

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**

**Table of Contents**

**Purpose**

**Introduction**

**Methods of Administration**

**Full-Length PPTA DHQ Administration Frequency**

**Abbreviated PPTA DHQ**

**Donor Acknowledgment Statement**

**Additional Questions**

**Capture Questions**

**Abbreviated PPTA DHQ Directions for Use Flow Chart Format**

**Donor Deferrals**

**Documentation**

**Maintenance/Change Control**

**Glossary**

**References**

**Flow Charts**



## **PPTA Abbreviated Donor History Questionnaire Directions for Use**

**Purpose:** The Plasma Protein Therapeutics Association (PPTA) Abbreviated Donor History Questionnaire (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 eligibility. 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 eligibility. 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: a Full-Length PPTA DHQ and corresponding Directions for Use, the PPTA aDHQ and corresponding Directions for Use, Risk Posters, Travel Poster, and a Medication List. The PPTA DHQ must be administered on the day of donation and before collection as per Title 21, Code of Federal Regulations, Part 630.10(c), effective May 23, 2016. 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.

**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 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 and content are unchanged. For example, when using in an electronic

format, the posters and medication list may be presented in blocks of applicable information rather than presented in a single screen. Questions directed at one sex can be omitted from sex-specific questionnaire. Also, if the process requires an answer to each question before advancing to the next question, an optional choice of “not sure” may be added. As stated above, a trained historian should be available to a prospective donor to answer any questions concerning eligibility or the donation process and to clarify each “not sure” response. For further instructions, refer to the CASI manufacturer’s instructions and operator’s manual.

If the 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 PPTA aDHQ as explained below.

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

**Optional Questions:** The PPTA aDHQ may be used to elicit information required by regulatory authorities outside of the US. Optional questions have been added to the aDHQ for this purpose. If used, they should be numbered consecutively.

**Donor Acknowledgment Statement:** The donor acknowledgment statement required by FDA regulation effective May 23, 2016 [21 CFR 630.10(g)(2)], has been added to the PPTA DHQ. At the completion of the questionnaire, donors must be asked to review the statement, agree not to donate if the donation could result in a potential risk to recipients and provide a signature or other documented acknowledgment. The use of the donor acknowledgement statement must be described in an SOP submitted to FDA/CBER in a BLA supplement.

**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 found acceptable 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.

**Capture Questions:** The PPTA aDHQ 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 eligibility. Some follow-up questions are included in the PPTA aDHQ 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.

**PPTA aDHQ Directions for Use Flow Chart Format:** The PPTA DHQ Directions for Use is modular and uses flow-charting to guide organizations through the DHQ process. Each question is a complete section that begins on a new page so that changes to the PPTA DHQ and the PPTA aDHQ can be easily modified in the PPTA DHQ Directions for Use. If a sourcing organization uses one or both of the optimal questions, the respective flow chart module should be numbered to match the question. 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 with respect to 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 eligibility 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 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 to support deferral of the donor “per company policy”. Per company policy cannot be less restrictive than 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:** PPTA is responsible for the maintenance of the PPTA DHQ project documents. Documents are posted on the PPTA website. Periodically the PPTA DHQ, the accompanying documents or the directions for use will be updated or revised by the PPTA DHQ Committee 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 changes 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 DHQ

### DONOR CLASSIFICATION

**Applicant Donor** – All individuals presenting themselves who have not been previously qualified as a donor within the past six (6) months.

**Qualified Donor** – All individuals who have been qualified for continued donations by successfully passing two donor medical history screenings and required viral testing.

### QUESTIONNAIRE TERMS

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

**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 who provides a history of having received an allogeneic dura mater graft. 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, [21 CFR 630 and 640] (as revised in the May 22, 2015 Final Rule) and in PPTA voluntary standards in its International Quality Plasma Program (IQPP). The requirements for the alternative and optional questions are located in European Commission Directive 2004/33/EC, Annex III.

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

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. *(contains requirements related to acupuncture, ear piercing, tattooing in the absence of sterile technique)*

FDA Memorandum, July 28, 1993: Deferral of Blood and Plasma Donors Based on Medications. *(contains requirements for finasteride, isotretinoin, etretinate, human pituitary-derived growth hormone and medical director responsibility to be aware of other drugs)*

Acetretin (Soriatine) Safety Information:

<http://www.drugs.com/pro/soriatane.html>

Aubagio (teriflunomide) Safety Information:

[https://www.aubagio.com/ms-therapy?s\\_mcid=ps-google-AO-branded-aubagio-efficacy#isi](https://www.aubagio.com/ms-therapy?s_mcid=ps-google-AO-branded-aubagio-efficacy#isi)

Dutasteride (Avodart) Safety Information:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/Safety-RelatedDrugLabelingChanges/ucm125499.htm>

Erivedge (vismodegib) Safety Information:

<http://www.erivedge.com/patient/about-erivedge/important-safety-info.html>

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.

Blood Products Advisory Committee Meeting June 16, 2000: Update on Sexual Transmission of HCV. (*documentation for the recommendation that having sex with or living with a person with asymptomatic hepatitis C does not defer the donor*)

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.

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

FDA Guidance, May 2010: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry.

FDA Guidance, November 2011: Requalification Method for Reentry of Donors Who Test Hepatitis B Surface Antigen (HBsAg) Positive Following a Recent Vaccination against Hepatitis B Virus Infection

FDA Guidance, October 2012: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, including Source Plasma, to Reduce Risk of Transmission of Hepatitis B Virus

FDA Guidance, February 2013: Implementation of an Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma

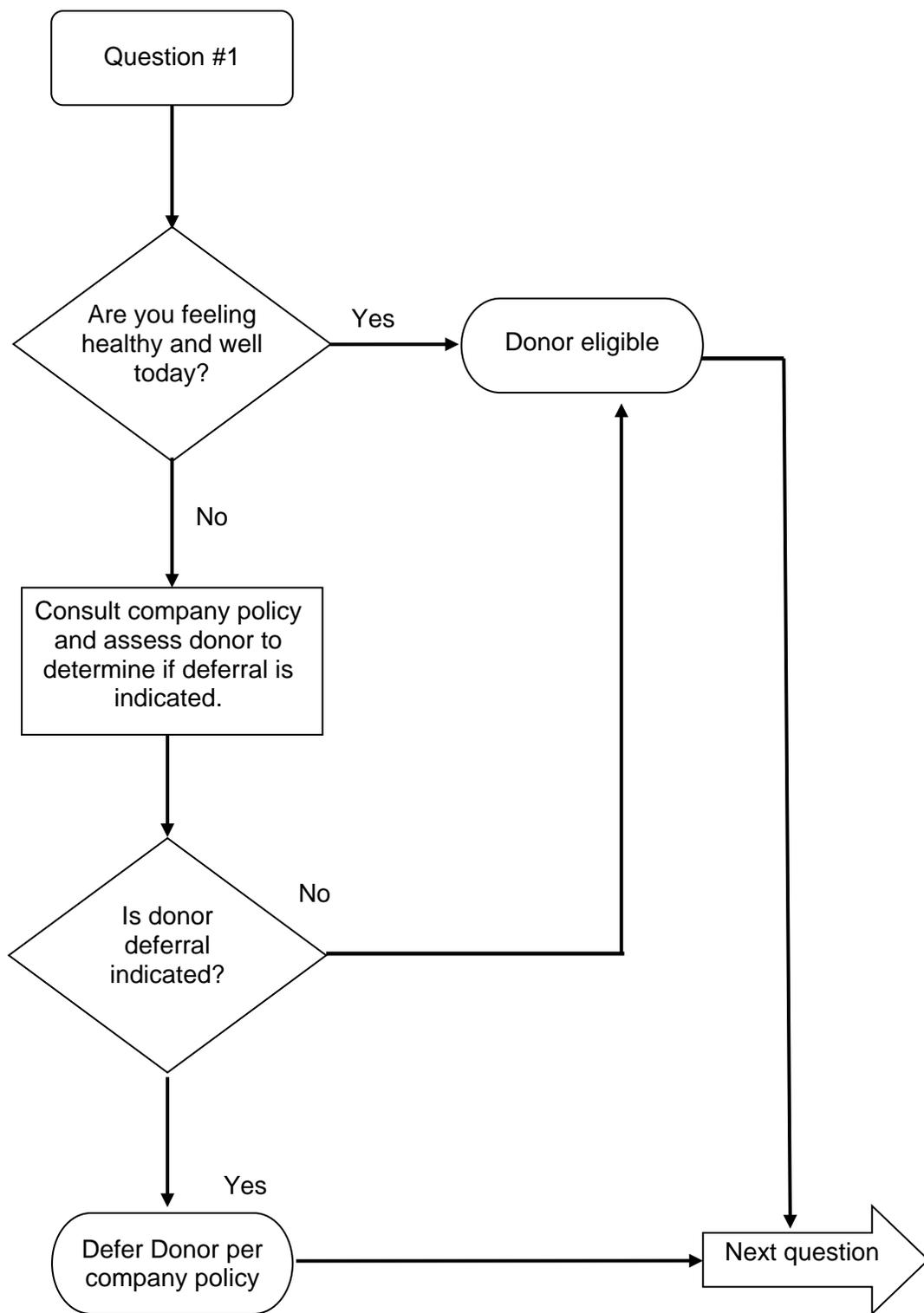
FDA Guidance, September 2014: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis

FDA Guidance, December 2015: Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products

FDA Guidance, January 2016: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products

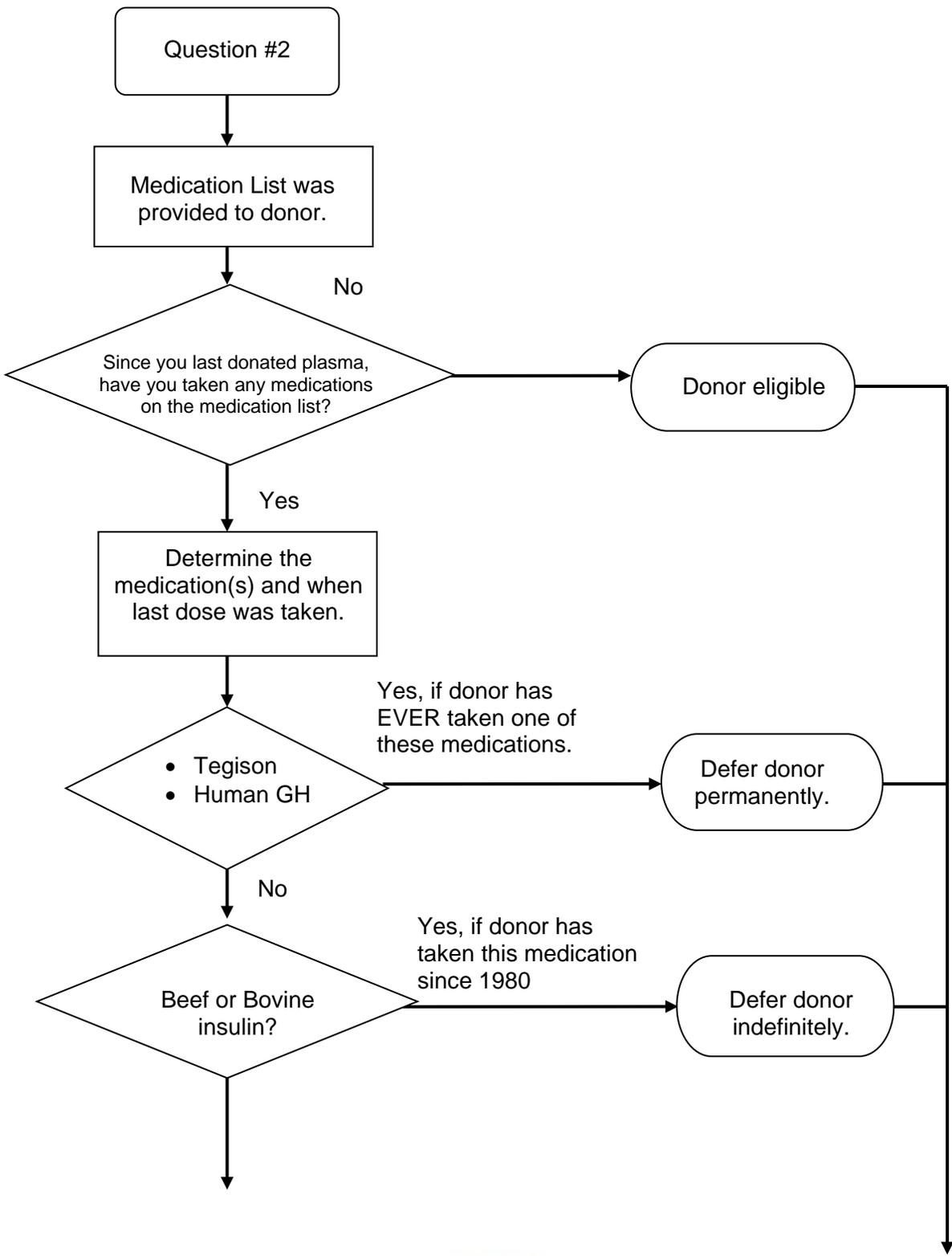
**Question #1:** Are you feeling healthy and well today?

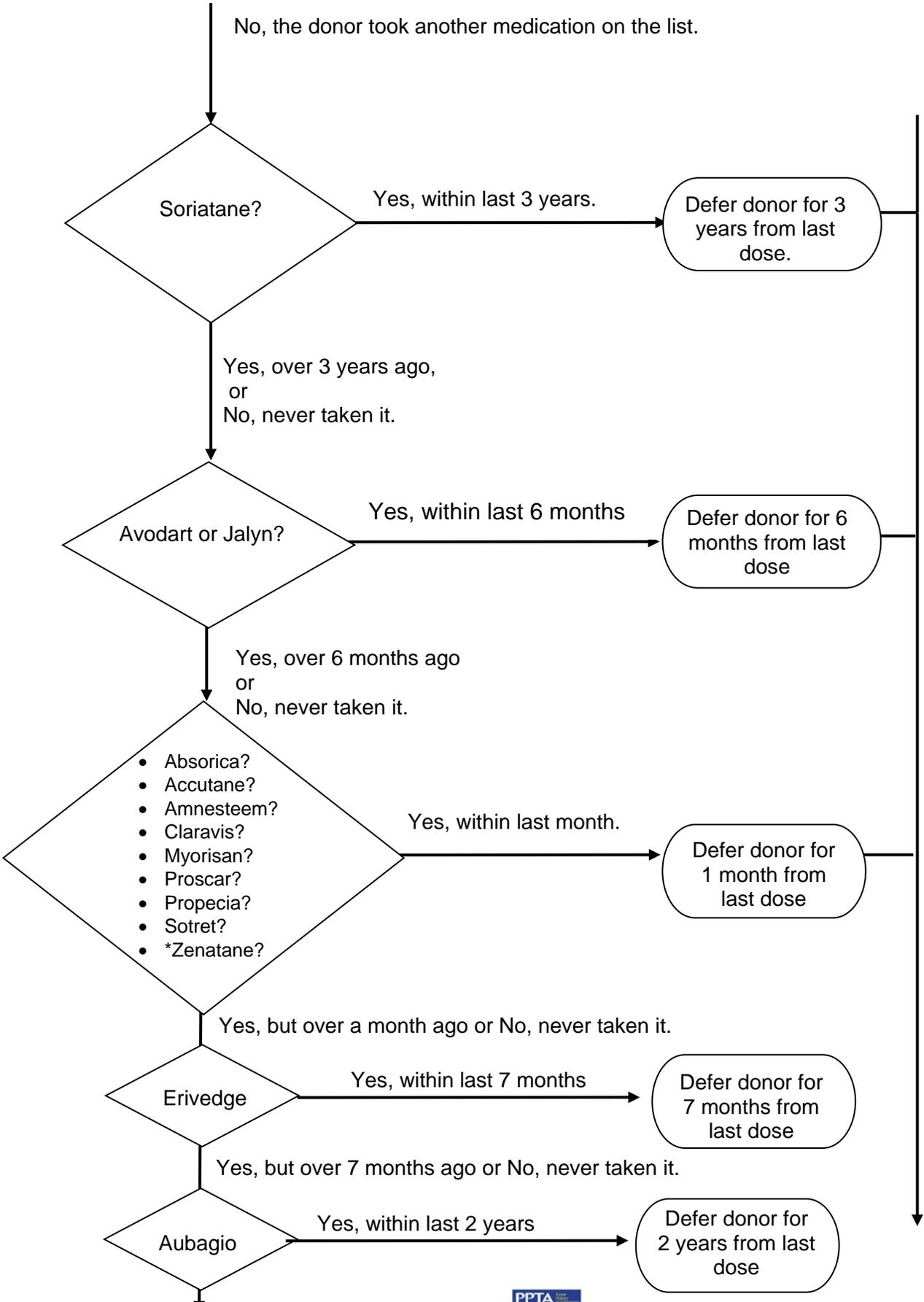
**Donor Eligibility:** A donor should be free of infectious diseases on the day of donation. Donors who are not in good health should not donate until it is determined that the underlying condition is not cause for deferral.

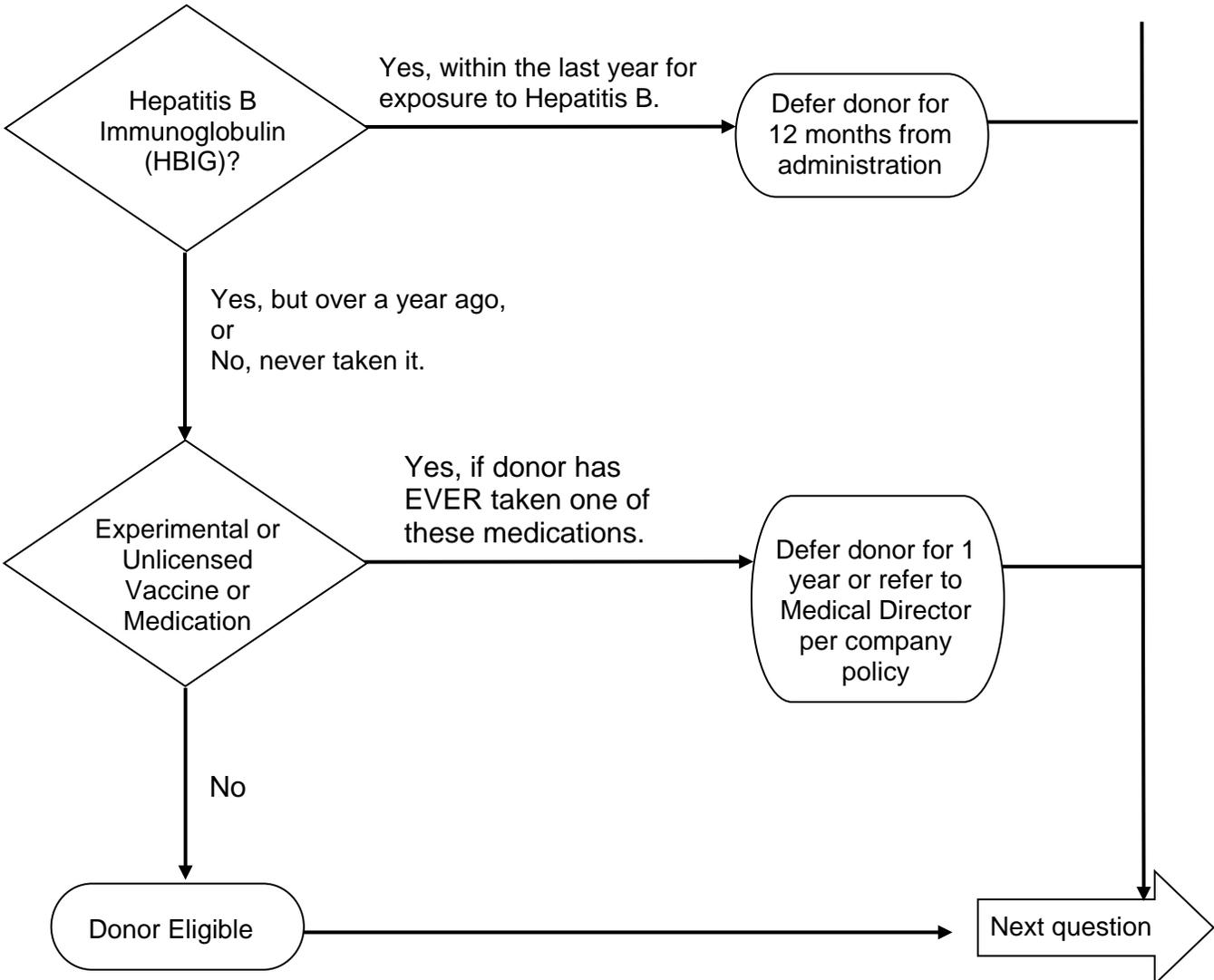


**Question #2:** Since you last donated plasma, have you taken any medications on the medication list?

**Donor Eligibility:** Donors taking certain designated medications in specific time frames must not donate plasma, whole blood or platelets.

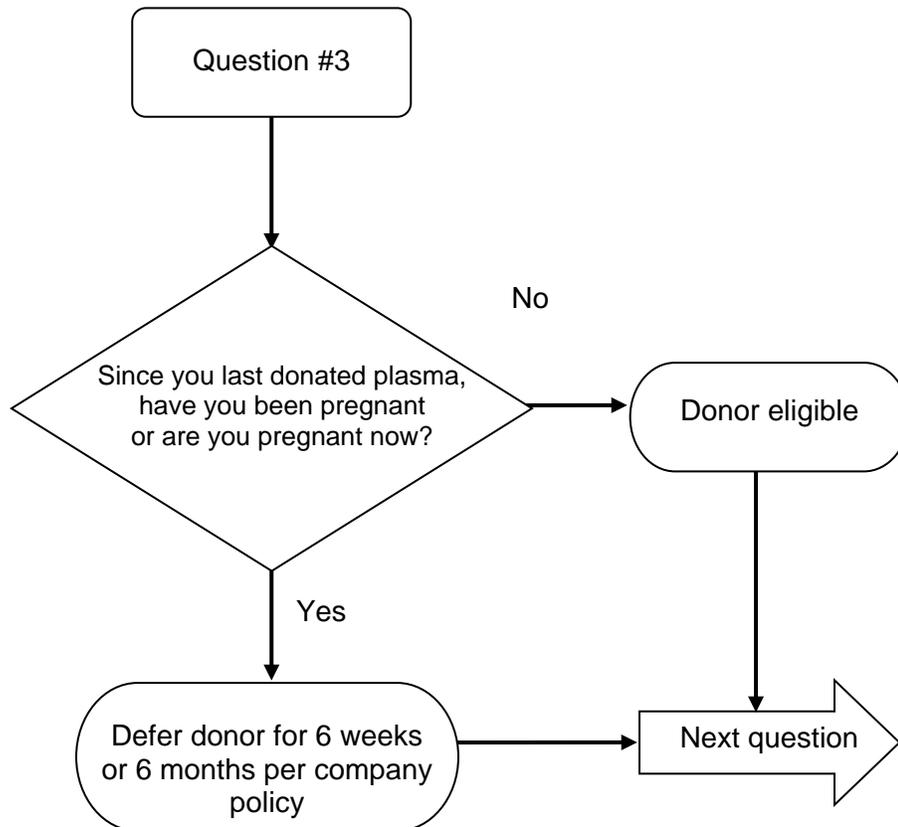






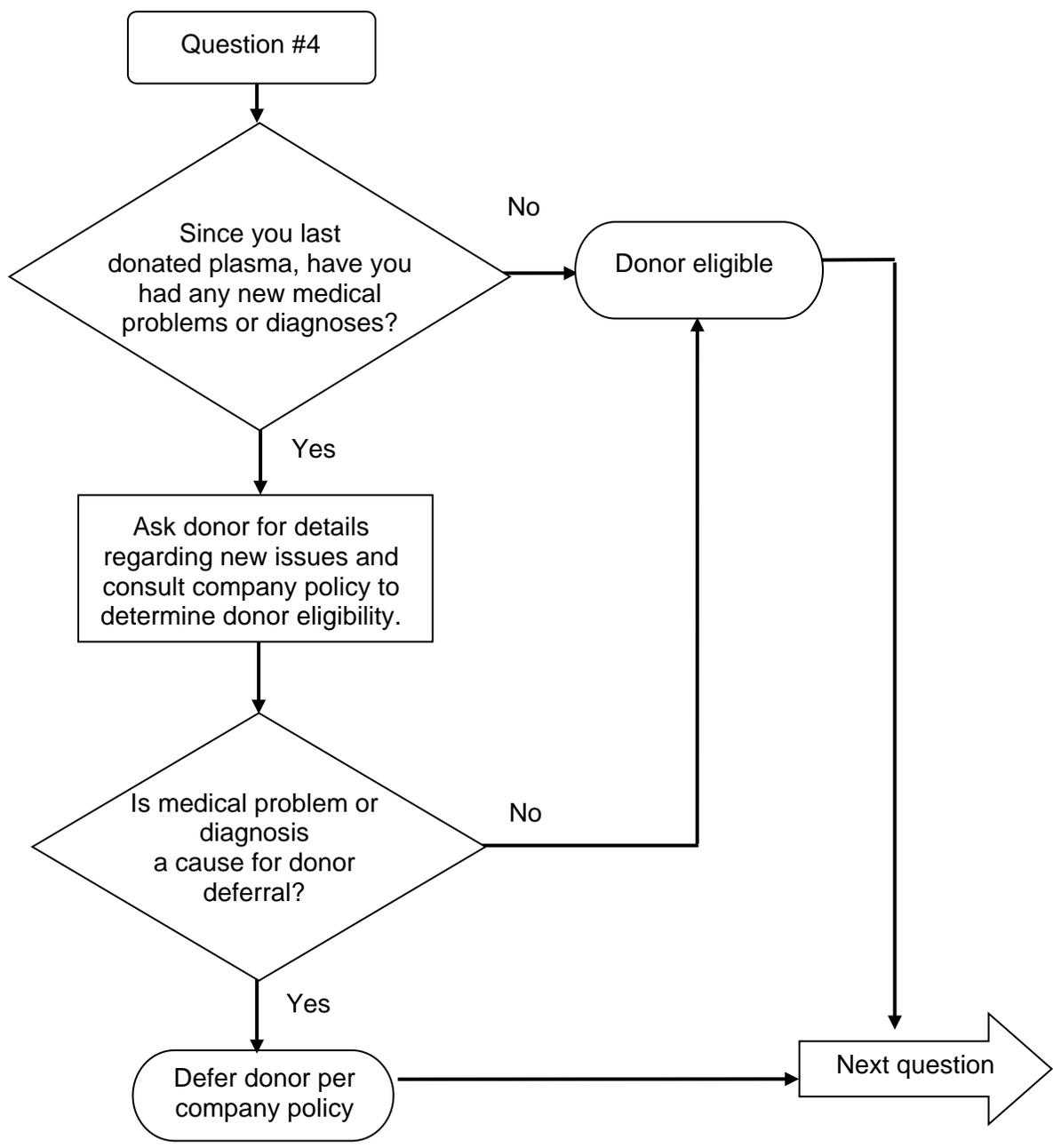
**Question #3:** Female Donors: Since you last donated plasma, have you been pregnant or are you pregnant now?

**Donor Eligibility:** A female with a known pregnancy or who has been pregnant in the last six weeks (six months if following European requirements) should not donate blood or plasma.



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

**Donor Eligibility:** Donors reporting new medical problems<sup>1</sup> or diagnoses must be evaluated to determine if the underlying medical condition is cause for deferral. Consult company policy.

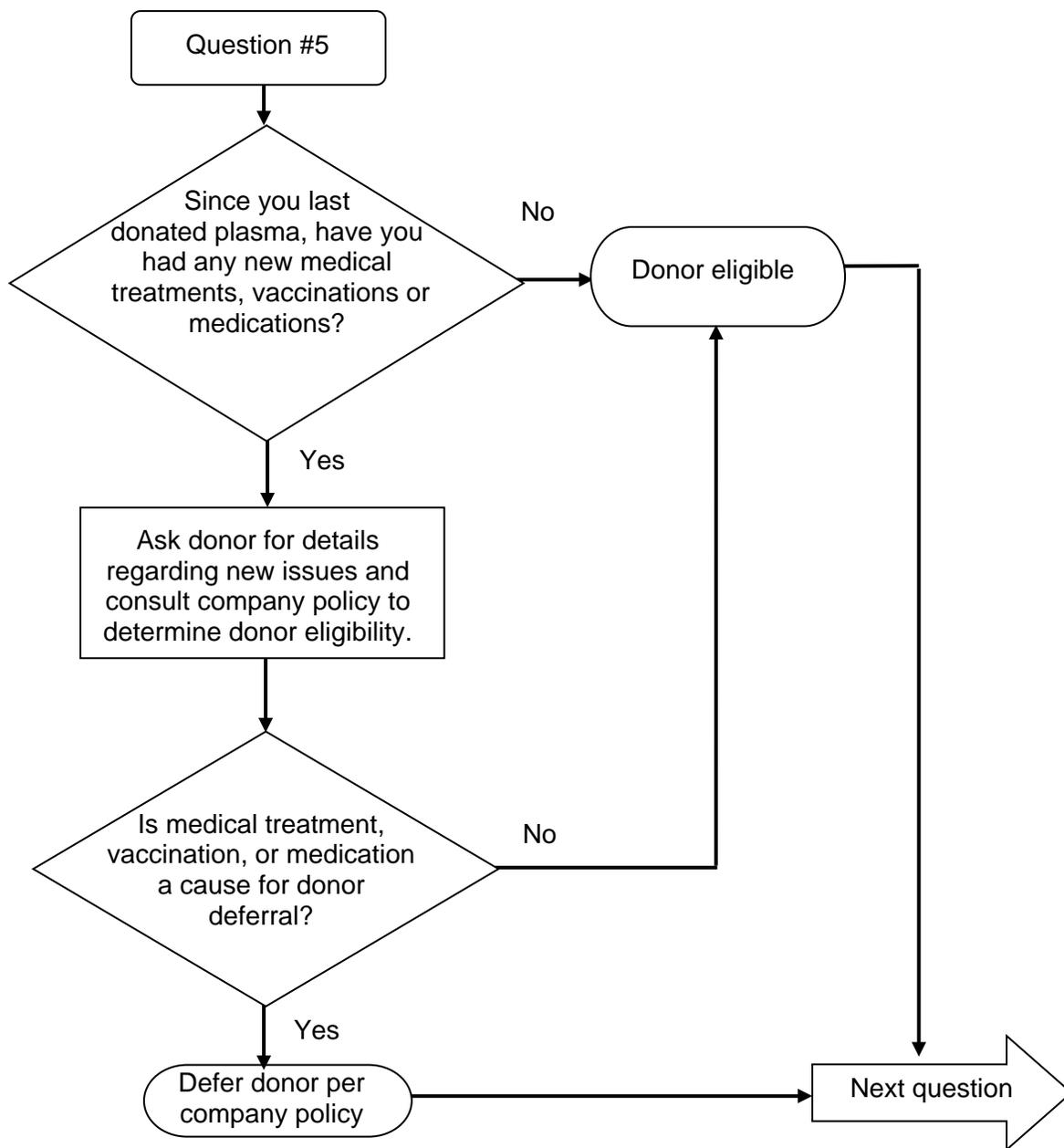


<sup>1</sup> Medical Problems include any medical condition the donor considers reportable. Examples may be nausea, headaches, muscle or skeletal pains.

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

**Donor Eligibility:**

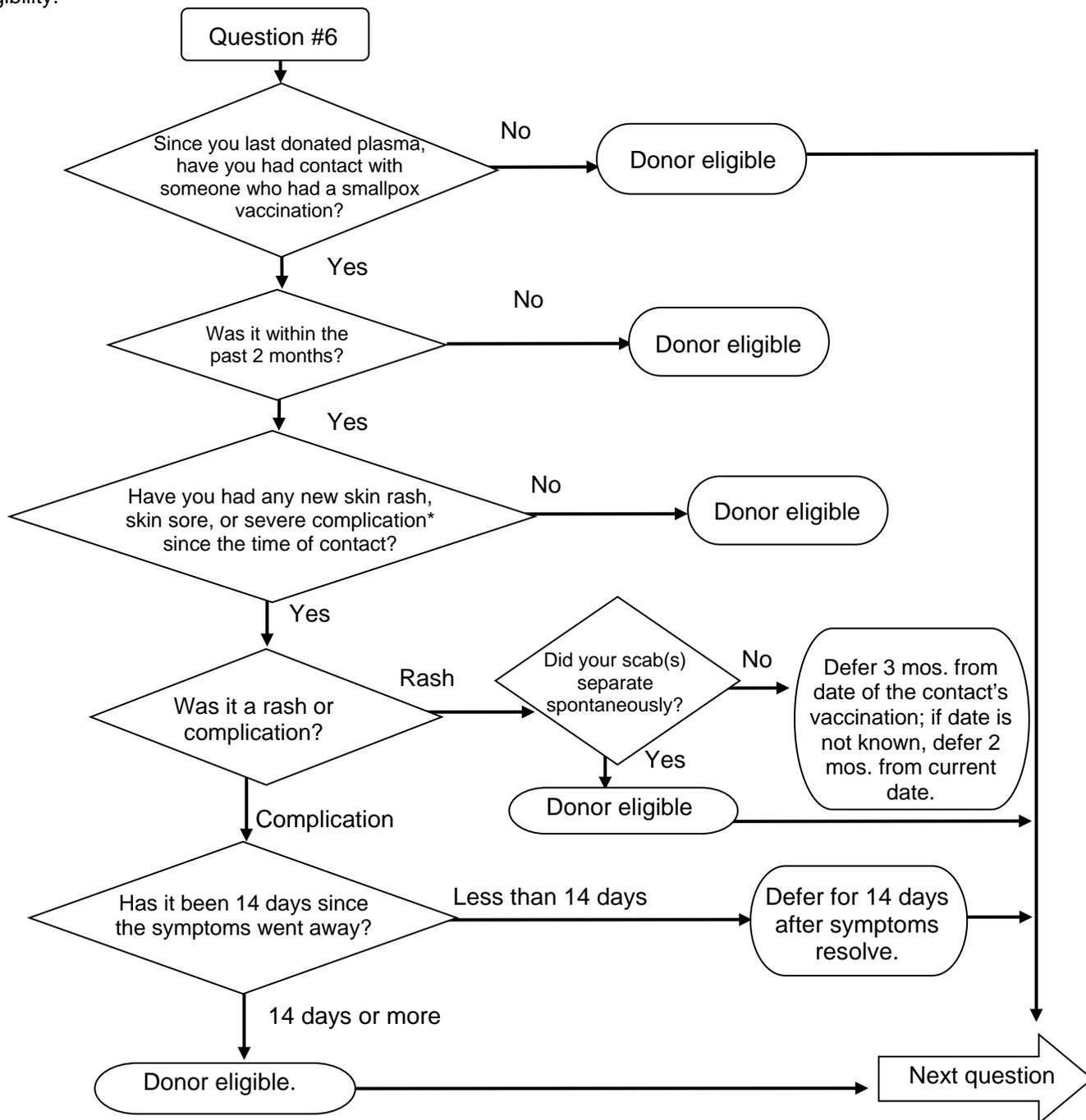
- Donors reporting new medical treatments<sup>2</sup> must be evaluated to determine if the underlying medical condition is cause for deferral. Consult company policy.
- Certain vaccinations may contain a live virus. A donor who has been exposed to a live virus via vaccination should not serve as a plasma donor for at least four weeks after the vaccination. For other vaccinations, consult company policy.



<sup>2</sup> 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?

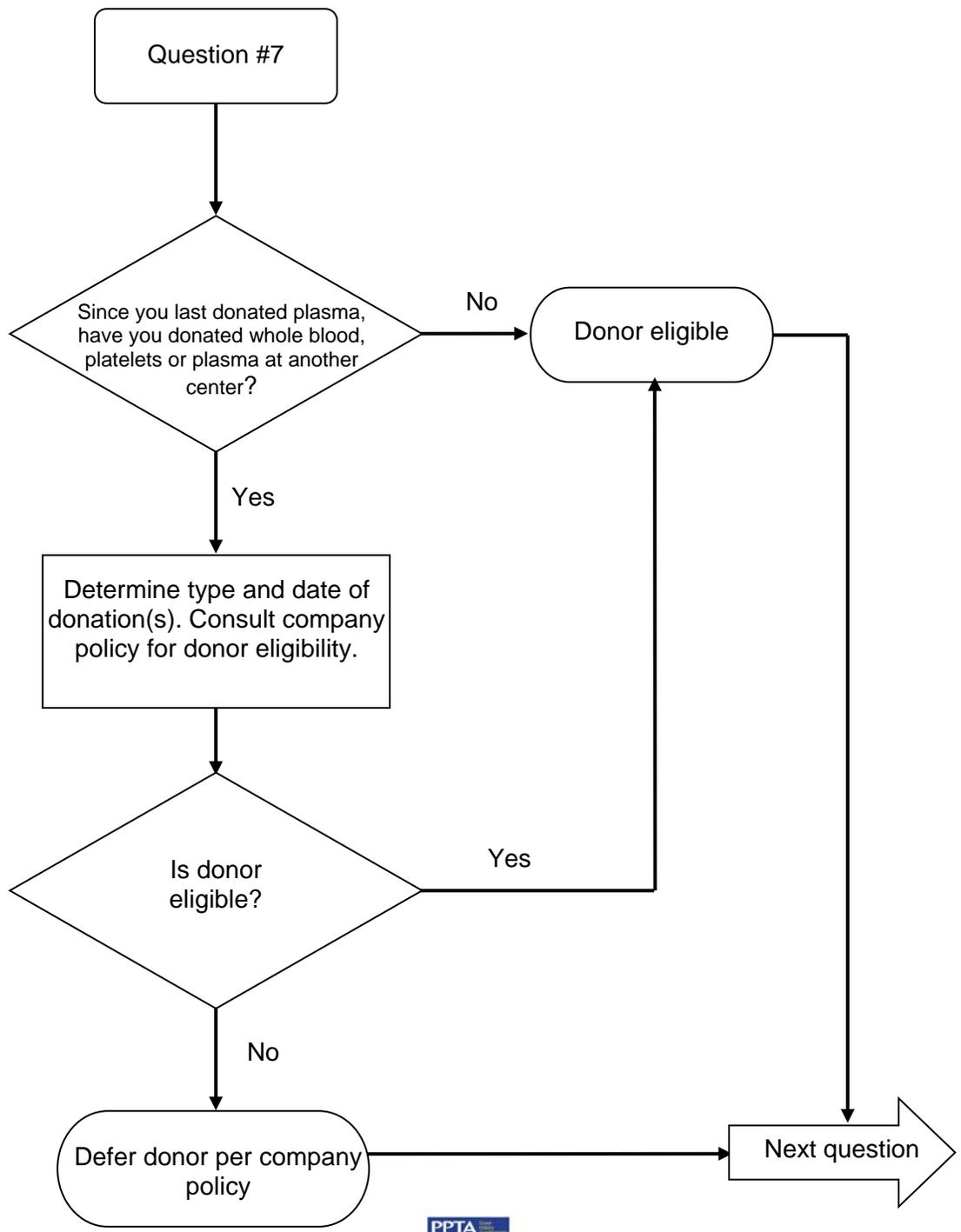
**Donor Eligibility:** Certain vaccinations may contain a live virus. A donor who has been exposed to a live virus via vaccination should not serve as a donor. For other shots, consult company policy to determine eligibility.



\*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.

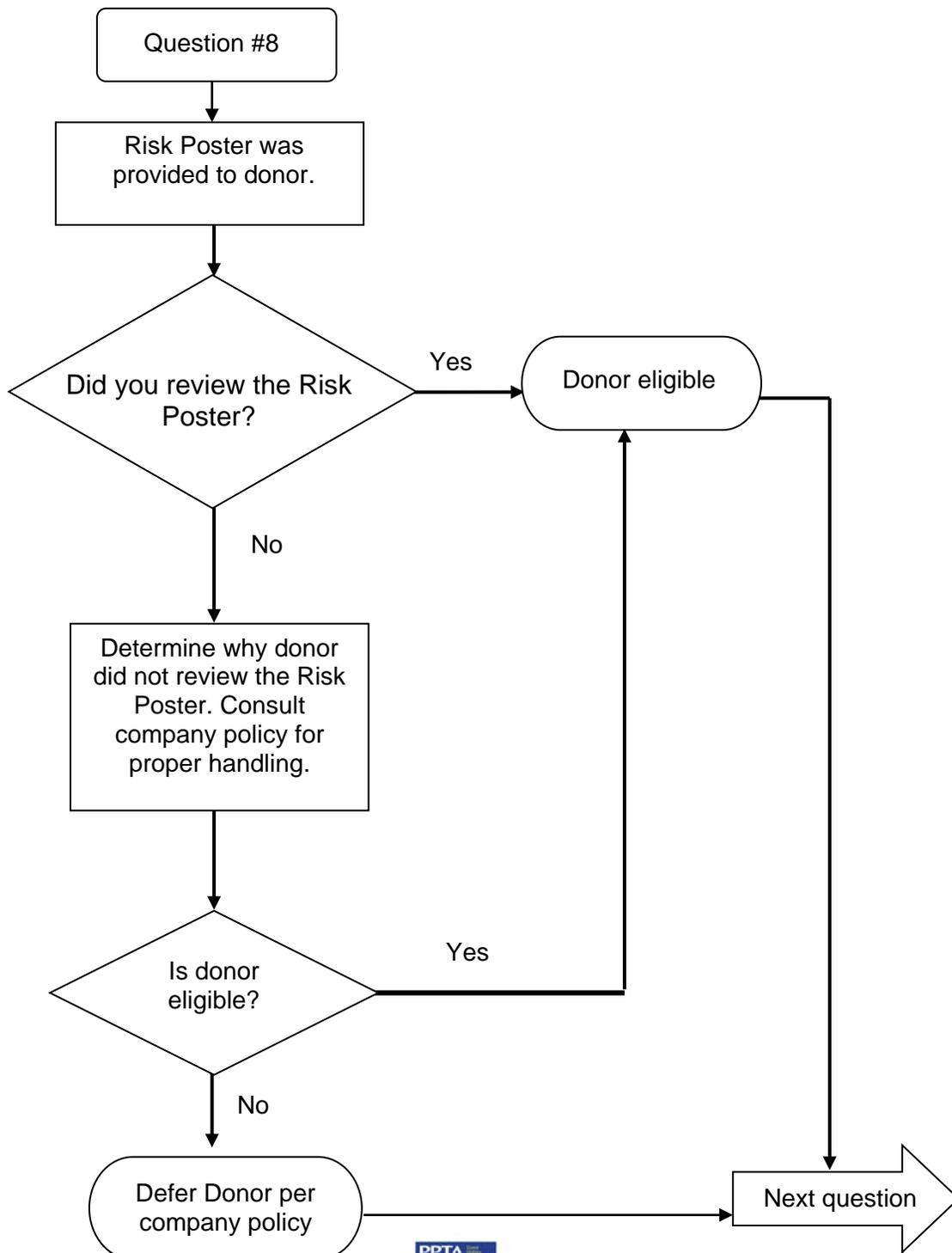
**Question #7:** Since you last donated plasma, have you donated whole blood, platelets or plasma at another center?

**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.



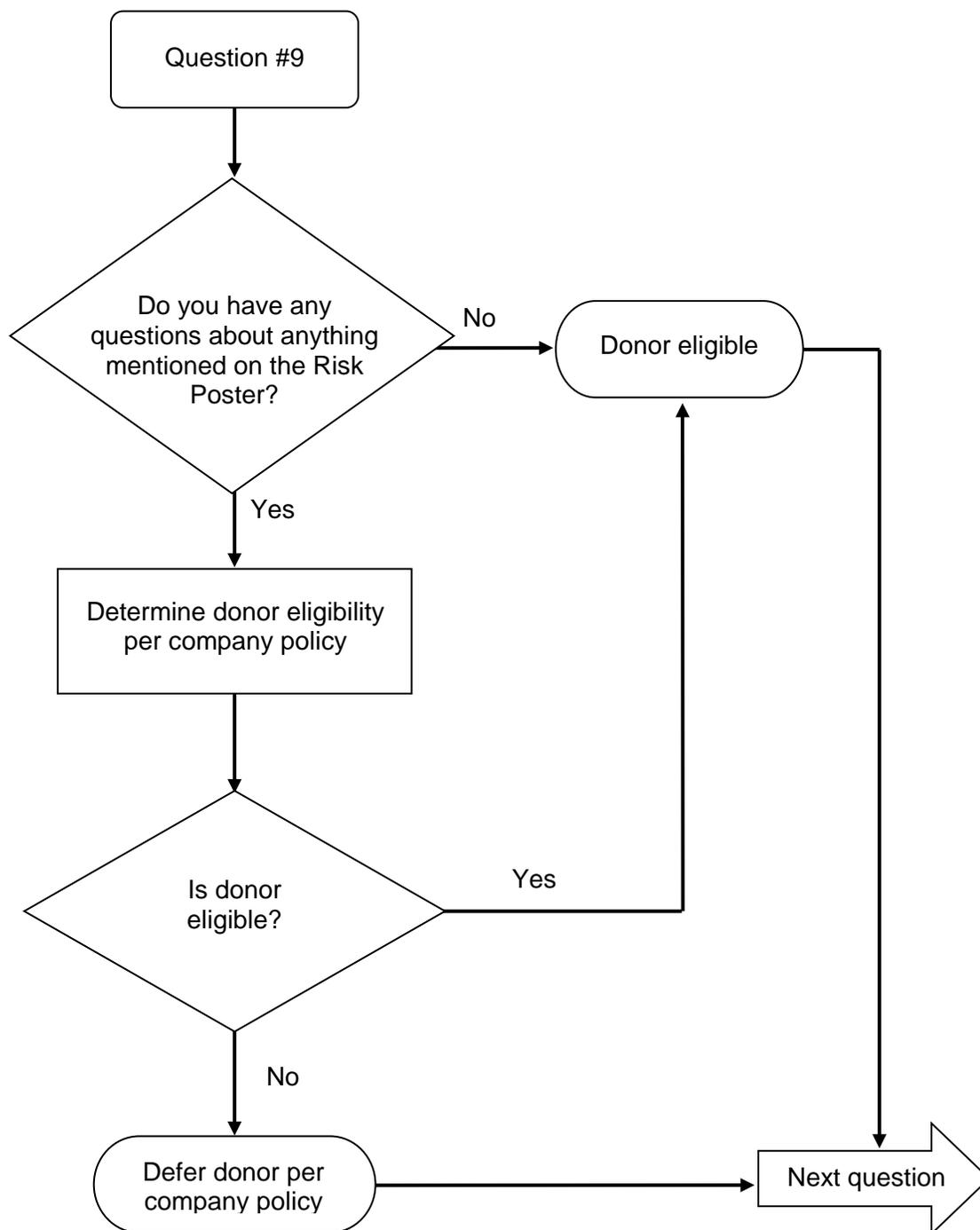
**Question #8:** Did you review the Risk Poster?

**Donor Eligibility:** The Risk 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 Risk Poster information provided during the donor interview to determine if they are at risk of transmitting infectious diseases. Risk Poster 1 should be provided to the donor if the questionnaire asks “in the past 12 months” regarding MSM behavior. Risk Poster 2 should be provided to the donor if the questionnaire asks “have you ever” regarding MSM behavior.



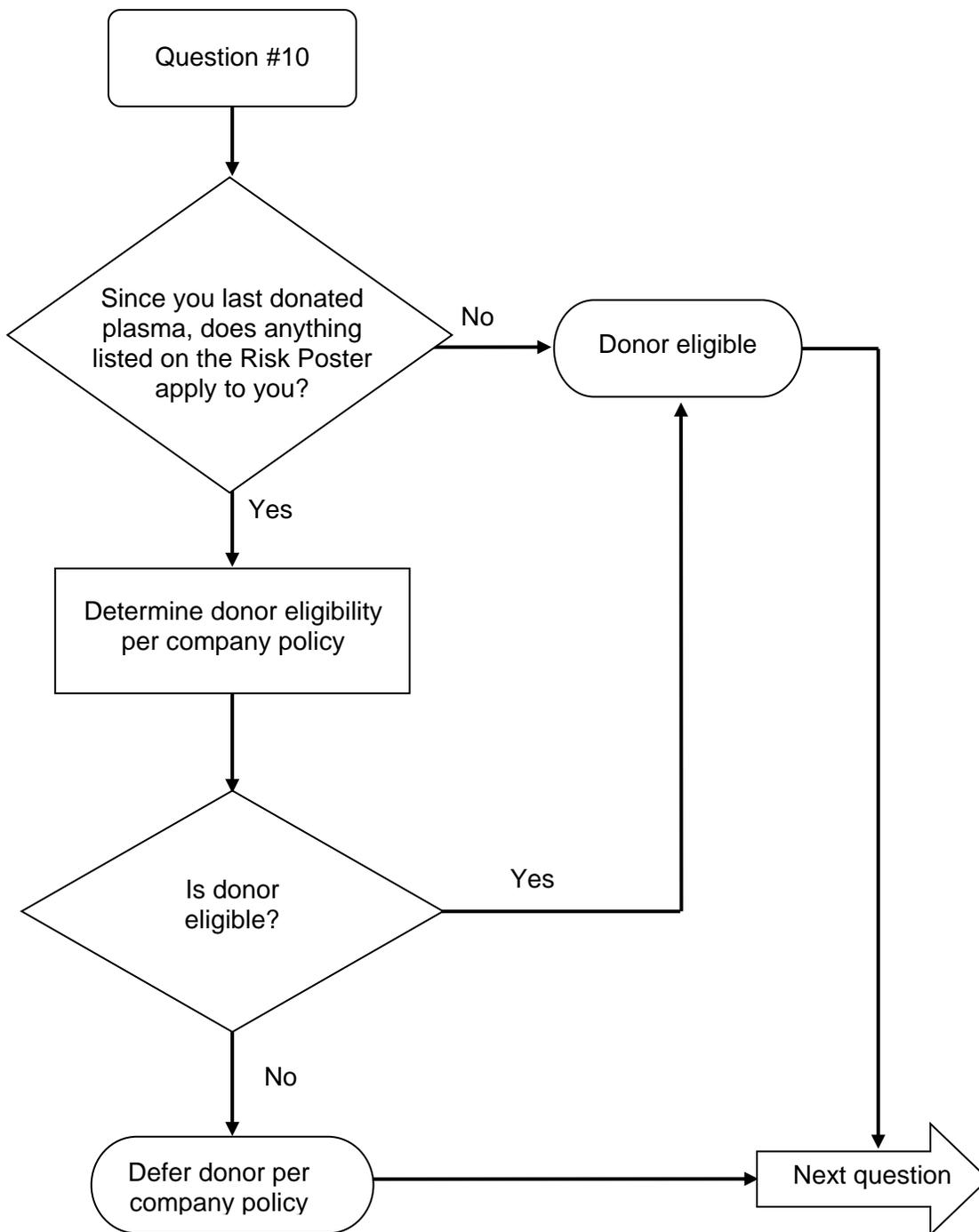
**Question #9:** Do you have any questions about anything mentioned on the Risk Poster?

**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.



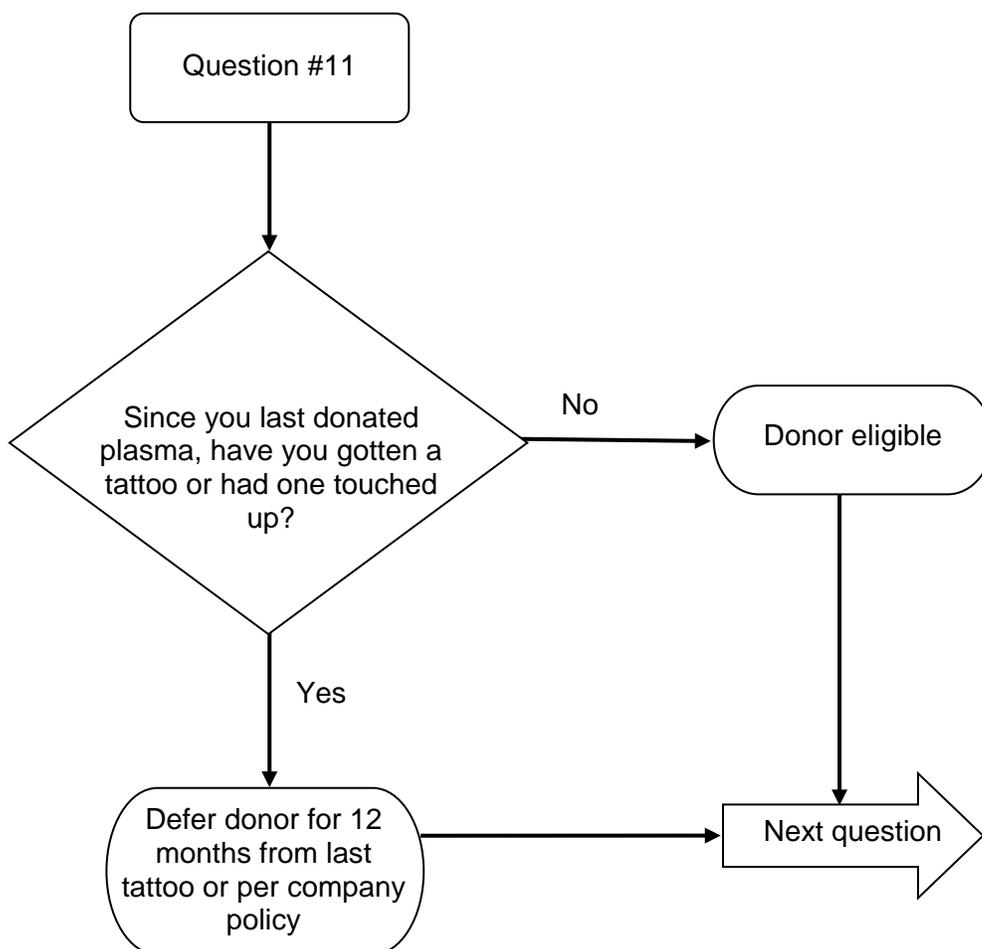
**Question #10:** Since you last donated plasma, does anything listed on the Risk Poster apply to you?

**Donor Eligibility:** The Risk Poster includes information on risk activities for HIV, 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.



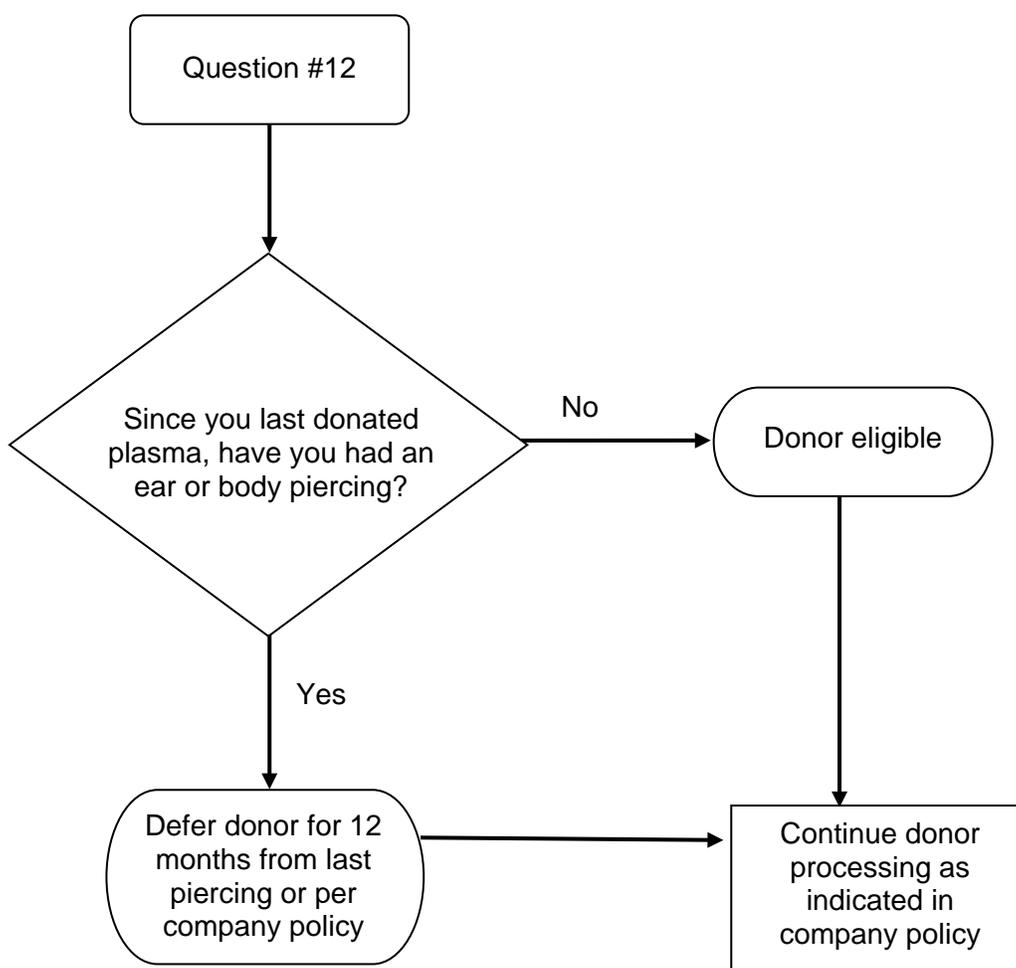
**Question #11:** Since you last donated plasma, have you gotten a tattoo or had one touched-up?

**Donor Eligibility:** Persons who have received a tattoo in the previous 12 months are deferred for 12 months (or 4 months if following EU requirements) 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). While FDA does not require donors be deferred if tattoos were applied using sterile methods, as described above, if you follow European requirements you must defer donors for a minimum of 4 months (with NAT testing).



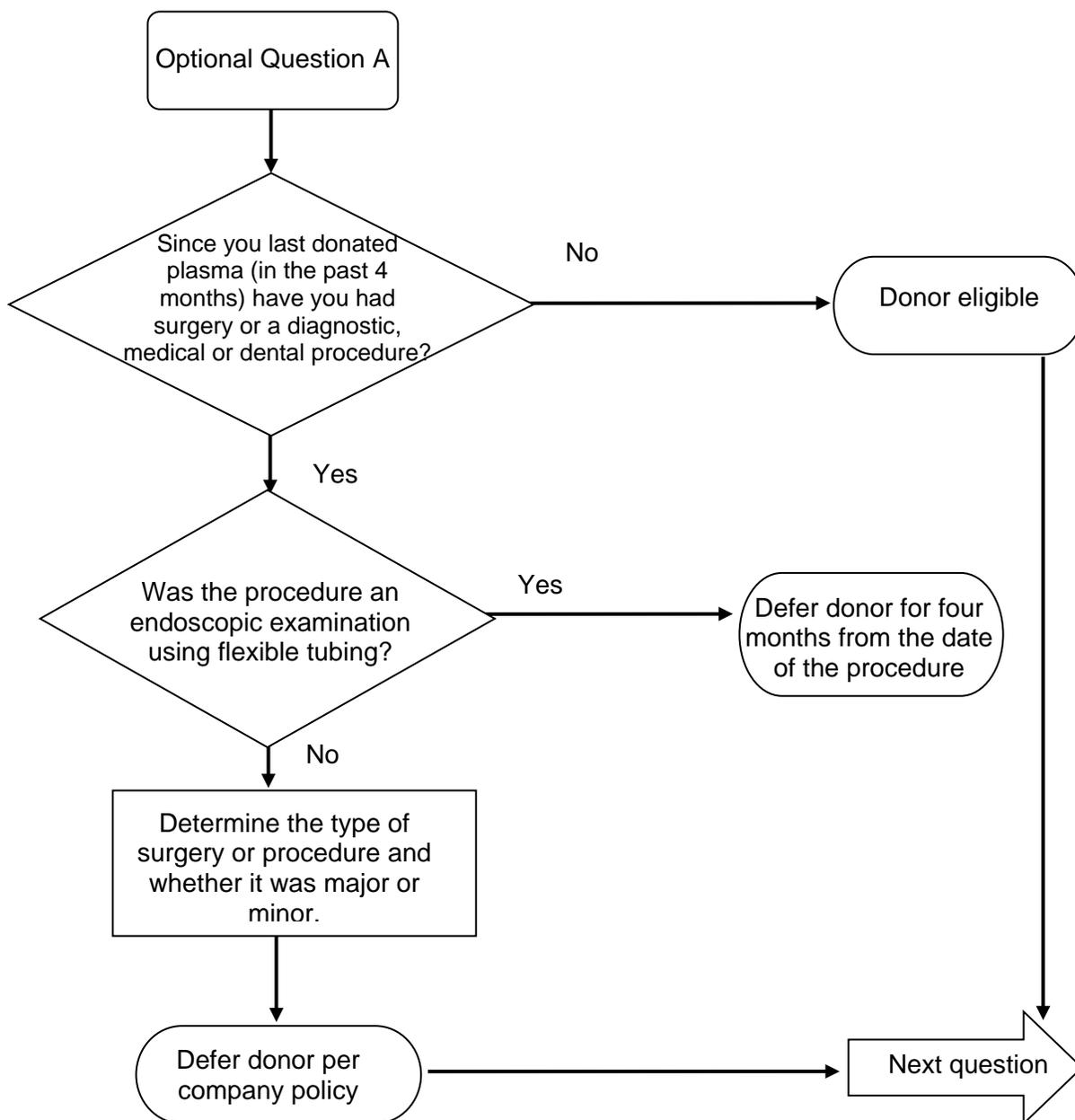
**Question #12:** Since you last donated plasma, have you had an ear or body piercing?

**Donor Eligibility:** Persons who have had ear or body piercing during the previous 12 months are usually deferred for 12 months (or 4 months if following EU requirements) 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. While FDA does not require donors be deferred if piercing was performed using sterile methods, as described above, if you follow European requirements, you must defer donors for a minimum of 4 months (with NAT testing).



**Optional Question A:** Since you last donated plasma, have you had surgery or a diagnostic, medical or dental procedure?

**Donor eligibility:** Outside of the US, some regulators have interpreted the European Commission Directive 2004/33/EC, Annex III to require that donors having certain surgical, diagnostic, medical or dental procedures be deferred for a period of time. Reasons for deferral vary from concerns for donor health to risks to the blood or blood components collected from the donors. Endoscopic examination using flexible tubing is specifically noted to require a four month deferral when NAT testing is performed.



**Optional Question B:** Since you last donated plasma, have you had acupuncture?

**Donor Eligibility:** European Commission Directive 2004/33/EC, Annex III, requires deferral of donors who have received acupuncture unless performed by a qualified practitioner and with sterile single-use needles.

