Educational Materials and Donor Consent

- Educational materials must be provided to the donor. The educational materials accompanying the FDA-approved donor history questionnaires include content required by the FDA and AABB**.** Some required elements include**:**
  - Explanation of the collection procedure.
  - Possible adverse reactions such as vasovagal reactions, citrate-related side effects (for apheresis), risk of iron deficiency.
  - Infectious disease testing that will be performed, the notification process for abnormal test results, reporting requirements to public health agencies for certain infectious diseases, possibility that testing cannot be performed (eg, inadequate sample).
  - Request that donors not donate if they think their blood could pose a risk or if they are seeking free testing.
- At each presentation, the donor must read the required educational materials, have the opportunity to ask questions, and acknowledge understanding of the information provided.
- Donor acknowledgement must be obtained at each donation, and the acknowledgement is provided by the donor's signature.
- For plasmapheresis and plateletpheresis donations, the center must also engage the donor at least annually in an informed consent dialogue.
- For minors, blood may be collected following applicable state law pertaining to consent from parents or guardians. AABB *Standards* requires that information about the donation process be provided to parents/guardians of minor donors when parental permission is required.
- Reasonable accommodation should be provided for donors who speak other languages and donors with impairments or disabilities, but ultimately it is the blood center's physician who decides if it is safe for a donation to proceed.

Allogeneic Donor Qualification Criteria

Donor Qualification by Focused Physical Exam and Donation Intervals

Title 21, CFR Part 630.10 requires a limited physical assessment of the donor which includes donor temperature, blood pressure, pulse, minimum weight, condition of skin at phlebotomy site and on arms, and hemoglobin/hematocrit levels.

Table 1-1. Physical Exam Requirements*

Parameter	AABB Reference Standard 5.4.1A; Title 21, CFR Part 630
Age	≥16 (or applicable state law); minor donors (as defined by state law) may donate with parental/guardian consent.
Blood pressure (BP)	BP must be within the following range: systolic = 90-180 mm Hg; diastolic = 50-100 mm Hg. Donors with a BP outside this range may be eligible after evaluation and approval by an on-site blood center physician.
Pulse	Pulse must be regular and between 50 and 100 beats per minute. Donors with an irregular pulse or pulse outside this range may be eligible with blood center physician approval.
Temperature	≤37.5 C (99.5 F) if measured orally, or equivalent if measured by another method.
Weight	≥110 lbs. Plasmapheresis donors must be weighed before donation. Self-reported weight acceptable for all other donation types. *Note:* Maximum whole-blood volume that can be collected during a donation is 10.5 mL/kg (includes samples).
Hemoglobin (hematocrit)†	Males: Hb ≥13.0 g/dL (Hct = 39%) Females: Hb ≥12.5 g/dL (Hct = 38%) *Note:* Female donors with a Hb between 12.0 and 12.5 g/dL (Hct between 36% and 38%) may donate if there are additional steps to ensure that an alternative standard adequately protects donor safety, in accordance with a procedure that has been found acceptable by the FDA.
Arm check	Phlebotomy site should be free of lesions. Check antecubital area for evidence of IV drug use (track marks), evidence of bacterial infection, or lesions that could prevent proper disinfection.
Platelet count	For plateletpheresis donors, a predonation sample must be taken for a platelet count. Platelet count must be ≥150,000 platelets/µL. *Note:* If collection site cannot obtain the platelet count result before start of donation (eg, mobile site), collection may proceed using an average of donor's prior platelet counts or a default platelet count for a first-time donor (as recommended by apheresis device manufacturer or blood center policy).

*Modified with permission from Eder and Muniz[1] [updated with data from AABB *Standards*[2(p60)] and the CFR].
†If donor's Hb is 12.5 g/dL, a 500-mL whole blood donation should yield 62.5 g Hb per Red Blood Cell unit. Low Hb/Hct is the most common cause of deferral in US blood donors. Hb/Hct screening does not ensure donor has adequate iron stores.

CFR = Code of Federal Regulations; FDA = Food and Drug Administration; Hb = hemoglobin; Hct = hematocrit.

Table 1-2. Donation Intervals

Donation Type	Donation Interval Requirement
Whole blood	8 weeks
2-unit red cell collection (double red)	16 weeks
Infrequent plasmapheresis	4 weeks
Plateletpheresis*	2 days (with no more than 2 procedures in a 7-day period)
Leukapheresis*	2 days (with no more than 2 procedures in a 7-day period)
Frequent plasmapheresis (source plasma)*	2 days (with no more than 2 procedures in a 7-day period)

*Limited to no more than 24 apheresis collections in a rolling 12-month period.

Table 1-3. Hemoglobin/Hematocrit Screening Methods

Method	Sample	Additional Information
Copper sulfate density	Capillary sample*	Not used as frequently as in the past.
Spectrophotometric Hb measurement	Capillary sample*	Most commonly used method in USA. Uses portable point-of-care device. Quantitative Hb result with 1.5% coefficient of variation (CV).
Hematology analyzer	Venous sample	≤1.2% CV

*Fingerstick capillary samples tend to have higher Hb values than venous samples. Earlobe capillary samples are not acceptable.

Hb = hemoglobin.

Health History Assessment

- AABB Donor History Questionnaire (DHQ) has been approved by the FDA and is widely used. Refer to Table 1-4. Other processes for determining donor eligibility must be approved by the FDA before use.
- To use the AABB DHQ, centers must implement the following in their entirety: 1) Blood donor educational materials; 2) full-length DHQ; 3) user brochure, including glossary and references; and 4) Medication Deferral List (see Table 1-5). AABB provides flowcharts for each question, but use is optional.

- The wording, order, and text of DHQ questions cannot be changed (except minor changes to time frames that are more restrictive than AABB/FDA requirements). Additional questions may be added at the end of the DHQ.
- DHQ can be self-administered or administered with direct oral questioning.
- If AABB or FDA do not address specific medical conditions, blood centers can develop their own criteria for these conditions (see Table 1-7).
- AABB has an abbreviated DHQ (aDHQ) for frequent donors that is FDA approved. Frequent donors are those who have completed the full-length DHQ on two separate occasions and have given one or more donations in the past 6 months. The aDHQ asks two "capture questions" about new diagnoses or treatments since the last donation, replacing 17 questions from the full DHQ.
- Occasionally, the blood center gets postdonation information (PDI) that would have deferred the donor if it had been reported at the time of donation. Donor deferral and subsequent actions such as product retrieval and consignee notification may be required based on potential hazard to a transfusion recipient. (*Note:* The FDA/AABB provide guidance on how to handle certain types of PDI.)

Table 1-4. Questions from AABB Donor History Questionnaire, Version 2.0*

AABB DHQ Question	Additional Information	Deferral
1. Are you feeling healthy and well today?	Donor should appear in good health and not have an infectious disease, including a cold, on donation day. Donor should not have an underlying condition that would cause deferral.	**Temporary** deferral.†
2. Are you currently taking an antibiotic?	Evaluate reason antibiotic was prescribed. Donors being treated for a bacterial infection should not donate.	**Temporary** deferral.† *Note:* If antibiotic is for prophylaxis only, donor may be eligible per facility's procedures.
3. Are you currently taking any other medication for an infection?	Evaluate reason for medication use to determine if donor has a viral, fungal, parasitic, or other infection transmissible by blood. Donors being treated for an infection should not donate.	**Temporary** deferral.† *Note:* If medication is for prophylaxis only, donor may be eligible per facility's procedures.
4. Have you taken any medications on the Medication Deferral List in the time frames indicated?	See Table 1-5 for AABB's Medication Deferral List.	A person taking a medication on the Medication Deferral List in the time frames indicated is deferred for the required period of time. See Table 1-5 for deferral requirements.