

of this section must contain the following information:

(1) A statement that the communicable disease testing was performed by a laboratory:

(i) Certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493; or

(ii) That has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services in accordance with those provisions;

(2) A listing and interpretation of the results of all communicable disease tests performed;

(3) The name and address of the establishment that made the donor-eligibility determination; and

(4) In the case of an HCT/P from a donor who is ineligible based on screening and released under paragraph (b) of §1271.65, a statement noting the reason(s) for the determination of ineligibility.

(c) *Deletion of personal information.* The accompanying records required by this section must not contain the donor's name or other personal information that might identify the donor.

(d) *Record retention requirements.* (1) You must maintain documentation of:

(i) Results and interpretation of all testing for relevant communicable disease agents in compliance with §§1271.80 and 1271.85, as well as the name and address of the testing laboratory or laboratories;

(ii) Results and interpretation of all donor screening for communicable diseases in compliance with §1271.75; and

(iii) The donor-eligibility determination, including the name of the responsible person who made the determination and the date of the determination.

(2) All records must be accurate, indelible, and legible. Information on the identity and relevant medical records of the donor, as defined in §1271.3(s), must be in English or, if in another language, must be retained and translated to English and accompanied by a statement of authenticity by the translator that specifically identifies the translated document.

(3) You must retain required records and make them available for authorized inspection by or upon request from

FDA. Records that can be readily retrieved from another location by electronic means are considered "retained."

(4) You must retain the records pertaining to a particular HCT/P at least 10 years after the date of its administration, or if the date of administration is not known, then at least 10 years after the date of the HCT/P's distribution, disposition, or expiration, whichever is latest.

[69 FR 29830, May 25, 2004, as amended at 70 FR 29952, May 25, 2005]

§ 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 risks.” The following information must accompany the HCT/P:

(i) The results of any donor screening required under § 1271.75 that has been completed;

(ii) The results of any testing required under § 1271.80 or 1271.85 that has been completed; and

(iii) A list of any screening or testing required under § 1271.75, 1271.80 or 1271.85 that has not yet been completed.

(3) If you are the establishment that manufactured an HCT/P used under the provisions of paragraph (d)(1) of this section, you must document that you notified the physician using the HCT/P that the testing and screening were not complete.

(4) In the case of an HCT/P used for an urgent medical need under the provisions of paragraph (d)(1) of this section, you must complete the donor-eligibility determination during or after the use of the HCT/P, and you must inform the physician of the results of the determination.

§ 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 reproductive 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.

(3) If you are the establishment that manufactured an HCT/P used under the provisions of paragraph (b)(1) of this section, you must document that you notified the physician using the HCT/P of the results of testing and screening.

(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:

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

(i) Human immunodeficiency virus;

(ii) Hepatitis B virus;

(iii) Hepatitis C virus;

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

(v) *Treponema pallidum*; and

(2) Communicable disease risks associated with xenotransplantation.