



Association for the  
Advancement of  
Blood & Biotherapies

**Implementation of Individual  
Donor Assessment  
and the  
Donor History Questionnaire  
Version 4.0 and Accompanying  
Materials  
TOOLKIT**

**Updated August 15, 2023**

**Check back for new information-  
This Toolkit will be updated frequently.**

# **Individual Donor Assessment and Implementation of the AABB Donor History Questionnaire Version 4.0 and Accompanying Materials Updated August 15, 2023 TOOLKIT**

This Individual Donor Assessment (IDA) and Donor History Questionnaire Version 4.0 (DHQ v4.0) Toolkit is intended to walk you through the updated information on IDA and in the [DHQ v4.0 and Accompanying Materials](#), dated May 2023, based on:

- ✓ FDA's formal acceptance in [Guidance](#) on May 11, 2023,
- ✓ Guidance documents listed in the [References](#)
- ✓ [AABB Standards](#) and [Association Bulletins](#)
- ✓ [AABB's Library of Individual Donor Assessment Resources](#) – FAQs, Training, Positive Communications
- ✓ [NEW INFORMATION](#)

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## BACKGROUND

- ❖ The AABB website includes a page designated for the [Donor History Questionnaire](#). Donor History Task Force is charged by AABB's Board of Directors with updating and maintaining the DHQ and Accompanying Materials for compliance with current regulatory requirements. The Task Force consists of member experts, including representatives from the American Red Cross, America's Blood Centers, the Armed Services Blood Program, Canadian Blood Services, the Plasma Protein Therapeutics Association, the Food and Drug Administration, the Centers for Disease Control and Prevention, consultants, an ethicist, and AABB's chief medical officer.
- ❖ This Toolkit has been developed to help you find all of the resources to assist with implementation of IDA and the DHQ v4.0 compliance efforts. It must not replace your full review of [DHQ v4.0 and Accompanying Materials](#) (including the aDHQ, if used), which comprise the system of documents formally recognized by FDA as acceptable for use in screening donors of blood and blood components consistent with FDA requirements and recommendations for donor eligibility.
- ❖ The [DHQ v4.0 and Accompanying Materials](#) provide:
  - ✓ Assessment of all prospective donors following an individual donor assessment approach that uses the same set of questions for each donor regardless of their sex.
  - ✓ Assessment of donors for use of PrEP/PEP/ART has been formally incorporated into DHQ v4.0 to evaluate donor eligibility and mitigate risks related to the suppression of HIV to undetectable levels in people taking antiviral medications, and the potential impact on donor testing for HIV infection as a result of such medications' suppressive effects.
    - FDA's May 2023 [Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry](#)
    - [AABB Association Bulletin #22-03 Updated Recommendations on Donor Deferral for Use of Antiretroviral Medications for HIV Prevention and Treatment including Long-Acting Injectable PrEP and the Impact on Blood Safety](#) outlines the recommendations.

## IMPLEMENTATION OF INDIVIDUAL DONOR ASSESSMENT

- ❖ **HOW DO I KNOW WHAT CHANGES HAVE TO BE MADE TO THE DHQ v4.0 DOCUMENTS?**  
Documents are linked in this toolkit to make it easy to identify the specific changes in each document. These crosswalks also detail the changes in DHQ v4.0:
  - ✓ [DHQ v2.1 Crosswalk to DHQ v4.0](#)
  - ✓ [aDHQ v2.1 Crosswalk to aDHQ v4.0](#)
 Refer to the checklist section for more detailed information on the required changes.

## ❖ DID AABB VERIFY THE NEW DHQ DOCUMENTS WERE ACCURATE AFTER THE FINAL GUIDANCE WAS RELEASED BY FDA?

Yes, AABB has reviewed the final guidance and validated the DHQ v4.0 documents before posting them on the AABB website on 5/11/23.

This table compares [Validation of Final HIV Guidance Against Draft Guidance](#)

- ✓ As part of AABB's ongoing commitment to cGMP, a validation of the final guidance against the draft guidance has been completed to ensure that all final recommendations have been incorporated into the DHQ v4.0.

## WHERE CAN I FIND NEW INFORMATION?

- [DHQ v4.0 Spanish Language Translation Toolkit](#) – August 2023
- [Timeline for Implementation of Individual Donor Assessments: Talking Points and FAQs for Blood Collection Facilities](#)
- [Information for Donors on Blood Centers' Implementation of Individual Risk Assessment](#) – public facing document
- [Hot Topic Discussion: Join FDA's Dr. Peter Marks for an Individual Donor Assessment Update](#) – May 25, 2023
  - FDA's follow-up responses to the Hot Topic Discussion (coming soon)
- [Hot Topic Discussion: Navigating Individual Donor Assessment and DHQ v4.0](#) – May 25
- Canadian Blood Services
- [Chart of FDA Recommended Deferrals to Reduce the Risk of HIV Transmission Through Blood and Blood Components](#)

## ARE THERE TRAINING RESOURCES?

Yes, [AABB's Library of Individual Donor Assessment Resources](#)

- ✓ The following resources were developed in consultation with LGBTQ+ organizations and in partnership with Canadian Blood Services and are consistent with FDA's January 2023 draft guidance.
- ✓ AABB is offering this suite of resources and educational programs free to the community, including:
  - [EDUCATIONAL TRAINING](#)
  - [TRAIN-THE-TRAINER PROGRAM](#)
  - Individual Donor Assessment Training Modules - On-Demand | Free Registration
    - [Register for Part I \(30 min\)](#)
    - [Register for Part II \(60 min\)](#)
    - [Register for Course Bundle \(Part I and II Together\)](#)
  - [FAQs on Individual Donor Assessment Screening](#)
  - [How Individual Donor Assessment Was Informed by Research](#)
  - [Chart of FDA Recommended Deferrals to Reduce the Risk of HIV Transmission Through Blood and Blood Components](#)

- [Individual Donor Assessment Conversations Training](#)
- [Individual Donor Assessment Primer: Sex-Positivity](#)
- [AABB News April 2023: A New Era of Blood Donor Eligibility](#)

## ARE THERE RESOURCES TO HELP CENTERS DEVELOP SOPS FOR BLOOD DONOR SAFETY FOR NONBINARY INDIVIDUALS WHO DO NOT IDENTIFY AS MALE OR FEMALE?

Yes, the donor Health and Safety Committee has developed the following resource:

### [DONOR HEALTH AND SAFETY CONSIDERATIONS FOR INDIVIDUALS WHO DO NOT IDENTIFY AS MALE OR FEMALE](#)

The Donor Health and Safety Committee (DHSC) has developed the following donor health and safety considerations for the collection of blood from individuals who do not identify as male or female.

#### 1. Predonation Minimum Hemoglobin Value

To protect the health and safety of a donor who does not identify as male or female, consider the use of the most protective minimum hemoglobin of 13.0 g/dL.

#### 2. Estimated Total Blood Volume (EBV) and Apheresis Donor Health and Safety

For specific questions related to apheresis collections of individuals who do not identify as male or female contact the apheresis device manufacturer.

Donor centers may consider the following information:

- To protect the health and safety of a donor who does not identify as male or female, consider the use of the more protective EBV with an automated apheresis device which does not provide a non-binary option for collection. The use of a more protective EBV is intended to protect the health and safety of the donor and reduces the risk of adverse reactions during apheresis collections.
- Some apheresis donor reactions are a function of the volume of blood drawn relative to EBV. Various nomograms for estimating EBV are generally based on an equation using donor height, weight, and gender. EBV calculations are significantly lower for females as compared to EBV calculations for males at the same height and weight.
  - For example, a 150-pound, 5'6" male has an EBV of 4.5 liters and a female of the same height and weight has a 4.1-liter EBV, i.e., a full 10% lower. (See: <https://www.mdcalc.com/blood-volume-calculation>).
- Donor centers may consider suggesting whole blood donations for a donor who does not identify as male or female if the apheresis device requires the input of gender for the computer calculation of EBV without an override option.

### 3. Pregnancy – Donor and Patient Safety

The AABB [Donor History Questionnaire v4.0 \(DHQ v4.0\)](#), formally accepted in FDA [guidance](#), poses all questions to all donors regardless of their sex.

- To protect **DONOR** health and safety, all donors are asked:

**DHQ Question #4:** “Are you pregnant now?”

This question protects the health and safety of a donor who is pregnant on the day of the donation attempt. For reasons of donor safety, an individual is deferred for 6 weeks from the last date of pregnancy.

- To protect the safety of both the **DONOR** and the **PATIENT** all donors are asked the following question for two reasons:

**DHQ v4.0 Question 35:** “Have you ever been pregnant?”

- 1) This question protects the health and safety of the **DONOR** by identifying a donor who has been pregnant in the past 6 weeks but is no longer pregnant at the time of donation. For reasons of donor safety, an individual is deferred for 6 weeks from the last date of pregnancy.
- 2) This question also protects the health and safety of the **PATIENT** by assessing for a history of pregnancy to mitigate the risk of Transfusion Related Acute Lung Injury (TRALI) caused by HLA antibodies.
  - TRALI is a rare but acute complication of transfusion that is often life-threatening.
  - The HLA antibodies causing TRALI are most often found in the plasma following pregnancy.
  - This question is used to identify donors who have been pregnant and will need donor testing for HLA antibodies to help prevent TRALI in a **PATIENT** recipient.

For additional information on TRALI risk mitigation, refer to:

- AABB [Association Bulletin #14-02](#) TRALI Risk Mitigation for Plasma and Whole Blood for Allogeneic Transfusion
- AABB Technical Manual, 20<sup>th</sup> edition, Chapter 22 *Noninfectious Complications of Blood Transfusion*
- AABB Standards for Blood Banks and Transfusion Services, 33<sup>rd</sup> edition

## DHQ v4.0 IMPLEMENTATION CHECKLIST

Read the following:

- ✓ The recommendations in [FDA guidance documents](#),
- ✓ [AABB Association Bulletin #22-03](#) and
- ✓ [AABB Standards](#) in the Reference section that are the basis for the updates in DHQ v4.0 and Accompanying Materials, dated May 2023.

Read the DHQ v4.0 and aDHQ v4.0 User Brochure:

- ✓ [AABB Full-Length DHQ 4.0 User Brochure](#) and
- ✓ [Abbreviated DHQ v4.0 User Brochure](#) for the instructions for appropriate use, limitations, options for adding questions, reformatting materials, etc.

### Following your policies and procedures for implementing a new version of the DHQ:

Implement the [AABB DHQ v4.0](#) including significant changes listed below:

- ✓ Individual Donor Assessment (IDA) - male-specific and female-specific questions are replaced by IDA questions as recommended in [FDA's May 2023 HIV Guidance](#):
  - **DHQ v4.0 Question #12:** In the past **3 months**, have you had sexual contact with a new partner? (refer to examples of "new partner" in the Blood Donor Educational Material)
  - **DHQ v4.0 Question #13:** In the past **3 months**, had sexual contact with more than one partner?
- ✓ PrEP/PEP/ART – Donor assessment for the use of PrEP/PEP/ART as recommended in [FDA's May 2023 HIV Guidance](#) and in [Association Bulletin #22-03](#) is formally incorporated into DHQ v4.0:
  - **DHQ v4.0 Question #11:** "In the past **3 months** have you taken any medication by mouth (oral) to prevent an HIV infection? (i.e., PrEP or PEP)"
  - **DHQ v4.0 Question #31:** "In the past **2 years**, have you received any medication by injection to prevent HIV infection? (i.e., long-acting antiretroviral PrEP or PEP)"
  - **DHQ v4.0 Question #34:** "Have you ever taken any medication to treat HIV infection?"
- ✓ HIV assessment questions for sexual contact for anyone who had "EVER received money, drugs..." and "EVER used needles to take..." were revised to align with the updated deferral criteria in [FDA's May 2023 HIV Guidance](#):
  - **DHQ v4.0 Question #16:** "In the past **3 months**, have you had sexual contact with anyone who has, in the past 3 months, received money, drugs, or other payment for sex?"
  - **DHQ v4.0 Question #18:** "In the past **3 months**, have you had sexual contact with anyone who has used needles in the past 3 months to inject drugs, steroids, or anything not prescribed by their doctor?"
- ✓ HIV assessment question #14 was updated to align with the language of [FDA's May 2023 HIV Guidance](#):
  - **DHQ v4.0 Question # 14:** "In the past **3 months**, have you had sexual contact with anyone who has ever had a positive test for HIV infection?"
- ✓ Modification of the DHQ v2.1 compound pregnancy question. DHQ v4.0 breaks this assessment into 2 questions posed to all donors regardless of sex:
  - **DHQ v4.0 Question #4:** "Are you pregnant now?"
  - **DHQ v4.0 Question #35:** "Have you ever been pregnant?"

- ✓ **Hepatitis Risk Assessment** – During the revision and review process for the DHQ v4.0, FDA established a 3-month deferral for hepatitis risk. The agency stated *“that revising the deferral periods for hepatitis risk factors to 3 months, consistent with deferrals for HIV risk factors, is expected to maintain the safety of blood components because nucleic acid testing for HBV and HCV can detect the viruses well within a 3-month period following initial infection.”*
- ✓ The agency’s decision to use this 3-month deferral period is formalized in the recommendations on page 3 of FDA’s [May 2023 Level 2 guidance](#) recognizing DHQ v4.0 as *“acceptable for use in screening donors of blood and blood components. These documents are consistent with FDA requirements and recommendations for donor eligibility.”*
- ✓ **AABB notes:** All regulatory references to a 12-month deferral for hepatitis risk were removed in 2015. FDA removed the regulations in 21 CFR 640.3 in the [May 2015 final rule](#) (see page 29904), including paragraph (c) which specifically referenced a 12-month deferral for hepatitis risk. Since the final rule became effective in May 2016, FDA has not issued recommendations specifying the deferral period for hepatitis risk.
  - **DHQ v4.0 Question #20:** “In the past **3 months**, have you had sexual contact with a person who has hepatitis?”
  - **DHQ v4.0 Question #21:** “In the past **3 months**, have you lived with a person who has hepatitis?”
- ✓ Requirement to assess for geographic risk of vCJD has been removed - Former DHQ v2.1 vCJD Risk assessment questions #30, #31 and #32 have been removed based on the recommendations in the [May 2022 CJD/vCJD Guidance](#).

Use the updated [AABB DHQ v4.0 Flowcharts](#) –

- ✓ FDA regulations, guidance hyperlinks, and AABB Standards references have been added throughout the Donor Eligibility statements in the Flowcharts.
- ✓ **Flowchart #4:** Assesses all donors for a pregnancy for the timeframe “Now”
- ✓ **Flowchart #5:** Information formerly on page 2 of the MDL has been relocated to this flowchart.
- ✓ **Flowchart #8:** Donor Eligibility includes the assessment of a “single unit red blood cell donor”.
- ✓ **Flowchart #9 and 9alt:** Assessment for receipt of the Jynneos vaccine is included.
- ✓ **Flowchart #10 and 10alt:** Assessment for receipt of the Jynneos vaccine is included.
- ✓ **Flowchart #16:** Donor Eligibility statement and flowchart include information to assess eligibility when a donor has uncertainty about when their sexual partner received money, drugs or other payment for sex.
- ✓ **Flowchart #18:** Donor Eligibility statement and flowchart include information to assess eligibility when a donor has uncertainty about when their sexual partner used needles to inject drugs, steroids, or anything not prescribed by their doctor.
- ✓ **Flowchart #20:** Was revised to assess a donor for a history of sexual contact with a person who has had hepatitis B or C. A donor who has had sexual contact with a person who has had other types of viral hepatitis, such as CMV or infectious mononucleosis, is not deferred.
- ✓ **Flowchart #21:** Was revised to assess a donor for “lived with” with a person who has had hepatitis B or C. A donor who has lived with a person who has had other types of viral hepatitis, such as CMV or infectious mononucleosis, is not deferred.
- ✓ **Flowchart #23:** Revised to differentiate types of contact “with someone else’s blood.”
- ✓ **Flowchart #24:** Donor Eligibility statement includes information on [permanent makeup](#).



- ✓ **Flowchart #25:** Donor Eligibility statement includes an FDA clarification differentiating the requirements for tattoo and piercing.
- ✓ **Flowcharts #26, 27, 28:** Donor Eligibility statements includes definitions of allogeneic and autologous.
- ✓ **Flowchart #33:** Donor Eligibility statement includes information to follow for evaluation of HIV test results which were subsequently shown to be falsely positive test results.
- ✓ **Question #37:** Was revised to differentiate receipt of a dura mater transplant and a xenotransplantation to reflect their different deferrals. (xenotransplant is an indefinite deferral and dura mater is a permanent deferral)

Use the [AABB Blood Donor Educational Material v4.0](#):

- ✓ Revised to align with the language and donor eligibility requirements of DHQ v4.0 and [FDA's May 2023 HIV Guidance](#).
- ✓ FDA's examples of a "new sexual partner" are included.  
A "new sexual partner" includes the following examples:
  - Having sex with someone for the first time  
OR
  - Having had sex with someone in a relationship that ended in the past, and having sex again with that person in the last 3 months.
- ✓ The importance of accurate and honest responses is established in the opening section of the education material to remove potential confusion.
- ✓ Content has been reorganized based on FDA's feedback.

**This Blood Donor Educational Material is used with both the DHQ and the aDHQ.**

Use the [AABB Medication Deferral List v4.0](#):

- ✓ Revlimid (lenalidomide) has been added with a 1-month deferral.
- ✓ HIV prevention and HIV treatment - brand and generic names replaced by a description which is more readily recognized and understood by the donor.
- ✓ Hepatitis B Immune Globulin timeframe has been revised from 12 months to 3 months to reflect the change in deferral for hepatitis risk exposure.
- ✓ Unlicensed (Experimental) Vaccine – Removed from the list. Vaccines are addressed in the DHQ and flowcharts.
- ✓ Experimental medication – timeframe has been revised to "As defined by the medical director."
- ✓ The information from page 2 of the MDL concerning how certain medications may affect eligibility has been relocated to Flowchart Question #5 for use by the donor historian.

**This Medication Deferral List is used with both the DHQ and the aDHQ.**

AABB will update this toolkit to make it easy to find additional resources as they are developed.

Report the implementation of AABB's DHQ v4.0 and Accompanying Materials, consistent with Section IV of the [FDA's May 2023 Implementation Guidance](#) and reporting requirements of [21 CFR 601.12](#), as a:

- ✓ **Minor change** in the Annual Report [[§601.12\(d\)](#)] to FDA when implemented as accepted by FDA or with minor changes to the v4.0 documents, as described in recommendations 1-4 of Section IV, page 3.

- ✓ **Moderate change** if implemented using “a computer-assisted interactive interview procedure,” which requires a CBE30 supplement [[§601.12\(c\)](#)], as described in recommendation 5 of Section IV, page 4. Refer to [FDA’s July 2003 guidance](#).
- ✓ **Major change** if implemented as a modified version of the FDA accepted DHQ v4.0 materials, which may require the submission of a PAS [[§601.12\(b\)](#)] for FDA approval prior to implementation of the major changes, as described in recommendation 6 of Section IV, page 4.

**REFERENCES** – The following FDA regulations and guidance documents, AABB Association Bulletin and Standards were incorporated into DHQ v4.0 and Accompanying Materials, dated May 2023:

- [Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Blood and Blood Components; Guidance for Industry](#) 05/2023
- [Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry](#) 05/2023
- [Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry](#) 12/2022
- [Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components; Guidance for Industry](#) (Updated May 23, 2022) - 5/2022
- [Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis; Guidance for Industry](#) - 12/2020
- Donor qualification requirements located in [21 CFR 630](#) and [21 CFR 640](#) (as revised in the [May 22, 2015 Final Rule](#))
- [AABB Standards for Blood Banks and Transfusion Services, 33rd edition](#)
- AABB [Association Bulletin #22-03 Updated Recommendations on Donor Deferral for Use of Antiretroviral Medications for HIV Prevention and Treatment including Long-Acting Injectable PrEP and the Impact on Blood Safety](#) - 9/2022

## Considerations for Source Plasma Collection:

The following example DHQs have been developed for consideration by collection establishments that must comply with international regulatory requirements and deferral policies such as those providing plasma for further processing (i.e., Source Plasma).

Blood centers may need to add certain questions to the end of the DHQ v4.0 and develop flowcharts to reflect the associated deferral for each question.

- ✓ If required to retain or add additional questions, they may be added at the end of the DHQ v4.0 following the last FDA accepted question.
- ✓ It is important to remember that the additional questions must not be inserted into the body of the FDA accepted questionnaire, as this would be considered a major change and trigger the need for FDA review and a Prior Approval Supplement.

## Example of the Blood Donor DHQ v4.0 with additional questions inserted at the end:

In the past <b>3 years</b> , have you		
32. Been outside the United States or Canada?	<input type="checkbox"/>	<input type="checkbox"/>
Have you <b>EVER</b>		
33. Had a positive test for HIV infection?	<input type="checkbox"/>	<input type="checkbox"/>
34. Taken any medication to treat HIV infection?	<input type="checkbox"/>	<input type="checkbox"/>
35. Been pregnant?	<input type="checkbox"/>	<input type="checkbox"/>
36. Had malaria?	<input type="checkbox"/>	<input type="checkbox"/>
37. Received a dura mater (or brain covering) graft or xenotransplantation product?	<input type="checkbox"/>	<input type="checkbox"/>
38. Had any type of cancer, including leukemia?	<input type="checkbox"/>	<input type="checkbox"/>
39. Had any problems with your heart or lungs?	<input type="checkbox"/>	<input type="checkbox"/>
40. Had a bleeding condition or blood disease?	<input type="checkbox"/>	<input type="checkbox"/>
41. Had a positive test result for <i>Babesia</i> ?	<input type="checkbox"/>	<input type="checkbox"/>
<b>Additional Questions</b>		
42. (Male Donors) In the past <b>3 months</b> , have you had sexual contact with another male?	<input type="checkbox"/>	<input type="checkbox"/>
43. (Female Donors) In the past <b>3 months</b> , have you had sexual contact with a male who had sexual contact with another male in the past 3 months?	<input type="checkbox"/>	<input type="checkbox"/>
44. From 1980 through 1996, did you spend time that adds up to 3 months or more in the United Kingdom countries of England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands?	<input type="checkbox"/>	<input type="checkbox"/>
45. From 1980 through 2001, did you spend time that adds up to 5 years or more in France or Ireland? <i>Time spent in Ireland does not include time spent in Northern Ireland which is part of the United Kingdom.</i>	<input type="checkbox"/>	<input type="checkbox"/>

46. 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?	<input type="checkbox"/>	<input type="checkbox"/>
47. Have you EVER had a corneal transplant?	<input type="checkbox"/>	<input type="checkbox"/>
48. In the past 4 months, have you had a colonoscopy or an upper GI endoscopic exam?	<input type="checkbox"/>	<input type="checkbox"/>