

AABB HPC DHQ Mtb and Sepsis – Additional Questions

Questions to be added to the “Area for Additional Questions” of the AABB Hematopoietic Progenitor Cell (HPC) Donor History Questionnaires (DHQs) to:

- Reduce the risk of transmission of Mycobacterium tuberculosis by human cells, tissues, and cellular and tissue-based products (HCT/Ps).
- Reduce the risk of transmission of disease agents associated with sepsis by HCT/Ps.

A. *Mycobacterium tuberculosis*

The questions below are based on the [FDA January 2025 Guidance, Recommendations to Reduce the Risk of Transmission of Mycobacterium tuberculosis by Human Cells, Tissues, and Cellular and Tissue-Based Products \(HCT/Ps\)](#);

1. Have you ever had a positive test for tuberculosis (TB) infection (including a positive skin test, blood test, or sputum test)?
2. Have you ever had a medical diagnosis of TB disease or infection?
3. Have you ever had a diagnosis of latent TB infection (LTBI)?
4. Were you **born in** an area of the world where TB is common (e.g., Latin American countries, the Caribbean, Africa, Asia, Eastern Europe, Russia)?
5. Have you ever **lived in** an area of the world where TB is common (e.g., Latin American countries, the Caribbean, Africa, Asia, Eastern Europe, Russia)?
6. Have you ever **traveled to** an area of the world where TB is common (e.g., Latin American countries, the Caribbean, Africa, Asia, Eastern Europe, Russia)?
7. Have you ever **lived in** a jail, prison, or correctional facility?
8. Have you ever **worked in** a jail, prison, or correctional facility?
9. Have you ever **lived in** a long-term care facility, or homeless shelter?
10. Have you ever **worked in** a long-term care facility, or homeless shelter?
11. Have you ever **lived with** (resided in the same dwelling) another person who has TB?
12. Have you **ever been a close contact** of another person with TB?
13. Do you have a **medical condition** that can impair your immune function (e.g., diabetes, chronic kidney disease/end stage renal disease with or without dialysis)?
14. Are you taking **medications** that can impair your immune function?

B. Sepsis

The question below is based on the FDA January 2025 Guidance, [Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products \(HCT/Ps\)](#);

15. Do you **currently** have a medical diagnosis of sepsis or suspicion of sepsis?

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HCT/P Process Flowchart A - Evaluation of a Potential HPC Donor for Risk Factors for Mtb

This Process Flowchart incorporates the recommendations of the [FDA January 2025 Guidance, Recommendations to Reduce the Risk of Transmission of Mycobacterium tuberculosis \(Mtb\) by Human Cells, Tissues, and Cellular and Tissue-Based Products \(HCT/Ps\)](#) (the 2025 FDA Mtb Guidance) for determining HCT/P (including HPC) donor eligibility.



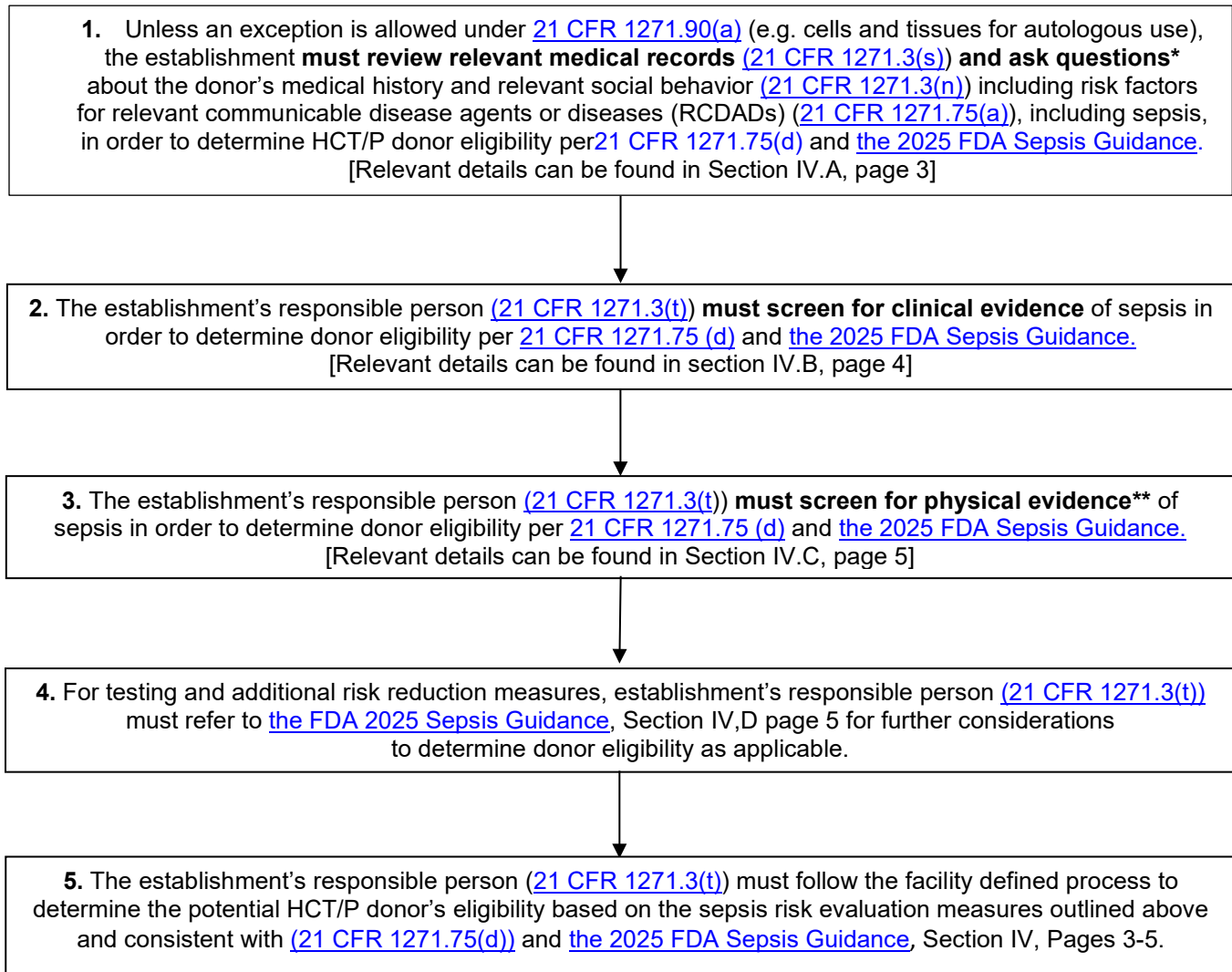
*If donor is less than 1 month of age, donor's birth mother must also be screened.

**For cadaveric HCT/P donor, review of relevant medical records ([21 CFR 1271.3\(s\)](#)) includes report of physical assessment of cadaveric donor ([21 CFR 1271.3\(o\)](#)).

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HCT/P Process Flowchart B - Evaluation of a Potential HPC Donor for Risk Factors for Sepsis

This Process Flowchart incorporates the recommendations of the [FDA January 2025 Guidance, Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products \(HCT/Ps\)](#), (the 2025 FDA Sepsis Guidance), for determining HCT/P (including HPC) donor eligibility.



*If donor is less than 1 month of age, donor's birth mother must also be screened.

**For cadaveric HCT/P donor, review of relevant medical records ([21 CFR 1271.3\(s\)](#)) includes report of physical assessment of cadaveric donor ([21 CFR 1271.3\(o\)](#)).

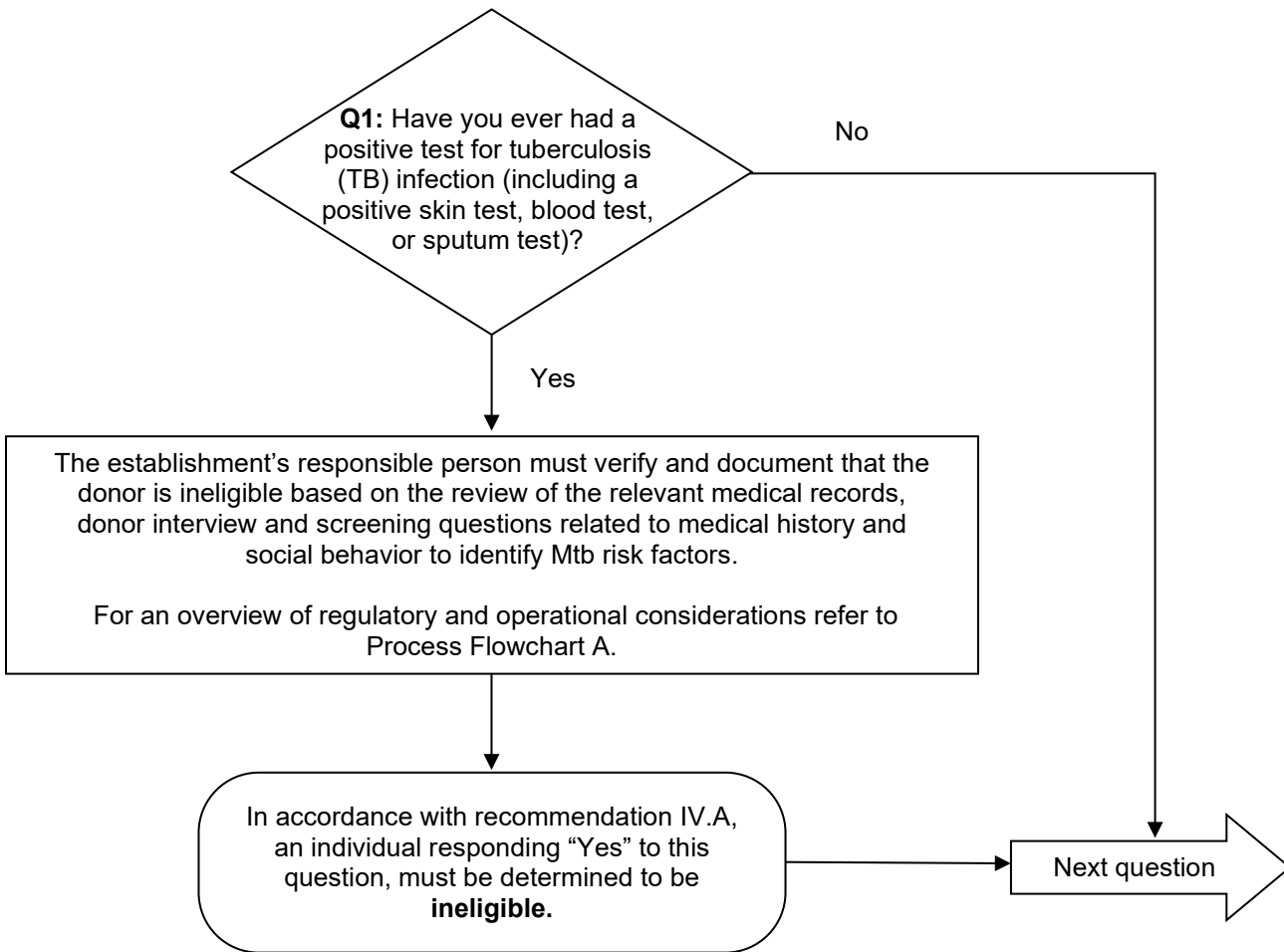
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Question 1: Have you ever had a positive test for tuberculosis (TB) infection (including a positive skin test, blood test, or sputum test)?

Donor Eligibility: A potential HCT/P donor with a positive test for TB infection has a risk factor for Mtb infection and must be determined to be ineligible based on the 2025 FDA Mtb Guidance recommendations Section IV, A,1, page 7, and the following FDA Guidance considerations:

- A potential HCT/P donor with a positive test for tuberculosis on any specimens is considered to exhibit clinical evidence of Mtb infection and must be determined ineligible; For example, a positive blood test such as Interferon Gamma Release Assay (IGRA) (e.g., T-SPOT.TB, QuantiFERON-TB Gold Plus, QuantiFERON-TB Gold In-Tube), a positive tuberculin skin test (TST) (also known as PPD, Mantoux, or tine test), or a positive test for TB infection on any specimen (i.e., mycobacterial culture, NAAT or PCR for Mtb DNA). [Section IV.B, page 8]

Reference: [FDA's 2025 Mtb Guidance](#)



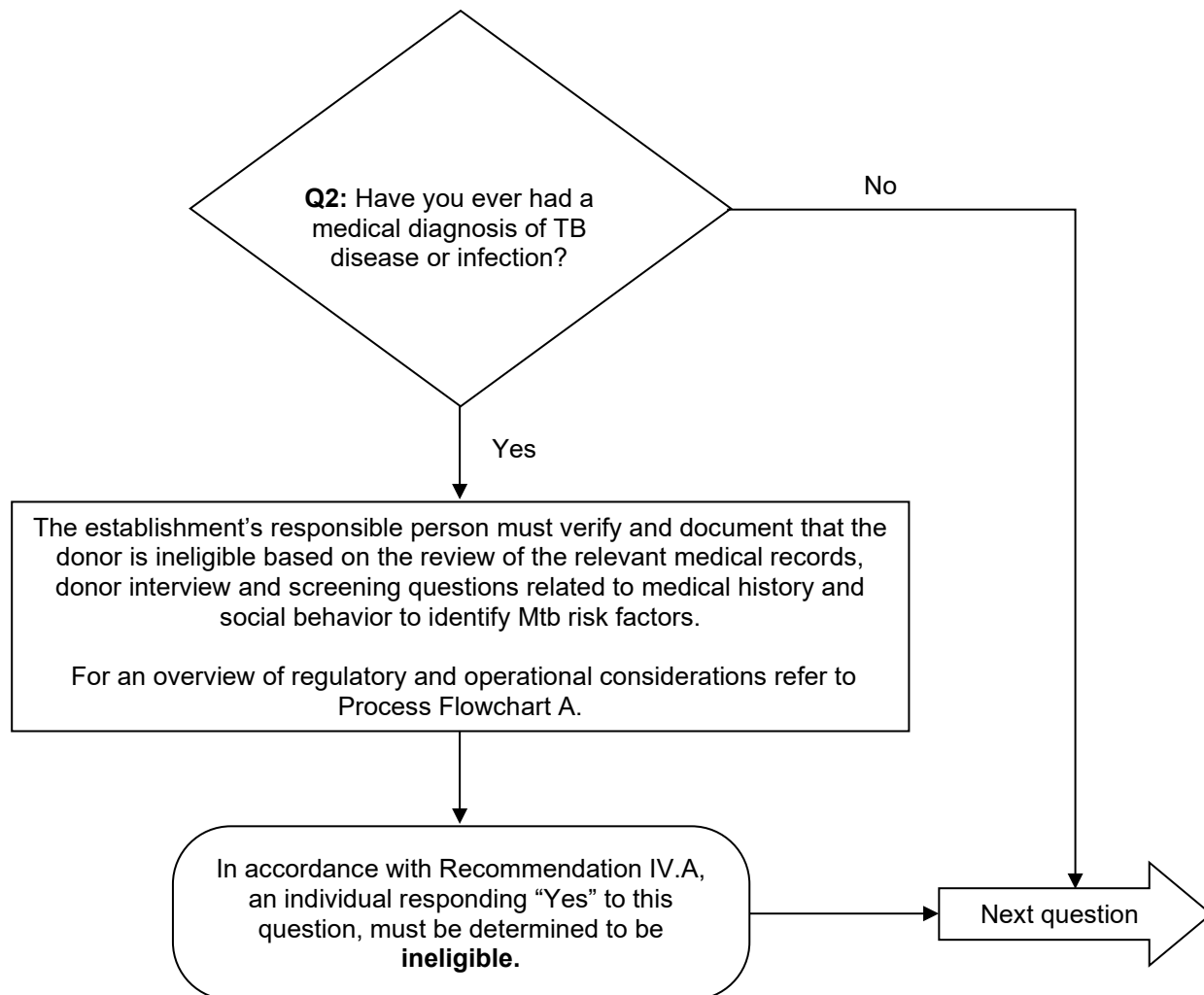
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Question 2: Have you ever had a medical diagnosis of TB disease or infection?

Donor Eligibility: A potential HCT/P donor with clinical evidence of Mtb infection such as medical diagnosis for TB disease or infection has a risk factor for Mtb infection and must be determined to be ineligible based on the 2025 FDA Mtb Guidance recommendations IV. A. 1, page 7, and the following FDA Guidance considerations:

- Mtb DNA has been identified in hematopoietic progenitor/stem cells (HPCs) derived from peripheral blood and bone marrow of donors with latent tuberculosis infection. [Section III.A.2, page 4]
- Viable Mtb has been cultured from mesenchymal stem cells in bone marrow of individuals previously thought to be successfully treated for pulmonary TB. [Section III.A.2, page 4]
- While the transmission of Mtb through HPCs used in hematopoietic stem cell transplantation has not been documented, there remains a potential risk of transmission. [Section III.A.2, page 4]

Reference: [FDA's 2025 Mtb Guidance](#)



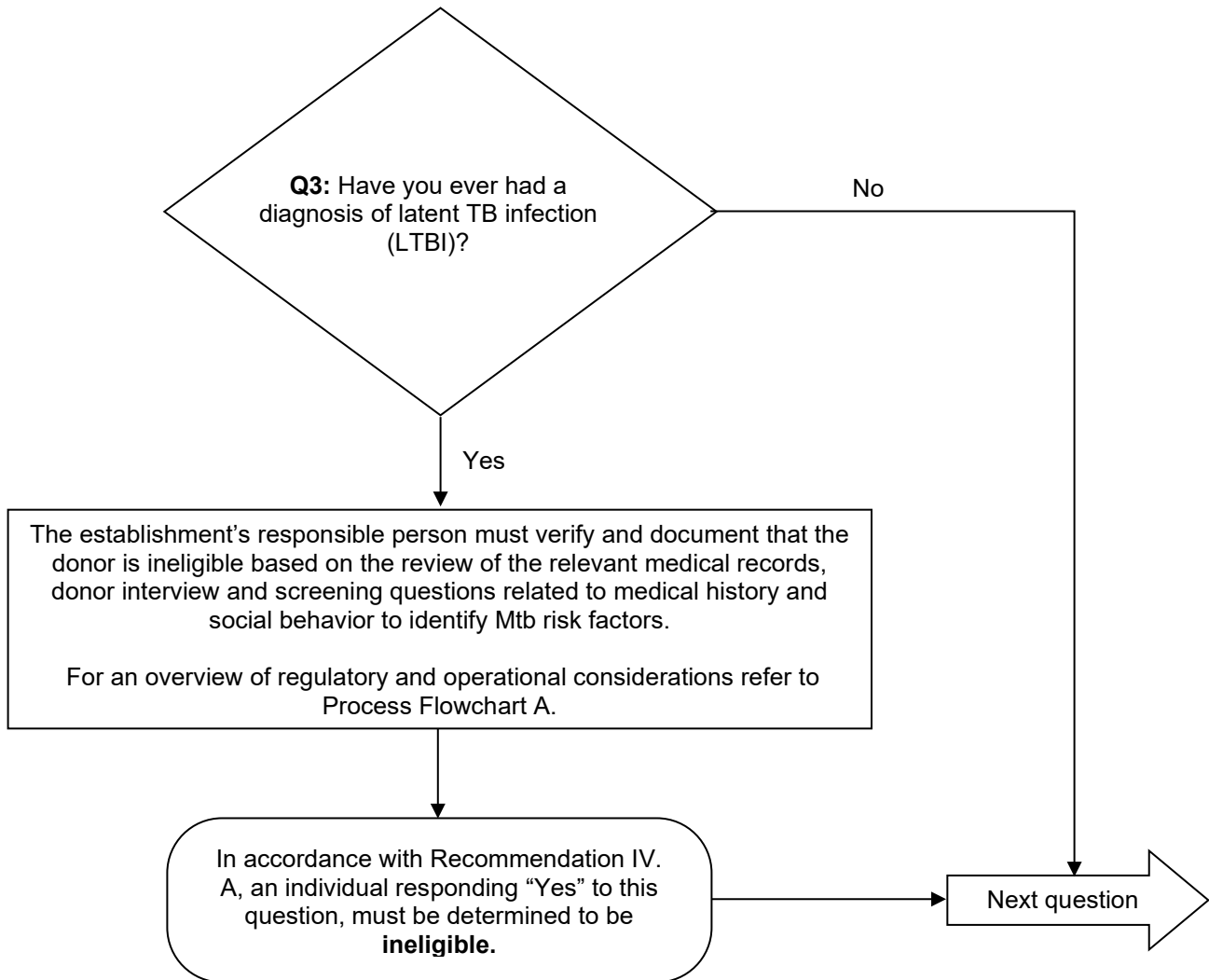
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Question 3: Have you ever had a diagnosis of latent TB infection (LTBI)?

Donor Eligibility: A potential HCT/P donor with LTBI has a risk factor for Mtb infection and must be determined to be ineligible based on the 2025 FDA Guidance recommendations IV, A,1, page 7, and the following FDA guidance considerations:

- People with LTBI do not feel sick and do not have any symptoms. They are infected with TB, but do not have TB disease. [Section II.A, page 2]
- Mtb DNA has been identified in hematopoietic progenitor/stem cells (HPCs) derived from peripheral blood and bone marrow of donors with LTBI. [Section III.A.2, page 4]
- Viable Mtb has been cultured from mesenchymal stem cells in bone marrow of individuals previously thought to be successfully treated for pulmonary TB. [Section III.A.2, page 4]
- While the transmission of Mtb through HPCs used in hematopoietic stem cell transplantation has not been documented, there remains a potential risk of transmission. [Section III.A.2, page 4]

Reference: [FDA's January 2025 Mtb Guidance](#)



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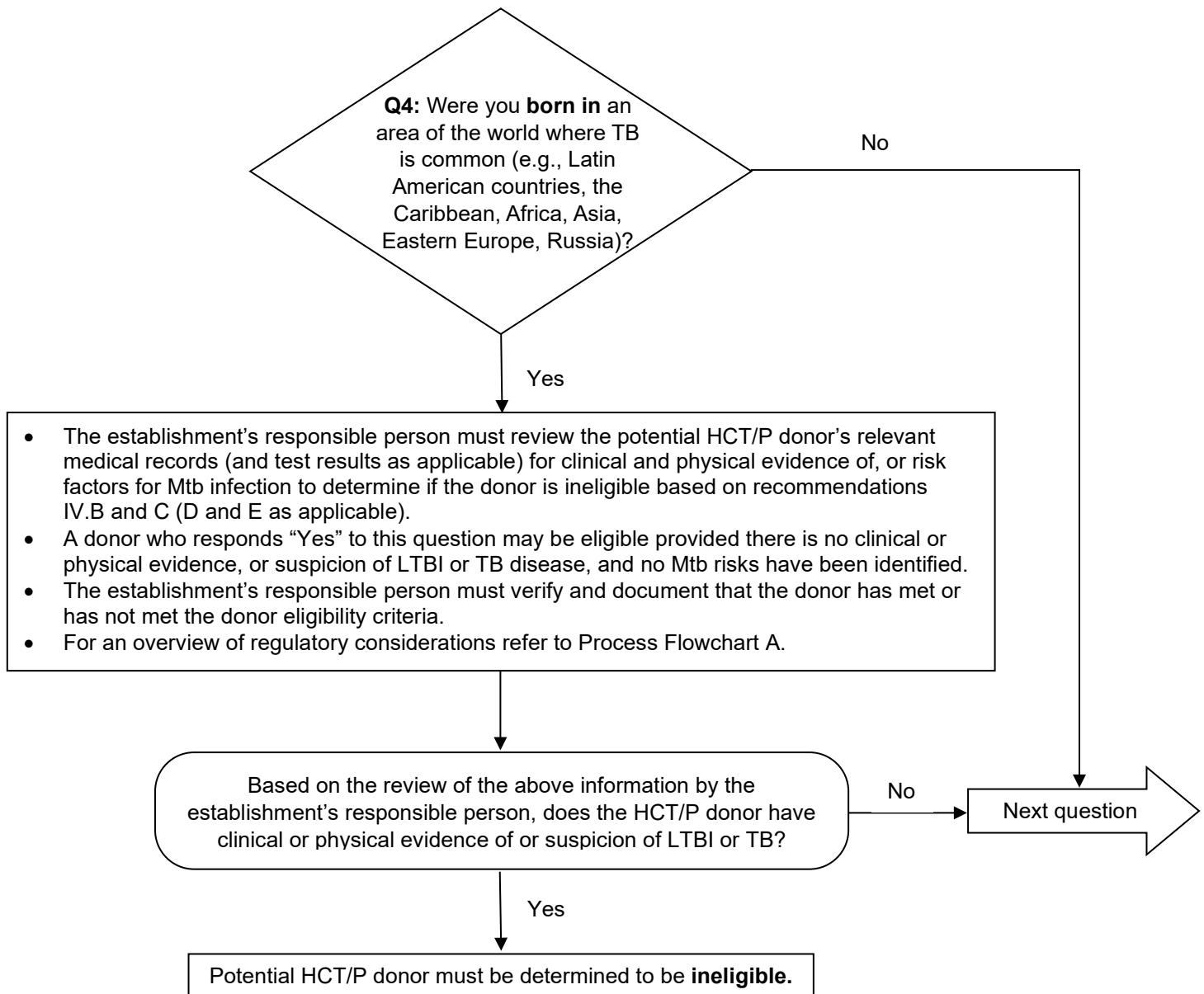
Question 4: Were you **born in** an area of the world where TB is common (e.g., Latin American countries, the Caribbean, Africa, Asia, Eastern Europe, Russia)?

Donor Eligibility: A potential HCT/P donor who is **born in** an area of the world where TB is common may be infected with Mycobacterium tuberculosis (Mtb), the organism that causes TB and may have a risk factor for Mtb infection based on the following FDA Guidance considerations:

- In some parts of the world, TB is endemic, and the disease burden is moderate to high. [Section II.A, page 2]

Note: Based on further screening recommendations in the 2025 FDA Mtb Guidance, Section IV.B and C (D and E as applicable), pages 7-11, the donor may be eligible provided there is no clinical or physical evidence, or suspicion, of LTBI or TB disease, and no communicable disease risks have been identified.

Reference: [FDA's 2025 Mtb Guidance](#) [Section IV.A, page 7]



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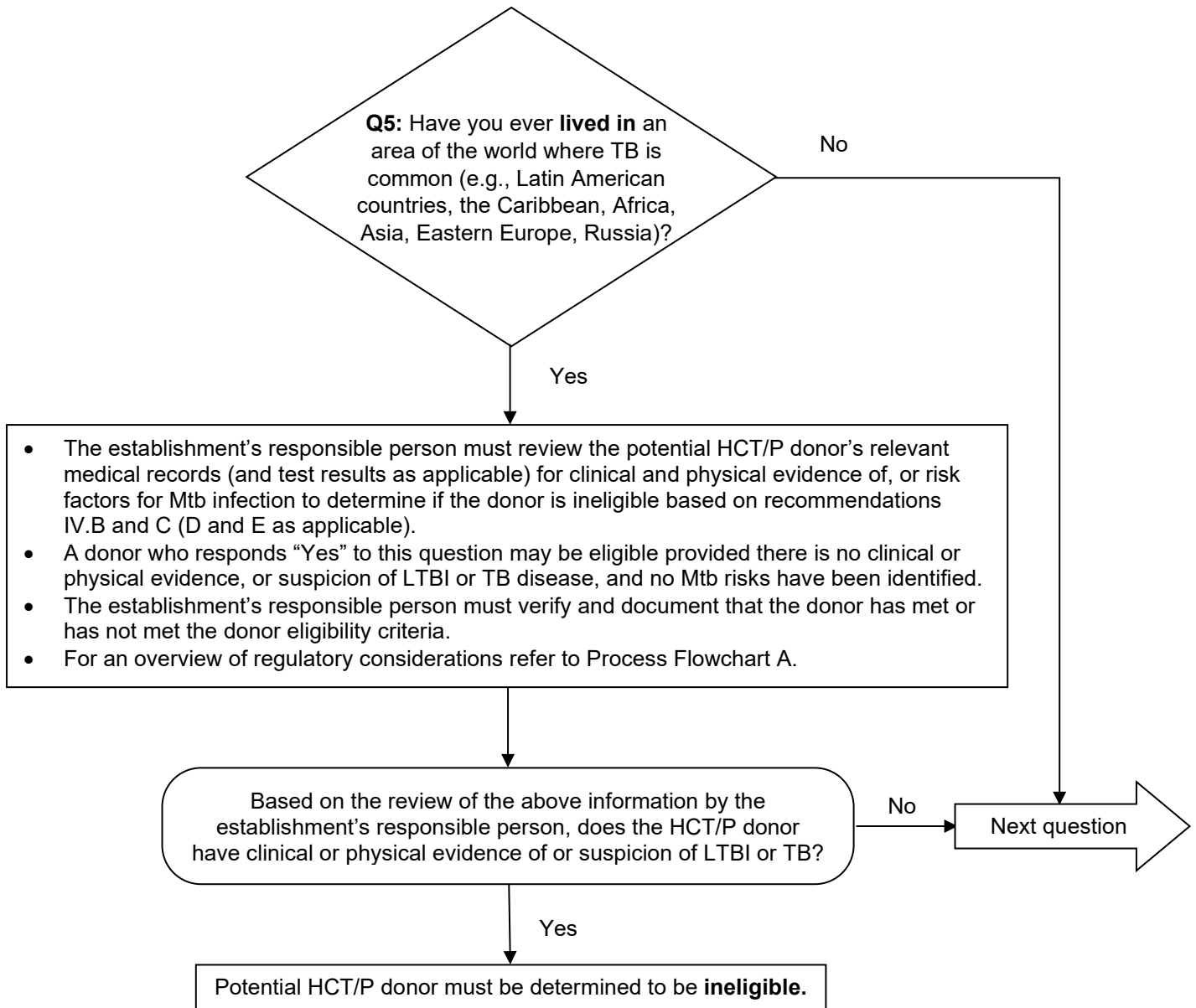
Question 5: Have you ever **lived in** an area of the world where TB is common (e.g., Latin American countries, the Caribbean, Africa, Asia, Eastern Europe, Russia)?

Donor Eligibility: A potential HCT/P donor who has **lived in** an area of the world where TB is common may be infected with Mycobacterium tuberculosis (Mtb), the organism that causes TB and may have a risk factor for Mtb infection based on the following considerations:

- In some parts of the world, TB is endemic, and the disease burden is moderate to high. [Section II.A, page 2]

Note: Based on further screening recommendation in FDA Guidance, IV.B and C (D and E as applicable), pages 7-11, the donor might be eligible provided there is no clinical or physical evidence, or suspicion, of LTBI or TB disease, and no communicable disease risks have been identified.

Reference: [FDA's 2025 Mtb Guidance](#) [Section IV.A, page 7]



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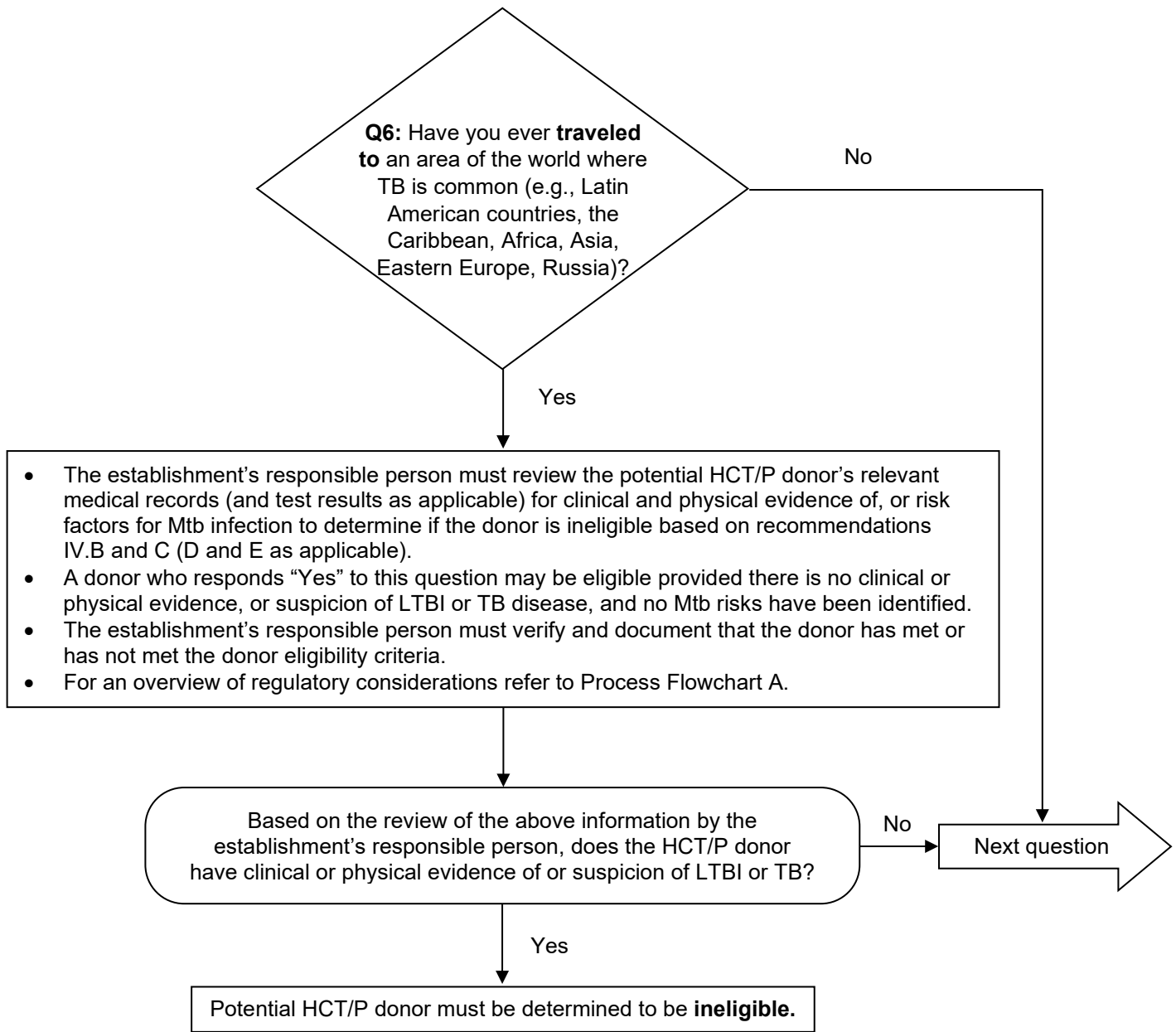
Question 6: Have you ever **traveled to** an area of the world where TB is common (e.g., Latin American countries, the Caribbean, Africa, Asia, Eastern Europe, Russia)?

Donor Eligibility: A potential HCT/P donor who **traveled to** an area of the world where TB is common may be infected with Mycobacterium tuberculosis (Mtb), the organism that causes TB and may have a risk factor Mtb infection based on the following FDA Guidance considerations:

- In some parts of the world, TB is endemic, and the disease burden is moderate to high. [Section II.A, page 2]

Note: Based on further screening recommendation in FDA Guidance, IV.B and C (D and E as applicable), pages 7-11, the donor might be eligible provided there is no clinical or physical evidence, or suspicion, of LTBI or TB disease, and no communicable disease risks have been identified.

Reference: [FDA's 2025 Mtb Guidance](#) [Section IV.A, page 7]



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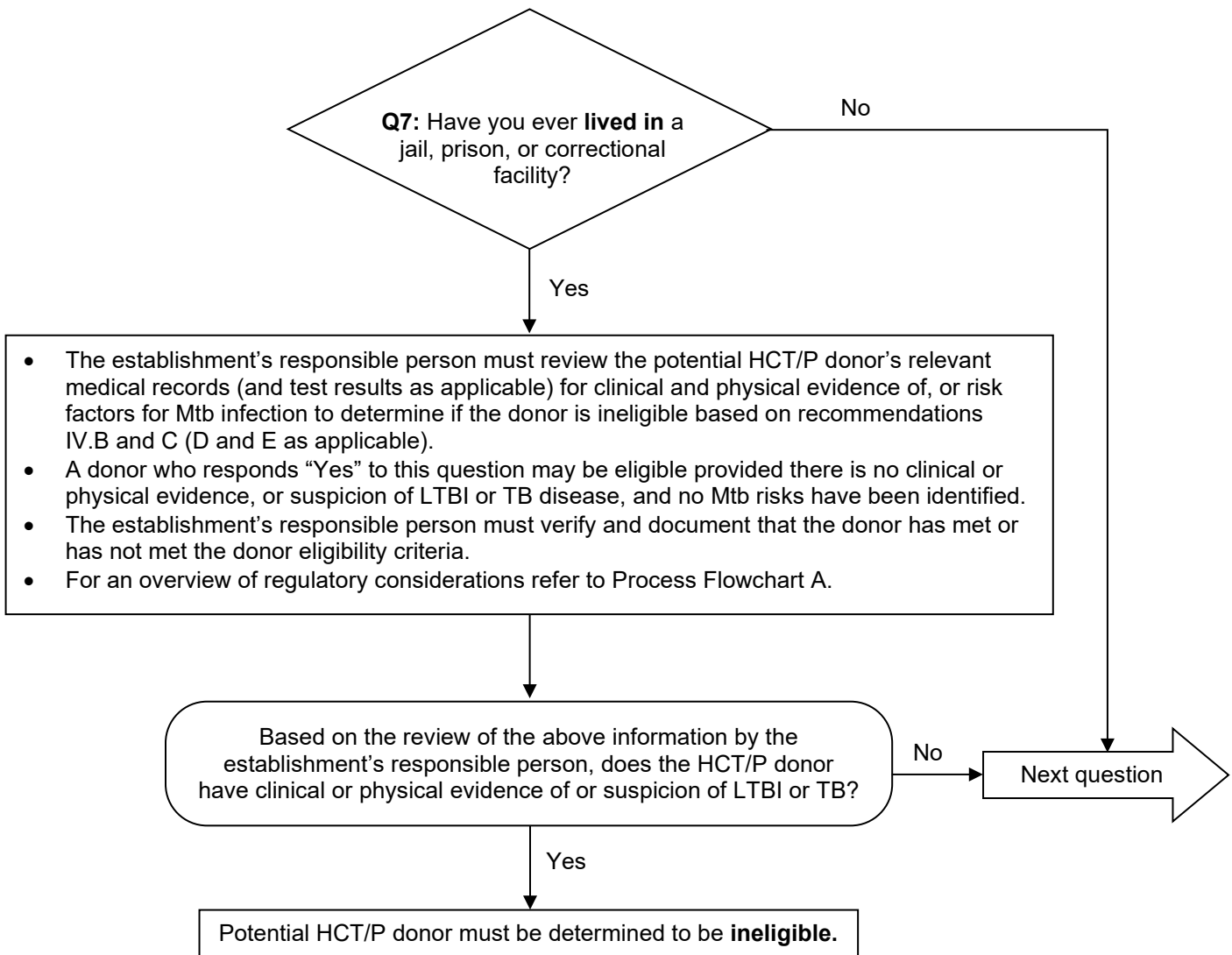
Question 7: Have you ever **lived in** a jail, prison, or correctional facility?

Donor Eligibility: A potential HCT/P donor who has **lived in** high risk congregate settings where TB could easily spread may be infected with Mycobacterium tuberculosis (Mtb), the organism that causes TB and may have a risk factor for Mtb infection based on the following FDA Guidance considerations:

- Risk factors for TB infection and disease include environmental factors leading to increased exposure to individuals with infectious tuberculosis (e.g., living or working in crowded facilities such as homeless shelters, long-term care facilities and nursing homes, incarceration in jails, prisons, correctional facilities, and other congregate settings). [Section II.A, page 3]
- Mtb transmission occurs primarily through inhalation of aerosol droplet nuclei containing the Mtb bacteria. Individuals who have the infectious TB can expel droplets nuclei containing the bacteria through coughing, sneezing, speaking and singing. [Section II.A, page 2]

Note: Based on further screening recommendation in FDA Guidance, IV.B and C (D and E as applicable), pages 7-11, the donor might be eligible provided there is no clinical or physical evidence, or suspicion, of LTBI or TB disease, and no communicable disease risks have been identified.

Reference: [FDA's 2025 Mtb Guidance](#) [Section IV.A, page 7]



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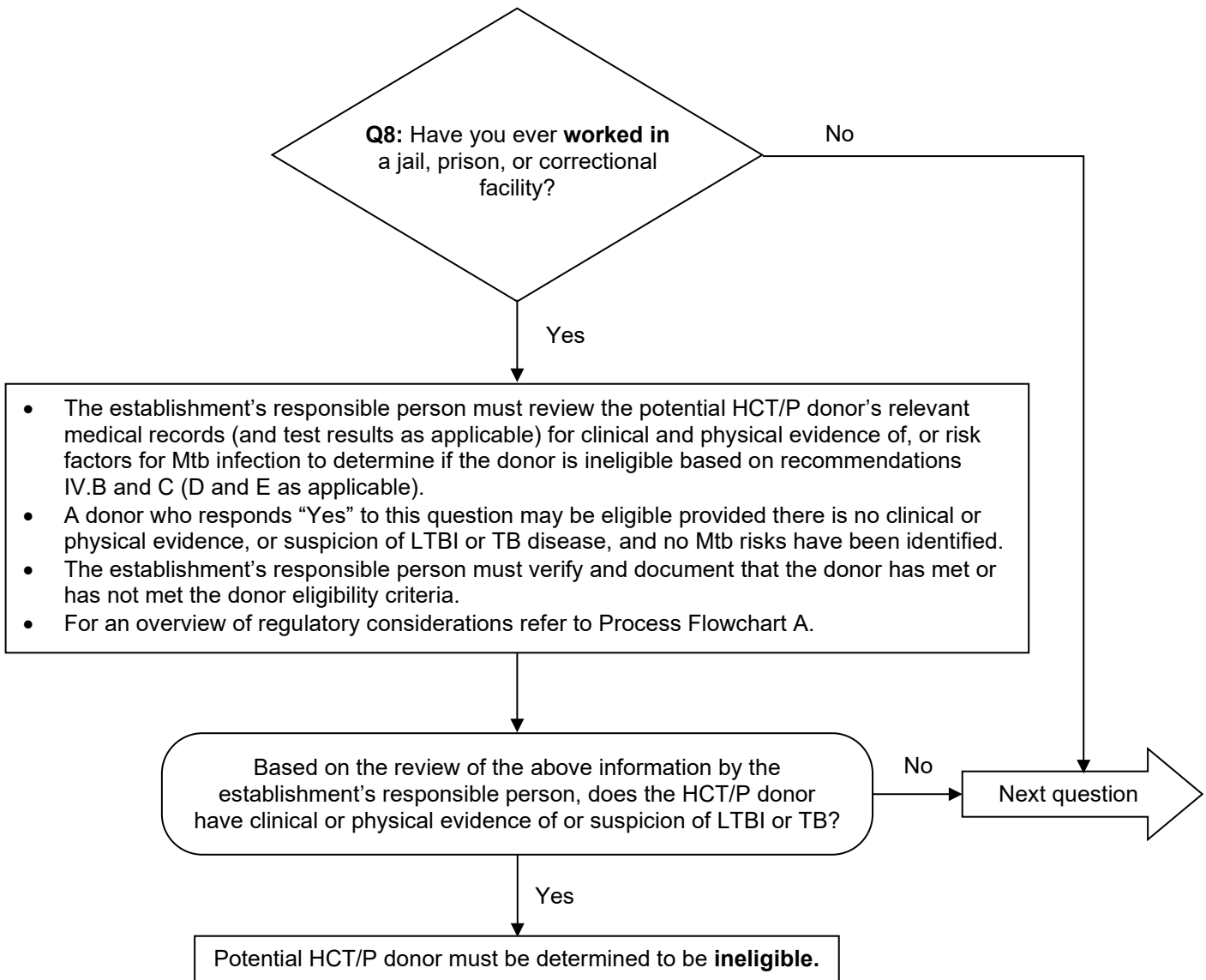
Question 8: Have you ever **worked in** a jail, prison, or correctional facility?

Donor Eligibility: A potential HCT/P donor who has **worked in** high risk congregate settings where TB could easily spread may be infected with Mycobacterium tuberculosis (Mtb), the organism that causes TB and may have a risk factor for Mtb infection based on the following FDA Guidance considerations:

- Risk factors for TB infection and disease include environmental factors leading to increased exposure to individuals with infectious tuberculosis (e.g., living or working in crowded facilities such as homeless shelters, long-term care facilities and nursing homes, incarceration in jails, prisons, correctional facilities, and other congregate settings). [Section II.A, page 3]
- Mtb transmission occurs primarily through inhalation of aerosol droplet nuclei containing the Mtb bacteria. Individuals who have the infectious TB can expel droplets nuclei containing the bacteria through coughing, sneezing, speaking and singing. [Section II.A, page 2]

Note: Based on further screening recommendation in FDA Guidance, IV.B and C (D and E as applicable), pages 7-11, the donor might be eligible provided there is no clinical or physical evidence, or suspicion, of LTBI or TB disease, and no communicable disease risks have been identified.

Reference: [FDA's 2025 Mtb Guidance](#) [Section IV.A, page 7]



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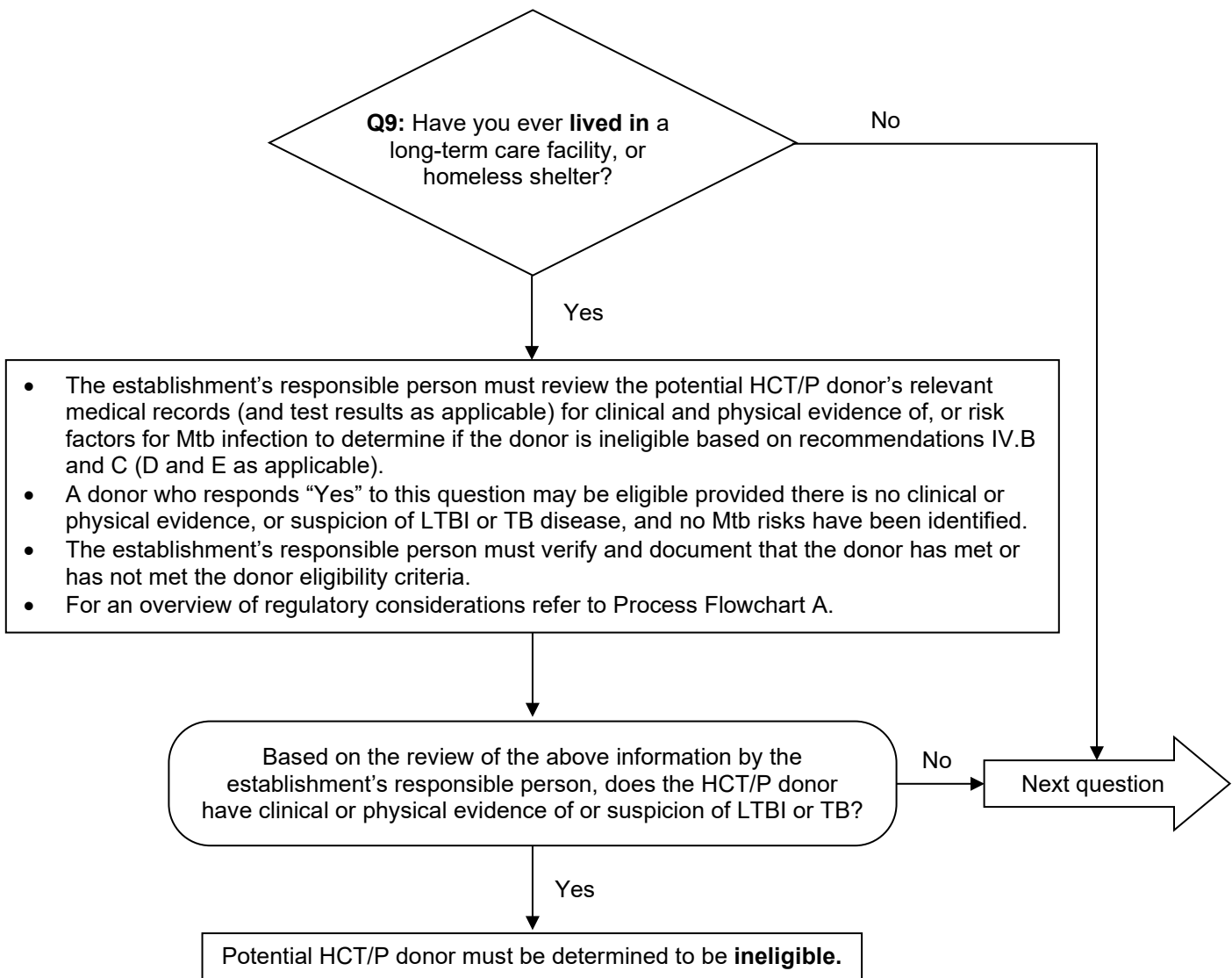
Question 9: Have you ever **lived in** a long-term care facility, or homeless shelter?

Donor Eligibility: A potential HCT/P donor who has **lived in** high risk congregate settings may be infected with Mycobacterium tuberculosis (Mtb), the organism that causes TB and may have a risk factor for Mtb infection based on the following FDA Guidance considerations:

- Risk factors for TB infection and disease include environmental factors leading to increased exposure to individuals with infectious tuberculosis (e.g., living or working in crowded facilities such as homeless shelters, long-term care facilities and nursing homes, incarceration in jails, prisons, correctional facilities, and other congregate settings). [Section II.A, page 3]
- Mtb transmission occurs primarily through inhalation of aerosol droplet nuclei containing the Mtb bacteria. Individuals who have the infectious TB can expel droplets nuclei containing the bacteria through coughing, sneezing, speaking and singing. [Section II.A, page 2]

Note: Based on further screening recommendation in FDA Guidance, IV.B and C (D and E as applicable), pages 7-11, the donor might be eligible provided there is no clinical or physical evidence, or suspicion, of LTBI or TB disease, and no communicable disease risks have been identified.

Reference: [FDA's 2025 Mtb Guidance](#) [Section IV.A, page 7]



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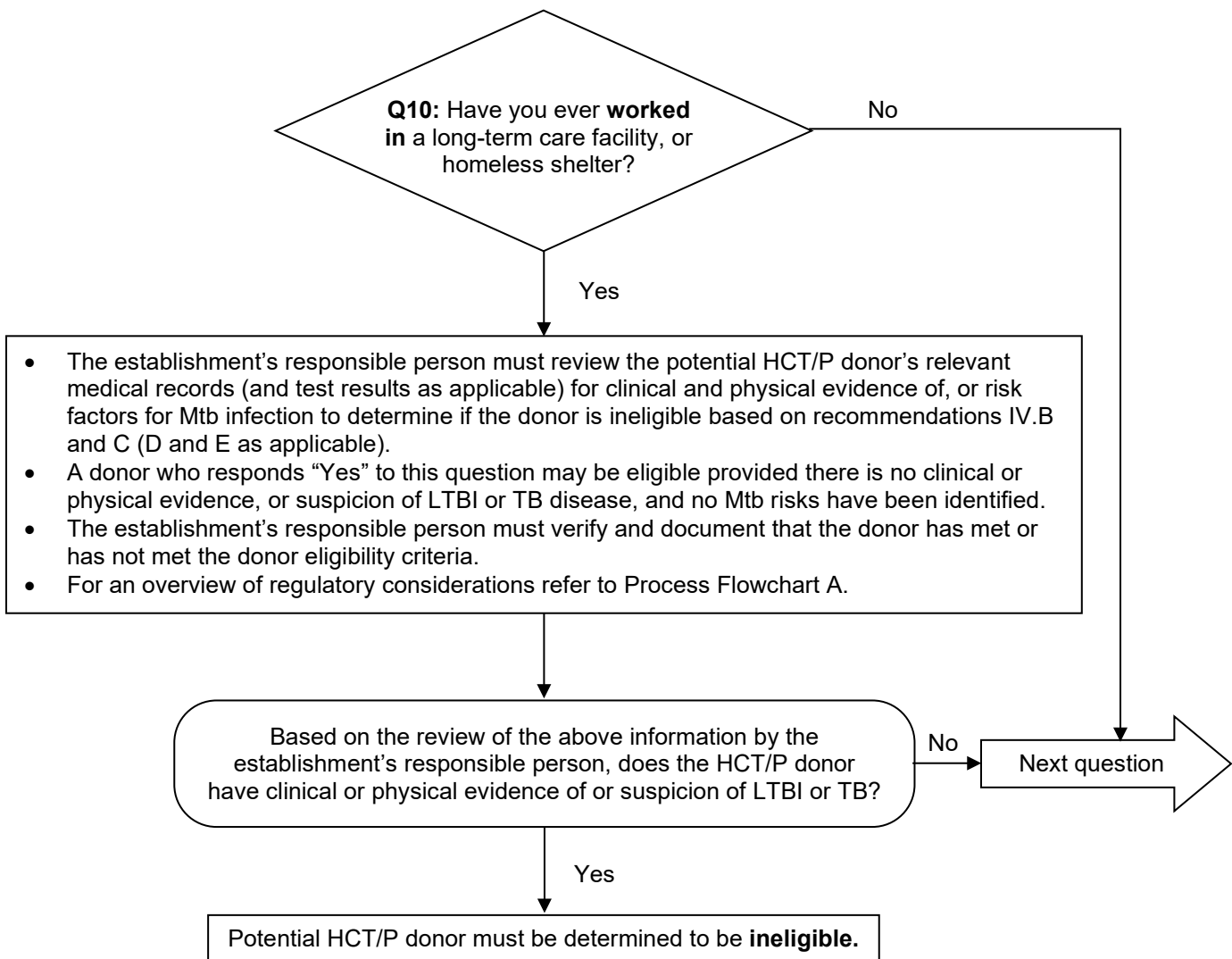
Question 10: Have you ever **worked in** a long-term care facility, or homeless shelter?

Donor Eligibility: A potential HCT/P donor who has **worked in** high risk congregate settings where TB could easily spread may be infected with Mycobacterium tuberculosis (Mtb), the organism that causes TB and may have a risk factor for Mtb infection based on the following considerations:

- Risk factors for TB infection and disease include environmental factors leading to increased exposure to individuals with infectious tuberculosis (e.g., living or working in crowded facilities such as homeless shelters, long-term care facilities and nursing homes, incarceration in jails, prisons, correctional facilities, and other congregate settings). [Section II.A, page 3]
- Mtb transmission occurs primarily through inhalation of aerosol droplet nuclei containing the Mtb bacteria. Individuals who have the infectious TB can expel droplets nuclei containing the bacteria through coughing, sneezing, speaking and singing. [Section II.A, page 2]

Note: Based on further screening recommendation in FDA Guidance, IV.B and C (D and E as applicable), pages 7-11, the donor might be eligible provided there is no clinical or physical evidence, or suspicion, of LTBI or TB disease, and no communicable disease risks have been identified.

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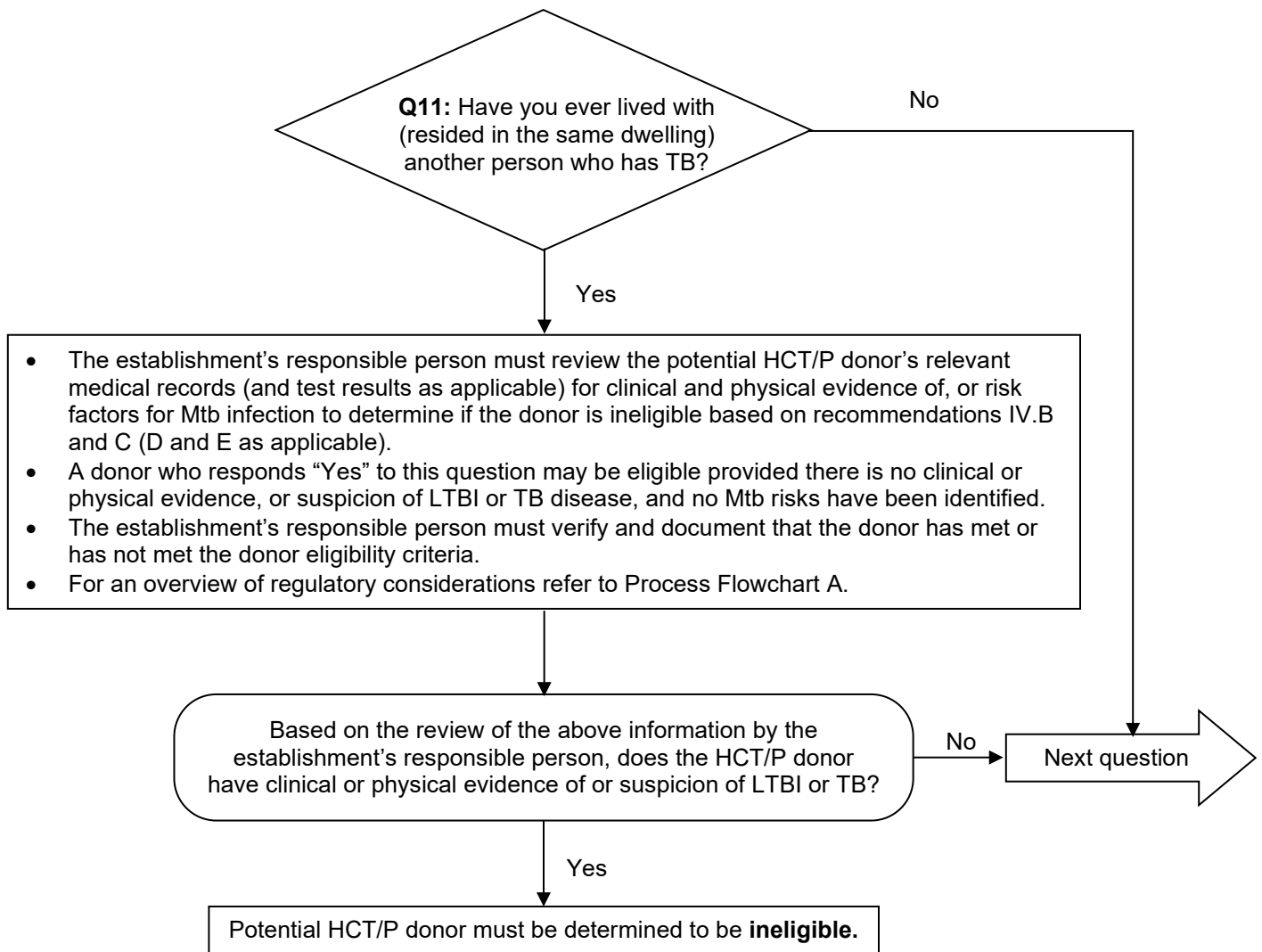
Question 11: Have you ever lived with (resided in the same dwelling) another person who has TB?

Donor Eligibility: A potential HCT/P donor who has **lived with** another person with TB may be infected with Mycobacterium tuberculosis (Mtb), the organism that causes TB and may have a risk factor for Mtb infection based on the following FDA Guidance considerations:

- Mtb transmission occurs primarily through inhalation of aerosol droplet nuclei containing the Mtb bacteria. Individuals who have the infectious TB can expel droplets nuclei containing the bacteria through coughing, sneezing, speaking and singing. [Section II.A, page 2]

Note: Based on further screening recommendation in FDA Guidance, IV.B and C (D and E as applicable), pages 7-11, the donor might be eligible provided there is no clinical or physical evidence, or suspicion, of LTBI or TB disease, and no communicable disease risks have been identified.

Reference: [FDA's 2025 Mtb Guidance](#) [Section IV.A, page 7]



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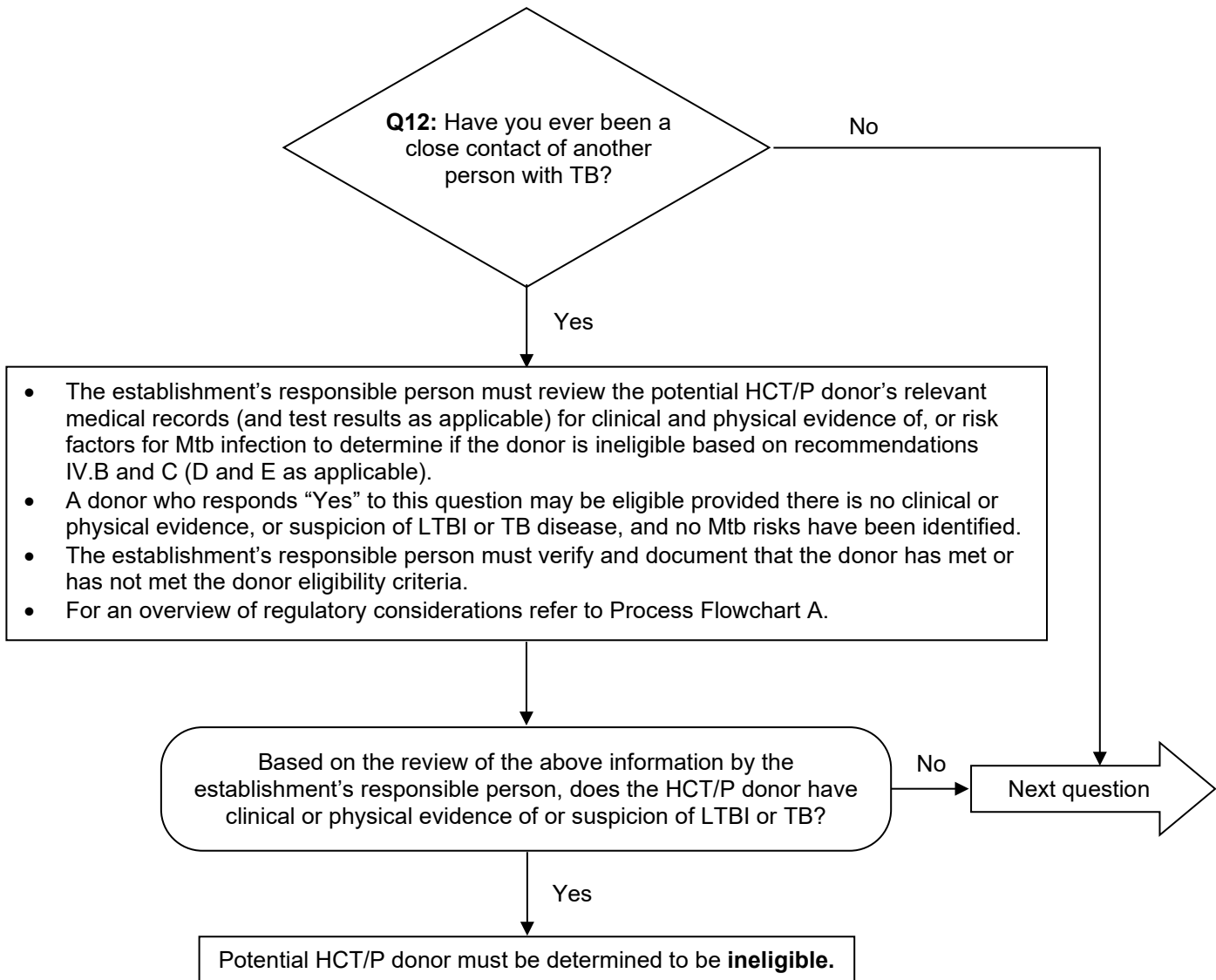
Question 12: Have you ever **been a close contact** of another person with TB?

Donor Eligibility: A potential HCT/P donor who has **been a close contact** of another person with TB may be infected with Mycobacterium tuberculosis (Mtb), the organism that causes TB and may have a risk factor for Mtb infection based on the following FDA Guidance considerations:

- Mtb transmission occurs primarily through inhalation of aerosol droplet nuclei containing the Mtb bacteria. Individuals who have the infectious TB can expel droplets nuclei containing the bacteria through coughing, sneezing, speaking and singing. [Section II.A, page 2]

Note: Based on further screening recommendation in FDA Guidance, IV.B and C (D and E as applicable), pages 7-11, the donor might be eligible provided there is no clinical or physical evidence, or suspicion, of LTBI or TB disease, and no communicable disease risks have been identified.

Reference: [FDA's 2025 Mtb Guidance](#) [Section IV.A, page 7]



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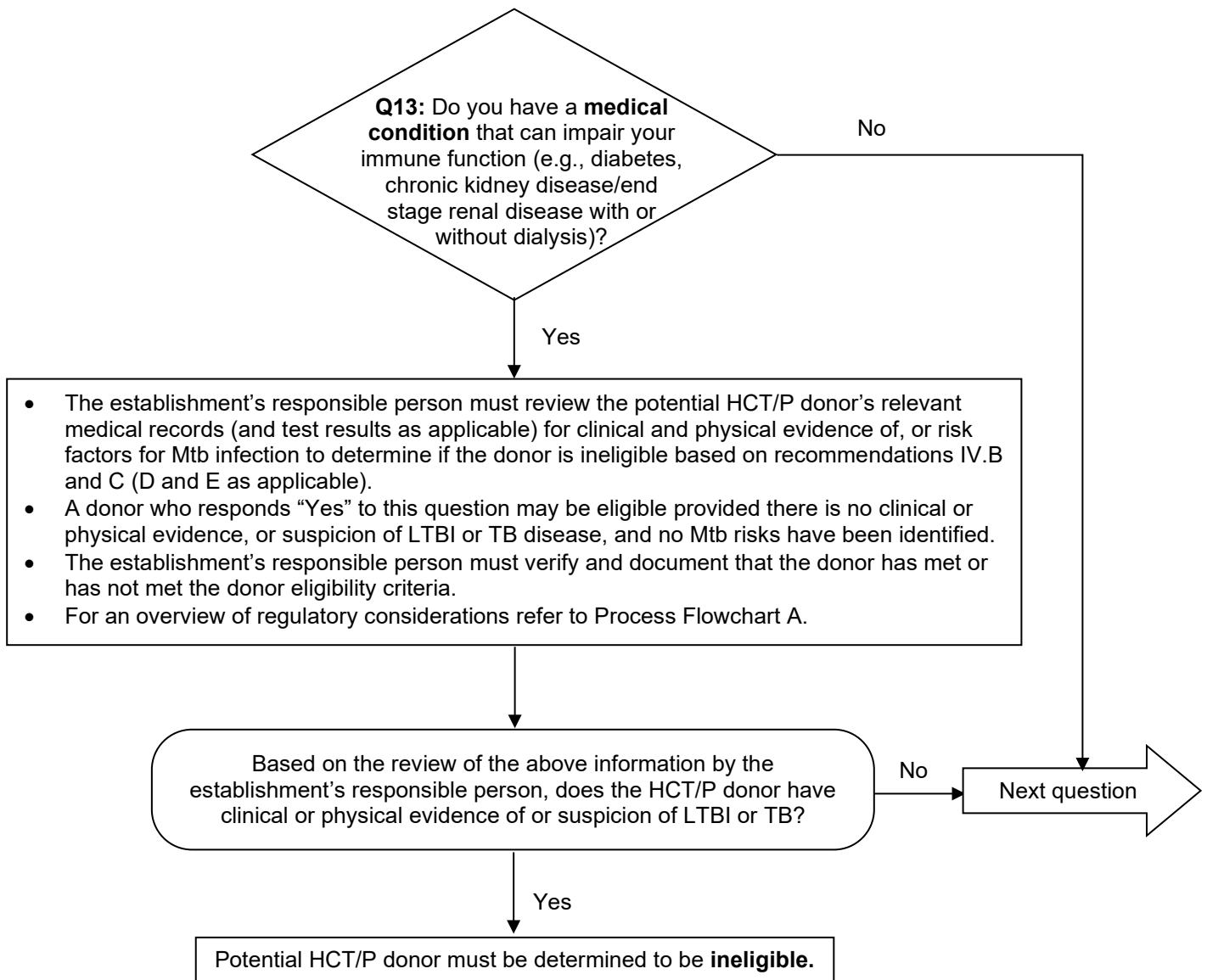
Question 13: Do you have a **medical condition** that can impair your immune function (e.g., diabetes, chronic kidney disease/end stage renal disease with or without dialysis)?

Donor Eligibility: A potential HCT/P donor who has a **medical condition** that could impair their immune function may have a risk factor for Mtb infection based on the following FDA Guidance considerations:

- Risk factors for TB infection and disease include common conditions associated with impaired immunity (e.g., chronic kidney disease, diabetes mellitus, malignancy, immunosuppressive therapy, etc.). [Section II.A, page 3]
- Whether or not an individual develops TB infection or disease following an exposure is a function of their immune response to the inoculum of Mtb bacilli, and might lead to latent infection, a state in which Mtb bacteria survive in the body in a dormant state and there is no evidence of clinical disease (i.e., LTBI). [Section II.A, page 2]

Note: Based on further screening recommendation in FDA Guidance, IV.B and C (D and E as applicable), pages 7-11, the donor might be eligible provided there is no clinical or physical evidence, or suspicion, of LTBI or TB disease, and no communicable disease risks have been identified.

Reference: [FDA's 2025 Mtb Guidance](#) [Section IV.A, page 7]



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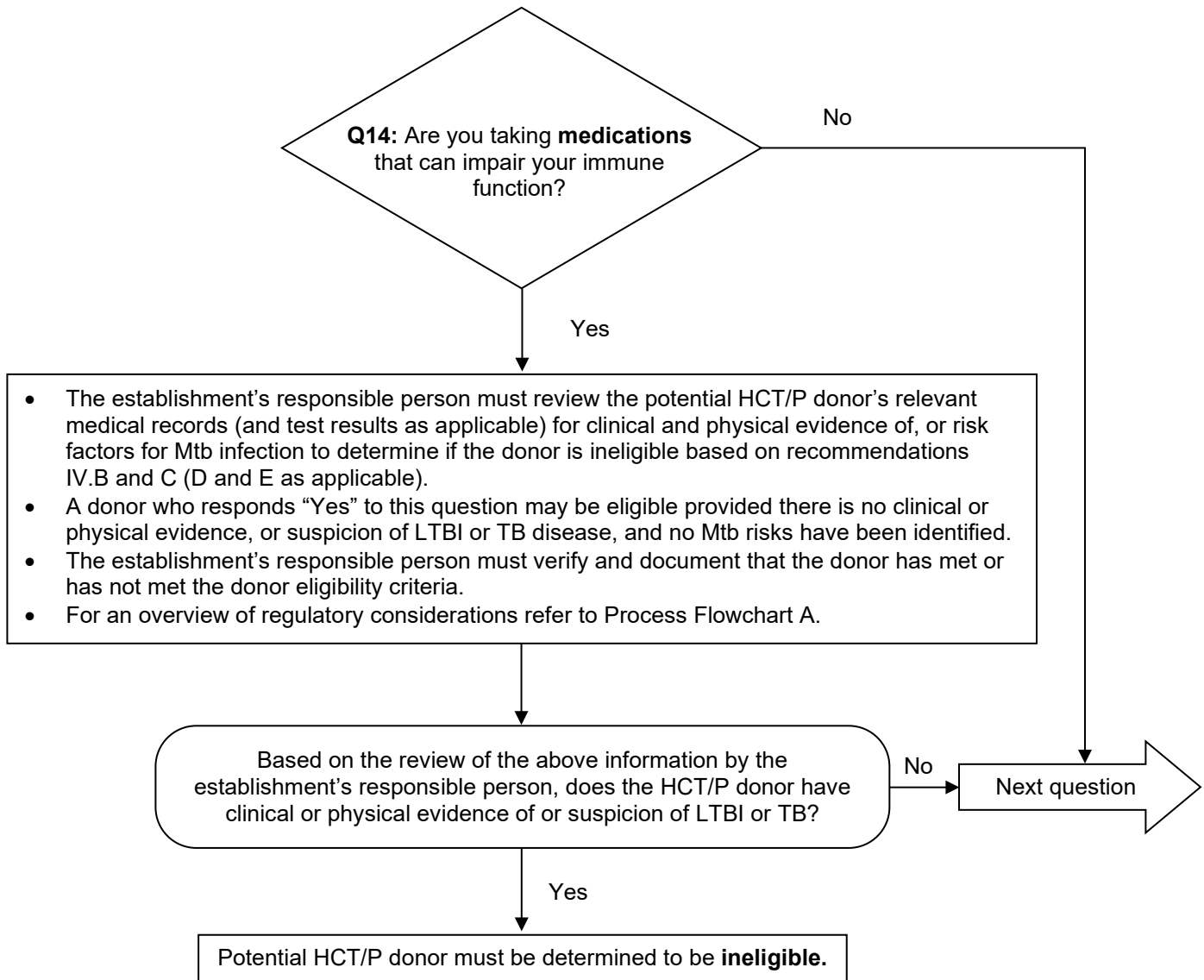
Question 14: Are you taking **medications** that can impair your immune function?

Donor Eligibility: A potential HCT/P donor who is taking a **medication** that could impair their immune function may have a risk factor for Mtb infection based on the following FDA Guidance considerations:

- Risk factors for TB infection and disease include common conditions associated with impaired immunity (e.g., chronic kidney disease, diabetes mellitus, malignancy, immunosuppressive therapy, etc.). [Section II.A, page 3]
- Whether or not an individual develops TB infection or disease following an exposure is a function of their immune response to the inoculum of Mtb bacilli, and might lead to latent infection, a state in which Mtb bacteria survive in the body in a dormant state and there is no evidence of clinical disease (i.e., LTBI). [Section II.A, page 2]

Note: Based on further screening recommendation in FDA Guidance, IV.B and C (D and E as applicable), pages 7-11, the donor might be eligible provided there is no clinical or physical evidence, or suspicion, of LTBI or TB disease, and no communicable disease risks have been identified.

Reference: [FDA's 2025 Mtb Guidance](#) [Section IV.A, page 7]



HPC DHQ Sepsis FLOWCHART

Question 15: Do you **currently** have a medical diagnosis of sepsis or suspicion of sepsis?

Donor Eligibility: A potential HCT/P donor who has a **current** medical diagnosis of sepsis or suspicion of sepsis has a risk factor for sepsis and must be determined to be ineligible based on the following FDA Guidance considerations:

- Sepsis is a clinical syndrome defined as life-threatening organ dysfunction caused by a dysregulated host response to infection. [Section II, page 2]
- The causative agents in sepsis include bacterial, mycobacterial, fungal and viral pathogens. [Section II, page 2]
- There is a risk of transmission by HCT/Ps of any infectious agent that could cause sepsis. [Section III, page 2]
- Various bacterial (including mycobacterial), fungal, and viral agents have been shown to be transmissible via use of HCT/Ps, and these agents have sufficient incidence and/or prevalence to affect the potential HCT/P donor population. [Section II.A, page 3]

Note: If a living donor appears healthy and does not have a recent history of sepsis or suspicion of sepsis, the donor is not considered to have a risk for sepsis. [Section IV.B, page 4]

Reference: [FDA's 2025 Sepsis Guidance](#)

