

This document is one component of the donor history questionnaire documents (Version No. 1.1, dated June 2005), prepared by the AABB Donor History Task Force. FDA's "Guidance for Industry: Implementation of Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Donors of Blood and Blood Components," dated October 2006, references this document.

**Donor History Questionnaire
User Brochure**

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Donor History Questionnaire User Brochure

Purpose: The User Brochure was designed to aid the donor historian in determining if a prospective donor is eligible to donate. Each blood center must have a standard operating procedure (SOP) related to donor suitability to be used in conjunction with the User Brochure. The User Brochure does not replace an SOP for determining donor suitability. Both the User Brochure and the SOP must be available to staff performing health histories. Alternately, the User Brochure contents may be transcribed into the SOP.

Introduction: The Donor History Questionnaire (DHQ) must be administered on the date of donation. All prospective donors must read the Donor Educational Materials prior to completing the DHQ. They also must be given the Medication Deferral List, and a list of BSE countries to be used with the DHQ. As an alternative, one or all of the lists can be prominently displayed at the donation site for the donors' use while they are completing the DHQ.

Collection facilities 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.

Methods of Administration: The method of administration of the DHQ should be in accordance with the blood center's SOP. Blood collection facilities are reminded that donor screening is an active process involving open communication between donors and trained donor historians, and that donors should be encouraged to voice questions and concerns at any time during the screening and donation process.

Self -Administration: The DHQ was designed for self-administration by the donor, with follow-up review by a trained donor historian. A knowledgeable historian should be available to the prospective donor to answer any questions concerning eligibility or the donation process. Since donors may not be able to determine whether they will be deferred until the questionnaire is reviewed with a donor historian, they should be instructed to complete the entire questionnaire. However, there will be circumstances in which the donor elects not to complete the questionnaire. For example, the donor may realize that he/she is not eligible to donate, or may simply wish to leave prior to completing the questionnaire. The blood center may elect to make an eligibility decision prior to completion of the entire questionnaire. That would be acceptable as long as the process is specified in the SOP.

However, the AABB Donor History Task Force wishes to point out that there might be an advantage to having the entire questionnaire completed. Some deferrals will be only temporary, but others are indefinite/permanent. Depending on the sequence of questions, a donor could be deferred temporarily, only to return at a later date and discover that he/she is permanently deferred due to the answer to another question that was not answered during the first visit.

Other methods of administration: Alternatively, the DHQ may be administered by a donor historian. If the questionnaire is not self-administered, but is administered by an historian, it is acceptable for an eligibility decision to be made prior to completion of the entire questionnaire as long as the process is specified in the SOP.

It is essential that the donor be encouraged to ask questions and that all of the donor questions are addressed by the donor historian. Local SOPs should require that donors be asked if they have any questions and if they have had their questions answered. This does not need to be a specific question on the questionnaire, but may be incorporated into the eligibility process and/or put into the donor consent.

DHQ Structure and Content: The DHQ questions were composed for ease of understanding by the prospective donor. The questionnaire, documents and procedure for use were designed, structured and evaluated collectively and are intended to be used together. The DHQ was evaluated for comprehension; therefore, the wording and the order of the questions should not be changed. The questions are grouped by time period beginning with a question about “today” and ending with questions relating to “have you ever.” A collection facility may make minor changes to the timeframe of a question on the DHQ only if the revision makes the screening criteria more restrictive (for instance, increasing the deferral for aspirin from 48 hours to 72 hours to meet State regulations). Blood centers may choose to add local questions to the end of the DHQ. If a collection facility chooses to add “local” questions they should be grouped at the end of the DHQ in the area designated for additional questions. Facilities should also use this area to incorporate new questions that are necessary due to new policies recommended by FDA and/or AABB. This area should be used until such questions can be formally incorporated into the DHQ by AABB. In order to delineate the proper order of the questions AABB will renumber the questions as needed when questions are added or deleted. Collection facilities may choose to use a different numbering system, but the order of the questions should not be changed. The Educational Material and Medication Deferral List must not be modified except for local additions which should be placed at the end of the materials.

Reformatting Materials: Centers may choose to format these documents to fit their own individual 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 (though for logistical purposes, the Task Force recommends against eliminating the numbers altogether)
- Experimenting with different font types, sizes and colors

- Experimenting with shading to assist donors in staying “on-line”
- Formatting the educational materials and/or medication deferral list as needed to use as a brochure, handout, poster, or whatever is appropriate to suit your own needs, as long as the **order, content, and wording** are unchanged.
- Editing the flowcharts to include medical criteria specific to your own center as long as any changes or additions are more restrictive; centers should not modify flowcharts to make them less restrictive.
- Gender specific questions: collection centers using Computer Assisted Screening may format the software to ask donors only gender-appropriate questions, so male donors will not be asked questions targeted to females and female donors will not be asked questions targeted to males. The same is true for screening administered by blood center staff. Male donors need not be asked questions targeted to females and female donors need not be asked questions targeted to males

Questions to detect donors at risk for HIV Group O: The questions related to Africa are recommended by FDA to identify donors who may be at risk for HIV group O infections. Blood collection agencies utilizing an HIV test that has been approved by FDA for blood screening to include a claim for detection of group O viruses may delete these questions from their screening questionnaire and may renumber the remainder of the questions (and related documents such as flow charts). All other centers must continue to use these questions as formatted.

Capture Questions: The DHQ uses **capture questions** that may require donor historian intervention or follow-up. Capture questions are questions that cover a broad topic, and when an affirmative answer is given, additional follow-up questions to elicit additional information are asked by the donor historian. Some follow-up questions are included in the User Brochure, but since specific donor eligibility criteria may vary from one blood center to another, an affirmative response to some questions may require consultation with the blood center's SOP. Blood centers may implement more restrictive deferral policies than described in the User Brochure per their local SOP.

Attention Questions: Additionally, in order to assure that donors who self-administer a paper DHQ maintain focus, several “**attention**” **questions are included**. An example of one of the attention questions is listed below.

In the past 6 weeks, have you been pregnant
or are you pregnant now? (Males check “I
am male”)

An inappropriate answer to the question would be a male answering “yes” or “no.” Each blood center must define the action of the donor historian when a donor inappropriately answers the attention questions. Attention questions may not be necessary when using other techniques to assure donor focus, such as an audio-visual assisted computer assisted self-interviewing system (CASI) or oral screening by a donor historian.

Documentation: Information impacting donor suitability obtained during follow-up questioning should be meticulously documented on the DHQ. If a donor is determined to be **ineligible** during follow-up questioning, the reason for deferral should be documented in a designated area on the DHQ. If a donor is determined to be **eligible** during follow-up questioning a detailed explanation for each question must be documented in sufficient detail in a designated area on the DHQ.

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, “Have you ever had hepatitis?”

Sample documentation: “Donor had hepatitis A at 7 years old; OK per SOP.”

Example #3: A donor answers “yes” to, “In the past three years have you been outside the United States or Canada?”

Sample documentation: “Donor traveled to rural area in Quintana Roo, Mexico 6 weeks ago; malaria risk; 12 months deferral.”

Each blood center’s SOP must define how the donor responses to the follow-up questions will be documented on the DHQ. Responses should be documented with sufficient detail to determine the reason for donor acceptance or deferral.

Flowcharts: The User Brochure provides flowcharts to guide the donor historian through the donor history questionnaire process. Each question is a complete section that begins on a new page, so that changes to the DHQ can be easily modified in the User Brochure. Each section 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.

Square -- Statement

Diamond -- Question/decision point

Oval -- Action

Arrow -- Move to the next question

Each question ends with an ARROW that indicates to “move to the next question;” however, blood centers must follow their established policies concerning whether or not the donor suitability process is terminated when it is known that the donor will be deferred.

These flow charts are intended as a resource, and use of the flowcharts is not required. Flowcharts may be revised by blood collection facilities to reflect local policy as long as deferrals are not made less strict than those required by AABB and FDA.

Donor Deferrals: For some questions, a “yes” answer calls for a required deferral, either indefinitely or for a specified period of time. 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 and when the donor may be eligible to return.

For other questions, a “yes” answer may not require a deferral; rather, it may trigger a line of questioning to determine if the donor is eligible. The donor historian will need to refer to the blood center’s SOP for follow-up questions to determine suitability. 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 ascertain the name of antibiotic and specific indication for use by the donor. Some blood centers may allow donors taking antibiotics for certain indications such as prophylaxis for acne to donate, as defined in their SOP. Other centers may, for simplicity, defer all donors taking antibiotics, regardless of the indication.

Change Control: Periodically the Donor History Questionnaire, the accompanying documents or the procedure for use will be updated or revised by the AABB Donor History Task Force as required for compliance with regulatory and accrediting agencies. AABB Institutions will be notified of the changes and timeline for implementation in existing publications and on the public area of the AABB website, and all updated documents will be made available on the website. It is the responsibility of collecting facilities to make changes in their 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 Donor History Questionnaire.

QUESTIONNAIRE TERMS

Attention Question – Questions in the Donor History Questionnaire that are designed to test if the donor is paying attention. EXAMPLE: In the past six weeks, have you been pregnant or are you pregnant now? (Males check: “I am Male”)

Capture Question – A question that covers a broad topic. When an affirmative answer is given, additional follow-up questions to elicit additional information are asked by the donor historian. EXAMPLE: Have you ever been to Africa? If the donor answers yes, additional questions must be asked.

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

TYPES OF CONTACT

Contact with Blood – (1) a needlestick 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 DEFERRAL

Indefinite Deferral – Prospective donor is unable to donate blood for someone else for an unspecified period of time due to current regulatory requirements. **EXAMPLE:** A prospective donor who states that they lived in England for 1 year in 1989 would be deferred indefinitely. This donor would not be able to donate blood until the current requirement changes. These donors may be eligible to donate autologous blood.

Permanent Deferral – Prospective donor will never be eligible to donate blood for someone else. **EXAMPLE:** A prospective donor states that he/she has Hepatitis C. Additionally, some permanent deferrals may result from the testing performed on a previous donation. These donors may be eligible to donate autologous blood.

Temporary Deferral – Prospective donor is unable to donate blood for a limited period of time. **EXAMPLE:** A prospective donor who has received a transfusion within the last 12 months would be deferred for 12 months from the date of the transfusion.

References

Donor qualification requirements are located in 21 CFR 640.3, 21 CFR 610.41 and AABB Standards for Blood Banks and Transfusion Services, current edition.

Additional donor qualification requirements may be found in FDA memoranda and guidance:

FDA Memorandum October 7, 1988: Revised Guidelines for the Collection of Platelets, Pheresis.

FDA Memorandum, December 12, 1991: Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing.

FDA Memorandum, April 23, 1992: Revised Recommendations for the Prevention of HIV Transmission by Blood and Blood Products.

FDA Memorandum, April 23, 1992: Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma, and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti HCV) in Blood Establishments.

FDA Memorandum, July 28, 1993: Deferral of Blood and Plasma Donors Based on Medications.

FDA Memorandum December 22, 1993: Donor Suitability Related to Laboratory Testing For Viral Hepatitis and a History of Viral Hepatitis.

FDA Memorandum July 26, 1994: Recommendation for Deferral of Donors for Malaria Risk.

FDA Memorandum, June 8, 1995: Recommendations for the Deferral of Current and Recent Inmates of Correctional Institutions as Donors of Whole Blood, Blood Components, Source Leukocytes, and Source Plasma.

FDA Memorandum, March 10, 1995: Revision of FDA Memorandum of August 27, 1982: Requirements for Infrequent Plasma Donors.

FDA Memorandum, December 14, 1995: Donor Deferral Due to Red Blood Cell Loss During Collection of Source Plasma.

FDA Memorandum December 11, 1996: Interim Recommendations for Deferral of Donors at Increased Risk for HIV-1 Group O Infections.

Blood Products Advisory Committee Meeting June 16, 2000: Update on Sexual Transmission of HCV.

FDA Guidance, February 2001: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods.

FDA Guidance, January 9, 2002: Revised Preventive Measures to Reduce the Possible Risk of Recent Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products.

Avodart Consumer Information, January 14, 2003:
www.fda.gov/cder/consumerinfo/druginfo/avodart.htm.

AABB Pulse Points No. 555, January 14, 2003: Association Bulletin #30-02: Donor Deferral Related to Use of AVODART™ (dutasteride).

FDA Guidance, December 2002: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients.

FDA Guidance, February 4, 2003 (corrected): Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients.

FDA Guidance, July 3, 2003: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires.

FDA Guidance, September 16, 2003: Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS.