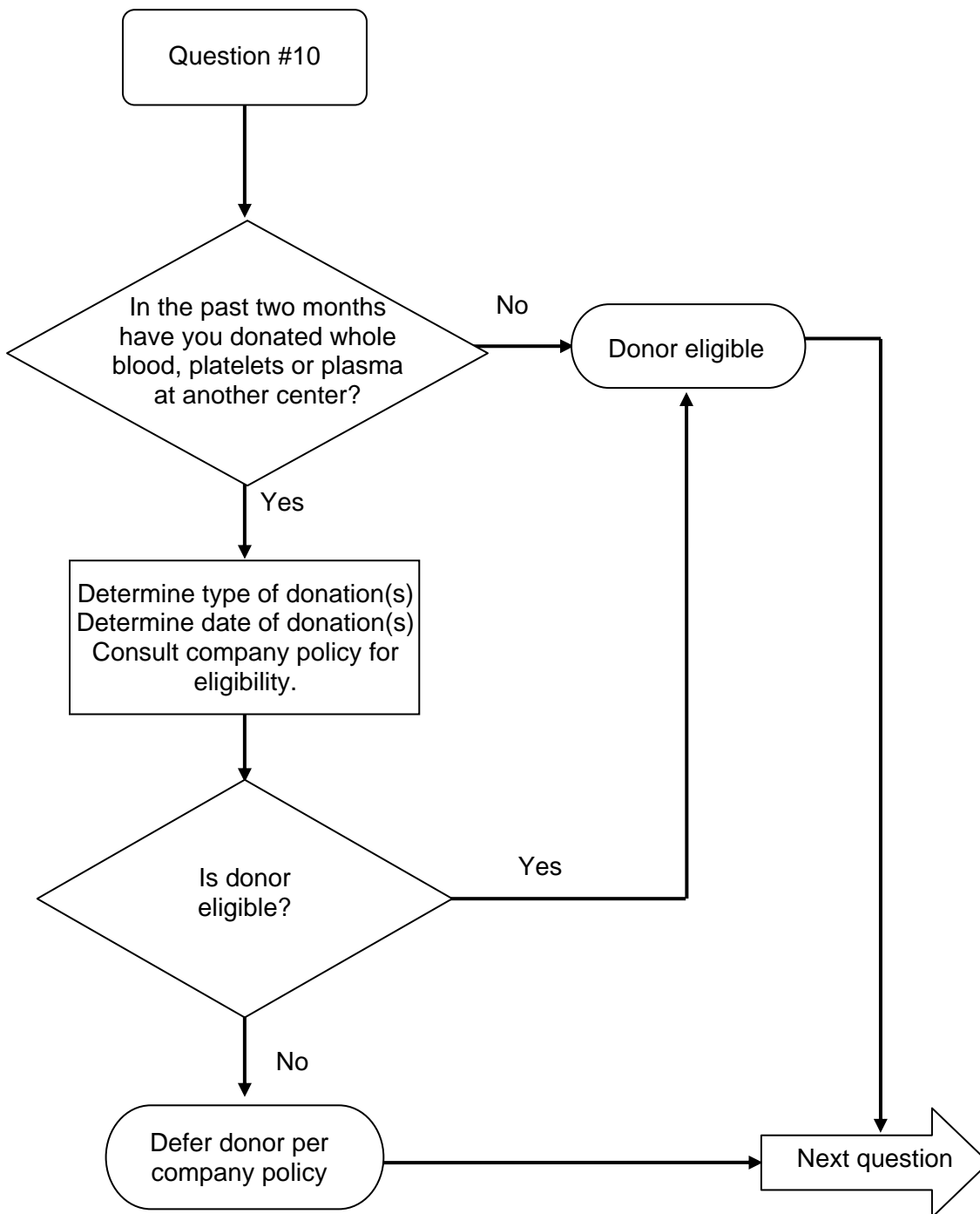
**Donor Eligibility:** Certain vaccinations may contain a live virus. A donor who has been exposed to a live virus via vaccination should not serve as a donor. For other shots, consult company policy to determine eligibility.



\*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.

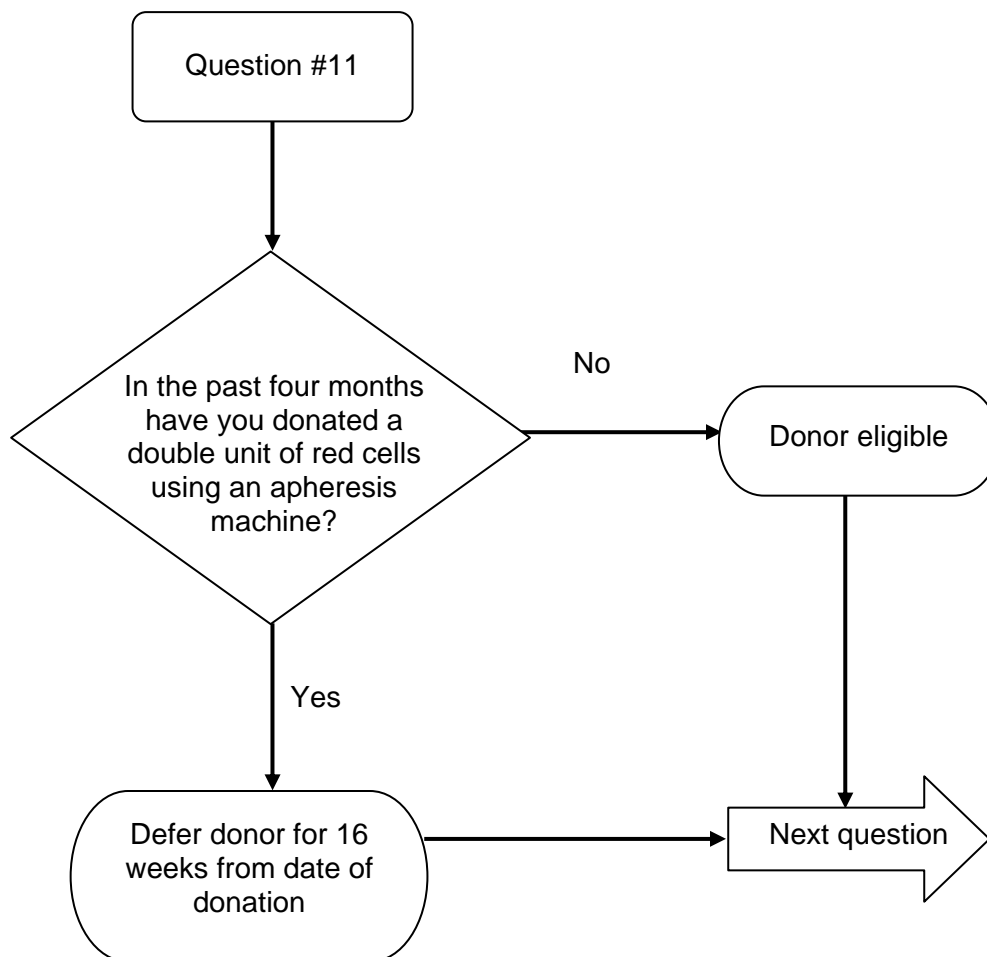
**Question #10:** In the past two months have you donated whole blood, platelets or plasma at another center?

**Donor Eligibility:** A donor who has donated a unit of whole blood should not donate blood or plasma for a period of 8 weeks. A donor who has donated platelets (cellular component that aids in clotting blood) or plasma by apheresis should not donate more than two times in a seven-day period at intervals of no less than two days apart. For other blood components or conditions of collection (e.g., less than a unit of whole blood), the donor should be deferred for the period established in the company policy.



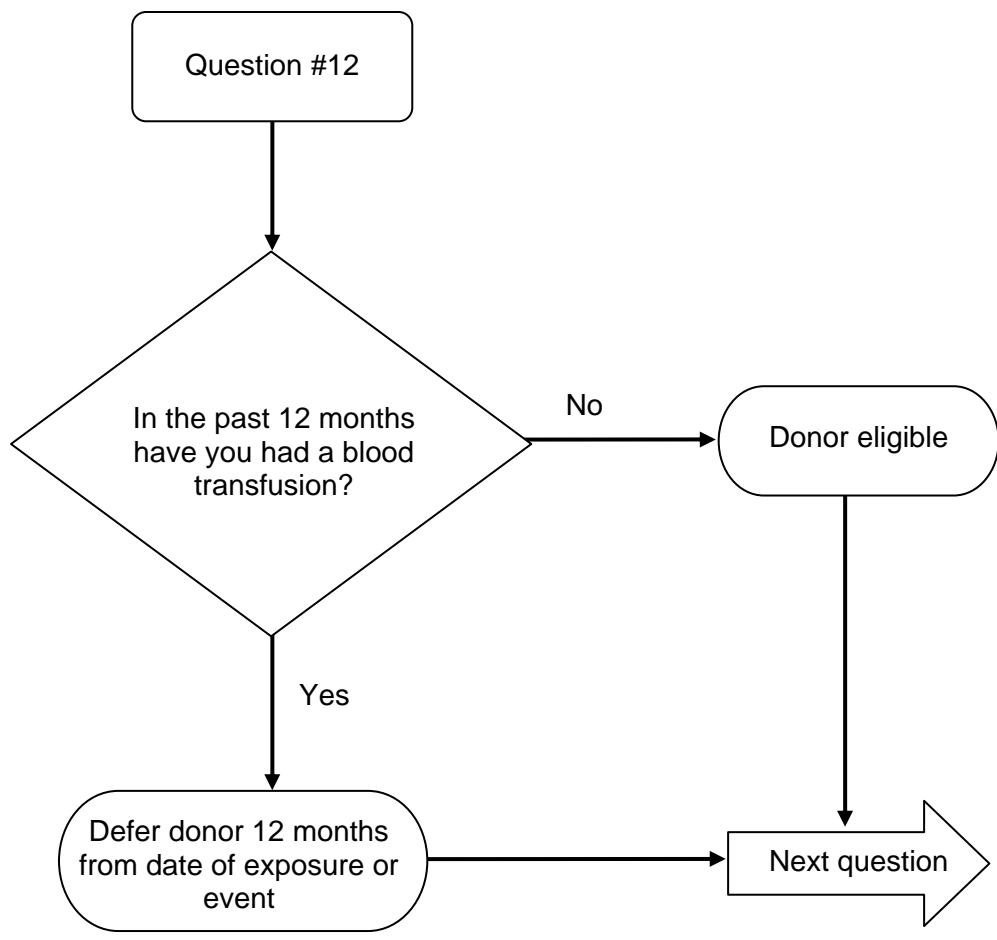
**Question #11:** In the past four months have you donated a double unit of red cells using an apheresis machine?

**Donor Eligibility:** A donor who has donated a double unit of red cells (*the volume of red cells in two units of blood*) by apheresis should not donate blood or plasma for a period of four months (16 weeks). The donor is attached to a machine similar to the one used for plasma donation. However, the donor's plasma is given back to the donor, and the blood collection facility keeps the two units of red blood cells. The 4-month deferral is needed for the donor to replace the red cells donated.



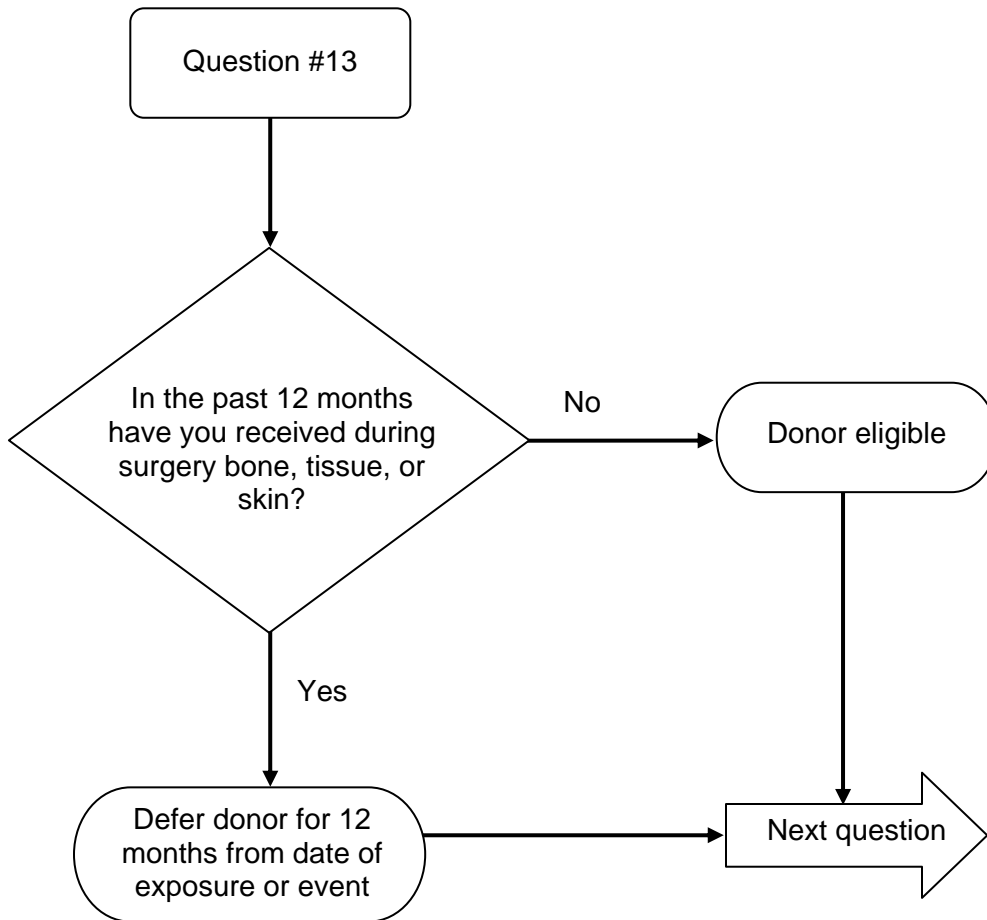
**Question #12:** In the past 12 months have you had a blood transfusion?

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



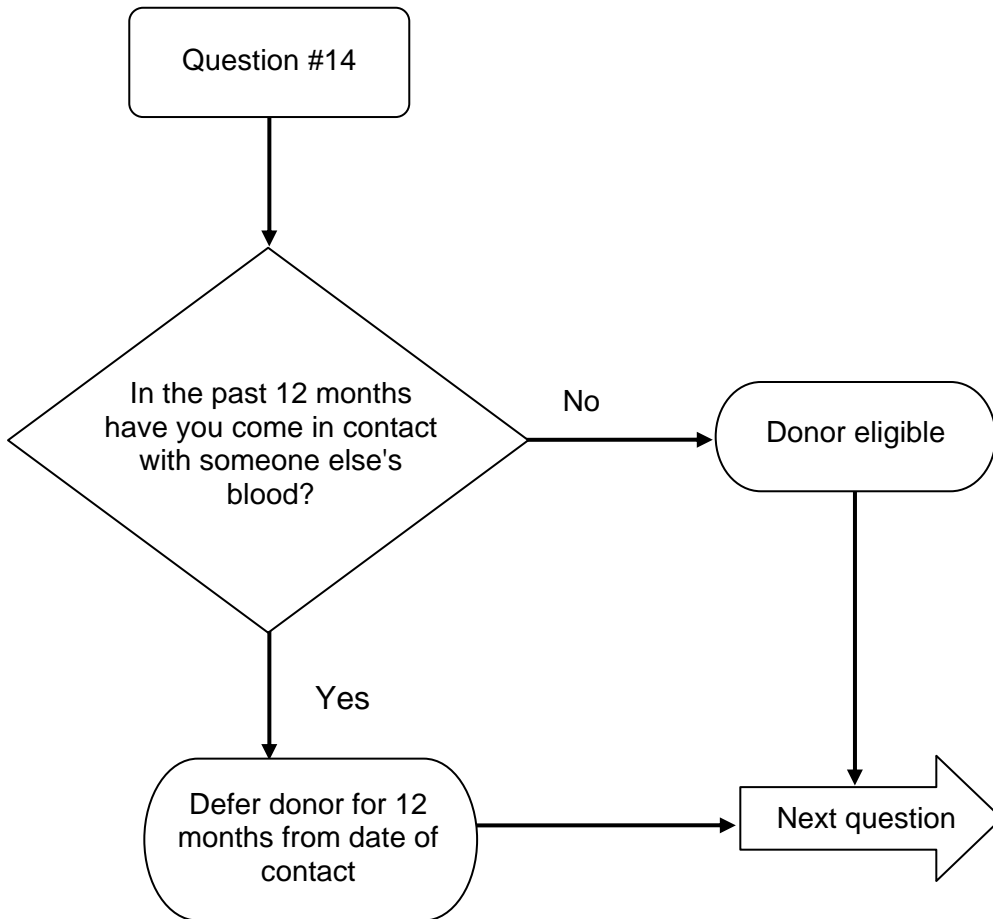
**Question #13:** In the past 12 months have you received during surgery bone, tissue, or skin?

**Donor Eligibility:** A donor who has been exposed to tissues during surgery should not donate blood or plasma for 12 months following exposure, due to possible transmissibility of infectious disease.



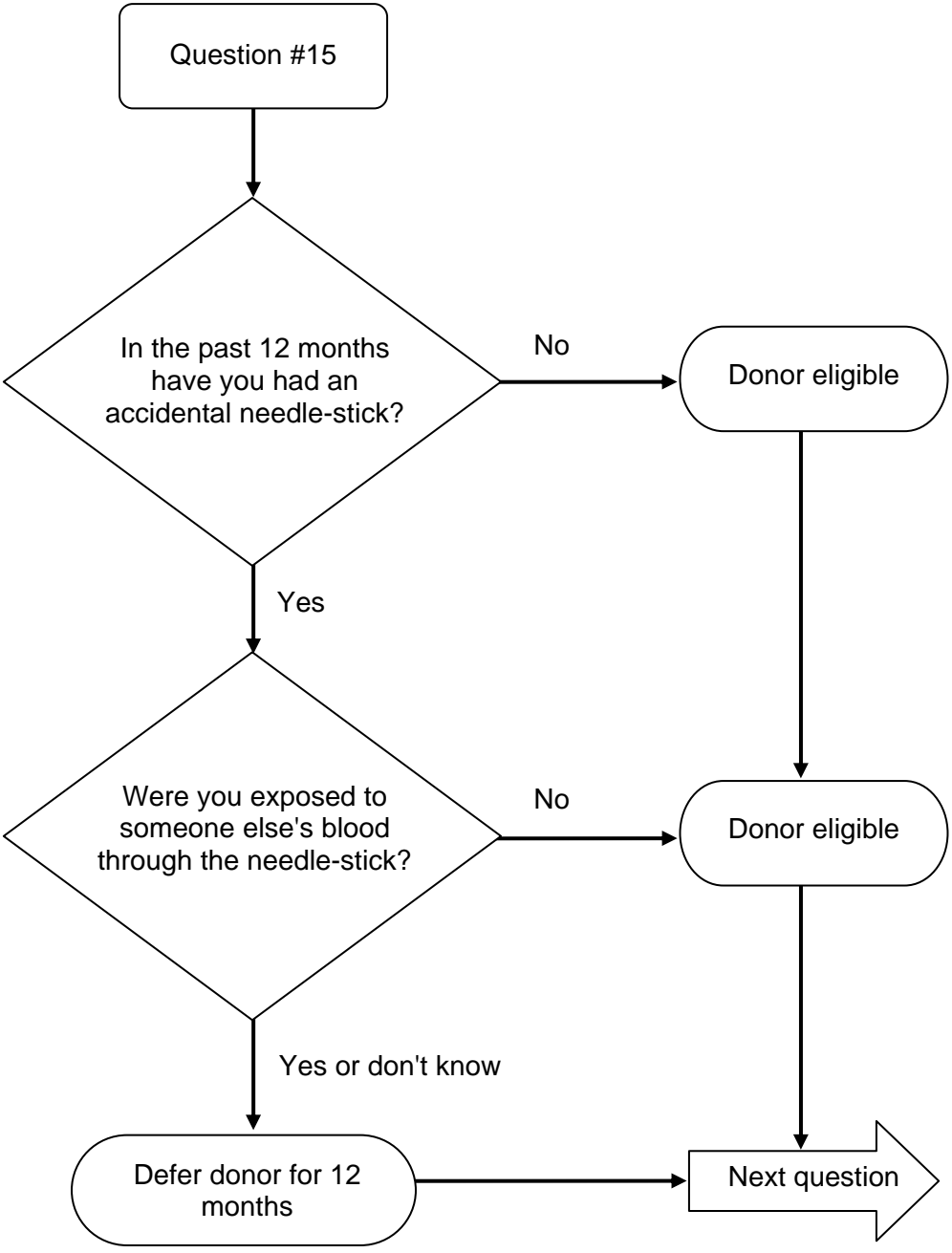
**Question #14:** In the past 12 months have you come in contact with someone else's blood?

**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 #15:** In the past 12 months have you had an accidental needle-stick?

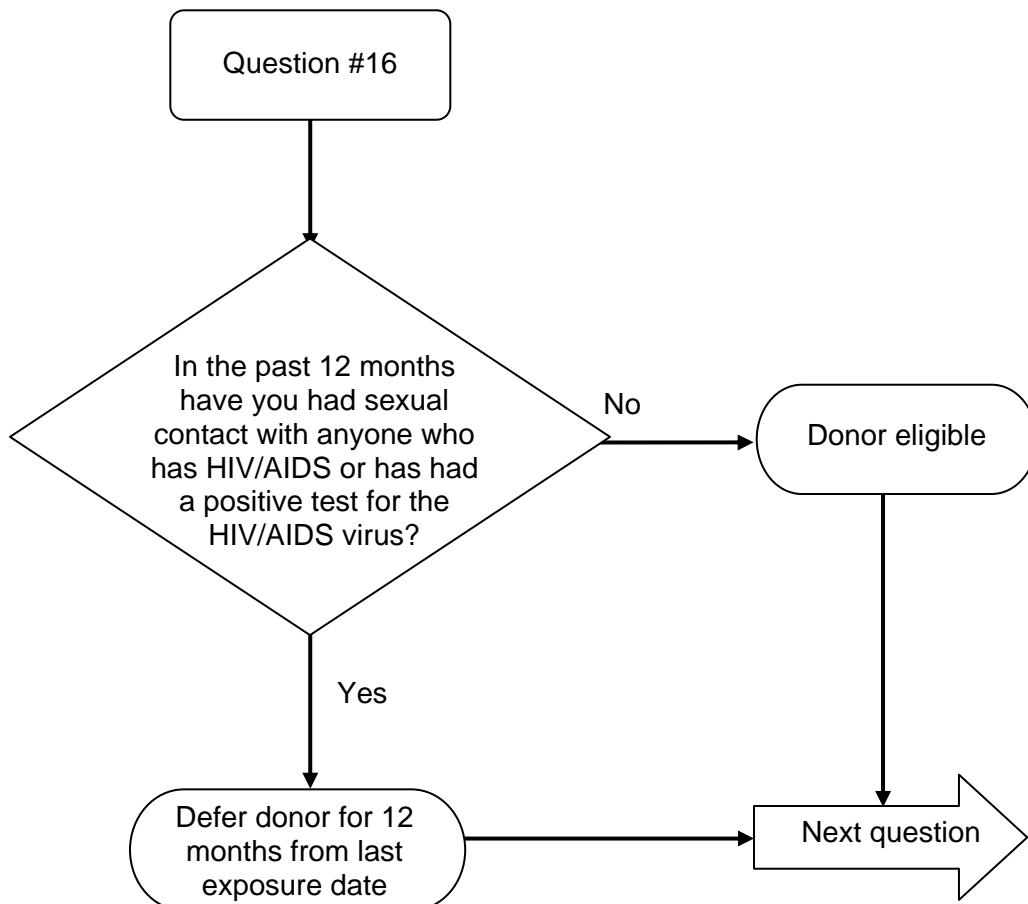
**Donor Eligibility:** A donor who has been exposed to someone else's blood through a needle-stick should not donate blood or plasma for 12 months following exposure, due to possible transmissibility of infectious disease.



**Question #16:** 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.

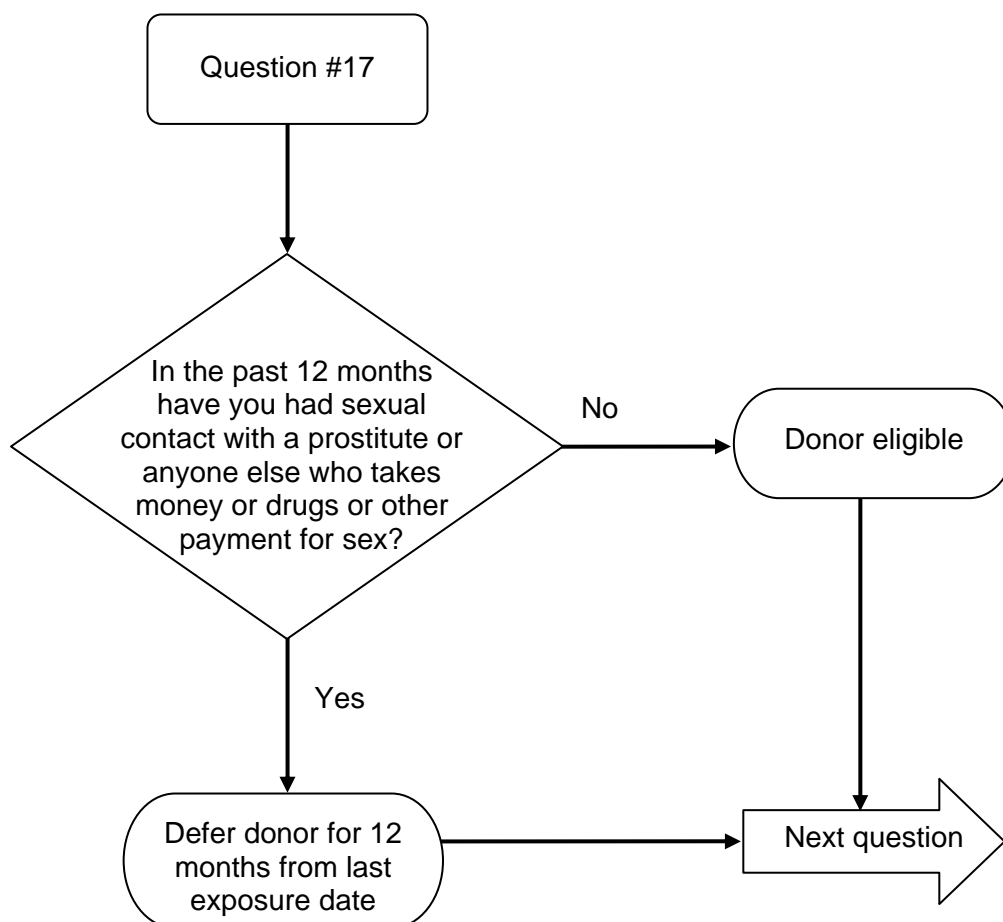
**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Risk Poster provided.



**Question #17:** 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 Risk Poster provided.

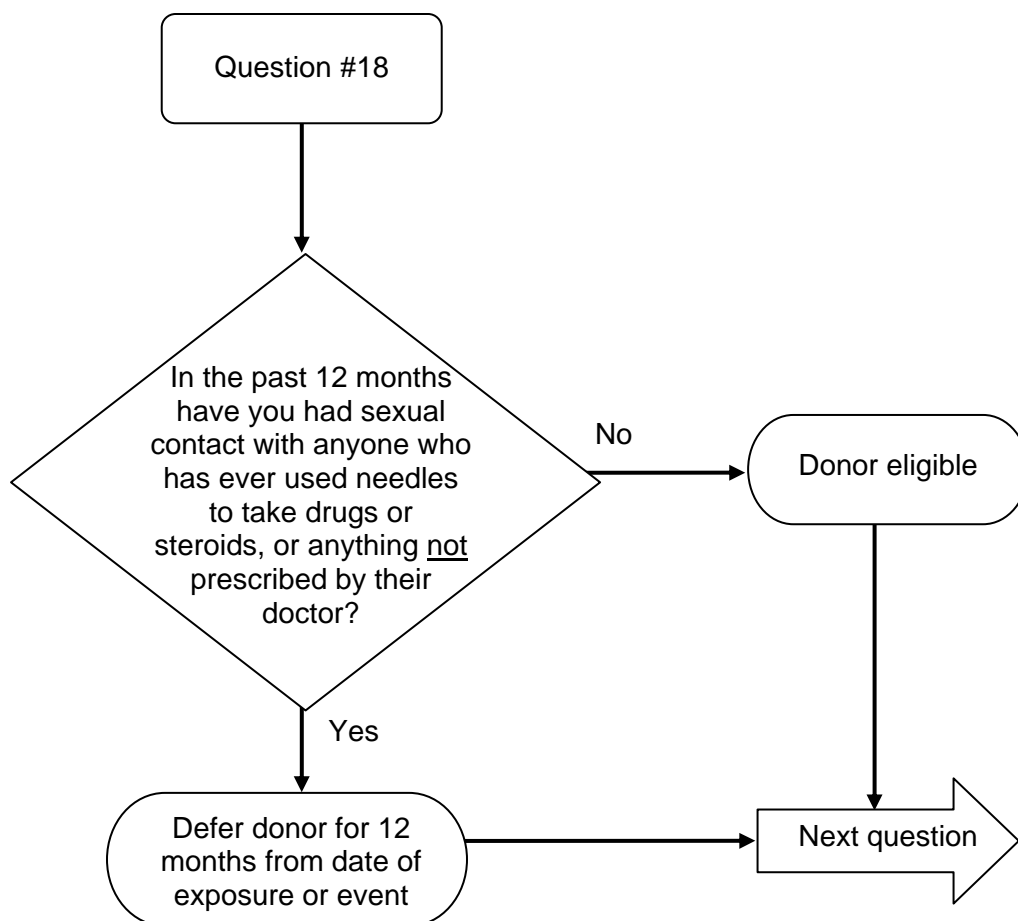


**Question #18:** In the past 12 months have you had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything not prescribed by their doctor?

**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 1:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Risk Poster provided.

**Note 2:** 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.

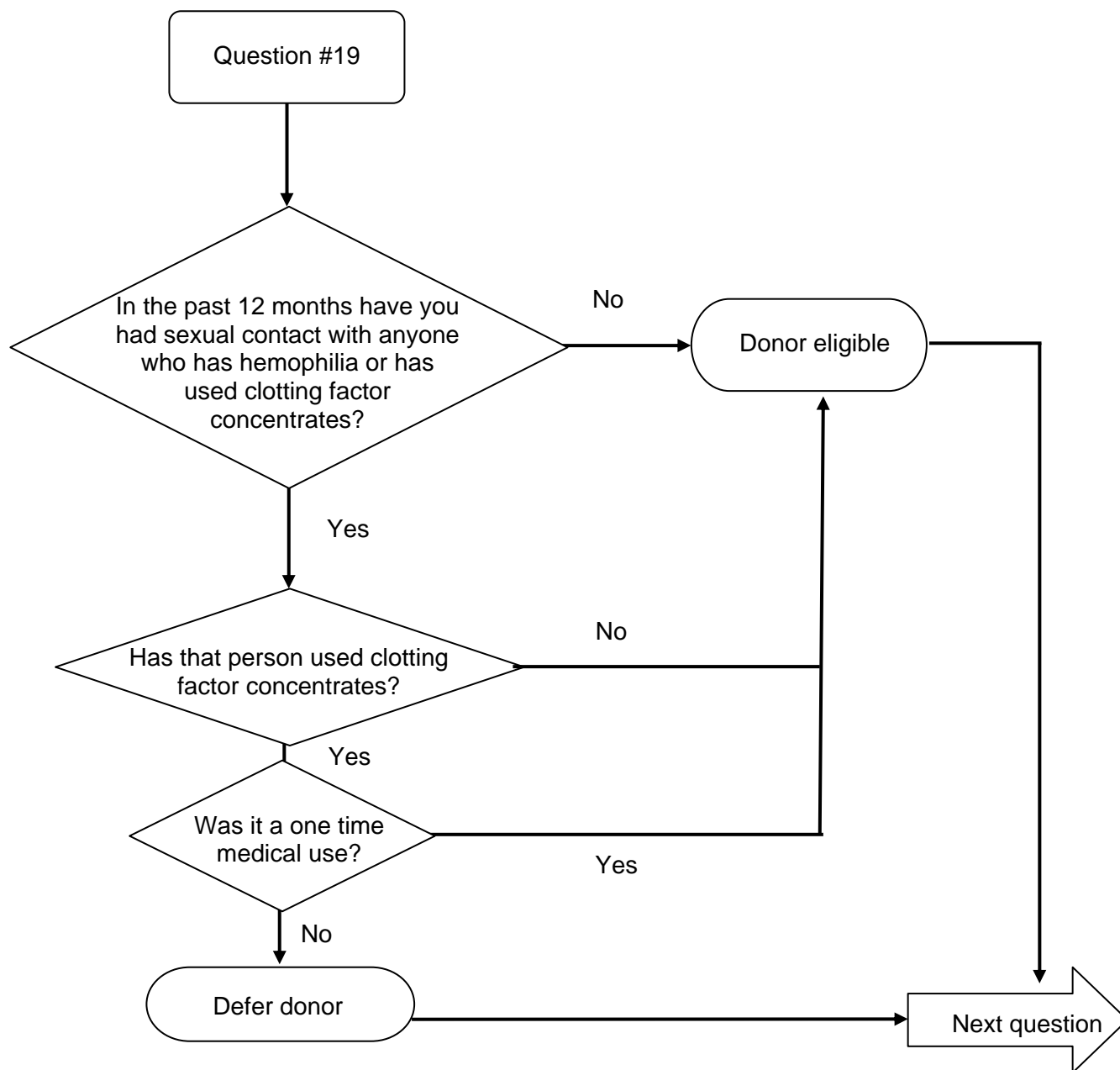


**Question #19:** In the past 12 months have you had sexual contact with anyone who has hemophilia or has used clotting factor concentrates?

**Donor Eligibility:** Persons who have had sexual contact with any person who has received clotting factor concentrates is deferred for 12 months. HIV and other diseases may be transmitted through sexual contact.

**Note:** Some hemophiliacs are not treated with clotting factor concentrates.

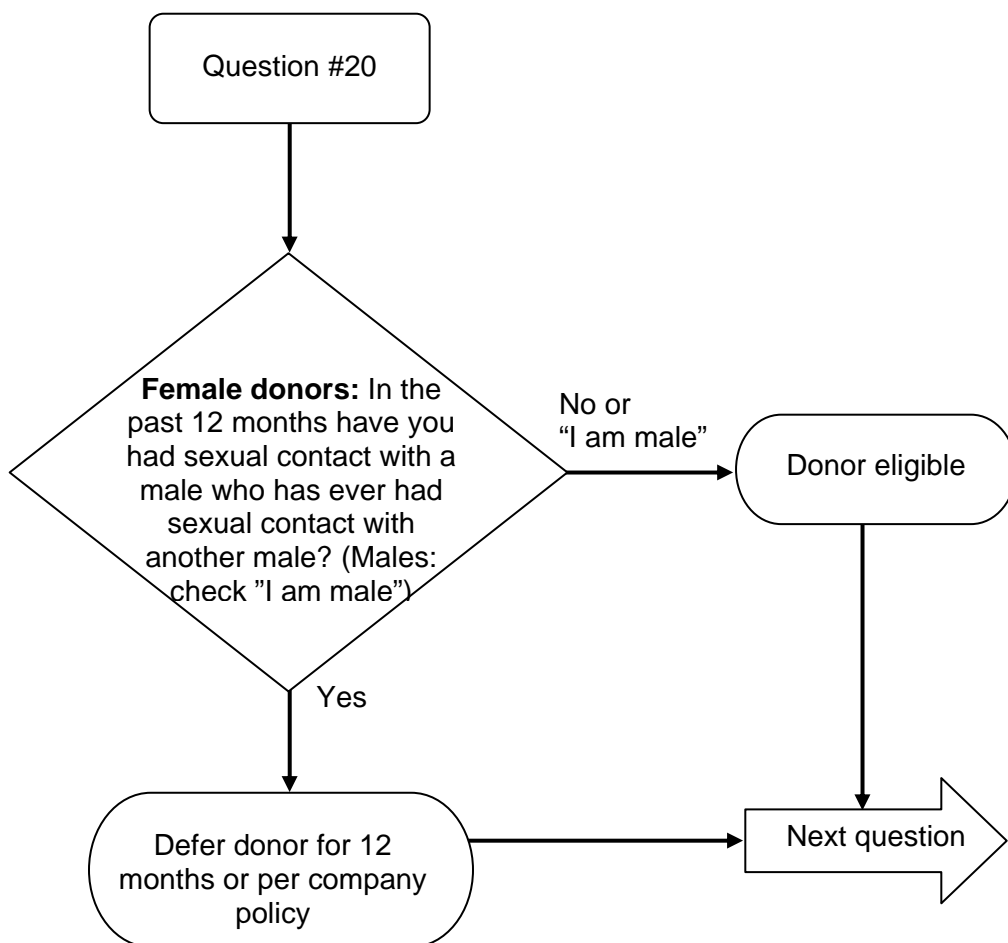
**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Risk Poster provided.



**Question #20:** 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.

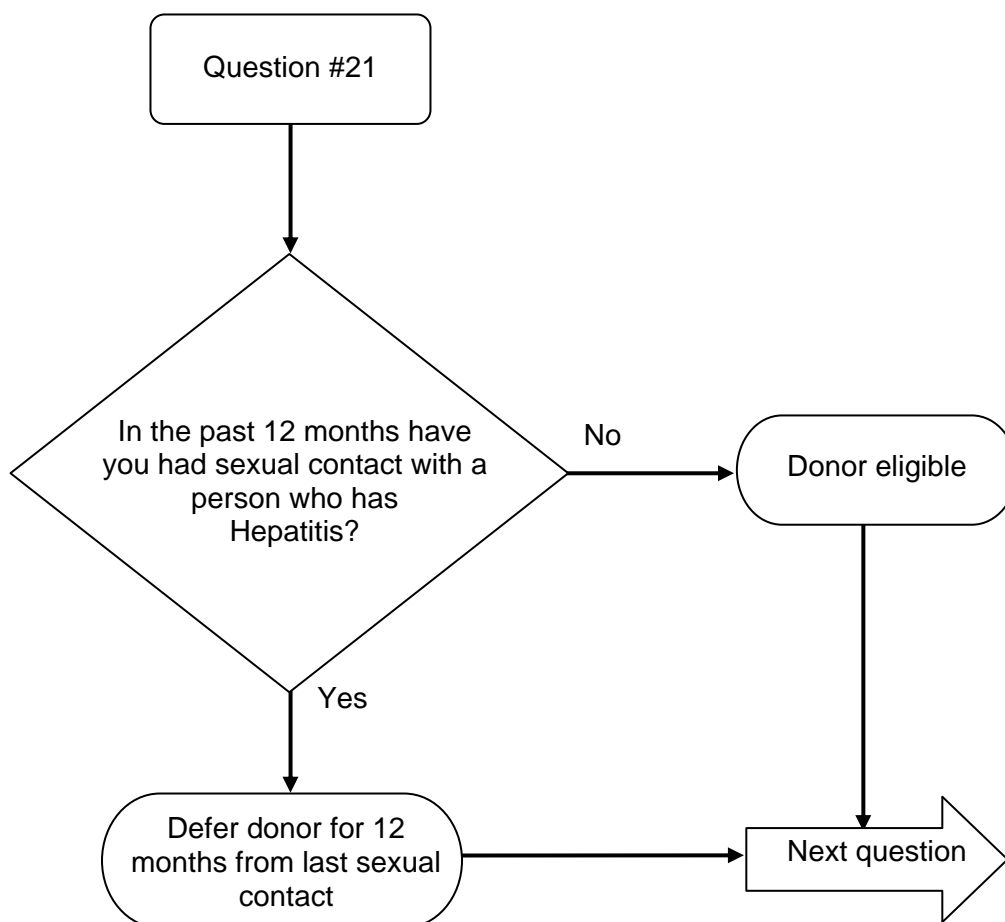
**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Risk Poster provided.



**Question #21:** 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.

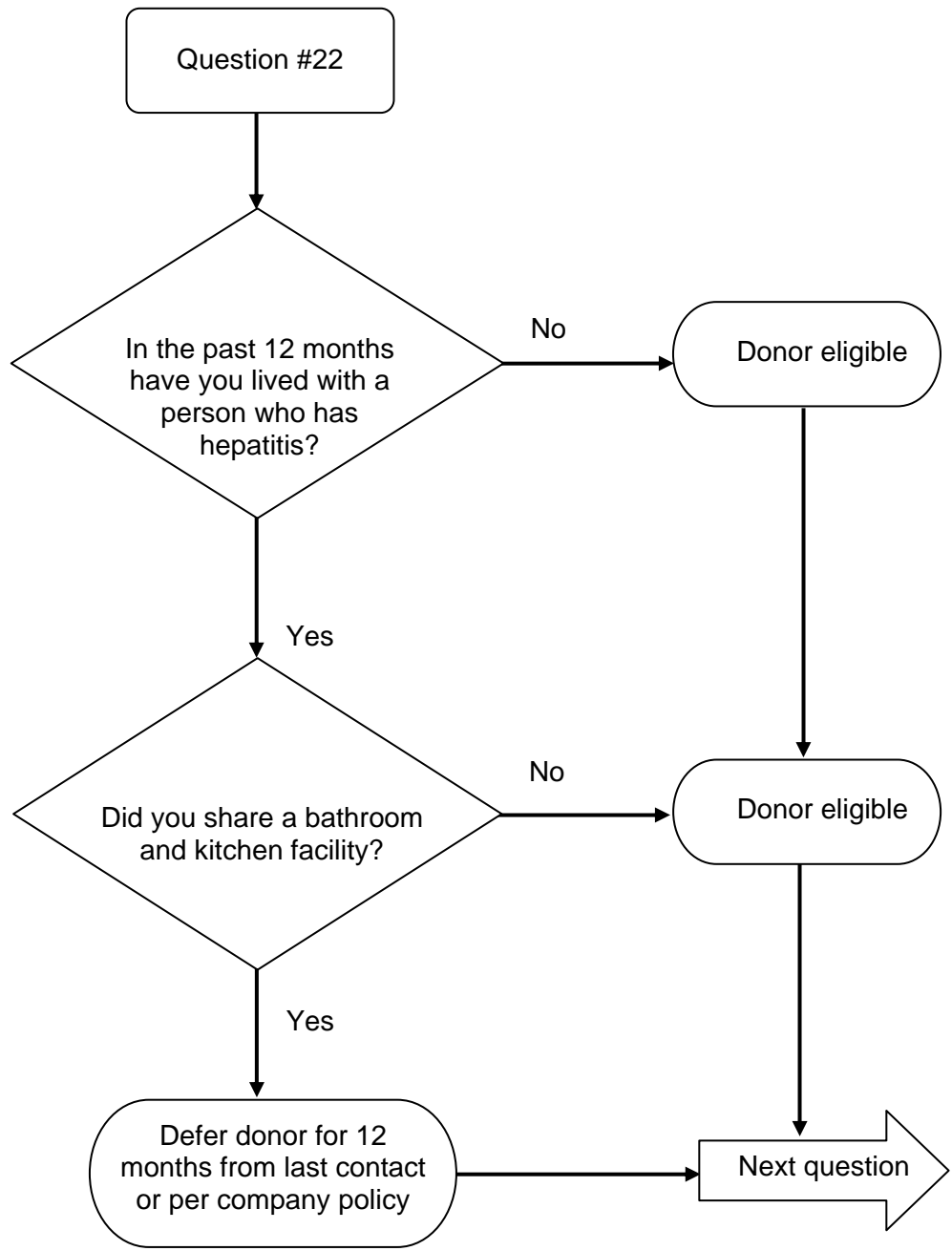
**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Risk Poster provided.



**Question #22:** In the past 12 months have you lived with a person who has hepatitis?

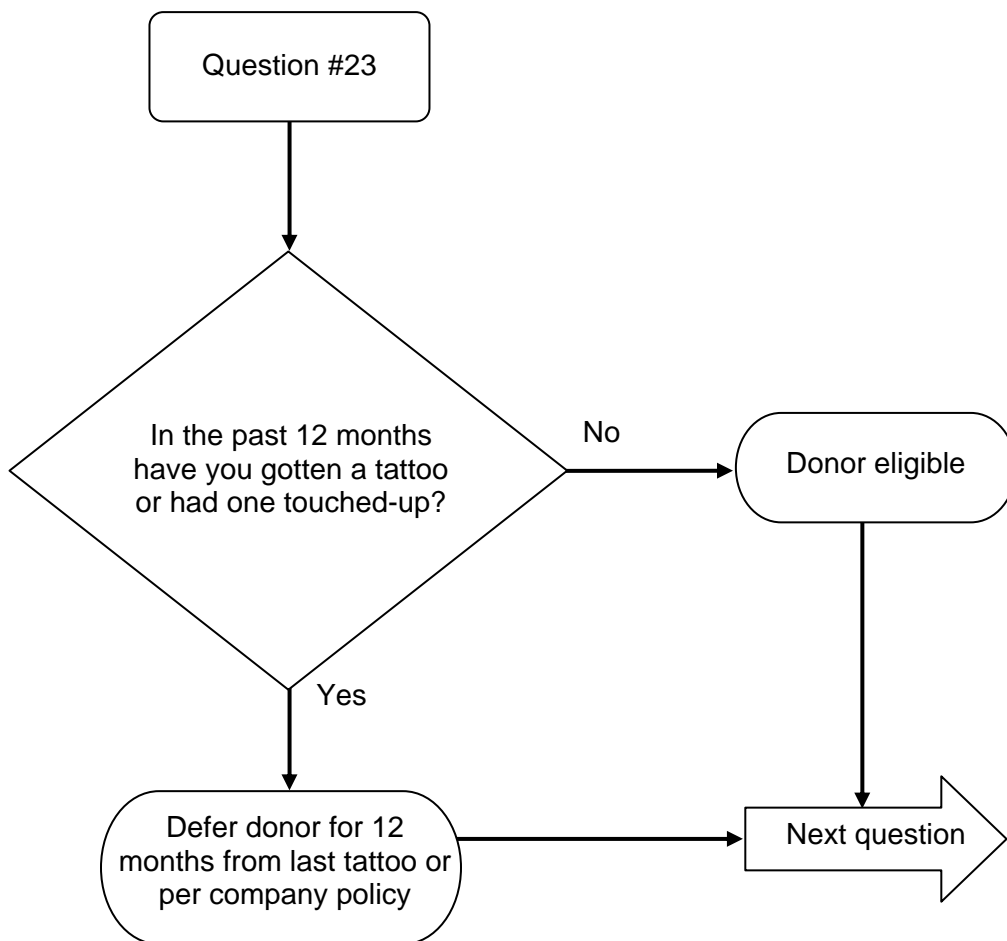
**Donor Eligibility:** Persons who have lived with a person who has hepatitis are deferred 12 months from the date of last contact. Hepatitis, particularly Hepatitis A and B, may be spread through saliva.

**Note:** "Lived with" means residing at the same address and sharing bathroom and kitchen facilities.



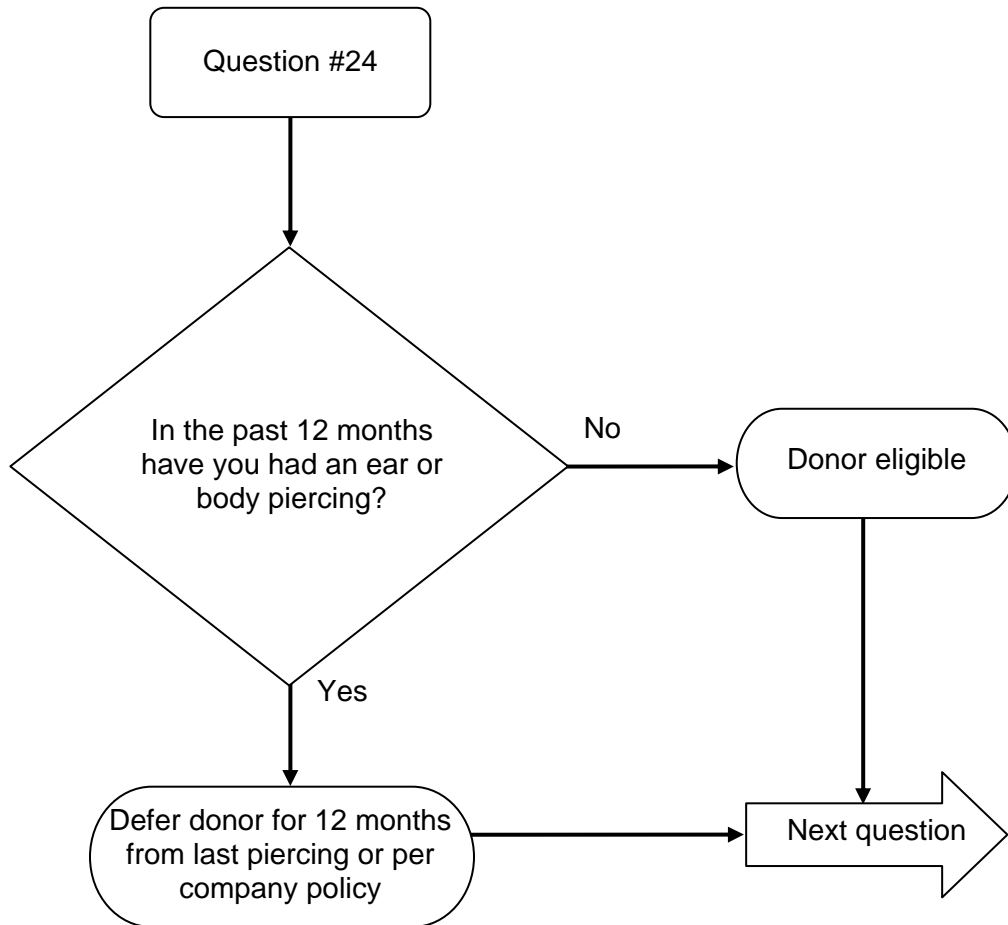
**Question #23:** In the past 12 months have you gotten a tattoo or had one touched-up?

**Donor Eligibility:** Persons who have received a tattoo in the previous 12 months are deferred for 12 months from the date of the tattoo application because there may be a risk of transmission of infectious diseases. If tattoos have been applied using sterile needles and non-reused ink (such as in establishments licensed by a state or credentialed by a responsible certifying body), donors may be acceptable for donation (follow company policy).



**Question #24:** In the past 12 months have you had an ear or body piercing?

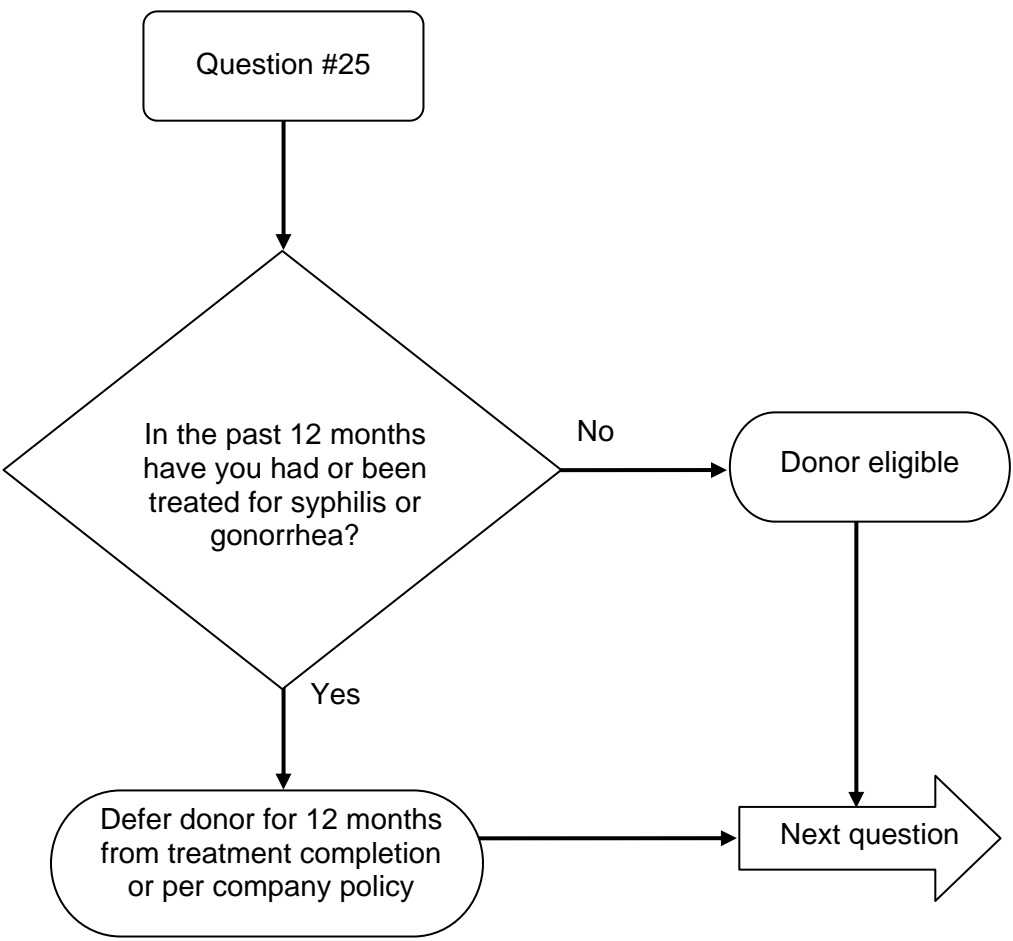
**Donor Eligibility:** Persons who have had ear or body piercing during the previous 12 months are usually deferred for 12 months from the date of procedure. Unless ear or body piercing have been done using single-use equipment, there may be a risk of transmission of infectious diseases.



**Question #25:** In the past 12 months have you had or been treated for syphilis or gonorrhea?

**Donor Eligibility:** Persons who have had syphilis or gonorrhea or treatment for either are deferred for a minimum of 12 months from the date that treatment is completed.

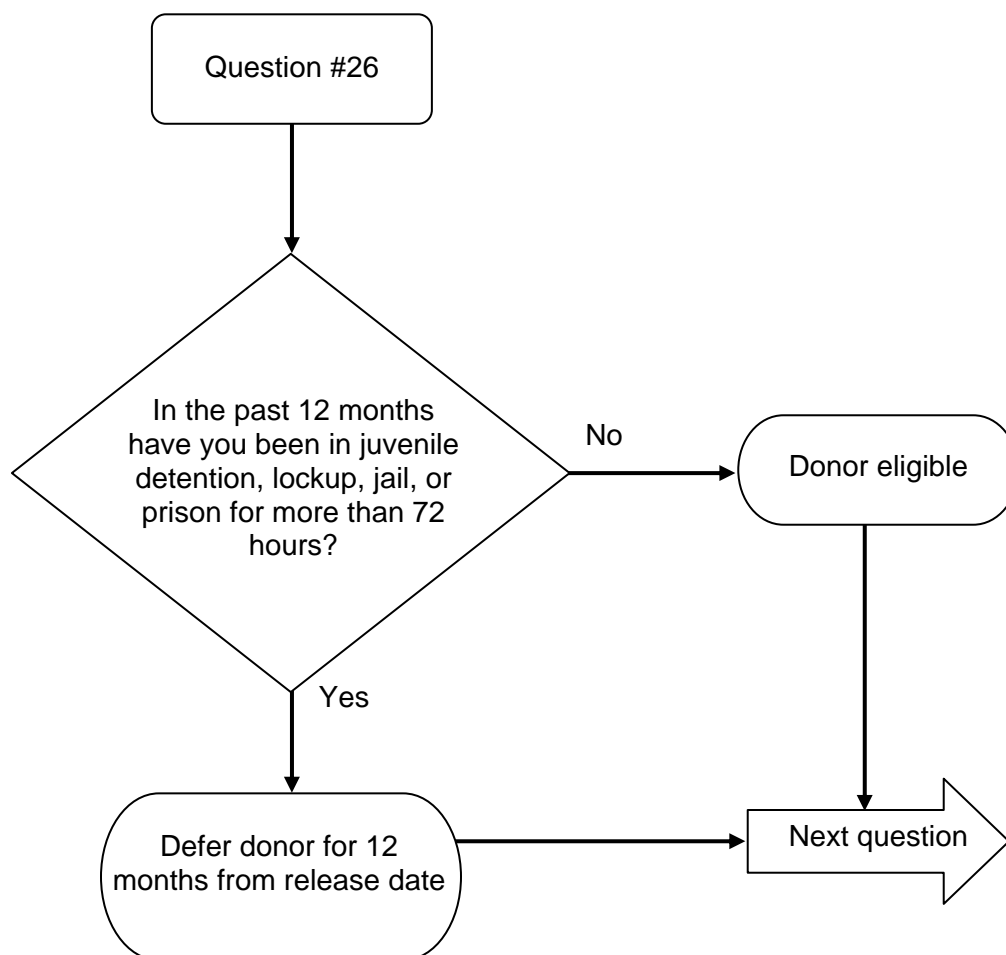
**Note:** Should a donor volunteer that they were tested and found positive for either syphilis or gonorrhea, deferral is indicated.



**Question #26:** 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 (three days) are deferred for 12 months from the date of occurrence. These persons are at higher risk for exposure to infectious diseases.

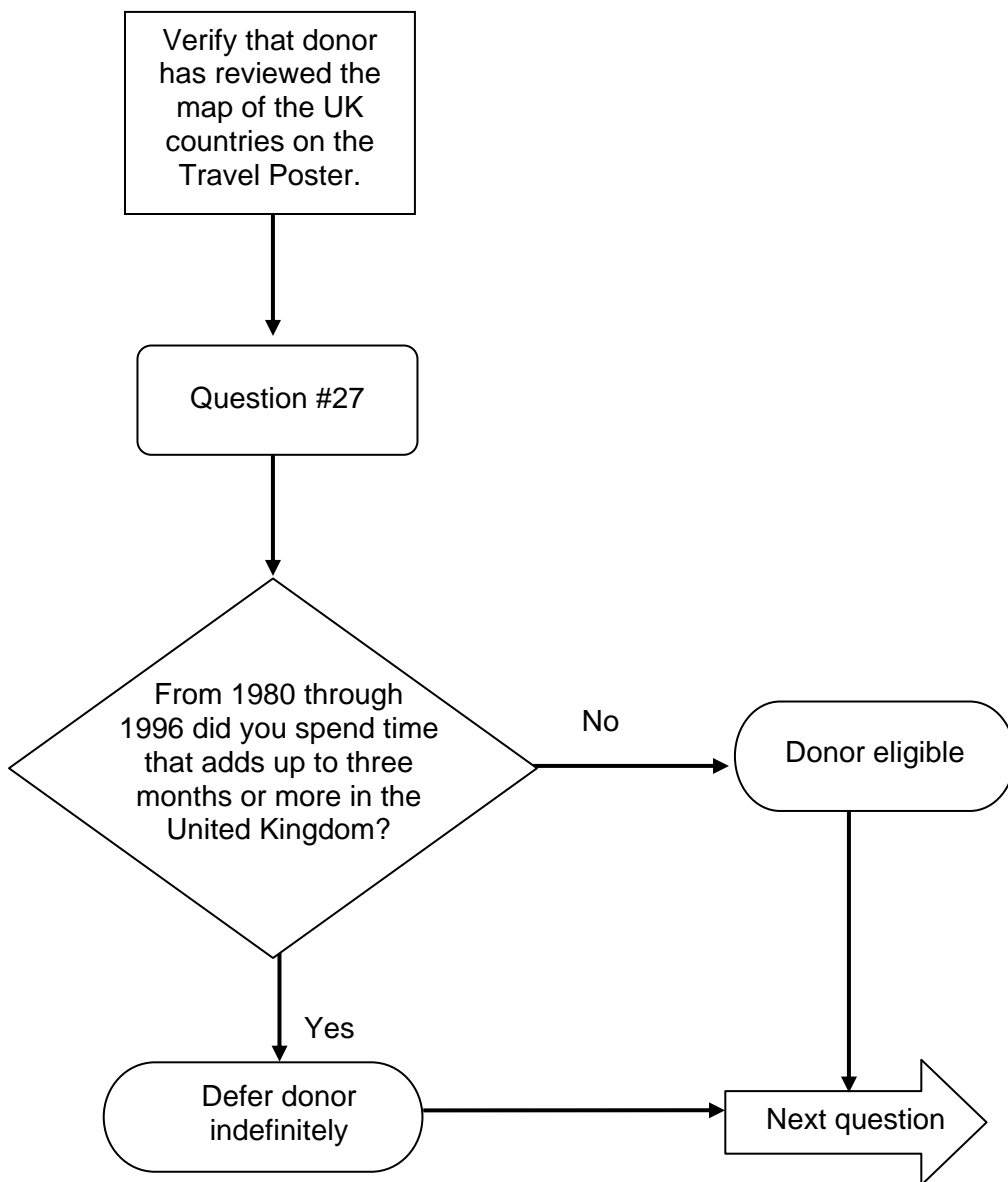
**Note:** The reason for incarceration (e.g. white-collar crimes) does not change the deferral.



**Question #27:** From 1980 through 1996 did you spend time that adds up to three months or more in the United Kingdom? (Review map of UK countries on the Travel Poster)

**Donor Eligibility:** Donors who have spent time that adds up to three months or more in the United Kingdom from 1980 through 1996 are indefinitely deferred. Donors may be at risk of developing vCJD from eating beef from the UK (England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or Falkland Islands.). There is a risk of transmitting vCJD through blood transfusion.

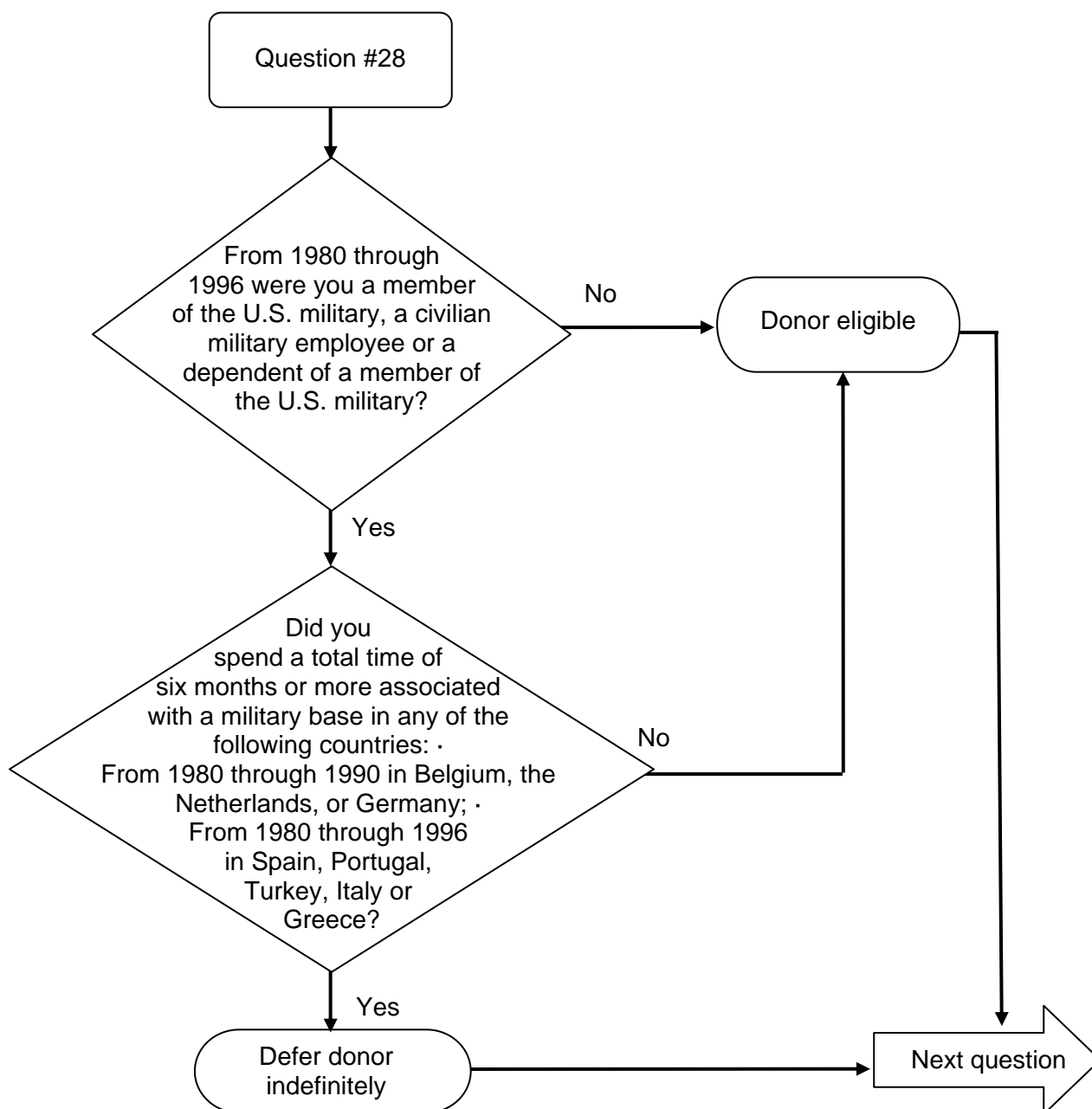
**Note:** Ask donor if they have reviewed the map of UK countries before answering this question. If Yes, proceed to reviewing answer. If No, ask donor to look at the map now. If the donor then answers yes, make correction if necessary as per company policy.



**Question #28:** 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 six 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. Much of the beef supplied to U.S. military bases during these time periods came from the United Kingdom (U.K.). As a result, these U.S. military personnel may be at risk of developing vCJD and transmitting vCJD through blood and plasma.

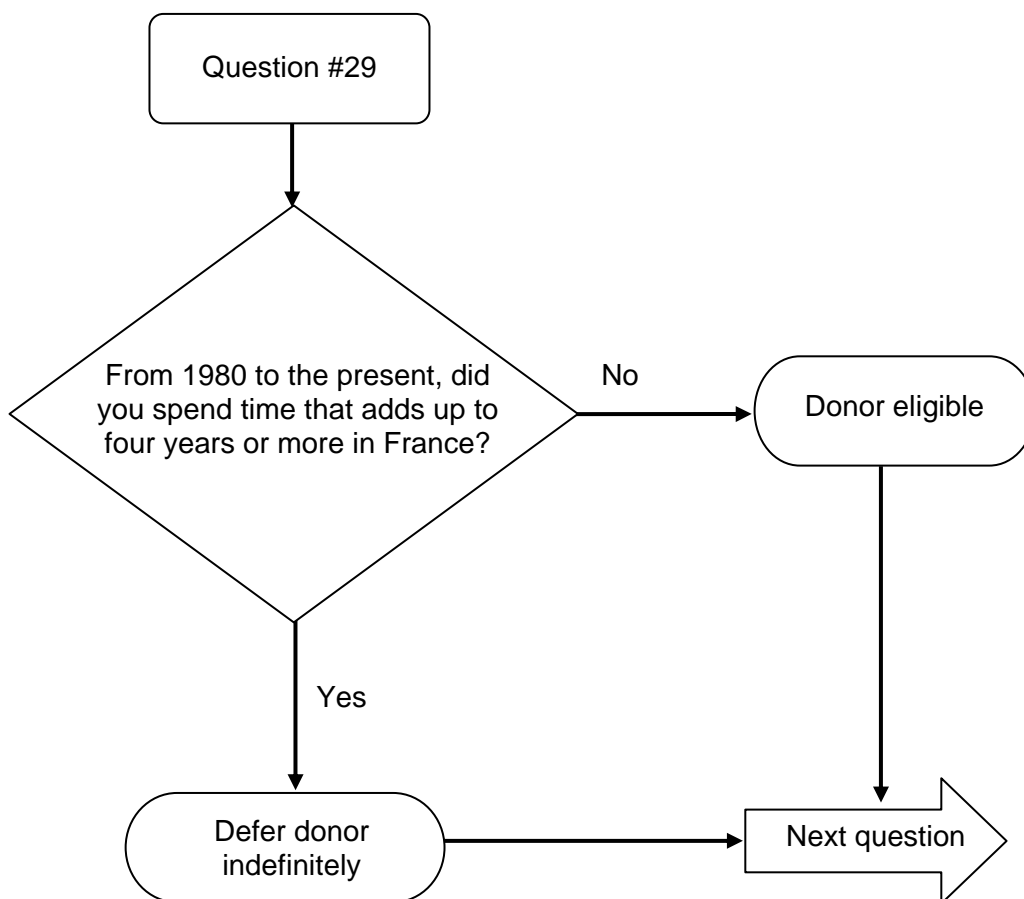
**Note:** The countries are listed on the Travel Poster as an additional aid in answering the follow-up question.



**Question #29:** From 1980 to the present, did you spend time that adds up to four years or more in France?

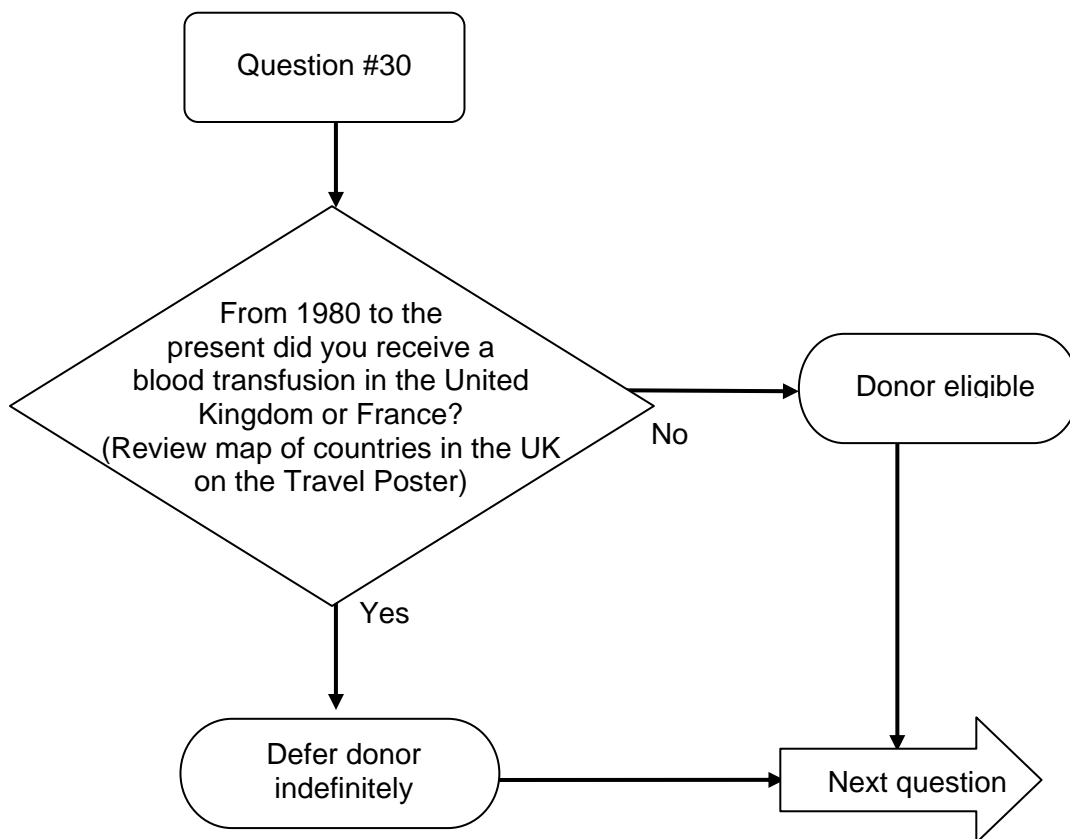
**Donor Eligibility:** Donors who have spent time that adds up to five years or more in France from 1980 to the present are indefinitely deferred. Donors may be at risk of developing vCJD from eating beef in France.

Note: It was determined that asking the donor if they have spent time up to four years or more in France, which is more restrictive than the FDA regulatory requirement, allows the question to coincide with the administration of the full length questionnaire to a qualified donor at the required yearly interval. This eliminates the need to ask this question every 4 months within the abbreviated questionnaire.



**Question #30:** From 1980 to the present did you receive a blood transfusion in the United Kingdom or France? (Review map of countries in the UK on the Travel Poster)

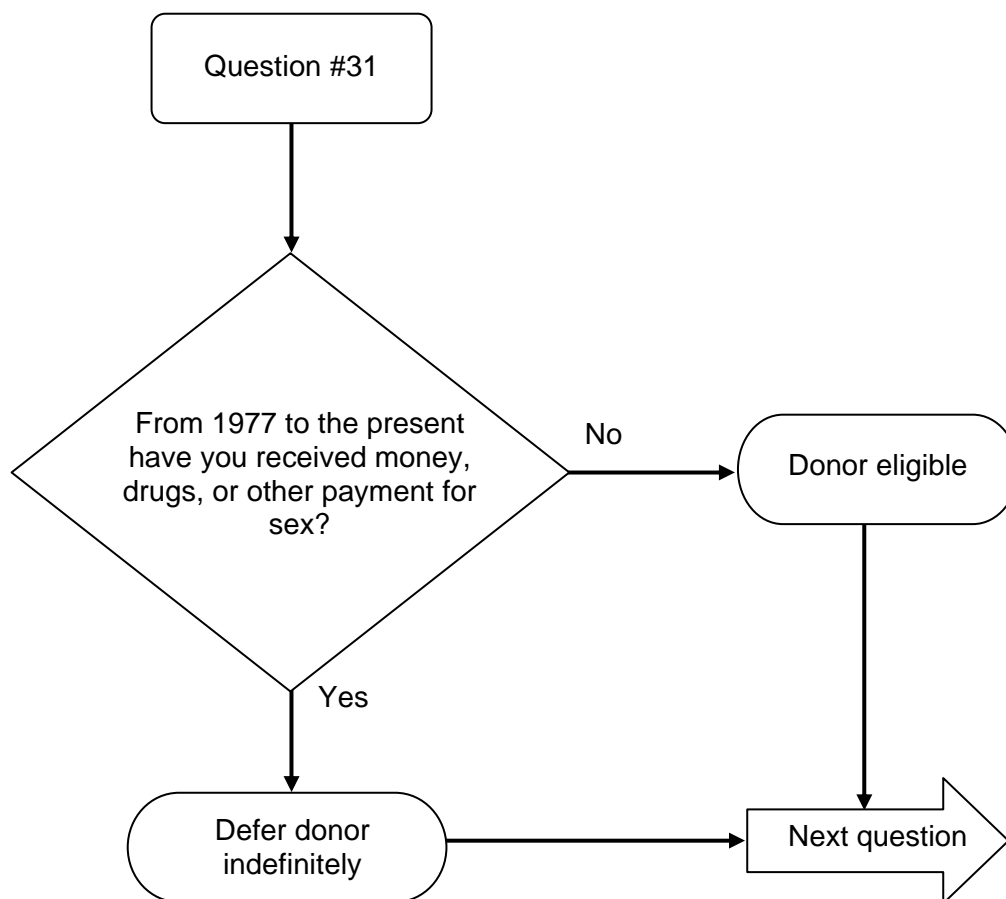
**Donor Eligibility:** Donors who received a transfusion of blood, platelets, plasma, cryoprecipitate, or granulocytes in the UK (England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands) or France from 1980 to the present are indefinitely deferred. Donors may be at risk of developing vCJD through transfusion.



**Question #31:** 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.

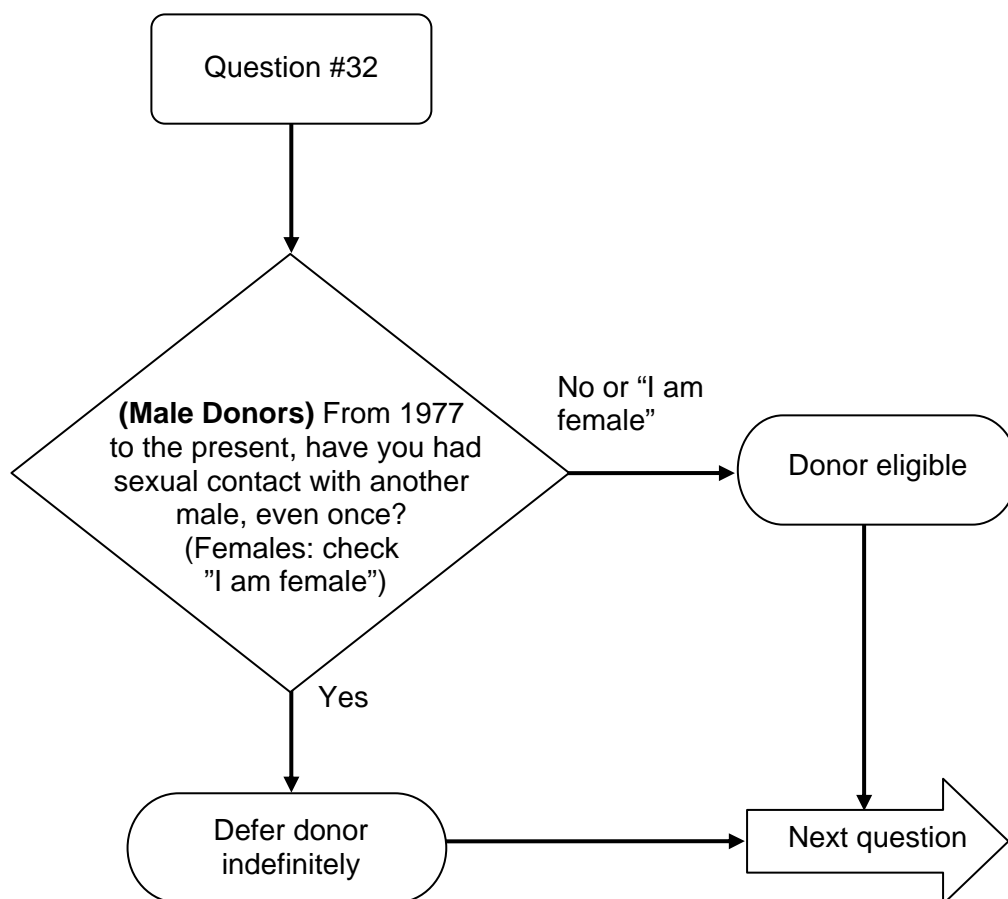
**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Risk Poster provided.



**Question #32:** (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 increased risk of transmitting infectious diseases.

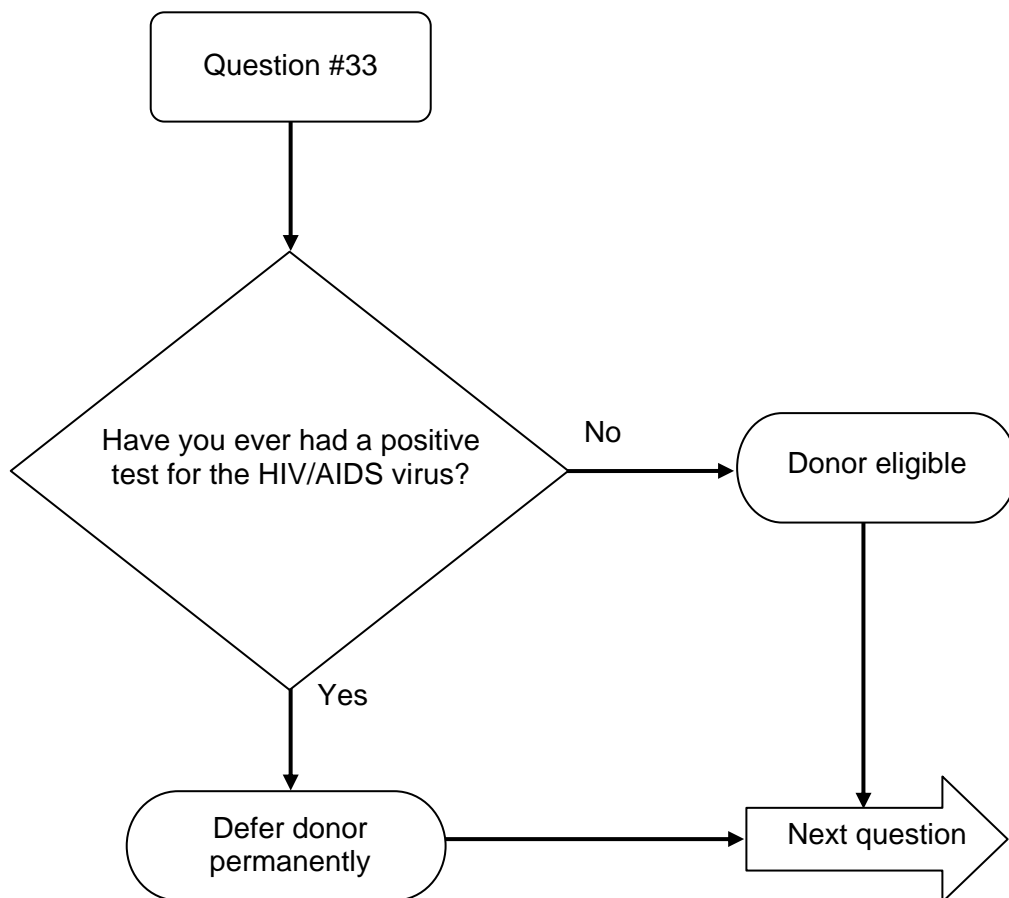
**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Risk Poster provided.



**Question #33:** Have you ever had a positive test for the HIV/AIDS virus?

**Donor Eligibility:** Donors with clinical or laboratory evidence of HIV/AIDS are permanently deferred.

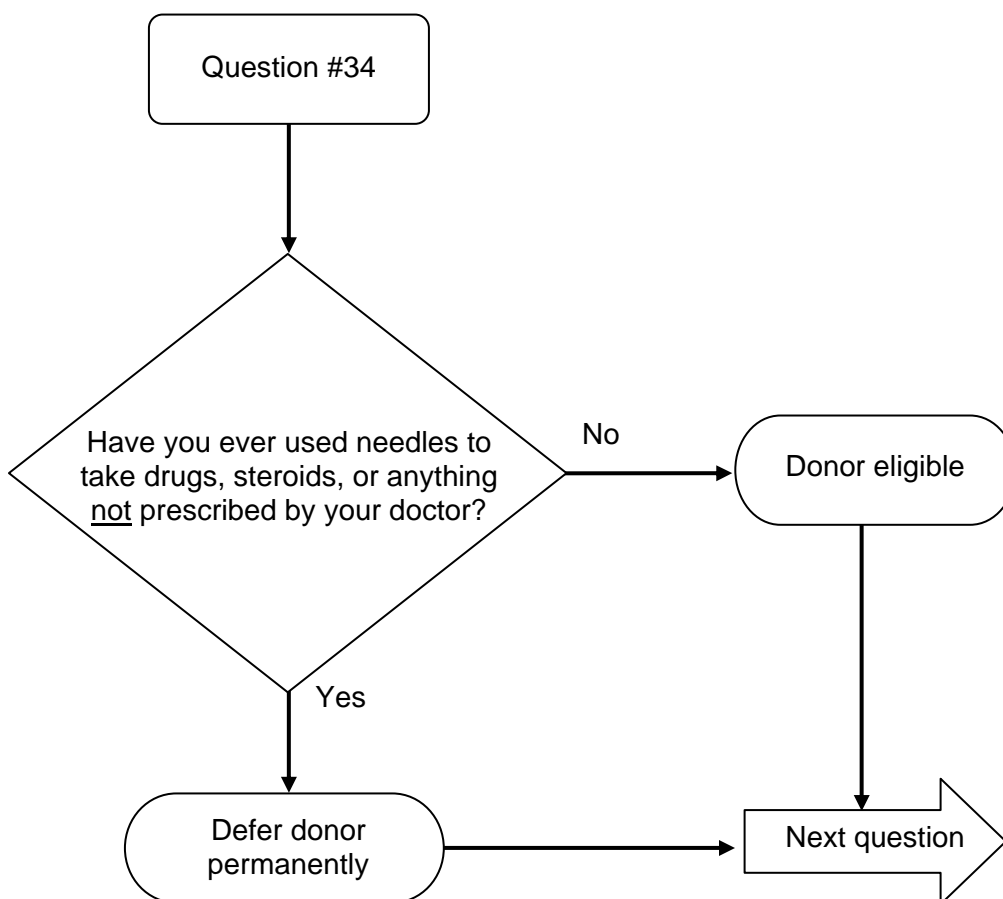
**Note:** Donors who have been re-entered through FDA-approved protocols may be eligible for donation.



**Question #34:** Have you ever used needles to take drugs, steroids, or anything not prescribed by your doctor?

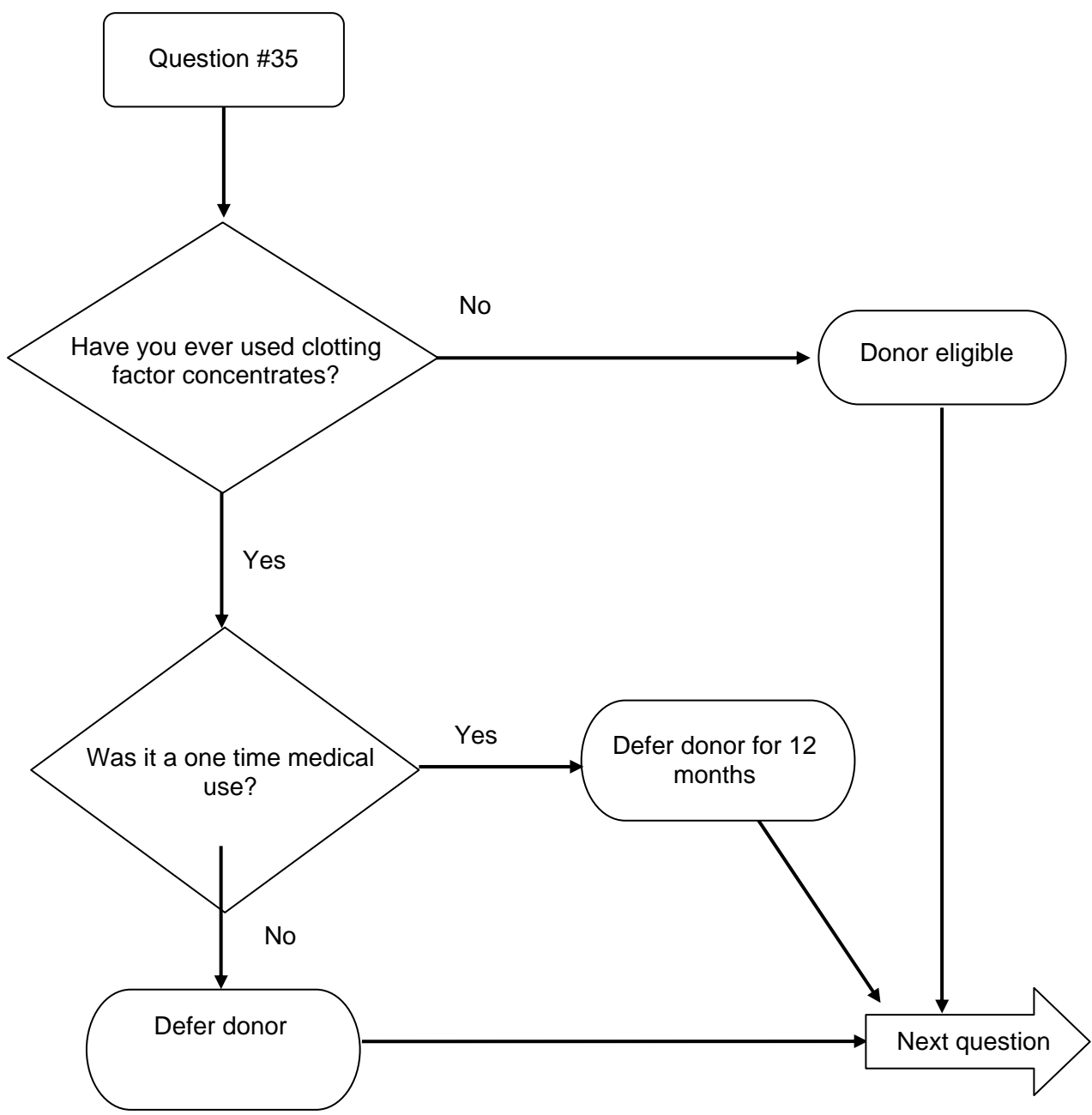
**Donor Eligibility:** Donors who have taken any drug with a needle are permanently deferred due to potential transmission of infectious disease.

**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.



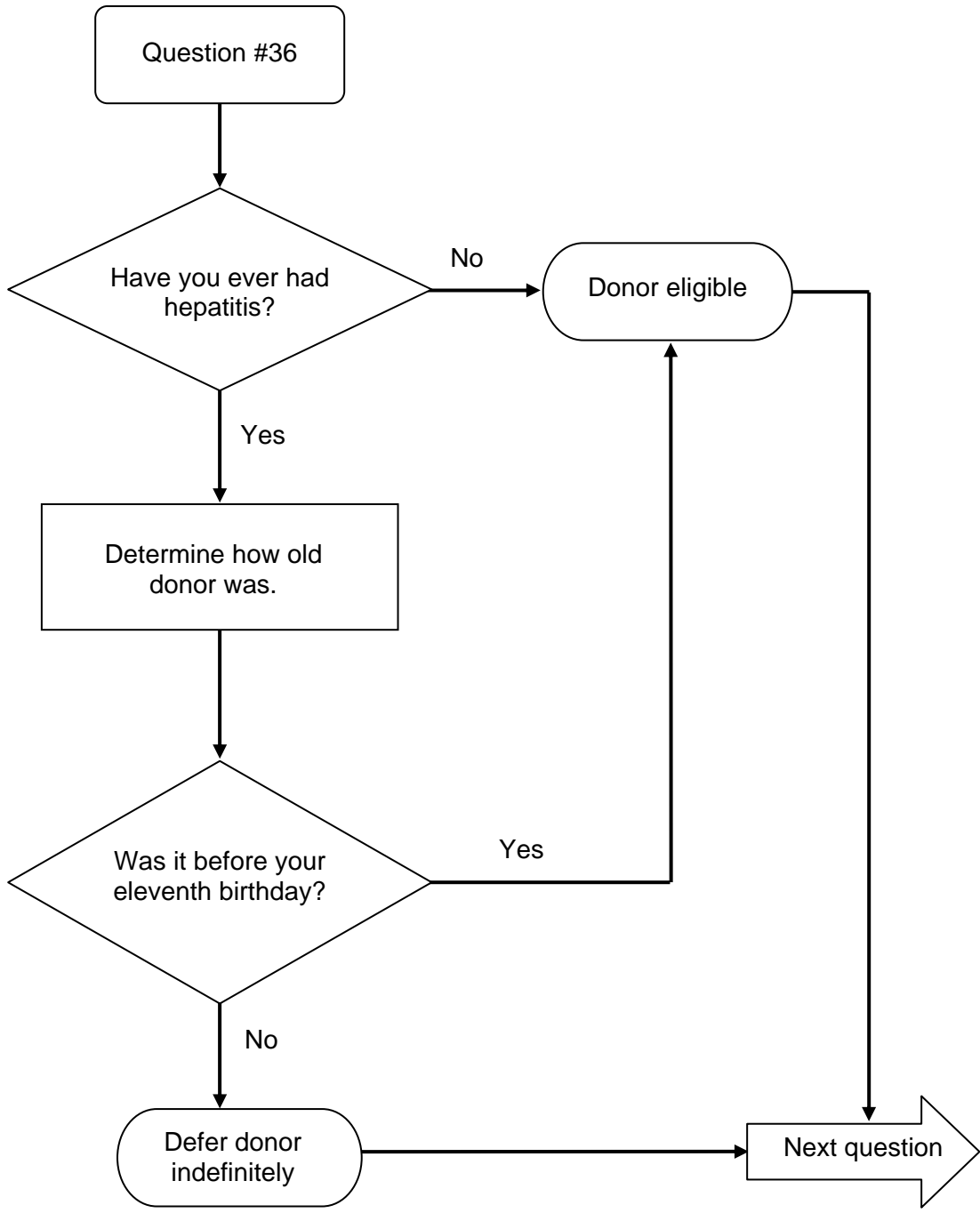
**Question #35:** Have you ever used clotting factor concentrates?

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



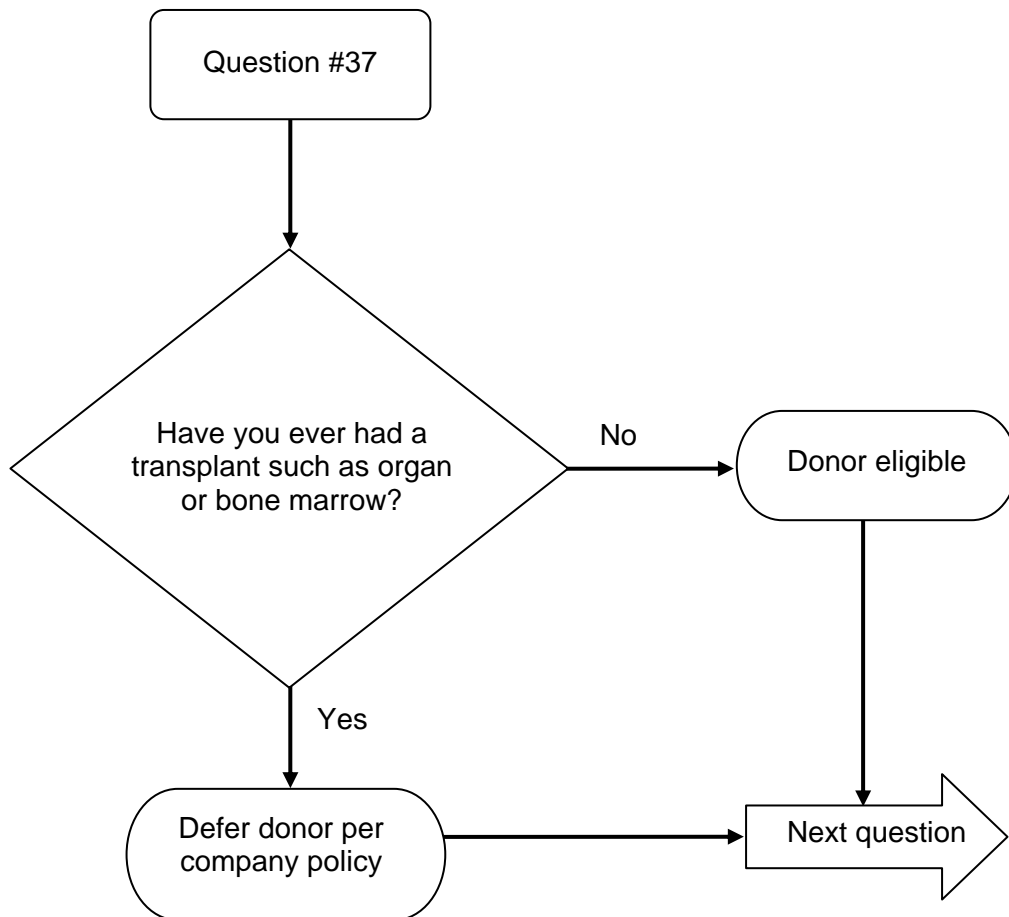
**Question #36:** Have you ever had hepatitis?

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



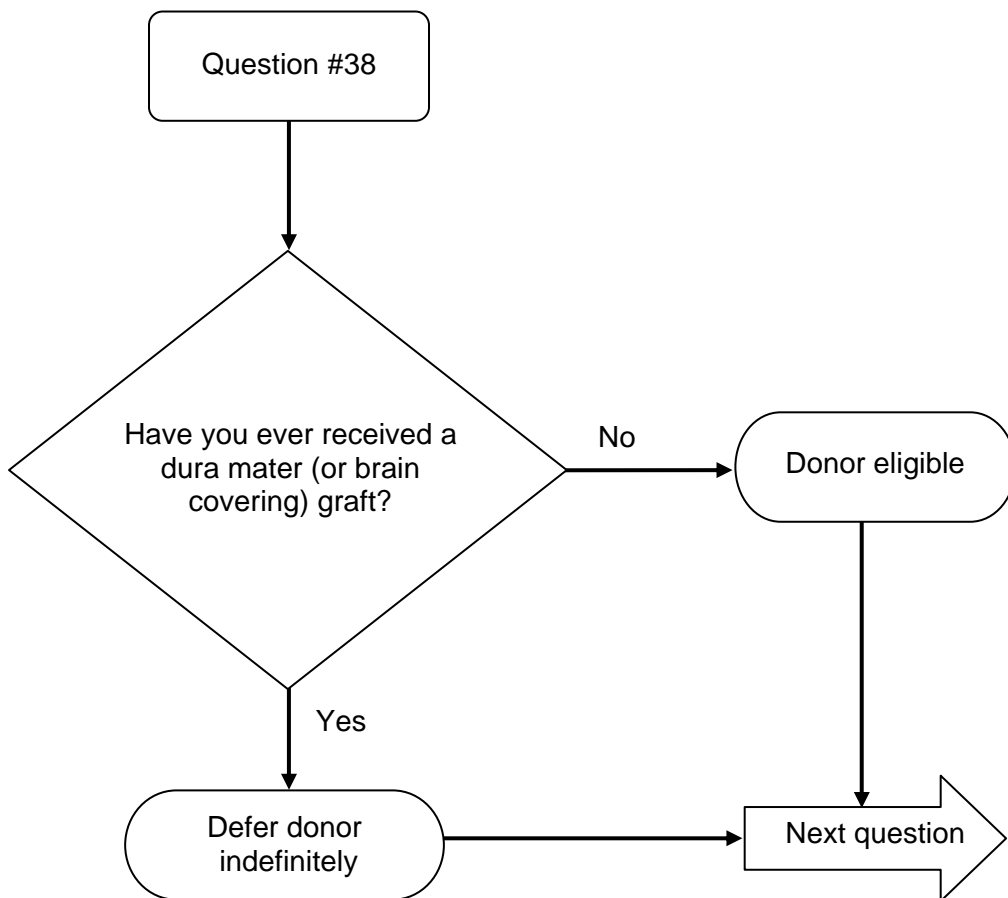
**Question #37:** Have you ever had a transplant such as organ or bone marrow?

**Donor Eligibility:** A donor who has had an organ or bone marrow transplant should not donate plasma.



**Question #38:** Have you ever received a dura mater (or brain covering) graft?

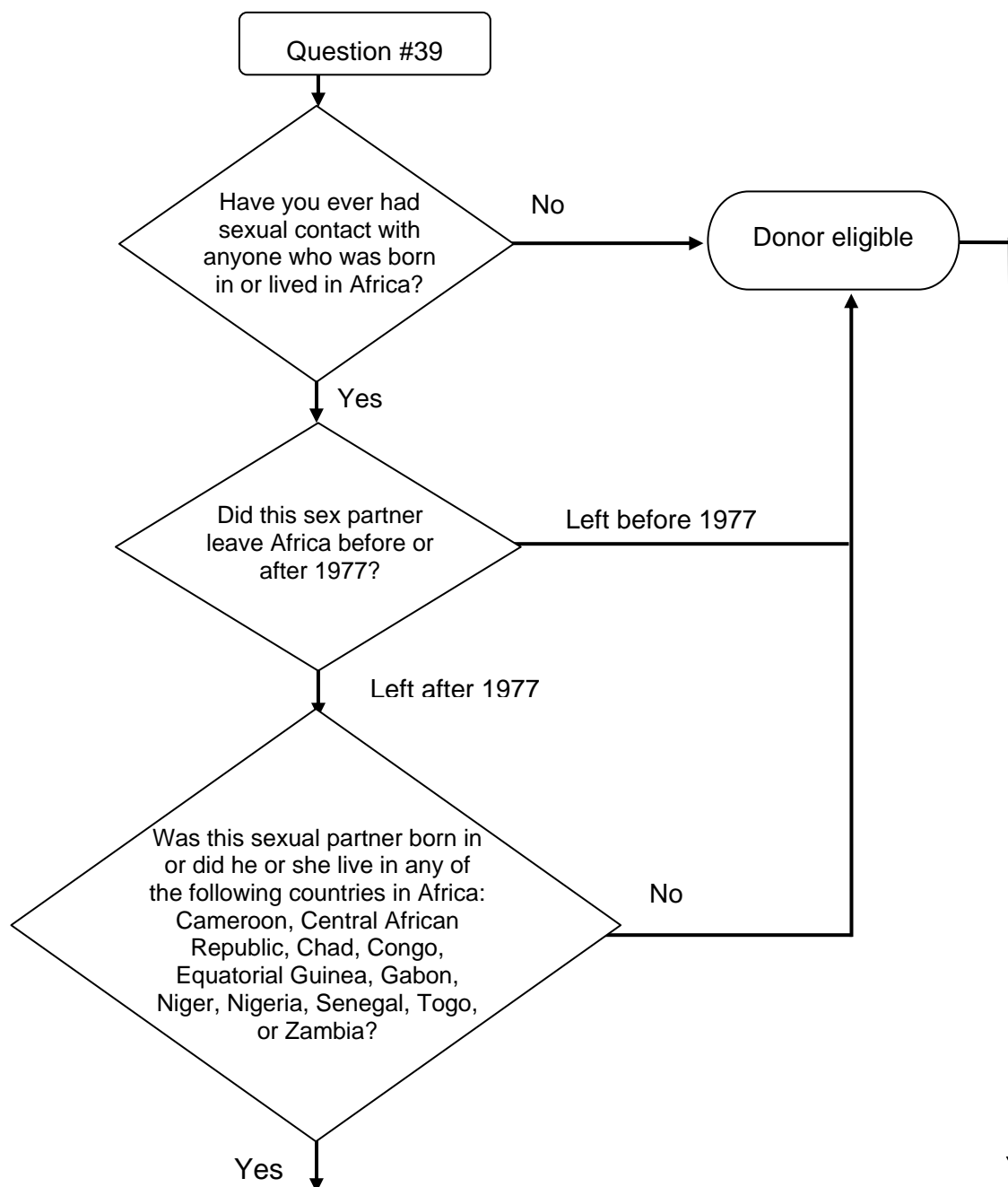
**Donor Eligibility:** Donors who have received a dura mater transplant or graft may be at risk for Creutzfeldt-Jakob disease and are indefinitely deferred.



**Question # 39:** 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 detected by current test methods.<sup>2</sup>

**Note:** Not all donors define “sex” or “sexual contact” in the same way. The donor must have read the Risk Poster.

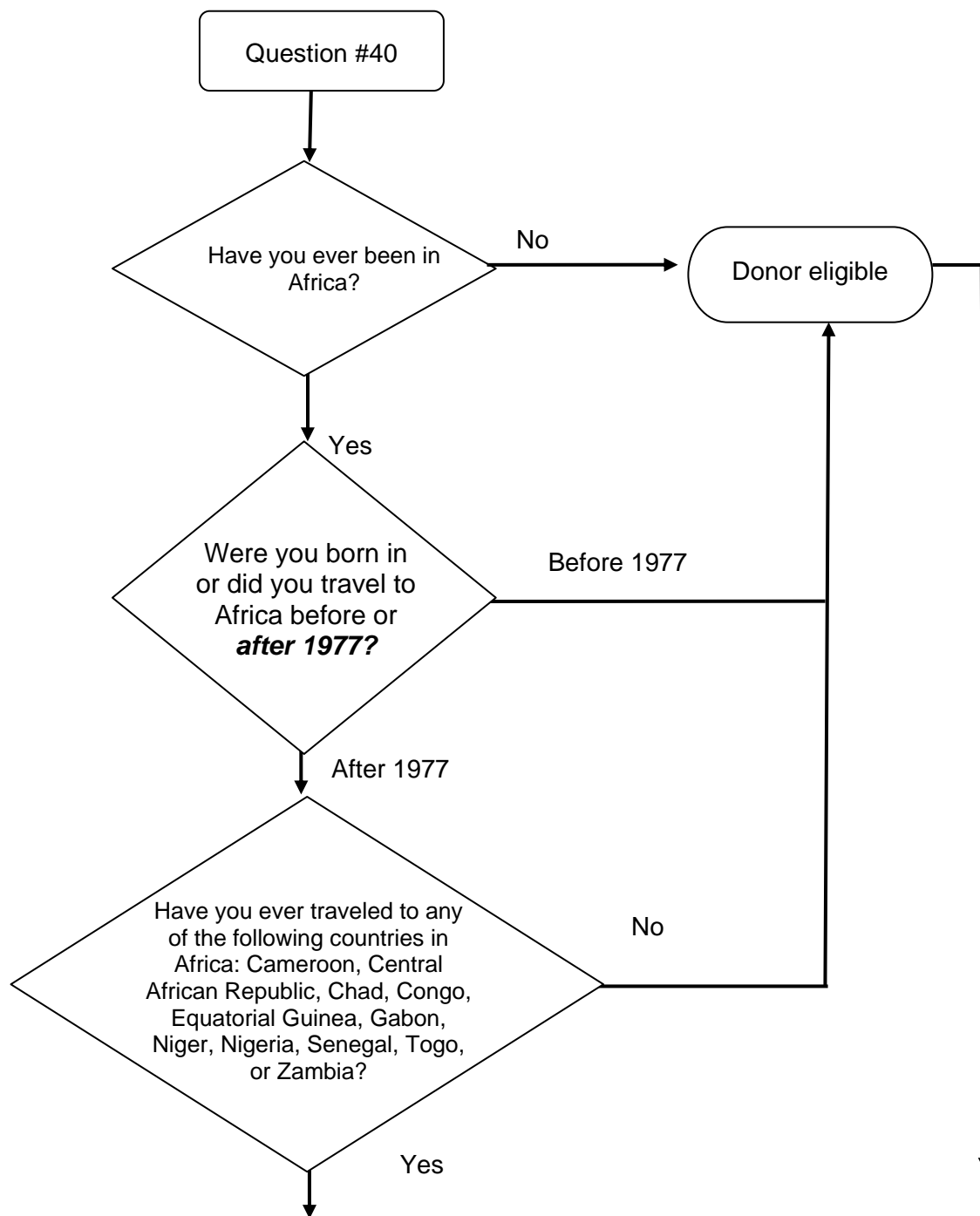


<sup>2</sup> Plasma sourcing organizations using an HIV test that has been approved by FDA to include a donor screening claim for detection of Group O virus may eliminate this question during screening and use the full-length questionnaire that deleted these questions and corresponding risk and travel poster.

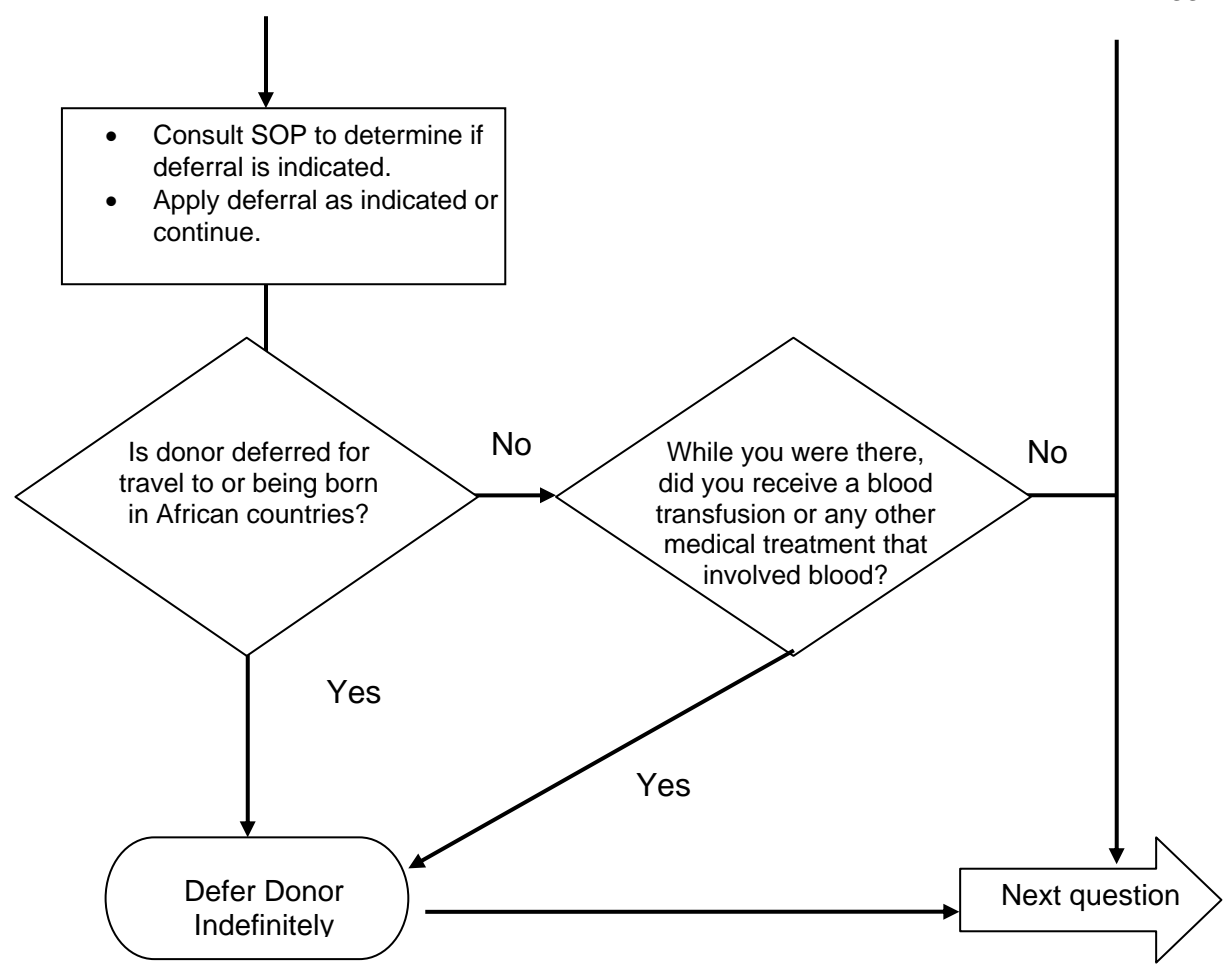


**Question # 40:** Have you ever been in Africa?

**Donor Eligibility:** Donors who have been 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.<sup>3</sup>

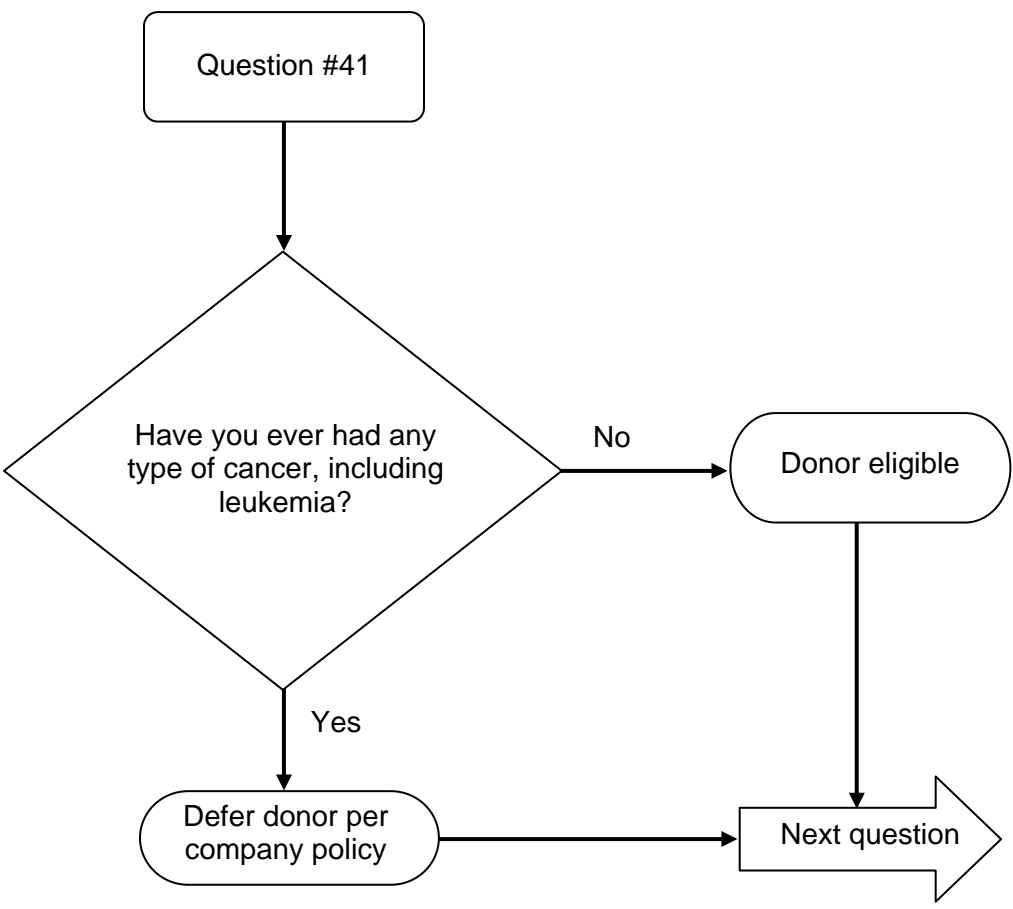


<sup>3</sup> Plasma sourcing organizations using an HIV test that has been approved by FDA to include a donor screening claim for detection of Group O virus may eliminate this question during screening and use the full-length questionnaire that deletes these questions and corresponding risk and travel poster.



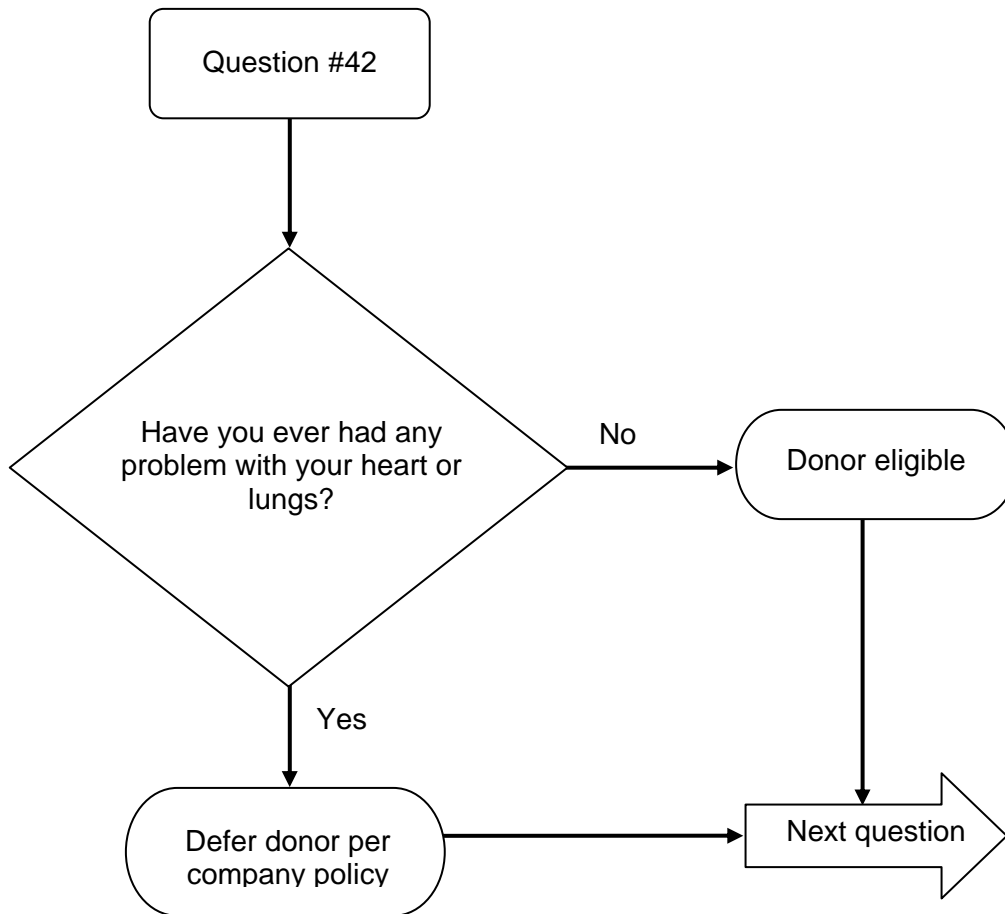
**Question #41 (#39 of Full-length Questionnaire I):** Have you ever had any type of cancer, including leukemia?

**Donor Eligibility:** Donors with a history of cancer must be evaluated and deemed eligible to donate per company policy.



**Question #42 (#40 of Full-length Questionnaire I):** Have you ever had any problem with your heart or lungs?

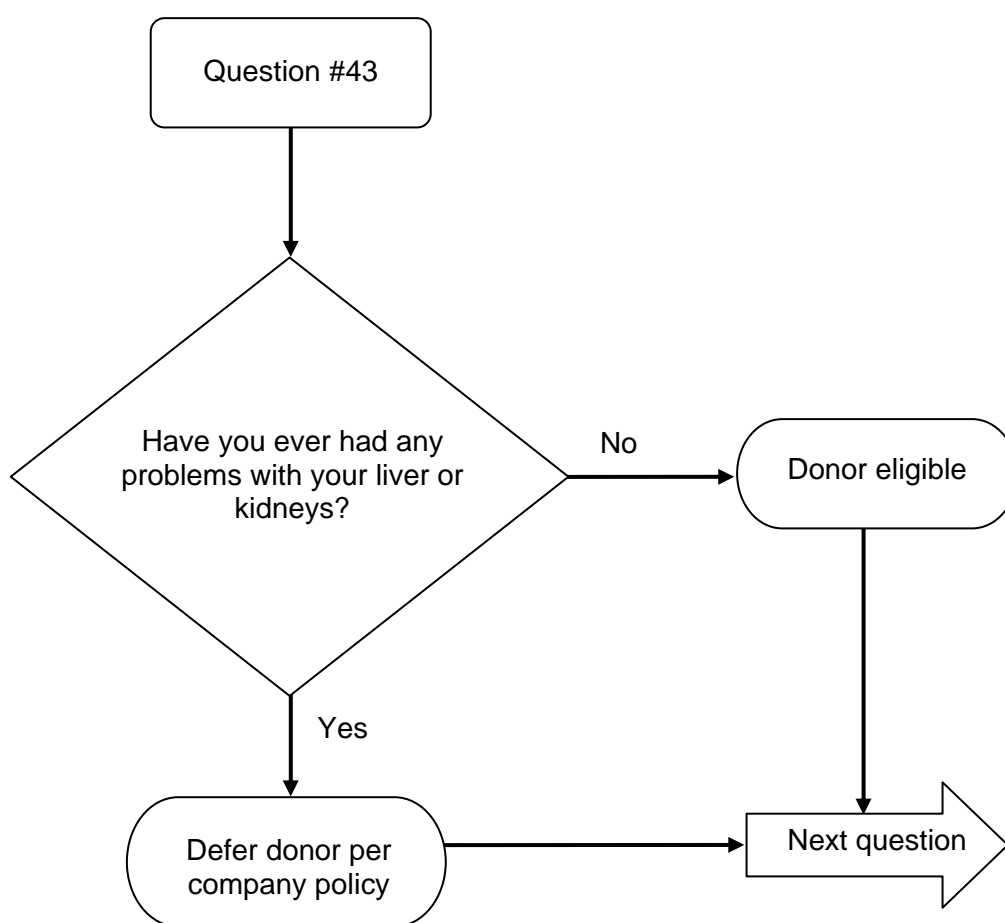
**Donor Eligibility:** Donors must be free of acute respiratory disease. Donors with a history of diseases of the heart and lungs, including acute diseases, must be evaluated (follow company policy).



**Question #43 (#41 of Full-length Questionnaire I):** Have you ever had any problems with your liver or kidneys?

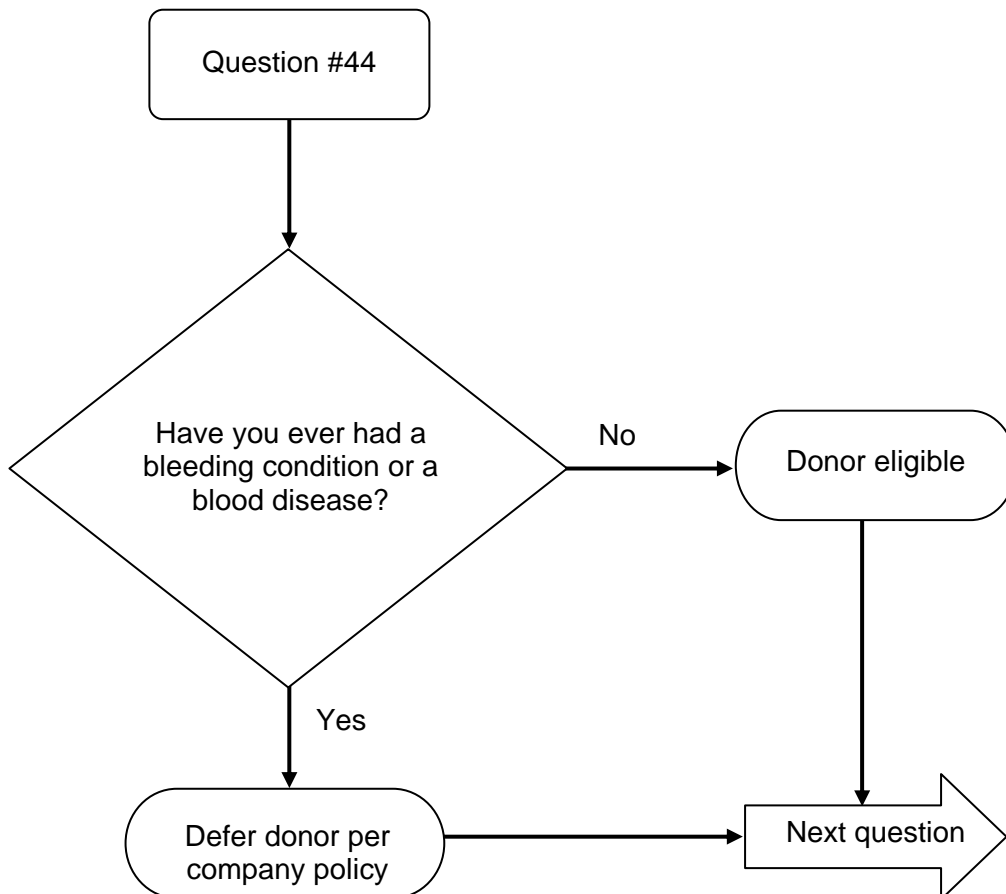
**Donor Eligibility:** Donors must be free of liver and kidney diseases. Donors with a history of diseases of the liver or kidneys must be evaluated (follow company policy).

**Note:** If donors need examples of liver and kidney diseases, some examples include: Kidney - kidney stones, renal insufficiency, renal disease, nephritis and liver – cirrhosis, fatty liver (cholestasis).



**Question #44 (#42 of Full-length Questionnaire I):** Have you ever had a bleeding condition or a blood disease?

**Donor Eligibility:** Donors with a history of bleeding problems should be evaluated (follow company policy).



**Question #45 (#43 of Full-length Questionnaire I):** 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 may be eligible.

