

### **59A-1.005 Standards for OPOs, Tissue Banks and Eye Banks.**

#### **(1) Organizational requirements.**

(a) Institutional identity. The purpose of the agency shall be clearly established and documented. Documentation of institutional identity shall include whether the agency is an independent agency or part of another institution. The agency shall have a functional identity with a professional staff and a commitment to maintain and preserve records and operating procedures for future reference and historical continuity. Policies and procedures shall be maintained for personnel and other agency activities.

1. Board of directors or advisory board. Each agency shall have a board of directors or an advisory board which provides consultation and direction on all policy-making decisions as well as issues of liability, fiduciary responsibility, and selection of the agency director. Where the agency operates within the jurisdiction of a state educational institution, or is a hospital-based facility, the responsibilities of this board shall not conflict with the responsibilities or span of control of the duly authorized administrator of the agency.

2. Agency director. All procedures and policies shall be developed and maintained under the supervision of an agency director appointed by the board of directors or advisory board or, in the case of a state educational institution, the duly authorized administrator of the agency. This person shall be qualified by training and experience for the scope of activities being pursued.

a. The agency director shall be responsible for all administrative operations including, but not limited to, compliance with these standards. If the agency director appointed does not have medical licensure, the agency shall have a licensed physician (or physicians) under contract to ensure compliance with all medical-legal aspects and with all requirements for specialist knowledge of the particular organs and tissues processed.

b. The agency director shall be the individual responsible for the daily operation of the agency. It is this person's responsibility to carry out policies of the board of directors or advisory board, and to prescribe technically acceptable means for retrieving, processing, quality control, storage, and distribution.

c. The agency director shall provide all staff members with adequate information to perform their duties safely and competently.

d. The agency director shall be responsible for ensuring that technical staff maintain competency by participation in training courses and technical meetings or other educational programs. Such training shall be recorded in the employees personnel file. Delegation of responsibility for technical work, record-keeping, and administration shall be made.

e. To ensure quality control the agency director shall be responsible for ensuring that the medical director prescribes tests and procedures for measuring, assaying, or monitoring properties of organs and tissues essential to the evaluation of their safety and usefulness, e.g., hepatitis B surface antigen (HBsAg), human immunodeficiency virus-1 antibody (anti-HIV-1) and human immunodeficiency virus-2 antibody (anti-HIV-2), and hepatitis C virus antibody (anti-HCV). Any clinical laboratory tests performed within a certified OPO, tissue bank or eye bank must comply with Chapter 483, F.S., and the Clinical Laboratories Improvement Act of 1988 (CLIA-88), as applicable.

f. The agency director shall establish a quality assurance program. This program shall include ongoing monitoring and evaluation of activities, identification of problems, and development of plans for corrective action. These procedures and records shall be reviewed at least annually and shall provide the basis for the development of the quality assurance program. Each agency shall document all aspects of its quality assurance program and maintain records of all quality assurance activities for a minimum of seven years for OPOs and ten years for tissue banks and eye banks.

g. The agency director shall appoint technical staff and be responsible for ensuring that staff have capabilities and training appropriate to their function.

3. Medical director. Each OPO, tissue bank, and eye bank shall employ or have under contract a physician medical director, licensed to practice medicine and surgery in the state in which the agency is incorporated. In the case of Florida-based agencies, the physician must be licensed to practice medicine and surgery in Florida. The medical director shall provide direction and supervision to coordinators and all other staff who assist in the procurement of organs, tissues, or eyes for transplantation. With the exception of organ procurement surgery, this may be by indirect physician supervision. The medical director or his physician designee shall be available at all

times, in person or by telephone, to provide medical direction, consultation, and advice in cases of tissue donation and retrieval. Responsibility for technical performance must rest with the licensed physician medical director.

4. Each agency director shall have a working relationship with medical examiner offices in the agency's service area.

5. Personnel policies and procedures. Job descriptions, including scope of activities, specific responsibilities, and reporting relationships, for all personnel shall be established by written personnel policies and procedures approved by the agency director.

6. Policies and procedures. Each agency shall maintain policies and procedures which detail all aspects of retrieval, processing, testing, storage, and distribution practices.

a. Each of these procedures shall be reviewed and affirmed in writing annually by the agency director or designee. Modifications of standard procedures and development of new procedures shall be approved by the agency director or designee.

b. Obsolete revised procedures shall be retained separately to maintain a historical sequence.

c. Copies of the agency's policies and procedures shall be available to the staff at all times. Technical staff shall be required to state in writing that they have read and understand the manual.

d. Copies of procedures from published literature cited by reference shall be attached in an appendix to the procedures manual.

e. Copies of the agency's policies and procedures shall be available to surveyors for the AHCA for inspection upon request.

f. Procedures shall be detailed and unambiguous.

(b) Records.

1. Donor and recipient records shall be accurate, complete and confidential, pursuant to Section 456.057, F.S. Donor record confidentiality shall not preclude access by surveyors for the AHCA when conducting an inspection or investigation pursuant to paragraphs 59A-1.009(1)(a), (b), (c), F.A.C., and the medical examiner for cases which fall within the medical examiner's jurisdiction, as established under Section 406.05, F.S. Donor medical records and a final hard copy of the results of all laboratory tests shall be reviewed and affirmed in writing by the medical director, designees, or medical contractee to ensure suitability of the donated organ(s) or tissue(s) for the intended application.

2. Documentation shall be concurrent with the performance of each activity in the retrieval, preparation, testing, storage, and distribution of organs and tissues in such a manner that all activities can be clearly traced. All records shall be legible and indelible and shall identify the person performing the procedures/tasks. The record shall include dates of entries and test results. The expiration period assigned to specific categories of processed tissues is to be recorded in the agency's policies and procedures.

3. Records shall be as detailed as necessary for a clear understanding of each activity and shall be available for inspection by surveyors for the AHCA when conducting an inspection or investigation pursuant to paragraphs 59A-1.009(1)(a), (b), (c), F.A.C., upon request and within the bounds of medical-legal confidentiality, pursuant to Section 456.057, F.S.

4. Each organ and tissue and any components derived therefrom shall be assigned, in addition to generic designation, one unique identification number which shall serve as a lot number to identify the material from retrieval through distribution and utilization.

5. Records shall identify the donor, document the pathological and microbiological evaluation of the donor, verify the conditions under which the organ or tissue is retrieved, processed and stored, if applicable, and indicate disposition of the transplanted organ or tissue. Maintenance of these records shall be the responsibility of the agency director or designee. All records concerning donor history and processing information shall be made available to the transplant surgeon upon request, except those infringing upon donor confidentiality.

6. All records and communication between the agency and its donors and patient recipients shall be regarded as confidential and privileged. Surveyors for the AHCA shall have access to records and communication at the time of the inspection as specified in Rule 59A-1.009, F.A.C.

7. Maintenance and certification records, if applicable, on facilities, instruments, and equipment, including their

monitors, shall be maintained. These records shall indicate dates of inspection, name of facility, and performance evaluations. Each agency shall include in its procedures manual, the monitoring, inspection and cleaning procedures and schedules for each piece of equipment. Documented cleaning schedules for laboratory equipment shall be maintained. Records of function checks requiring interpretation of findings must include the interpretation. Records must include:

- a. Temperature of incubators when in use;
- b. Spore lot number and expiration date used for autoclave function check; and
- c. Control and test results.

8. An adverse reactions file shall be maintained pursuant to Rule 59A-1.011, F.A.C.

9. All of these records shall be retained for seven years for OPOs and ten years for tissue banks and eye banks after distribution of organs or tissues and be available for AHCA inspection.

(2) Safety and environmental control. Written procedures for the operation of the agency shall be established and approved by the agency director. Instructions for action in case of emergency or exposure to communicable disease, chemical and biological hazard precautions shall be included.

(a) Human waste items shall be disposed so as to minimize any hazard to personnel or the environment. Dignified and proper disposal procedures shall be used to obviate recognizable human remains. Any organs or tissues from a donor whose blood test for HIV or hepatitis pursuant to Section 381.0041, F.S., that are confirmed as positive by confirmatory testing shall be destroyed, treated, or disposed, in accordance with Section 381.0098, F.S., Chapter 403, Part IV, F.S., and Chapter 64E-16, F.A.C.

(b) Each agency shall comply with Occupational Safety and Health Administration (OSHA) rules 29 Code of Federal Regulations (CFR) Part 1910.1030, 1991. These rules establish requirements for minimizing exposure to hepatitis, HIV, and other blood-borne pathogens.

(3) Facilities and equipment.

(a) Facilities shall be designated for the specialized purposes for which they are to be used and shall be maintained in a clean and orderly manner. All instruments and equipment shall be subject to regularly scheduled maintenance and calibration. All temperature measuring devices must be calibrated against U.S. Bureau of Standards certified thermometers. Refrigerators and freezers used for the storage of tissues shall have monitors. Each agency shall have established procedures to follow in the event of electrical failure.

(b) There shall be policies and procedures to define limited access available for review by surveyors for the AHCA as specified in Rule 59A-1.009, F.A.C. Access shall be limited to agency employees, contractual employees of the agency, and surveyors for the AHCA. A security system or physical configuration shall be provided to prevent entry of unauthorized persons.

(4) Ethical standards.

(a) Each OPO, tissue bank, and eye bank shall have policies to avoid conflicts of interest. The policy shall ensure that no employee of the OPO, tissue bank and eye bank shall:

1. Have any interest, financial or otherwise, direct or indirect;
2. Engage in any business transaction or professional activity; or
3. Incur any obligation of any nature which is in substantial conflict with the full and competent performance of duties in the agency in which he or she is employed.

(b) In the event that services other than obtaining referral or consent are provided to the procuring agency, that procuring agency may make arrangements to pay expenses incurred for services rendered. Reimbursement to the individual shall not be in conflict with the personnel policies of the primary employer.

(5) Community involvement and educational standards.

(a) Each OPO, tissue bank and eye bank shall assist hospitals in establishing and implementing protocols for making routine inquiries regarding organ and tissue donations by potential donors.

(b) Each agency shall maintain documentation, that shall be available for review by surveyors for the AHCA, of educational services provided to the community, health care professionals and hospitals in the agency's service area.

(c) Documentation of education of professionals shall be maintained. Documentation of donor hospital policies, procedures, characteristics and donor related activities shall be kept. Written agreements between the hospital and

the agency shall document these activities.

(d) Each agency shall produce or have available literature and media items that will provide education for donation of organs, tissues, or eyes. Each agency shall be responsible for establishing and assisting in the dissemination of these materials.

(6) Agency investigations. Each agency shall provide to the AHCA, upon request, a copy of any audit, review, or study performed by any federal or accreditation organization that has or is reviewing that agency.

(7) Acquisition of organs and tissues.

(a) General.

1. Agency personnel shall ensure that consent for donation is obtained in compliance with Chapter 765, F.S.

2. Agency personnel shall be trained regarding obtaining and documenting consent for donation.

3. Consent shall be obtained from the donor, next of kin, or other designated legal entity in order of priority and availability according to Section 765.512, F.S.

4. The original signed consent form shall remain a part of the patient's hospital medical record if signed at the hospital.

5. A copy of the original signed consent form or record of telephone consent shall be retained in the agency's donor record.

(b) Informed consent.

1. Permission to obtain organs and tissues from donors by informed consent shall be as defined in Rule 59A-1.003, F.A.C., and shall be documented in writing. The consent form shall include the organs and tissues for which permission is granted (e.g., bone from the upper or lower extremities or bone from below the waist). Information provided shall be written or spoken in language understandable to the donor or the donor's next of kin.

2. Permission to retrieve organs and tissues from non-living donors shall be sought from next of kin in order of legal precedence as required by Section 765.512, F.S. In any cases falling under the provisions of Chapters 406 and 765, F.S., the permission of the medical examiner or appropriate designee shall be obtained prior to the procurement of any organ(s) and tissue(s). The donor records shall indicate the name of the contact person in the medical examiner's office, date and time of contact, and limitations, if any, imposed by those giving permission (e.g., DO NOT TOUCH CHEST).

(8) Premortem donations under the Anatomical Gift Statute. Written consent expressed by a living person to donate organs and tissues under provisions of the Anatomical Gift Statute, Chapter 765, Part X, F.S., are legally valid and permits organ procurement organizations, tissue banks, and eye banks to procure organs and tissues without further authorization from next of kin.

(9) Compensation for donors. Monetary compensation other than reimbursement of donation-related expenses is prohibited.

(10) Sale of anatomical matter. Sale of one of a pair of organs (such as an eye or kidney) by a living donor for financial compensation is illegal under Public Law 98-507, s. 301; 42 United States Code s. 274e; and Chapter 873, F.S.

(11) Donor selection. Suitability of a specific individual for organ and tissue donation shall be based upon the medical history and clinical status of the donor and the need for particular organs and tissues. Consent must be obtained from the medical examiner, if appropriate.

(a) Criteria for evaluating a potential donor include presence of infectious disease, malignant disease (with specific exceptions), neurological degenerative disease, and diseases of unknown etiology or any other diseases or conditions which may be transferred to the recipient. Administration of human pituitary gland extracts (growth hormone) precludes tissue donation. In equivocal situations, a specialist in the particular area of medicine shall be consulted. Criteria as published according to the Administrative Procedures Act (APA), U.S. Code, Title 5, Chapter 5, ss. 500-706, incorporated herein by reference, shall be followed for OPOs, tissue banks and eye banks.

(b) Evaluation of the donor record shall be performed by a licensed physician or a professional familiar with the conditions for which the procured organs or tissues will be used so that organs or tissues procured shall not be the source of any toxic or harmful effects per se when transplanted to another individual.

(c) Age of the donor shall be a significant consideration in the effective transplantation of certain organs or

tissues but does not preclude an individual from donation. The medical director or designee shall be responsible for donor selection.

(d) The medical director, designee, or medical contractee shall have the responsibility to document in writing that the donor is acceptable according to the criteria established in this rule.

(12) Reconstruction. Each agency shall have a policy for the reconstruction of the body which is integral to maintaining the dignity of the donor.

(13) Quality assurance. The agency's quality assurance program shall include a method for the transplanting surgeon to report adverse reactions from the transplantation of organ(s) and tissue(s) to the source OPO, tissue bank or eye bank, which in turn shall forward the adverse reaction information to the AHCA as described in Rule 59A-1.011, F.A.C.

(14) Recall procedures. A written procedure shall exist for recall of organs or tissues or notification of recipient agencies of the possibility of contamination, defects in processing, preparation or distribution, or other factors affecting suitability of the organs or tissues for their intended application. Procedures for documenting the steps in recall shall be included in the agency's policies and procedures.

(15) Look back procedures. Each OPO, tissue bank, and eye bank shall have procedures for notifying the transplanting agency or physician that they may have received infected organs or tissues. Documentation of look back procedures shall be included in the agency's policies and procedures.

(16) HIV notification requirements. Notification of HIV test results to donors and recipients of organs, tissues, and eyes in this state shall be in accordance with Section 381.0041, F.S., and Rule 64D-2.005, F.A.C.

(17) Data collection. Each organ procurement organization, tissue bank, and eye bank shall collect, maintain, and report the following data annually to the AHCA:

(a) Number of donors by age and race;

(b) Type of donation;

(c) Cause of death for all donors;

(d) Donor source (hospital, medical examiner, or funeral home);

(e) Number of organs retrieved and number of tissue allografts and eyes processed;

(f) Disposition of processed organs, tissues, and eyes with respect to in-state, national, or international distribution; and

(g) Revenues derived from retrieving, processing, or distributing organs and eye tissue, and revenues derived from retrieving, processing, storing or distributing tissues;

(h) Expenses associated with retrieving, processing, or distributing organs and eye tissue, and expenses associated with retrieving, processing, storing or distributing tissues.

(18) Revision of standards. All proposed revisions, additions, and deletions shall be reviewed for acceptance or rejection at least annually by the Florida Statewide Organ and Tissue Procurement and Transplantation Advisory Board's Standards Subcommittee. Recommendations from the Standards Subcommittee shall be reviewed by the Florida Statewide Organ and Tissue Procurement and Transplantation Advisory Board and subsequently submitted to the AHCA for consideration and appropriate action.

(19) Fair and equitable system. Each agency shall establish and document a system of distribution that is just, equitable, and fair to all patients served by the agency. Documentation of distribution (date of requests for, offer of, and delivery of organs and tissues) shall be available for examination by authorized individuals, including surveyors for the AHCA. Access to organs and tissues shall be provided without regard to recipient sex, age, religion, race, creed, color or national origin.

