Association for the Advancement of Blood & Biotherapies

Ebola Toolkit to Assist with the Evaluation of Blood Donor Eligibility, Deferral, Product Management and Risk of Ebola Disease

Updated
July 6, 2026

This toolkit is intended for blood collection establishments. For FDA information specific to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), please refer to Ebola Disease Information for HCT/P Establishments.

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Information for Biotherapies Facilities:
At this time, FDA's Office of Therapeutic Products (OTP) has not issued donor eligibility recommendations specific to Ebola disease risk for HCT/P donors. Until FDA provides more specific guidance, AABB-accredited biotherapies facilities may consider blood donor eligibility information related to Ebola risk when evaluating their policies and processes. See AABB's Evaluating Donors for Risk of Ebola Disease webpage and information below.

I. Introduction

This Ebola Toolkit is intended to supplement your understanding of the recommendations in the FDA's June 2026 Guidance, Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to an Ebola Disease Outbreak. These tools support a smooth transition for the implementation of the guidance recommendations in the event of an Ebola outbreak, when FDA communicates the recommendations in section III.A.2 and III.B should be implemented and specifies the countries for which donor residency and travel history should be assessed. The checklist is included as a "quick reference," and the flowchart maps a clear path for implementation of donor screening, deferral, and inventory management. These tools contain relevant hyperlinks to support compliance efforts as you ensure policies and procedures consistently meet FDA's specific expectations for additional safety during the period of risk. A link to the final guidance itself appears in the title of the checklist.

IMPORTANT NOTE:
FDA's July 29 Safety and Availability Notice, Important Information for Blood Establishments Regarding Ebola Disease and Blood Donation, triggers the use of additional measures (updated Ebola disease questions and Donor Educational Material) provides the list of countries for which donor travel and residency should be assessed:

"Considering the current Ebola disease outbreak in the Democratic Republic of the Congo (DRC) and Uganda, we refer blood establishments to the recommendations in our guidance document to update their donor eligibility processes accordingly, including asking donors about residency or travel to the DRC and Uganda."

[Checklist begins on the next page]

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AABB Checklist for FDA's June 2026 Ebola Recommendations

USE WITH RECOMMENDATIONS IN SECTIONS III.A, B & C, PAGES 3-7 OF THE GUIDANCE

III.A Donor Educational Material and Donor History Questionnaire

Within 12 weeks of June 29, 2026, FDA recommends:

Implementation of Recommendations in section III.A.1, pages 3-4: "…***self-deferral of donors with a history of Ebola disease should provide sufficient protection***"

_____Review AABB Blood Donor Education Material

_____Update donor educational material to include self-deferral for Ebola disease.

When FDA communicates that the recommendations in section III.A.2 and III.B. should be implemented and specifies the countries for which donor residency and travel history should be assessed – Implement within 4 weeks:

_____**Modify your DHQ and aDHQ** [III.A.2, page 4]**:**

Refer to AABB Ebola DHQ modified to **assess individuals for Ebola risk.**

_____**Modify your Ebola Donor Education Material** [III.A.1, page3 3-4] to assist donors in answering the additional questions for Ebola risk.

Refer to AABB Ebola Education Material; CDC: Ebola Disease Basics page which includes "Signs and Symptoms" information.

III.B. Donor Deferral – Implement within 4 weeks:

Defer a donor for Ebola risk [III.B, page 5]. Ebola is a transfusion-transmitted infection under 21 CFR 630.10(e)(2) and (h):

_____**Update SOPs for eligibility and deferral requirements.**

Refer to AABB Ebola flowcharts for donor eligibility and deferral criteria.

III.C. Product Retrieval, Quarantine, and Notification – Implement within 4 weeks:

Blood and Blood Components Collected from Donors at Risk for Ebola Virus Infection or Disease Because of Risk Factors Related to Residency, Travel or Close Contact [III.C.1 page 6]**:**

_____**Quarantine/destroy** all undistributed in-date products from such a donor.

_____**Notify consignees** to retrieve/quarantine/destroy blood products from such a donor, if distributed for transfusion or for further manufacture*

*For plasma pooled for further manufacturing, refer to recommendation III.C.1.b, page 6.

Blood and Blood Components Collected from Donors Later Determined to Have Ebola Disease [III.C.2 pages 6 & 7]**:**

_____**As soon as possible**, contact FDA upon learning of the donor's Ebola disease risk based on donation in the 8 weeks prior to disease onset or any time after disease onset.

_____**Notify** state and local public health authorities, as applicable.

_____**Promptly retrieve/quarantine** the blood products collected in the 8 weeks prior to disease onset, if collected from a donor who should have been deferred for Ebola risk.

_____If transfused, transfusion services should notify the transfusion recipient's physician of record regarding the need for notification and monitoring of the recipient for possible Ebola disease.

_____Manufacturers should contact the appropriate FDA review division to discuss the adequacy of their risk analysis if plasma collected from such a donor has been pooled for further manufacturing or manufactured into a finished product.

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Flowchart for Implementation of FDA's June 2026 Ebola Recommendations

By September 2026: Update your Donor Educational Material for use during periods when there are no countries with an Ebola disease outbreak consistent with recommendations in section III.A.1 of the guidance.

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Trigger additional Ebola recommendations:
During an Ebola disease outbreak, FDA, in consultation with CDC, will communicate when the recommendations in section III.A.2 and III.B should be implemented and specify the countries for which donor residency and travel history should be assessed.

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Within 4 weeks from the date FDA communicates that the recommendations should be implemented, you must:

1. Implement Ebola Donor Education Material to assist donors with the Ebola questions. Refer to AABB Ebola Education Material. [VI, page 8 and III.A.2. page 4]
2. Update your DHQ to assess donors for Ebola risk. Refer to AABB Ebola DHQ and flowcharts to add 5 questions *to the end of the AABB DHQ*. [III.A.2. page 4]

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III.A.2. Donor Risk Assessment and III.B Donor Deferral

Consistent with AABB model DHQs, assess individuals for symptoms of recent or current illness with Ebola disease, and travel to, or residence in, an area endemic for Ebola disease (as required by 21 CFR 630.10(e)(2), as follows:

a. A history of Ebola disease. Defer indefinitely. [III.B.1, page 5]
   Does not apply to convalescent plasma collection for treatment of Ebola disease [as described in section III.B.1, page 5.]
b. A history of residence in or travel to a country with an Ebola disease outbreak as specified by FDA. Defer for 8 weeks from date of departure [III.B.2, page 5].

In addition, further assess prospective donors for risk in the past 8 weeks based on:

- A history of close contact with a person confirmed to have Ebola disease or a person under investigation (PUI) for Ebola disease in whom diagnosis is pending. Defer for 8 weeks from date of last exposure [III.B.1 page 5].
  Close contact is defined as contact that could have resulted in direct exposure to body fluids such as blood, urine, stool, saliva, semen, vaginal fluids or vomit, such as healthcare workers and other persons who care for, have lived with, or have otherwise been in contact with a PUI or a person confirmed to have Ebola disease. [III.A.2.a, page 4]
- A history of sexual contact with a person known to have recovered from Ebola disease prior to that instance of sexual contact, regardless of the time since the person's recovery. Defer for 8 weeks from date of last contact [III.B.1, page 5].
- A history of notification by a public health authority that he or she may have been exposed to a person with Ebola disease. Defer for 8 weeks from date of last contact [III.B.2, page 5].

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III.C. Perform Product Retrieval, Quarantine, and Notification

1. Quarantine/destroy all undistributed in-date products from a donor who should have been deferred for Ebola disease risk. [III.C.1. page 6]
   a. Notify consignees to retrieve/quarantine/destroy blood products, if you distributed products for transfusion or for further manufacture from a donor who should have been deferred. [III.C.1.a page 6]
   b. For plasma pooled for further manufacturing refer to recommendation [III.C.1.b, pages 6 & 7].
2. Products collected from a donor later determined to have Ebola disease:
   As soon as possible, contact FDA upon learning of the donor's Ebola disease risk based on donation in the 8 weeks prior to disease onset or any time after disease onset. Notify state and local public health authorities, as applicable. [III.C.2. page 6]
   a. Promptly retrieve/quarantine the blood products collected in the eight weeks prior to disease onset, if collected from a donor who should have been deferred [III.C.2.a, pages 6 & 7].
      - If transfused, transfusion services should notify the transfusion recipient's physician of record regarding the need for notification and monitoring of the recipient for possible Ebola disease.
   b. Manufacturers should contact the appropriate FDA review division to discuss their conduct of adequate risk analysis if plasma collected from such a donor has been pooled for further manufacturing or manufactured into a finished product. [III.C.2.b, page 7]