

§ 1270.1

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1270.15 Recall and destruction of human tissue.

AUTHORITY: Secs. 215, 311, 361, 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271).

SOURCE: 58 FR 65520, Dec. 14, 1993, unless otherwise noted.

§ 1270.1 Scope.

(a) The regulations in this part apply to banked human tissue and to establishments or persons engaged in the recovery, processing, storage, or distribution of banked human tissue.

(b) Regulations in this chapter as they apply to drugs, biologics, devices or other FDA-regulated commodities do not apply to banked human tissue, except as specified in this part.

§ 1270.3 Definitions.

(a) *Act* for the purpose of this part means the Public Health Service Act, section 361 (42 U.S.C. 264).

(b) *Banked human tissue* means any tissue derived from a human body, which:

(1) Is intended for administration to another human for the diagnosis, cure, mitigation, treatment, or prevention of any condition or disease;

(2) Is recovered, processed, stored, or distributed by methods not intended to change tissue function or characteristics;

(3) Is not currently regulated as a human drug, biological product, or medical device;

(4) Excludes kidney, liver, heart, lung, pancreas, or any other vascularized human organ; and

(5) Excludes semen or other reproductive tissues, human milk, and bone marrow.

(c) *Vascularized* means containing the native vasculature which continues to carry blood after transplantation.

(d) *Donor* means a human being, living or dead, who is the source of tissue for transplantation.

(e) *Recovery* means the obtaining from a donor of tissue that is intended for use in human transplantation.

(f) *Processing* means any activity to prepare, preserve for storage, and/or remove from storage to assure the potency, quality and/or sterility of human tissue for transplantation.

(g) *Distribution* includes any transfer of human tissue from one establishment or individual to another establishment or individual (including importation), whether or not such transfer is entirely intrastate and whether or not possession of the tissue is taken.

(h) *Storage* means holding tissue in any facility other than the facility at which the tissue is to be implanted.

(i) *Quarantine* means the identification of banked human tissue as not suitable for transplantation or the holding of banked human tissue in an area clearly identified as being for quarantine.

§ 1270.5 Donor testing and screening.

(a) Donor blood specimens shall be tested for the following communicable disease serological markers by tests approved for such uses by the Food and Drug Administration:

(1) Human immunodeficiency virus-1 antibody (anti-HIV-1);

(2) Human immunodeficiency virus-2 antibody (anti-HIV-2);

(3) Hepatitis B surface antigen (HBsAg); and

(4) Hepatitis C virus antibody (anti-HCV).

(b) Such infectious disease testing shall be performed by a laboratory appropriately certified under the Clinical Laboratories Improvement Act of 1988 (CLIA).

(c) Banked human tissue shall be quarantined or accompanied by records indicating that the donor's blood has been tested and found negative in approved tests for anti-HIV-1, anti-HIV-2, HBsAg, and anti-HCV.

(d) Banked human tissue shall be quarantined from donors who, within 48 hours prior to taking the blood sample, have been transfused with four or more units of blood, blood components, colloids or crystalloids in adults, or any transfusions within 48 hours in children under 12 years of age, unless:

(1) A pretransfusion blood sample is available for infectious disease testing; or

(2) An adequate algorithm is used to ensure that there is not hemodilution sufficient to alter test results.

(e) Determination that a donor of banked human tissue intended for transplantation is suitable shall in-