

**USER BROCHURE**  
**for the**  
**Abbreviated Donor History Questionnaire**  
**and Accompanying Materials**

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**USER BROCHURE  
for the  
Abbreviated Donor History Questionnaire  
and Accompanying Materials**

**PURPOSE**

The User Brochure is designed to guide blood centers collecting blood and blood components in the use of the Abbreviated Donor History Questionnaire (aDHQ) and all accompanying materials.

**INTRODUCTION**

AABB’s Donor History Task Force (DHTF), comprised of professional member experts, developed the aDHQ and the accompanying materials to be used as part of the screening process to establish donor eligibility. AABB submitted the aDHQ and accompanying materials to the Food and Drug Administration (FDA) for review. The FDA issued guidance to officially recognize the aDHQ and accompanying materials, as submitted, to be acceptable for use by blood centers collecting blood and blood components.

Blood centers using these screening materials should be aware that these materials were tested in English-speaking donor and non-donor groups and, due to practical limitations, could not be tested in all possible settings, including with non-English speaking donors.

It is important to note that both the full-length DHQ and aDHQ, and accompanying documents are designed, structured, and evaluated collectively for comprehension and effectiveness. Use of the aDHQ is limited to qualified frequent donors with no changes to their eligibility. The list of questions is consistent with the DHQ but abbreviated to replace multiple questions with a single question designed to detect a change in eligibility. This is discussed in more detail in the section “**Criteria for using the aDHQ.**” The accompanying materials were designed to be used together, as follows:

- The User Brochure and Flowcharts assist the donor historian performing the screening process to determine donor eligibility. Flowcharts are intended as a resource, and use of the flowcharts is not required. Flowcharts may be revised to reflect local policy as long as deferrals are not made less strict than those required by AABB and FDA.
- The Blood Donor Educational Material and the Medication Deferral List assist the donor in understanding the donation process, risk criteria for transmitting disease to the transfusion recipient, recalling details of travel and medications taken, and other information necessary to protect the safety of the transfusion recipient and the donor.

**ABBREVIATED DONOR HISTORY QUESTIONNAIRE**

**Criteria for using the aDHQ:** A returning blood donor is eligible to use the aDHQ when the frequent donor criteria are met AND the blood center has a system in place to identify donors that meet the criteria for use of the aDHQ. The blood center should have a method to inform the donor of the last donation date to assist the donor with the appropriate timeframe to answer questions beginning “Since your last donation...” If the system indicates a donor is not eligible to use the aDHQ, this determination may be overridden by a supervisor with appropriate documentation.

A frequent donor qualified to use the aDHQ is defined as a person who

- has previously donated two times using the full-length DHQ, with

- one of those two donations occurring within the previous six months.

A frequent donor who is qualified to use the aDHQ and is then deferred, is eligible to use the aDHQ on the next donation if:

- The deferral was based on a physical finding (such as hemoglobin, temperature, pulse, blood pressure, platelet count), OR
- The deferral period was less than 6 months, AND
- The frequent donor attempts to donate again within 6 months of the last successful donation.

A returning donor who was qualified to use the aDHQ is required to use the full-length DHQ for two successful donations before returning to the aDHQ (within 6 months of the last successful donation) if:

- The donor is deferred for 6 months or greater.
- The donor does not return to donate within 6 months.

For these purposes, “successful donation” means a donor is determined to be eligible to donate without regard to the success of the collection process.

Blood centers are not required to use the aDHQ. A donor who is eligible to use the aDHQ can use the full-length DHQ without any adverse impact on the process or product suitability. However, use of the aDHQ by a donor who does not meet the criteria is not acceptable. The blood center’s SOPs must identify actions to be taken, when an aDHQ is used by a donor who did not meet the criteria for use, to ensure that all components of the collection are quarantined until the donor eligibility questions are answered, the donor is determined to be eligible to donate as required in 21 CFR 630.10 and 630.15, and the products are suitable for use. Consistent with existing requirements, a biological product deviation report must be submitted to the FDA if any component of the improper collection was distributed prior to establishing the donor’s eligibility.

**aDHQ Structure and Content:** The DHTF developed the aDHQ based on principles of cognitive psychology. The goal of this format is to facilitate donor understanding of questions and accurate recall of relevant activities, and to expedite the process. Please note the following:

- The questions are grouped into common timeframes that follow a timeline. The aDHQ begins with questions about “today,” moving to questions requiring recall from progressively longer periods of time, and finally asks “Since your last donation.” The progression through time assists the donor in recalling information.
- The questions are designed to be more easily understood by the donor. Compound questions are not used to streamline the process for follow-up by the donor historian.
- The process uses capture questions. This means a single question is designed to capture information on a broad topic. Additional questions from the flowchart are asked by the donor historian only when a response requires additional information to complete the evaluation.
- The list of questions on the aDHQ is consistent with those on the full-length DHQ. When possible, the aDHQ uses a single, broad question that is adequate based on the criteria for use by a frequent donor. For example, the single question “Since your last donation, have you had any new medical treatments?” on the aDHQ replaces several related questions on the full-length DHQ. Frequent donors using the aDHQ are able to provide the same information in less time with fewer questions to answer.

Refer to the section on “Change Control and Limitations” for additional information and limitations on changes to the aDHQ and accompanying materials.

**Administering the aDHQ:** The aDHQ must be administered on the date of donation. All donors must read the Blood Donor Educational Material and use the Medication Deferral List prior to completing the aDHQ. Donors may be handed individual copies or the materials can be prominently displayed at the donation site for the donors’ use while they are completing the aDHQ. Additional information on these materials is provided in related sections.

The method of administration should follow the blood center’s SOP for donor screening. Blood centers are reminded that donor screening is an interactive process involving open communication between the donor and donor historian regarding confidential information. Blood center SOPs:

- Should provide an opportunity for the donors to voice questions about the aDHQ, the Blood Donor Educational Material, and the Medication Deferral List, or concerns about the donation process;
- Should require that donors be asked if they have further questions and if their questions have been answered. This can be incorporated into the donor eligibility process and/or put into the donor consent, and does not need to be a specific question on the aDHQ.

Providing a setting that protects the donor’s privacy is a critical component for an effective donor screening process. The setting must be adequate to ensure the donor is able to complete the aDHQ and discuss information in a confidential manner which is consistent with AABB’s Standards for Blood Banks and Transfusion Services.

**Self-Administration:** As described earlier, the aDHQ was designed for self-administration, with review and follow-up by a trained donor historian. Donors can use a hard copy or computer assisted aDHQ. Donors should be instructed to complete the entire aDHQ to provide the best eligibility determination. Complete information is preferred to ensure that multiple reasons for deferral are considered. However, there will be circumstances in which the donor submits an incomplete aDHQ. For example, the donor may simply wish to leave prior to completing the aDHQ. Blood center SOPs should define options for management of information received when the aDHQ is not completed.

**Other Methods of Administration:** Alternatively, the aDHQ may be administered by a donor historian. The goals and approach for this process remain the same with alternative methods.

**Documentation:** Information impacting donor eligibility should be meticulously documented on the aDHQ. If a donor is determined to be ineligible during the screening process, the reason for deferral should be documented in a designated area on the aDHQ. Likewise, if a donor is determined to be eligible during follow-up questioning, an explanation for each question must be documented in sufficient detail in a designated area on the aDHQ. The blood center’s SOP should define the process to be used for documenting this information as shown in the following example:

Example: A donor answers “yes” to: “Since your last donation, have you been outside the United States or Canada?”

Sample documentation: “Donor traveled to Nayarit, Mexico; malaria endemic, 3-month deferral, date of departure from malaria area: 6 weeks ago, length of stay: two weeks.”

## ACCOMPANYING MATERIALS

**Blood Donor Educational Material:** The Blood Donor Educational Material is read by the donor at the time of donation. The Blood Donor Educational Material informs the donor by providing an overview of the donation process and includes information about:

- The importance of accurate and complete answers on the aDHQ;
- The importance of eligibility information such as medications, travel and risk, behaviors for transmission of disease from the donor to the patient;
- The various steps in the collection and testing of the donation;
- And, what happens after the donation process.

**Medication Deferral List:** Refer to the current Medication Deferral List for relevant medications and relevant timeframes that must be reviewed. This list identifies medications taken within a specified time frame that must be considered when establishing donor eligibility. Medications on the lists require donor deferral to protect the health and safety of the transfusion recipient. The Medication Deferral List posted on the AABB website may differ from the list officially recognized by the FDA and posted on the FDA website. As updates are required, the DHTF will make changes to the Medication Deferral List that will be announced in AABB publications prior to posting the new version on the AABB website.

**Flowcharts:** The User Brochure provides for use of optional flowcharts to guide the donor historian through the screening process. These flowcharts are intended to serve as a resource but the use of the flowcharts is NOT REQUIRED if the blood center has an equivalent method for evaluating responses to the aDHQ. Flowcharts are developed and maintained by the DHTF and may be revised by blood centers to reflect local policy, provided deferrals are either more restrictive or consistent with those required by AABB and FDA.

A flowchart has been designed for each question and contains the following information:

Question: Question number and the question.

Donor Eligibility: This section provides additional information to the donor historian on donor eligibility requirements for each question.

Note: Optional field; additional relevant information relating to the donor question.

Flowchart: Each question is flow-charted using standard flow-charting symbols.

Rectangle/Square -- Statement

Diamond -- Question/decision point

Oval -- Action

Arrow – Indicates direction on the flowchart

Each flowchart ends with an ARROW that indicates to “move to the next question;” however, it must be emphasized that donor eligibility decisions are based on the blood center’s SOPs. For some questions, a “yes” answer requires the donor be deferred. A required deferral is designated in the flow chart by the Action “Defer donor.” The donor historian may need to refer to the blood center’s SOP to determine if or when the donor may be eligible to return. The blood center may elect to end the donor screening process at the time of deferral OR may continue with the remainder of the questions on the aDHQ based on the SOP. For other questions, a “yes” answer may trigger a line of questioning to determine if the donor is eligible. The donor historian will refer to the blood center’s SOP for follow-up questions to determine eligibility. This type of deferral is designated in the flowchart by the Action “Defer donor per SOP.” For example, if a donor answers “yes” to the question “In the past 3 months, have you had a tattoo?” A blood center may ask additional questions to identify whether the tattoo was applied by a state regulated

entity with sterile needles and non-reused ink. Some blood centers may allow donation, as defined in their SOP. Other blood centers may elect to defer all donors who have had a tattoo in the past 3 months.

## **CHANGE CONTROL AND LIMITATIONS**

**Adding Questions:** Blood centers may choose to add “local” questions in the area designated for additional questions found at the end of the aDHQ. Blood centers should also use this area to incorporate new questions that are necessary due to new requirements or recommendations from FDA and/or AABB. This area should be used until such questions are formally incorporated into the aDHQ by the DHTF. At that time, AABB questions will be renumbered, as needed, to maintain the proper order of presentation. Blood centers may choose to use a different numbering system, but the order of the questions should not be changed. Blood centers may implement more restrictive deferral policies than are required by AABB and FDA.

Blood centers should highlight or otherwise draw attention to new or modified questions, both local and/or generated by FDA/AABB, for one year to make all donors aware of the change. If the question must be asked at each donation, the question will remain indefinitely on the aDHQ.

**Reformatting Materials:** Blood centers may choose to format these documents to fit their own use. Examples of such modifications include:

- Formatting the questions on the page in a single column, double columns, single page, double pages, etc.
- Placing the numbers in front of the answer boxes, behind the answer boxes, or leaving them out entirely. However, for ease of use and accuracy in the screening process, the DHTF recommends against eliminating the numbers altogether.
- Use of different font types, sizes, and colors.
- Use of shading to assist donors in staying “on-line”
- Formatting the Blood Donor Educational Material and the Medication Deferral List as needed to use as a brochure, handout, poster, or whatever is appropriate to suit local needs, provided the order, content, and wording are unchanged.
- Adding additional medications to the Medication Deferral List based on a more stringent policy, provided all medications on the original list developed by the AABB DHTF remain unchanged.
- Blood centers using computer assisted screening, may format the software to ask donors only gender-appropriate questions. This means male donors will not be asked questions directed to females and female donors will not be asked questions directed to males.

**Limit on Changes to Documents Recognized by the FDA:** As described earlier, FDA reviewed the aDHQ and accompanying materials as components of a system for establishing donor eligibility. FDA’s guidance recognizes these documents as acceptable as submitted. Once revised by a blood center, documents are no longer recognized by FDA as AABB documents if there are changes to the content, order, and language, other than the additions and reformatting described above, or the use of less restrictive criteria. The guidance is available on the FDA website, [www.fda.gov](http://www.fda.gov), as a Blood Guidance.

**AABB’s Revisions to the aDHQ:** Periodically, the aDHQ, and/or accompanying materials will be revised by the DHTF as improvements are needed or for compliance with new requirements from FDA and/or AABB. AABB will follow the process described earlier in this brochure to

revise and submit *draft* documents to FDA for review *and acceptance*. Once the documents are *accepted* by the FDA, the newly revised aDHQs and accompanying materials will be posted on the public area of the AABB website for implementation. AABB will provide notification of the changes and the timeline for implementation in AABB publications. It is the responsibility of blood centers to revise 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 aDHQ and accompanying materials.

**Capture Question** – A single question that covers a broad topic to simplify the process. When an affirmative answer is given, additional follow-up questions to elicit relevant information are asked by the donor historian.

**Self-administered aDHQ**– A questionnaire that the donor completes on his/her own, followed by donor historian review.

### **Types of Contact**

**Contact with Blood** – (1) a needle stick 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. Example: house, dormitory, apartment.

### **Types of Donor Deferral**

**Indefinite Deferral** – Prospective donor is unable to donate blood for someone else for an unspecified period of time due to current regulatory requirements. The indefinite deferral would no longer apply if regulatory requirements changed and the donor qualified for re-entry based on results of improved testing methods or a change in the impact of the relevant transfusion transmitted infection, also referred to as RTTI. Indefinitely deferred donors may be eligible to donate autologous blood.

**Permanent Deferral** – Prospective donor is deferred from donation with no possibility for re-entry. Permanently deferred donors may be eligible to donate autologous blood.

Example of permanent deferral: A prospective donor states that he/she has Creutzfeldt-Jakob Disease. Additionally, some permanent deferrals may result from the testing performed on a previous donation. Permanently deferred donors may be eligible to donate autologous blood.

**Temporary Deferral** – Prospective donor is deferred from donation for a specified period of time. Temporarily deferred donors may be eligible to donate autologous blood.

Example of temporary deferral: A prospective donor who received a transfusion within the last 3 months would be deferred for 3 months from the date of the transfusion.