
Collection and Production of Components

5.2 Information, Consents, and Notifications

5.2.1 Donor Education

The blood bank shall have procedures to ensure that the following requirements are met for all donors before donation*:

- 1) Donors are given educational materials regarding the donation process.
- 2) Donors are given educational materials regarding relevant transfusion-transmitted infections.*
- 3) Donors are informed of the importance of providing accurate information.
- 4) Donors are informed that they should not donate blood in order to obtain infectious disease testing services and that there are circumstances in which testing is not performed.
- 5) Donors are given education materials regarding the risks of postdonation iron deficiency, and mitigation strategies.
- 6) Donors are informed of the importance of withdrawing themselves from the donation process if they believe that their blood is not suitable for transfusion.†
- 7) Donors acknowledge that the educational materials have been read.



Guidance

#1) It is important that information be provided to donors so that they can understand that donating blood poses certain issues to their health and the health of the recipient. This information is provided to donors in the form of educational materials that the donor is asked to read before completing a donor history questionnaire (DHQ). This information is so important that the AABB DHQ includes a question to determine if the donor has read and understood the educational materials. One of the ways to meet some of the requirements listed in Standard 5.2.1 is to use the AABB DHQ educational materials. Whether the AABB DHQ educational materials cover each of the items in Standard 5.2.1 will be listed along with guidance for that item.

#2) For the protection of the recipient's health the donor must be informed about relevant transfusion-transmitted infections (RTTIs). The AABB DHQ does include language that covers risks for human immunodeficiency virus (HIV) and hepatitis as well as alerting donors that their donation will be tested for these and other RTTIs.

#3) The donor screening questionnaire relies on the donor providing honest and accurate information. Again this is included in the AABB DHQ educational materials.

#4) Some individuals may wish to be tested for infectious diseases, including HIV, without presenting to their health care provider or other testing site. Because there is a window period between the time a person gets infected with an RTTI and when the infectious agent has replicated in the body enough to be able to be detected by the tests currently used, it is important that no one donates to determine whether they are infected or not. Even if the donor is beyond the window period, it is important to avoid staff handling infectious blood or having infectious blood mistakenly released for transfusion. In addition, some donors erroneously think blood facilities test for agents such as gonorrhea or chlamydia. The AABB DHQ materials cover this issue.

*21 CFR 630.10.

†FDA Guidance for Industry: Recommendations for Assessment of Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus (January 2017).

#5) Donors may become iron deficient from donating blood. Hemoglobin and hematocrit have been shown to be poor measures of total iron stores. Donors should be advised that they will be losing iron with their blood donation, and advised of measures the blood bank donor can take that may help to maintain the iron stores. Recent studies have indicated that diet alone is usually not sufficient to replace the iron lost from a whole blood donation within an 8-week Whole Blood donation interval. Several measures that may help reduce the risk of iron deficiency due to blood donation, such as taking iron replacement after donating, using ferritin testing to guide iron replacement or donation frequency, increasing intervals between donations, limiting the number of annual donations, etc.

The AABB DHQ educational materials do NOT address this issue as it is up to each facility or organization and its medical director to determine what actions to take to meet this standard and to incorporate them into their policies and procedures. However, facilities must provide educational information regarding the iron loss from donation and potential measures to reduce the risk of iron deficiency. Additional resources can be found in Association Bulletin 17-02 (Updated strategies to limit or prevent iron deficiency in blood donors. Association bulletin #17-02. Bethesda, MD: AABB, 2017. [Available at <http://www.aabb.org/programs/publications/bulletins/Docs/ab17-02.pdf> (accessed November 20, 2019).]) and the AABB Donor Iron Deficiency Risk-Based Decision Making Report.

#6) This section is intended to protect the health of the recipient. It reflects concerns about RTTIs such as malaria and variant Creutzfeldt-Jakob disease (vCJD). It also address other conditions such as polycythemia vera, cancer, use of certain medications, etc. The AABB DHQ educational materials do not address this issue. Information should be on the educational materials instructing donors on how they can contact the center after leaving donation site to indicate that their donation should not be used for transfusion. This can be a phone number or an email address for which messages are checked in a timely fashion.

#7) Because the educational materials have important information that donors should read before donation, it is appropriate that the donors indicate in some manner that they have done so. The AABB DHQ includes a question to this effect that the donor must answer yes or no. However, it may also be appropriate to include the fact in the donor consent.



5.2.2

When parental permission is required, the collection facility shall have a process to provide information to parent(s) or legally authorized representative(s) of the donor concerning the donation process, and potential adverse effects related to the donation. Standard 5.2.1, #5 applies.

Guidance

The minor donor should be encouraged to share the postdonation educational materials with his/her parent or legal guardian. These materials must include the contact information for the donor center should the parent, legal guardian, or legal representative need to contact the donor center.



5.2.3

Donor Consent

The consent of all donors shall be obtained on the day of donation and before collection. Elements of the donation procedure shall be explained to the prospective donor in understandable terms. The explanation shall include information about risks of the procedure, tests performed to reduce the risks of relevant transfusion-transmitted infections to the allogeneic recipient, and requirements to report donor information, including test results, to state or local health departments. The donor shall have an opportunity to ask questions and have them answered and to give or refuse consent for

donation. In the case of a minor or a legally incompetent adult, consent shall be addressed in accordance with applicable law.

Guidance

Many of the elements of the donation procedure are explained in the education materials. It may be appropriate to have the donor assert that he or she has read the educational materials as part of the donor consent.

Some elements to consider during the consent process:

- 1) *Need for privacy in the consent process.* A donor must be free to disclose a potential reason that s/he may be a suboptimal donor, and must be able to ask and answer potentially embarrassing questions.
- 2) *Understandability of the information on which consent is based.* The language in which the information is presented may not be well-matched to the candidate, in either language or usage. Even a high-quality translation does not guarantee understanding by people whose language differs from the language of origin of the informative materials. Technical language is a possible barrier to understanding for many candidates, even if there is no traditional language barrier. Best practice includes asking questions to confirm understanding before accepting consent as valid.
- 3) *Use of donors who are not legally or practically competent to give consent.* It is appropriate to protect the candidate donor from “situational coercion,” even if the law does not. This may not be a concern if a 15-year-old who lacks an uncommon antigen lack (eg, Gerbich-negative) wants to donate and his or her parents support the donation. But it may be an issue if the potential donor is incompetent for a reason other than age, or if the potential donor is younger.
- 4) *Special questions may arise in special circumstances.* Example: Who can give permission in lieu of consent? Several states allow donation without parent/guardian permission if 17 or older, and allow donation if 16 or older with parent/guardian permission or if emancipated. State law is in most cases silent about the use of a younger donor in a special circumstance. State law is in most cases silent about the use of an incompetent adult as a donor. If one draws a parallel to customary research practice and to the federal regulations concerning research involving children [45 CFR 46(Subpart D)], one would have a hierarchy according to the degree of risk and the potential for direct personal benefit. Blood donation would not generally present the prospect of direct personal benefit (in the absence of iron overload), so risk greater than minimal risk would generally not be allowable (with the exception of the special circumstances outlined in 45 CFR 46.407). That being said, blood donation would meet the regulatory definition of “no greater than minimal risk.” Unless there is direct personal benefit (or “407” criteria are met), assent by the child is required. From this perspective, a donation by a willing donor would not be a major ethical problem even if the donor isn’t legally able to give consent. Legal consultation is nonetheless appropriate in such a circumstance (especially as local laws may vary), and documentation is important and includes satisfaction of the criteria for the low risk and ethical propriety of the donation as well as approval of the medical director.



5.2.4

Donor Notification of Abnormal Findings and Test Results

The medical director shall establish a process to notify all donors (including autologous donors) of any medically significant abnormality detected during the predonation evaluation or as a result of laboratory testing or recipient follow-up. In the case of autologous donors, the referring physician shall also be notified. Appropriate education, counseling, and referral shall be offered.*

*21 CFR 630.40 and 21 CFR 630.10(g)(1).