

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 505. ANATOMICAL GIFTS**

Unofficial Version

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Appendix A. Anatomical Donation form [REVOKED]

[**Authority:** 63 O.S.Supp. 1987, § 2214 et seq., as amended]

[**Source:** Codified 12-31-1991]

SUBCHAPTER 1. GENERAL PROVISIONS

- 310:505-1-1. Purpose
- 310:505-1-2. Anatomical Donation form adopted
- 310:505-1-3. Definitions

310:505-1-1. Purpose

The purpose of this Chapter is to provide rules for anatomical gifts, tissue banks, and eye banks as required by the Uniform Anatomical Gift Act, 63 O.S. Supp. 1999, Section 2201 et seq., as amended.

[**Source:** Amended at 18 Ok Reg 1711, eff 5-25-01]

310:505-1-2. Anatomical Donation form adopted [REVOKED]

[**Source:** Revoked at 18 Ok Reg 1711, eff 5-25-01]

310:505-1-3. Definitions

The following words and terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise.

"Act" means the Uniform Anatomical Gift Act [63 O.S. Supp. 1999, §2201 et. seq.]

"Commissioner" means the Commissioner of Health.

"Department" means the Oklahoma State Department of Health.

"Designated anatomical gift representatives" means either organ procurement representatives, designated requestors, appropriately trained tissue bank employees when requesting consent for donation of bone, skin, or connective tissue, or appropriately trained eye bank employees when requesting consent for donation of whole eyes, corneas, or other parts of eyes.

"Designated requestor" means an individual designated in writing by the hospital, who has completed a course offered or approved by a designated and qualified Organ Procurement Organization (OPO) or who has equivalent training and experience. Such courses shall be designed in conjunction with the tissue and eye bank community in the methods for approaching potential donor families and requesting organ, tissue, or eye donation.

"Existing eye bank" means any eye bank in Oklahoma which was operating on November 1, 1997 and has been in continuous operation since that date.

"Existing tissue bank" means any tissue bank in Oklahoma which was operating on November 1, 1999 and has been in continuous operation since that date.

"Eye bank" means a person, corporation, partnership, association or other legal entity established, operated, or maintained for the procurement, storage, and/or distribution of whole eyes, corneas, or other parts of eyes.

"General medical surgical hospital" means a hospital maintained for the purpose of providing hospital care in a broad category of illness and injury. {63 O.S. Supp. 1999, § 1-701}

"New eye bank" means any eye bank in Oklahoma which was not in operation on November 1, 1997.

"New tissue bank" means any tissue bank in Oklahoma which was

not in operation on November 1, 1999.

"Organ procurement representative" means an individual who has been appropriately trained and is employed by a qualified organ procurement organization designated by the Health Care Financing Administration (HCFA) to *perform or coordinate the surgical recovery, preservation, and transportation of organs and that allocates organs to prospective recipients* {63 O.S. Supp. 1999, § 2202(9)} for a particular service area.

"Tissue bank" means a person, corporation, partnership, association or other legal entity established, operated, or maintained for the procurement, storage, and/or distribution of bone, skin, or connective tissue.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

SUBCHAPTER 3. ANATOMICAL GIFTS

- 310:505-3-1. Requirement to request consent for anatomical gift
- 310:505-3-2. Procedures for requesting consent for anatomical gift
- 310:505-3-3. Certificate of request for anatomical gift
- 310:505-3-4. Approved means of giving consent
- 310:505-3-5. Coordination of anatomical gift activities

310:505-3-1. Requirement to request consent for anatomical gift

Each general medical surgical hospital with fifty (50) or more licensed beds shall ensure that when a person who is determined to be potentially suitable for organ, tissue, or eye donation dies in the hospital, a request for consent for anatomical gift is made when such a request is required by the Act. The hospital shall ensure that each request for consent for anatomical gift is made by a designated anatomical gift representative, and that each such request is made of the appropriate person as described in the Act.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-3-2. Procedures for requesting consent for anatomical gift

Each general medical surgical hospital with fifty (50) or more licensed beds shall establish written policies and procedures describing:

- (1) Who may execute an anatomical gift under the Act;
- (2) The classes of persons and priority of the classes of persons who may consent to a request for anatomical gift of a decedent's body or part of a body under the Act;
- (3) The names and contact information for all hospital designated requestors and the contact information required to initiate the referral process to the designated OPO, tissue bank, or eye bank if they act as designated requestors for the hospital;
- (4) The name and location of the designated OPO for their service area and procedures for how to contact the OPO twenty-four (24) hours a day;
- (5) The names and locations of all tissue and eye banks with which the hospital has agreements to cooperate in the retrieval,

processing, preservation, storage, and distribution of tissues and eyes;

(6) The methodology for approaching donor families and requesting organ, tissue, or eye donation which encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(7) How to document a request for anatomical donation and the outcome of the request;

(8) The quality assurance activities used to monitor the identification of potential donors, appropriate requests for consent for anatomical gifts are made, and that outcomes of requests for anatomical gifts are documented.

(9) A method of notifying administrators if other hospital policies, procedures, or processes interfere with the identification or maintenance of potential donors, or in the retrieval of all usable organs, tissues, and eyes.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-3-3. Certificate of request for anatomical gift

(a) The hospital shall ensure that a copy of the completed Certificate of Request For Anatomical Gift is included in the medical records of the decedent when a person who is determined to be potentially suitable for organ, tissue, or eye donation dies in the hospital.

(b) The Certificate of Request for Anatomical Gift shall include:

- (1) Identifying information for the hospital and the decedent;
- (2) Information on any deferrals of donation made by an OPO, tissue bank, or eye bank;
- (3) Identifying information for the requested party and the requesting party;
- (4) A description of the specifics and circumstances of the request and the outcome of the request.
- (5) A description of the organs and tissues donated when a request is granted and any limitations or special wishes for the gift;
- (6) A declaration of consent for the gift and signature blocks for the requested party and the requesting party.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-3-4. Approved means of giving consent

(a) Consent for an anatomical gift may be given in person, or by telephone, telegraph, facsimile, electronic mail, or other electronic means when the identity of the person giving consent can be reasonably assured.

(b) The hospital shall request written confirmation of in person verbal consent, or consent received by telephone, electronic mail, or other electronic means. The requested party's signature on ODH Form 942 shall be deemed to meet this requirement.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-3-5. Coordination of anatomical gift activities

The hospital shall work cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues,

reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes takes place.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

SUBCHAPTER 5. TISSUE BANKS

- 310:505-5-1. Permits
- 310:505-5-2. Permit applications
- 310:505-5-3. Compliance with Federal, State, and local laws
- 310:505-5-4. Enforcement
- 310:505-5-5. Accreditation and notification
- 310:505-5-6. Medical director
- 310:505-5-7. Technical operations personnel
- 310:505-5-8. Tissue distribution
- 310:505-5-9. Annual report

310:505-5-1. Permits

(a) **Requirement for a permit.** Each tissue bank operating in Oklahoma shall hold a valid permit issued by the Department. Each permit shall be issued for a period not to exceed thirty-six (36) months provided all the requirements of this Chapter are met, and shall automatically expire on the last day of the thirty-sixth month from the date of issue if not renewed.

(b) **Permit fee.** Application for a permit shall be made on a form provided by the Department for that purpose. A non-refundable fee of one thousand dollars (\$1000.00) shall accompany each permit application. Any application received by the Department without a fee shall not be considered or processed.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-5-2. Permit Applications

(a) **Initial applications.** Each new tissue bank shall submit a complete application for permit to operate a tissue bank and include with the completed application and fee:

- (1) A map or narrative description which identifies the proposed service area;
- (2) A description of the tissue transplantation needs in the proposed service area;
- (3) An explanation of the probable impact of the new tissue bank on existing tissue banks providing services in the proposed service area;
- (4) Evidence of accreditation by the American Association of Tissue Banks (AATB) or another nationally recognized accreditation organization for tissue agencies approved by the Commissioner;
- (5) The name of the Medical Director and evidence that he or she is currently licensed to practice medicine in Oklahoma; and
- (6) The names and credentials of all technical operations personnel who meet the requirements of OAC 310:505-5-7.

(b) **Existing tissue banks.** Existing tissue banks applying for a permit for the first time after the effective date of these rules

shall not be required to provide the information required at OAC 310:505-5-2(a)(1 - 3).

(c) **Renewal application.** At least ninety (90) days prior to the expiration of their current permit, each tissue bank shall submit to the Department a complete application for permit to operate a tissue bank and include with the completed application and fee:

(1) Evidence of accreditation by the AATB or another nationally recognized accreditation organization approved by the Commissioner;

(2) The name of the Medical Director and evidence that he or she is currently licensed to practice medicine in Oklahoma; and

(3) The names and credentials of all technical personnel who meet the requirements of OAC 310:505-5-7, including evidence of current certification by the AATB or another nationally recognized accrediting or certifying organization for tissue agencies and personnel approved by the Commissioner.

(d) **Notice of initial permit application.** After a complete application for permit and fee for a new tissue bank has been received, the Department shall cause public notice of the new tissue bank to be published in the newspaper with the greatest circulation in the proposed service area of the new tissue bank. The Department shall also provide written notice of the initial permit application to each tissue bank in the state holding a current permit.

(e) **Action on permit application.** The Department shall act to issue or deny each initial and renewal permit application within seventy-five (75) days of the publication of the notice for initial permit application, and within seventy-five (75) days of receipt of the complete application and fee for renewal permit application.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-5-3. Compliance with Federal, State, and local laws

Each tissue bank shall comply with applicable Federal, State, and local laws.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-5-4. Enforcement

(a) **Denial, revocation, suspension, non-renewal of permit.** The permit of a tissue bank may be denied, revoked, suspended, or not renewed for failure to comply with the provisions of the Act or the rules of this Chapter.

(b) **Appeals.** Appeals of Department actions against a permit or a permit holder shall be conducted according to the Administrative Procedures Act and Chapter 2 of this Title (310:002).

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-5-5. Accreditation and notification

(a) Within one (1) year after receipt of a permit, each tissue bank shall be accredited by the AATB or another nationally recognized accreditation organization for tissue agencies approved by the Commissioner in order to hold, or be eligible to hold a

permit.

(b) Each permitted tissue bank shall notify the Department in writing within ten (10) days of the loss of accredited status required by OAC 310:505-5-5(a).

[Source: Added at 18 Ok Reg 1711, eff 5-25-01; Amended at 19 Ok Reg 385, eff 11-19-2001(emergency); Amended at 19 Ok Reg 1050, eff 5-13-2002]

310:505-5-6. Medical director

Each tissue bank shall have a medical director who is a physician licensed to practice medicine in Oklahoma with appropriate training and experience in tissue bank services.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-5-7. Technical operations personnel

(a) Each tissue bank shall employ sufficient technical operations personnel to meet the procurement, testing, quality control, and quality assurance needs for the number and type of tissue units recovered, processed, stored, and distributed to ensure that a safe and reliable product is provided.

(b) Each tissue bank shall employ at least one technician holding current certification as a Certified Specialist in tissue bank procedures for recovery, processing, storage, and distribution of skin, bone, and connective tissue by the AATB or other nationally recognized accrediting or certifying organization for tissue agencies and personnel approved by the Commissioner.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-5-8. Tissue distribution

Each tissue bank shall give priority in tissue distribution to the Oklahoma medical community and to Oklahoma patients.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-5-9. Annual report

(a) Each tissue bank in Oklahoma shall prepare and submit an annual report to the Department based on the previous calendar year's twelve month period of January 1st through December 31st.

(b) Annual reports shall be provided to the Department by March 31st of each calendar year.

(c) During a tissue bank's first year of operation, the annual report shall be based on the period from the first day of operation to December 31st of that year.

(d) Each annual report shall include at least the following information:

- (1) The accreditation status of the tissue bank;
- (2) A report of all regulatory, accreditation, or internal inspections which result in findings that impact the quality of the product or services provided by the tissue bank;
- (3) The names and certification statuses of all technical personnel who meet the requirements of OAC 310:505-5-7.
- (4) The name and qualifications of the current medical director including evidence the medical director is currently licensed to practice medicine in Oklahoma;

(5) The type and geographic origins of all donor tissue procured; and

(6) The number and types of units of processed tissue used for patients in the service area of the tissue bank.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

SUBCHAPTER 7. EYE BANKS

- 310:505-7-1. Requirement for a permit
- 310:505-7-2. Permit applications
- 310:505-7-3. Compliance with Federal, State, and local laws
- 310:505-7-4. Enforcement
- 310:505-7-5. Accreditation and notification
- 310:505-7-6. Medical director
- 310:505-7-7. Technical operations personnel
- 310:505-7-8. Tissue distribution
- 310:505-7-9. Annual report

310:505-7-1. Requirement for a permit

Each eye bank operating in Oklahoma shall hold a valid permit issued by the Department. Once issued, a permit to operate an eye bank shall be valid as long as the permitted eye bank is in continuous operation and meets all provisions of the Act and the rules promulgated thereto.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-7-2. Permit application

(a) **Initial application.** New eye banks shall submit a complete application for permit to operate an eye bank and include with the completed application an initial non-refundable fee equal to one quarter of one percent (0.25%) of the capital cost of the proposed eye bank, with a minimum fee of five hundred dollars (\$500.00). Any application received by the Department without a fee shall not be considered or processed.

(b) **Application requirements for new eye banks.** New eye banks shall also include the following along with the completed application and fee:

- (1) A map or narrative description which identifies the proposed service area;
- (2) A description of the eye and eye tissue needs in the proposed service area;
- (3) An explanation of the probable impact of the new eye bank on existing eye banks providing services in the proposed service area;
- (4) Evidence of accreditation by the Eye Bank Association of America (EBAA) or another nationally recognized accreditation organization for eye banks approved by the Commissioner;
- (5) The name of the Medical Director and evidence that he or she is a board-certified ophthalmic surgeon currently licensed to practice medicine in Oklahoma; and
- (6) The names and credentials of all technical operations personnel who meet the requirements of OAC 310:505-7-7.

(c) **Application requirements for existing eye banks.** Existing

eye banks applying for a permit for the first time after the effective date of these rules shall not be required to pay a fee or provide the information required at OAC 310:505-7-2(a)(1 - 3).

(d) **Notice of initial permit application.** After a complete application for permit and fee for a new eye bank has been received, the Department shall cause public notice of the new eye bank to be published in the newspaper with the greatest circulation in the proposed service area of the new eye bank. The Department shall also provide written notice of the initial permit application to each eye bank in the state holding a current permit.

(e) **Action on initial permit application.** The Department shall issue or deny each initial permit application within seventy-five (75) days of the publication of the notice. An initial permit shall expire thirty-six (36) months from the date of issue. If construction is not completed and the eye bank is not in operation prior to the expiration date of the permit, the permit shall be void.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-7-3. Compliance with Federal, State, and local laws

Each eye bank shall comply with applicable Federal, State, and local laws.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-7-4. Enforcement

(a) **Denial, revocation, or suspension of a permit.** The permit of a eye bank may be denied, revoked, or suspended for failure to comply with the provisions of the Act or the rules of this Chapter.

(b) **Appeals.** Appeals of Department actions against a permit or a permit holder shall be conducted according to the Administrative Procedures Act and Chapter 2 of this Title (310:002).

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-7-5. Accreditation and notification

(a) Each eye bank shall be accredited within one year of beginning operation by the EBAA or another nationally recognized accreditation organization for eye banks approved by the Commissioner in order to hold, or be eligible to hold a permit.

(b) Each permitted eye bank shall notify the Department in writing within ten (10) days of the loss of accredited status required by OAC 310:505-7-5(a).

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-7-6. Medical director

Each eye bank shall have a medical director who is a board certified ophthalmic surgeon licensed to practice medicine in Oklahoma with appropriate training and experience in eye bank services.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-7-7. Technical operations personnel

(a) Each eye bank shall employ sufficient technical operations personnel to meet the procurement, testing, quality control, and quality assurance needs for the number and type of eyes and eye tissue units recovered, processed, stored, and distributed to ensure a that safe and reliable product is provided.

(b) Each eye bank shall employ at least one person holding current certification as a Certified Eye Bank Technician by the EBAA or other nationally recognized accrediting or certifying organization for eye banks and personnel approved by the Commissioner.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-7-8. Tissue distribution

Each eye bank shall give priority to the Oklahoma medical community and to the needs of patients being treated in Oklahoma.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

310:505-7-9. Annual report

(a) Each eye bank in Oklahoma shall prepare and submit an annual report to the Department based on the previous calendar year's twelve month period of January 1st, through December 31st.

(b) Annual reports shall be provided to the Department by March 31st of each calendar year.

(c) During an eye bank's first year of operation, the annual report shall be based on the period from the first day of operation to December 31st of that year.

(d) Each annual report shall include at least the following information:

(1) The accreditation status of the eye bank;

(2) A report of all regulatory, accreditation, or internal inspections which result in findings that impact the quality of the product or services provided by the eye bank;

(3) The names and certification statuses of all technical personnel who meet the requirements of OAC 310:505-7-7.

(4) The name and qualifications of the current medical director including evidence the medical director is a board certified ophthalmic surgeon and currently licensed to practice medicine in Oklahoma;

(5) The numbers and geographic origins of all donor corneas and whole eyes procured; and

(6) The number and geographic destinations of corneas and other parts of eyes.

[Source: Added at 18 Ok Reg 1711, eff 5-25-01]

APPENDIX A. ANATOMICAL DONATION (FORM) [REVOKED]

[Source: Revoked at 18 Ok Reg 1711, eff 5-25-01]