MEDICAL ADVISORY

July 28, 2014

The following changes were made at the June 27, 2014 meeting of the Medical Advisory Board, and will become effective September 1, 2014, except where noted:

**D1.110 EBAA Contraindications to Transplant**

Tissues from persons with the following are potentially health threatening for the recipient(s) or pose a risk to the success of the surgery and shall not be offered for surgical purposes:

A. All Ocular Donors

1. death of unknown cause and there is likelihood of other exclusionary criteria;
2. congenital rubella;
3. Reye's Syndrome within the past three months;
4. Active viral encephalitis of unknown origin or progressive encephalopathy (e.g., subacute sclerosing panencephalitis, progressive multifocal leukoencephalopathy, etc.);
5. active bacterial or viral meningitis;
6. active bacterial or fungal endocarditis;
7. suspected rabies and persons who, within the past six months, were bitten by an animal suspected to be infected with rabies;
8. Down Syndrome-exclusive for penetrating keratoplasty or anterior lamellar keratoplasty;
9. intrinsic eye disease;
   a. retinoblastoma;
   b. malignant tumors of the anterior ocular segment or known adenocarcinoma in the eye of primary or metastatic origin;
   c. active ocular or intraocular inflammation: conjunctivitis, keratitis, scleritis, iritis, uveitis, vitreitis, choroiditis, retinitis; or
   d. congenital or acquired disorders of the eye that would preclude a successful outcome for the intended use, e.g., a central donor
corneal scar for an intended penetrating keratoplasty, keratoconus, and keratoglobus;  
10. active leukemias; or  
11. active disseminated lymphomas;  

D1.230 Non-Required Testing Results

All non-required positive infectious disease tests must be reported to the eye bank’s medical director, who must review and act on them, or the eye bank must have a standard policy regarding the action to be taken in response to the individual test.

All conflicting infectious disease test results must be reported to the:
• eye bank’s medical director, who must review and act on them; and
• EBAA, within 45 days

E1.100 Recovery

The donor’s identity shall be verified prior to recovery. Recovery may be performed via enucleation or in situ method.

Povidone-iodine solution shall contact the surface of any ocular tissue intended for transplantation at least once between the time of the donor’s death and tissue preservation (e.g. corneoscleral disc in Optisol-GS or whole eye in moist chamber). Excess povidone-iodine solution should be irrigated from the ocular surface prior to preservation. The concentration, volume of solution, and the duration of ocular surface exposure to the solution shall be specified in the eye bank’s operating procedures.

The corneoscleral disc shall initially be examined with a penlight or portable slit lamp for clarity, epithelial defects, foreign objects, contamination and scleral color prior to enucleation or in-situ corneoscleral disc excision. portable slit lamp for clarity, epithelial defects, foreign objects, contamination and scleral color prior to enucleation or in-situ corneoscleral disc excision.

F1.100 Slit Lamp Examination

The corneoscleral disc shall be examined for epithelial and stromal pathology and in particular endothelial disease using slit lamp biomicroscopy. Whole eyes to be distributed for lamellar processing must have the same examination. Corneoscleral discs that have been processed for lamellar keratoplasty
procedures shall be re-evaluated by slit lamp biomicroscopy to ensure that there was no damage to the relevant transplantable tissue.

Document the observations of the slit lamp examination with particular attention to the epithelium, stroma, and endothelium such as, but not limited to, scars, edema, significant arcus, striae, epithelial defects, guttata, polymegathism, pleomorphism, infiltrates, or foreign bodies.

**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, final 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, reasonably likely/probably or definitely due to donor tissue, be of a systemic nature 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, or proven to have been transmitted by transplantation be due to 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.

**JI.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.

**All tissues:**

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 globe, sclera).
4. If cornea has had additional processing (e.g. lamellar, laser shaped), clearly indicate this on the label.
5. Date and time of donor’s death
6. Date and time of initial preservation (for both corneoscleral disc and sclera).
7. Expiration date of tissue.
8. A statement that the tissue is intended for single patient application only, and that it is not to be considered sterile.
9. **A statement that the tissue is not to be considered sterile unless tissue has been subjected to a validated process to ensure sterility.**
10. Type of storage solution.

**Short and intermediate term preserved tissues:**

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

**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:

**All Tissues**

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
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.).
7. If processed for laser assisted keratoplasty:
   a. Morphology and dimensions of cut
   b. Pre and post-processing slit lamp reports
   c. Pre and post-processing endothelial cell density reports
8. If processed for lamellar or endothelial keratoplasty:
   a. Estimate thickness of transplant portion (not applicable to DMAEK/DMEK grafts).
   b. Diameter of cut
   c. Pre and post-processing slit lamp reports (short and intermediate term use and all tissues used for optical uses)
   d. Pre and post-processing endothelial cell density reports for tissue intended for endothelial keratoplasty use (For tissue deemed suitable for procedures in which the transplant outcome is dependent upon viable endothelium)
9. Age of donor
10. Cause of death

11. Death Date and time

12. Preservation date and time

13. Additional tissue processing date and time

14. The time that cooling of ocular tissues and/or refrigeration of the body was begun

15. Name of technician who enucleated, excised, processed, and evaluated the tissue

16. Slit lamp report/date of each evaluation.

17. Specular microscopy report/date of each evaluation.

18. 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 final distribution

19. A summary of records reviewed regarding the eligibility of tissue for transplant

**Short and intermediate term preserved tissues:**

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. Slit lamp report/date of each evaluation (required for long term preserved tissues intended for optical, as opposed to tectonic, surgeries)
9. Specular microscopy report/date of each evaluation for tissue deemed suitable for procedures in which the transplant outcome is dependent upon viable endothelium (e.g., endothelial keratoplasty).

L2.000 Packaging, Sealing and Packing for Transport

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

M1.400 Minimum Information to Be Retained

Forms for retaining donor and recipient or consignee information shall be established and shall be readily accessible for inspection by the EBAA Accreditation Board. Eye bank records shall include the following minimum information:

See Section L1.000 for information to be included on the Tissue Report Form.

1. Eye bank identification number unique to each tissue graft
2. Name of eye bank
3. Type of storage solution
4. Storage solution lot numbers
5. Unique donor identification number
6. Name of donor (or if import tissue, name of importing eye bank and their unique ID number)
7. Age of donor
8. Cause of death
9. Death date and time
10. Enucleation or in-situ excision date and time
11. Preservation date and time
12. The time that cooling of ocular tissues and/or refrigeration of the body was begun
13. Additional tissue processing date and time
14. Slit lamp report(s)
15. Endothelial cell density(ies) (if applicable)
16. Name of enucleator/processor/evaluator/technician
17. Name of surgeon or consignee receiving tissue
18. Tissue readily traceable from donor to consignee for each unique graft number (See Section M1.500)
19. Date, time, method of transportation
20. Utilization of tissue: i.e., surgical, research, training
21. Printed results of all EBAA required and non-required infectious disease screening tests
22. Microbiologic screening results if performed
23. Microbiologic reports of positive donor rim cultures from the receiving surgeon if reported
24. Adverse reactions if reported
25. Documentation that postoperative outcome information from the transplanting surgeon has been requested

**M1.600 Statistical Reporting**

Each eye bank shall report statistics to the EBAA in accordance with a policy established by the EBAA Board.

*Each source eye bank shall report information on surgical technique and indications for surgery.*

**Glossary:**

**Adverse Reaction (EBAA reportable).** Any communicable or other disease that is *possibly*, reasonably likely/probable or *definite/certain* proven to have been transmitted by transplantation of donor eye tissue including infection and biologic dysfunction. See also *Eye Bank Association of America (EBAA) Medical Standard G1.000.* (Reference: Guidance Document for Investigating and Reporting Adverse Reactions Reporting to the EBAA)

**Distribution.** A process of allocation of ocular tissue for transplant, research or educational use. This process includes, receipt of request, selection, inspection and release of appropriate tissue, to a qualified 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.

**Organ Culture.** Stored in a nutrient medium at 28° to 37° *Celsius.*

**Sterile.** The absence of detectable, viable, microorganisms (refer to ANSI/AAMI ST79:2010).

**Sterilization.** A validated method used to render instrumentation and ocular tissue free from viable microorganisms, including spores (refer to ANSI/AAMI ST79:2010/A42:2013).