

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

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**USER BROCHURE**  
**for the**  
**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 full length Donor History Questionnaire (DHQ) and all accompanying materials.

**INTRODUCTION**

AABB’s Donor History Task Force (DHTF), comprised of professional member experts, developed the DHQ and the accompanying materials to be used as part of the screening process to establish donor eligibility. AABB submitted the DHQ and accompanying materials to the Food and Drug Administration (FDA) for review. The FDA issued guidance to officially recognize the DHQ 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 the DHQ and accompanying documents are designed, structured, and evaluated collectively for comprehension and effectiveness. 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.

**DONOR HISTORY QUESTIONNAIRE**

**DHQ Structure and Content:** The DHTF developed the DHQ 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 time frames that follow a timeline. The DHQ begins with questions about “today,” moving to questions requiring recall from progressively longer periods of time, and finally asks “Have you ever.” 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.

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

**Administering the DHQ:** The DHQ 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 DHQ. 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 DHQ. 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 DHQ, 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 DHQ.

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 DHQ 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 DHQ was designed for self-administration by the donor, with review and follow-up by a trained donor historian. Donors can use a hard copy or computer assisted DHQ. Donors should be instructed to complete the entire DHQ 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 DHQ. For example, the donor may simply wish to leave prior to completing the DHQ. Blood center SOPs should define options for management of information received when the DHQ is not completed.

**Other Methods of Administration:** Alternatively, the DHQ 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 DHQ. 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 DHQ. 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 DHQ. The blood center’s SOP should define the process to be used for documenting this information. Here are two examples of adequate documentation:

Example #1: A donor answers “yes” to: “Are you currently taking an antibiotic?”

Sample documentation: “Donor taking tetracycline daily for acne prophylaxis: OK per SOP.”

Example #2: A donor answers “yes” to: “In the past three years 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 DHQ;
- 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 time frames 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 list 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 DHQ. 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.

Flow Chart: 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 DHQ 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 flow chart by the Action "Defer donor per SOP." For example, if a donor answers "yes" to the question "Are you currently taking an antibiotic?" A blood center may ask additional questions to identify the name of antibiotic and specific indication for use by the donor. Some blood centers may allow donation if a donor is taking antibiotics for certain indications, such as prophylaxis for acne, as defined in their SOP. Other centers may elect to defer all donors taking antibiotics, regardless of the drug or its indication.

## **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 DHQ. 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 DHQ 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.

**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 DHQ 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 DHQ:** Periodically, the DHQ, 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 DHQs 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 DHQ 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 DHQ** – 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. EXAMPLES: 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 hepatitis B. 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.