MEDICAL ADVISORY

November 20, 2014

The following changes were made at the October 16, 2014 meeting of the Medical Advisory Board, and will become effective January 1, 2015, except where noted:

B1.000 **Active Membership**

In order for an eye bank to become an active member of the Eye Bank Association of America (EBAA), it must comply with the EBAA Bylaws and the following:

1. Demonstrate compliance with EBAA Medical Standards.
2. Maintain accreditation status by passing the site inspection as administered by the EBAA Accreditation Board.
3. Demonstrate proficiency in any aspect of eye banking including recovery, processing, tissue storage, evaluation, donor eligibility determination and distribution.
4. Proficiency shall be demonstrated by providing documentation, at the time of completing the application, of the handling of at least 25 surgical corneas for each eye bank function for which it is seeking accreditation.
5. Certify compliance with applicable Federal and State regulations.
6. Register with ICCBBA for a Facility Identification Number (FIN) by June 30, 2015.

Once accredited, an eye bank must be inspected and reaccredited at least every three years to maintain active membership in the EBAA.

C3.400 Procedures Manual

Each eye bank shall maintain its own policies and procedures manual that details all aspects of its specific eye bank functions, and quality assurance practices. Each procedure must be initially approved, signed, and dated by the Director and Medical Director. An annual review of each eye bank's procedure with signing and dating by the Director and Medical Director is required. Each eye bank must maintain copies of

each procedure it uses and the length of time the procedure was in use. Procedures must be readily available to personnel in the area where operations are performed.

Eye banks shall utilize ICCBBA Eye Bank Technical Advisory Group (EBTAG) nomenclature to describe ocular tissue classes and attributes, effective June 30, 2015.

C3.510 Eye Bank Functions Performed by Another Establishment

Any EBAA accredited organization engaging with another establishment that performs eye banking functions prior to distribution must either:

1. Document that the establishment is currently EBAA accredited for the eye bank functions performed; or
2. Document that the establishment is in compliance with EBAA medical standards, state and federal regulations appropriate to the eye bank functions performed. This option requires a written agreement and the EBAA accredited organization is responsible for performing compliance audits. Policies and procedures shall describe the audit plan, scope, and frequency.

G1.000 **Quality Assurance**

Each eye bank shall have a formally established quality assurance program. This program shall include:

- Establishment and maintenance of procedures for all functions performed by the eye bank (including review, approval, and revision)
- Monitoring and evaluation of functions through periodic audits by an individual(s) not regularly involved in the processes being monitored
- Identification of problems and complaints relating to activities (receiving, investigating, evaluating, and documenting information relating to eye banking requirements)
- Development of plans for corrective actions, including monitoring for effectiveness

The quality assurance program shall address applicable requirements relating to the following areas:

1. Facilities
2. Environmental control
3. Equipment
4. Supplies and reagents
5. Recovery

6. Processing and processing controls
7. Labeling controls
8. Storage
9. Receipt, pre-distribution shipment, and distribution
10. Donor eligibility determinations, donor screening, and donor testing
11. Tissue evaluation

Each eye bank shall document all aspects of its quality assurance program. Records relating to the quality assurance program shall be maintained for a minimum of ten years. These records shall be made available at the time of site inspection.

The Quality Assurance Program shall establish a system for reporting, documenting, and investigation of deviations. Deviations for distributed tissue relating to core CGTPs must be reported to the federal regulators and EBAA.

The eye bank's quality assurance program shall include a method for the receiving surgeon to report adverse reactions from the transplantation of corneal, scleral, or other ocular tissue to the distributing eye bank. The distributing eye bank must forward the adverse reaction information to the source eye bank, which made the donor eligibility determination. The source bank must perform an investigation and must report the adverse reaction information within 30 days to the EBAA office for review by the Medical Advisory Board. In accordance with FDA 1271.350, adverse reactions involving a relevant communicable disease must be reported to the FDA within 15 calendar days of receipt of the information if the adverse reaction is fatal, life-threatening, results in permanent impairment or damage or requires medical or surgical intervention.

The source bank must notify all entities involved in the recovery, processing, storage, distribution, tissue evaluation, and donor eligibility determination of the results of the investigation. Each of the involved entities must maintain documentation of the adverse event and results of the investigation forwarded to it by the source bank.

Infection of a systemic nature that the medical director's investigation determines to be possibly, likely/probable or definitely due to donor tissue must be communicated to all entities that recovered organs or received or recovered tissues from that donor.

An adverse reaction reportable to the EBAA is any communicable or other disease that is possibly, reasonably likely/probable, or definite/certain to have been transmitted by transplantation of donor eye tissue, including infection (as manifested by endophthalmitis, keratitis or systemic disease) and biologic dysfunction (such as immediate endothelial failure, donor corneal dystrophy, malignancy, or evidence suggestive of prior refractive surgery). If systemic

infectious disease such as HIV, hepatitis, syphilis, West Nile Virus (WNV), or Creutzfeldt Jakob Disease (CJD) develops in a recipient, whether or not it is suspected to be due to donor tissue, this must be reported to the EBAA office. The Medical Director shall receive and review all adverse reaction reports, documenting any corrective actions he/she determines are indicated.

J1.000 **Labeling**

All ocular tissue distributed for surgical use shall be in a container which is clearly and indelibly labeled to include at least the information below.

<u>All tissues:</u>

1. Name of source eye bank.
2. Tissue identification number. There must be a unique identification number for each ocular tissue or fraction thereof.
3. Type of tissue (e.g. cornea, whole eye, sclera).
4. If cornea has had additional processing (e.g. lamellar, laser shaped), clearly indicate this on the label.
5. Expiration date of tissue.
6. A statement that the tissue is intended for single patient application only.
7. A statement that the tissue is not to be considered sterile unless tissue has been subjected to a validated process to ensure sterility.
8. Type of storage solution.
9. Utilize ISBT 128 identifiers to label ocular tissue products, effective January 1, 2016. These identifiers include the Donation Identification Number (DIN), Product Code, and all dates.
10. ISBT 128 data structures shall be used within two-dimensional (2-D) symbols (Data Matrix) to label ocular tissue products distributed internationally, effective January 1, 2017.

<u>Short and intermediate term preserved tissues:</u>

1. Date and time of donor's death.
2. Date and time of initial corneal/scleral preservation.

K1.200 Distribution Compliance

Compliance with EBAA medical standards shall be maintained in eye bank functions performed through distribution. An eye bank performing final distribution shall inform the consignee, in writing, of requirements for tracking and traceability, outcomes and adverse reaction reporting. Compliance with applicable laws, regulations and standards in eye bank functions performed after distribution is the responsibility of the consignee.

L1.000 Documentation to Accompany Donor Tissue

L1.100 Tissue Report Form

For special research studies, by recommendation of the Medical Advisory Board and approved by the EBAA Board of Directors, certain specific data may be masked on the tissue report form and label. A copy of the tissue report form shall accompany the tissue. The tissue report shall contain the following:

<u>All Tissues:</u>

1. Name of (Source) eye bank
2. Location of eye bank
3. Telephone number of eye bank
4. Eye bank identification number unique to each tissue graft. Effective January 1, 2016, utilize ISBT 128 Donation Identification Number (DIN) and Product Code.
5. Type of storage solution
6. If cornea is processed, clearly indicate the type of processing performed or the indicated use (e.g. endothelial keratoplasty, posterior lamellar keratoplasty, anterior lamellar keratoplasty, laser assisted keratoplasty, etc.).

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7. Report requirements by processing type according to Matrix II.
8. Name and EBAA Accreditation Status of each establishment that performs any of the following steps in the preparation of tissue: recovery, processing, storage, evaluation, donor eligibility determination and distribution
9. A summary of records reviewed regarding the eligibility of tissue for transplant

<u>Short and intermediate term preserved tissues:</u>

1. Age of donor
2. Cause of death
3. Death date and time
4. Preservation date and time
5. Additional tissue processing date and time
6. The time that cooling of ocular tissues and/or refrigeration of the body was begun
7. Name of technician who enucleated, excised, processed, and evaluated the tissue
8. Report requirements by processing type according to Matrix II.

Post-Processing Reporting Requirements					
Processing Type	**Morphology and Dimensions of Cut**	**Diameter of Cut**	**Pachymetry**	**Pre/Post-Processing Slit Lamp Exam**	**Pre/Post-Processing Endothelial Cell Density Reports**
LAK	**Yes**	No	No	**Yes**	**Yes**
DSAEK	No	**Yes**	**Yes**	**Yes**	**Yes**
DSEK	No	**Yes**	**Yes**	**Yes**	**Yes**
DMAEK	No	No	No	**Yes**	**Yes**
DMEK	No	No	No	**Yes**	**Yes**
ALK	No	**Yes**	**Yes**	**Yes**	No
Short Term Preservation	*As above*	*As above*	*As above*	**Yes***	**Yes****
Intermediate Term Preservation	*As above*	*As above*	*As above*	**Yes***	**Yes****
Long Term Preservation	*As above*	*As above*	*As above*	**Yes***	**Yes****

*only for tissue intended for optical, as opposed to tectonic surgeries

**only for tissue deemed suitable for procedures in which the transplant outcome is dependent upon viable endothelium

L2.000 Packaging, Sealing and Packing for Transport

Each tissue for distribution shipment shall be individually packaged and sealed with a tamper-evident seal or enclosed in a tamper evident container.

Each tissue for predistribution shipment transported by a secondary carrier shall be sealed with a tamper-evident seal or enclosed in a tamper-evident container.

Corneal tissue in intermediate-term storage solution shall be packaged using a method designed to maintain cool conditions and prevent freezing. The package content should demonstrate remaining coolant effect at the time of use or removal to mechanical storage or replacement of the coolant. For tissue preserved by other methods such as long-term preserved, organ culture, or short-term preserved tissue, the packaging method shall be appropriate to the method of preservation used. Packing shall be done so that the tissue label and documentation to accompany the tissue do not become wet. Special instructions shall be included on a Package Insert. See *Section L1.200*.

M1.000 Eye Bank Records

Eye banks shall utilize ICCBBA Eye Bank Technical Advisory Group (EBTAG) nomenclature to describe ocular tissue classes and attributes, effective June 30, 2015.

All records shall utilize ISBT 128 identifiers, effective January 1, 2016. This includes the Donation Identification Number (DIN) and Product Code.

M1.100 Length of Storage

All records shall be kept for a minimum of ten years from the date of transplantation/implantation, distribution or whichever is longer.

Glossary

Distribution. A process of allocation of tissue for transplant, research or educational use. This process includes receipt of request, selection, inspection and release of tissue, to a consignee such as a surgeon, surgical center or educational research center. The principles of tracking, traceability and adverse reaction reporting will be maintained throughout the process of distribution.

Pre-Distribution Shipment. Shipment of tissue in quarantine within an establishment or between establishments (recovering eye bank to processing eye bank) of tissue that has not been released for distribution. Tissue must be shipped in quarantine.