

59A-1.003 Definitions.

For the purpose of this section the word, phrase, or term:

(1) “Adverse reaction” means ~~an event where there is potential for the unanticipated transmission of communicable disease or malignancy, the patient’s unfavorable physical response to the transplantation of an organ or tissue with regard to the transmission of infections of other diseases of potential danger.~~

(2) “Agency” means ~~the Florida Agency for Health Care Administration an organ procurement organization (OPO), tissue bank, or eye bank.~~

(3) “Agent” means any person who has express or implied authority to obligate or act on behalf of an entity.

~~(4) “AHCA” means the Florida Agency for Health Care Administration.~~

~~(4)(5)~~ “Allograft” means the transplantation of tissue or organ taken from one individual of the same species as the recipient but with different hereditary factors.

~~(5)(6)~~ “Applicant” means a person who has applied to the ~~Agency~~AHCA for a certificate to operate an organ procurement organization, tissue bank, or eye bank.

~~(6)(7)~~ “Brain death” means the determination of death under provisions of Section 382.009, F.S., where there is the irreversible cessation of the functioning of the entire brain, including the brain stem.

~~(7)(8)~~ “Cardiorespiratory (cardiac) death” means the cessation of life which is manifested by the loss or absence of spontaneous heart beat and breathing.

~~(8)(9)~~ “Certificate” means a certificate to operate as an organ procurement organization, tissue bank, or eye bank which is issued by the ~~Agency~~AHCA to those ~~OPOs, Eye Banks or Tissue Banks~~agencies which meet and maintain compliance with this rule.

~~(9)(10)~~ “Clean, non-sterile” means the use of methods and techniques that reduce gross contamination.

~~(10)(11)~~ “Coercion” means the exercise of undue influence so that free choice of donation is diminished or lost.

~~(11)(12)~~ “Compensation” means monetary payment or other forms of retribution for a donation.

~~(12)(13)~~ “Container (final container)” means the immediate unit, bottle, vial, ampule, tube, or other receptacle containing grafts as distributed.

~~(13)(14)~~ “Coordinators” means registered nurses, physicians’ assistants, or other medically trained personnel who assist in the medical management of organ donors or in the surgical retrieval of organs, tissues, or eyes for transplantation.

~~(14)(15)~~ “Designee” means one who has been assigned a duty or duties, and who has the necessary training and educational qualifications to act on behalf of ~~an agency~~ director or medical director of an ~~OPO, Eye Bank or Tissue Bank~~agency.

~~(15)(16)~~ “Distribution” means the shipment and delivery of final container grafts for recipient use.

~~(16)(17)~~ “Donation” means the free and voluntary gift of one or more organs or tissues for the purpose of transplant surgery.

~~(17)(18)~~ “Donor” means a medically acceptable person where appropriate permissions have been obtained to procure organ(s) and tissue(s) according to the provisions of Chapter 735, Part V732, F.S., or if applicable, Chapter 406, F.S.

~~(18)(19)~~ “Eye bank” means a public or private entity which is involved in the retrieval, processing or distribution of human eye tissue for transplantation. Funeral homes or direct disposers engaged solely in the retrieval of eye tissue are not considered an eye bank for these purposes.

~~(19)(20)~~ “Facilities” means any area used for retrieval, processing, testing, storage, or distribution of organs, tissues, and tissue components.

~~(20)(21)~~ “Graft” means a piece of skin, bone, or other tissue to be transplanted to another place on the human body.

~~(21)(22)~~ “Gross autopsy” means the anatomical examination of a body without microscopic examination.

~~(22)(23)~~ “Indirect supervision” means the direction that is provided to coordinators and other staff under protocols expressly approved by the licensed physician medical director. The medical director or his physician designee shall always be available, in person or by telephone, to provide medical direction and consultation.

~~(23)(24)~~ “Informed consent” means permission to procure an organ(s) and tissue(s) from a non-living donor which is obtained only under circumstances that provide the prospective donor or donor’s next of kin sufficient opportunity to consider whether or not to agree to such donation and that minimize the possibility of coercion or undue influence.

~~(24)(25)~~ “Label” means written, printed, or graphic matter on the container or package or any such matter clearly visible through the immediate carton, receptacle, or wrapper.

~~(25)(26)~~ “Lessee” means a person who contracts with another person to occupy or use space to serve as an agency.

~~(26)(27)~~ “Moratorium” means an immediate suspension of activity.

~~(27)(28)~~ “Next of kin” means the person or persons most closely related to a deceased individual as designated by applicable law.

~~(28)(29)~~ “Organ” means a body part such as a heart, kidneys, pancreas, liver, lungs, that requires vascular reanastomosis.

~~(29)(30)~~ “Organ procurement organization (OPO)” means a public or private entity designated as an OPO by the Secretary of the U.S. Department of Health and Human Services (HHS) which is engaged in the process of recovering organs for the purposes of transplantation.

~~(30)(31)~~ “Organ Procurement and Transplantation Network (OPTN)” means the corporation under the Public Health Service Act that approves transplant programs to ensure that all organ donors meet minimum standards and requirements.

~~(31)(32)~~ “Package” means the immediate carton, receptacle, or wrapper, including all labeling matter therein and thereon, and the contents of the one or more enclosed containers.

~~(32)(33)~~ “Person” means any natural person, partnership, association, joint venture, trust, governmental entity, corporation, health facility, organ procurement organization, tissue bank, eye bank, or any other entity.

~~(33)(34)~~ “Preservation” means the proper combination of conditions that serve to protect organs from decay during established periods.

~~(34)(35)~~ “Procedure” means a series of activities followed in a regular and definite order.

~~(35)(36)~~ “Processing” means the procedure employed after organ or tissue retrieval and before storage of the final container material; includes identification of the organ or tissue, organ or tissue treatment, preparation of components from such organ or tissue, testing, labeling, and associated record-keeping.

~~(36)(37)~~ “Procure” means the removal of transplantable organs or tissues for the benefit of one or more patients.

~~(37)(38)~~ “Procurement” as it applies to an OPO and eye bank means the retrieval, processing or distribution of organs and eye tissues; procurement as it applies to a tissue bank means the retrieval, processing, storage or distribution of tissues.

~~(38)(39)~~ “Quality assurance” means the monitoring procedures that ensure and document that the entire agency (e.g., facilities, personnel, methods, practices, and records) conforms with these standards.

~~(39)(40)~~ “Quality control” means laboratory tests and procedures for measuring or monitoring properties of organs and tissues essential to the evaluation of their safety or usefulness.

~~(40)(41)~~ “Retrieval” means the excision of organs or tissues from a donor’s body.

~~(41)(42)~~ “Revocation” means removing an agency’s certificate to operate in the state.

~~(42)(43)~~ “Sensitizing agents” means any foreign substance capable of inducing a state of altered reactivity in which the recipient reacts with an immediate or delayed exaggerated response when reexposed to the foreign agent.

~~(43)(44)~~ “Storage” means the proper combination of conditions that serve to protect tissues from decay during established periods.

~~(44)(45)~~ “Suspension” means the temporary cessation of a state-certified organ or tissue procurement agency.

~~(45)(46)~~ “Tissue” means any non-visceral collection of human cells and their associated intercellular substances.

~~(46)(47)~~ “Tissue bank” means a public or private entity which is involved in at least one of the following activities: a) retrieving, processing, storing, or distributing viable or nonviable human tissues to clinicians who are not involved in the procurement process; b) retrieving, processing, and storing human tissues in one institution and making these tissues available to clinicians in other institutions; or c) retrieving, processing, and storing human tissues for individual depositors and releasing these tissues to clinicians at the depositor’s request. Establishments such as transplantation centers and other hospitals which store tissue only for a short term pending scheduled surgery within the same facility but do not otherwise participate in the retrieving, processing, or distribution of tissue would not be regulated under these provisions.

~~(47)(48)~~ “Transplant safety” means the assurance of relative freedom from harmful effect to persons affected, directly or indirectly, by a transplant when administered, taking into consideration the character of the transplant in relation to the condition of the recipient at the time.

~~(48)(49)~~ “Transplant physician” means a licensed practitioner who performs surgical repair or replacement using organs or tissues donated by a living or non-living donor.

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