

Ebola Disease Information for HCT/P Establishments

NOTE: The Example Questions and Flowcharts provided by AABB are offered as examples that HCT/P establishments *may wish to consider* as part of their donor eligibility assessment process when evaluating the FDA considerations described below. The FDA's communication includes considerations for voluntary implementation of HCT/P donor screening related to the current Ebola disease outbreak but is not issued as guidance to industry with specific donor screening recommendations. Establishments remain responsible for determining whether and how such examples may be voluntarily incorporated into their existing procedures to determine an individual's eligibility to donate HCT/Ps.

The FDA's Office of Therapeutic Products (OTP) July 10, Safety & Availability communication, [Important Information for Human Cell, Tissue, and Cellular and Tissue-based Product \(HCT/P\) Establishments Regarding Ebola Disease and HCT/P Donation](#) to HCT/P establishments does not issue specific donor screening recommendations in guidance related to the current Ebola disease outbreak.

FDA noted that existing donor screening measures to determine eligibility to donate, including donor medical history interviews ([21 CFR 1271.3\(n\)](#)), clinical and physical evidence of infection, and review of relevant medical records ([21 CFR 1271.3\(s\)](#)), may identify donors with risk factors, conditions, or evidence of infection and result in a donor being determined ineligible to donate.

FDA further stated that based on information currently available establishments may also “wish to consider” additional factors related to the current outbreak when evaluating an individual's eligibility to donate, including whether in the 21 days prior to HCT/P recovery, the donor:

- was diagnosed with or suspected of having Ebola disease
- had close contact with a person confirmed to have or suspected of having Ebola disease
- resided in or travelled to a country with widespread transmission of Ebola disease (See Map of Impacted Areas: <https://www.cdc.gov/ebola/situation-summary/index.html>)
- was notified by a federal, state, or local public health authority that they may have been exposed to a person with Ebola disease

[Example DHQ Questions and Flowcharts to Evaluate HCT/P Donors for Ebola Risk begin on the next page]

NOTE: Use of these examples is voluntary and not driven by OTP guidance recommendations. Consistent with the notice, which states that establishments “may wish to consider” certain factors, these materials are intended solely to assist establishments that choose to incorporate those considerations when evaluating an individual’s eligibility to donate. They would be added to the end of their HPC DHQ in the Area for Additional Questions.

EXAMPLE QUESTIONS to Evaluate HCT/P Donors for Ebola Disease Risk:

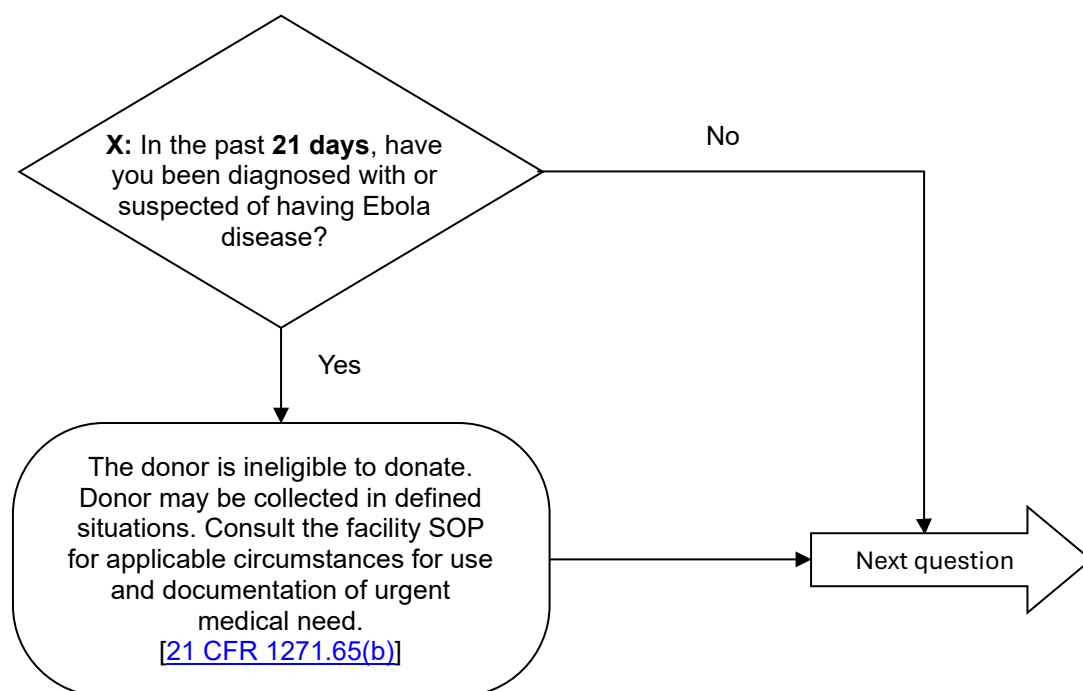
Use this area for additional questions <i>EXAMPLES – NUMBER PER YOUR POLICY</i>	Yes	No
Ebola Question X: In the past 21 days , have you been diagnosed with or suspected of having Ebola disease?	☐	☐
In the past 21 days , have you had close contact (e.g. contact with bodily fluids such as blood, urine, feces, saliva, semen) with a person, living or deceased, confirmed to have or suspected of having Ebola disease?	☐	☐
Ebola Question X: In the past 21 days , have you resided in or traveled to a country with widespread transmission of Ebola disease? See Map of Impacted Areas: https://www.cdc.gov/ebola/situation-summary/index.html)	☐	☐
Ebola Question X: In the past 21 days , were you notified by a federal, state, or local public health authority that you may have been exposed to a person with Ebola disease?	☐	☐

[Flowcharts begin on the next page]

EXAMPLE FLOWCHARTS to Evaluate HCT/P Donors for Ebola Disease Risk

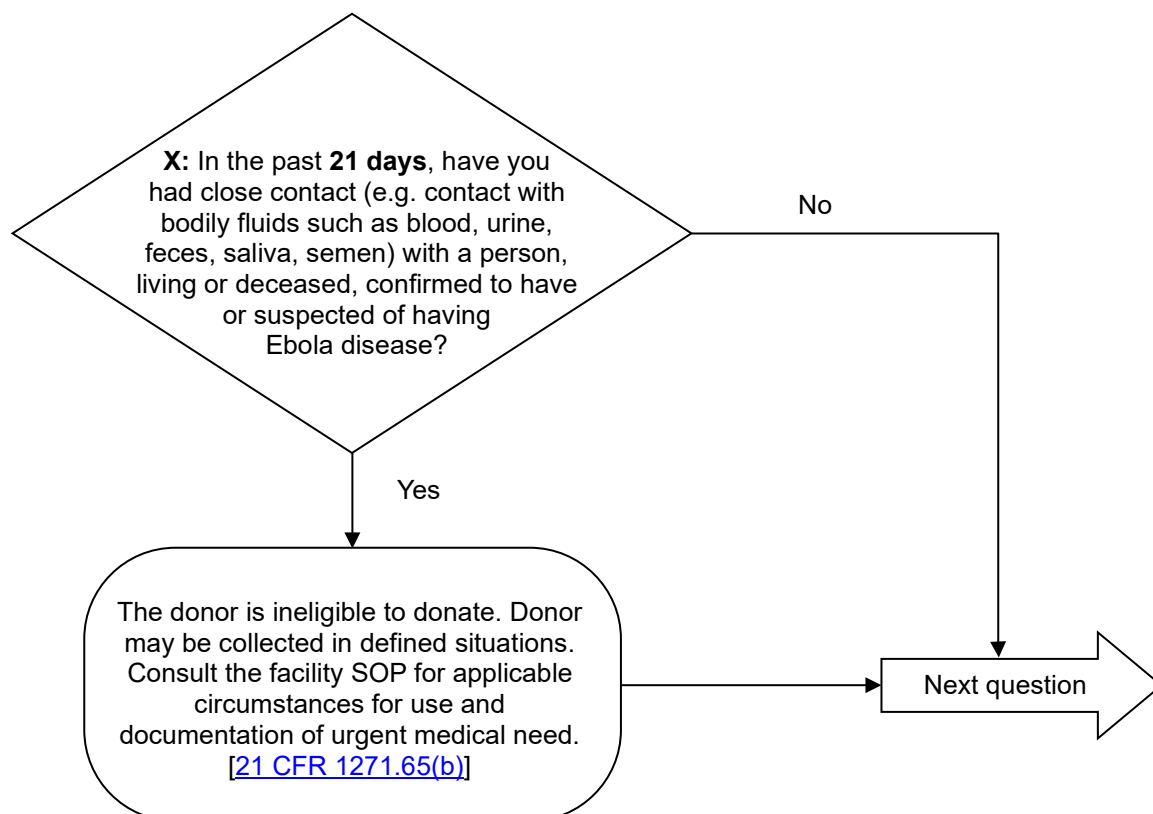
Ebola Question X: In the past **21 days**, have you been diagnosed with or suspected of having Ebola disease?

Donor Eligibility: A person who has been diagnosed with or suspected of having Ebola disease in the 21 days prior to HCT/P recovery is determined to be ineligible to donate.



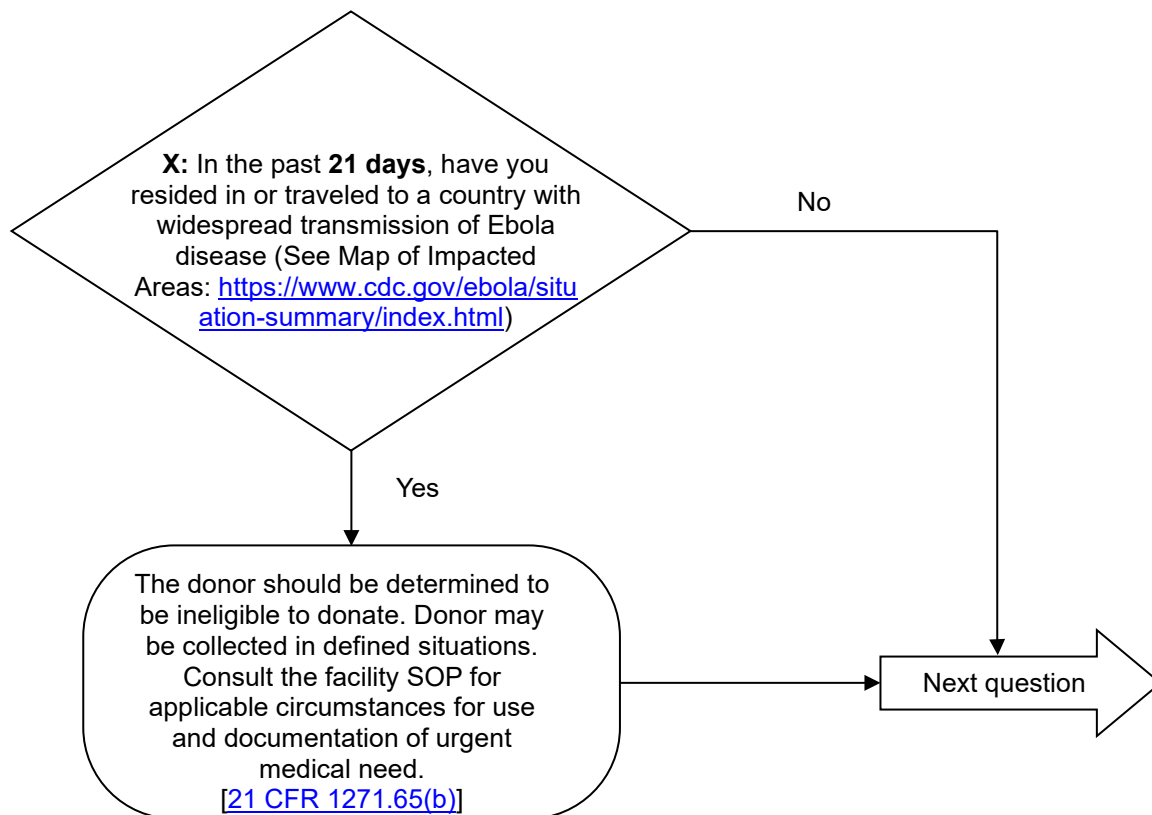
Ebola Question X: In the past **21 days**, have you had close contact (e.g. contact with bodily fluids such as blood, urine, feces, saliva, semen) with a person, living or deceased, confirmed to have or suspected of having Ebola disease?

Donor Eligibility: A person who has had close contact or direct exposure to the body fluids (blood, urine, feces, saliva, semen) of a person, living or deceased, confirmed to have or suspected of having Ebola disease in the 21 days prior to HCT/P recovery is determined to be ineligible to donate based on the risks associated with that exposure.



Ebola Question X: In the past **21 days**, have you resided in or traveled to a country with widespread transmission of Ebola disease (See Map of Impacted Areas: <https://www.cdc.gov/ebola/situation-summary/index.html>)

Donor Eligibility: A person who has resided in or traveled to a country with widespread transmission of Ebola disease in the 21 days prior to HCT/P recovery should be determined to be ineligible. The facility's authorized person must take this risk factor into consideration when determining an individual's eligibility to donate.



Ebola Question X: In the past **21 days**, were you notified by a federal, state, or local public health authority that you may have been exposed to a person with Ebola disease?

Donor Eligibility: A person who has been notified by a federal, state, or local public health authority in the 21 days prior to HCT/P recovery that they may have been exposed to a person with Ebola disease should be determined to be ineligible. The facility's authorized person must take this risk factor into consideration when evaluating an individual's eligibility to donate.

