Guidance for Industry

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

Additional copies of this guidance are available from the Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or from the Internet at http://www.fda.gov/cber/guidelines.htm.

For questions on the content of the guidance contact the Division of Blood Applications, Office of Blood Research and Review, CBER, at 301-827-3543, or by fax at 301-827-3534.

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Contains Nonbinding Recommendations

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GUIDANCE FOR INDUSTRY

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate FDA staff. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

Blood and plasma establishments (hereafter referred to as "blood establishments") that collect blood and blood components intended for transfusion or for further manufacture may present donor screening questions to the donor by several methods. The blood establishment should choose the method that works best within its donor screening procedures. This guidance is intended for those blood establishments that wish to implement self-administered donor questionnaires, which allow donors to answer the pre-donation questions on their own; however, you (the blood establishment) may elect to continue to administer the donor questions by direct oral questioning. The guidance provides the recommendations of the Food and Drug Administration (FDA) for implementing self-administered donor questionnaires. In addition, the 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. This guidance finalizes the draft guidance of the same title dated April 2002. It 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."

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA's guidances means that something is suggested or recommended, but not required.

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 have recommended that 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. Consequently, we are evaluating methods to streamline the interview process while maintaining and improving the accuracy and completeness of the information in order to better protect the health of donors and ensure the safety, purity, and potency of blood products.

You must determine the donor's suitability on the day of each donation (§§ 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 purity and potency (Ref. 2).

We define the self-administered, pre-donation questionnaire as one in which the donor reads or listens to the medical/health history questions and/or high-risk questions and documents his/her answers. A self-administered questionnaire process allows a donor to answer the pre-donation screening questions without direct oral questioning by collection personnel. We are not including donor identification or demographic questions (e.g., name, address, social security number) in this definition. 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, but are not limited to:

1. Questions presented on printed forms. The donor reads the questions and documents the answers on the form. Your personnel review the answers.

2. Audio and/or video presentation of the questions. The donor reviews the questions by listening to a recording or watching a video and documents the answers. 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 review the answers. Published studies have shown that computer-assisted interactive questionnaires that have an audio component provide an effective method to elicit sensitive information from the donors (Ref. 3, 4). [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 do not address this process in this guidance because it is not a self-administered process.]

The recommendation in our draft guidance entitled "Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires," dated April 2002, to not allow new donors to self-administer the donor questionnaire was discussed at the Blood Products Advisory Committee meeting on September 12, 2002. The committee pointed out that all the methods for administering the donor questionnaires were comparable for eliciting information from new donors, but stated that additional studies were needed to determine the efficacy of the various methods to provide a safe blood product. Because the methods are comparable, we have removed that recommendation from this final guidance. Consistent with the final guidance, new donors may self-administer the donor questionnaire.

This guidance 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 describes how you may change your current pre-donation donor screening interview procedure to a self-administered format.

This guidance also advises licensed blood establishments how to report the change to a self-administered questionnaire format to FDA under § 601.12, "Changes to an Approved Application," and what information they should submit. Licensed blood establishments that are already approved to implement a self-administered donor questionnaire do not need to report this change again to FDA. 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 (CGMP) regulations in 21 CFR Parts 210, 211, and 606, as well as all other applicable regulations, including product standards in Part 640 and the computer record keeping requirements of 21 CFR Part 11.

III. RECOMMENDATIONS FOR IMPLEMENTING SELF-ADMINISTERED DONOR QUESTIONNAIRES

A. Recommendations for All Self-Administered Procedures

1. You must describe the self-administered procedures in your written standard operating procedures (SOPs) (§ 606.100(b)). You must adequately train your personnel in these procedures (§ 600.10(b) and 606.20(b)).

2. The donor must complete the self-administered questionnaire on the day of donation (§§ 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 (§ 606.40(a)(1)). You should ensure that the donor is answering the questions in a confidential setting.

4. You should have a method at each donation to ensure that the donor understands the questions (e.g., additional verbal or written questions). This should include an evaluation of the donor's ability to read and understand the language of the self-administered questionnaire, regardless of its medium (written, audio, or visual). Published studies have shown that individuals with low medical literacy may not reliably complete self-administered questionnaires (Ref. 5). You must defer donors who do not appear to be providing reliable answers to the questions (§ 640.63(d)).

5. You should provide options for donors who prefer direct oral questioning or who would like or need assistance in completing the questionnaire.

6. 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 should be in a language that the donor readily understands. You should instruct the donor to read and/or listen to the full question before answering and leave the answer blank if he or she does not understand a question. Your personnel should be available to answer questions.

7. The donor should answer all applicable questions on the questionnaire, as defined by your SOP. The donor does not need to complete the questionnaire if he or she is deferred early in the questioning process.

8. You should have a method to review the questionnaire for completeness and accuracy before allowing the donor to donate and to question the donor further, when necessary to determine the donor's suitability. 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). If there are multiple reasons to defer the donor, you must document all reasons for deferral on the donor record (§ 606.160(b)(1)(ii)).

9. If you revise your questionnaire to include new or modified questions, you should highlight, or otherwise draw attention to, the new or modified questions for one year so that all donors (new donors and donors who have previously donated at your facility) will be aware of the change. You should have a method to ensure consistent implementation of revised questionnaires.

10. You should monitor the effectiveness of the self-administered questionnaire in identifying unsuitable donors (e.g., by evaluating post-

donation information reports, infectious disease marker rates, specific deferral trends, biological product deviation reports, post-transfusion infectious disease reports).

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

Current audio/visual (AV) technology may encompass electronic media such as 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 as well as AIDS/HIV educational materials to the donors. The donors may play these recordings and document their answers to the questions.

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

1. 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. If more than one donor will be listening to the audio and/or watching the audio/visual display at one time, your SOP should include provisions regarding the appropriate number of donors for joint listening or viewing to ensure privacy when answering 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. The computer software may or may not make decisions on the suitability of the donors depending on the responses to the questions. Under Section 510 of the Federal Food, Drug, and Cosmetic Act, your computer system's functionality may require 510(k) clearance (Ref. 6).

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 it 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 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 collection 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 in sections III.A and III.B, you should consider the following items when implementing the self-administered computer-assisted interactive questionnaire:

1. You should validate all aspects of your computer system for its intended use. You should perform this validation consistent with the provisions contained in FDA guidance documents (Refs. 7-8) and in § 820.100.

2. The computer system record keeping functions, including electronic signatures and records, must comply with the requirements in Part 11 (Refs. 9-10).

3. 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

If you change your donor interview process to include self-administering the high-risk behavior questions, as described in this guidance, using your currently approved questionnaire, you should supplement your license application and report this change to us as a Changes Being Effective in 30 Days (CBE30) supplement under § 601.12(c) (Ref. 11).

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

Licensed blood establishments that are already approved to implement a self-administered donor questionnaire do not need to report this change to FDA. However, you may wish to review your procedures to ensure that they are consistent with this guidance. If you revise your procedures to be consistent with this guidance, you may report this to us in your Annual Report under § CFR 601.12(d).

B. Submission Content for All Self-Administered Procedures

For assistance in preparing your supplement, see our "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'" (Ref. 12). You should include the following items in your supplement:

1. FDA Form 356h, "Application to Market a New Drug, Biologic or 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 each donor's ability to provide reliable answers. 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 capabilities and functions of the computer system used by the blood establishment.

3. The addresses of any blood collection facilities where you will install the computer 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. You should 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, Center for Biologics Evaluation and Research, at 301-827-3543 or fax 301-827-3534.

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)

2. FDA memorandum, "Revised Guideline for the Collection of Platelets, Pheresis," October 7, 1988. (http://www.fda.gov/cber/memo.htm)

3. Cooley PC, Rogers SM, Turner CF, et al. Using touch screen audio-CASI to obtain data on sensitive topics. Computers in Human Behavior, 2001; 17:285-93.

4. Turner CF, Ku L, Rogers SM, et al. Adolescent sexual behavior, drug use, and violence: Increased reporting with computer survey technology. Science 1998; 280:867-73.

5. Al-Tayyib AA, Rogers SM, Gibble, JN, et al. Effect of low medical literacy on health survey measurements. American Journal of Public Health, 2002; 92(9); 1478-81.

6. FDA Correspondence, Letter to Blood Establishment Computer Software Manufacturers, March 31, 1994.

7. FDA, "Draft Guideline for the Validation of Blood Establishment Computer Systems," September 28, 1993. (http://www.fda.gov/cber/guidelines.htm)*

8. FDA, "Guidance for Industry: General Principles of Software Validation; Final Guidance for Industry and FDA Staff, " January 11, 2002. (http://www.fda.gov/cber/guidelines.htm)

9. FDA Final Rule, "Electronic Records; Electronic Signatures," March 20, 1997 (62 FR 13430-13467) (http://www.access.gpo.gov/su_docs/aces/aces140.html)

10. FDA, "Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures, Scope and Application," February 20, 2003. (http://www.fda.gov/cber/guidelines.htm)*

11. FDA, "Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture," August 7, 2001. (http://www.fda.gov/cber/guidelines.htm)

12. FDA, "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,'" May 10, 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.