

This document is one component of the PPTA donor history questionnaire documents. The PPTA donor history questionnaire documents must be used collectively.

PPTA Abbreviated Donor History Questionnaire Directions for Use

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PPTA Abbreviated Donor History Questionnaire Directions for Use

Purpose: The PPTA Abbreviated Donor History Questionnaire (PPTA aDHQ) 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 aDHQ 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)¹ and corresponding Directions for Use, an Abbreviated PPTA DHQ and corresponding Directions for Use, two Risk Posters¹, two Travel Posters, 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

^{1 1} 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 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 Administration Frequency: The Full-Length PPTA DHQ will be administered during the donor's initial visit (Applicant 1 donation), second visit if that visit occurs within six months of the initial visit (Applicant 2 donation), and then annually, or any time that the donor does not meet the criteria for the use of the Abbreviated DHQ as explained below.

Abbreviated PPTA DHQ: The PPTA Abbreviated DHQ was designed to elicit important information from the frequent plasma donor. A plasma donor is eligible to use the Abbreviated PPTA UDHQ version after the second Applicant donation and as long as the donor remains a Qualified Donor. The Full-length PPTA UDHQ must be administered at the annual physical examination and whenever the donor reverts to Applicant status.

Additional Questions: Plasma sourcing organizations may choose to add "local" additional questions to the end of the PPTA aDHQ. If a collection facility chooses to add "local" questions they should be grouped at the end of the aDHQ 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 question section until a revised strategy for incorporation is approved by FDA. If the new question(s) results 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.

Capture Questions: The abbreviated 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 abbreviated 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 abbreviated 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.

Donors at risk for HIV-1 Group O: 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 eliminate references to Africa from their screening process. To assist in the ease of administration of screening on this topic, PPTA created two risk posters to be used with the abbreviated questionnaire. If the source plasma organization uses a test approved to detect HIV-1 Group O, the organization may use the risk poster that does not reference Africa. The appropriate version of the Risk Poster chosen should be used in its entirety. The Travel Poster is not referenced in the abbreviated questionnaire and need not be used in conjunction with the abbreviated questionnaire.

Abbreviated 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, 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, 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.

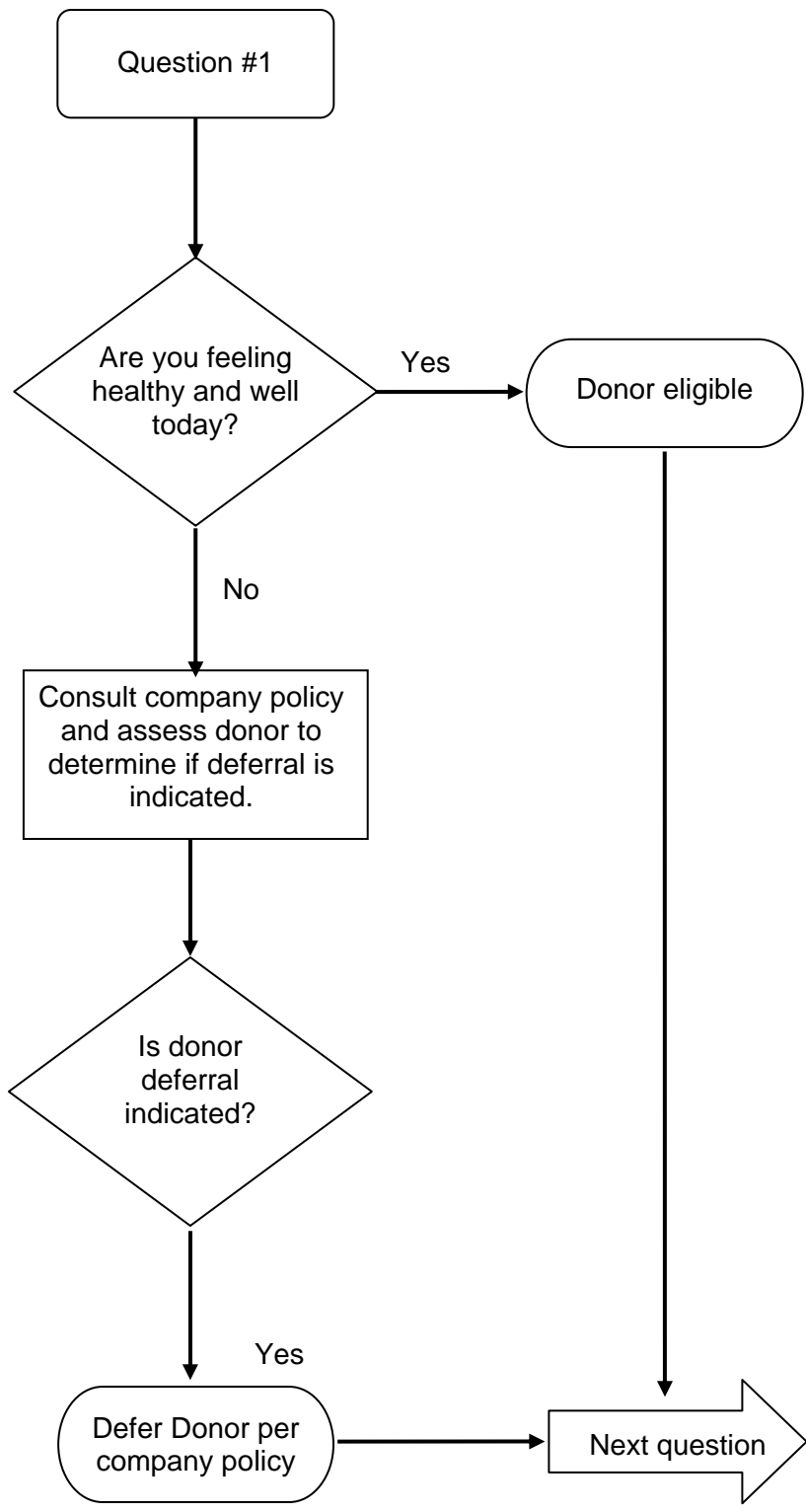
FDA Draft Guidance, August 8, 2006: Amendment (Donor Deferral for Transfusion in France Since 1980) to "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products"

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.

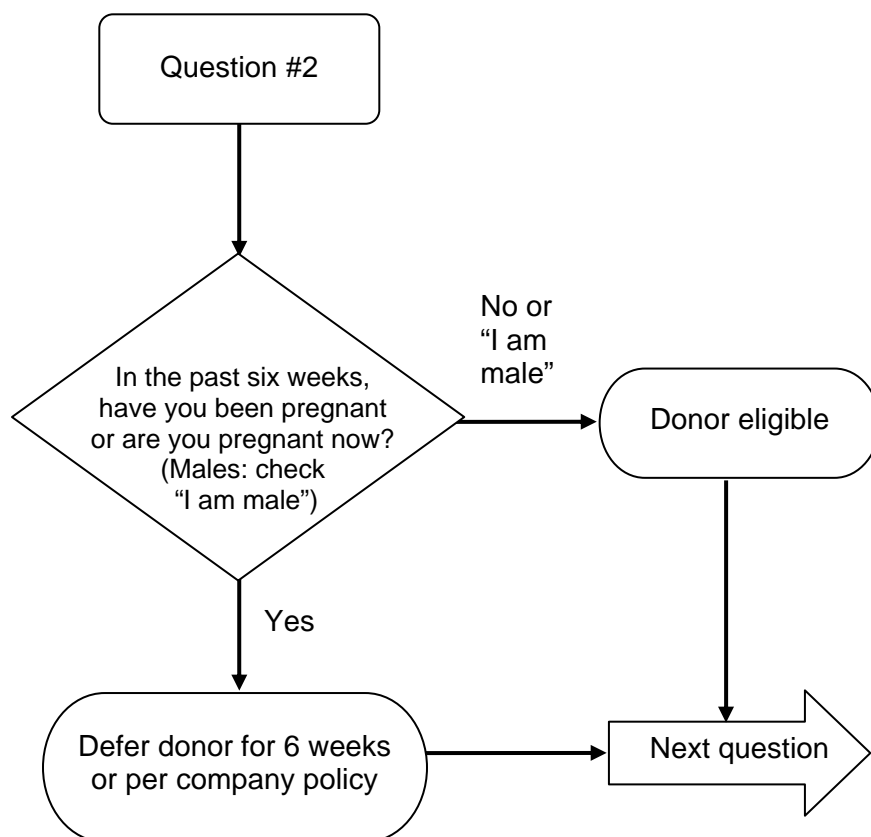
Question #1: Are you feeling healthy and well today?

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.



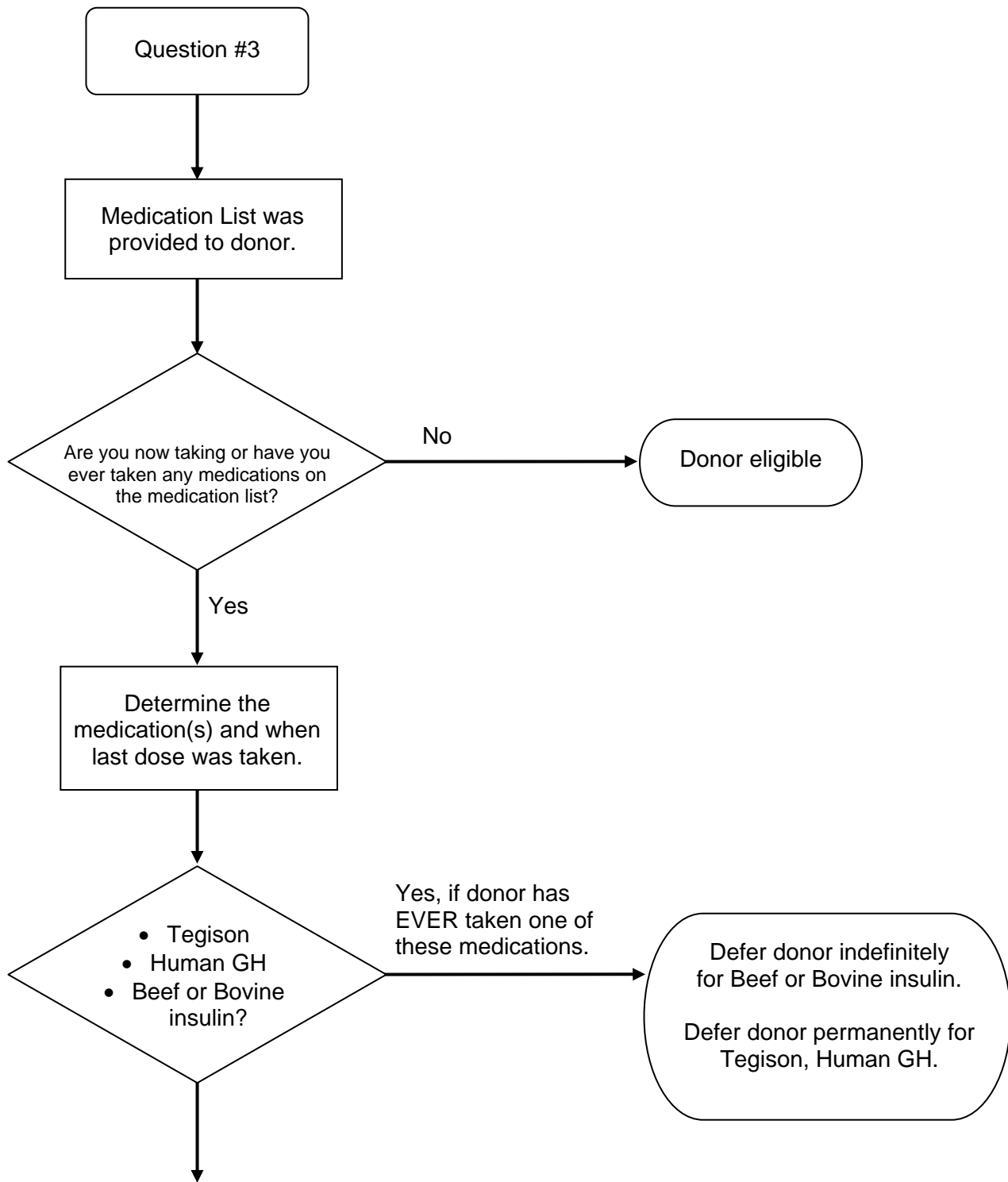
Question #2: In the past six weeks, have you been pregnant or are you pregnant now? (Males: check "I am male")

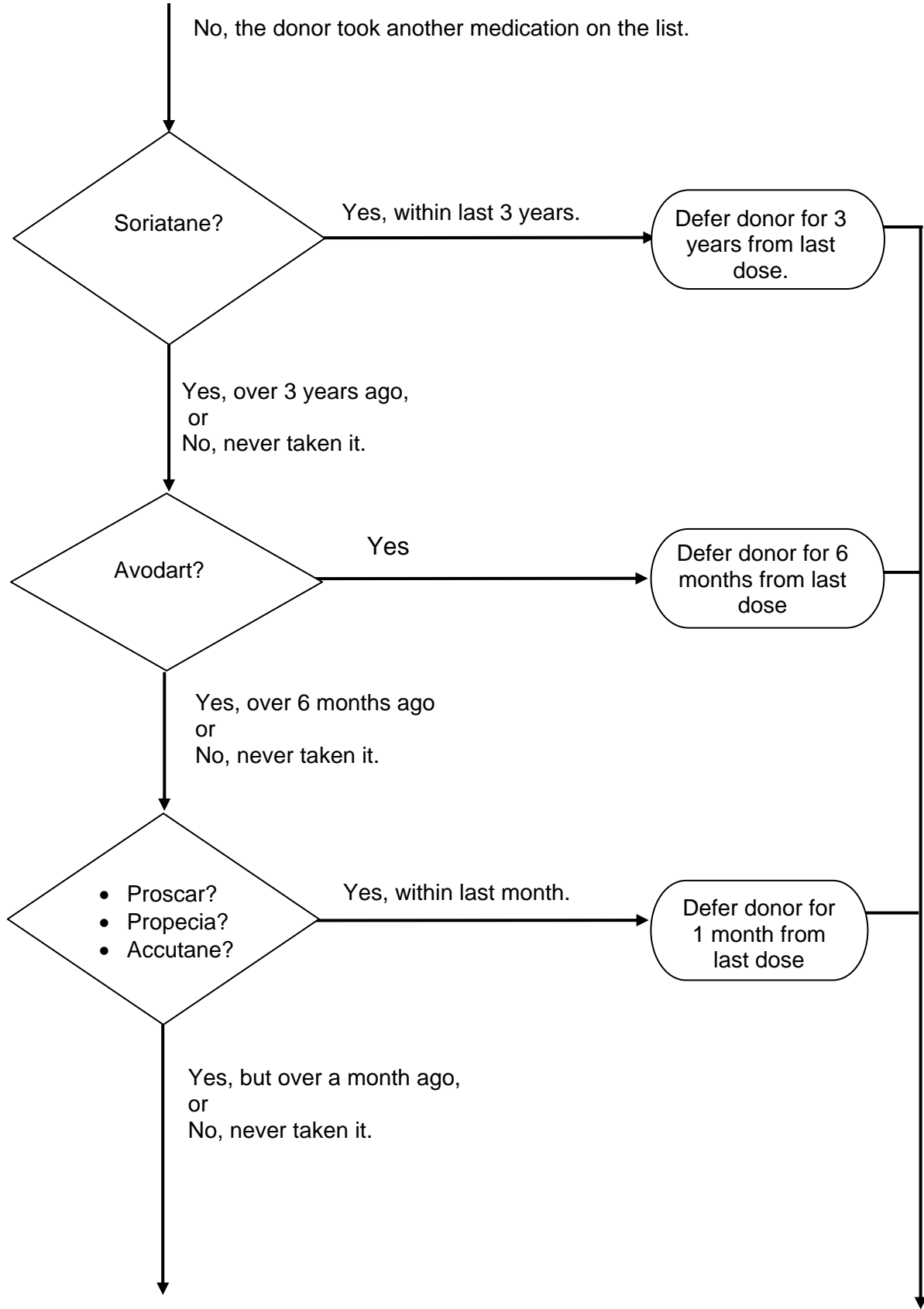
Donor Eligibility: A female with a known pregnancy or who has been pregnant in the last six weeks should not donate blood or plasma.

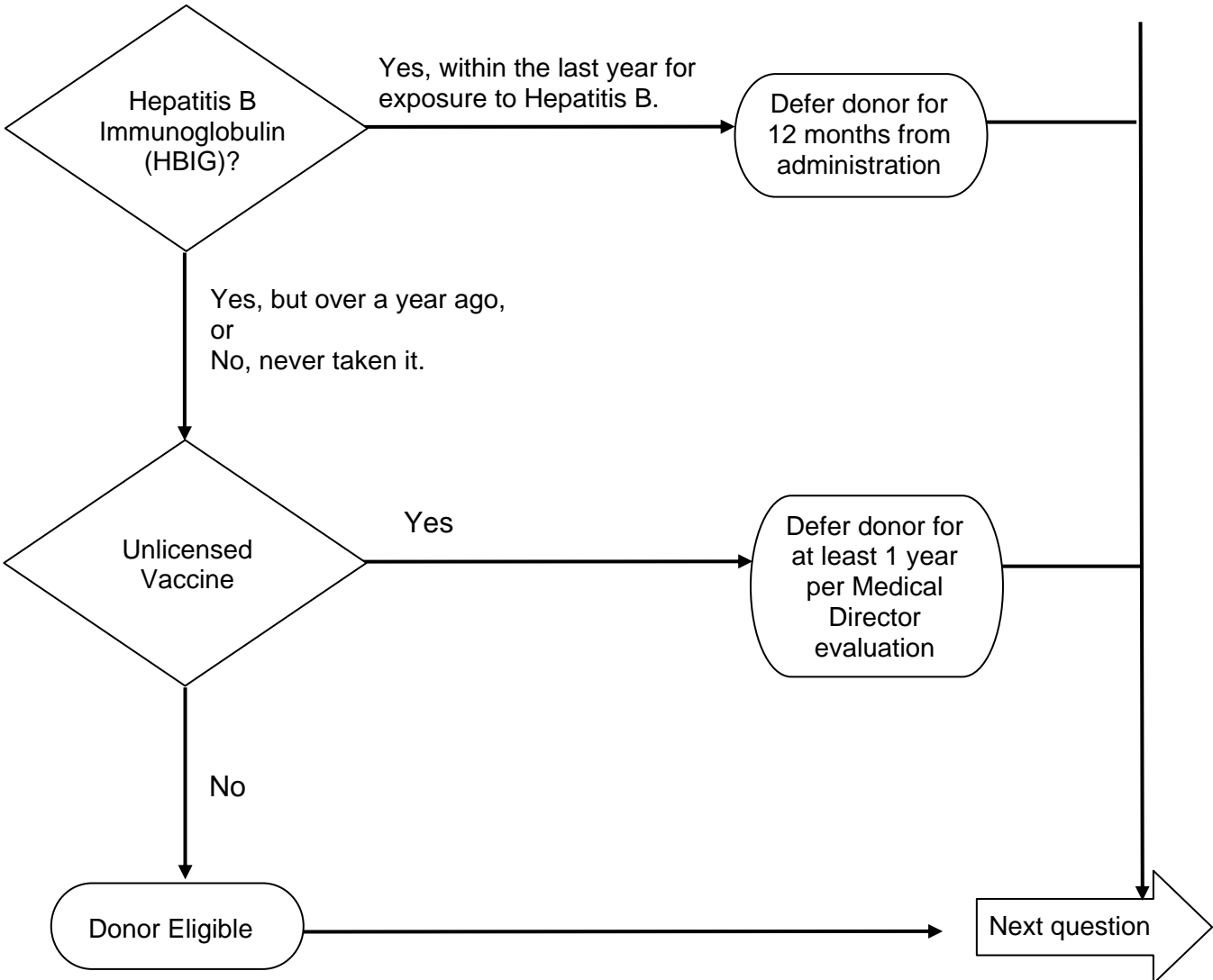


Question #3: Since you last donated plasma, are you now taking or have you ever taken any medications on the medication list?

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



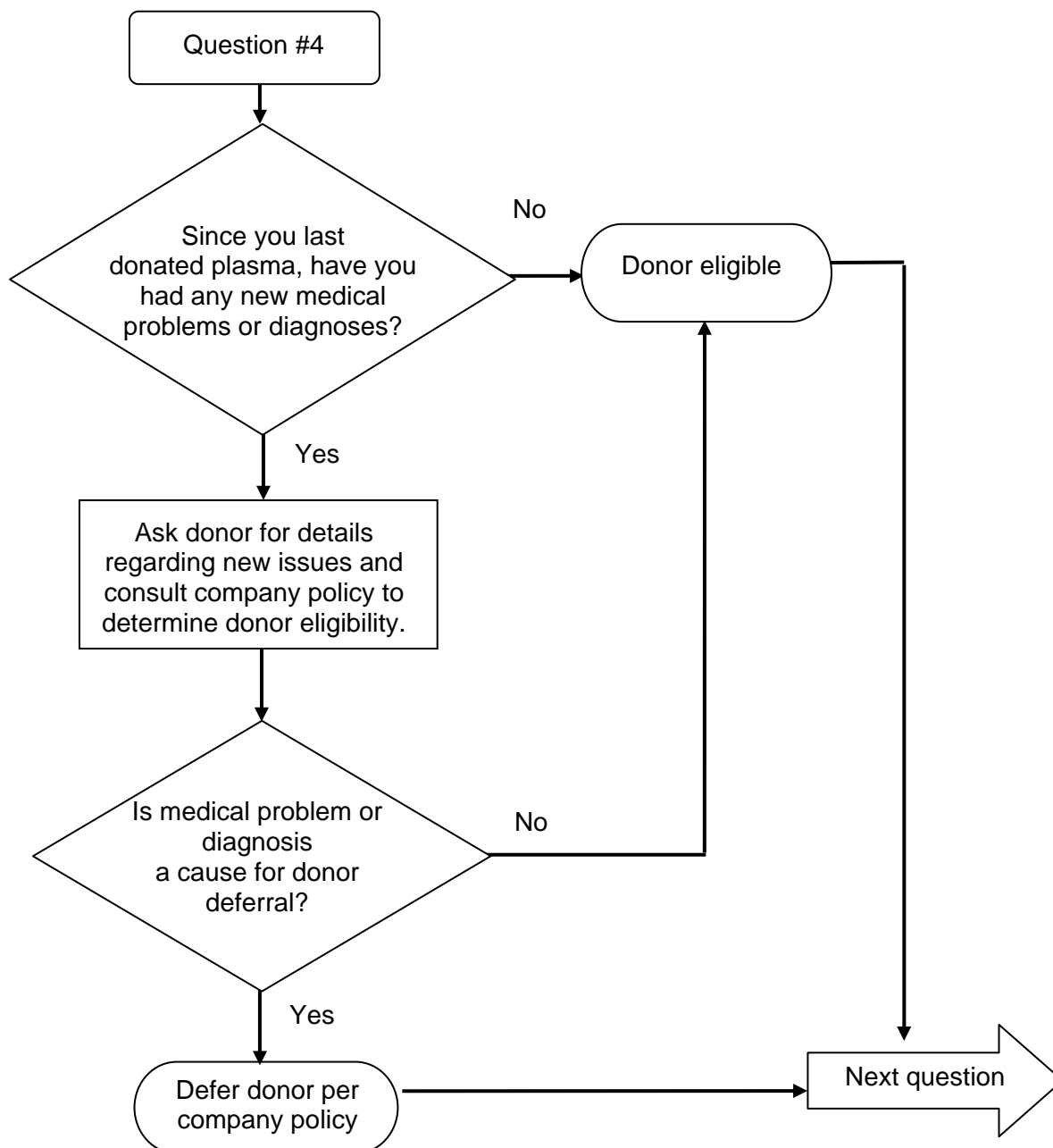




Question #4: Since you last donated plasma, have you had any new medical problems or diagnoses?

Donor Eligibility:

- Donors reporting new medical problems², diagnoses or treatments³ must be evaluated to determine if the underlying medical condition is cause for deferral. Consult company policy.
- Certain vaccinations may contain a live virus. A donor who has been exposed to a live virus via vaccination should not serve as a plasma donor for at least four weeks after the vaccination. For other vaccinations, consult company policy.



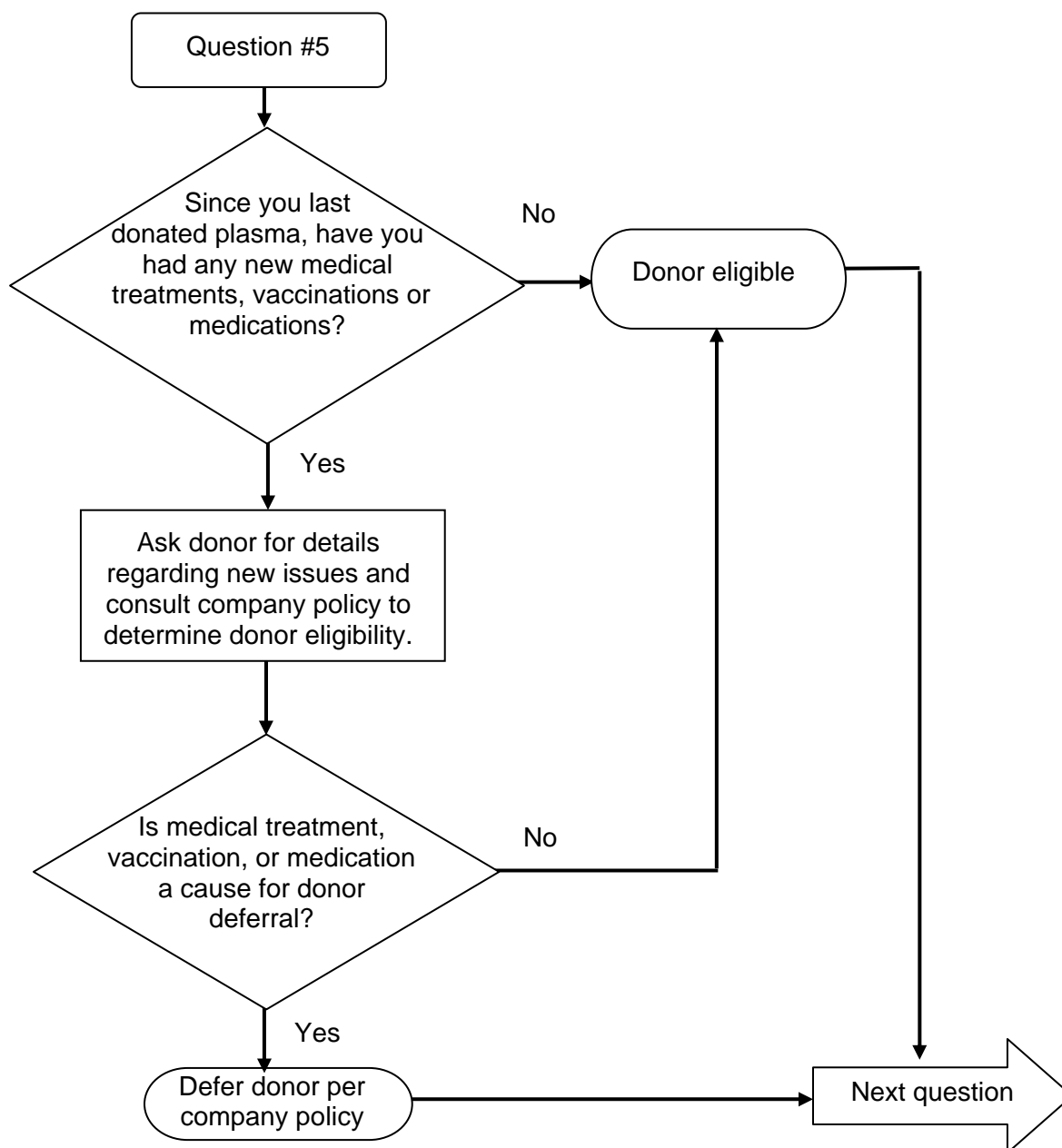
² Medical Problems include any medical condition the donor considers reportable. Examples may be nausea, headaches, muscle or skeletal pains.

³ Treatments may include physical therapy, chiropractic, or other regimen or therapy in a health care environment.

Question #5: Since you last donated plasma, have you had any new medical treatments, vaccinations or medications?

Donor Eligibility:

- Donors reporting new medical problems⁴, diagnoses or treatments⁵ must be evaluated to determine if the underlying medical condition is cause for deferral. Consult company policy.
- Certain vaccinations may contain a live virus. A donor who has been exposed to a live virus via vaccination should not serve as a plasma donor for at least four weeks after the vaccination. For other vaccinations, consult company policy.

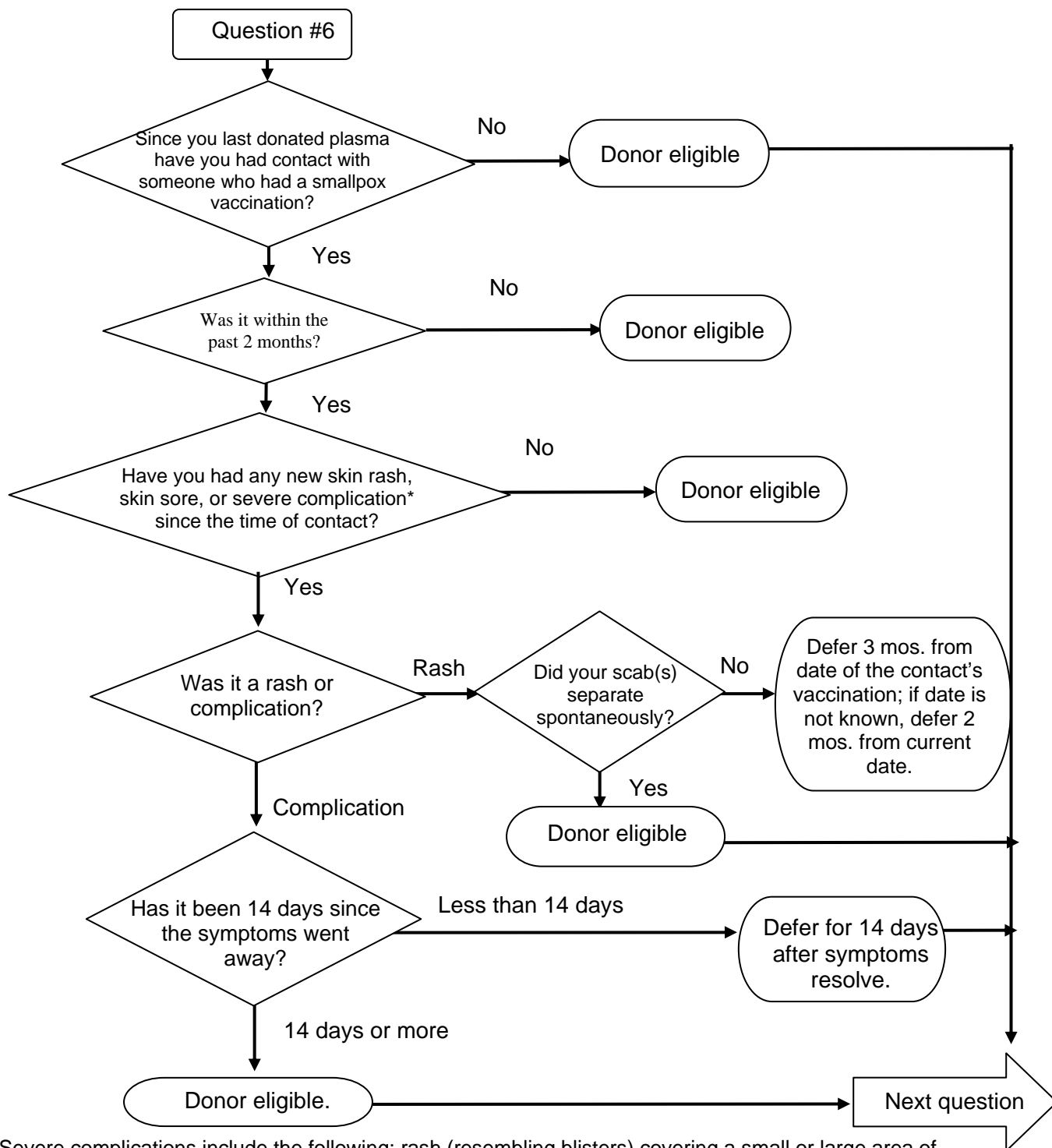


⁴ Medical Problems include any medical condition the donor considers reportable. Examples may be nausea, headaches, muscle or skeletal pains.

⁵ Treatments may include physical therapy, chiropractic, or other regimen or therapy in a health care environment.

Question # 6: Since you last donated plasma 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.

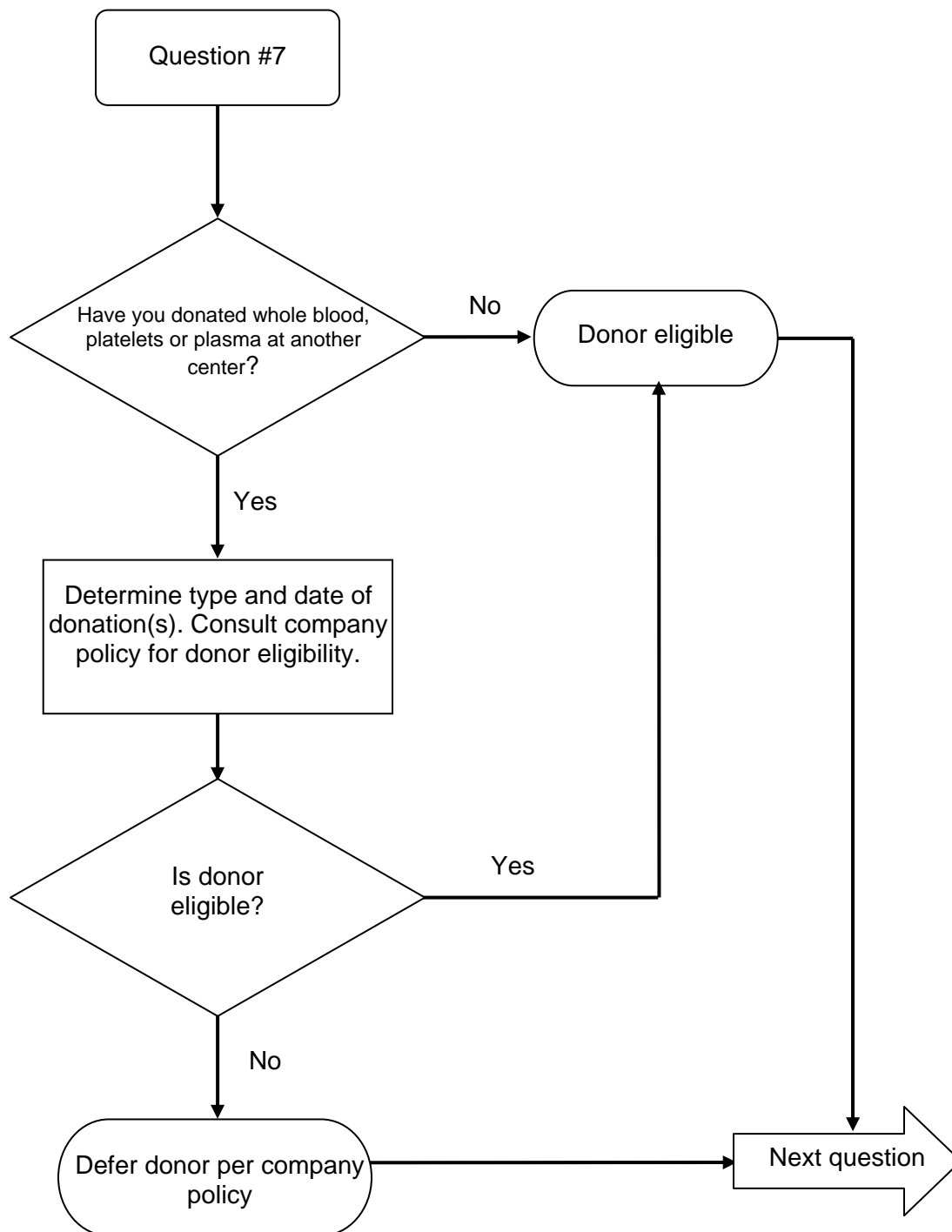


*Severe complications include the following: rash (resembling blisters) covering a small or large area of the body; necrosis (tissue death) in the area of exposure; encephalitis (inflammation of the brain);

infection of the cornea (eye) and localized or systemic skin reaction in someone with eczema or other chronic skin condition.

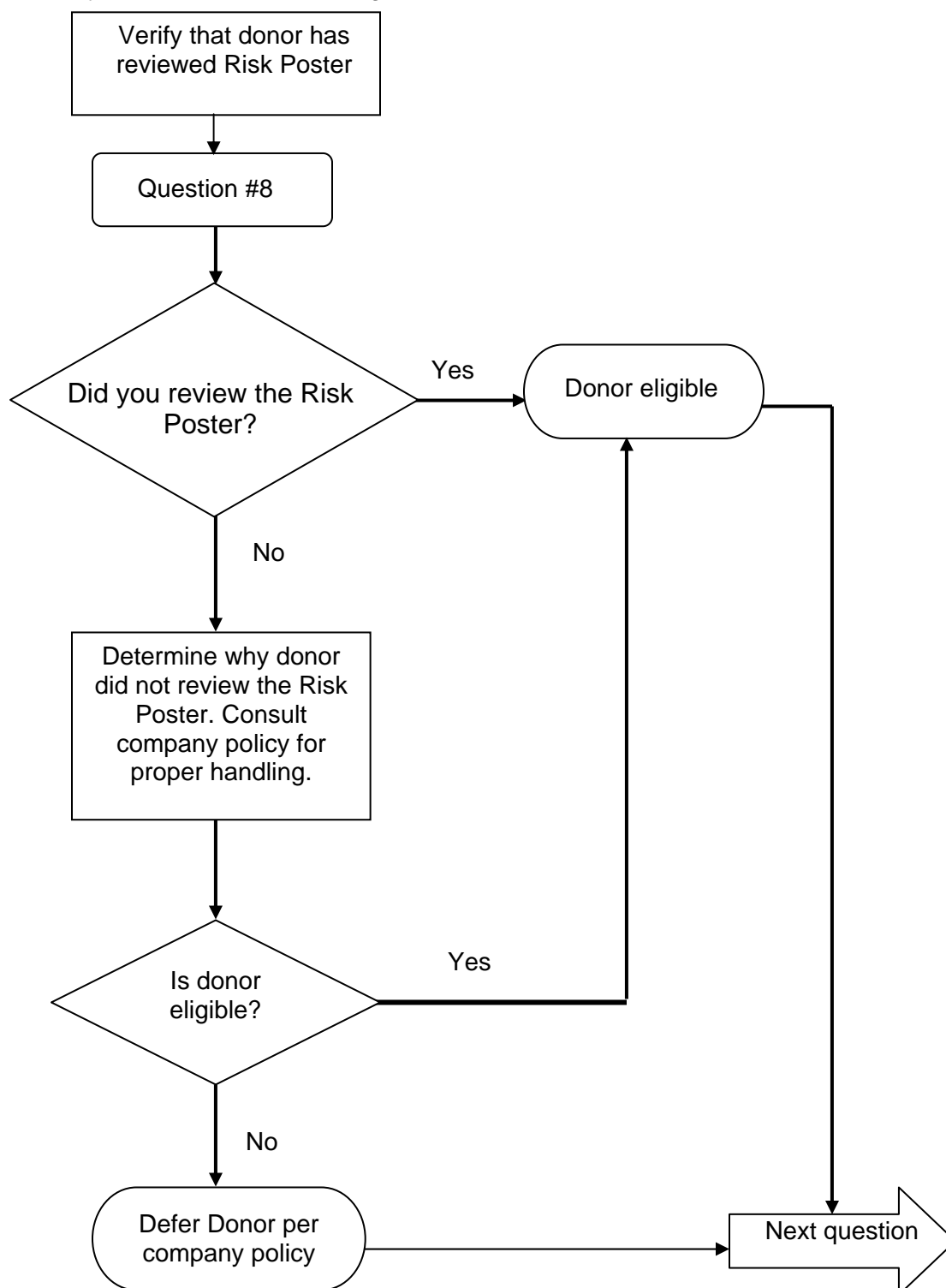
Question #7: Have you donated whole blood, platelets or plasma at another center?

Donor Eligibility: A donor who has donated a unit of whole blood should not donate blood or plasma for a period of eight weeks. A donor who has donated a double unit of red blood cells by apheresis should not donate blood or plasma for a period of 16 weeks. A donor who has donated platelets 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 #8: Did you review the Risk Poster?

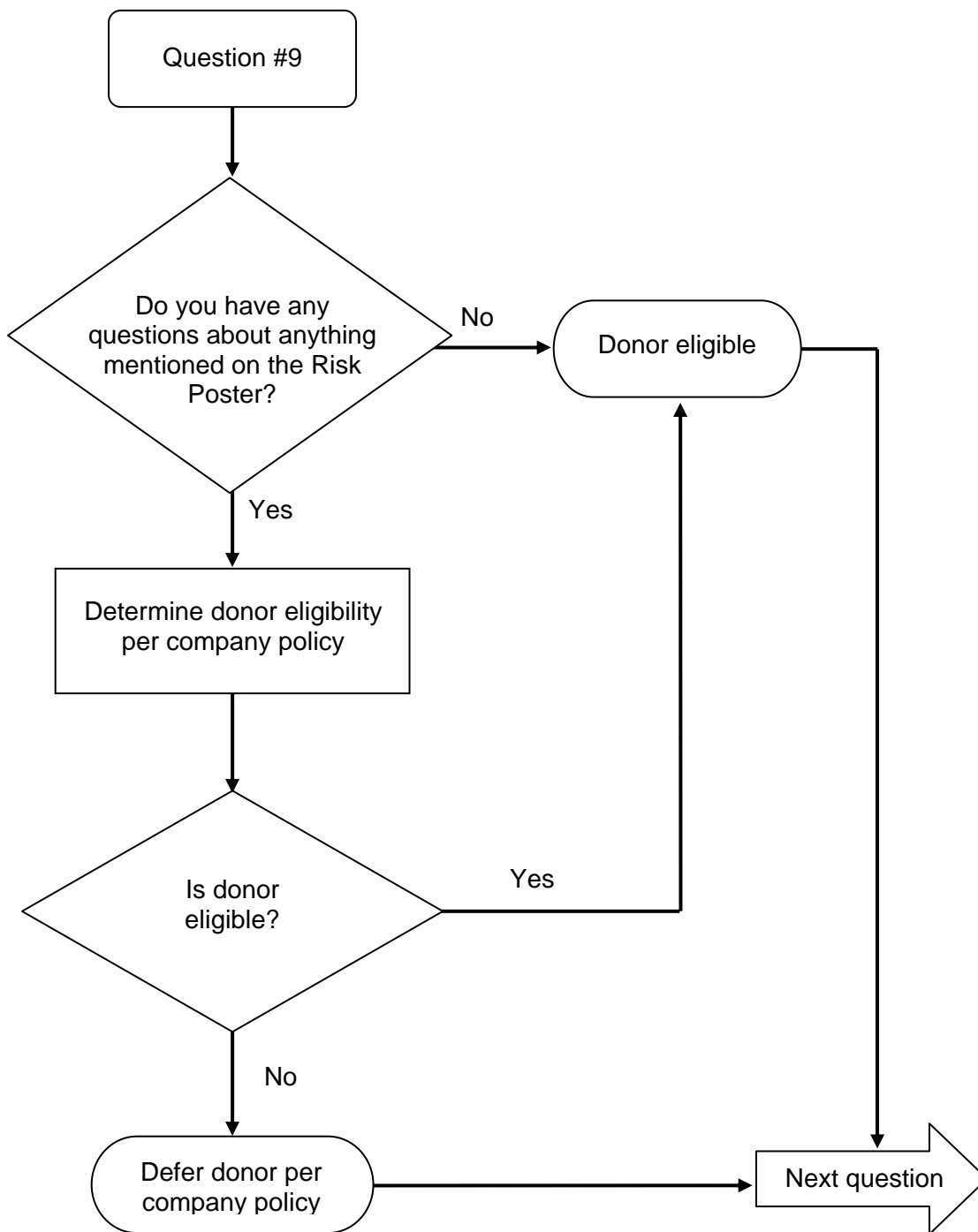
Donor Eligibility: The Risk Poster⁶ includes information on risk activities for HIV/AIDS, viral hepatitis, and other infectious diseases that may be transmitted through blood. Therefore, potential plasma donors must read Risk Poster information provided during the donor interview to determine if they are at risk of transmitting infectious diseases.



⁶ There are two risk posters available for use. The version used is dependent on whether the source plasma organization uses a test approved to detect HIV-1 Group O.

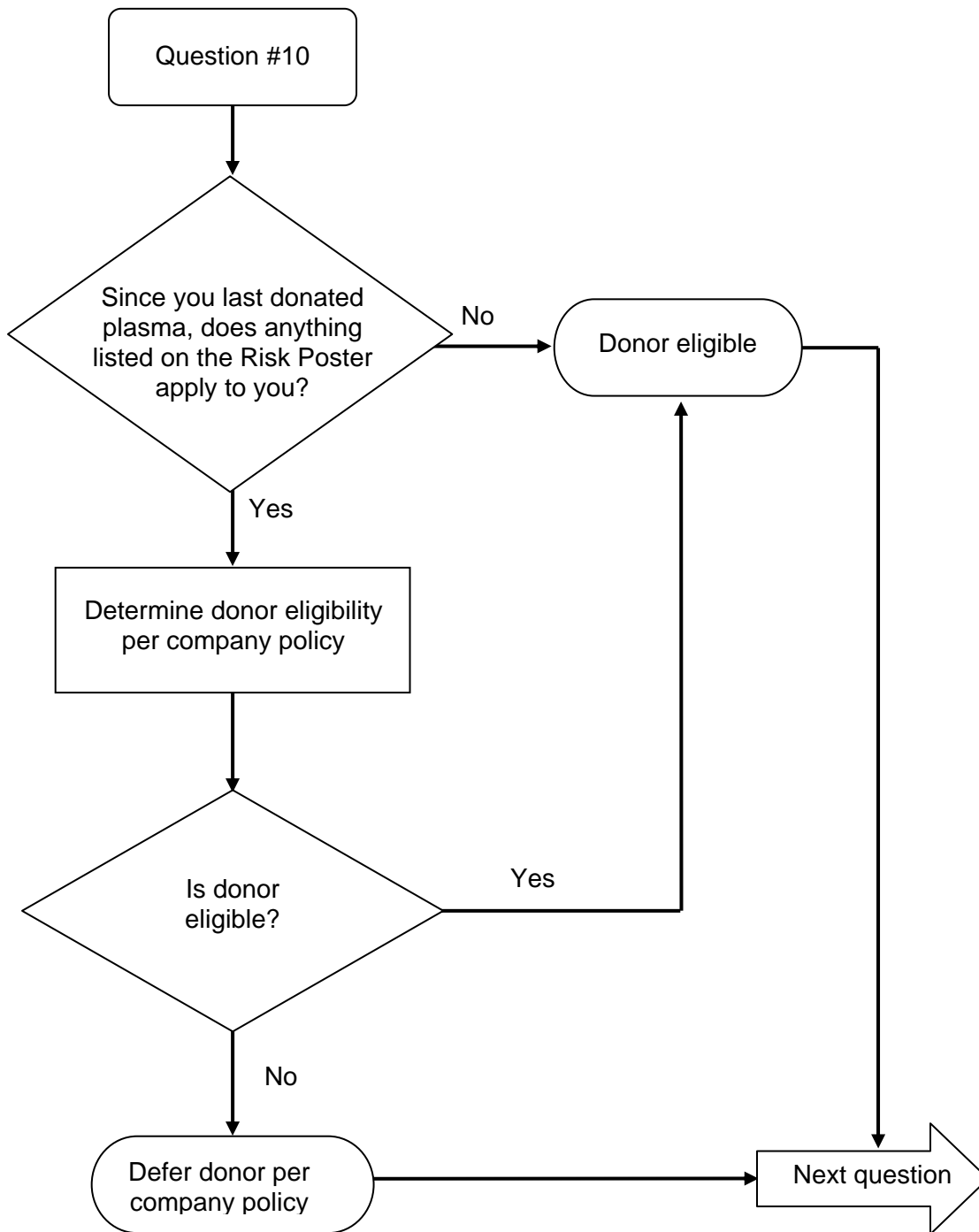
Question #9: Do you have any questions about anything mentioned on the Risk Poster?

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. Therefore, any change in risk activities reported by the donor must be evaluated to determine donor eligibility. For donor deferral follow company policy.



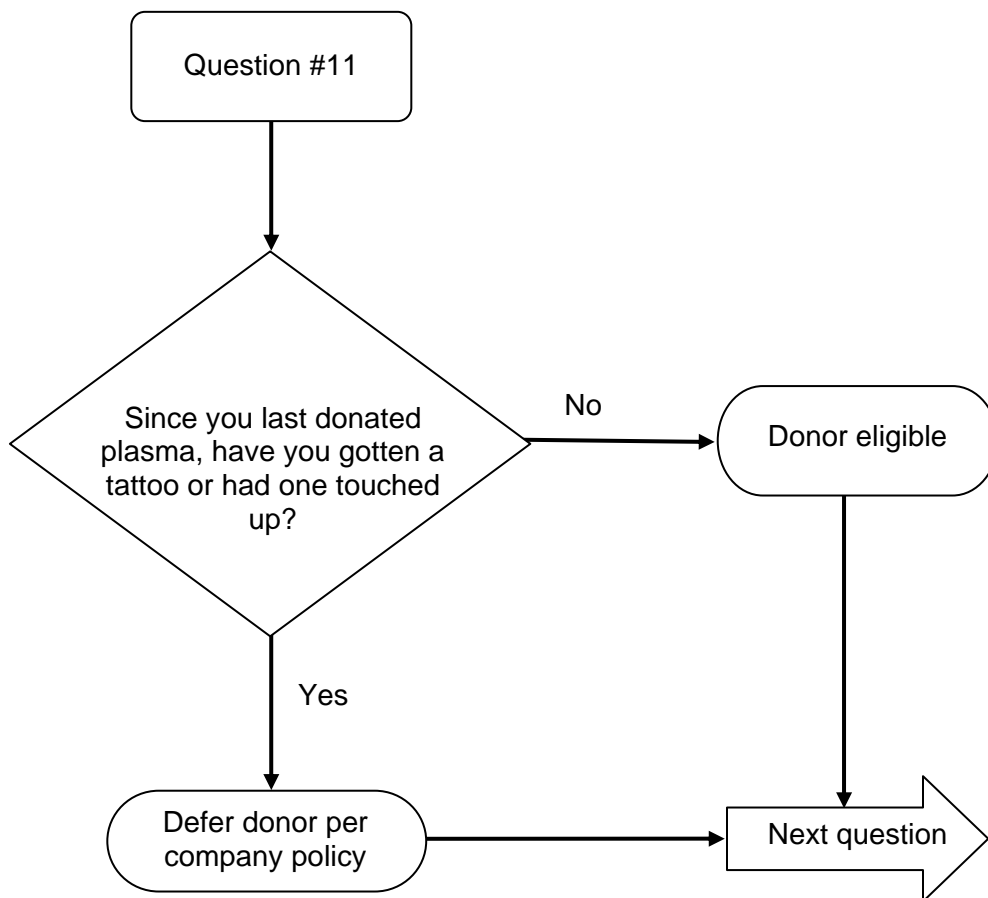
Question #10: Since you last donated plasma, does anything listed on the Risk Poster apply to you?

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, any change in risk activities reported by the donor must be evaluated to determine donor eligibility. For donor deferral follow company policy.



Question #11: Since you last donated plasma, 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 #12: Since you last donated plasma, 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 has been done using single-use equipment, there may be a risk of transmission of infectious diseases.

