

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

Source Plasma Full-Length PPTA Donor History Questionnaire (DHQ) Directions for Use

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

Purpose: The Full-Length Plasma Protein Therapeutics Association (PPTA) Donor History Questionnaire (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 eligibility. Each source plasma collection organization must have a standard operating procedure (SOP) related to donor eligibility 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: the Full-Length PPTA DHQ with acknowledgment statement and corresponding Directions for Use, a PPTA Abbreviated DHQ (aDHQ) with acknowledgment statement and corresponding Directions for Use, a Risk Poster, and a Medication List. The PPTA DHQ must be administered on the day of donation and before collection per Title 21, Code of Federal Regulations, 630.10(c). The plasmapheresis center staff must provide to the prospective donor the Risk Poster, 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 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 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 is designed to meet the regulatory requirements of the US Food and Drug Administration (FDA); however, plasma sourcing organizations supply source plasma globally and often must adhere to regulatory requirements outside of the US. The PPTA DHQ has been designed to offer alternative questions (i.e., pregnancy and MSM) and optional questions (e.g., acupuncture and history of fainting). If an organization chooses to use an alternative question, its use necessitates moving the question to a different heading and removing the original question. For pregnancy, adopting a six month deferral rather than the US-required six weeks necessitates relocating the question under a new heading, “in the past six months,” which should be placed between “in the past four months” and “in the past 12 months.” For MSM, the question will need to be moved from “in the past 3 months” to “have you ever.” There may be other questions that require more restrictive time periods than allowed in the revision 2.1. For example, if following European requirements, questions related to blood exposure, such as “had a transfusion” will need to be moved to “in the past 4 months” heading. Optional questions selected by the organization should remain within the appropriate headings. Questions will need to be renumbered in consecutive order by the plasma sourcing organization.

Donor Acknowledgment Statement: At the completion of the questionnaire, donors must be asked to review the acknowledgment statement, agree not to donate if the donation could result in a potential risk to recipients and provide a signature or other documented acknowledgement. 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 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 found acceptable 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.

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 eligibility. 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.

Full-Length PPTA DHQ Administration Frequency: The Full-Length PPTA DHQ was designed as a standalone 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 (aDHQ) 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 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. For example, if a sourcing organization uses alternative and/or optional questions that require moving and renumbering in the DHQ, the respective flow chart module should also be moved and renumbered. 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 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 3 months would be deferred for 3 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] 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:

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

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>

Valproate Safety Information:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/018081s046_18082s031lbl.pdf

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

FDA Guideline for Collection of Blood or Blood Products from Donors with Positive Tests for Infectious Disease Markers ("High Risk" Donors); October 1989

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

FDA Guidance, October 2001: Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax

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, August 2006: Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies

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

FDA Recommendations for Management of Donors at Increased Risk for Human Immunodeficiency Virus Type 1 (HIV-1) Group O Infection, August, 2009

FDA Guidance, December 2010: "Lookback" for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV. (This document supersedes the guidance document of the same title, dated August 2007.)

FDA Guidance, June 2011: Donors of Blood and Blood Components: Notification of Donor Deferral, Small Entity Compliance Guide

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 the Risk of Transmission of Hepatitis B Virus

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, January 2017: Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus

FDA Guidance, September 2017: Requalification of Donors Previously Deferred for a History of Viral Hepatitis after the 11th Birthday

FDA Guidance, December 2017: 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. (This document supersedes the guidance of the same title, dated 5/2010.)

FDA Guidance, October 2019: Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus

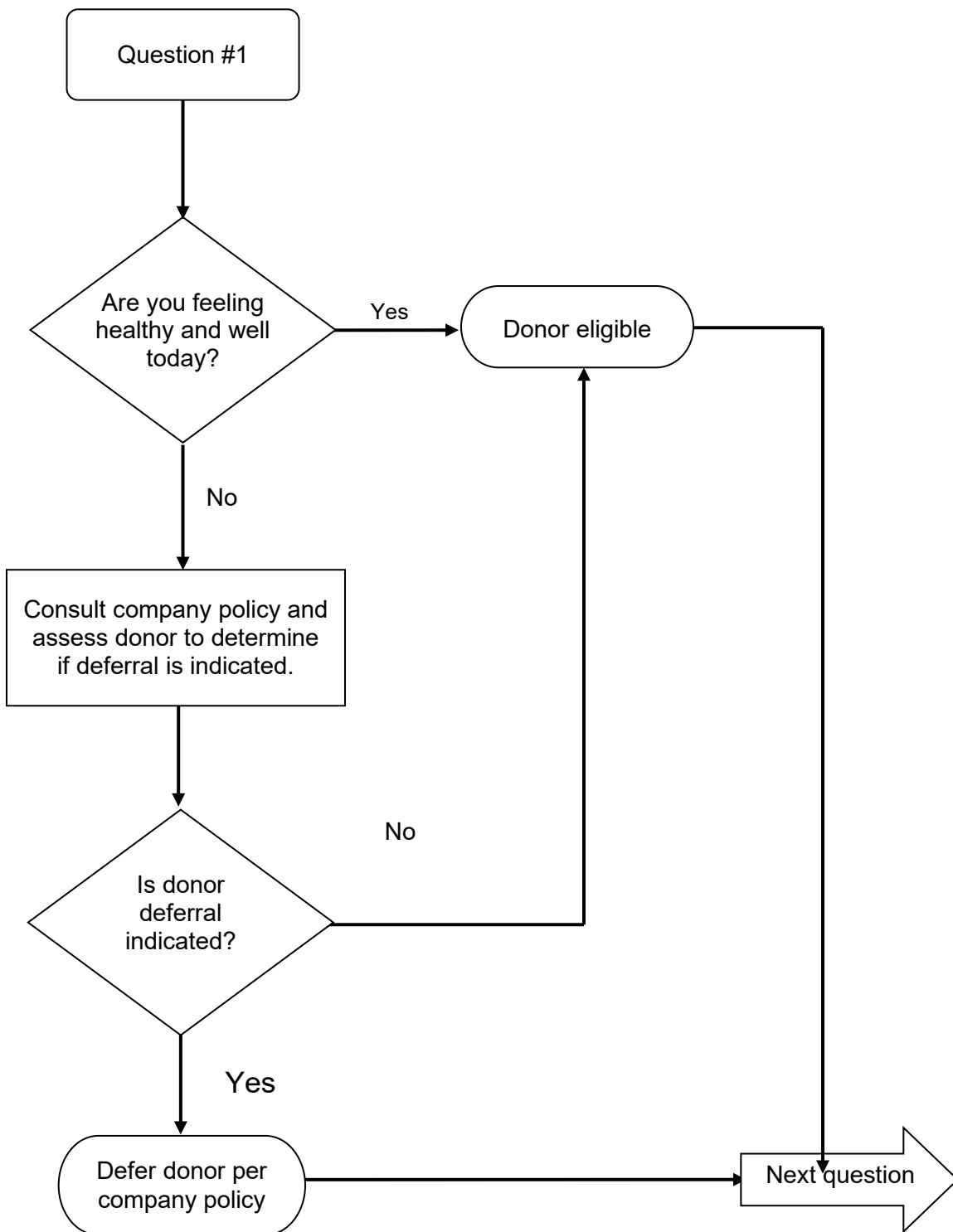
FDA Guidance, April 2020: Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products

FDA Guidance, April 2020: Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components

FDA Guidance, April 2020: Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency

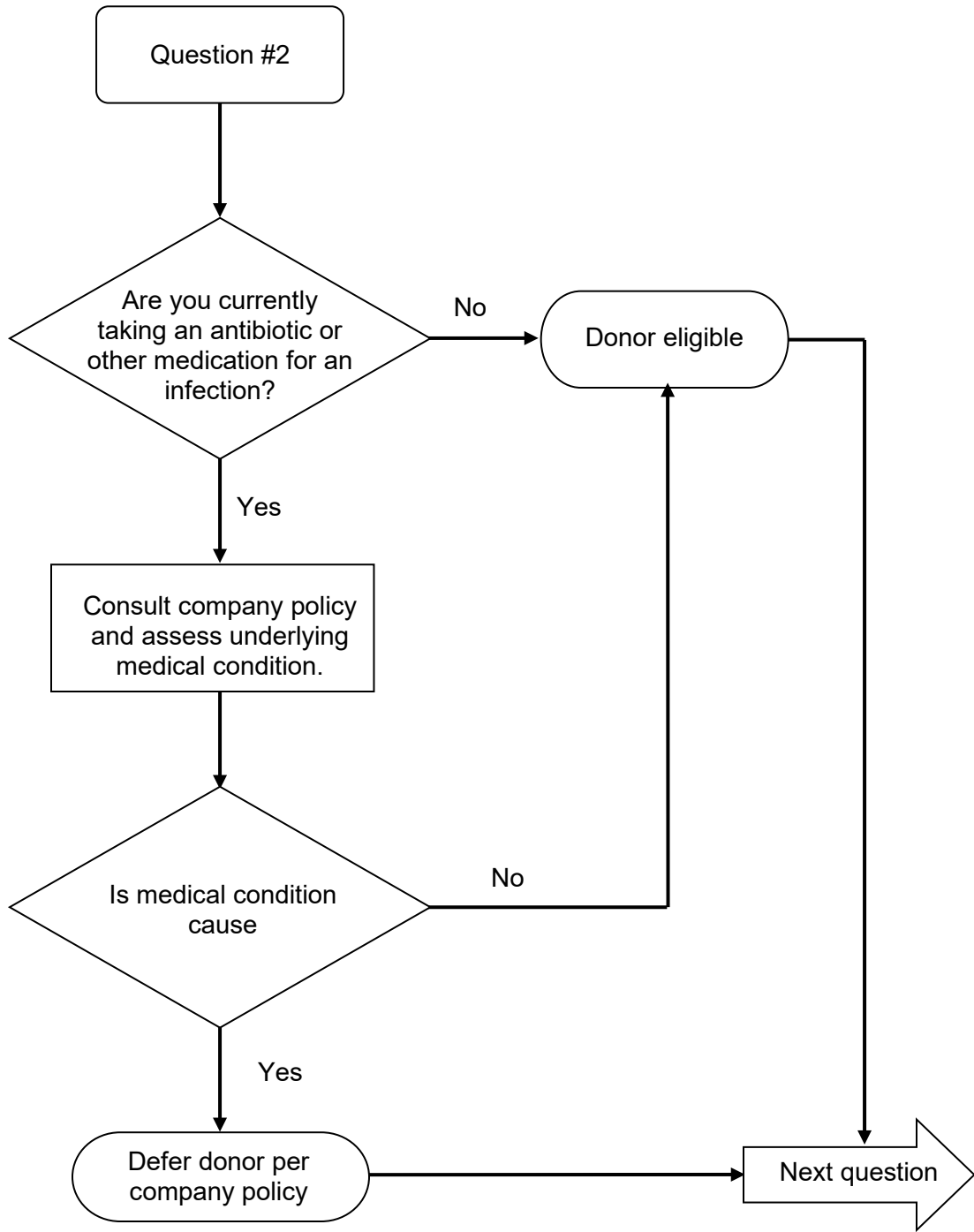
Question #1: Are you feeling healthy and well today?

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.



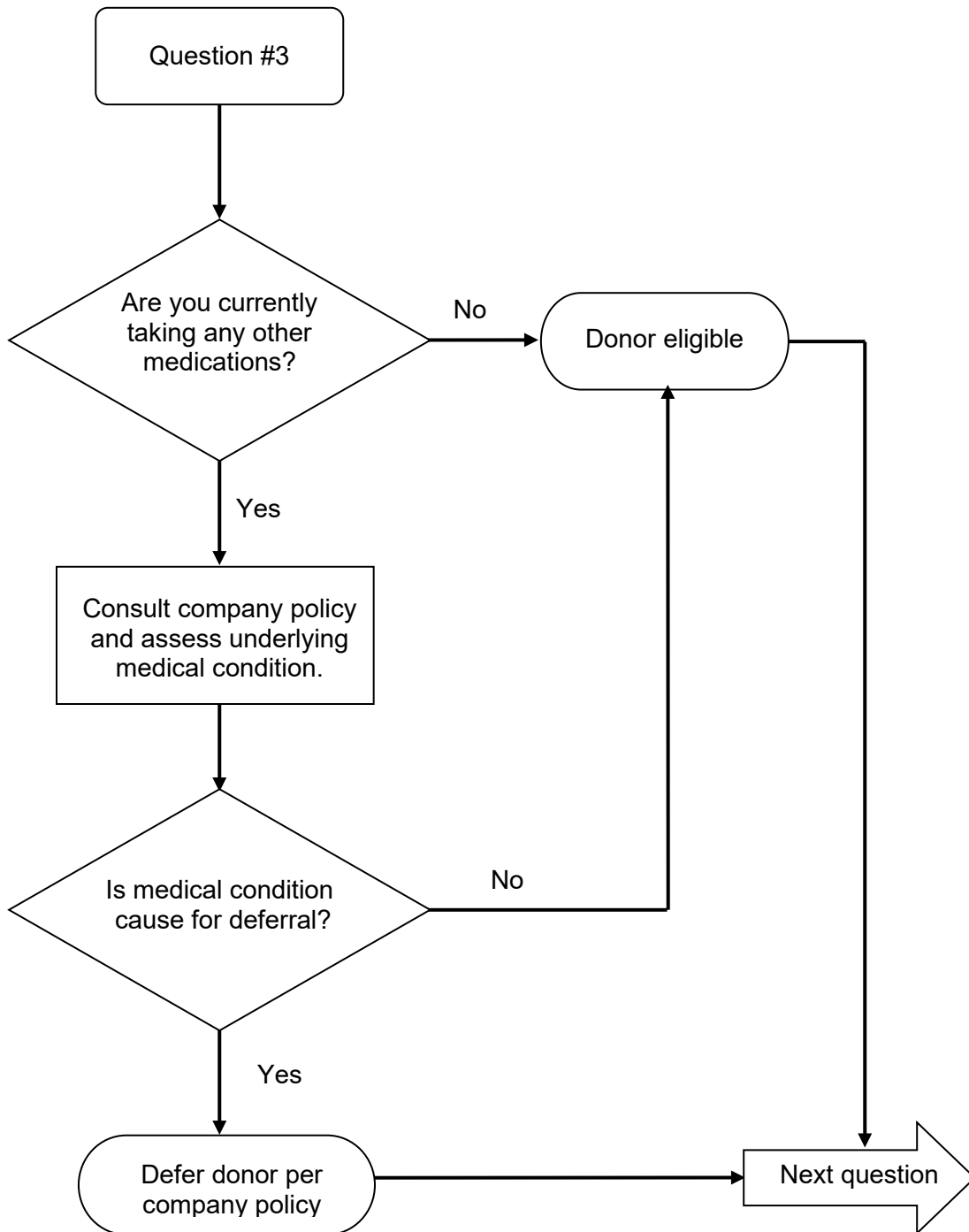
Question #2: Are you currently taking an antibiotic or other medication for an infection?

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?

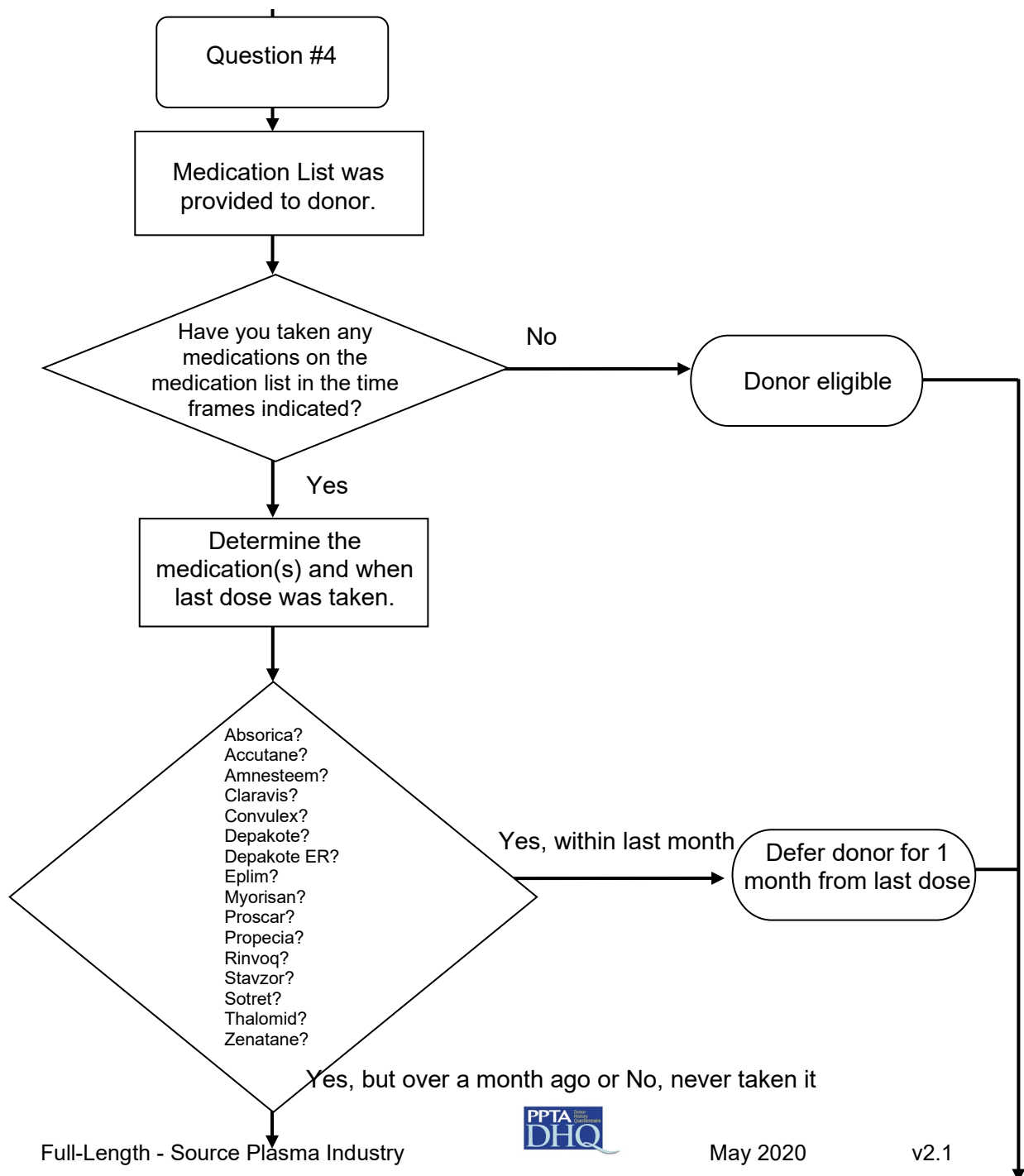
Donor Eligibility: The reason for use of a medication to treat a medical condition must be evaluated (follow company policy).

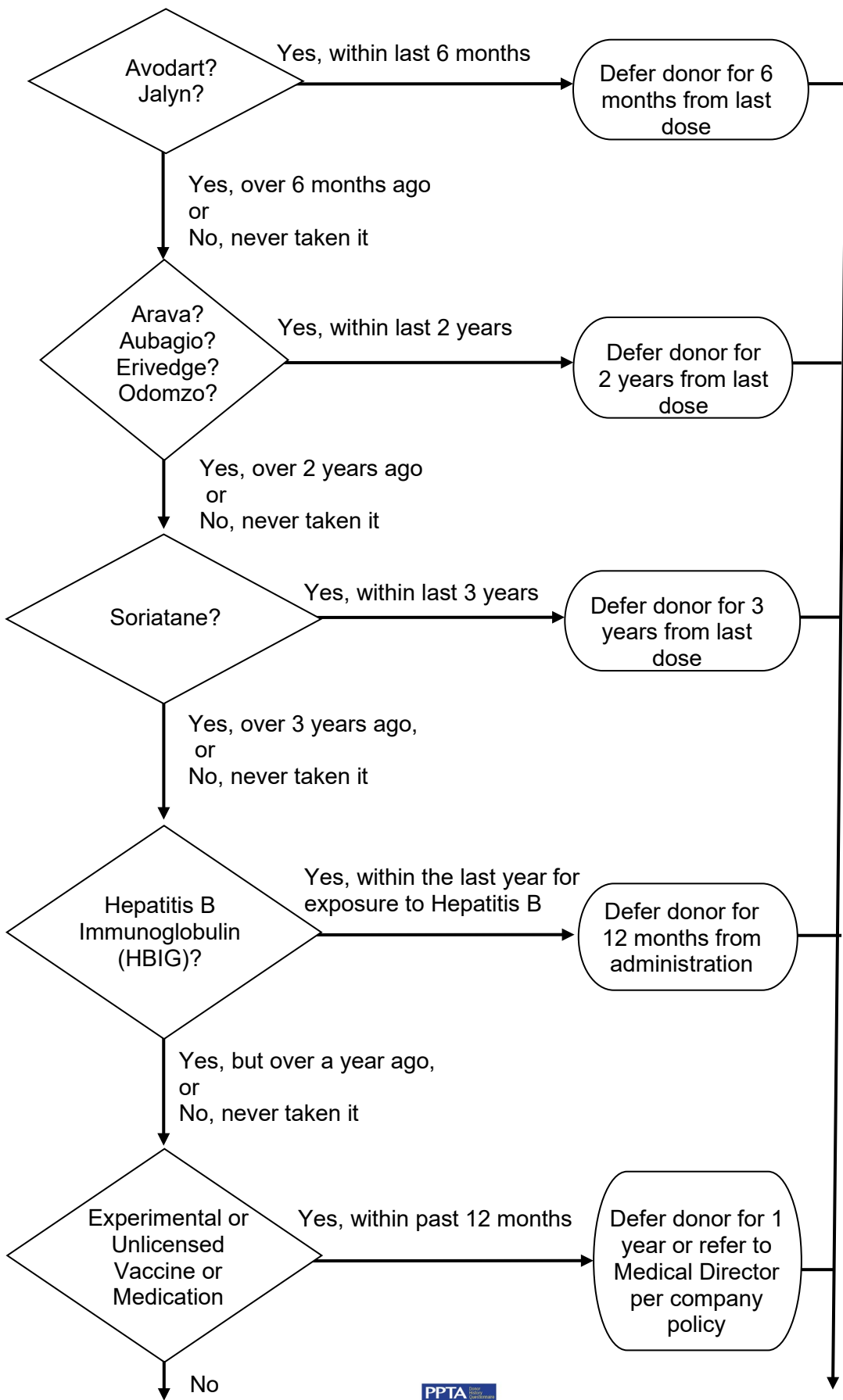


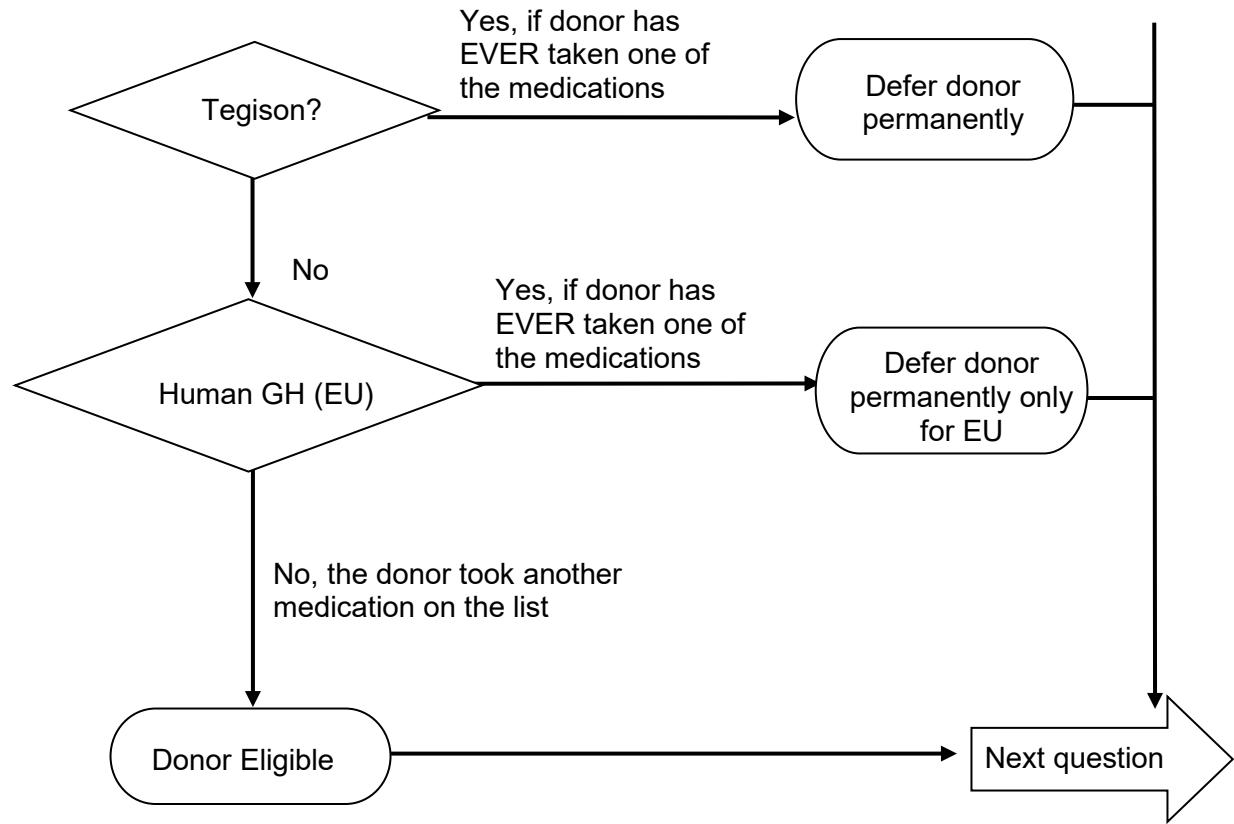
Question #4: Have you taken any medications on the medication list in the time frames indicated?

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

Note: With revision 2.1, deferral for receiving human growth hormone is removed from the medication list. However, deferral is required in the EU. If following EU requirements, "Growth hormone from human pituitary glands" must be added to the medication list with the indication "delayed growth in children," deferral period "ever," and reason for deferral "harm patients who received medications prepared from your plasma by increasing the risk of transmitting CJD or vCJD."



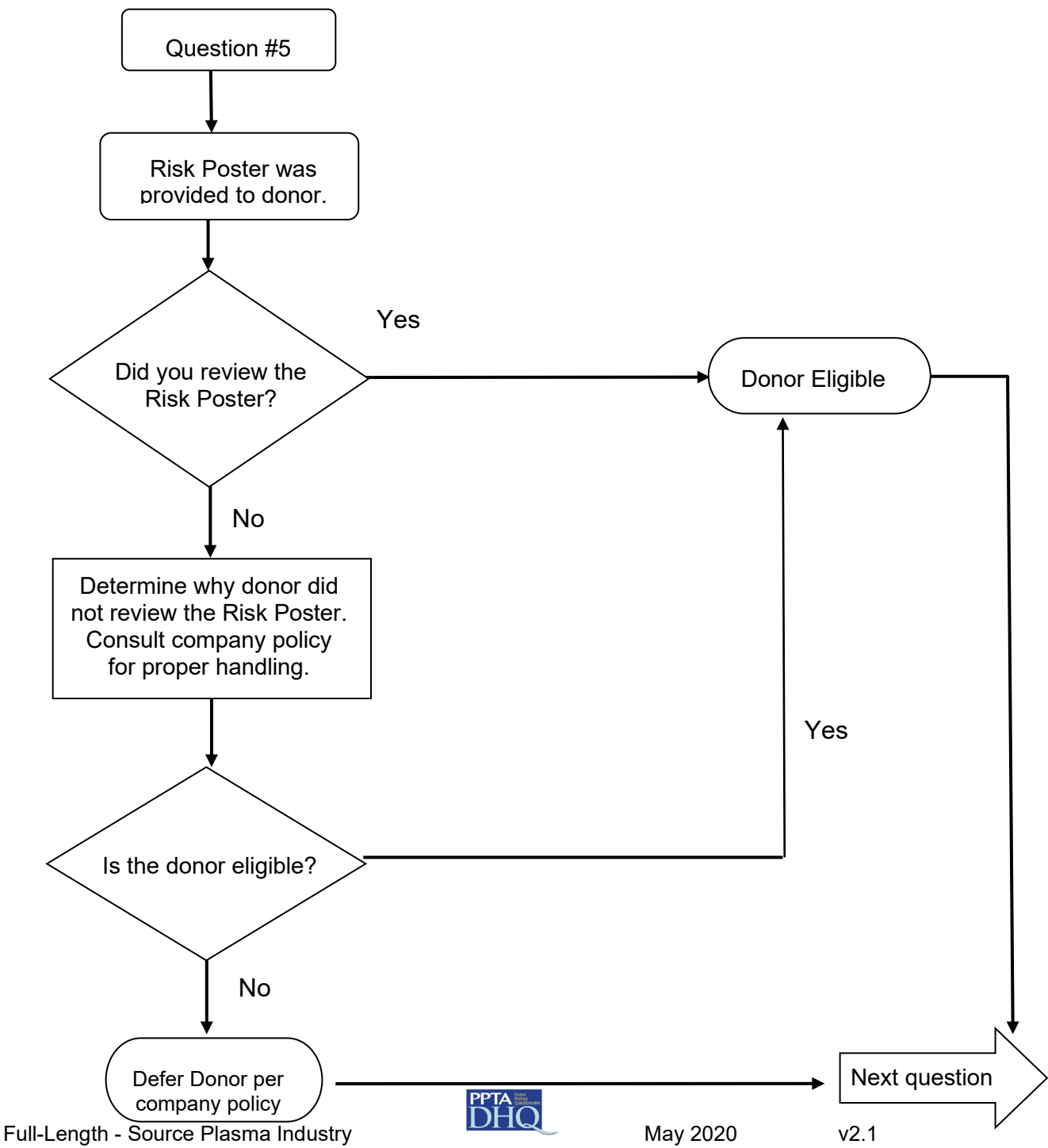




Question #5: Did you review the Risk Poster?

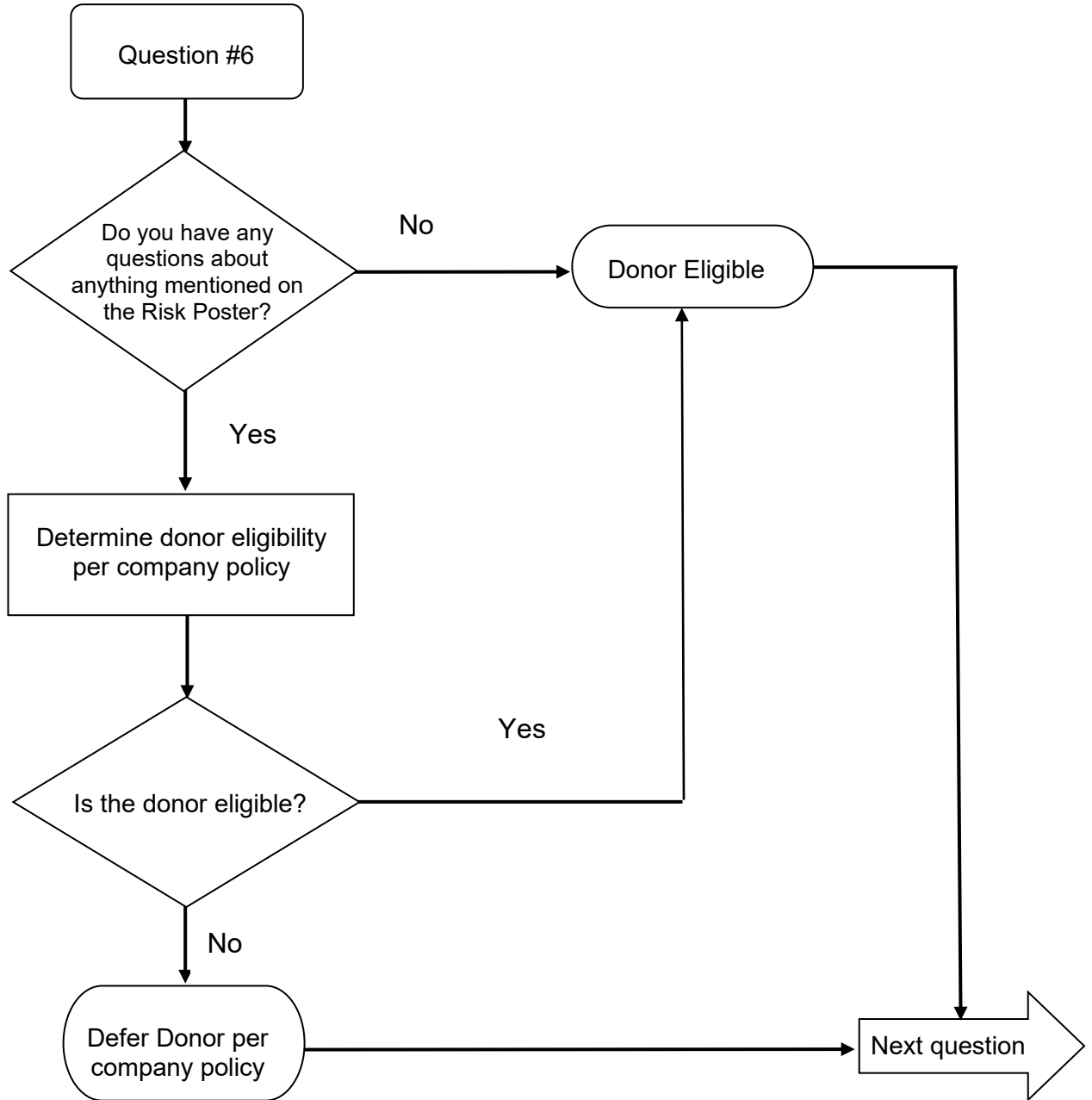
Donor Eligibility: The Risk Poster includes information on risk activities for HIV, viral hepatitis, and other infectious diseases that may be transmitted through blood. Therefore, potential plasma donors must read the Risk Poster information provided during the donor interview to determine if they are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

Note: The Risk Poster includes deferral periods recommended by FDA in April 2020. If companies use more restrictive deferral periods than are recommended by FDA, the Risk Poster must be updated to reflect company policies. The deferral time periods should be displayed in the appropriate chronological order from “Ever” to “Currently have.”



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

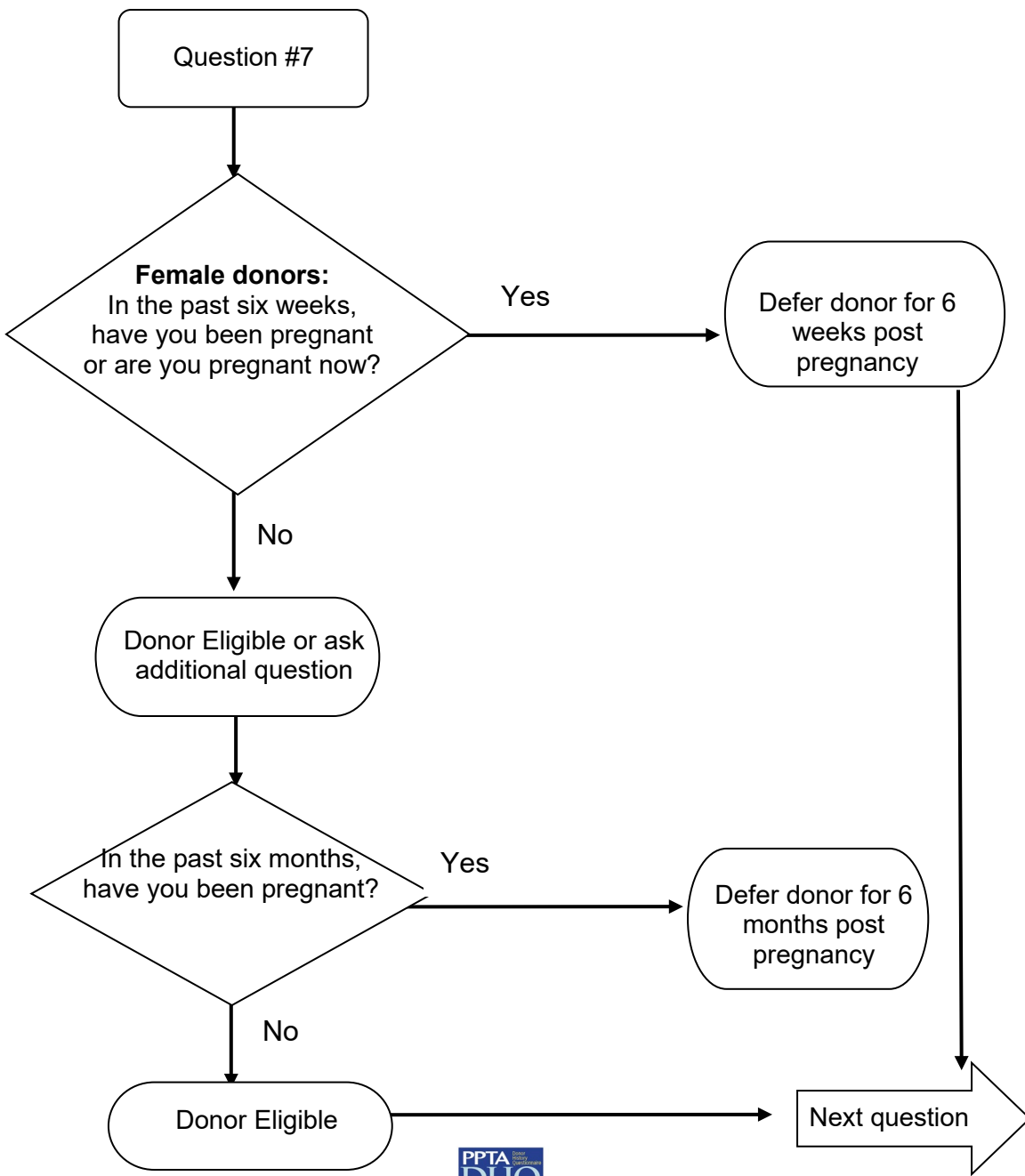
Donor Eligibility: The Risk Poster includes information on risk activities for HIV, viral hepatitis, and other relevant transfusion transmissible infections (RTTI). Donors should be encouraged to ask questions if material is not understood. For donor deferral follow company policy.



Question #7: Female donors: In the past six weeks, have you been pregnant or are you pregnant now?

Donor Eligibility: In the US, a female with a known pregnancy or who has been pregnant in the last 6 weeks should not donate blood or plasma. Other regions of the world require a 6 month deferral post-pregnancy. **In order to separate plasma for manufacturing for different regions, donors may be asked an additional question if answering “no” to the 6 week question.**

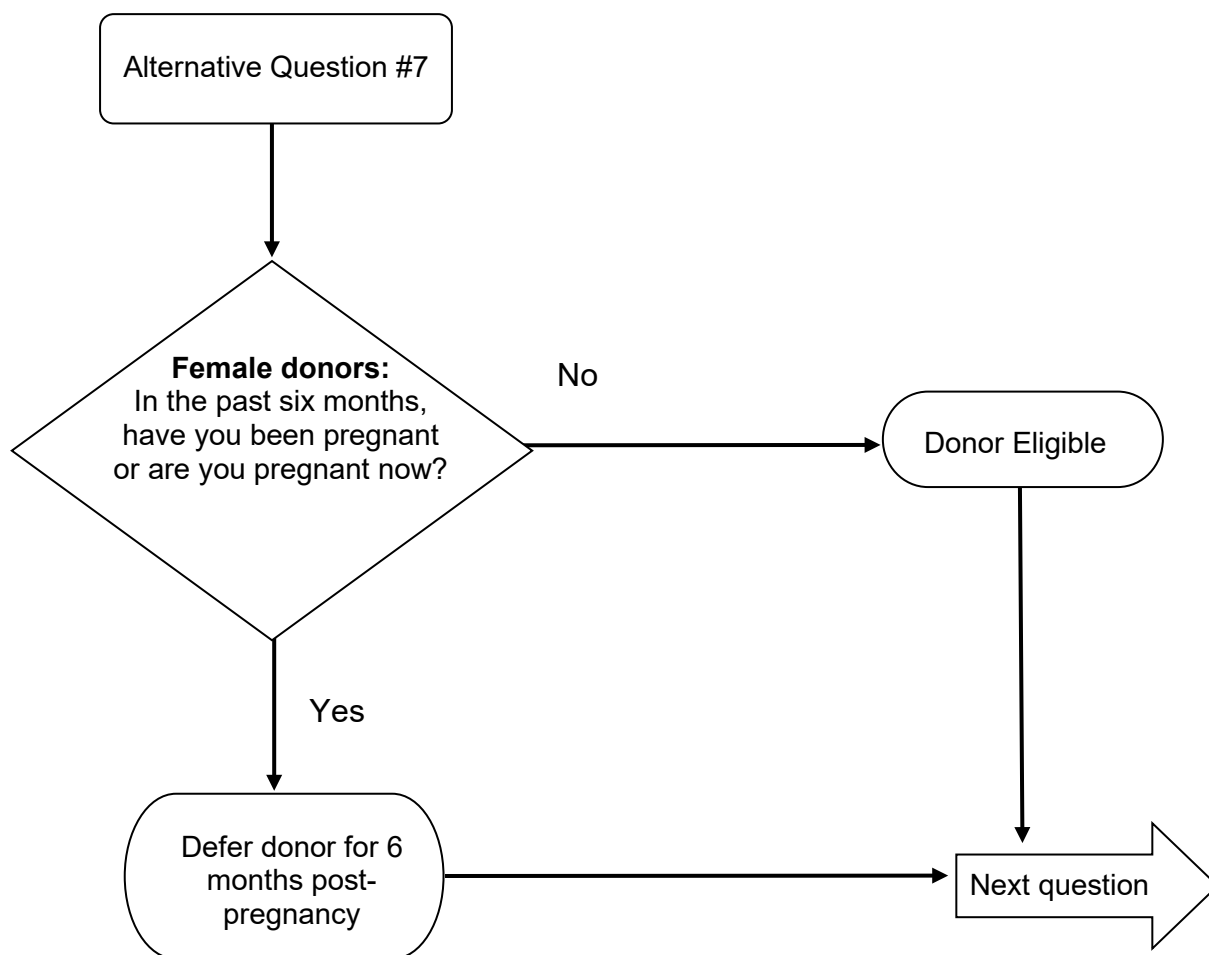
Note: If your company only follows a 6 month deferral, you may choose the alternative Question 7, which will need to be moved to new section, “In the past six months,” which must be placed between “In the past four months” and “In the past 12 months” section of the questionnaire and renumbered.



Alternative Question #7: Female donors: In the past six months, have you been pregnant or are you pregnant now?

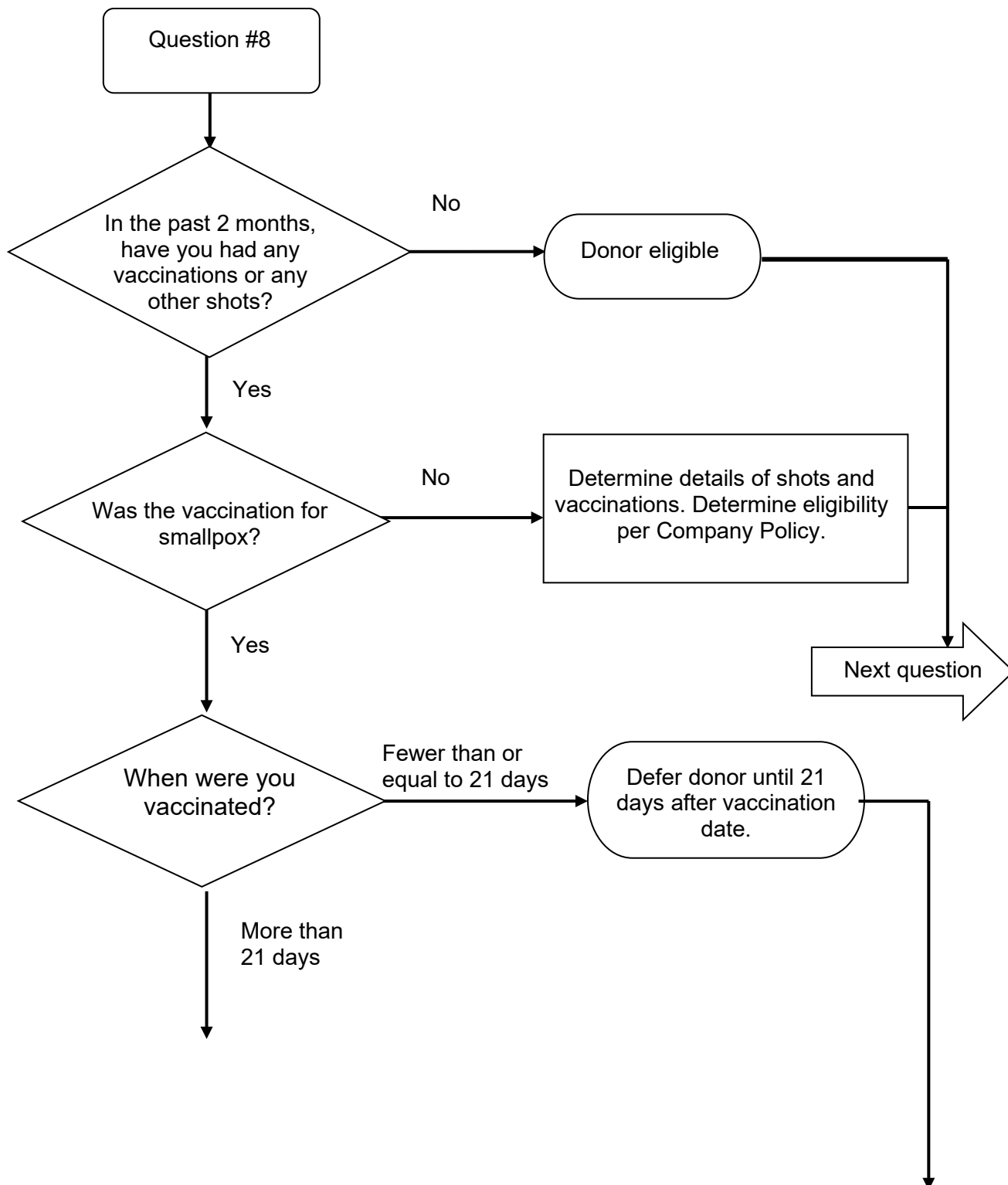
Donor Eligibility: The European Commission Directive 2014/33/EC, Annex III requires that a female with a known pregnancy or who has been pregnant in the last six months should not donate blood or plasma.

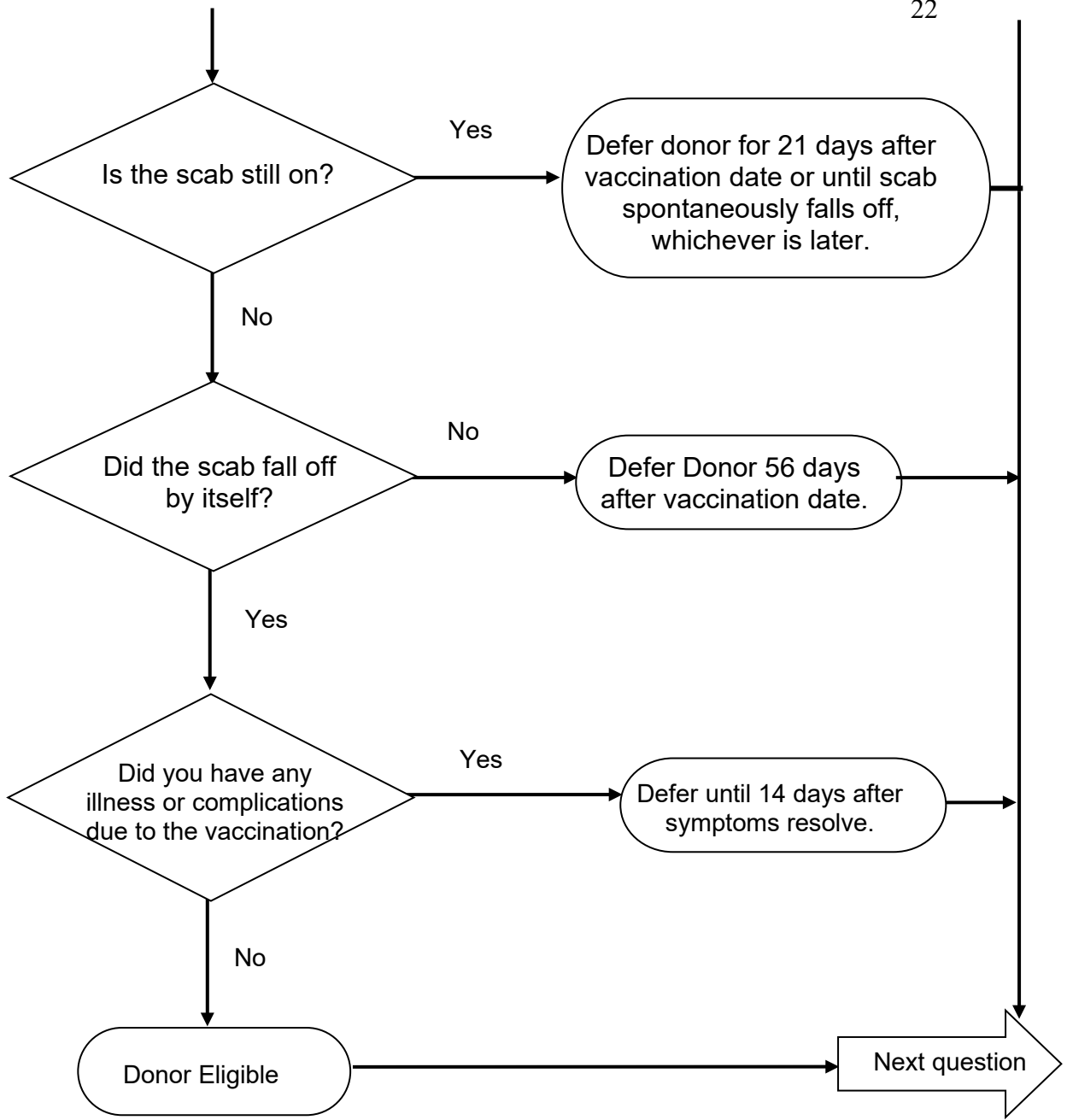
Note: If your company only follows a six month deferral, you may choose the alternative Question 7, which will need to be moved to new section, "In the past six months," which must be placed between "In the past four months" and "In the past 12 months" section of the questionnaire and renumbered.



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

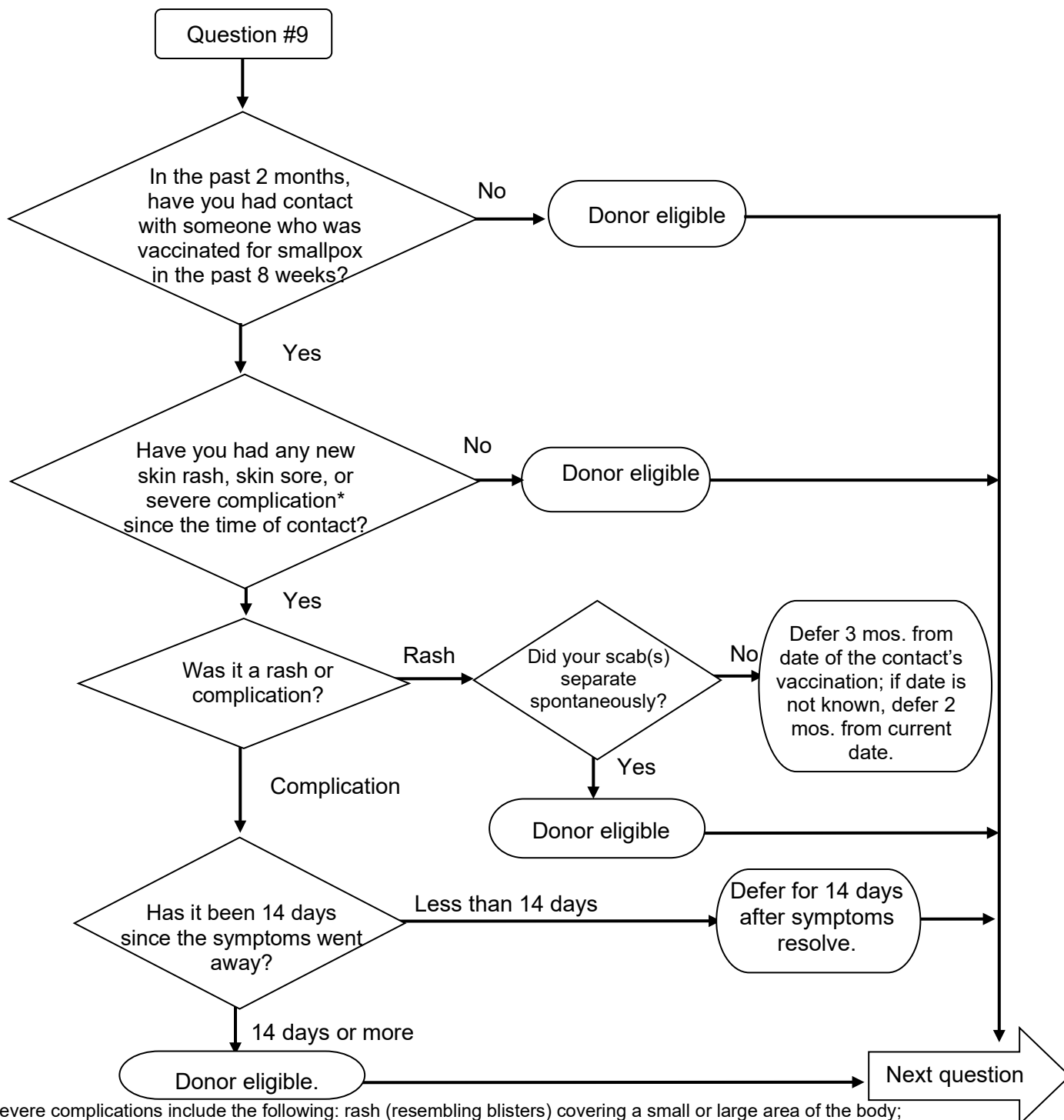
Donor Eligibility: Certain vaccinations may contain a live virus. A donor who has been exposed to a live virus via vaccination should not serve as a donor. For other shots, consult company policy to determine eligibility.





Question #9: In the past two months, have you had contact with someone who was vaccinated for smallpox in the past 8 weeks?

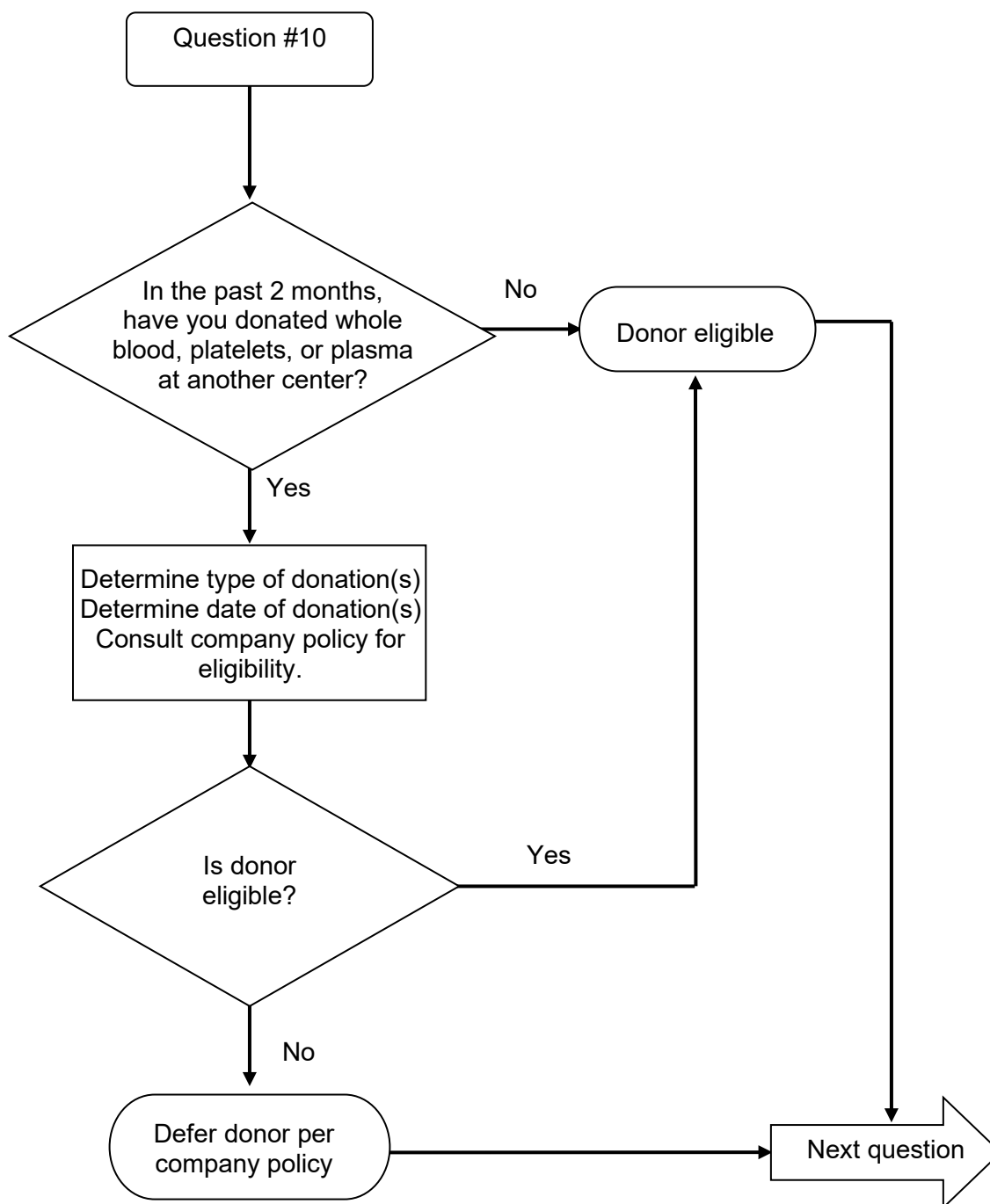
Donor Eligibility: Certain vaccinations may contain a live virus. A donor who has been exposed to a live virus via vaccination should not serve as a donor. For other shots, consult company policy to determine eligibility.



*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.

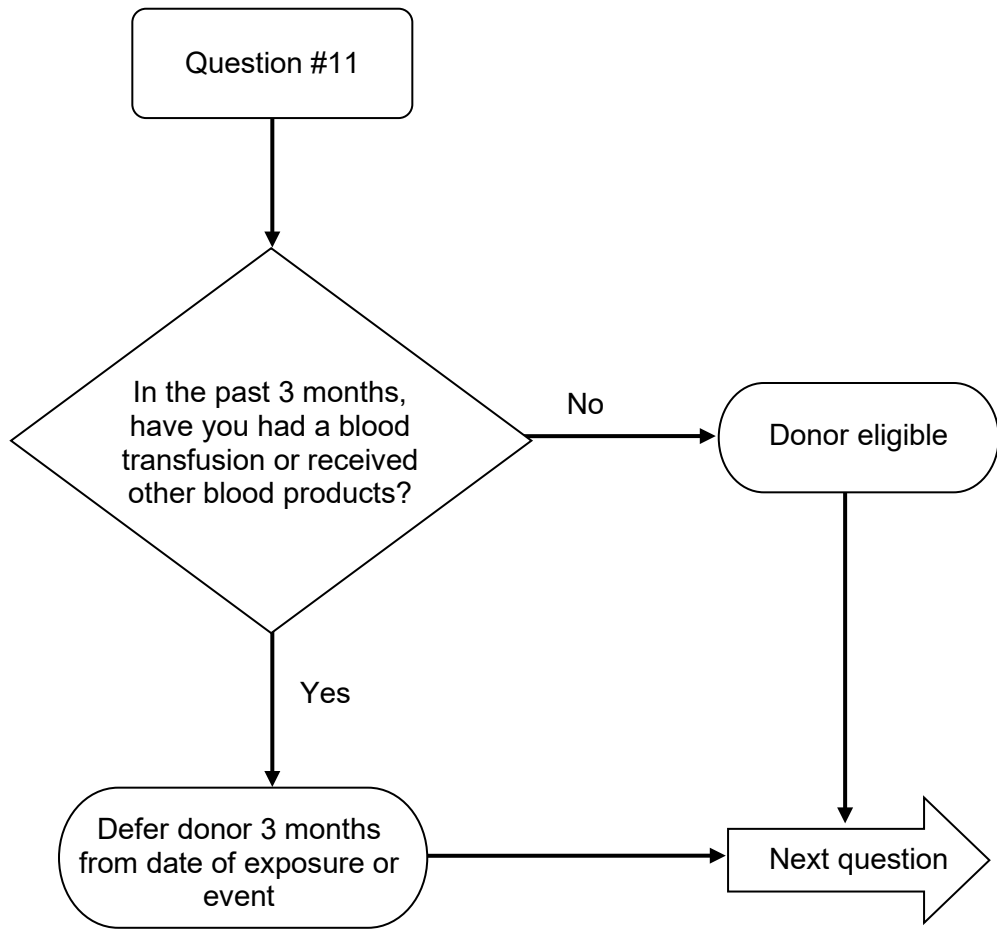
Question #10: In the past two months, have you donated whole blood, platelets, or plasma at another center?

Donor Eligibility: A donor who has donated a unit of whole blood should not donate blood or plasma for a period of 8 weeks [21 CFR 630.15(b)(6)(i)]. A donor who has donated platelets (cellular component that aids in clotting blood) or plasma by apheresis should not donate more than 2 times in a seven-day period at intervals of no less than 2 days apart. [21 CFR 640.64(b)(8)]. 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.



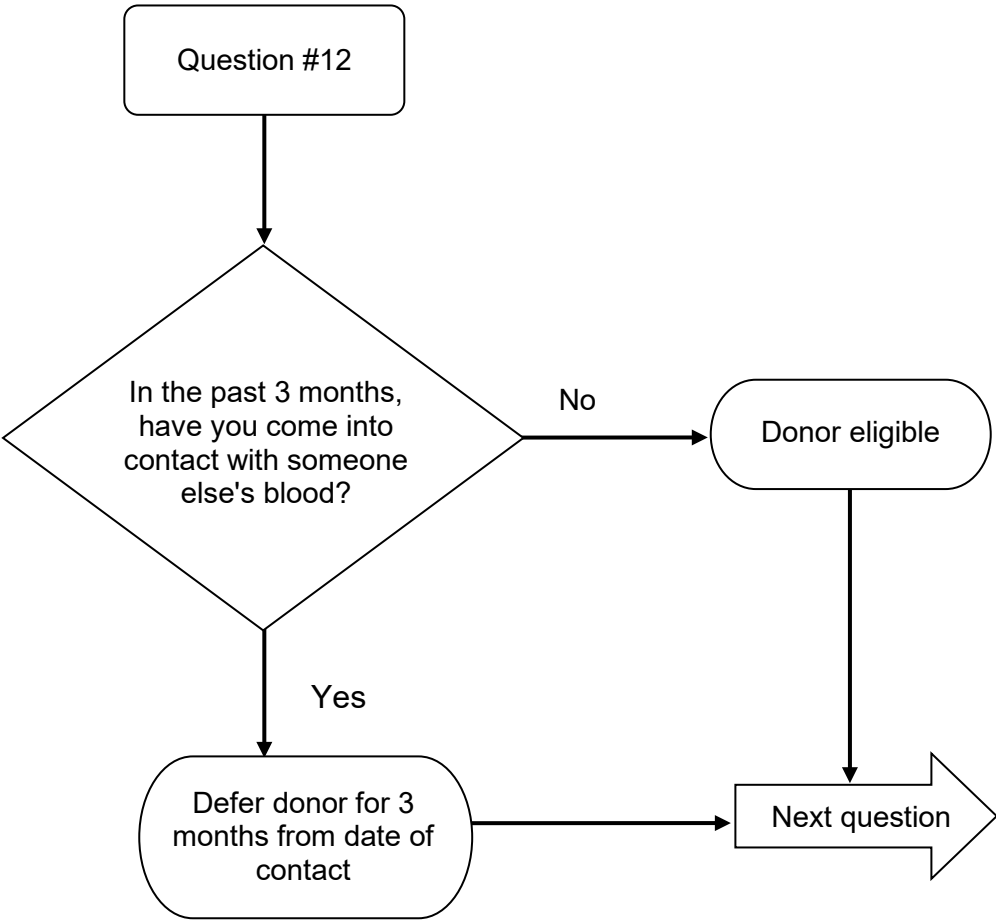
Question # 11: In the past 3 months, have you had a blood transfusion or received other blood products?

Donor Eligibility: A donor who has received a transfusion of blood, platelets, plasma, or other blood component should not donate blood or plasma for 3 months following the transfusion, due to possible transmissibility of infectious disease.



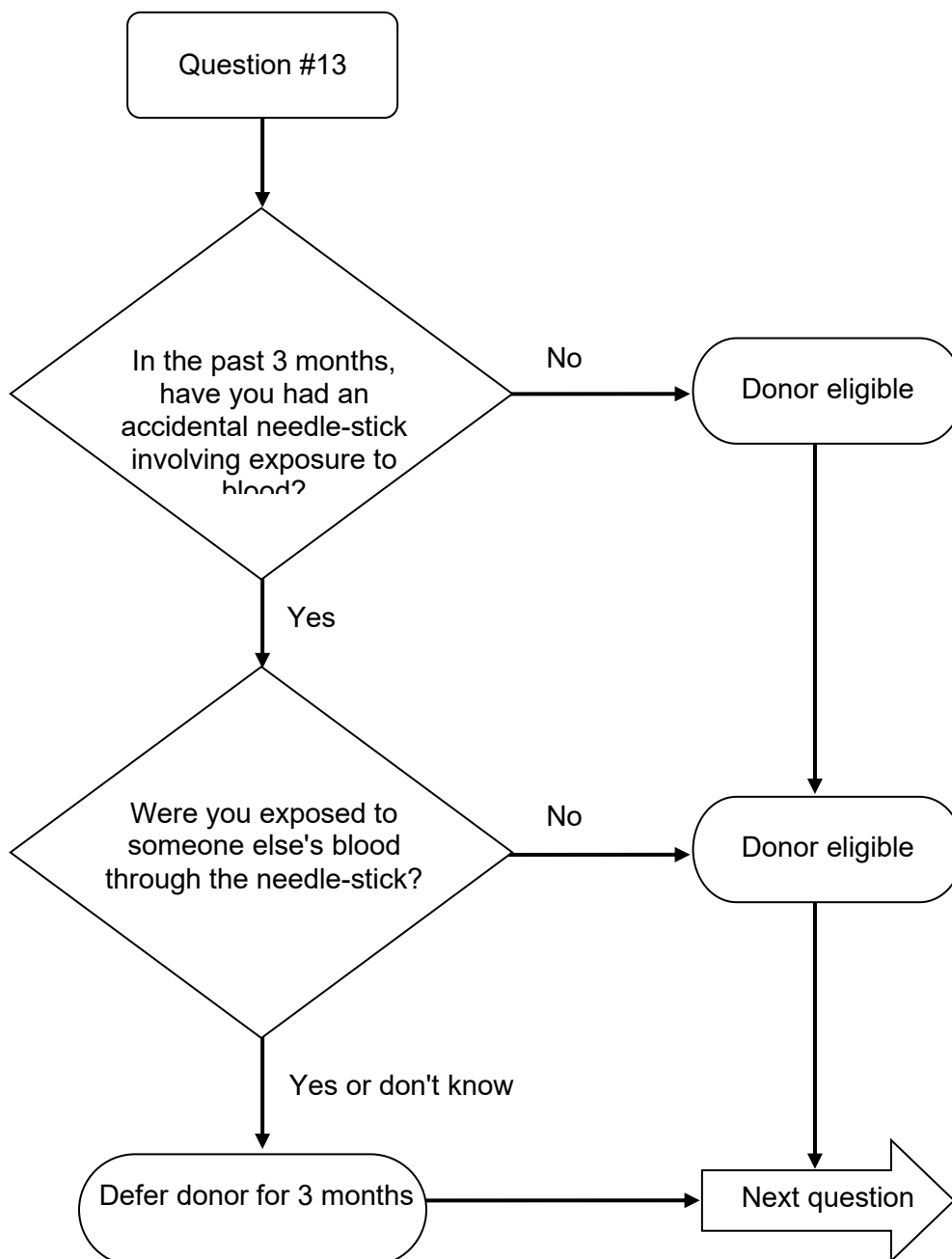
Question #12: In the past 3 months, have you come into contact with someone else's blood?

Donor Eligibility: Persons who have had one of the following during the preceding 3 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 3 months from the date of exposure. Infectious diseases may be spread through contact with blood.



Question #13: In the past 3 months, have you had an accidental needle-stick involving exposure to blood?

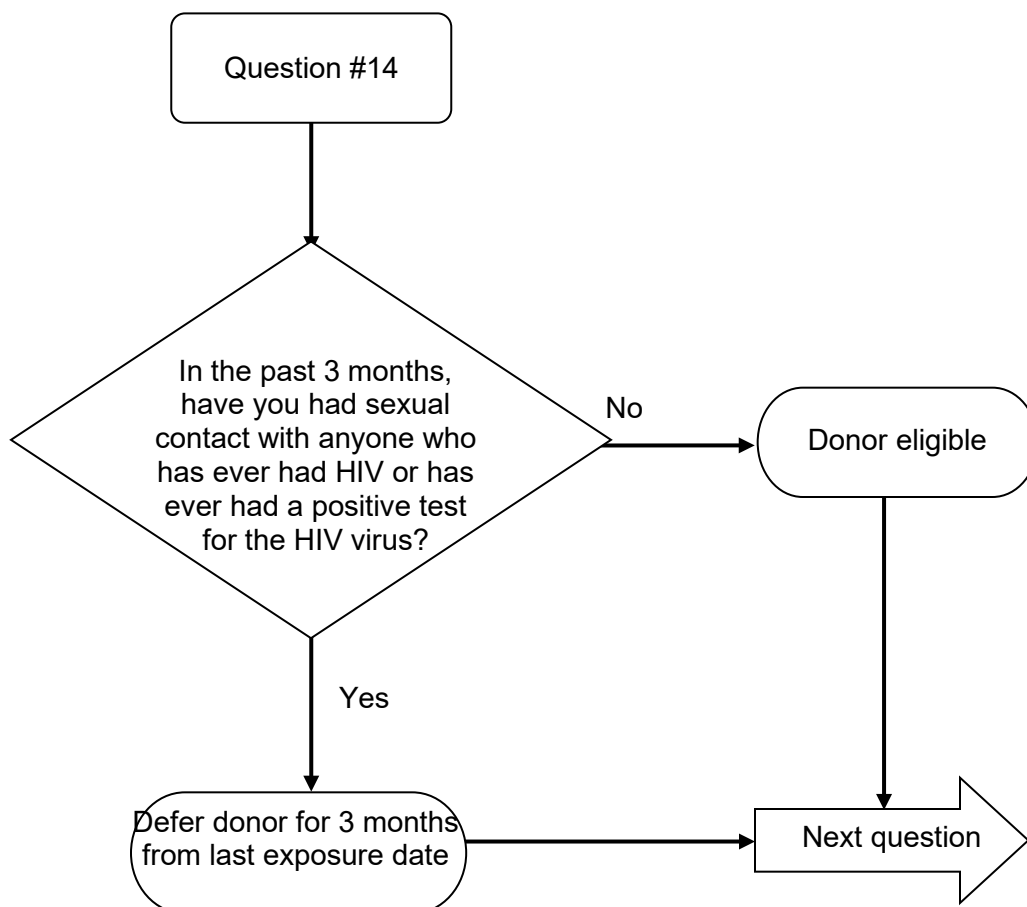
Donor Eligibility: A donor who has been exposed to someone else's blood through a needle-stick should not donate blood or plasma for 3 months following exposure, due to possible transmissibility of infectious disease.



Question #14: In the past 3 months, have you had sexual contact with anyone who has ever had HIV or has ever had a positive test for the HIV?

Donor Eligibility: Persons who have had sexual contact with persons with clinical or laboratory evidence of HIV infection are deferred for 3 months from the date of last contact. HIV may be transmitted through sexual contact with an infected person.

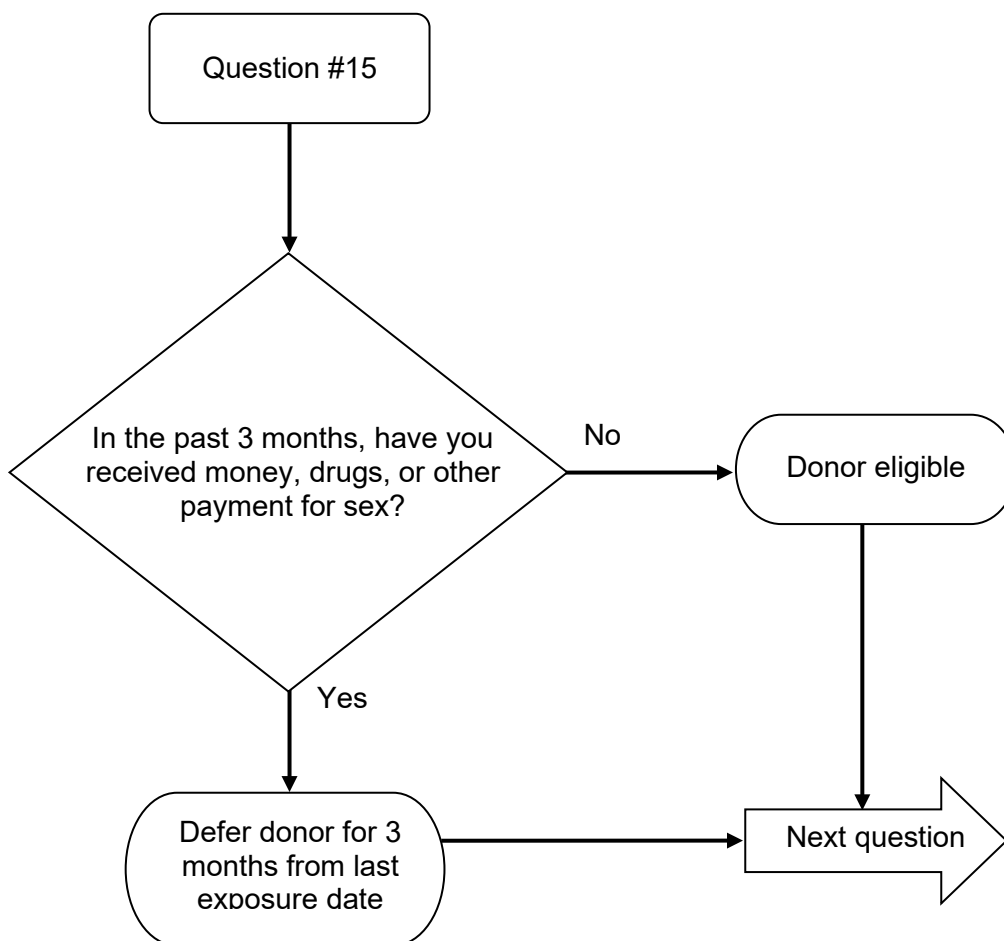
Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Risk Poster provided.



Question #15: In the past 3 months, have you received money, drugs, or other payment for sex?

Donor Eligibility: Donors who received money, drugs, or other payment for sex are deferred for 3 months. HIV and other diseases may be transmitted by sexual contact.

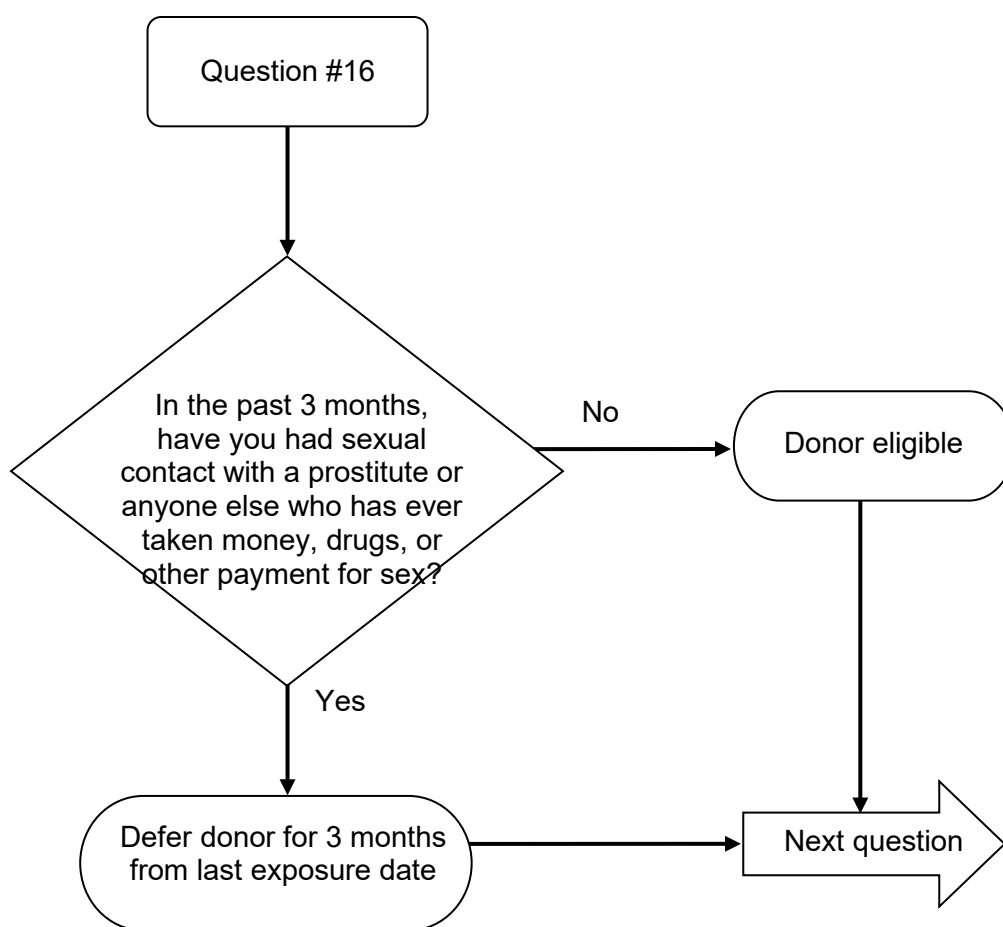
Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Risk Poster provided.



Question #16: In the past 3 months, have you had sexual contact with a prostitute or anyone else who has ever taken money, drugs, or other payment for sex?

Donor Eligibility: Persons who have had sexual contact with anyone who has received money or drugs in exchange for sex (sexual contact) are deferred for 3 months from the date of the last sexual contact. HIV and other diseases may be transmitted through sexual contact. The person who engaged in sex for money or injection drug use could have been infected at any time; therefore, the need to query about their “ever” status.

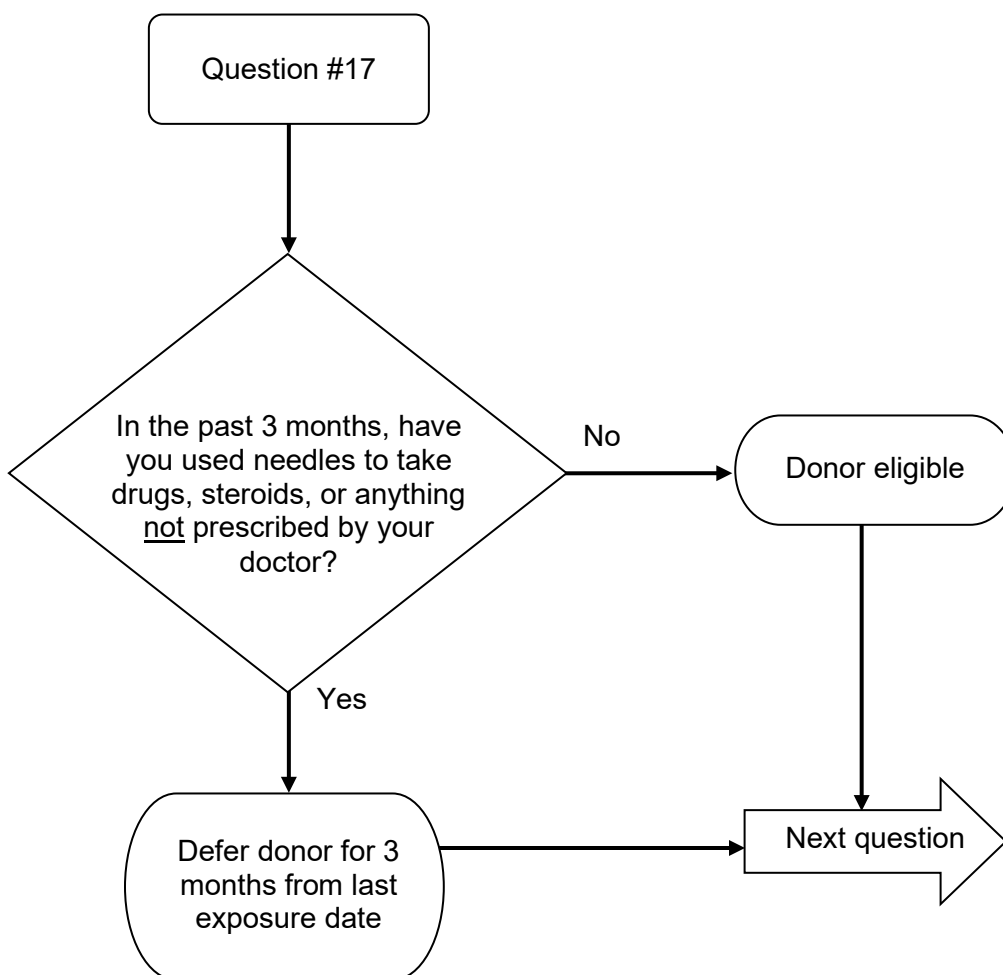
Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Risk Poster provided.



Question #17: In the past 3 months, have you 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 deferred for 3 months due to potential transmission of infectious disease.

Note: The phrase "used needles" 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 for intravenous use.

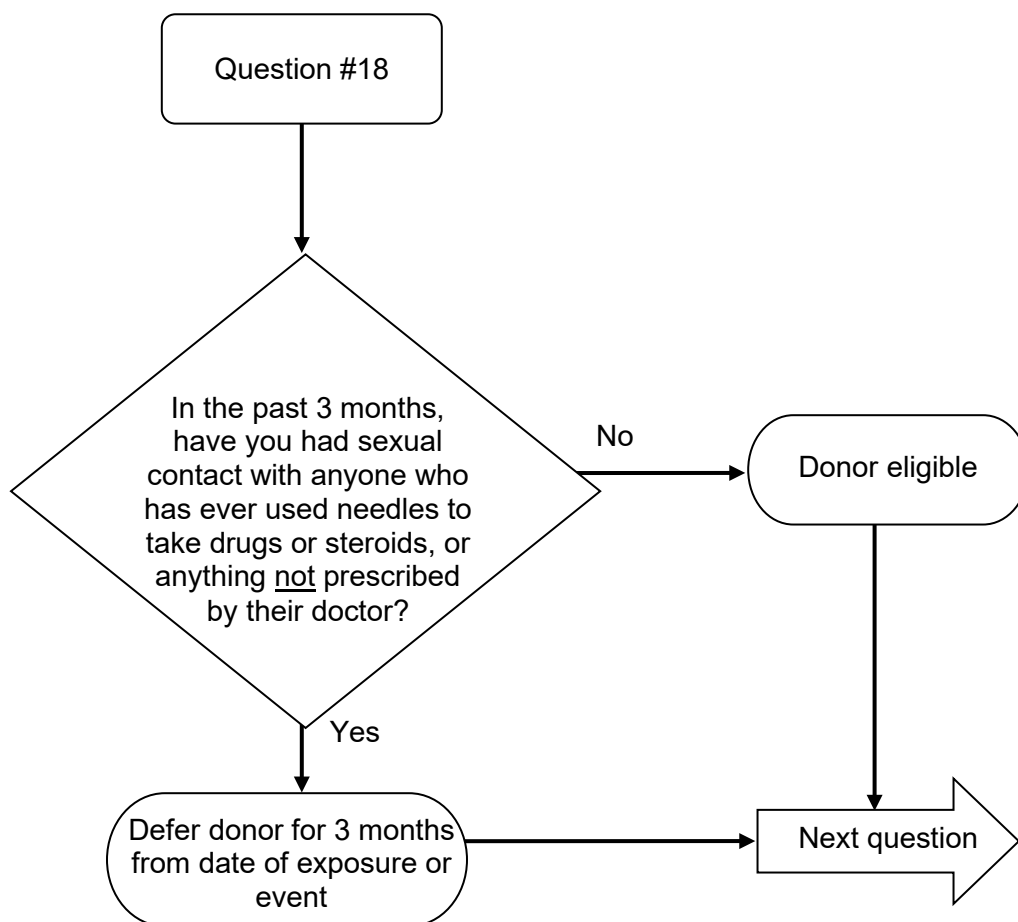


Question #18: In the past 3 months, have you had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything not prescribed by their doctor?

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 3 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 "used needles" 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 for intravenous use.

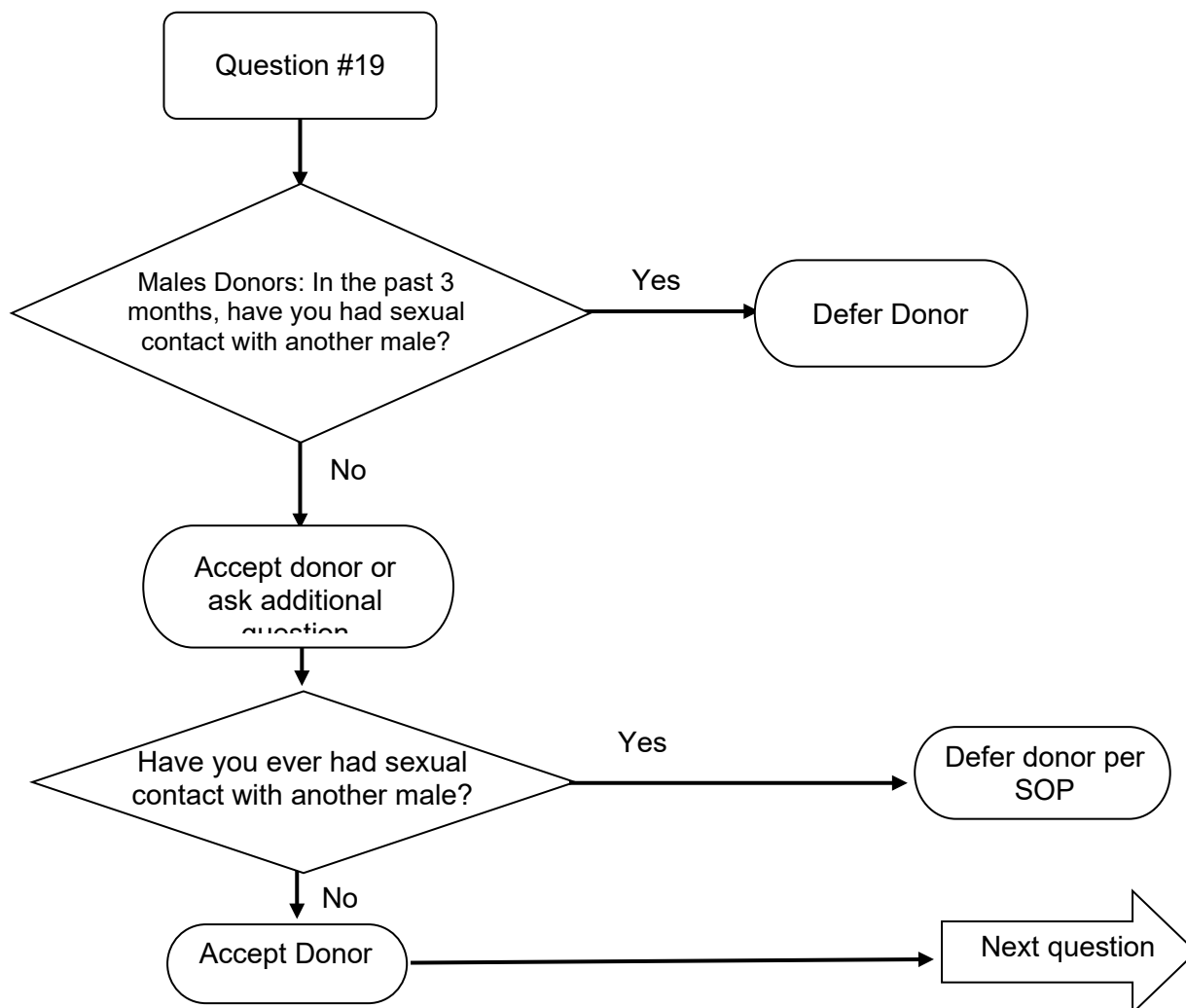


Question #19: Male Donors: In the past 3 months, have you had sexual contact with another male?

Donor Eligibility: A male who has had sexual contact with another male is at increased risk for transmitting HIV and other infectious diseases and is deferred for 3 months from the date of the last sexual contact with a male. HIV and other diseases may be transmitted through sexual contact.

Some regions of the world do not recognize a temporary deferral of any length or have deferral periods that are different than the 3-month deferral period. In order to separate plasma for manufacturing for different regions, donors may be asked an additional question, "Have you ever had sexual contact with another male?" If there is no option for a temporary deferral, companies may wish to use the alternative Question 19, which must be placed in the "Have you ever" section of the questionnaire and renumbered.

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



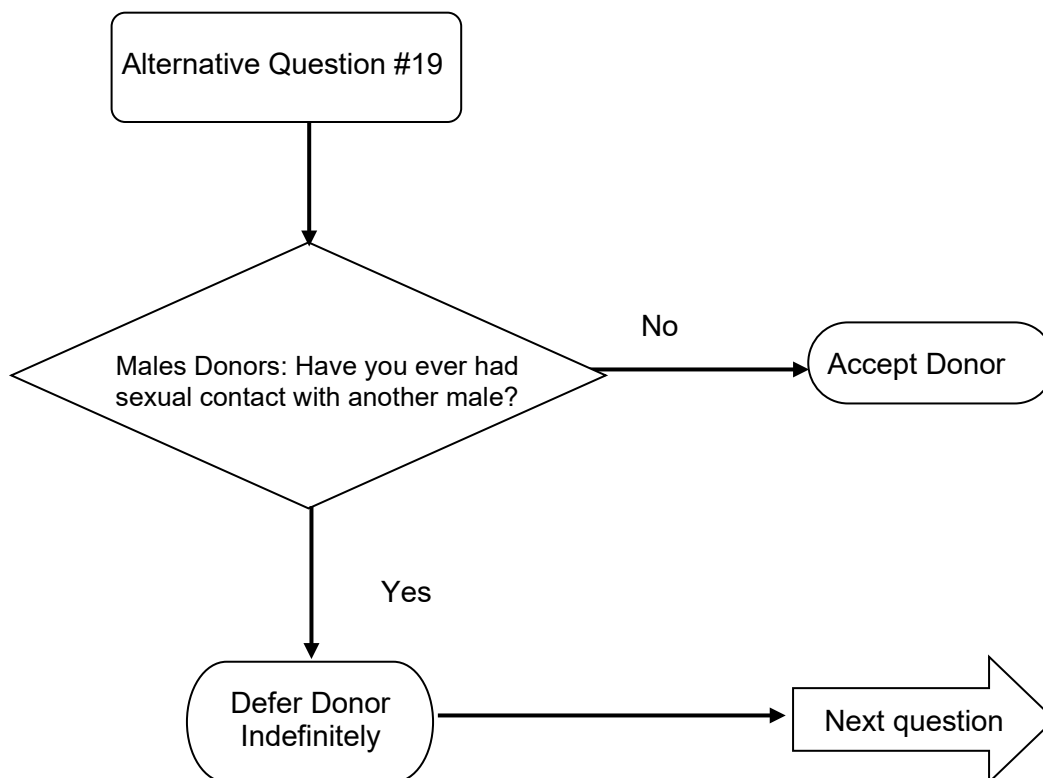
Alternative Question #19: Male Donors: Have you ever had sexual contact with another male?

Donor Eligibility: Male donors who have ever had sexual contact with another male are indefinitely deferred in some regions of the world.

Note 1: If alternative question is used, the question and flowchart must be moved to the “Have you EVER section” and renumbered.

Note 2: In the US, previous donor eligibility was determined using the timeframe “since 1977.” For donors who may provide discrepant information between “since 1977” and “ever,” donor eligibility will require companies to assess “per company policy.”

Note 3: Not all donors define “sex” or “sexual contact” in the same way. The donor must have read the Risk Poster provided.

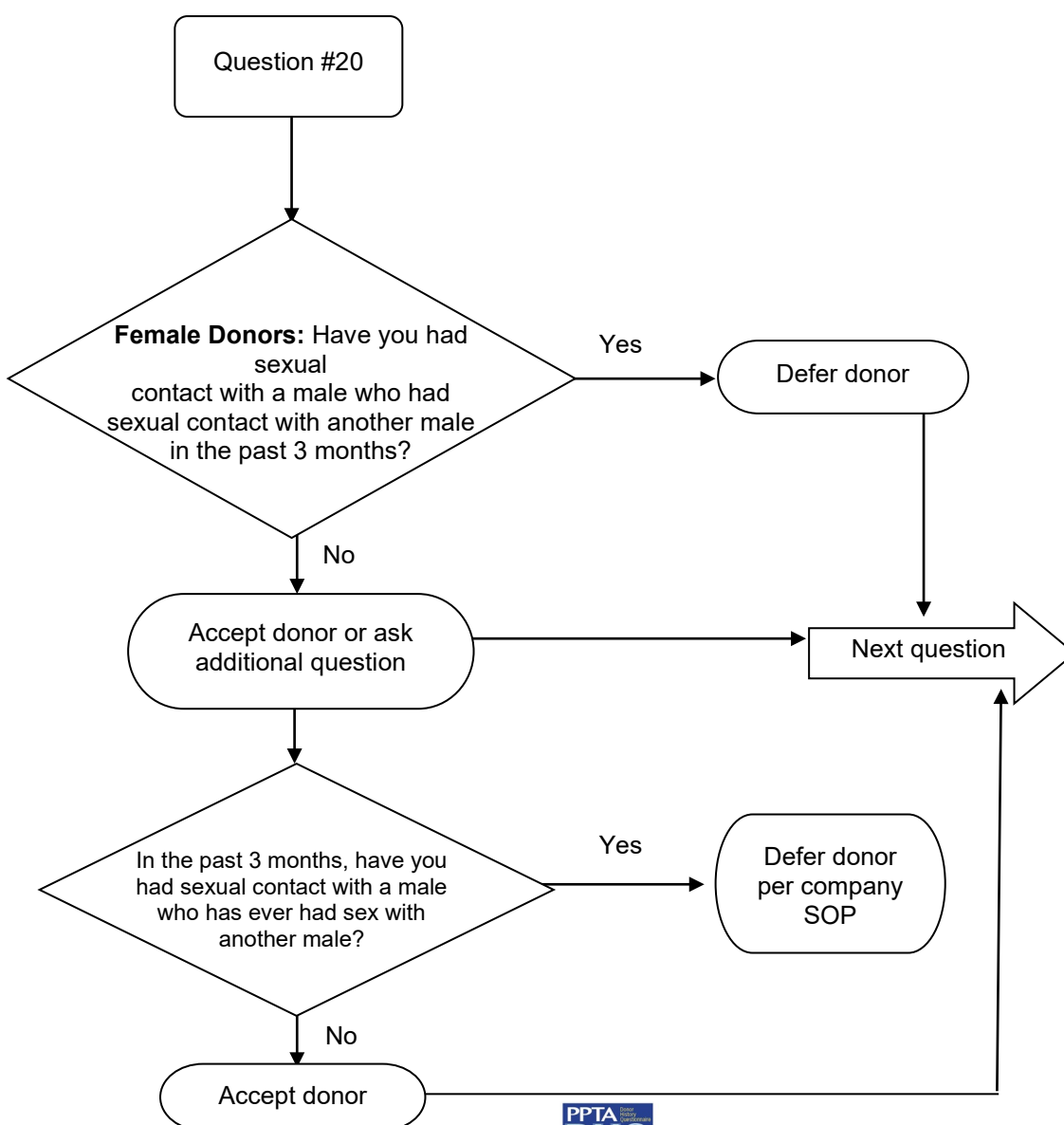


Question #20: Female Donors: In the past 3 months, have you had sexual contact with a male who had sexual contact with another male in the past 3 months?

Donor Eligibility: A male who had sexual contact with another male is at increased risk for transmitting HIV and other infectious diseases. The sexual contacts of the male are also at increased risk for transmitting HIV and other infectious diseases and are deferred for 3 months from the date of the last sexual contact. HIV and other diseases may be transmitted through sexual contact.

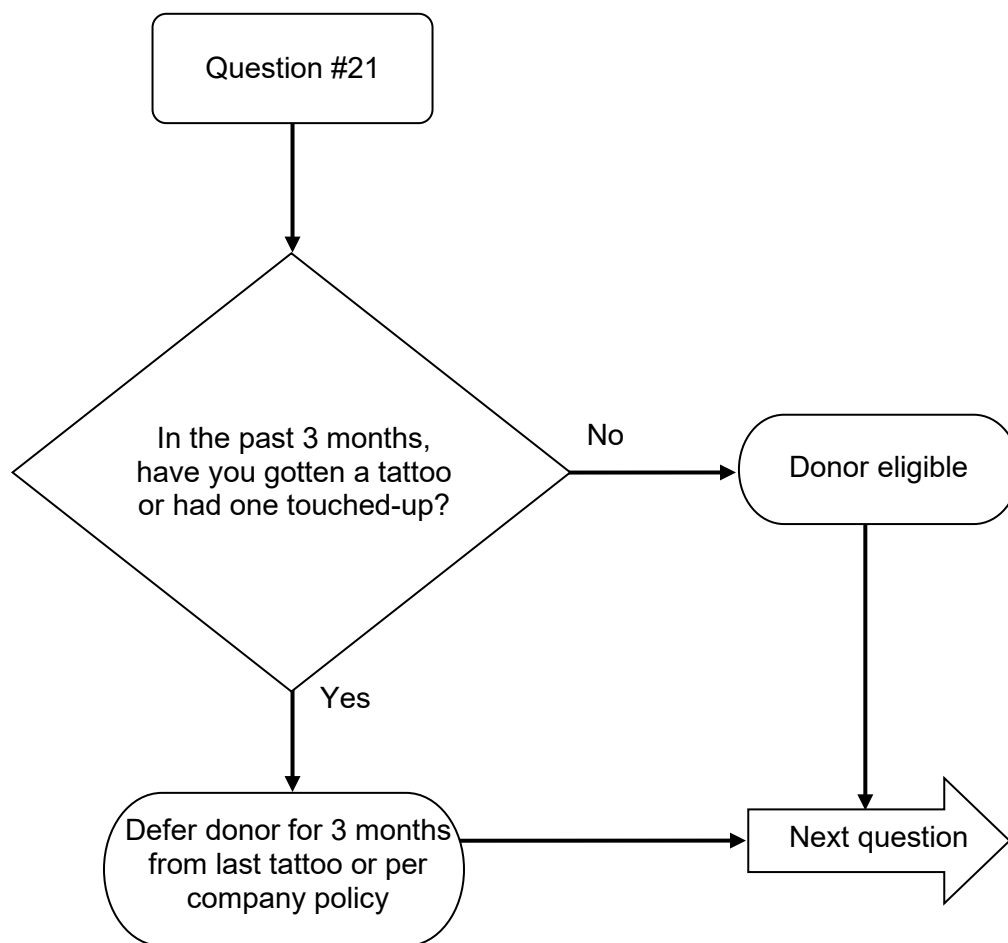
Some regions of the world do not recognize a temporary deferral of any length or for MSM. Companies may elect to ask a follow-up question to capture a female donor who has had sexual contact with a male who has ever had sex with another male.

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



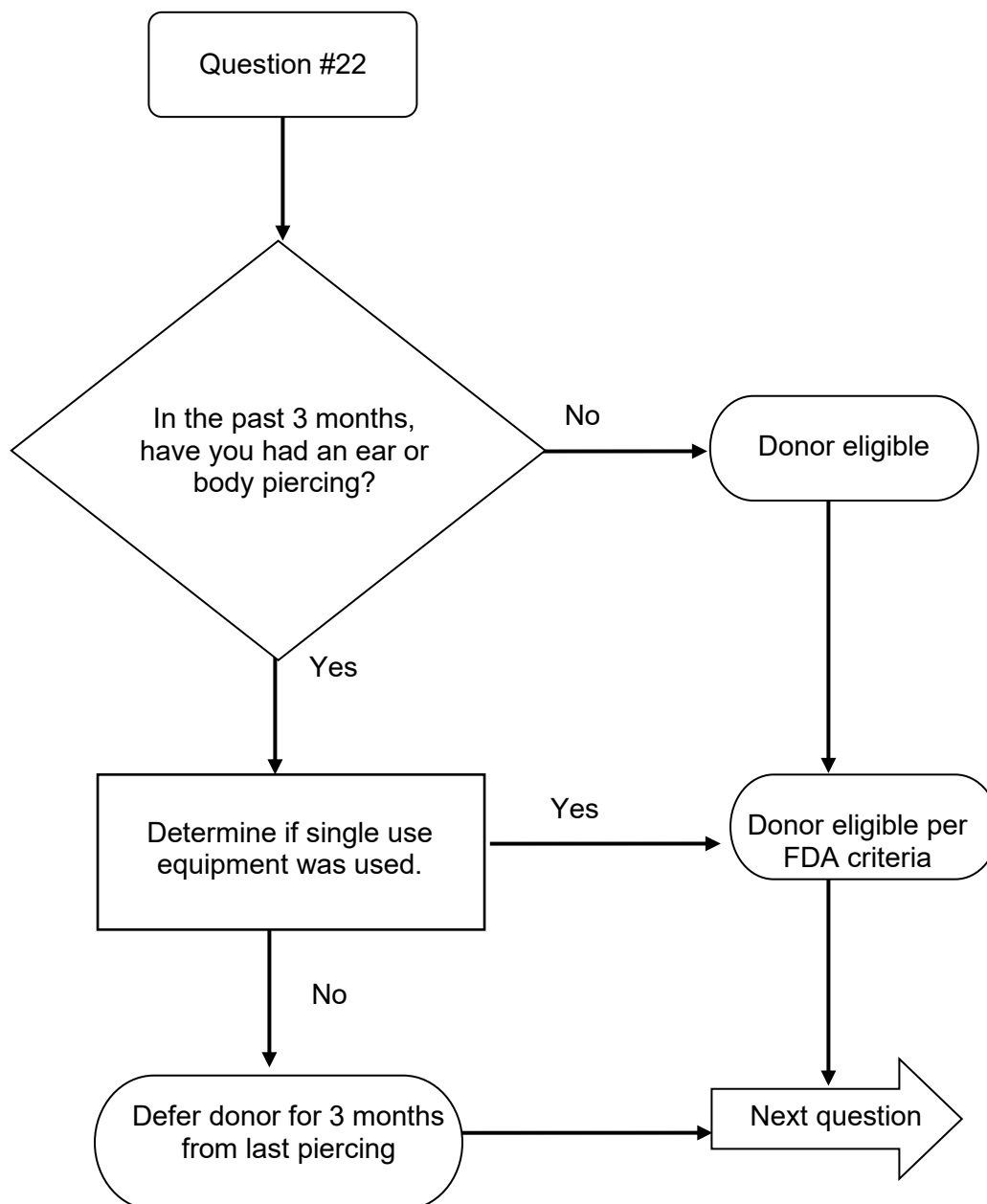
Question #21: In the past 3 months, have you gotten a tattoo or had one touched-up?

Donor Eligibility: Persons who have received a tattoo in the previous 3 months are deferred for 3 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. 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 #22: In the past 3 months, have you had an ear or body piercing?

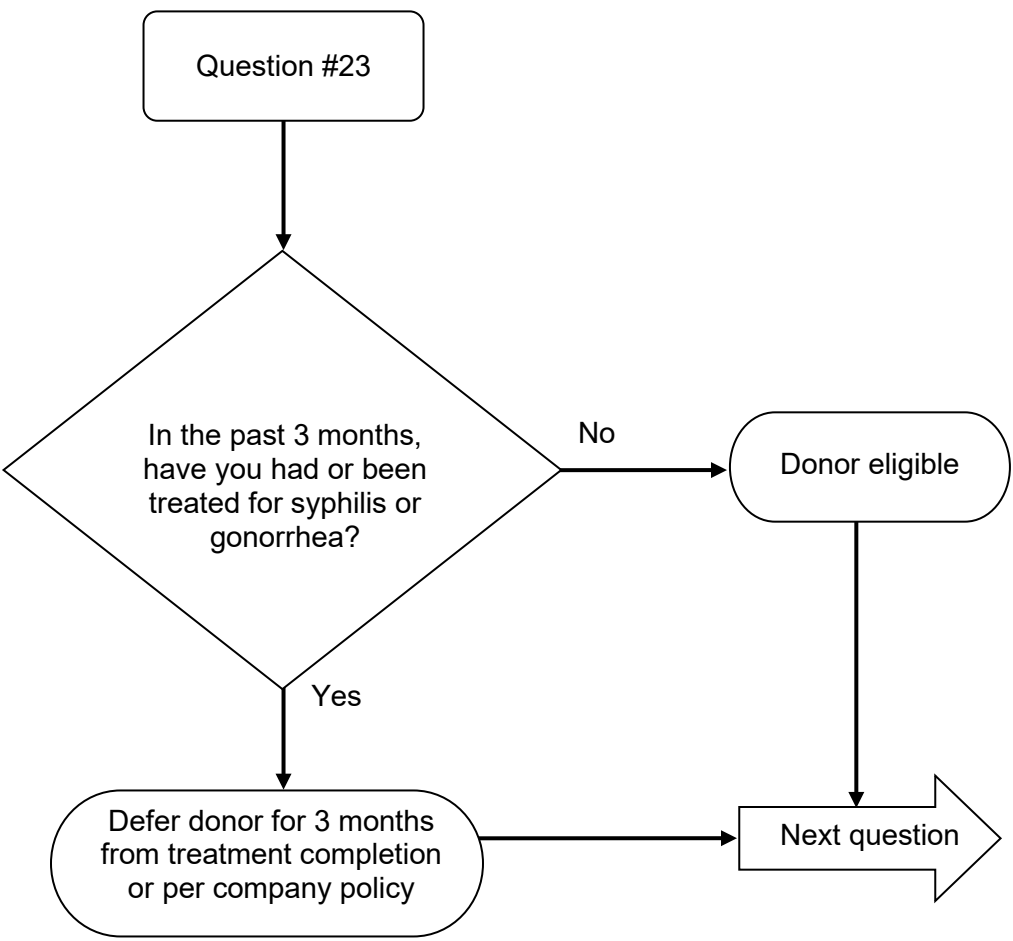
Donor Eligibility: Persons who have had ear or body piercing during the previous 3 months are usually deferred for 3 months from the date of procedure, unless ear or body piercing have been done using single-use equipment. There may be a risk of transmission of infectious diseases if the equipment is re-used. 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).



Question #23: In the past 3 months, have you had or been treated for syphilis or gonorrhea?

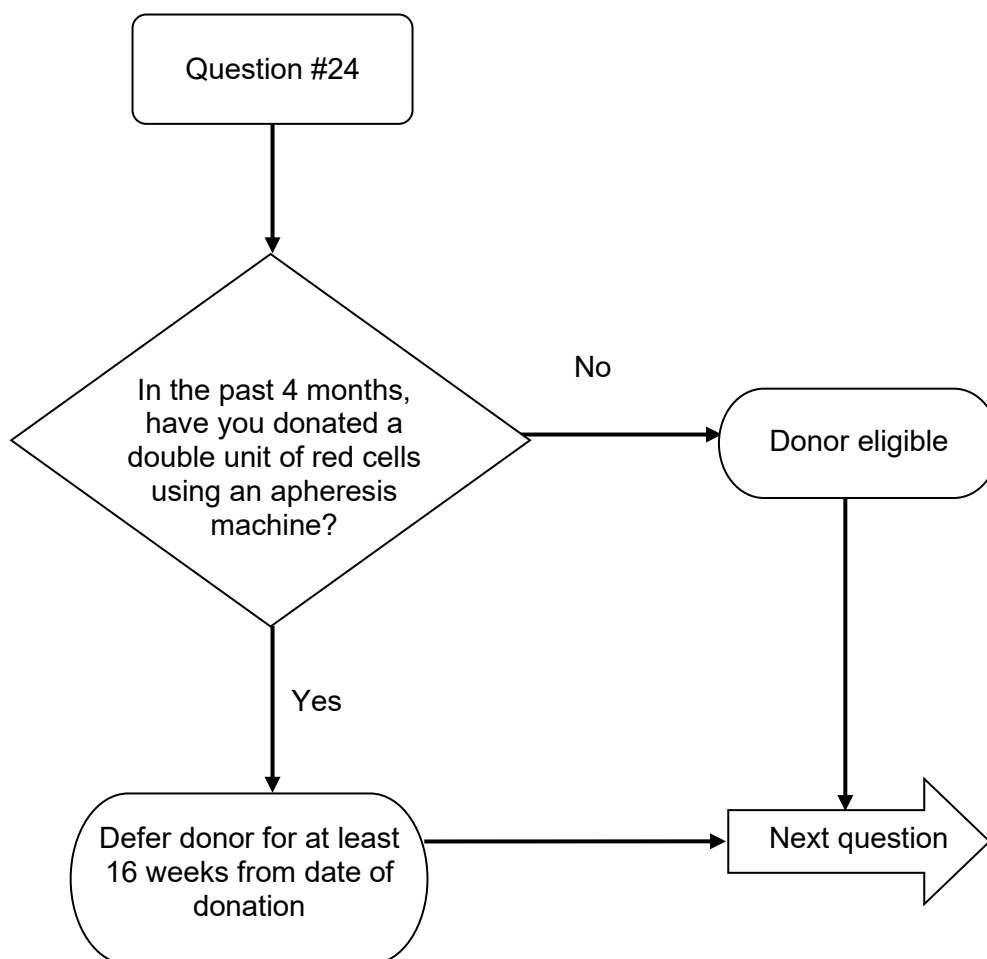
Donor Eligibility: Persons who have had syphilis or gonorrhea or treatment for either are deferred for a minimum of 3 months from the date that treatment is completed.

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



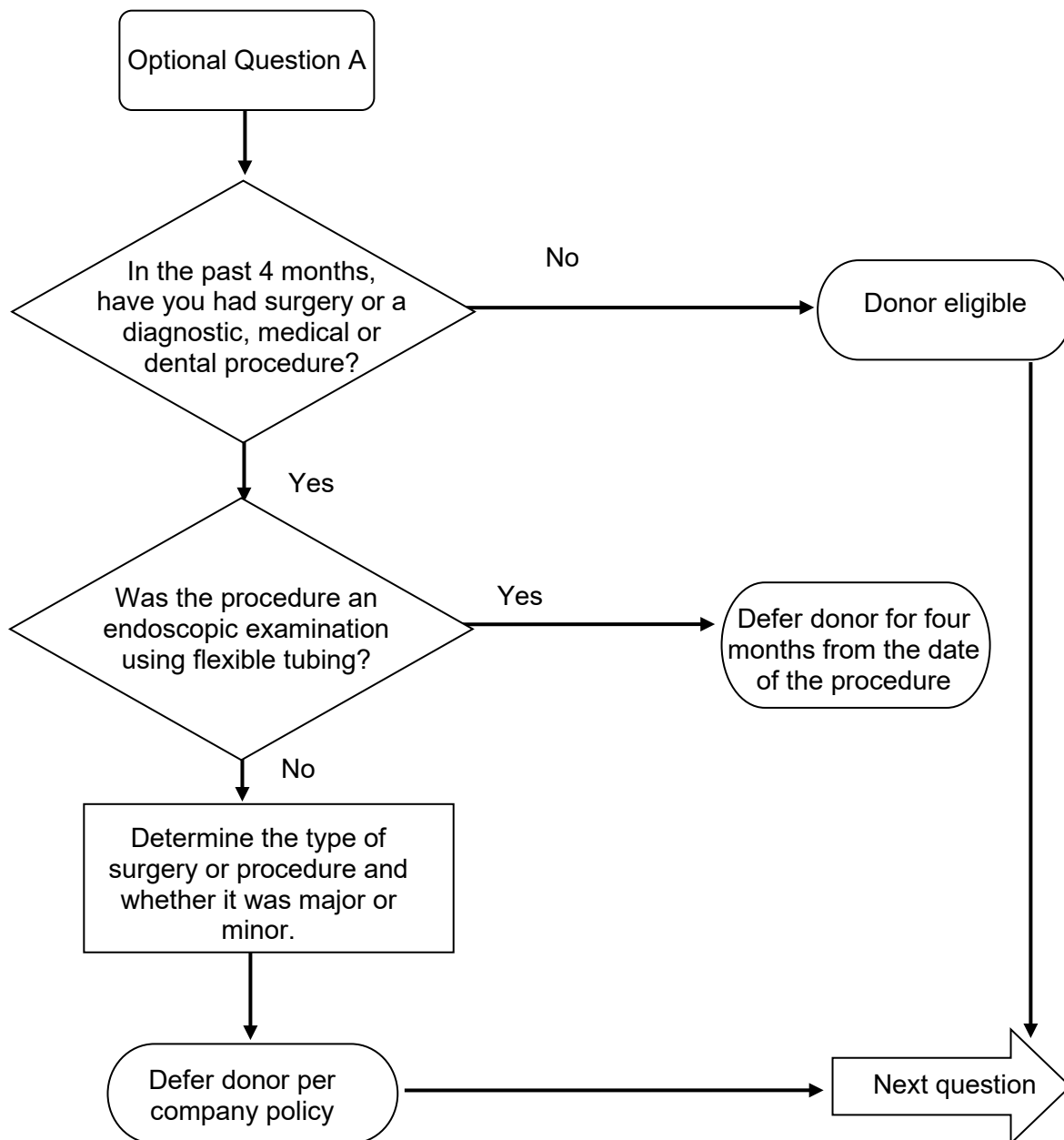
Question #24: In the past 4 months, have you donated a double unit of red cells using an apheresis machine?

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 minimum period of 16 weeks. [21 CFR 630.15(b)(6)(ii)]. 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 16-week deferral is needed for the donor to replace the red cells donated. Should a donor answer "yes" to the question, the company may defer the donor or assess if it has been at least 16 weeks since the double unit of red cells was collected.



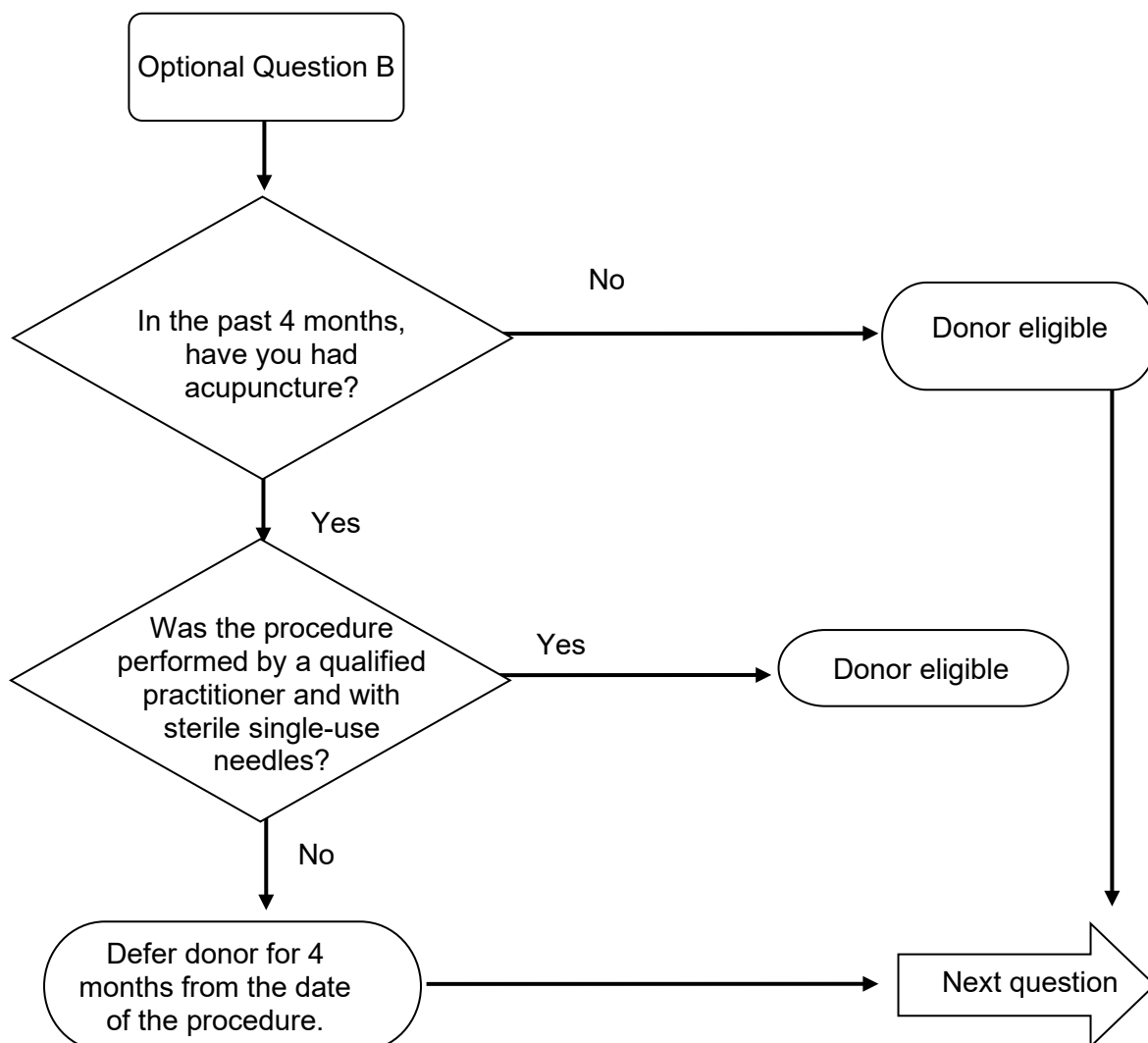
Optional Question A: In the past 4 months, have you had surgery or a diagnostic, medical or dental procedure?

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 4-month deferral when NAT testing is performed.



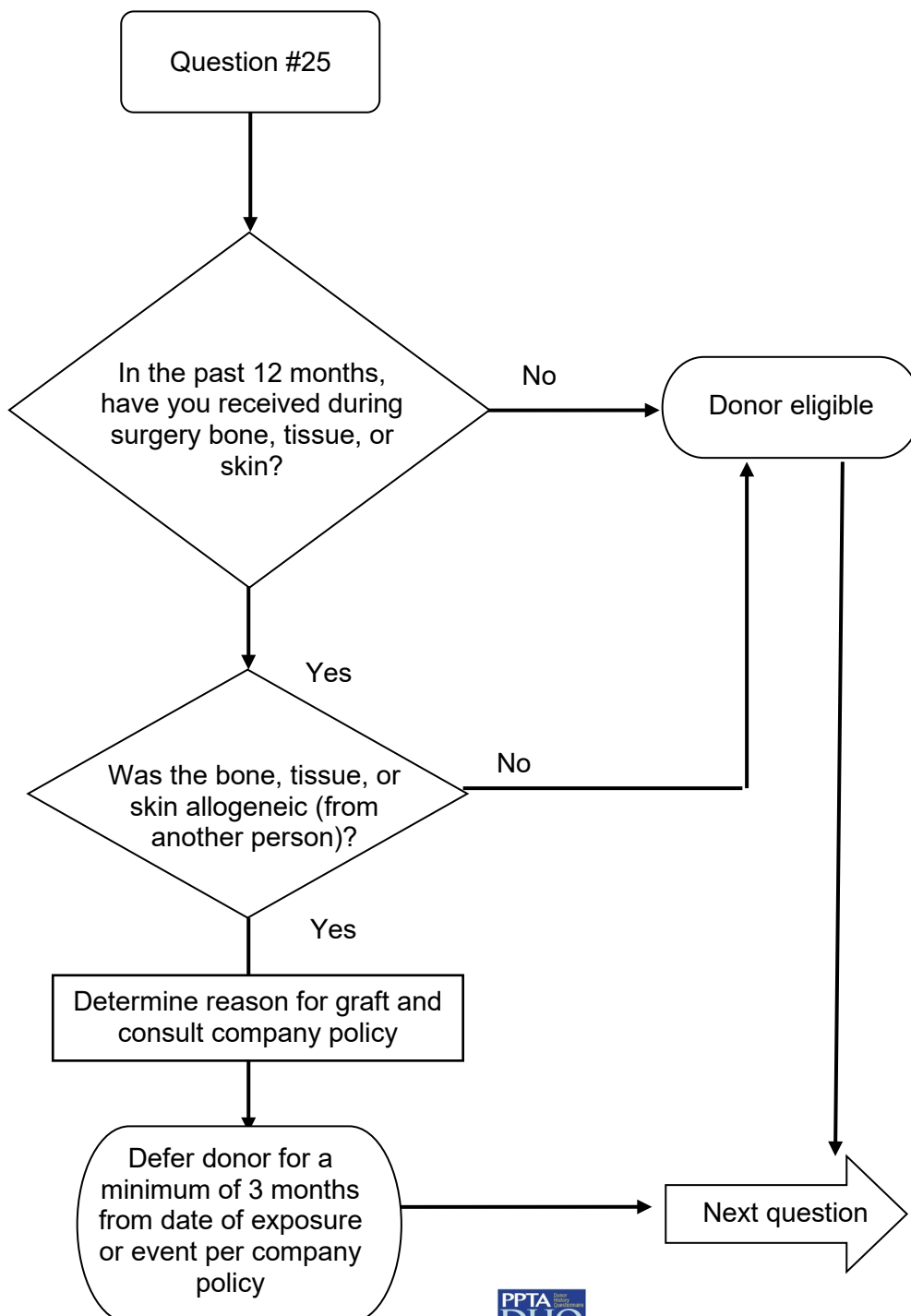
Optional Question B: In the past 4 months, have you had acupuncture?

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.



Question #25: In the past 12 months, have you received during surgery bone, tissue, or skin?

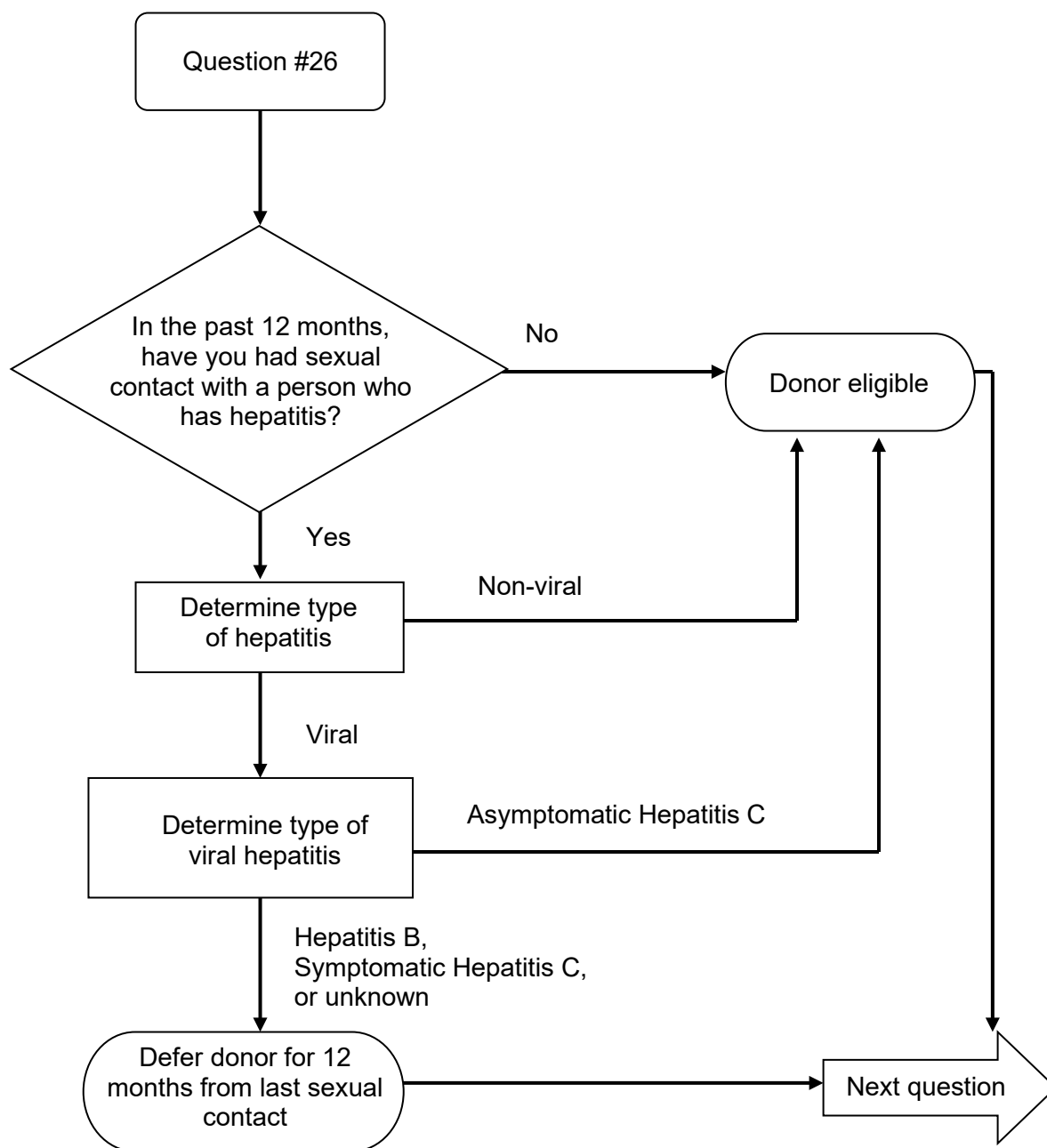
Donor Eligibility: A donor who has been exposed to allogeneic tissues during surgery should not donate blood or plasma for a minimum of 3 months following exposure, due to possible transmissibility of infectious disease. Depending on the type of graft and for donor health reasons, companies may elect to defer for a longer period of time. Therefore, the donor is asked the question in the 12-month time frame and deferred per company policy.



Question #26: 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 B, may be spread through sexual contact.

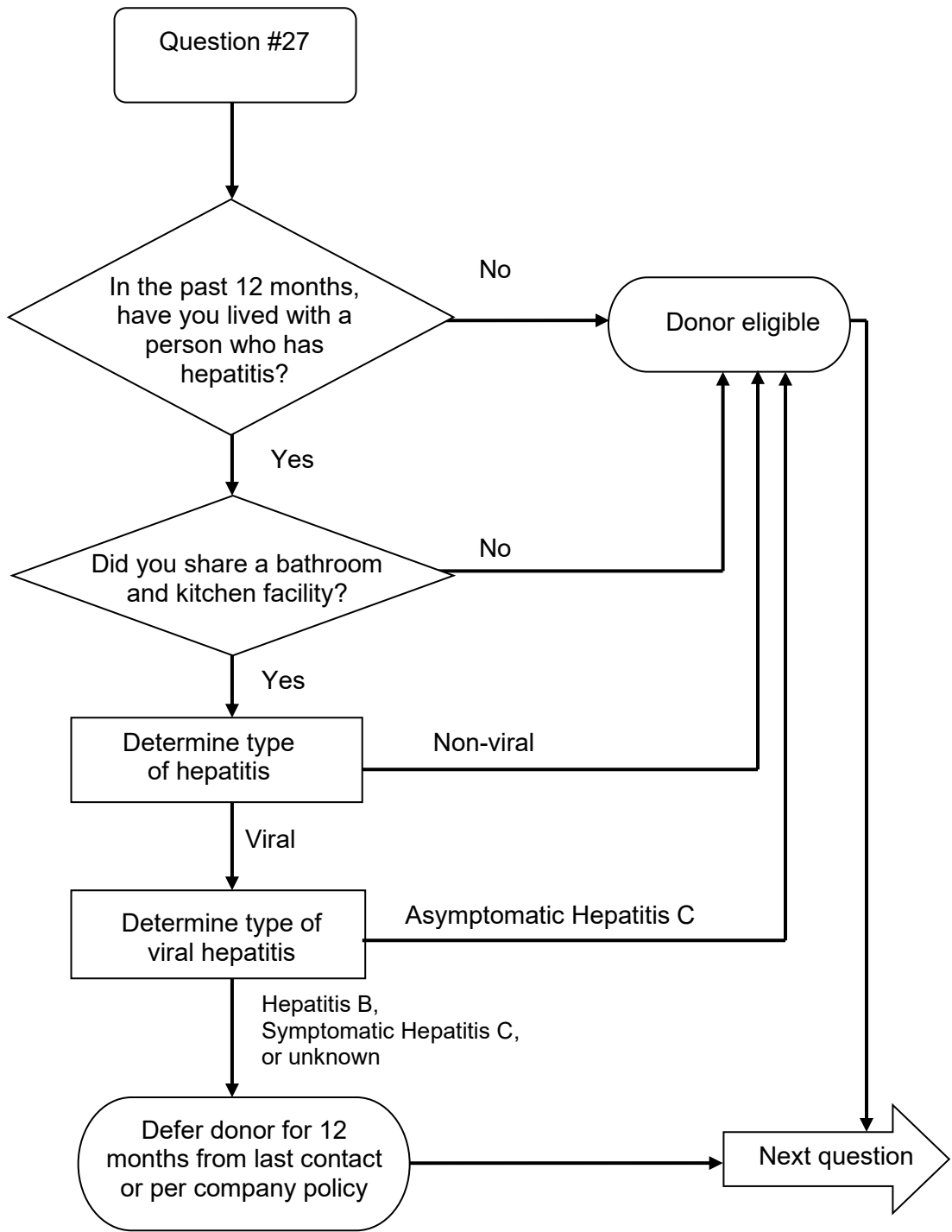
Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Risk Poster provided.



Question #27: 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 B, may be spread through saliva.

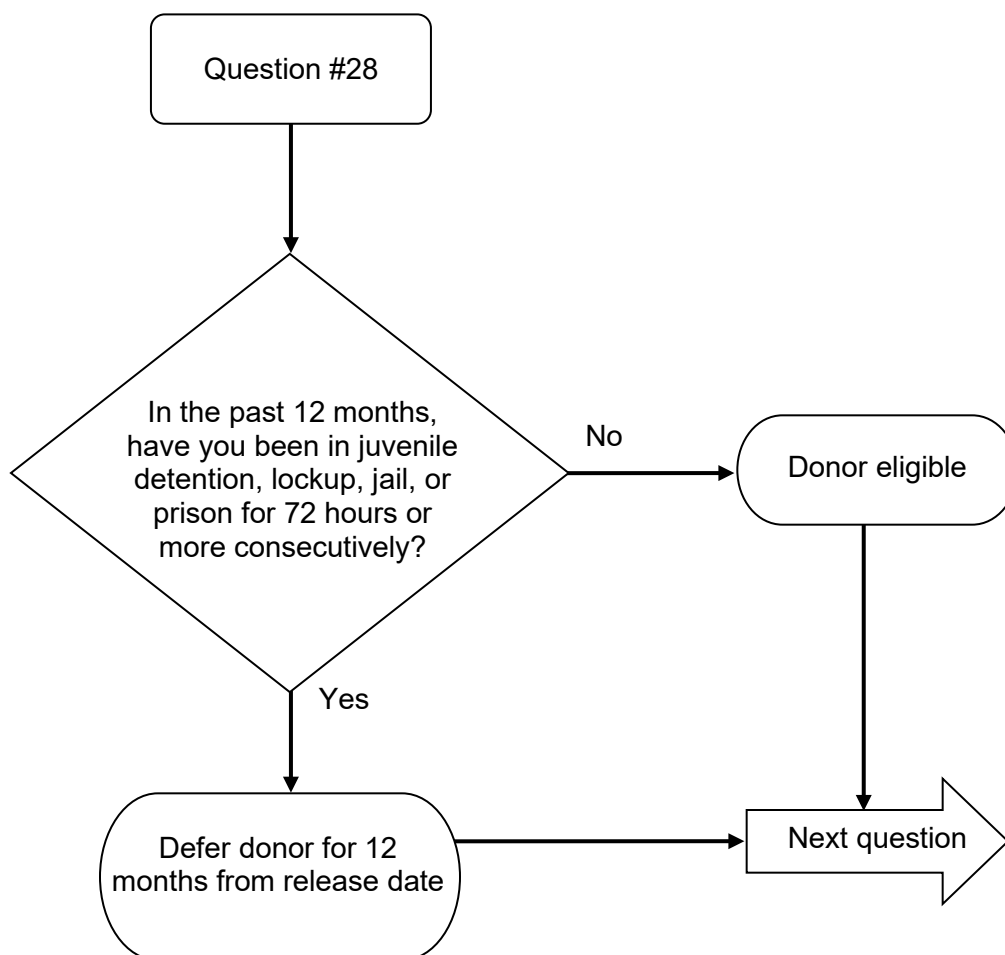
Note: "Lived with" means residing at the same address and sharing bathroom and kitchen facilities.



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

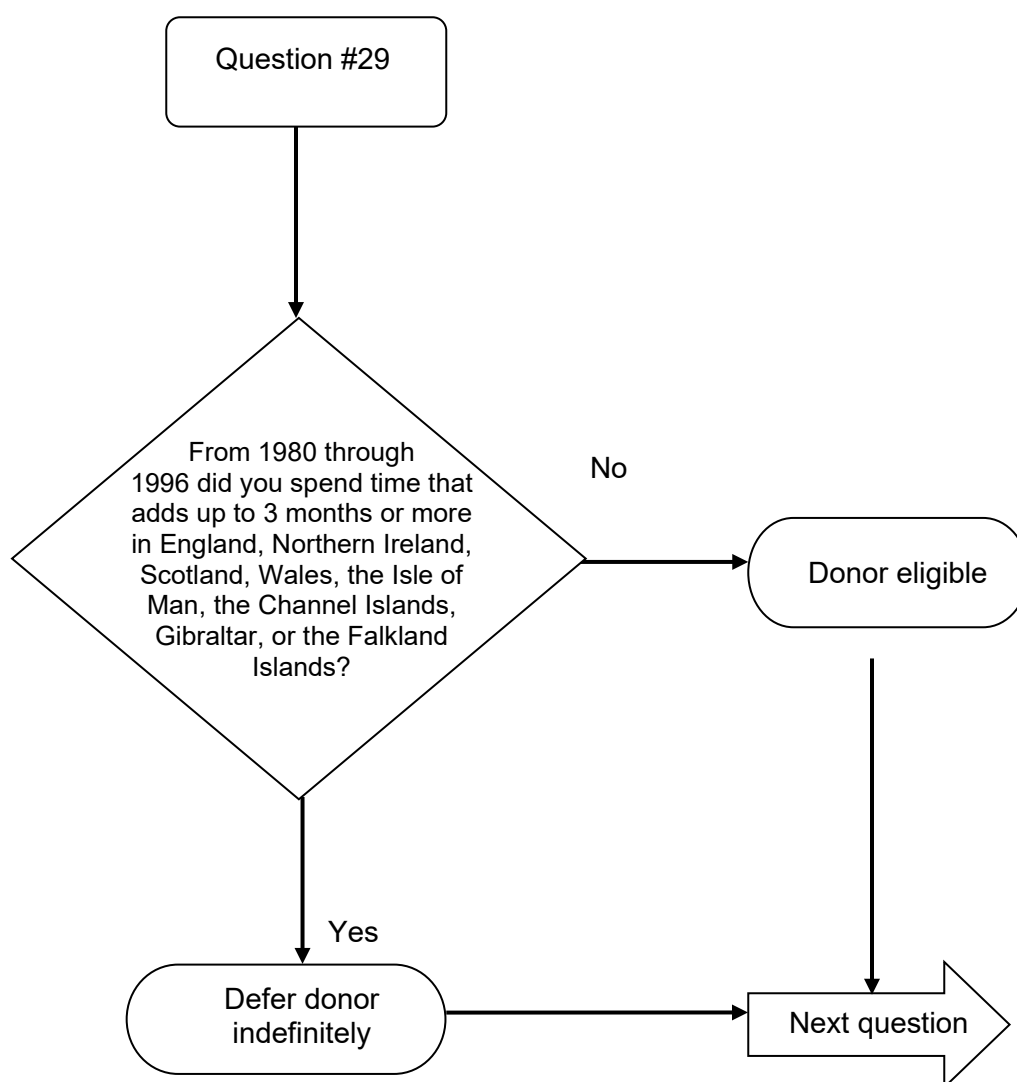
Donor Eligibility: Persons who have been detained or incarcerated in a facility (juvenile detention, lockup, jail, or prison) for 72 hours or more consecutively (three days) are deferred for 12 months from the date of occurrence. These persons are at higher risk for exposure to infectious diseases.

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



Question #29: From 1980 through 1996 did you spend time that adds up to three months or more in England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands?

Donor Eligibility: Donors who have spent time that adds up to three months or more in the UK 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.



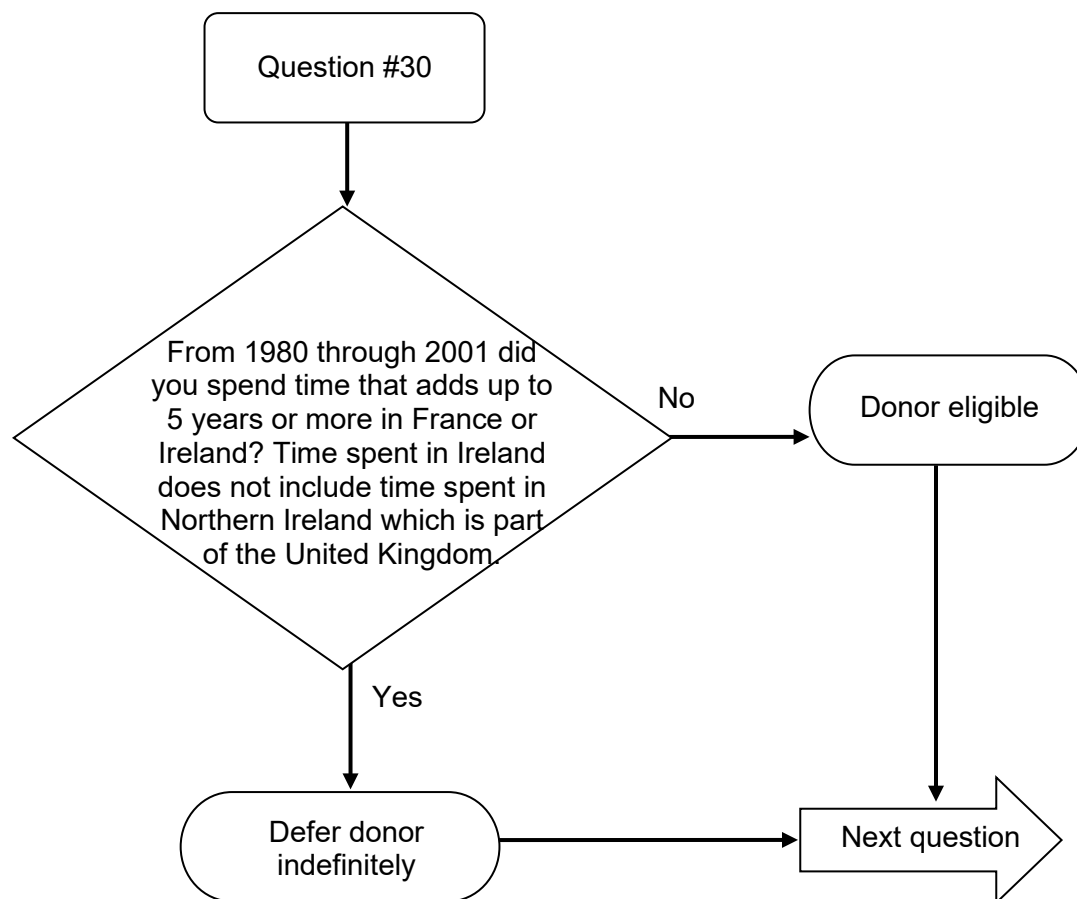
Question #30: From 1980 through 2001, did you spend time that adds up to five years or more in France or Ireland? .Time spent in Ireland does not include time spent in Northern Ireland which is part of the United Kingdom.

Donor Eligibility: Donors who have spent time that adds up to five years or more cumulatively in France or Ireland from 1980 through 2001 may be at risk of developing vCJD from eating beef in France or Ireland and is indefinitely deferred. There may be risk of transmitting vCJD through blood transfusion.

Note:

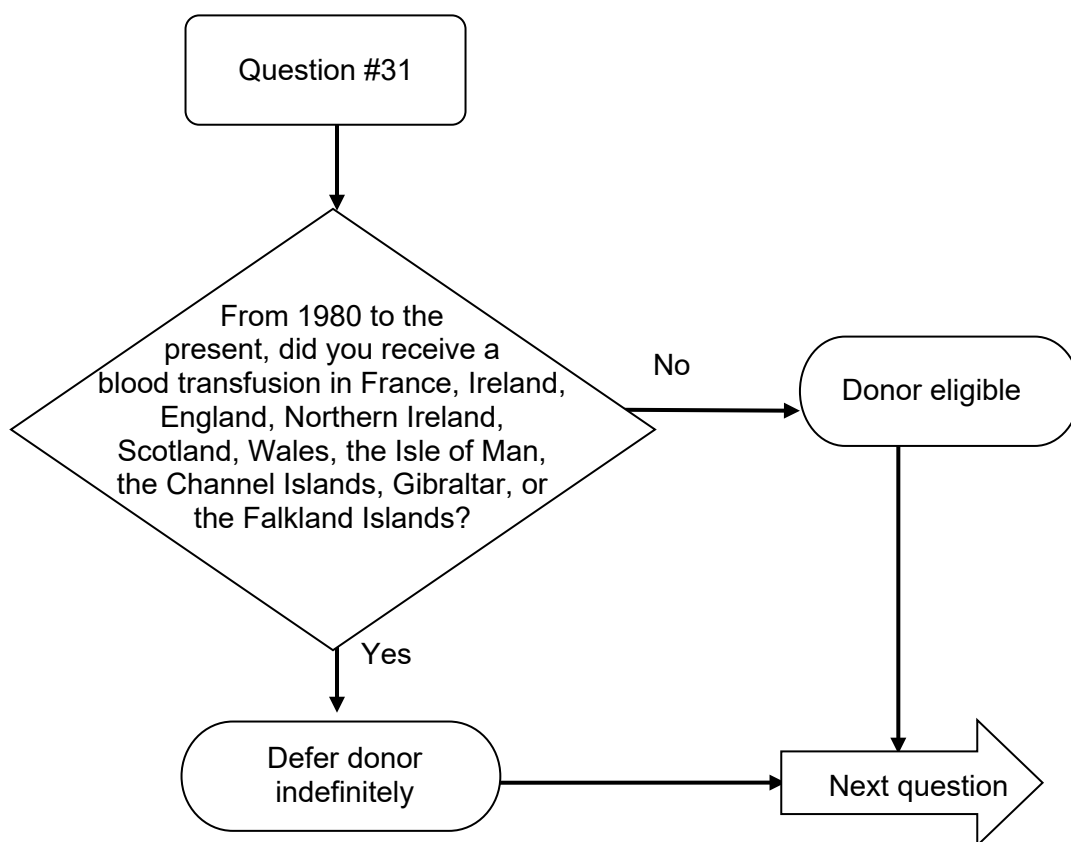
As described in the April 2020 CJD Guidance:

- This assessment does not include time spent in Northern Ireland, which is a part of the United Kingdom (England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands), and is evaluated separately in Question 29.
- The deferral for France does not include the overseas departments.



Question #31: From 1980 to the present, did you receive a blood transfusion in France, Ireland, England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands?

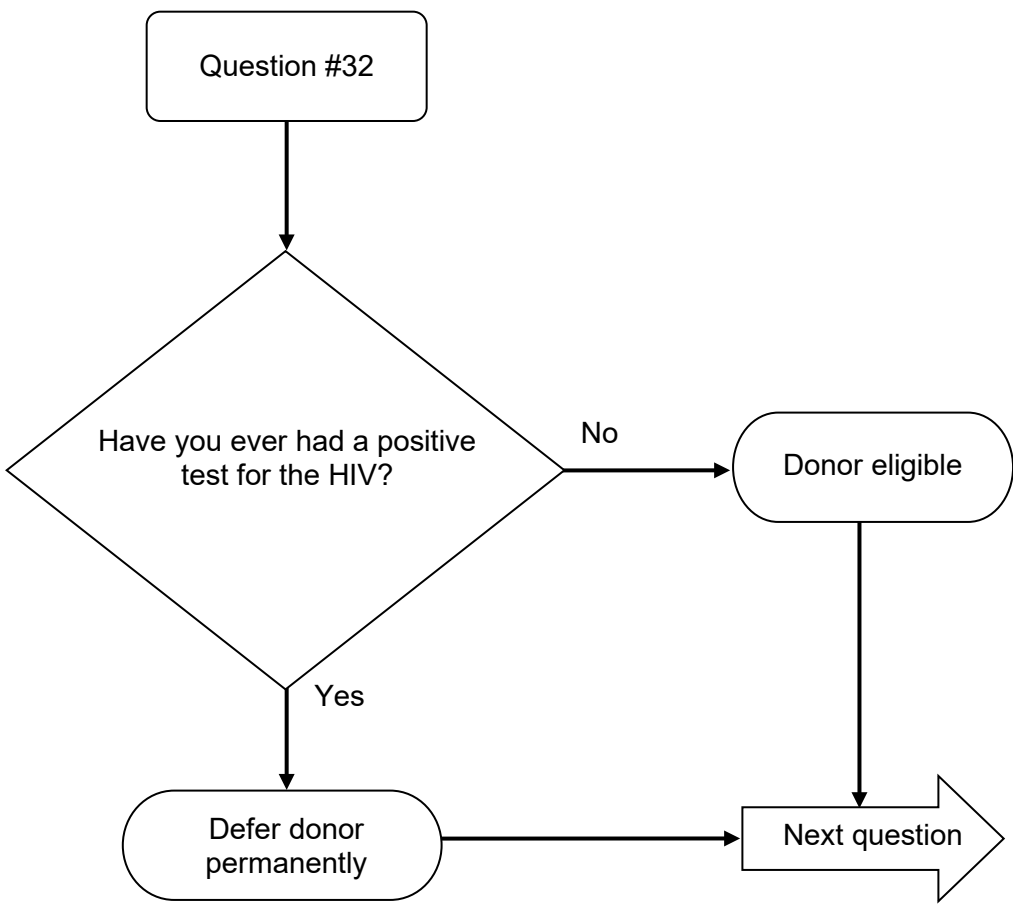
Donor Eligibility: Donors who received a transfusion of blood, platelets, plasma, cryoprecipitate, or granulocytes in France, Ireland, England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands from 1980 to the present are indefinitely deferred.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



Question #32: Have you ever had a positive test for the HIV?

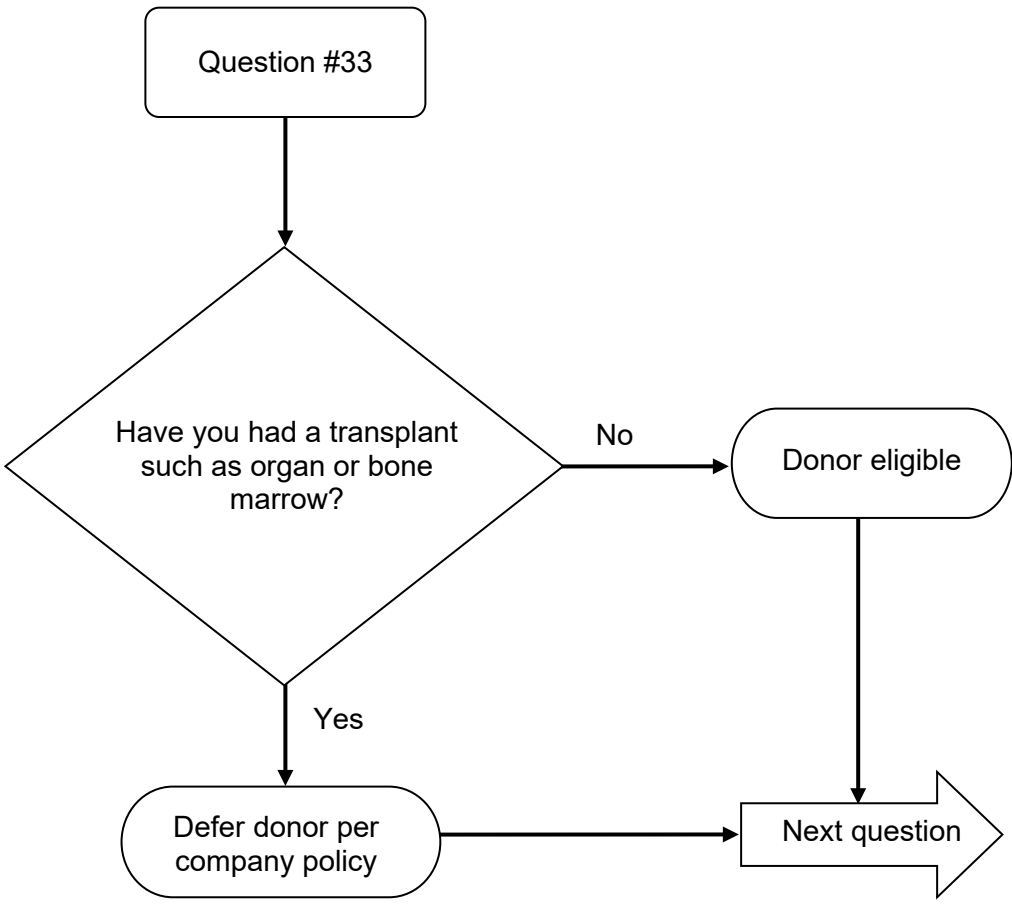
Donor Eligibility: Donors with clinical or laboratory evidence of HIV are permanently deferred.

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



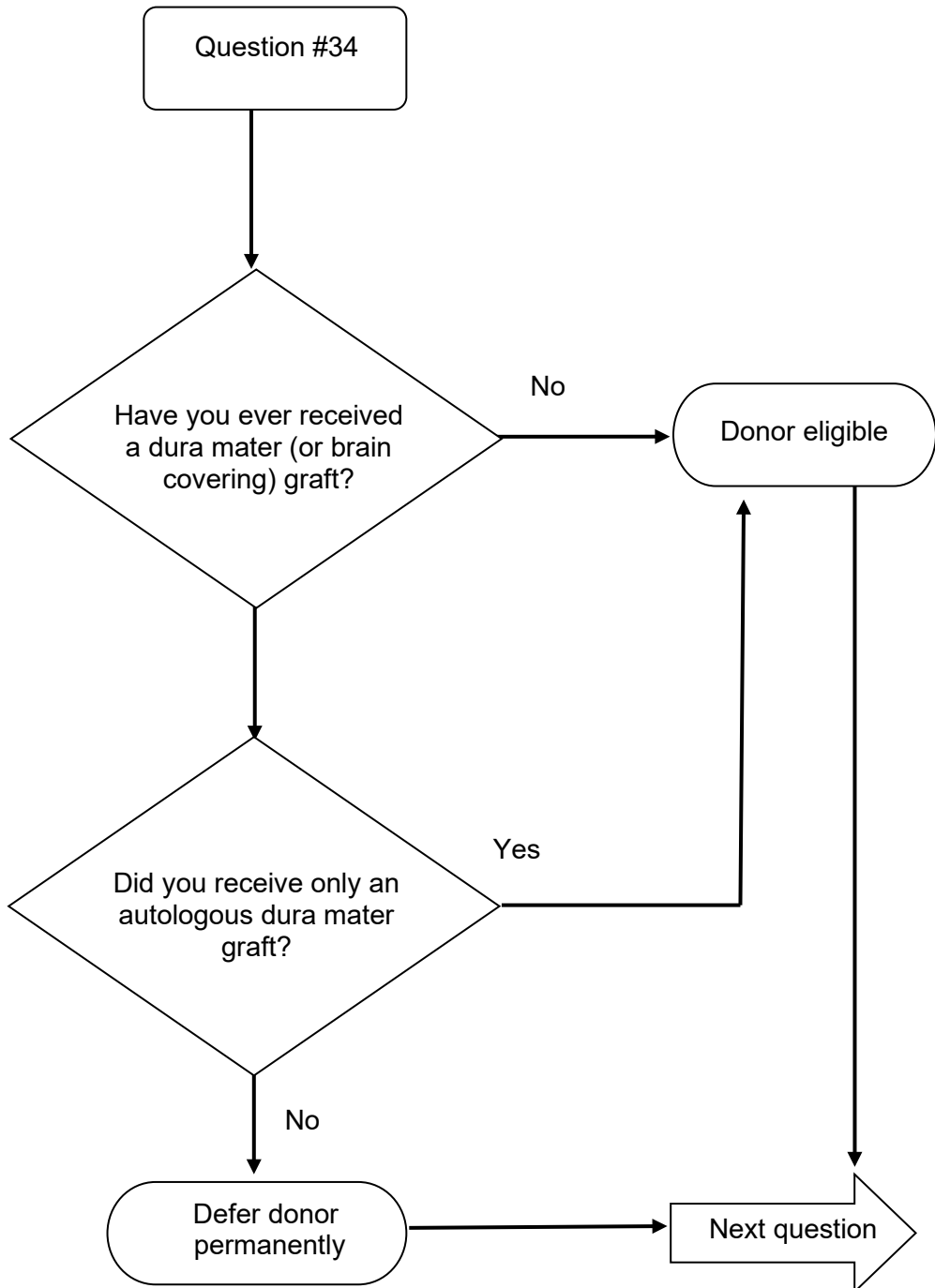
Question #33: Have you ever had a transplant such as organ or bone marrow?

Donor Eligibility: A donor who has had an organ or bone marrow transplant should not donate plasma. Exceptions can be made on a case-by-case basis per company policy; however, deferral cannot be less than 3 months.



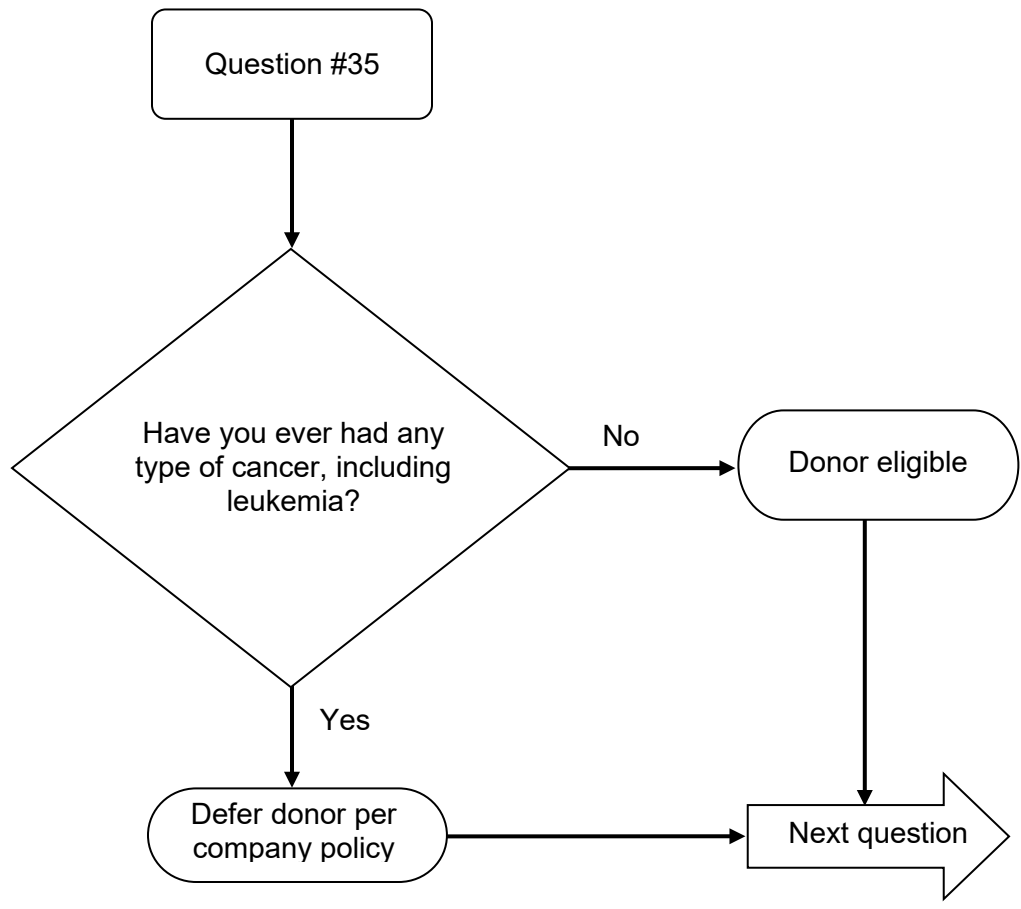
Question #34: Have you ever received a dura mater (or brain covering) graft?

Donor Eligibility: Donors who have received a human cadaveric (allogeneic) dura mater transplant or graft may be at risk for Creutzfeldt-Jakob disease and are permanently deferred. Autologous dura mater grafts are acceptable.



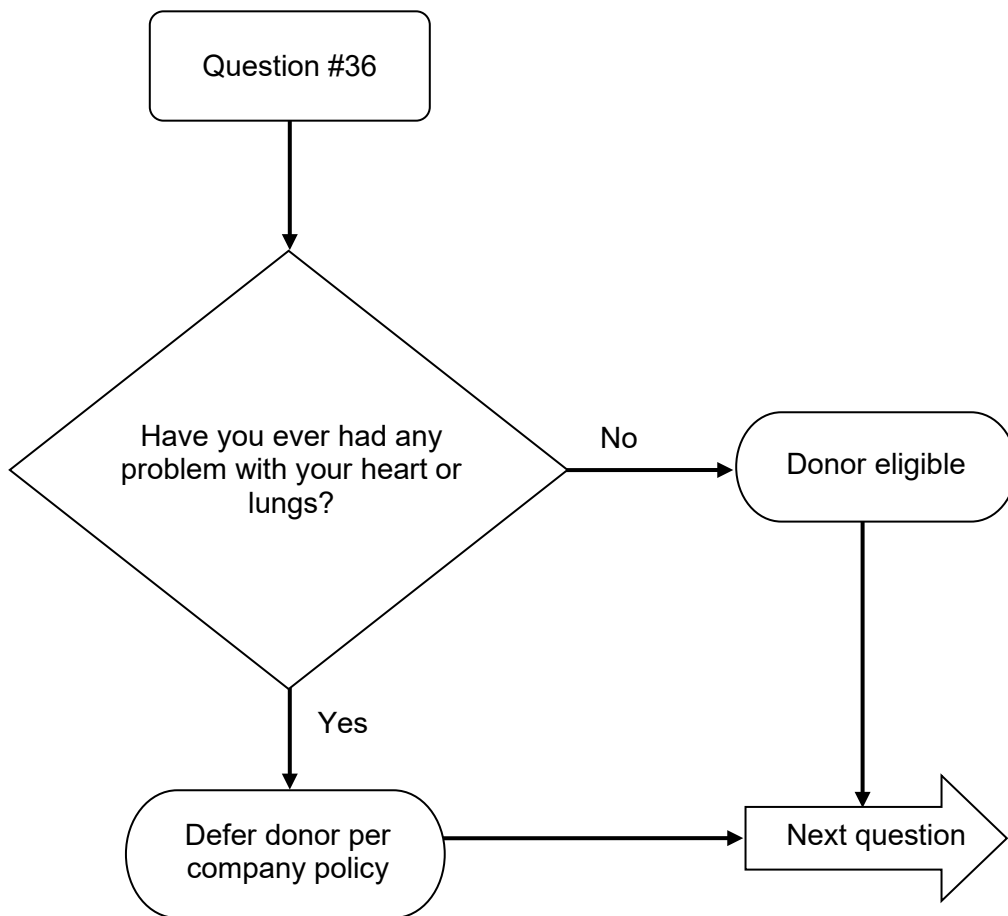
Question #35: Have you ever had any type of cancer, including leukemia?

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



Question #36: Have you ever had any problem with your heart or lungs?

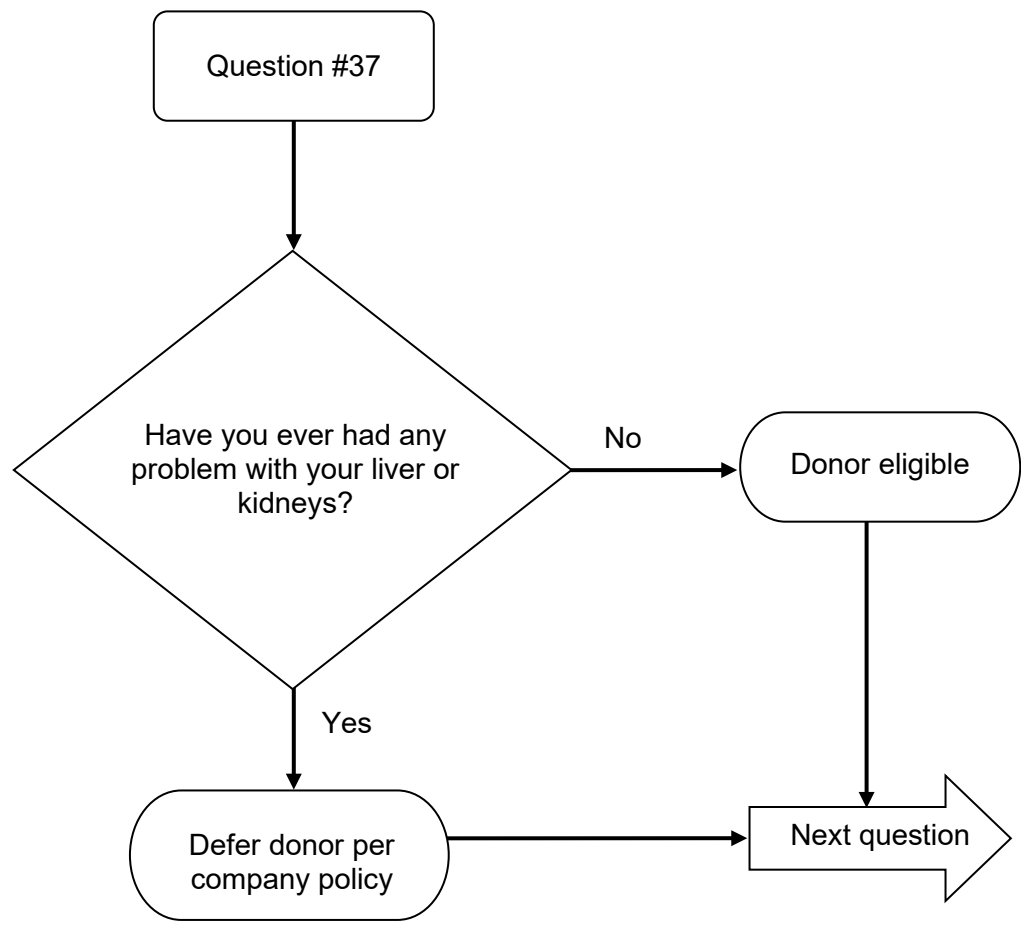
Donor Eligibility: Donors must be free of acute respiratory disease. Donors with a history of diseases of the heart and lungs, including acute diseases, must be evaluated (follow company policy).



Question #37: Have you ever had any problem with your liver or kidneys?

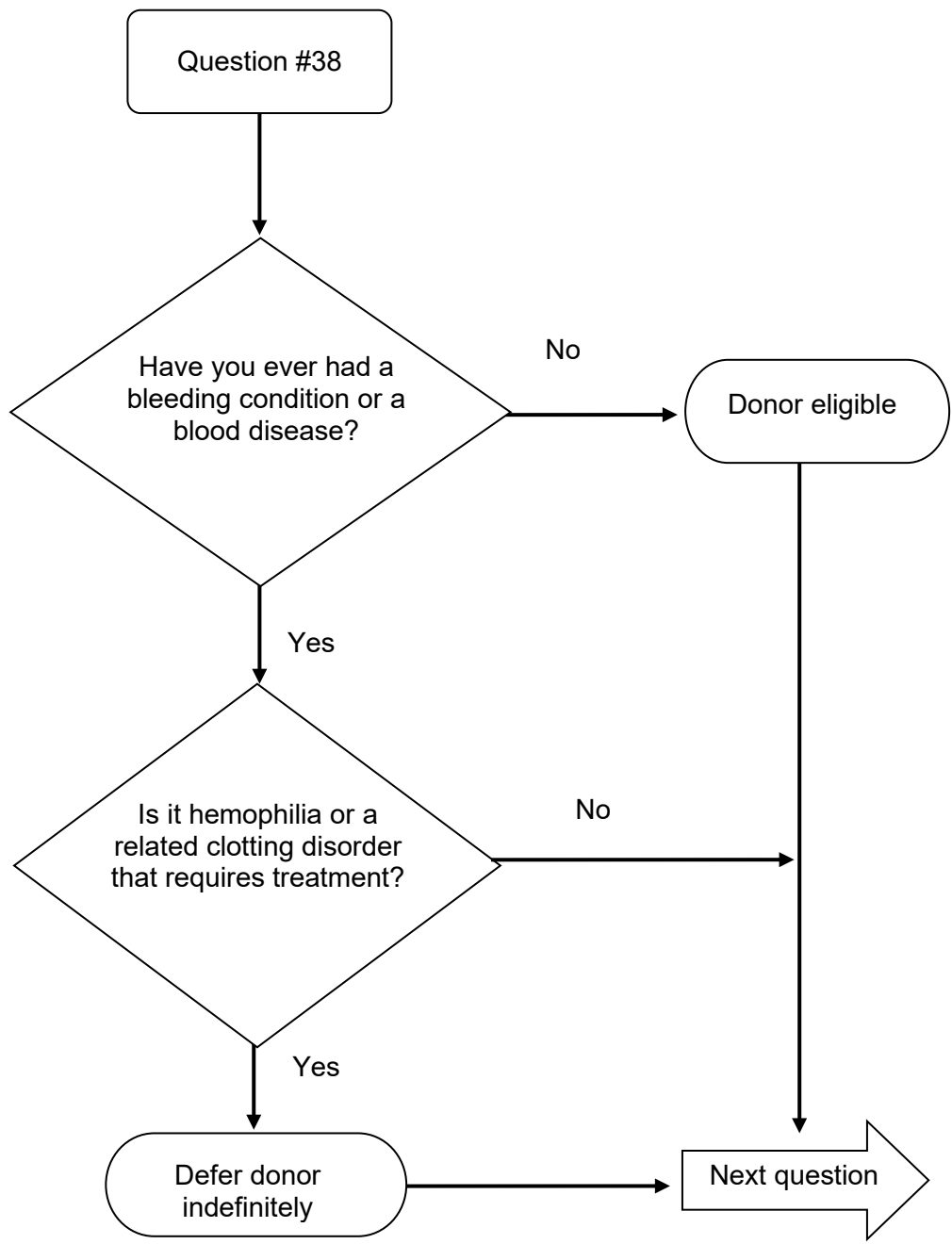
Donor Eligibility: Donors must be free of liver and kidney diseases. Donors with a history of diseases of the liver or kidneys must be evaluated (follow company policy).

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 #38: Have you ever had a bleeding condition or a blood disease?

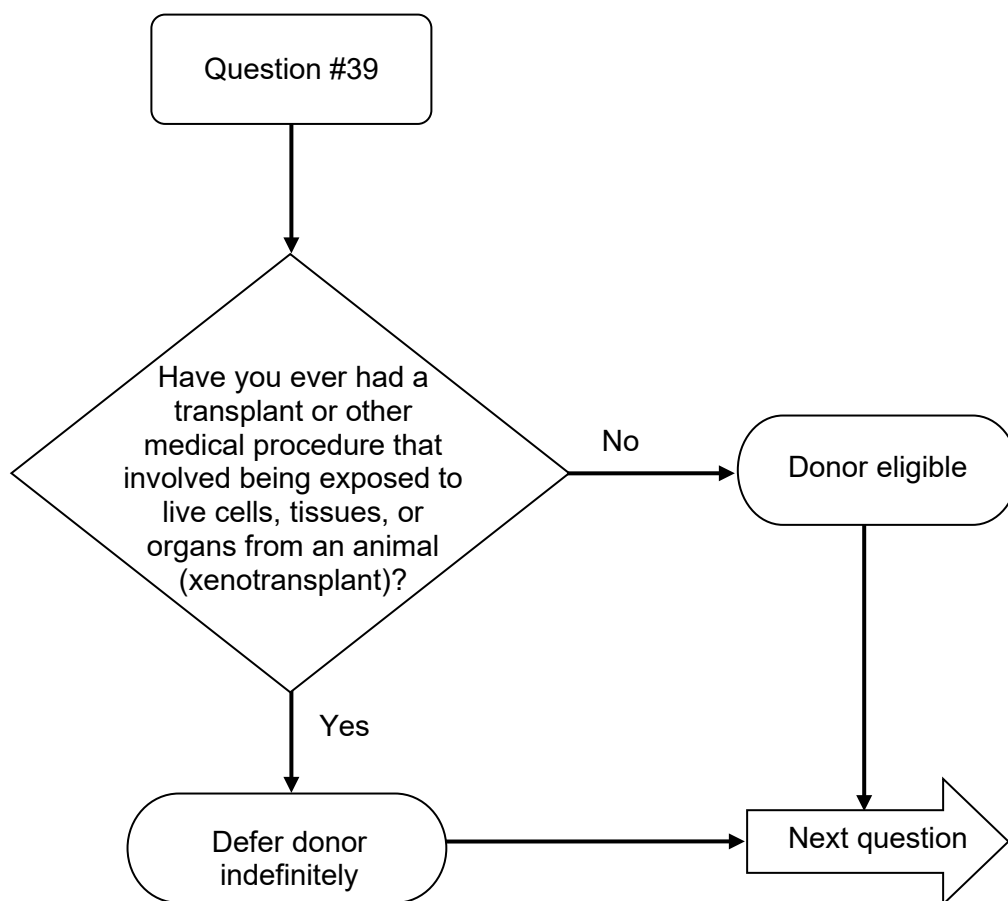
Donor Eligibility: A person with hemophilia or related clotting disorders that requires treatment should be deferred to prevent harm by the large bore needles used during the donation process.



Question 39: Have you ever had a transplant or other medical procedure that involved being exposed to live cells, tissues, or organs from an animal (xenotransplant)?

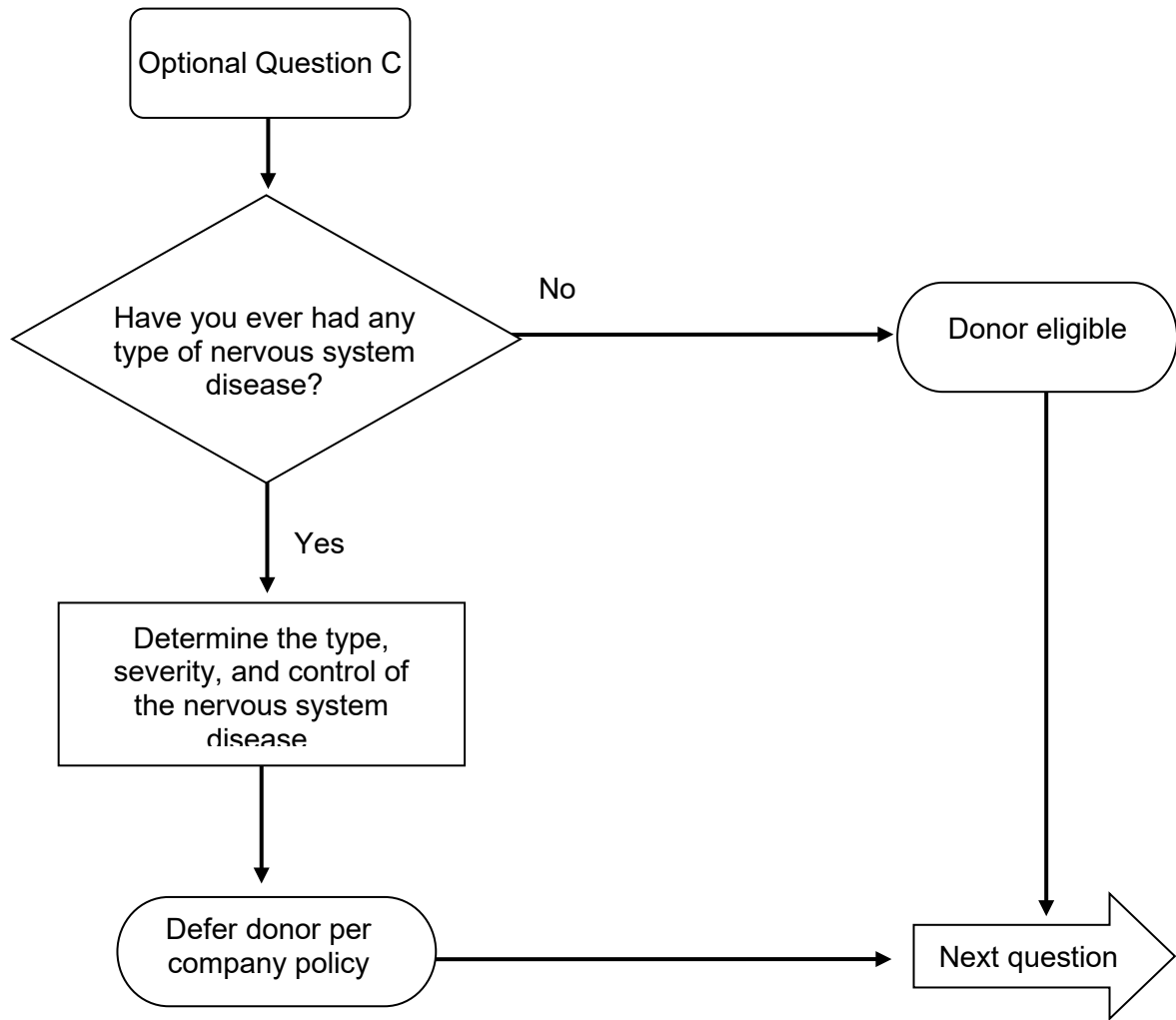
Donor eligibility: A person who has received a xenotransplantation product is indefinitely deferred. Xenotransplantation is defined to include any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a nonhuman animal source (xenotransplantation products) or (b) human body fluids, cells, tissues or organs that have had ex vivo contact with live nonhuman animal cells, tissues or organs.

Note: Nonliving biological products or material from nonhuman animals, such as porcine heart valves and porcine insulin, are not classified as xenotransplantation products for the purposes of this definition.



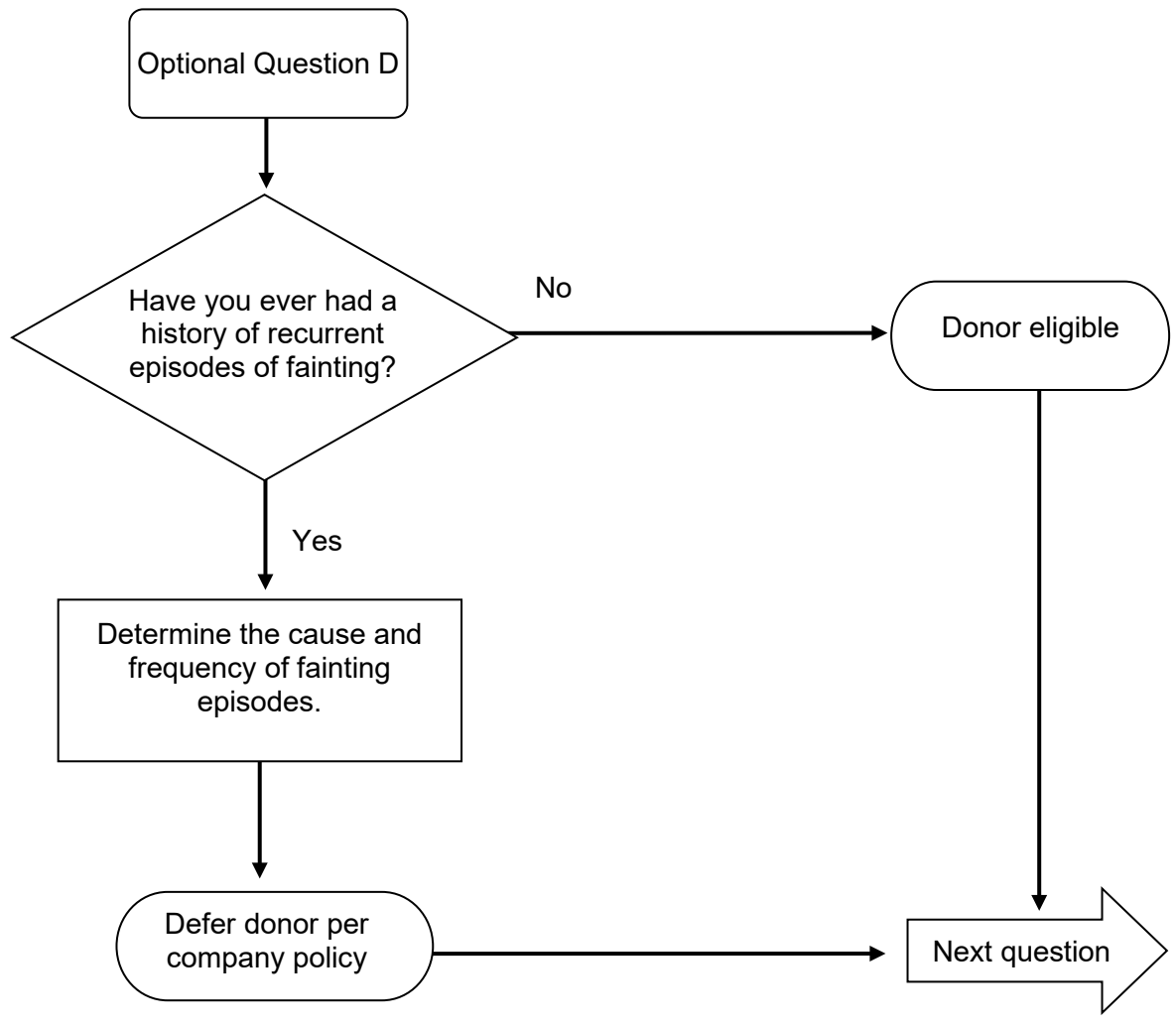
Optional Question C: Have you ever had any type of nervous system disease?

Donor Eligibility: The European Commission Directive 2004/33/EC requires that donors with a history of serious central nervous system disease be permanently deferred.



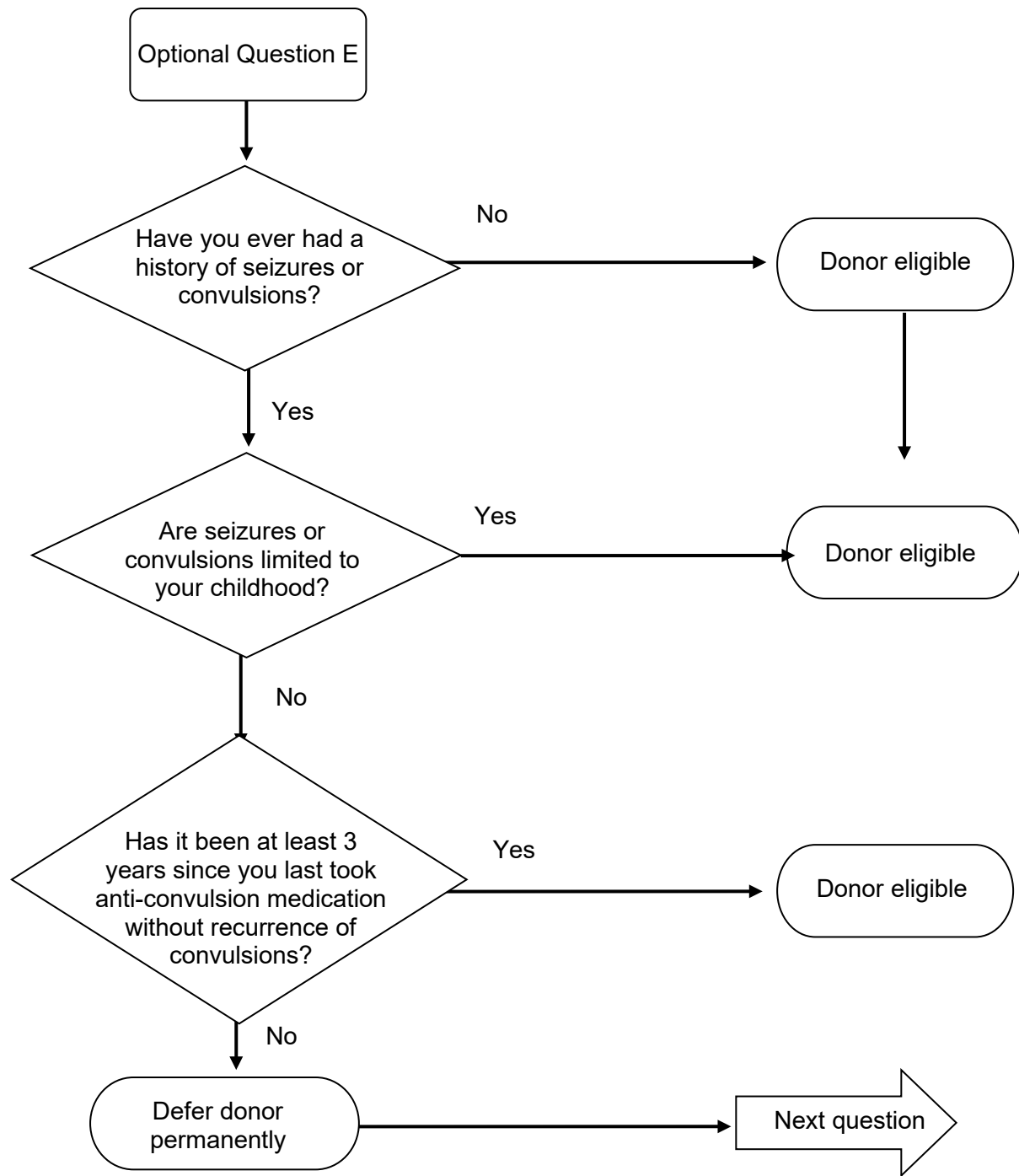
Optional Question D: Have you ever had a history of recurrent episodes of fainting?

Donor Eligibility: The European Commission Directive 2004/33/EC requires that donors providing a history of repeated episodes of syncope (fainting) be permanently deferred.



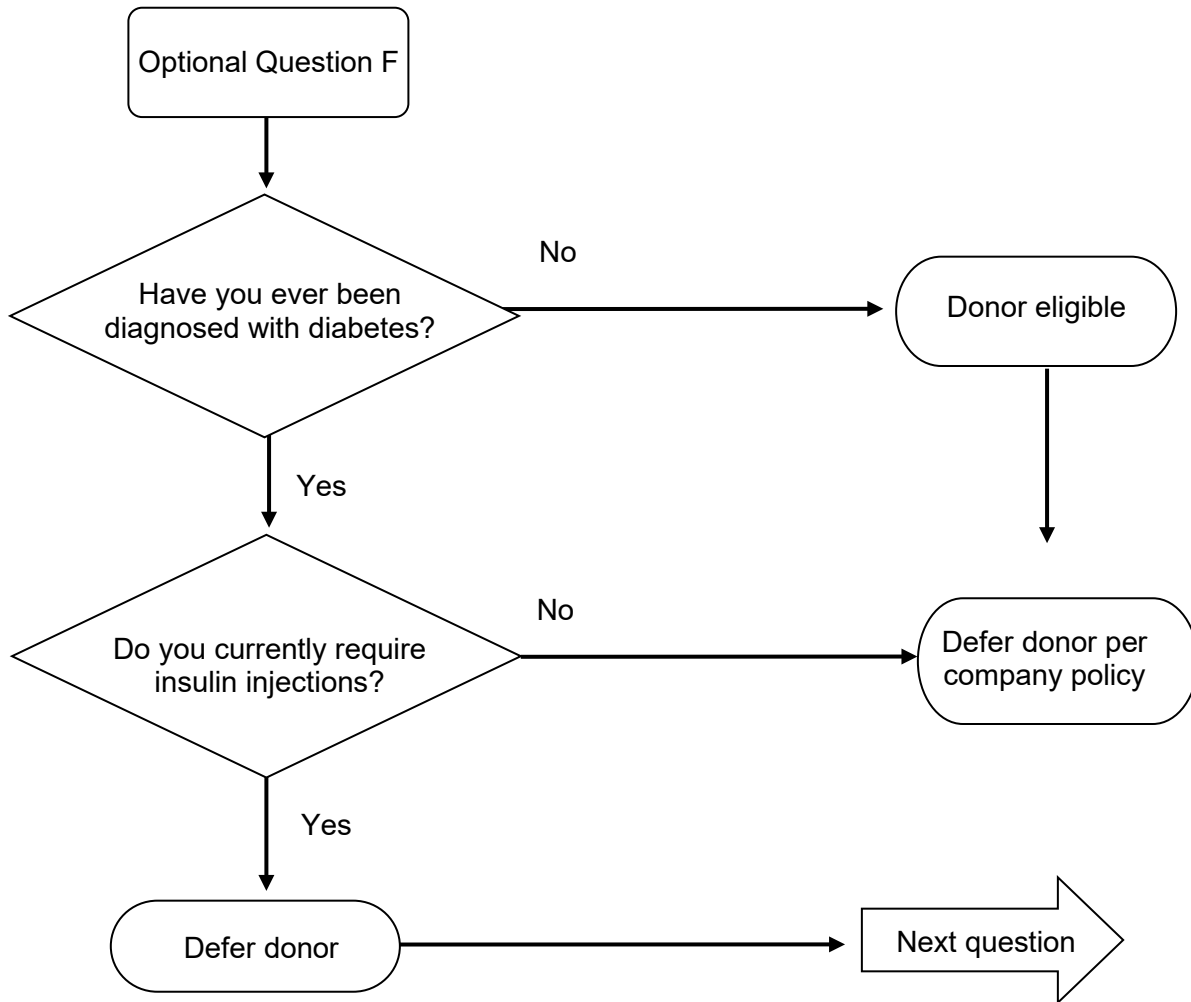
Optional Question E: Have you ever had a history of seizures or convulsions?

Donor Eligibility: The European Commission Directive 2004/33/EC requires that donors providing a history of convulsions, other than childhood convulsions or where at least three years have elapsed since the date the donor last took anticonvulsion medication without any recurrence of convulsions, be deferred.



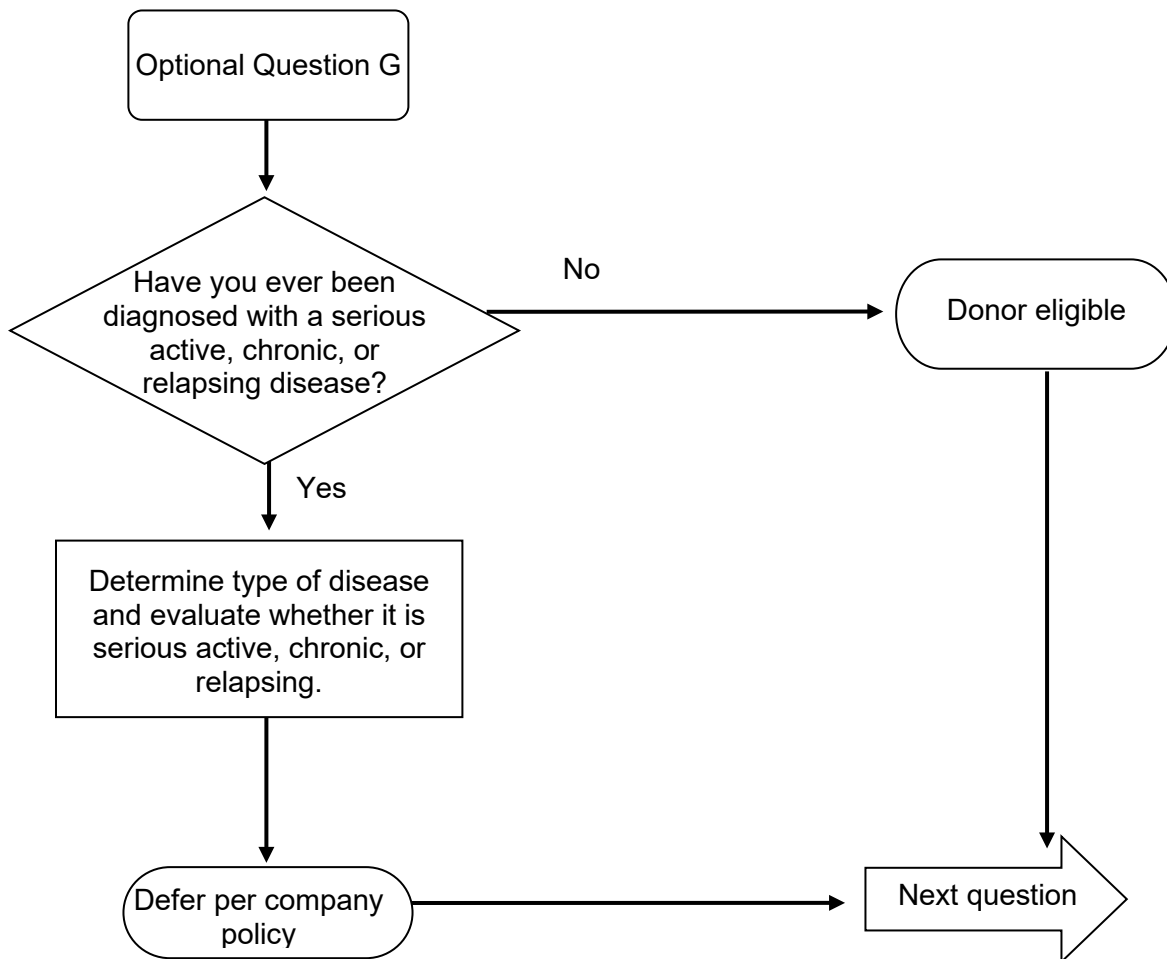
Optional Question F: Have you ever been diagnosed with diabetes?

Donor Eligibility: The European Commission Directive 2004/33/EC requires that donors with diabetes who are being treated with insulin be deferred.



Optional Question G: Have you ever been diagnosed with any other serious active, chronic, or relapsing disease?

Donor Eligibility: The European Commission Directive 2004/33/EC requires that donors with serious active, chronic, or relapsing disease be permanently deferred. Diseases can fall into the categories of gastrointestinal, genitourinary, immunological, or metabolic.



Optional Question H: Have any of your blood relatives had Creutzfeldt-Jakob disease?

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

Note: If laboratory testing (gene sequencing) shows that the donor does not have a mutation associated with familial CJD, the donor is eligible. Gene sequencing of the donor is not necessary to demonstrate that the donor is not at risk for familial CJD. Sequencing of the family member with CJD or the appropriate parent of the donor, if the CJD-affected family member was a second-degree relative, may be sufficient to demonstrate that the donor does not have a mutation associated with familial CJD.

