Food and Drug Administration, HHS

§ 1271.60 What quarantine and other requirements apply before the donor-eligibility determination is complete?

(a) Quarantine. You must keep an HCT/P in quarantine, as defined in §1271.3(q), until completion of the donor-eligibility determination required by §1271.50. You must quarantine semen from anonymous donors until the retesting required under §1271.85(d) is complete.

(b) Identification of HCT/Ps in quarantine. You must clearly identify as quarantined an HCT/P that is in quarantine pending completion of a donor-eligibility determination. The quarantined HCT/P must be easily distinguishable from HCT/Ps that are available for release and distribution.

(c) Shipping of HCT/Ps in quarantine. If you ship an HCT/P before completion of the donor-eligibility determination, you must keep it in quarantine during shipment. The HCT/P must be accompanied by records:

(1) Identifying the donor (e.g., by a distinct identification code affixed to the HCT/P container);
(2) Stating that the donor-eligibility determination has not been completed; and
(3) Stating that the product must not be implanted, transplanted, infused, or transferred until completion of the donor-eligibility determination, except under the terms of paragraph (d) of this section.

(d) Use in cases of urgent medical need. (1) This subpart C does not prohibit the implantation, transplantation, infusion, or transfer of an HCT/P from a donor for whom the donor-eligibility determination is not complete if there is a documented urgent medical need for the HCT/P, as defined in §1271.3(u).

(2) If you make an HCT/P available for use under the provisions of paragraph (d)(1) of this section, you must prominently label it “NOT EVALUATED FOR INFECTIOUS SUBSTANCES,” and “WARNING: Advise patient of communicable disease distribution, disposition, or expiration, whichever is latest.

§ 1271.65 How do I store an HCT/P from a donor determined to be ineligible, and what uses of the HCT/P are not prohibited?

(a) Storage. If you are the establishment that stores the HCT/P, you must store or identify HCT/Ps from donors who have been determined to be ineligible in a physically separate area clearly identified for such use, or follow other procedures, such as automated designation, that are adequate to prevent improper release until destruction or other disposition of the HCT/P in accordance with paragraph (b) or (c) of this section.

(b) Limited uses of HCT/P from ineligible donor. (1) An HCT/P from a donor who has been determined to be ineligible, based on the results of required testing and/or screening, is not prohibited by subpart C of this part from use for implantation, transplantation, infusion, or transfer under the following circumstances:

(i) The HCT/P is for allogeneic use in a first-degree or second-degree blood relative;

(ii) The HCT/P consists of reproductive cells or tissue from a directed re-productive donor, as defined in §1271.3(l); or

(iii) There is a documented urgent medical need as defined in §1271.3(u).

(2) You must prominently label an HCT/P made available for use under the provisions of paragraph (b)(1) of this section with the Biohazard legend shown in §1271.3(h) with the statement “WARNING: Advise patient of communicable disease risks,” and, in the case of reactive test results, “WARNING: Reactive test results for (name of disease agent or disease).” The HCT/P must be accompanied by the records required under §1271.55.

(c) Nonclinical use. You may make available for nonclinical purposes an HCT/P from a donor who has been determined to be ineligible, based on the results of required testing and/or screening, provided that it is labeled:

(1) “For Nonclinical Use Only” and

(2) With the Biohazard legend shown in §1271.3(h).

§ 1271.75 How do I screen a donor?

(a) All donors. Except as provided under §1271.90, if you are the establishment that performs donor screening, you must screen a donor of cells or tissue by reviewing the donor’s relevant medical records for:

(i) Risk factors for, and clinical evidence of, relevant communicable disease agents and diseases, including:

(1) Human immunodeficiency virus;

(2) Hepatitis B virus;

(3) Hepatitis C virus;

(4) Human transmissible spongiform encephalopathy, including Creutzfeldt-Jakob disease;

(5) Treponema pallidum; and

(6) Human transmissible spongiform encephalopathy, including Creutzfeldt-Jakob disease;

(ii) Communicable disease risks associated with xenotransplantation;

(b) Donors of viable, leukocyte-rich cells or tissue. In addition to the relevant communicable disease agents and diseases for which screening is required under paragraph (a) of this section, and except as provided under §1271.90, you must screen the donor of viable, leukocyte-rich cells or tissue by reviewing...