

Guidance for Industry

Streamlining the Donor Interview Process: Recommendations for Self- Administered Questionnaires

DRAFT GUIDANCE

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GUIDANCE FOR INDUSTRY

Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires

This guidance document represents FDA’s current thinking on implementing self-administered donor questionnaires. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

I. INTRODUCTION

This guidance document provides the recommendations of the Food and Drug Administration (FDA) for implementing self-administered donor questionnaires in blood and plasma establishments (hereafter referred to as “blood establishments”) that collect blood and blood components from donors. This guidance also supersedes Section I.A of FDA’s memorandum dated April 23, 1992, entitled “Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products.” In addition, this guidance describes the information the licensed blood establishments should include in a biologics license application supplement or annual report when they intend to implement self-administered questionnaires.

II. BACKGROUND

A donor’s suitability to donate blood and blood components is determined in part by a medical/health history/high risk behavior interview [21 CFR 640.3 and 640.63]. Blood establishments began formal questioning of blood donors about their health in the 1950s with the development of the first donor screening questionnaire. Since then, the number of questions and the amount of information captured during the questioning process has increased due to FDA requirements and recommendations and voluntary standards, resulting in an increasingly complex and time-consuming process. For example, we currently recommend you ask the high-risk behavior questions by direct oral questioning (Ref. 1). This guidance updates those recommendations to allow blood donors to self-administer the high-risk behavior questions.

Blood establishments are concerned that the current donor questionnaire process is burdensome for the following reasons: a) the donor questionnaire is complicated; b) the donor interview process makes increasing demands upon limited resources at the blood collection facilities (e.g., time and personnel); and c) many donors are concerned about answering personal questions in front of a stranger. We are committed to improving the efficiency and effectiveness of the donation process and we are evaluating methods to streamline the interview process while

maintaining and improving the accuracy and completeness of the information in order to protect the health of donors and ensure the safety, purity, and potency of blood products.

You, the blood establishment, must determine the donor's suitability on the day of each donation [21 CFR 640.3(a) and 640.63(a)]. Collection personnel use pre-donation screening questions to assist them in determining donor suitability. The questions are an integral part of the donation process to help personnel assess risks to the donor from the donation process. In addition, the questions help to ensure product safety by addressing hazards that may not be detectable by laboratory testing and help to ensure product potency (Ref. 2).

A self-administered questionnaire process allows a donor to answer the pre-donation screening questions (medical/health history and/or the high-risk behavior questions) without direct oral questioning by collection personnel. You may elect to allow donors to self-administer only the medical/health history questions, only the high-risk behavior questions, or both, as long as you do not jeopardize donor safety and product safety, purity, and potency. There are several options available for self-administering the donor questionnaire. These include:

1. Questions presented on printed forms. The donor reads the questions and documents the answers on the form. Your personnel review the answers. We will refer to this method as a manual procedure in this document.
2. Audio and/or video presentation of the questions. The donor reviews the media and documents the answers on a printed form. Your personnel review the answers.
3. Computer-assisted interactive interview. The donor reviews the questions on a computer screen and enters the answers electronically. Your personnel print and review the answers. [Note: Some blood collection facilities use computer programs to display the questions to personnel, who question the donor and enter the responses into the computer. We will not address this process in this guidance, because it is not a self-administered process.]

This guidance document does not address the informed consent process. We also do not address specific screening questions, a specific questionnaire, or, for licensed blood establishments, how to submit changes to the questions on your currently approved questionnaire. Instead, this guidance document describes how you may change your current pre-donation donor screening interview procedure to a self-administered format in your blood establishment.

This guidance also advises licensed blood establishments how to report this change to FDA under 21 CFR 601.12, Changes to an Approved Application, and what information they should submit. Unlicensed registered blood establishments implementing self-administered donor questionnaire procedures do not need FDA approval for this change. Both licensed and unlicensed registered blood establishments are subject to the Current Good Manufacturing Practice (GMP) regulations in Title 21 Code of Federal Regulations (CFR), Parts 210, 211, and 606, as well as all other applicable regulations, including product standards in 21 CFR Part 640 and the computer recordkeeping requirements of 21 CFR Part 11.

III. RECOMMENDATIONS FOR IMPLEMENTING SELF-ADMINISTERED DONOR QUESTIONNAIRES:

A. Recommendations for Manual Procedures

We define the manual self-administered pre-donation questionnaire as one in which the donor reads the medical/health history questions and/or high-risk questions and documents his/her answers on a printed answer form. We are not including donor identification or demographic questions (e.g., name, address, social security number, etc.) in this definition.

1. You must describe the self-administered procedures in your written standard operating procedures (SOP) [21 CFR 606.100(b)]. You must adequately train your personnel on these procedures [21 CFR 600.10(b) and 606.20(b)].
2. The donor must complete the self-administered questionnaire on the day of donation [21 CFR 640.3(a) and 640.63(a)], before blood collection at the donation site.
3. You must provide an appropriate environment for individuals to complete their donor questionnaire in a private setting [21 CFR 606.40(a)(1)]. You should ensure that the donor is answering the questions in a confidential setting and your personnel should be available to answer questions.
4. You should not allow new donors to self-administer the donor questionnaire. New donors are donors who have never donated at your facility or who have not donated or have not qualified as donors for a specific interval described in your SOP. This is to allow your personnel to fully educate the new donor about their responsibilities in donating blood products and help ensure that barriers of limited literacy, attention, and comprehension do not compromise the donor qualification process (Ref. 3). An exception is that new donors may use computer-assisted interactive procedures that include an audio component (See section III.C.1).
5. You should have a method at each donation to assure the donor understands the questions (e.g., additional verbal or written questions, etc.). This should include an evaluation of the donor's ability to read and understand the language of self-administered questionnaire, regardless of the media (written, audio or visual) of the questionnaire.
6. You should provide options for donors who prefer direct oral questioning or who would like or need assistance in completing the questionnaire.
7. You should provide the donor with written or verbal instructions on how to properly complete the questionnaire, including how to request assistance, if needed. The instructions and questionnaire must be in a language that the donor readily understands. You should instruct the donor to leave an answer blank if he

or she does not understand a question. You should also instruct the donor not to sign the questionnaire until your personnel have reviewed it.

8. The donor should answer all applicable questions on the questionnaire, as defined by your SOP. You should review the questionnaire before blood collection to assure the donor answered all the questions and question the donor further, when appropriate. If you modify answers or document the donor's answer to blank questions after clarification from the donor, you should annotate the entries (e.g., reviewer's initials, further explanation of comments, etc). If there are multiple reasons to defer the donor, you must document all reasons for deferral on the donor record [21 CFR 606.160(b)(1)(iii)].
9. If you revise your questionnaire to include new or modified questions, you should administer the new or modified questions to all donors by direct oral questioning or provide all donors with a detailed description of the changes. The donors may self-administer the revised questionnaire after you have explained the changes.
10. As part of your overall quality assurance program, you should assess the effectiveness of the self-administered questionnaire in identifying unsuitable donors (e.g., by evaluating post-donation information reports, etc.).

B. Additional Recommendations for the Use of Audio/Visual Tools

Current audio/visual (AV) technology encompasses audiocassette tapes and compact discs, videotape (e.g., VHS), digital videodisks, and digitized recordings played on a computer. You may use these media to present the medical/health history and/or high-risk behavior questions, and AIDS/HIV educational materials to the donors. The donors may play these recordings and document their answers to the questions on your printed donor questionnaire form. Studies have shown that visual-based systems accompanied by an audio component provide the most accurate collection of sensitive data (Ref. 4).

In addition to the recommendations described in section III.A, you should consider the following items when implementing the self-administered questionnaire using audio and visual media:

1. Some recording media are prone to distortion or skipping due to scratches, magnet exposure, or debris. Before implementation and periodically thereafter, you should verify and document that the audio portion is understandable, in accordance with a written SOP. You should have a written SOP for administering the questionnaire when the audio/visual tools are not available.
2. The content of the audio recording should match the information displayed in the video. When you revise your written materials or questionnaire, you should also change the video and audio recording to match the written materials. If you provide the donor with written AIDS/HIV educational materials, they should correlate with the video and/or audio recording.

3. Instruct new donors to immediately document answers to questions on the questionnaire as the recording asks the questions, and not answer before the recording finishes stating the question. If you allow the donors to adjust the speed of the audio recording and/or visual display, you should instruct the donor to listen to or read the whole question before responding. This will help ensure that the donor will hear and see complete questions, including any new or revised questions.
4. Your system may allow the donor to pause the recording to replay the question, or to ask for clarification. If the donor is not able to pause the recording, you should instruct the donor to leave the answer blank until he or she can discuss the question with your personnel.
5. You should monitor the donor's attentiveness and be ready to intervene if the donor appears confused or inattentive.
6. Your SOP should define how many donors may self-administer the questionnaire while listening to or watching the recording at the same time. If more than one donor is listening to the recording and/or watching the visual display at one time, you should ensure that the donors have privacy when answering the questions and are not discussing answers to the questions.

C. Additional Recommendations for Computer-Assisted Interactive Procedures

In the self-administered computer-assisted interactive interview procedure, the donor reviews the questions on a computer screen and enters the answers electronically into the software program managing the interview process. Personnel print the electronically captured answers and review them with the donor. The computer software may or may not make decisions on the suitability of the donors depending on the responses to the questions. Your computer system's functionality may require 510(k) clearance (Ref. 5, 6).

NOTE: The computer system used in the computer-assisted interactive interview procedure includes any hardware and software needed to perform the process. It may be a stand-alone system, used solely to conduct the donor interview, or may interface with other computer systems at the same or other locations. It may be a desktop or laptop computer or a handheld device. The software may have data storage capabilities or may send data to a printer for hardcopy printout. In addition, the computer system may or may not be accessible from a remote location. The user interface may present both video and audio data to the user via monitors, headphones, etc. Donors and center personnel may input data or responses via keyboard, microphone, or a pointing device such as a mouse, touch screen, or stylus. The system may use pictures or drawings to illustrate the topic of the displayed questions.

In addition to the recommendations described in sections III.A and III.B, you should consider the following items when implementing the self-administered computer-assisted interactive questionnaire:

1. New donor may use computer-assisted interactive procedures provided there is an audio component with the system.
2. Printers should be in a location that is accessible only to your personnel. You should review a printed copy of the questions and responses with the donor and both you and the donor should sign and date the questionnaire.
3. You should validate all aspects of your computer system for its intended use. You should perform this validation on the system (software and hardware) at the blood collection facility. Your validation should include testing the interfaces and peripheral hardware, where applicable. In addition, you should validate your system after each upgrade (Ref.7).
4. The computer system record keeping functions, including electronics signatures and records, must comply with the requirements in 21 CFR Part 11 (Refs. 8, 9, 10).
5. You should have a written SOP for administering the questionnaire when your computer system is not available.

IV. PROCEDURES FOR SUPPLEMENTING THE BIOLOGICS LICENSE APPLICATION TO INCLUDE THE USE OF SELF-ADMINISTERED DONOR QUESTIONNAIRES

A. General Submission Information

You should submit a Prior Approval Supplement (PAS) under 21 CFR 601.12(b) if you revise your current donor questionnaire to be less restrictive than previously approved and the changes are not consistent with other FDA guidance documents (Ref. 11).

In addition, if you revise your AIDS/HIV educational materials, the information should be consistent with your donor questionnaire. You should submit a PAS under 21 CFR 601.12(b), if these revisions are less restrictive than previously approved and are not consistent with other FDA guidance documents. If the revisions are more restrictive than previously approved, you may report this change to us in your Annual Report under 21 CFR 601.12(d).

If you change your donor interview process to include self-administering only the medical/health history questions from your currently approved donor questionnaire (i.e., you are not changing the process for high risk behavior questions) you may report this change to us in your annual report under 21 CFR 601.12(d).

If you change your donor interview process to include self-administering the high-risk behavior questions using your currently approved questionnaire, as described in this guidance, you should supplement your license application and report this change to us in the following categories:

1. Changes Being Effective in 30 Days (CBE30) under 21 CFR 601.12(c)
 - a) Manual procedures.
 - b) Audio/Visual procedures.
 - c) Computer-assisted interactive procedures where all the following statements regarding the computer system are true:
 - Operates as a stand-alone system or is isolated to an internal network within the same facility.
 - Is not interfaced with other computer systems performing different functions, either at the same blood collection facility or at other facilities, including any regulated devices.
 - Does not make decisions about donor suitability.
 - Is not modified by the user.

2. PAS under 21 CFR 601.12(b)

Computer-assisted interactive procedures where any of the following statements regarding the computer system are true:

- Is connected to computer-assisted interactive systems at other facilities either through a virtual private network or the public Internet.
- Can be accessed from remote locations (Web access system).
- Is interfaced with other computer systems performing different functions, either at the same blood collection facility or at other facilities, including any regulated devices.
- Is able to make decisions about donor suitability.
- Is modified by the user.

B. Submission Content for Manual Procedures and Audio/Visual Tools

You should include the following items in your supplement submission. [See our guidance document entitled “Guidance for Industry For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 356h, ‘Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use’”, for assistance in preparing your supplement (Ref. 12).]

1. FDA Form 356h “Application to Market a New Drug, Biologic and an Antibiotic Drug for Human Use.”
2. A cover letter describing your request and the contents of your submission.
3. A written SOP incorporating the self-administered questionnaire process. Include a copy of the instructions to prospective donors on how to complete the donor questionnaire, and your procedures for determining and documenting donor comprehension. The SOP should also include alternate procedures for when you cannot use your self-administered process.

C. Additional Submission Content for Computer-Assisted Interactive Procedures

In addition to the submission content described in section IV.B, you should include the following items when supplementing your biologics license application to include the use of the self-administered computer-assisted interactive questionnaire:

1. The name of the software manufacturer, program name and version or release number.
2. A description of the computer system’s capabilities and functions used by the blood establishment.
3. The addresses of any blood collection facilities where you will install the system and a description of the interface between facilities, if applicable.
4. The computer system user on-site validation protocol. If applicable, the validation should include any interfaces with other computer systems. Do not submit the actual validation data. Your validation data should be readily available for review at the time of FDA inspections.
5. An SOP that accurately incorporates the computer system manufacturer's instructions for use. The SOP should include alternate procedures for when your computer system is not available.
6. A copy of the printed questionnaire.
7. A printout of all screens.

V. FOR MORE INFORMATION

If you have questions regarding the self-administered questionnaire or about computer system requirements, call the Division of Blood Applications, CBER, at 301-827-3543 (fax: 301-827-3534).

VI. REFERENCES

1. FDA memorandum, “Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products,” April 23, 1992. (<http://www.fda.gov/cber/memo.htm>)
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3. Mayo, D.J., Rose, A.M., Matchett, S.E., et al. Screening potential blood donors at risk for human immunodeficiency virus. *Transfusion* 1991; 31(5):466-74.
4. Turner, C.F., Ku, L., Rogers, S.M., et al. Adolescent sexual behavior, drug use, and violence: Increased reporting with computer survey technology. *Science* 1998;280:867-73.
5. Letter to Blood Establishment Computer Software Manufacturers, March 31, 1994. (by fax at 888-CBER-FAX)
6. Federal Food, Drug and Cosmetic Act, Section 510, February 1998. (<http://www.fda.gov/opacom/laws/fdact/fdctoc.htm>)
- *7. FDA guidance, “Draft Guideline for the Validation of Blood Establishment Computer Systems,” September 28, 1993. (by fax at 888-CBER-FAX)
8. FDA final rule, “Electronic Records; Electronic Signatures; Final Rule,” March 20, 1997 (Vol. 62, No. 54, 13430-13467) [Docket No. 92N-0251]. (http://www.access.gpo.gov/su_docs/aces/aces140.html)
- *9. FDA draft guidance, “Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures; Glossary of Terms,” August, 2001. (<http://www.fda.gov/cber/guidelines.htm>)
- *10. FDA draft guidance, “Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures; Validation,” August, 2001. (<http://www.fda.gov/cber/guidelines.htm>)
11. FDA guidance, “Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture”, July, 2001. (<http://www.fda.gov/cber/guidelines.htm>)
12. FDA guidance, “Guidance for Industry For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the

Draft – Not for Implementation

Completion of the Form FDA 356h ‘Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use’, May, 1999. (<http://www.fda.gov/cber/guidelines.htm>)

* These draft guidance documents have been issued but are not for implementation. Once finalized, they will represent the agency’s current thinking on that topic.