per deciliter of blood, or a hematocrit value that is equal to or greater than 39 percent.

(ii) An autologous donor must have a hemoglobin level no less than 11.0 grams of hemoglobin per deciliter of blood, or a hematocrit value no less than 33 percent.

(4) *Pulse*. The donor's pulse must be regular and between 50 and 100 beats per minute. A donor with an irregular pulse or measurements outside these limits may be permitted to donate only when the responsible physician determines and documents that the health of the donor would not be adversely affected by donating.

(5) *Weight*. The donor must weigh a minimum of 50 kilograms (110 pounds).

(6) *Skin examination*. (i) The donor's phlebotomy site must be free of infection, inflammation, and lesions; and

(ii) The donor's arms and forearms must be free of punctures and scars indicative of injected drugs of abuse.

(g) *Are there additional requirements for determining the eligibility of the donor*? You must obtain the following from the donor on the day of donation:

(1) *Proof of identity and postal address*. You must obtain proof of identity of the donor and a postal address where the donor may be contacted for 8 weeks after donation; and

(2) *Donor's acknowledgement*. (i) Prior to each donation, you must provide information to the donor addressing the elements specified in paragraphs (g)(2)(ii)(A) through (E) of this section and obtain the donor's acknowledgement that the donor has reviewed the information. You must establish procedures in accordance with § 606.100 of this chapter to assure that the donor has reviewed this material, and provide for a signature or other documented acknowledgement.

(ii) The donor acknowledgement must not include any exculpatory language through which the donor is made to waive or appear to waive any of the donor's legal rights. It must, at a minimum clearly address the following:

(A) The donor has reviewed the educational material provided under paragraph (b) of this section regarding relevant transfusion-transmitted infections;

(B) The donor agrees not to donate if the donation could result in a potential risk to recipients as described in the educational material;

(C) A sample of the donor's blood will be tested for specified relevant transfusion-transmitted infections;

(D) If the donation is determined to be not suitable under § 630.30(a) or if the donor is deferred from donation under § 610.41 of this chapter, the donor's record will identify the donor as ineligible to donate and the donor will be notified under § 630.40 of the basis for the deferral and the period of deferral;

(E) The donor has been provided and reviewed information regarding the risks and hazards of the specific donation procedure; and

(F) The donor has the opportunity to ask questions and withdraw from the donation procedure.

(h) *What must you do when a donor is not eligible*? You must not collect blood or blood components from a donor found to be ineligible prior to collection based on criteria in §§ 630.10 or 630.15, or deferred under § 610.41 of this chapter or § 630.30(b)(2), unless this subchapter provides an exception. You must defer donors found to be ineligible and you must notify the donor of their deferral under § 630.40.

§ 630.15 Donor eligibility requirements specific to Whole Blood, Red Blood Cells and Plasma collected by apheresis.

(a) *What additional donor eligibility requirements apply when you, an establishment that collects blood or blood components, collect Whole Blood or Red Blood Cells by apheresis*?

(1) *Donation frequency must be consistent with protecting the health of the donor*.

(i) For a collection resulting in a single unit of Whole Blood or Red Blood Cells collected by apheresis, donation frequency must be no more than once in 8 weeks, and for apheresis collections resulting in two units of Red Blood Cells, the donor must not donate more than once in 16 weeks.

(ii) The limitations in paragraph (a)(1)(i) of this section apply unless the responsible physician examines the donor at the time of donation and one of the following conditions exists:

(A) The donation is for autologous use as prescribed by the donor's physician and the responsible physician determines and documents that the donation may proceed; or

(B) The donation is a dedicated donation based on the intended recipient's documented exceptional medical need and the responsible physician determines and documents that the health of the donor would not be adversely affected by donating.

(2) *Therapeutic phlebotomy*. When a donor who is determined to be eligible under § 630.10 undergoes a therapeutic phlebotomy under a prescription to promote the donor's health, you may collect from the donor more frequently than once in 8 weeks for collections resulting in a single unit of Whole Blood or Red Blood Cells, or once in 16 weeks for apheresis collections resulting in two units of Red Blood Cells, provided that the container label conspicuously states the disease or condition of the donor that necessitated phlebotomy. However, no labeling for the disease or condition is required under this section if:

(i) The donor meets all eligibility criteria;

(ii) The donor undergoes a therapeutic phlebotomy as prescribed by a licensed health care provider treating the donor for:

(A) Hereditary hemochromatosis; or

(B) Another disease or condition, when the health of a donor with that disease or condition will not be adversely affected by donating, and the donor's disease or condition will not adversely affect the safety, purity, and potency of the blood and blood components, or any products manufactured from them, and the collection is in accordance with a procedure that has been found acceptable for this purpose by FDA; and

(iii) You perform without charge therapeutic phlebotomies for all individuals with that disease or condition.

(b) *What additional donor eligibility requirements apply when you, an establishment that collects blood or blood components, collect Source Plasma or plasma by plasmapheresis*?

(1) *Medical history and physical examination*. Except as provided in § 630.25:

(i) The responsible physician must conduct an appropriate medical history and physical examination of the donor on the day of the first donation or no more than 1 week before the first donation and at subsequent intervals of no longer than 1 year.

(ii) The responsible physician must examine the donor for medical conditions that would place the donor at risk from plasmapheresis. If the donor is determined to be at risk, you must defer the donor from donating.

(iii) The responsible physician must conduct a new medical history and physical examination of a donor who does not return for 6 months.

(2) *What requirements apply to obtaining informed consent*?

(i) The responsible physician must obtain the informed consent of a plasma donor on the first day of donation or no more than 1 week before the first donation, and at subsequent intervals of no longer than 1 year.

(ii) The responsible physician must obtain the informed consent of a plasma donor who does not return within 6 months of the last donation.

(iii) The responsible physician must explain the risks and hazards of the procedure to the donor. The explanation must include the risks of a hemolytic transfusion reaction if the donor is given the cells of another donor and the risks involved if the donor is immunized. The explanation must be made in such a manner that the donor may give their consent and has a clear opportunity to refuse the procedure.

(iv) If a donor is enrolled in a new program, such as an immunization or special collection program, the responsible physician must again obtain an informed consent specific for that program.

(3) *Weight*. You must weigh a donor at each donation.

(4) *Total protein level*. You must determine the donor's total plasma protein level before each plasmapheresis procedure. The donor must have a total plasma protein level of no less than 6.0 grams per deciliter and no more than 9.0 grams per deciliter in a plasma sample or a serum sample.

(5) *Examination before immunization*. (i) No more than 1 week before the first

immunization injection for the production of high-titer antibody plasma, the responsible physician must conduct an appropriate medical history and physical examination, as described in paragraph (b)(1) of this section, in addition to assessing the general donor eligibility requirements under § 630.10. It is not necessary to repeat the medical history and physical examination requirement in paragraph (b)(1) of this section, if the immunized donor's plasma is collected within 3 weeks of the first immunization injection.

(ii) You are not required to repeat the medical history and physical examination required under paragraph (b)(1) of this section for a donor currently participating in a plasmapheresis collection program and determined to be eligible under § 630.10 unless the medical history and physical examination are due under paragraph (b)(1)(i) or (b)(1)(iii) of this section.

(6) *Deferral of donors due to red blood cell loss.* (i) You must defer a donor from donating plasma by plasmapheresis for 8 weeks if the donor has donated a unit of Whole Blood, or a single unit of Red Blood Cells by apheresis. However, you may collect plasma by plasmapheresis after a donation of Whole Blood or a single unit of Red Blood Cells by apheresis after at least 2 calendar days have passed, provided that the extracorporeal volume of the apheresis device is less than 100 milliliters.

(ii) You must defer a donor from donating plasma by plasmapheresis for a period of 16 weeks if the donor donates two units of Red Blood Cells during a single apheresis procedure;

(iii) You must defer a donor for 8 weeks or more if the cumulative red blood cell loss in any 8 week period could adversely affect donor health.

(7) *Exceptions to deferral due to red blood cell loss.* You are not required to defer a Source Plasma donor from donating plasma by plasmapheresis due to red blood cell loss if the following conditions are met:

(i) The responsible physician examines the donor at the time of the current donation and determines and documents that the donor is in good health and the donor's health permits the plasmapheresis;

(ii) The donor's plasma possesses a property, such as an antibody, antigen, or protein deficiency that is transitory, of a highly unusual or infrequent specificity, or of an unusually high titer;

(iii) The special characteristics of the donor's plasma and the need for plasmapheresis of the donor under § 630.20(b) are documented at your establishment; and

(iv) The extracorporeal volume of the apheresis device is less than 100 milliliters.

(8) *Malaria.* Freedom from risk of malaria is not required for a donor of Source Plasma.

(9) You must comply with other requirements for collection of plasma in part 640 of this chapter and this part including restrictions on frequency of collection as specified in §§ 640.32 and 640.65 of this chapter.

§ 630.20 Exceptions for certain ineligible donors.

After assessing donor eligibility under §§ 630.10 and 630.15, an establishment may collect blood and blood components from a donor who is determined to be not eligible to donate under any provision of § 630.10(e) and (f) or § 630.15(a) if one of the following sets of conditions are met:

(a) The donation is for autologous use only as prescribed by the donor's physician, the donor has a hemoglobin level no less than 11.0 grams of hemoglobin per deciliter of blood or a hematocrit value no less than 33 percent, and the responsible physician determines and documents that the donor's health permits the collection procedure; or

(b) The donation is collected under a Source Plasma collection program which has received prior written approval from the Director, Center for Biologics Evaluation and Research, to collect plasma for further manufacturing use into in vitro products for which there are no alternative sources, the donor meets the criteria in § 630.10(f)(1) through (6), and the responsible physician determines and documents for each donation that the donor's health permits the collection procedure, and the collection takes place under the medical oversight specified