



Tab B
EBAA Medical Procedures



**EYE BANK
ASSOCIATION
of AMERICA**

PROCEDURES MANUAL

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A1.000 Introduction and Purpose

Standardization of eye banking procedures was one of the founding missions of the Eye Bank Association of America (EBAA) when it was established in 1961. The first edition of the EBAA's Medical Standards was introduced to member eye banks in 1980. A Technician's Manual followed in 1982. The Technician's Manual served as a detailed source of information and training manual for new technicians. This Procedures Manual is not intended to replace the Technician's Manual, nor to serve as a training manual for new eye bank technicians.

The purpose of this manual is to operationalize the EBAA Medical Standards and to establish clinically accepted baseline practice for each eye banking procedure. It is intended that these procedures are written broadly enough to allow for acceptable variation from one eye bank to another, yet specific enough so that procedures will not vary too widely from one eye bank to another or outside the scope of accepted ophthalmologic practice. Included with most procedures is a suggested list of materials needed. ***Each eye bank should develop its own unique set of procedures which are compatible with EBAA Medical Standards. This manual presents one set of procedures believed to be compatible with the EBAA Medical Standards.***

While this Procedures Manual is not a substitute for an eye bank's own procedure manual, we hope it will serve as the framework upon which each eye bank develops its own personalized set of procedures. An individual eye bank's procedure manual should include more specific and personalized information.

Periodic revisions to the EBAA Procedures Manual were performed by members of the Technician Education Committee with the final approval by the Medical Advisory Board.

Created February 1992.

Revised: 6/92, 11/93, 6/94, 10/94, 10/96, 10/99, 10/00

B1.100 EBAA Membership and Accreditation

Policy: The Eye Bank shall meet all of the requirements for membership and accreditation in compliance with EBAA Bylaws, Medical Standards, Membership Criteria and Criteria for Accreditation.

Materials: The current version of the following references shall be used:
EBAA Medical Standards
EBAA Criteria for Accreditation
EBAA Criteria for Technician Certification and Re-Certification

Procedure:

Membership

1. Application for new members shall be made to the Eye Bank Association of America (EBAA) by contacting the EBAA office and following the current procedure for membership application.
2. Complete the application forms and required information and submit to the EBAA.
3. The application shall be reviewed by the EBAA Membership Committee and response sent to the Eye Bank.
4. The Eye Bank shall provide all required information to the EBAA together with any prescribed fees and shall keep the EBAA informed as to the Eye Bank Medical Director, Director, status of required CEPT, location and any organizational changes that might occur.
5. Current membership status provides each Eye Bank member certain rights and privileges such as access to information, House of Delegate attendance and votes determined by volume of transplantable corneal tissue distributed.

Accreditation

1. Upon notification from the EBAA, the Eye Bank shall apply for accreditation or re-accreditation at least (every three years) and will file the necessary documents and fees for the accreditation visit.
2. Each office and laboratory of the Eye Bank that meets the Accreditation Board's definition of processing shall receive an On-Site Accreditation Visit and will strive to meet or exceed the criteria set forth in the current version of the EBAA Medical Standards.
3. The Eye Bank will strive to correct any cited differences identified by the accreditation inspection process by submitting a corrective action plan within the specified time frame. The Eye Bank will also complete corrective actions and provide the necessary documentation to the Accreditation Board Chair within the specified time frames.
4. The Director is responsible for ensuring that the Eye Bank Policies are in compliance with the current EBAA Medical Standards.
5. The Director is responsible for notifying the EBAA of any changes in the eye bank's Director, Medical Director, supervisory CEPT, facility location, name, or corporate organization.

C2.000 Training, Certification, and Continuing Education of Technical Personnel

Purpose:

To outline the requirements for training, certification, and continuing education of eye bank technical personnel.

Materials needed:

Eye bank training syllabus
Form or method to record attendance of staff

Procedure	Rationale
1. All new full and part-time technicians must attend an eye bank orientation training program. This training program shall comply with any state laws relating to retrieval of donor eye tissue or enucleator certification. Each eye bank must document participation of technical staff in all training sessions.	1. To ensure complete and effective training of new eye bank technical personnel.
2. At least one member of the eye bank's technical staff must be EBAA certified by successfully completing the EBAA Technician Certifying Examination. This certification must be renewed every three years.	2. See EBAA Medical Standards section C1.300.
3. Continuing education programs for each technical staff member must be provided.	3. See EBAA Medical Standards section C2.000.
4. A written record of all technical meetings must be maintained.	
5. The medical director shall review the eye bank's technical policies and procedures manual annually and make changes as necessary in accordance with any changes in EBAA Medical Standards or scientific/clinical advances in the practice of eye banking.	5. To ensure active participation and approval of the medical director on technical policies and procedures.
6. The Medical Director shall meet with the eye bank's technical staff on a periodic basis to review technical operations.	
7. The medical director must designate in writing all non-EBAA certified technicians who are qualified and authorized to perform eye bank laboratory procedures.	7. See EBAA Medical Standards section C1.300.

C3.000 Facilities

C3.100 Eye Bank Laboratory

Purpose:

To provide an environment suitable for processing human eye tissue for surgical use and research that is in compliance with the EBAA Medical Standards and applicable federal (FDA) and state regulations.

Materials needed:

Room with limited access, i.e., locked door
Sink with a drain and running water
Adequate counterspace
Adequate stable electrical source
Storage space for supplies and instruments
Class 100 Hood or Class II or Class III Biosafety Cabinet per EBAA Medical Standard E1.200
Refrigerator with temperature recording device
Slit lamp biomicroscope

Procedure

1. The eye bank laboratory must be large enough to carry out the volume of eye banking functions handled and to accommodate the number of technicians working at any given time.
2. Ideally, the laboratory should be in close proximity to the eye bank's administrative offices, as well as to the medical director.
3. The eye bank laboratory must have the following:
 - A. Door that can be locked, to ensure limited access to eye bank personnel only.
 - B. Sufficient grounded outlets from a stable electrical source.
 - C. Adequate countertop space.
 - D. Sink with drain and running water.
 - E. Class 100 Hood or Class II or Class III Biosafety Cabinet
 - F. Refrigerator with a temperature recording device and either an emergency power source or a power failure alarm.
4. Laboratory cleaning records for counters, sinks and storage cabinets must be maintained. See procedure C3.200.

Rationale

1. See EBAA Medical Standards section C3.100.
3. Any equipment that would be damaged by power fluctuations requires surge protection.

Eye bank equipment such as the refrigerator used to store eye tissue and corneal storage medium must have an emergency back-up power supply or an alarm system that will notify someone in the event of a power failure. See EBAA Medical Standard C3.200.
4. Cleaning records must be available for site visit inspections, per EBAA Medical Standard section C3.100.

C3.200 Equipment Maintenance and Cleaning

Purpose:

To ensure and document that all equipment is inspected, maintained and cleaned on a regular basis.

Materials needed:

Class 100 Hood or Class II or Class III Biosafety Cabinet
Refrigerator with temperature recording device
Slit lamp biomicroscope
Specular microscope (optional)
Cleaning logs
Maintenance logs
Inspection and certification records for Class 100 Hood or Biosafety Cabinet
Autoclave, if used
Incubator, if used
CDC cleaning agent

Procedure

1. The Class 100 Hood or Biosafety cabinet must be inspected and certified at least annually and each time it is moved. Certification documentation must be maintained for at least three years and be available for review at time of site inspection.
2. The hood or biosafety cabinet shall be cleaned with a CDC recommended cleaning agent such as 10% sodium hypochlorite in water and before and after each use. Each cleaning shall be recorded. These records shall be kept for at least three years and must be available for EBAA site inspection.
3. If an incubator is used for cultures, the eye bank must meet applicable accreditation requirements as outlined in EBAA Medical Standards section G1.200:
 - A. A policy and procedure on the collection, reading, and recording of results must be included in the eye bank's procedure manual.
 - B. The incubator must be cleaned in accordance with manufacturers' instructions using a CDC recommended cleaning agent. Old cultures should be discarded. All cleaning and maintenance records must be kept for three years and must be available for EBAA site inspection.

Rationale

1. To assure proper functioning of the HEPA filters.
2. Appropriate cleaning and disinfection of the tissue processing area is essential for infection control and to prevent cross contamination.
3. To provide optimal conditions for microbial growth of specimens.
 - B. Routine cleaning ensures that no cross contamination of specimens occur.

4. The refrigerator with temperature recording device that can be checked without opening the refrigerator:
 - A. Must be recorded daily to ensure that the refrigerator temperature remains within 2-6°C. Document any deviations and corrective action taken.
 - B. Recording graph paper must be changed as prescribed by the cycle it covers, i.e., daily, weekly or monthly.
 - C. Check recording device temperature for accuracy at least once a year against an NIST calibrated thermometer.
 - D. In the event of a power failure, there must be a provision for immediate notification and action to be taken.
 - E. The inside of the refrigerator must be cleaned periodically with a CDC recommended cleaning solution.
 - F. All cleaning and maintenance records must be kept for three years and available for EBAA site inspection.
 - G. The refrigerator must be maintained for the exclusive use of eye banking.
 - H. The refrigerator must have clearly labeled areas for quarantine, surgical, and research ocular tissue.

5. If an autoclave is used by the Eye Bank:
 - A. The autoclave must be cleaned as often as recommended by manufacturer with a CDC recommended cleaning solution. All cleaning and maintenance records must be kept for three years and available for EBAA site inspection.
 - B. Chemical indicators or sterilization process indicators must be placed inside each instrument tray or wrapped kit. Indicators should be placed in an area which is the most difficult for the sterilant to penetrate.
 - C. All articles to be sterilized must be wrapped in materials that meet recommended sterilization standards. (See Good Hospital Practice: Steam Sterilization and Sterility Assurance in AAMI Standards and Recommended Practices, Vol. 2.)

4. To ensure that ocular tissue and preservation media are stored at the prescribed temperature.
 - A. See EBAA Medical Standards section C3.200.
 - B. The recording pen should never print over the same time period more than one time.
 - C. This is to verify the accuracy of the recording device.
 - D. See EBAA Medical Standards section C3.200.
 - E. Routine cleaning of the tissue storage area is essential for infection control and to prevent transfer of microorganisms.
 - H. See EBAA Medical Standards section C3.200.

- B. Indicators do not prove sterility has been achieved, but they do allow detection of certain procedural errors and equipment malfunctions.

- D. Place indicator tape on the outside of each package. A lot number and expiration date must be noted on each item sterilized.
 - E. Record the date, lot number, load contents, the exposure time and pressure, operator name, and whether a biological indicator test was used and the results for each sterilization cycle.
 - F. Annual certification to validate temperature, pressure and time must be conducted and documented.
 - G. Monitor the efficiency of the sterilization process at least once each week with a reliable biological indicator that employs spores of established resistance. For steam sterilizers, this is *Bacillus Stearothermophilus*. All items from this run must be quarantined until results are received, usually at 48 hours, and/or a written protocol for recall of all items must be in place.
6. Biological-indicator test packs shall be used during initial installation testing of steam sterilizers and following any major repairs. Biological-indicator test packs should also be used routinely in sterilization loads at least weekly, but preferably daily. Composition of a 16-towel challenge pack can be found in Perkins or AAMI Standards.
 7. Cleaning and maintenance records for all other instruments and equipment used, such as the slit lamp biomicroscope and specular microscope must be kept for three years and be available for EBAA site inspection.
 8. All cleaning and maintenance procedures must be recorded for each piece of equipment used. All cleaning procedures should clearly delineate the type of cleaning solution used and the frequency of cleaning.
- D. External indicators are used to differentiate processed from non-processed items, not to establish whether adequate sterilization has taken place.
6. The condition of the equipment, the expertise of the sterilization operator, and other factors determining success or failure of a steam sterilization cycle may vary. The less frequently a sterilizer is used, the greater the opportunity for an unnoticed problem that could affect sterilization. Biological-indicator test packs provide a useful means to monitor the efficiency of sterilization practices.
 8. Cleaning and maintenance records shall be available for EBAA site visit inspection. They shall be kept for at least three years.

C3.300 Instruments and Glassware Cleaning Maintenance

Purpose:

To maintain instruments to assure that they function properly, to minimize or prevent trauma to eye tissue during procurement and preservation, and to adequately clean for effective sterilization.

Materials needed:

- Instruments to be cleaned
- Instrument cleaner
- Instrument lubricant
- Mechanism for instrument sterilization

Procedure	Rationale
1. Protective apparel, including protective clothing, goggles and gloves shall always be worn while cleaning instruments.	1. Observe Universal Precautions to protect against transmission of AIDS and hepatitis.
2. Decontaminate instruments to remove all potentially biohazardous material such as tissue or blood by immersion in a CDC recommended disinfectant solution such as 10% sodium hypochlorite. Be sure that all blades are in a fully open position.	2. To reduce or minimize the opportunity for potentially infectious microorganisms to remain on instruments.
3. Transfer instruments to a solution of warm water and low sudsing, non-corrosive detergent that does not contain phosphates or alkali metals.	3. Low sudsing detergents minimize wear and tear of the instruments; less dulling and rusting occurs.
4. Soak instruments according to manufacturers' guidelines/directions.	4. Soaking helps remove debris, tissue, and blood that may stain instruments.
5. Use a hard bristle brush to remove stubborn stains.	5. To avoid debris becoming baked on instruments, use a brush for scissors, especially in the box joints.
6. Rinse instruments thoroughly using tap water and dry carefully.	6. Instruments should be dried thoroughly to avoid rusting.
7. Inspect instruments for proper function and have any dull or faulty instruments repaired or replaced.	7. To remove any dull or poorly functioning instruments from use and to send immediately for sharpening, repair and/or replacement.
8. Lubricate all instruments, particularly those with moveable parts by immersion in instrument lubricant if cleaner does not contain lubricant. Allow the lubricant to work in to the moveable joints by opening and closing them while submerged in the solution.	8. Protects instruments against rusting, staining, and corrosion.
9. Remove the instruments from the lubricant and allow them to dry. Do not rinse or wipe the lubricant off.	9. Improves function, lessens growth of bacteria, and allows for steam penetration.

10. Package or wrap instruments for sterilization and note the expiration date and lot number on the outside to ensure kits are used within the appropriate time period or within the appropriate period which guarantees sterility based on the type of packaging used. Steam sterilization at 121°C (250°) for 30 minutes is recommended. Chemical indicators or sterilization process indicators must be placed inside each kit.
11. Glassware, such as eye jars should first have all tissue removed, followed by soaking according to manufacturers' instructions in a CDC recommended disinfectant. Using a brush and detergent, scrub caps and jars thoroughly. Rinse carefully with pyrogen-free water and allow to air dry.
12. Package separately for sterilization or include within enucleation instrument tray.

10. See Procedure C3.200, 5(b).

C3.400 Procedures Manual

Purpose:

To describe the method for developing, updating and archiving a Policy and Procedures manual.

Material Needed:

Computer word processing program (or a typewriter)
Paper and printer
EBAA Medical standards
FDA Rule 21CFR Part 1270
Applicable State regulations
Occupational Health and Safety Administration Guidelines
Centers for Disease Control - Universal Precautions

Procedure	Rationale
1. Determine an alphanumeric format to identify each policy and outline each procedure.	1. This will provide consistency throughout the document. One example is to use the format of the EBAA Medical Standards document, i.e. A1.000.
2. Develop a policy statement corresponding with each section of the EBAA Medical Standards document. Include relevant state and federal guidelines.	2. To be current with each guideline set by EBAA Medical Standards, develop a corresponding policy applicable to the Eye Bank's specific policies. Avoid putting administrative policies in the technical manual.
3. Along with developing a policy for each section, detail a procedure for each, where applicable.	3. Any policy that requires action by the laboratory staff will require a written procedure.
4. There are at least two elements to a procedure. A. Materials Needed: Under a heading, list the materials needed, specifying sterile supplies and non sterile-sterile supplies, where applicable. B. Method: Number steps in sequence to be performed according to the chosen format. Avoid lengthy paragraphs. Also may include rationale or underlying principles for the outlined steps, definition of terms, references, etc.	
5. Insert forms and reference material in the appendix. Appropriately reference the location of this material throughout the document, e.g., See Appendix A.	

6. Insert a header to identify the document, e.g., Corneal Laboratory Policy and Procedure Manual. Insert a footer to identify the institutional name, along with the month and year. Provide enough space on the first page of each procedure to document the date of approval, subsequent revision dates and the signatures of the medical director and the director of the eye bank.
7. Number all pages. Create a Table of Contents.
8. Proofread the document for grammatical and typographical errors.
9. Each policy and procedure is initially approved by the medical director and director of the eye bank by signing and dating the section. Any updates to the manual are approved in the same manner. Universal, single page sign-off for the entire manual is not appropriate.
10. Review the manual at least annually to identify any needed updates.
11. Before printing an updated version of the manual, insert the current date where applicable.
12. Print a hard copy of the initial document and any subsequent changes and submit them to the laboratory staff for review.
13. Archive the previous year's copy of the manual, including the appendices, outdated policies and/or procedures and review statements from the laboratory staff, for reference.

6. Documents the dates of implementation, reviews and updates. See EBAA Medical Standards section C3.400.
7. It will make referencing a section easier.
9. See EBAA Medical Standards section C3.400.
10. Maintains eye bank's practice in compliance with current standards and regulations. Required by EBAA Medical Standards C3.400.
12. To document the staff's' comprehension of the policies and procedures.
13. See EBAA Medical Standards section C3.400.

C3.600 Infection Control and Safety

Purpose:

To minimize the risk of transmission to eye bank personnel of HIV, hepatitis, and other infectious diseases and to outline precautions that all eye bank personnel must follow.

Definition of terms:

Exposure Control Plan: Mandated by OSHA, this requires employers to identify in writing tasks and procedures as well as job classifications where occupational exposure can occur. The plan must be reviewed annually and must be accessible to employees and to OSHA.

Exposed Worker: Individual exposed, as described above, while performing eye banking responsibilities.

Human Exposure: Contact with blood or other body fluids through percutaneous inoculation or contact with open wounds, non-intact skin, or mucous membranes.

Infectious Materials: As defined by OSHA, these include semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid visibly contaminated with blood and all body fluids in situations where it is difficult or impossible to differentiate between body fluids. It also includes any unfixed tissue or organ other than intact skin from a human (living or dead) and HIV containing cells or cultures.

Universal Precautions: As defined by the CDC and OSHA. Treating body fluids/materials as if infectious and emphasizing work practice controls, such as handwashing and needlestick precautions that are mandatory.

Materials needed:

Red biohazard bags and/or fluorescent orange biohazard labels
Protective eyewear (goggles or face shield)
Mask
Gloves
Protective moisture impermeable clothing
Puncture resistant sharps container
Sink with running water
CDC recommended disinfectant
Soiled linen container

Procedure

1. All blood and body fluids including tissues, are potential sources of infection.
2. Place blood specimens in clear plastic bags and label with blood/body fluid precaution stickers.
3. Place disposable paper products contaminated with blood or body fluids in red biohazard bags and properly dispose of.
4. Similarly bag and label contaminated linen to alert laundry personnel.

Rationale

1. Under Universal Precautions blood and body fluids of all patients are considered potentially infectious for HIV, hepatitis and other bloodborne pathogens.
2. To minimize any transmission of infectious material to other individuals or the environment.

5. Wear gloves at all times while handling blood, body fluids, or tissues. This is essential, particularly when there are cuts, scratches, or dermatologic lesions on the technician's hands.
 6. Careful hand washing after removing gloves is mandatory.
 7. Keep hands in good condition. Use hand lotion following handwashing to prevent skin breakdown.
 8. Use of other protective measures including protective eyewear, masks, and protective clothing, such as moisture resistant gowns, is mandatory.
 9. Shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated.
 10. Always adhere to needle-stick precautions. Do not bend, recap or replace needles. Instead place used needles in a puncture-resistant sharps container designated for this purpose.
 11. Minimal handling of blood-contaminated scalpel blades is essential. Take extra care to prevent self-injury. Used scalpel blades must be disposed of in a puncture resistant sharps container. If an appropriate disposal container is not available, use a glass jar or specimen container with a lid to transport needles to a proper container.
 12. Notify your supervisor immediately in the event of a needle puncture. Complete and submit a needle-stick report as directed by your eye bank. Document treatment and counseling with the date and time of injury. This report should be filed in the eye bank technician's personnel record and shall be available for review at the time of EBAA site visit inspection.
 13. Blood and body fluid spills and instruments that come into direct contact with blood or tissues should be cleaned with a CDC recommended disinfectant. Exposure time should be according to manufacturers' instructions.
 14. Eating, drinking, smoking, applying cosmetics or lip balm and handling contact lenses are prohibited in work areas where there is reasonable likelihood of exposure.
5. Cuts or lesions on hands provide an entry point for infectious pathogens.
 6. This further reduces the opportunity for transmission of microorganisms.
 8. To prevent exposure to open wounds, non-intact skin, or mucus membranes such as in the nose or eyes.
 10. To prevent accidental needle stick injuries, which might expose a technician to infectious disease.
 11. All sharps must be carefully placed in red labeled sharps container.
 12. An incident report should be completed indicating the treatment offered or action taken, as appropriate.
 13. It has been determined by CDC and OSHA that 1:10 dilution of sodium hypochlorite is very effective against HIV and HBV.

15. Food and drink shall not be kept in refrigerators, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.

16. Procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

17. Each eye bank shall have an Exposure Control Plan as stipulated in OSHA's final rule which shall include the offer of free hepatitis B vaccination within 10 working days of initial assignment unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune or the vaccine is contraindicated for medical reasons. Employees who decline to accept the vaccine shall sign a statement to that effect. Post exposure evaluation and follow-up must also be included in the plan. The plan must be reviewed and updated annually and must be available to employees.

18. Annually review all current OSHA and CDC regulations to ensure compliance. This includes providing in-service education to all eye bank technical staff on infection control and **Universal Precautions** and documenting same. This should be done for staff identified in the exposure control plan as having the potential for accidental hazardous exposure.

18. See the Final Rule as published in the Federal Register, Vol. 56, No. 235, December 6, 1991.

C3.700 Biohazardous Waste Disposal

Purpose:

To properly dispose of human eye tissue remains in such a manner as to minimize hazard to eye bank personnel and the environment and to comply with local, state and federal regulations.

Definition of terms:

Decontamination: Removal of, or neutralization of, injurious agents from ground, buildings, clothing, etc.

Incinerate: Complete destruction of all organic matter by fire.

Materials needed:

Red biohazard bag
Pressure sensitive fluorescent orange biohazard labels
Facility for decontamination or incineration

Set up:

Potentially biohazardous waste must be isolated and discarded appropriately. Each eye bank must have an appropriate mechanism, as defined by local, state and federal law, to properly decontaminate and/or dispose/incinerate biohazardous waste.

Procedure	Rationale
1. Wrap all tissue waste, serum, and blood in a dignified manner to obfuscate any recognizable human remains. Document ocular tissue disposal through the use of a "Disposal Log" and note tissue disposal in the donor record.	1. To minimize hazard to personnel and environment. See EBAA Medical Standards section C3.700.
2. Label all biohazardous waste with the OSHA designated biohazardous symbol and bag in red biohazard bags within a sealed, puncture resistant container for transport to a decontamination facility or incineration facility, according to your eye bank's policy and procedure, and local, state and federal regulations.	
3. Universal Precautions for healthcare workers must be strictly observed and adhered to while labeling, wrapping, bagging, and transporting biohazardous waste.	3. See procedure C3.600.

D1.000 Donor Screening

D1.200 Documentation of Donor Information

Purpose:

To provide comprehensive uniform eye donor screening to ensure the highest quality ocular tissue for surgical use.

Materials needed:

Donor/referral screening form
Pen; black ink is recommended
Phone
Quiet area to obtain information or phone referral
Copy of EBAA Medical Standards

Procedure

1. Complete a thorough screening of the donor by obtaining all available medical/social history and post mortem findings from accepted sources listing the guidelines set forth by the EBAA Medical Standards.
2. Collect all pertinent eye donor information using a uniform screening form at time of telephone referral and/or chart review. The source of the information shall be noted, including the name and title or position of the individual who provided the information and the eye bank technician or volunteer who recorded the information on the eye bank's form.
3. A complete donor medical screening evaluation record shall include, but is not limited to, the following data:
 - A. Name of eye bank person recording/obtaining the information
 - B. Date and time referral received
 - C. Origin of referral, i.e., hospital, OPO, funeral home, etc.
 - D. Name of hospital or facility where donor expired
 - E. Full name and title of person providing information
 - F. Phone number and unit/location

Rationale

1. To ensure high quality human eye tissue for surgical use and avoid transmission of any infections or disease from donor to recipient. See EBAA Medical Standards section D1.100.
2. To ensure consistent recording of complete medical history on each donor within the EBAA established guidelines. See EBAA Medical Standards section D1.200.
3. Baseline information needed for follow-up and to obtain additional information after donation.

- G. Name of donor. This should be verified and should match that on the consent form at the time of ocular tissue recovery.
- H. Age
- I. Weight/Height
- J. Sex
- K. Race
- L. Unique Identification Number, i.e. social security number, medical record number, driver's license number, passport number, etc.
- M. Date of this hospital admission and admitting diagnosis.
- N. Date and time of declaration of brain death, if applicable.
- O. Date and time of asystole (cessation of cardiopulmonary function).
- P. Cause of death (must never be recorded as cardiac arrest or cardiopulmonary arrest).
- Q. Name and complete address and relationship of consenting next-of-kin.
- R. Consent/permission obtained and for what tissues.
- S. Whether donor is a medical examiner's or coroner's case.

- 4. To provide identification to be compared with the identification of the donor at the facility prior to recovery of ocular tissue to ensure that ocular tissue is removed from the correct donor.
- H. Essential donor information used to determine use of ocular tissue. See EBAA Medical Standard D1.400.
- I. Provides data to evaluate the overall physical condition of the donor and calculate plasma dilution.
- J. Provides statistical and demographic data
- K. Provides statistical and demographic data
- L. Provides unique ID number to identify donor.
- M. Provides additional information as to the donor's medical condition prior to death.
- N. Time of brain death, which is the legal time of death important in solid organ donation, may be several hours before asystole. For the purpose of ocular tissue donation, the cessation of cardiac function (asystole) is the more critical time.
- P. All deaths are a result of cessation of cardiac and pulmonary function. The actual cause of death should be a disease pathology or trauma that resulted in a cardiac arrest, i.e., cardiac arrest secondary to congestive heart failure with congestive heart failure actually being the primary cause of death.
- Q. Verifies priority of next-of-kin.
- R. See procedure D1.300.
- S. Due to legal implications surrounding medical examiner or coroner cases, no eye tissue may be removed without prior permission from the medical examiner or coroner.

- T. Whether an autopsy will be performed.
- U. Ventilator support: Duration in hours or days.
- V. Previous ocular history, e.g., known eye disease, injury, or surgery; name of ophthalmologist, if available.
- W. Transfusion/Infusion History record date, time, number of units, and product type.
- X. Name and phone number of attending family physician.
- Y. Past medical/social history, including past or current history of any contraindications listed in section D1.110 and D1.120 of the EBAA Medical Standards.
- Z. A visual head-to-toe inspection of each eye donor should be performed and recorded. Look for needle tracks, fresh tattoos that may hide parenteral drug use, and other high-risk behaviors. The webs of fingers and toes should be carefully examined, as well as the groin and behind the knees.

- T. Further medical information must be obtained following autopsy, including presence of infections or cancer, as well as actual cause of death. This information must be recorded and filed as part of the donor's record. See EBAA Medical Standards section D1.200.
- U. Prolonged respiratory support may increase the donor's chances of compromised defense mechanisms leading to secondary systemic infections.

As a result of administration of muscle relaxants to ventilator supported patients, corneal tissue is at increased risk for bacterial invasion or damage. Decrease or absence of normal blink reflexes alter the body's ability to naturally lubricate and protect the integrity of the eye.
- V. Any notations of history of eye disease or injuries require thorough evaluation. Prior eye surgery or disease may have traumatized or damaged the corneal endothelium. See EBAA Medical Standards sections D1.120, #13-14.
- W. Plasma dilution associated with infusions/multiple transfusions may affect test results. See EBAA Medical Standards section G1.220. Calculation of a plasma dilution algorithm must comply with FDA approved methodology and must include both plasma volume and blood volume assessments.
- X. Appropriate medical personnel who cared for donor should be contacted to obtain additional medical history, if needed, and all information obtained should be signed, dated, timed, and labeled with donor identification number. Development of a telephone/consult documentation form is suggested. See EBAA Medical Standards section D1.000.
- Y. Documentation that all items listed by the EBAA Medical Standards as contraindications for surgical use have been thoroughly reviewed during screening to eliminate risk of transmission of disease or infection to recipient is required. See EBAA Medical Standards sections D1.100 and D1.120.
- Z. To check for evidence of intravenous drug abuse or other known high-risk behavior for AIDS and hepatitis.

- 1) Medications, including antibiotics, should be recorded.
 - 2) Temperature or temperature range over last 48 hours, noting any variations.
 - 3) Dates and results of lab tests, including (but not limited to) WBC, platelet count, VDRL or RPR, blood, urine and sputum cultures, chest x-rays, and other relevant serology that may have been performed such as HBsAg, liver enzymes, HIV or HCV screening.
 - 4) Notation of the presence of eye care during hospitalization. A post mortem eye prep for donation shall be routinely recommended and should be performed, according to your eye bank's policy.
 - 5) Whether donor was refrigerated prior to recovery, and length of time.
 - 6) Notation of the interval between death, enucleation, excision and preservation.
4. Completely record all of the above information on your eye bank's screening form. Follow your eye bank's protocol for review of data by your Medical Director or designee prior to release of ocular tissue for surgical use.

- 1) Antibiotics may be an indicator that the donor had an infection.
 - 2) Elevation of temperature or hypothermia can be related to factors associated with infectious process or altered metabolic or neurologic function.
 - 3) Evaluation of laboratory data provides further information in determining donor suitability. All results should be evaluated while keeping in mind total patient history and course of illness.
 - 4) Proper donor eye maintenance pre-donation and post mortem are essential to preserve the integrity and quality of ocular tissue for surgical use. See procedure D1.600.
 - 5) Refrigeration information could be important in determining transplant suitability if large time frame has elapsed between time of death and recovery. See Medical Standard D1.500.
 - 6) See EBAA Medical Standard D1.500.
4. See EBAA Medical Standards section K1.000.

D1.210 Medical Examiner/Coroner/Pathologist

Purpose:

To delineate minimum information an eye bank must record from the medical examiner, coroner, or pathologist performing an autopsy or inquest.

Materials needed:

Form for recording autopsy or inquest findings
Pen, black ink recommended

Procedure

1. Follow procedure D1.200 to document donor information. Note whether this is a coroner or medical examiner case and/or whether an autopsy is to be performed.
2. Gross autopsy results should be obtained prior to release of ocular tissue for surgical use.
3. Record the pathologist's finding, including cause of death, on the form provided by the eye bank. Sign and date this information.
4. Record the following minimal information
 - A. Name of pathologist performing autopsy.
 - B. Date of autopsy
 - C. Cause of death per autopsy findings
 - D. Any evidence of high risk for HIV, hepatitis or other infectious disease, such as needle tracks, as defined by EBAA Medical Standard D1.100.
 - E. Signature of pathologist or name, signature date and time of eye bank technician taking verbal information.
 - F. Name of person providing verbal autopsy findings.
 - G. Any signs of infection or sepsis

Rationale

1. Not all coroner's or medical examiner cases are autopsied. Also, autopsies may be performed by a pathologist other than a medical examiner or coroner.
2. The pathologist may discover that the donor had transmissible disease or infection or was at risk for hepatitis or HIV.
3. The form may be completed and signed by the pathologist or may be a verbal report recorded by the eye bank technician.
4. Cause of death by "gross findings" will generally not include histology. Final autopsy reports should be obtained and reviewed when available.

D1.300 Consent

Purpose:

To ensure that informed, legally correct consent for eye or corneal donation is obtained from the legal next-of-kin or legally authorized individual such as the medical examiner or coroner as stipulated under local or state law prior to removal of any ocular tissue.

Materials needed:

Consent form
Pen, black ink is recommended
Telephone with recording device and tape
Quiet area to obtain information

Procedure

1. Consent for ocular tissue donation should be obtained using one of the following four methods:

A. Written: As described below:

- 1) Under the Uniform Anatomical Gift Act, enacted in all 50 states, a consent signed by the legal next-of-kin must be in order of priority in accordance with state law. The consent shall include, but not be limited to, the following information: Name of donor, relationship of the donor to the person signing the permission, signature of next-of-kin, witness(es), and the type of tissue donated, e.g., whole eye or cornea only.
- 2) Consent may be obtained by any individual designated by his/her employing institution representing option of eye donation to the family.
- 3) Consent must be witnessed in accord with state law.
- 4) Consent must clearly indicate permission for the ocular tissues donated such as whole eyes or corneas only. The next-of-kin should be informed of the differences and implications of each.

Rationale

- 1) State law defines who may give permission for donation. Next-of-kin must be informed regarding what tissues can be recovered and be fully aware of what will be taken to avoid any misunderstanding or confusion after the donation has occurred. See EBAA Medical Standard D1.300.
- 2) As long as the next-of-kin is approached in a respectful, dignified, and professional manner, any individual may be designated by the hospital to obtain consent for donation of tissues and/or organs. Requestor should receive training in accordance with 47 CFR Part 482, Conditions of Participation.
- 3) One or two additional witnesses may be required. Consult your state and local law.
- 4) Permission for ocular tissue donation should provide the prospective donor's next-of-kin sufficient understandable information and opportunity to consider whether or not to agree to such donation. It should also minimize the possibility of coercion or undue influence.

- 5) Consent must clearly specify the organization authorized to recover eyes/corneas. [or "...to accept the eye/cornea donation."]
- B. Telephone: As defined by state law.
 - C. Living donor: Check your local and state regulations. Permission is usually obtained from the person who is donating. Per your state law, the next-of-kin may or may not be required to give consent as well.
 - D. Implied/Medical Examiner:
 - 1) In any case which falls under the medical examiner's/coroner's jurisdiction, consent from the coroner or medical examiner must be obtained prior to removal of tissue.
 - 2) Some states have coroner/medical examiner laws which permit corneal removal with coroner/medical examiner consent in the absence of expressed permission from next-of-kin. Check your state law and your eye bank's policy.
2. Original consent form should remain with the donor's record at the institution. A copy of the consent form must be obtained by the eye bank for their records.
 2. See the OBRA of 1987, your state's required request law, and JCAHO requirements. Each hospital must document compliance with state and national routine referral, routine inquiry or required request laws. Check with the hospital for their procedure.

D1.600 Ocular Tissue Donor Maintenance

Purpose:

To retard the deterioration of eye/corneal tissue following cardiac asystole, prior to recovery of ocular tissue.

Materials needed:

Wet ice packs (such as rubber gloves filled with crushed ice) Note: Ice should be wet ice
Sterile ophthalmic broad-spectrum antibiotic solution, sterile normal saline or balanced salt solution (BSS)
Lubricating ointment for ventilator maintained donors
Paper tape
Pillow or head block

Procedure

1. Instill sterile ophthalmic antibiotic solution two gtt (drops) o.u., or sterile saline or balanced salt solution prior to recovery of ocular tissue.
2. Close eyelids completely and gently. Lightly apply paper tape if indicated in local eye bank's procedures. Use of tape on eyelids not completely closed may result in adhesive contaminating the surface of the cornea and causing epithelial damage.
3. Lightly apply wet ice packs over eyes, securing gently in place.
4. Elevate the donor's head.
5. Record whether these procedures were carried out on your eye bank's donor screening form or donor information form.

Rationale

1. Provides lubrication and moistening of corneal tissue. Antibiotic solution retards microbial growth prior to enucleation or in situ corneal removal.
2. Prevents natural opening of lids due to decreased muscle tone and post mortem relaxation of eye lids, which exposes corneal epithelium to air, resulting in damage to eye tissue. Paper tape will prevent tape burns to lids and reduce chances of removing eyelashes.
3. Wet ice provides a cool environment around the eyes in an attempt to decrease the effects of metabolic byproducts (toxins) on eye tissue, which occur naturally within the body after death.
4. Prevents pooling of blood in head to decrease incidence of bleeding and swelling in eye region following enucleation.
5. This information should be used to evaluate the suitability of the corneal tissue for surgical use.

E1.000 Procurement and Preservation Procedures

E1.050 Pre-ocular Tissue Recovery and Donor Preparatory Procedures

Purpose:

To delineate standardized procedures for preparation of the donor and activities to be completed before the removal of the ocular tissue by enucleation or in situ corneal excision.

These procedures include the following:

- Verifying consent for ocular tissue removal
- Checking the donor's history and medical record
- Identification of the donor
- Physical examination/inspection of the donor
- Work site preparation
- Supplies and set up of the field
- Donor preparation procedures: Irrigation and prep of the operative site
- Set up of the sterile field
- Draping of the donor
- Penlight Examination
- Draw blood sample

Materials Needed:

1. Sterile Supplies:

- Sterile ophthalmic irrigating solution, e.g., normal saline or balanced salt solution
- Sterile antibiotic solution (for in situ excision)
- Sterile gloves
- Sterile gown or sterile sleeves
- Sterile supplies used in whole eye enucleation and in situ corneal excision. See procedure E1.100 and E1.200.
- Povidone-iodine antiseptic swabs or sterile preoperative skin prep tray
- Alcohol swabs
- Syringe needle or a vacutainer apparatus to draw blood
- Moisture impermeable table drape and antiseptic solution to clean work table

2. Non-Sterile Supplies:

- Forms (Screening form, enucleation/excision form, donor information form per your eye bank's policy)
- Non sterile gloves
- Protective moisture impermeable clothing
- Protective eyewear (goggles or face shield)
- Mask
- Cap to cover hair
- Sterile scrub brush for hands
- Non-sterile supplies used in whole eye enucleation and in situ corneal excision
- Penlight

Procedure

1. Transport supplies to donor site

Rationale

Check expiration dates and integrity of sterile instrument kits before leaving the eye bank laboratory. Pack necessary instruments kit(s), as well as all necessary supplies, and transport in clean bag or case to donor site. The eye bank must have a specific policy and procedure for back up instruments which may be missing from the kit or which become contaminated. This may be accomplished by taking an extra kit.

2. Verify consent for ocular tissue removal

Obtain and review the consent form. Confirm that it has been completed fully and has signatures of consenting legal next-of-kin. Leave original in the donor's chart and take a photocopy for the eye bank's record. See procedure D1.300. If your eye bank uses a means of obtaining consent other than written consent it is essential that the consent procedure conforms to state law and that documentation of the consent is retained.

3. Review the donor's medical history by means of chart review or interviews with knowledgeable medical staff.

4. Identify the donor

Match the name on the consent form to the name on the donor's ID tag, e.g., toe tag or bracelet. Never assume the identity of the donor in the absence of checking appropriate sources on the body.

5. Put on protective apparel

Follow all eye bank procedures related to Universal Precautions.

Put on protective apparel, including gloves, mask, cap to cover hair, protective eye wear such as goggles, safety glasses or face shield, and moisture impermeable protective clothing.

6. Perform gross inspection of the donor. Examine the entire body of the donor for evidence of needle tracks, fresh homemade tattoos, male to male sexual contact or physical signs of HIV, hepatitis, evidence of sexually transmitted diseases. If in-situ is to be performed, use a penlight to grossly examine the eyes for signs of infection, corneal damage, embedded foreign bodies or previous surgery. Examination of the entire body may require assistance to remove clothing and turn the body. Also see procedure D1.200 (Y).

To assure sterility of instruments and supplies.

2. To verify whether consent is for whole eyes or corneas only and that consent is valid prior to removal of any ocular tissue.

3. To double-check the accuracy of all reported information.

4. To prevent removal of ocular tissue from the wrong donor.

5. To protect the eye bank technician from potential exposure to infectious disease.

6. To provide and record further evidence that the donor is in physically acceptable condition and free of signs of high risk for AIDS, hepatitis or other infection. See EBAA Medical Standard F1.200: Slit-lamp Examination.

7. Draw a blood sample

See procedure E1.700. Be sure to verify the donor's transfusion history and whether a pre-transfusion sample is required. Always strictly adhere to **Universal Precautions** when drawing a blood sample. Immediately label every sample with the donor's identification number and date and time of draw. The sample may be drawn before or after the ocular tissue has been recovered, per your eye bank's policy.

8. Prepare the work site

Identify a suitable worktable, Mayo stand, or counter space near the donor on which to set up your sterile field. If necessary, clean this area with a disinfectant and/or cover the surface with a moisture impermeable barrier drape. The sterile field will be set up on this area.

9. Prepare the donor

A. Elevate the donor's head if this has not already been done.

B. Gently open each eye-lid and thoroughly irrigate the corneal and conjunctival sac of each eye following the procedure approved by the eye bank medical director. The procedure must include rinses of each eye with a sterile ophthalmic solution such as a normal saline or balanced salt solution. Additional rinses with ophthalmic povidone-iodine solutions may also be included. Irrigation of the eyes with a broad-spectrum ophthalmic antibiotic such as gentamicin or polymyxin B may also be included in the irrigation procedure. Care should be given to rinse povidone-iodine solutions and antibiotics from each eye with sterile ophthalmic solutions such as sterile saline within reasonable time limits (about 2 minutes).

C. Clean the orbital area and surrounding skin, using alcohol or gauze moistened with water.

D. Perform a prep of the operative area (the operative site) using povidone-iodine solution. Do not use Hibiclens or PhisoHex, as this has been shown to be toxic to the cornea. The technique used to perform the prep should be a standard pre-operative skin prep. (See

7. To obtain the serum necessary for EBAA required serology.

8. To ensure a clean area for set up of the sterile field.

A. To prevent pooling of blood in the orbital area which could lead to excessive bleeding, swelling, and bruising post ocular tissue removal.

B. To remove debris, microorganisms and other sources of contamination from the donor's eye. Antibiotic solution retards and prevents microbial growth. Povidone-iodine solutions must be carefully removed from ocular surfaces to prevent corneal toxicity.

C. To remove gross blood, dirt, or debris from the donor's skin.

D. The use of friction mechanically removes microorganisms. This is combined with an antiseptic solution to further kill organisms and reduce the microbial population to the minimum possible.

Berry and Kohn's or other surgical textbook for illustrations and in depth discussion.) The prep should start at the medial canthus of the upper closed eyelid and move out, around and below the lid, over the bridge of the nose, in an ever-widening circular pattern. Do not go over the same area twice. Cleanse each orbital area in this manner at least twice.

Following this, a povidone-iodine paint may be applied, per your eye bank's protocol. Avoid getting any povidone-iodine solution or paint into the eye during the prep.

- E. Remove your prep gloves and dispose of them in a biohazard bag. The next step is setting up the sterile field, scrubbing and donning sterile gloves, and beginning the enucleation or in situ corneal excision procedure.

10. Prepare the sterile field

- A. Prepare the sterile field by first placing the sterile instrument tray on your prepared work surface. Remove the plastic dust cover if one has been applied. Verify that the instrument tray is sterile by checking the expiration date and the integrity of the wrap. Carefully open the inner wraps. Open additional sterile supplies or equipment, such as cotton-tipped applicators, 4 x 4 gauze, and eye jars by carefully peeling the bags and flipping the items onto the sterile field. If performing an in situ excision, set up the vials or chambers containing corneal preservation medium adjacent to your sterile field, but not touching the field.
- B. Open the outside package(s) of sterile gloves and sterile gown or sleeves. Scrub hands and forearms from fingertips to elbows, using an antiseptic scrub brush or solution such as Hibiclens or povidone-iodine. Scrub for three to five minutes using standard OR scrub technique (see Berry and Kohn). Rinse thoroughly and dry with a sterile towel, drying from fingertips to elbows.
- C. Don sterile gloves using aseptic technique. Double glove if this is your eye bank's policy. Remove any glove powder if indicated or necessary per your eye bank's policy.
- D. Don sterile gown or sleeves by slipping on and over gloved hands.

- A. Develop a sterile conscience to protect the sterile field from inadvertent contamination.

- B. See OR textbook such as Berry and Kohn's for a more detailed and illustrated guide on scrubbing. If a sterile gown is not used, sterile sleeves may be substituted.

- D. If double gloving, the second pair of gloves are donned after the sterile gown or sleeves.

11. Drape the donor

Drape the donor with sterile drapes according to your eye bank's policy. Place a fenestrated sterile eye drape over each eye so that both eyes can be visualized. Once in place, do not move the drape(s) around. At this point consider only the inner area of the drape to be sterile.

11. The drape(s) provides the enucleator with a sterile surface around each eye on which to work.

In order to avoid contaminating the second eye, both eyes should be draped at once with a fenestrated drape to expose each eye. One drape for each eye, may be used as long as a portion of one drape does *not* overlap the opposite eye.

E1.100 Enucleation

Purpose:

To provide a standardized method for the aseptic removal of human eye tissue.

This procedure describes the basic technique for performing an eye enucleation according to EBAA standards. Certain portions of the procedure are at the discretion and direction of your eye bank's medical director. Please refer to your eye bank's procedures manual as directed.

Materials needed:

1. Sterile Supplies:

A sterile instrument tray: (The tray may be either steam or gas sterilized, appropriately wrapped, labeled with expiration date, and stored in plastic according to your eye bank's policy.)

- 1 Small curved scissors
- 1 Large curved enucleation scissors
- 1 Small (mosquito) curved hemostat
- 1 Small muscle hook (retractor)
- 1 Small toothed forceps
- 1 Eyelid speculum
- 2 Fenestrated eye drapes or 1 double-fenestrated drape
- 2 Plain drapes (optional, if the fenestrated drapes are moisture impermeable)
- 1 Hemostat for handling ophthalmic irrigating solution
- 2 x 2 gauze sponges
- Cotton balls
- Sterile cotton-tipped applicators
- Sterile eye jars, either glass or plastic. The eye jars may be sterilized within your instrument tray or separately. They should contain dental roll, gauze, or metal cage to hold the eye.

Sterile gloves (at least 2 pair)
Sterile gown or sleeves

2. Non-sterile Supplies:

Styrofoam container for transporting the eyes
Personal protective equipment.

Procedure

1. All donor preparatory and pre ocular tissue recovery procedures should be performed according to procedure E1.050.
2. Set up the sterile right and left eye jars. Check instruments to be sure none are missing or damaged.
3. According to your eye bank's policy, begin with the left or right eye. Using 2 x 2 gauze or a cotton tipped applicator, gently open the upper eyelid by pulling towards the top of the head, insert the closed lid speculum under the upper and lower eyelids near the nose. Slowly open

Rationale

3. This provides access to the eye during the enucleation procedure.

the speculum while moving toward the middle of the eye. Be very careful not to touch the cornea with the speculum.

4. Grasp the conjunctiva with the forceps, near the lateral edge of the cornea at the limbus. Cut the conjunctiva with the small, round tip scissors pointed away from the cornea. Continue this 360° all the way around the cornea.
5. Insert the closed scissors under the conjunctiva and perform a blunt dissection.
6. Using muscle hook and small scissors elevate and sever ocular muscles. A hemostat may be applied to clamp the muscle prior to cutting.
7. With the globe still rotated laterally, insert the closed blades of the large enucleation scissors behind the back of the eye. Open the blades slightly and position the optic nerve between the blades. Push the scissors towards the back of the orbit and cut the optic nerve, leaving 5-10mm stump.
8. Use the hemostat, which is clamped to the medial rectus muscle, to gently lift the globe from the socket. Carefully cut any remaining connective tissue.
9. If using eye jars with metal cages, place the eye in the metal cage with the cornea facing up. Place the optic nerve through the bottom hole of the cage and hang the hemostat from the optic nerve. Secure the eye in the jar by either clamping or pinning the optic nerve. Place the cage back in the jar.

If a cage is not used, prepare a bed with gauze or cotton dental roll and place the eye in the jar with the cornea facing up. Make sure that the cornea is not rubbing against the sides or top of the jar.

10. Pour a **small amount** or approximately 5 ml of balanced salt, antibiotic solution, or other sterile ophthalmic irrigating solution over the eye (just enough to moisten the cotton or gauze in the bottom of the jar). If you are using a non-sterile

4. Cutting the conjunctiva provides the enucleator access to the ocular muscles and optic nerve and removes a membrane that may be contaminated with bacteria.

5. To facilitate access to the ocular muscles.

6. This description of cutting the ocular muscles is one of several ways to remove the eye. Please refer to your local eye bank's procedure manual for any variation. All 6 ocular muscles must be isolated and severed; however, the order and technique may differ. Be careful not to puncture the globe during severing of the muscles. The sclera is thinnest underneath the insertion sites of the ocular muscles. Do not traumatize the cornea during this procedure.

7. A 5-10mm optic nerve stump will assure that it is not cut too close to the posterior so as to risk puncture and collapse of the globe. A generous stump also allows for sufficient length to anchor the eye in the cage, if used by pulling the stump through the bottom.

9. Although pins have been used to secure the eye in the cage, they introduce increased risk of puncture to the ocular tissue and the eye bank technician. They may also be difficult to remove.

10. Handling of a non-sterile bottle will contaminate your glove unless you use a sterile instrument such as a hemostat or test tube holder to handle it. Gauze is an unacceptable barrier and cannot be used to handle non-sterile items.

bottle, handle the bottle with a sterile hemostat. Otherwise, you must reglove. If you have double-gloved, remove outer gloves following handling of the non-sterile bottle.

11. Repeat steps (1-13) above for the other eye. The second eye should already be draped.

12. Donor Reconstruction

A. Remove drapes

B. Place a folded piece of gauze or a cotton ball in the socket and insert eye caps per your eye bank's policy. Close the eyelids and gently wipe off the povidone-iodine or other solution by patting with moist gauze.

C. If necessary, control excessive bleeding. Check with your local funeral directors and follow your eye bank's protocol. Trocar buttons, local cauterizing agents, gel foam, and other techniques may be used.

D. Leave the donor's head elevated.

E. Remove surgical gloves, place the lids on both jars, being careful NOT to touch the inside of the jar.

F. Label each eye jar (see procedure J1.000) and place both jars in transport container with frozen water beginning to melt to maintain the temperature between 2 - 6°C.

G. Record information about the enucleation in the donor's medical record according to your eye bank's policy.

H. Complete the eye bank's enucleation form, as required.

I. Leave a form or attach a tag to the body informing the funeral director that the eyes have been removed and to keep the head elevated. Also give the eye bank's name, location, and phone number with instructions to notify the eye bank if there are any questions or problems.

J. Don nonsterile gloves and rewrap the donor in the body bag or shroud and return to the storage location from which it was removed.

K. Clean the work area. Discard all used disposables in a biohazard bag and all sharps in a sharps container.

B. To restore the appearance of the donor. Minimal or gentle manipulation of the eyelids will help decrease post-mortem discoloration and swelling.

C. These procedures may be developed in consultation with your local funeral director and skin or tissue bank.

E. Surgical gloves should be removed so that the exterior of the jars are not contaminated with eye tissue or body fluid, avoiding the creation of a potential biohazard.

G. To fulfill JCAHO requirements on documentation of tissue and organ removal.

L. Rewrap instruments for return to the eye bank or for cleaning and sterilization by the facility if that is your eye bank's protocol.

M. Transport the eyes to the eye bank as soon as possible.

L. Be sure that used instruments are marked as biohazardous during transport.

E1.200 Corneoscleral Rim Removal: In situ

E1.210 In situ Excision

Purpose:

To provide a standardized method for the aseptic in situ removal of corneal tissue for surgical use that will minimize endothelial cell loss and contamination, and maximize the number and quality of cells that are ultimately grafted.

Materials needed:

Skin prep tray, povidone-iodine or other microbicidal solution and sterile 4 x 4's or
Sterile ophthalmic irrigant solution, such as sterile saline
Sterilized appropriately wrapped instrument tray to include the following:

- 1 Lid speculum
- 2 Forceps with teeth
- 2 Pair of iris or tenotomy scissors
- 2 #11 or #15 blades
- 1 Corneal section scissors, Castroviejo scissors, or Aebli Scissors
- 1 Pair of forceps to handle lids of medium (optional)

2 sterile corneal storage containers (e.g. corneal viewing chambers)

2 vials of corneal tissue culture preservation medium

Two single fenestrated drapes or one double fenestrated drape, or sterile towels

Cultures or other items specified by your eye bank if culturing of the corneoscleral rim at time of removal is desired.

Procedure

1. All donor preparatory and pre ocular tissue recovery procedures should be performed according to procedure E1.050.
2. Some eye banks may perform a culture at the time of procurement. Please refer to section G1.000 and your eye bank's policy for specific direction about cultures.
3. Label the corneal storage containers, loosen the caps to the top thread, and place these adjacent to a top corner of the sterile field. If sterile containers are dropped onto the sterile field the containers are labeled as soon as possible at the end of the procedure.
4. If required by the coroner or medical examiner, label test tubes for blood and vitreous samples and position near the sterile field along with the syringe, needle, and cosmetic restoration materials.
5. Open the eyelid using a sterile cotton tipped applicator and insert a solid blade eye speculum.

Rationale

3. Take care in the positioning of the storage medium vials to avoid accidentally knocking over the vials while reaching for instruments if they are at the bottom of the field or contaminating the field by reaching over if they are at the top of the field.

6. Lift and cut the conjunctiva at the limbus 360° around the cornea using small toothed forceps and iris or tenotomy scissors. Any adhesions between the conjunctiva and the anterior globe are separated so that the conjunctiva is not in contact with the anterior globe to within 5 mm of the limbus. Remove any remaining conjunctiva by carefully scraping from the limbus with a scalpel blade (#11 or #15).
7. Isolate the instruments and scalpel used to scrape the conjunctiva from the other instruments on the sterile field. Use these only for the same purpose on the opposite eye.
8. Make an incision through the sclera 2 mm - 4 mm from the limbus and parallel to the limbus. Carefully cut all the way through the sclera without perforating the choroid.
11. Extend the scleral incision 360° around the cornea using corneal section scissors (Castroviejo or Aebli). Avoid perforating the choroid, breaking into the anterior chamber, or causing any deformation of the cornea's normal curvature.

The scissor blades should not be visible in the anterior chamber.

Keep the incision parallel to the limbus to produce an even scleral rim between 2 mm - 4 mm in width.

10. Inspect the incision to ensure it is complete and that the anterior chamber is intact. If the incision has been made properly, the corneoscleral button should be attached to the uvea (ciliary body-choroid) only at the scleral spur.
11. Cultures of the incision site may be taken at this time, per your eye bank's policy.
12. Complete the corneal removal using one pair of small forceps to hold the scleral rim stationary and a second set of small forceps, an iris spatula, or similar technique to push the ciliary body-choroid downward and away from the corneoscleral button.

6. The conjunctiva tissues should be considered contaminated with microorganisms. Therefore it is necessary to completely remove the conjunctiva at the limbus.
7. The conjunctiva is considered a contaminated membrane. Use of this same blade would introduce microorganisms into the incision area.
8. Perforation of the choroid causes vitreous leakage, which may collapse of the globe including the anterior chamber and compromise the corneal endothelium. Additionally, vitreous leakage would make cosmetic restoration more difficult.
9. Trauma to the cornea during excision due to bending, loss of the anterior chamber, or collapse of the globe through vitreous loss may compromise its suitability for surgical use.

This indicates that the anterior chamber has been inadvertently entered, which may damage the corneal endothelium.

Scleral rim width is important: because some surgical corneal holding devices require a minimum of 2 mm rim while other such devices require a rim no wider than 4 mm. Also, cutting a rim less than 2 mm wide greatly increases the chance of entering the anterior chamber while performing the peritomy.

10. The risk of endothelial trauma or corneal contamination is greatest at this stage of the excision process.
12. Aqueous fluid should escape from the anterior chamber at this point assuring that the anterior chamber was indeed intact.

13. Gently separate remaining adhesions away from the corneoscleral button working side to side and taking great care to avoid pulling on the cornea and creating folds. The corneoscleral rim should never be allowed to drop back down while making this separation. The corneoscleral button must never be pulled in such a way as to cause cross-corneal tension.

Care must also be taken to prevent the cornea from contacting the eyelids or other facial skin while removing it from the eye.

14. Continue to hold the cornea by the scleral rim with the small toothed forceps, transfer it to a labeled storage medium container. The pre-loosened cap is lifted off the vial using sterile forceps immediately prior to placing the cornea in the medium and replaced immediately afterward. If forceps are not used, reglove before starting on the next cornea.
15. Examine the posterior chamber for a crystalline lens.
16. Repeat the excision on the second eye (Steps 1-15). After the second cornea is placed in storage medium, both container caps are tightened and appropriately labeled.
17. Completion
 - A. Dispose of sharps in a sharps container.
 - B. Remove drapes. Insert eye caps. Close the eyelids and remove all remaining prep solution with gauze and water or alcohol.
 - C. Leave the donor's head elevated.
 - D. Record information about the excision in the donor's medical record according to your eye bank's policy.
 - E. Complete the eye bank's excision form, as required.
 - F. Leave a form or attach a tag to the body informing the funeral director that the corneas have been removed and to keep the head elevated. Also give the eye bank's name, location, and phone number with

13. To avoid stretching or folds leading to potential loss of endothelial cells.

To avoid contamination of the ocular tissue.

14. Removing the vial cap at the time the cornea is placed in the storage medium minimizes the medium's exposure to airborne contaminants.
15. To inspect for signs of previous cataract surgery which would possibly contraindicate use of the ocular tissue for penetrating keratoplasty per EBAA Medical Standards section D1.120, depending on your eye bank's policy.
 - A. Sharps are disposed as soon as possible to decrease the risk of exposure to contaminated sharps.
 - B. To restore the appearance of the donor.
 - D. To fulfill JCAHO requirements on documentation of tissue and organ removal.
 - F. As a courtesy to the local funeral director. Also, hopefully, the funeral director will notify the eye bank before discussing problems related to the eye removal with the family.

instructions to notify the eye bank if there are any questions or problems.

- G. Don non sterile gloves and rewrap the donor in the body bag or shroud and return to the storage location from which it was removed.
- H. Clean the work area. Discard all used disposables in a biohazard bag.
- I. Rewrap instruments for return to the eye bank or for cleaning and sterilization by the facility if that is your eye bank's protocol.
- J. Transport the corneas to the eye bank as soon as possible.

E1.220 Laboratory Corneal Excision

Purpose:

To provide a standardized method for the aseptic preservation of corneal tissue in the laboratory that will minimize endothelial cell loss and contamination and maximize the number and quality of cells that are ultimately grafted.

Materials needed:

Sterile Supplies

Sterile gown or sleeves
Sterile gloves
Sterile scrub brush for scrubbing hands
1 sterile towel
Sterile ophthalmic irrigating solution
Sterile ophthalmic broad spectrum antibiotic or antimicrobial solution
2 vials corneal storage medium
2 sterile corneal containers (e.g. corneal viewing chambers)
2 mini tipped culturettes (if cultures are performed by the eye bank)
Sterile cotton-tipped applicators
Sterile gauze
Jars containing whole eyes
Appropriately wrapped sterilized instrument tray containing the following:

2 Small toothed forceps
2 Scalpel handles
2 #11 or #15 blades
1 Corneal section scissors, or Castroviejo or Aebli scissors
2 Tenotomy or iris scissors
1 Hemostat
1 Forceps to handle cages and/or solution bottles
2 Medicine cups or other small 30 cc glass/steel container

Non-Sterile Supplies

Class 100 Hood or Class II or Class III Biosafety Cabinet or an operating room
Moisture impermeable protective clothing
Mask
Cap to cover hair
Protective eyewear (goggles or face shield)
Slit Lamp
Evaluation Form
CDC recommended disinfectant solution

Procedure

1. Slit lamp globes. Perform the corneal removal (excision) in the laboratory in a Class 100 Hood or Biosafety Cabinet following a whole eye enucleation. Wipe down and air dry the work surface of the hood or cabinet with a disinfectant solution immediately prior to use. Turn on laminar airflow of hood and allow to run at least fifteen minutes according to manufacturers' instructions prior to use. Document cleaning of

Rationale

1. Minimizes the risk of contamination by providing a decontaminated work surface. Allows laminar flow to be established.

the hood according to each eye bank's policies and procedures.

2. Don appropriate protective apparel consistent with the biological safety cabinet being used.
3. Place sterile instrument pack, eye jars, antibiotic or antimicrobial solution, and corneal storage medium containers on the prepared surface of the laminar airflow work surface. If sterile corneal storage containers are dropped onto the sterile field, the containers are labeled as soon as possible at the end of the procedure.
4. Position the eye jars so that they are immediately adjacent to the edge of the sterile field formed when the sterile instrument pack is opened. The eye jar lids are removed and placed with inner side up next to their respective jars. The labeled storage medium vials are positioned so that they also will be adjacent to the sterile field. Remove the caps of the vials. Position eye jars and medium vials to ensure that left and right specimen bottles are clearly and readily identified.
5. Uncap a 10 cc bottle of broad range sterile ophthalmic antibiotic solution or a povidone-iodine solution container and place near the eye jars and medium vials, according to your eye bank's policy.
6. Using aseptic technique set up the sterile field by opening the wraps of the sterile instrument tray. Alternatively, a sterile moisture impermeable barrier drape may be opened and placed on the work surface of the laminar airflow hood or cabinet, followed by opening sterile instruments in peel packs and dropping them onto it. Avoid contaminating the sterile field created by touching or reaching over the field. Using aseptic technique, open individually wrapped sterile items, such as gauze or sterile cotton-tipped applicators and flip onto the sterile field with the surgical instruments.
7. Scrub three to five minutes according to procedure E1.050. Dry hands with a sterile towel. Using aseptic technique don sterile gloves and gown or sleeves. Double glove if this is your eye bank's policy.
8. Fold a sterile 4 x 4 gauze sponge to form a long strip.

2. Use of a biosafety cabinet with a plexiglass shield protects the technician and tissue. Therefore, protective eye wear and mask in particular may not be necessary. However, if tissue is opened outside of the hood, e.g., while slit lamping the whole globe, full protective apparel is still required.

5. Antibiotic or antiseptic application to the whole eye prior to corneal excision reduces the microbial population. (Povidone-iodine 0.5% solution has demonstrated effectiveness as an anti-fungal agent.).

8. This is used to hold the eye during the corneal removal.

9. Lift the eye and the eye cage, if one is used, from the eye jar with sterile forceps (or the cage with a sterile cotton-tipped applicator.) Remove the pin if one is in place from the optic nerve with a hemostat.

Remove the eye from the cage using forceps to grasp a rectus muscle.

10. Soak or irrigate the eye using an antibiotic solution for 3 to 5 minutes in a sterile medicine cup according to your eye bank's policies and procedures. Avoid contaminating the sterile field by wetting of a cloth drape, if one is used. Irrigation should be performed over a metal instrument pan or a moisture impermeable drape.
11. Wrap the eye securely with the gauze strip several times around the equator.
12. Lift and cut any remaining conjunctiva at the limbus and extending out 5 mm from the limbus using small toothed forceps and iris or tenotomy scissors. The exposed sclera may be carefully scraped from the limbus outward with a scalpel blade (#11 or #15) to remove all remaining conjunctival tissue. It is important to remove all conjunctiva flush to the limbus.
13. Isolate the instruments and scalpel blade used to remove the conjunctiva from the other instruments on the sterile field. Use these only for the same purpose on the opposite eye.
14. Pick up the gauze-wrapped globe and hold with one hand.
15. Make an incision through the sclera 2 mm - 4 mm from the limbus and parallel to the limbus. Carefully cut all the way through the sclera without perforating the choroid.
16. Extend the scleral incision 360° around the cornea using corneal section scissors (Castroviejo or Aebli). Avoid perforating the choroid, breaking into the anterior chamber, or causing any deformation of the cornea's normal curvature. The scissor blades should not be visible in the anterior chamber.

Keep the incision parallel to the limbus to produce an even scleral rim between 2 mm and 4 mm in width.

10. Studies have shown that whole globe immersion is superior to irrigation for removal of microbes (see reference list.)

12. To remove microbial contaminants that may be present on the conjunctival tissue.

13. The conjunctiva is considered a contaminated membrane. Use of the same instruments could introduce microorganisms into the incision area.

15. Perforation of the choroid causes vitreous leakage, which may collapse the globe including the anterior chamber. This would compromise the corneal endothelium.

16. Trauma to the cornea during cutting due to bending, loss of the anterior chamber, or collapse of the globe through vitreous loss would severely compromise its suitability for surgical use.

Scleral rim width is important because some surgical corneal holding devices require a minimum 2 mm rim while other devices require a rim no wider than 4 mm. Also, cutting a rim less than 2 mm wide greatly increases the chance of

17. Inspect to be certain the incision is complete and that the anterior chamber is intact. If the incision has been made properly, the corneoscleral button should be attached to the ciliary body-choroid only at the scleral spur.
18. A culture of the incision site may be performed at this time, per your eye bank's policy.
19. Set the wrapped eye down near the center of the sterile field which may be stabilized by attaching a sterile hemostat. Complete the corneal removal using one pair of the small forceps to hold the scleral rim stationary and a second set of small forceps, an iris spatula or similar technique to push the ciliary body-choroid downward and away from the corneoscleral button. Gently separate remaining adhesions from the corneoscleral button working side to side. The corneoscleral rim must never be pulled in such a way as to cause cross-corneal tension. The corneoscleral rim should never be allowed to drop back down onto the anterior chamber.
20. Continue to hold the cornea by the scleral rim with the small toothed forceps and transfer it to a labeled corneal storage container from which the caps have already been removed.
21. Examine the posterior chamber for crystalline lens.
22. Carefully unwrap and return the remaining posterior segment to its respective eye jar. Avoid contaminating the posterior segment, instruments, or surgical gloves.
23. Repeat the procedure on the second eye.
24. After the second cornea is placed in storage medium, replace both container caps and tighten. Replace the lids on the eye jars. The containers with the ocular tissue are immediately labeled and sealed and the tissue refrigerated according to each eye bank's policies and procedures.
25. Dispose of sharps in a sharps container. Instruments and eye jars are immediately cleaned according to your eye bank's policy and procedure. Discard all disposables in a biohazard receptacle.

entering the anterior chamber while performing the peritomy.

17. The risk of endothelial trauma and cell damage is greatest at this stage of the excision process.
19. To avoid pulling on the cornea and creating folds. Aqueous fluid should escape from the anterior chamber at this point assuring that the anterior chamber was indeed intact.

Never allow the cornea to drop back down once the removal has started. Doing so may cause endothelial cell damage if the cells come in contact with the iris.
20. The vials may remain open under the laminar airflow hood or biosafety cabinet for a period of 1 hour, which is acceptable operating room practice.
21. Inspect for signs of previous cataract surgery, which would possibly contraindicate use of the corneal tissue for penetrating keratoplasty, depending on your eye bank's policy (See EBAA Medical Standards (D1.120).

24. See procedures I1.000 and J1.000.

25. Sharps are disposed as soon as possible to decrease the risk of exposure to contaminated sharps. See procedure C3.300 for care of instruments.

26. Immediately after use, wipe down the work surface of the hood with a disinfectant and allow to air dry. Document these cleaning procedures according to your eye bank's policies and procedures.

26. See EBAA Medical Standards C3.300.

E1.300 Use of Short and Intermediate Term Preservation Media

Purpose:

To describe the use and storage of short and intermediate term corneal preservation media.

Definition of terms:

Short or intermediate term corneal storage media: liquid preservation media used to maintain the viability of donor corneas prior to corneal transplantation.

Materials needed:

Class 100 Hood or Class II or Class III Biosafety Cabinet
Sterile instruments
Moisture impermeable protective clothing
Mask
Cap
Sterile Gloves

Procedure

1. Store corneal preservation media at a temperature in accordance with the manufacturer's recommendation. Once refrigerated, media must be stored at 2 – 6° C (2 – 8°C per Optisol package insert) in a monitored refrigerator with a temperature recording device. This device should be visible without opening the refrigerator.
2. If an eye bank manufactures its own media, the procedures used must be in accordance with FDA's Good Manufacturing Practices, and must be documented in the eye bank's procedure manual.
3. Visually inspect each vial or container of preservation medium prior to use for turbidity, color change indicating a pH shift (if phenol red has been added as an indicator), precipitates, or foreign bodies, which may indicate possible microbial contamination. Also check expiration dates. Inspect containers for cracks or leakage.
4. If contamination of preservation medium vials/containers is suspected, do not use the medium for corneal tissue storage. The lot number shall be reported immediately and returned to the manufacturer.
5. Record the lot numbers and expiration date of each vial of preservation medium used for each cornea on the corneal information form that accompanies the ocular tissue.

Rationale

1. A monitored refrigerator assures that media is stored within the prescribed temperature range.

A portable recorder can be used for off-site storage (away from the eye bank laboratory) or media can be stored in a hospital pharmacy by contractual agreement.
2. See EBAA Medical Standards section E1.300.
3. To prevent the use of preservation media suspected of being contaminated, which could result in an adverse reaction in a recipient, such as endophthalmitis.
5. To facilitate recall of media or notification to receiving surgeons of medium being recalled by the manufacturer.

E1.400 Long-Term Preservation

Purpose:

To describe the long-term storage of donor corneas for surgical use.

Procedure

1. Organ Culture

- A. Donor corneas for penetrating keratoplasty may be preserved for longer periods, i.e., 1 month or more using organ culture techniques.
- B. If an eye bank uses organ culture techniques, the policies and procedures must be recorded and available for review at the time of EBAA site visit inspection.
- C. Organ culture techniques must provide for the aseptic preservation and storage of corneal tissue.

2. Cryopreservation

Donor corneas can be cryopreserved and stored in liquid nitrogen for several years. This method uses a cryoprotective agent, such as dimethyl sulfoxide (DMSO), to prevent the formation of damaging intracellular ice crystals. Donor corneas are frozen in a controlled-rate freezer down to liquid nitrogen temperature.

Rationale

- 1. These preservation methods are more complicated than preservation in short or medium-term corneal storage medium and are not in common use in the U.S. at present. Organ culture is reported to be the preservation of choice in the United Kingdom and some western European countries.
- 2. If an eye bank elects to use cryopreservation methods, a detailed policy and procedure shall be included in the eye bank's written policies and procedures manual.

E1.500 Whole Globe Storage for Surgical Use

Purpose:

To delineate the methods used for storage of whole globes for surgical use.

Definition of terms:

Moist chamber: A closed container with cotton gauze moistened with sterile saline or other sterile ophthalmic solution to provide a moist environment. The container is never completely filled with liquid so that the entire eye is immersed.

Decontamination: To reduce surface contamination by antimicrobial action.

Materials needed:

Sterile Supplies

A sterile instrument tray:

2 Large toothed forceps

1 Hemostat

2 Sterile eye jars or medicine cups for soaking eyes

2 Sterile eye jars containing gauze

2 Cotton tipped applicators

1 Sterile ophthalmic irrigating solution, e.g., normal saline, balanced salt solution or antibiotic solution

1 Sterile ophthalmic broad spectrum antibiotic solution vial

Sterile towel

Sterile gloves

Sterile gown or sleeves

Sterile Instrument pack or tray containing the following:

Sterile scrub brush for hands

Jars containing donor eyes

Non-sterile Supplies:

Prep gloves

Moisture impermeable protective clothing

Mask

Cap to cover hair

Protective eyewear (goggles or face shield)

Class 100 Hood or Class II or Class III Biosafety Cabinet

Refrigerator and/or freezer and/or liquid nitrogen container

CDC recommended disinfectant

Procedure

1. Turn on laminar airflow of the hood or biosafety cabinet and allow to run according to manufacturers' instructions prior to use. Wipe down work surface with disinfectant and allow to air dry.
2. Place jars containing eyes and all sterile instruments and supplies on work surface of hood or biosafety cabinet.

Rationale

3. Don appropriate protective apparel, per procedure E1.050.
4. Position the eye jars so that they are immediately adjacent to the edge of the sterile field formed when the sterile instrument pack is opened. The eye jar lids are removed and placed with inner side up next to their respective jars. Position eye jars to ensure that left and right specimen bottles are clearly and readily identified.
5. Uncap a 10 cc bottle of broad range sterile ophthalmic antibiotic solution or a povidone-iodine solution and place near the eye jars according to your eye bank's policy.
6. Set up the sterile field by opening wraps of the sterile instrument tray. Alternatively, a sterile moisture impermeable barrier drape may be opened and placed on the work surface of the hood or biosafety cabinet followed by opening sterile instruments in peel packs and dropping them on. Avoid contaminating the sterile field created by touching or reaching over the field. Open individually wrapped sterile items, such as gauze or sterile cotton-tipped applicators and flip onto the sterile field with the surgical instruments.
7. Scrub three to five minutes according to procedure E1.000, and dry hands with a sterile towel. Don sterile gloves and gown or sleeves.
8. Lift the eye and the eye cage, if one is used, from the eye jar with sterile forceps (or the cage with a sterile cotton-tipped applicator.) Remove the fastener, if one is in place, from the optic nerve with a hemostat.

Remove the eye from the cage using forceps to grasp a rectus muscle.
9. Soak or irrigate the eye using a povidone-iodine or antibiotic solution for 3 to 5 minutes in a sterile medicine cup according to your eye bank's procedure. Avoid contaminating the sterile field by wetting of a cloth drape, if one is used. Irrigation should be performed over a metal instrument pan or a moisture impermeable drape.
10. Transfer the whole eye with sterile forceps from antibiotic/antiseptic soaking solution to sterile eye jars for storage.

5. Antibiotic or antiseptic application to the whole eye prior to corneal excision reduces the microbial population and potential contamination.

9. Studies have shown that whole globe immersion is superior to irrigation for removal of microbes (see reference list.)

11. Store whole globes for lamellar keratoplasty (LK) either in a moist chamber at 2 – 6°C or frozen at 0° C. The temperature and length of storage are determined by the medical director and must be recorded in your eye bank's procedure manual.
12. Store whole globes for penetrating keratoplasty (PK) in a moist chamber at 2 – 6°C for 24-48 hours, or as instructed by your eye bank medical director.
13. Record the method and date of storage on the tissue information form.
14. Wipe down the work surface of the hood or cabinet with a disinfectant solution immediately after use and allow it to air dry. Document these cleaning procedures according to your eye bank's Policies and Procedures.

11. Ocular tissue used for LK does not require an intact endothelium.
12. This environment provides for short-term preservation of the cornea.

E1.600 Scleral Preservation

Purpose:

To provide uniform procedures for the aseptic preservation of scleral tissue for surgical use using either 70% or greater concentration of ethyl alcohol, sterile glycerin, or a broad spectrum antibiotic solution.

Materials needed:

1. Sterile Supplies

- 2 Tissue forceps
- 2 small scissors, e.g., corneal tissue or iris scissors
- Sterile scalpels or handles
- Sterile #10 or #11 blades
- Sterile gauze
- Sterile jars
- Sterile towel
- Sterile gown or sterile sleeves
- Sterile gloves
- Sterile vials of preservation media, e.g., alcohol, glycerin
- Eye tissue

2. Non-sterile Supplies

- Moisture impermeable protective clothing
- Hair cap
- Mask
- Protective eyewear (goggles or face shield)
- Sterile scrub brush for hands
- Sterile towel
- Class 100 Hood meeting Federal Standard 209(b) or Class II or Class III biosafety cabinet meeting National Sanitation Foundation Standards or an operating room
- Sealing material, e.g., shrink wrap

Procedure

1. Assemble sterile instruments and supplies under the hood or biosafety cabinet. Preserve sclera at time of corneal preservation or refrigerate remaining ocular tissue following removal of corneas and preserve sclera later within time frame determined by the eye bank medical director. If sclera is stored for later preservation, wipe down the work surface of the hood or cabinet with a disinfectant solution immediately after use and allow it to air dry.
2. Maintain the sterile field following preservation of the corneal tissue, or set-up new sterile field. Don protective clothing, cap, mask and eyewear. Scrub and don sterile gloves and sterile gown or sleeves.
3. Grasp the remainder of the eye using sterile forceps and place onto the center of the sterile field. Perform a careful inspection of the

Rationale

1. Sclera must be preserved using aseptic technique, the same as when preserving corneal tissue for transplantation.
2. See procedures E1.050 and E1.200.
3. Note any abnormalities of the globe such as discoloration, tumors, or thinning. Any information regarding ocular history noted on the

remaining ocular tissue. It is important that aseptic technique be used and the sterile field is not compromised at any time.

4. Inspect sclera for any muscle attachments, fascia, or connective tissue that remain adhered to the whole globe. Carefully excise any attachments using iris scissors and tissue forceps.
5. Gently remove intraocular material by running iris scissors between the sclera and choroid layer of the globe. Using forceps, iris scissors, sterile gauze or cotton tipped applicators, remove intraocular material.
6. Using sterile cotton-tipped applicators and gauze, clean the inside of the globe to remove all choroid and tissue fragments. Gauze, applicator, or entire globe may be soaked in antibiotic solution if needed to aid in the cleaning process.
7. Reshape sclera to its original spherical form, if necessary, after cleaning. Scleral tissue should be as smooth and round as possible prior to submersion in selected storage medium.
8. If sclera is to be segmented, section the sclera into desired sizes prior to placing in storage medium.
9. Using sterile cotton-tipped applicator or forceps gently place clean sclera into prepared sterile jars containing selected storage medium.
10. Place lids on containers and secure tightly. Seal lids with shrink-wrap, or other sealing material.
11. Label all storage containers with appropriate identification as follows:
 - A. Source eye bank, name, and location
 - B. Type of ocular tissue (Sclera)
 - C. Preservation method: Glycerin, concentration of alcohol used, or frozen tissue
 - D. Unique donor identification number for each piece
 - E. Date/Time of death
 - F. Date/Time of preservation
 - G. Statement that ocular tissue is for single patient use and culturing is recommended.
 - H. Serology results and the statement that the tissue was procured from a donor who was non-reactive when tested for HIV antibody,

screening form or patient's chart should be reviewed and thorough follow-up completed to rule out any problems that might be present with the eye tissue.

4. Since conjunctival tissue is an excellent medium for bacterial growth, it is important to rid the sclera of as much excess conjunctiva as possible. A thoroughly clean piece of scleral tissue is required for surgical use.
5. Running scissors between the sclera and choroid layers helps to gently separate the choroid layer from the scleral wall and facilitates a clean dissection of the intraocular material.
6. Facilitates complete removal of all tissue or particulate material. Antibiotic soak loosens any remaining tissue fragments and reduces the microbial flora.
7. Due to the dehydration of the scleral tissue, reshaping becomes difficult, even after soaking in sterile normal saline prior to surgery.
10. Prevents contamination of ocular tissue by leakage or evaporation (for alcohol preservations). Break in seal indicates tampering and potential contamination.
11. All ocular tissue must be labeled with a unique eye bank identification record number for proper quality control assurance. Proper labeling is required according to EBAA Medical Standards. See procedure J1.000.

hepatitis B surface antigen and hepatitis C antibody using a test approved by the U.S. Food and Drug Administration.

12. Record preservation information on the form used by your eye bank.
13. Sclera should be distributed in the same manner as corneal tissue for surgical use. Recipient records must be kept and a package insert form must accompany each piece of sclera with information to include recommended storage temperature and re-hydration instructions.

Accepted Sclera Preservation Media

1. Alcohol Preservation: 70% or greater concentration of ethyl alcohol

- A. Using forceps or sterile cotton-tipped applicator, clean sclera is placed in either prefilled sterile containers or 70% or greater concentration of ethyl alcohol is carefully added to the sterile containers so that the sclera is completely submerged in the alcohol solution.

- B. **Sclera *must* remain in alcohol solution for at least 5 days prior to distribution.**

- C. Length of storage and storage temperature should be determined by your eye bank's medical director and recorded in the eye bank's procedure manual.

2. Sterile Glycerin

- A. Glass eye jars should be prepared with molecular sieves, fill to a level deemed appropriate by your medical director, and steam sterilized with the lid loosened to allow for steam to penetrate the sieves.

- B. The jars containing the sterile molecular sieves should be filled with sterile glycerin to a level deemed appropriate by your medical director. Transfer sclera using sterile forceps and immerse in the sterile glycerin.

3. Cryopreservation (Freezing)

- A. Sterile eye jars should be filled with an ophthalmic broad-spectrum antibiotic solution.

- B. Transfer the sclera to the solution.

13. Refer to EBAA Medical Standards section J1.000, Labeling, K1.000, Distribution of Tissue, L1.000, Documentation to accompany donor tissue and M1.000, Eye Bank Records.

- A. Accomplishes complete dehydration of the scleral tissue.

- B. To provide adequate time for complete dehydration of ocular tissue.

- C. See EBAA Medical Standards section E1.600.

- A. Maintains a softer sclera.

- A. Retards microbial growth and is bacteriocidal.

- C. Leave the sclera at room temperature in the antibiotic solution for 1 to 2 hours.
- D. Aseptically remove the sclera from the antibiotic solution and place in sterile container which will withstand ultra low freezing temperatures.
- E. Freeze the sclera at -80°C or lower in liquid nitrogen or freezer.

Length of storage and handling instructions

Per EBAA Medical Standards, a preservation date for use of ocular tissue shall be indicated.

Instructions in the form of a package insert for reconstituting or re-hydrating the sclera and preoperative handling must be provided with the tissue to the receiving surgeon.

- C. Activates bactericidal properties of antibiotic.

See EBAA Medical Standards section E1.600.

E1.700 Blood Drawing

Purpose:

To describe the procedure for obtaining a blood sample from a donor for the purpose of serologic testing.

Materials needed:

Sterile Supplies:

10cc syringe
Sterile povidone-iodine or alcohol swab to prep the skin
16 or 18 gauge needle or vacutainer needle and holder
10cc red top vacutainer tube

Non-Sterile Supplies

Exam gloves
Moisture impermeable protective clothing
Protective eyewear
Biohazard labels
Plastic Ziplock bag
Blood specimen transportation box/container

Procedure

1. Verify the IV infusion/transfusion status of the donor. Seek a pre-infusion specimen per EBAA Standard G1.220, if appropriate.
2. Set up supplies near the donor.
3. Select the blood draw site. The major vessels such as the subclavian vein and the femoral artery are the easiest. A blood sample may also be drawn from the heart.
4. Put on gloves and other protective apparel.
5. Cleanse skin with alcohol or povidone-iodine at the site from which you wish to draw.
6. Locate the appropriate anatomic landmarks that overly the chosen vessel. For example, to obtain a blood sample from the subclavian vein, the needle should be inserted through the skin, above the right clavicle (collar bone) at a 30 angle, towards the throat and parallel to the clavicle.

Rationale

1. See EBAA Medical Standards section G1.220. Plasma dilution from blood products, colloids and crystalloids may affect test results and make detection of HIV 1/2 antibodies difficult leading to false negative results. Check with your local blood bank for specific volumes of each blood product administered.
3. Decision may be influenced by coroner or medical examiner preference, if this is a coroner or medical examiner case.
4. Adherence to **Universal Precautions** is mandatory.
5. To avoid contaminating the needle and therefore the blood sample with skin contaminants that may affect the results.

7. Insert needle full length to hub of syringe and pull back plunger. Blood will enter the needle when the vessel has been entered. Or, if using a vacutainer system, insert needle and connect the red top vacuum tube.
8. If blood does not enter syringe, pull back slightly and angle needle differently until you enter the vessel and see a blood return.
9. Draw approximately 10 cc of blood.
10. Carefully and slowly inject blood into red top tube, taking extreme care to avoid a needlestick.
11. Use **Universal Procedures**. Do not recap needle. Discard into appropriate sharps container.
12. Apply pressure over puncture site and gently rub skin to close puncture and stop bleeding.
13. Label tube with date and time of draw, name of donor, a donor identification number, and initials of the technician.
14. Avoid freezing the blood sample while storing or transporting.
15. Transport specimen to laboratory
16. To provide a cleaner non-hemolyzed serum sample, the blood may be spun down in a centrifuge. Pipette the serum from the top and transfer to a clean tube and label. Extra serum may be archived in the eye bank laboratory freezer, if directed by your eye bank's policy and procedure manual.

Avoid or minimize hemolysis by using a large bore needle. Also, wait until blood is fully clotted before spinning down serum.
17. Record results of serologic testing on the donor ocular tissue record prior to release of tissue for surgical use. ***Tissue must not be shipped prior to receipt and recording of non-reactive (negative) results from a hardcopy report.***
18. Attach copy of laboratory results in printed form to the donor record.

10. Inject or transfer blood slowly and carefully into tube to prevent hemolysis.
11. See procedure C3.600.
14. Freezing will hemolyze the cells and make it virtually impossible to obtain serum.
15. Ship blood and tissue according to your state and federal guidelines.

See EBAA Medical Standards sections G1.220-G1.260.

17. To avoid the possibility that tissue will be surgically implanted prior to receipt of required serology results.

E1.800 Transfer of corneal tissue

Purpose:

To describe an accepted method for the transfer of corneal tissue to different medium or storage chamber.

Materials needed:

Sterile Supplies

Sterile forceps 2X3
Class 100 Hood or Class II or Class III Biosafety Cabinet or Operating Room
Tissue in medium
Vial of sterile corneal tissue preservation medium or chamber
Sterile moisture impermeable drape
Sterile scrub brush for hands
Sterile towel to dry hands
Sterile gown or sterile sleeves
Sterile gloves

Non-Sterile Supplies

Shrink seal
Label
Mask
Cap to cover hair
Protective eyewear
CDC recommended disinfectant

Procedure

1. Turn on laminar airflow of hood or biosafety cabinet and allow to run according to manufacturers' specifications prior to use.
2. Wipe down work surface of hood or cabinet with disinfectant and allow to air dry per procedure E1.220.
3. Open sterile moisture impermeable drape on work surface of hood or cabinet.
4. Remove tissue stored in tissue culture medium from refrigerator and set under hood next to drape. Place next to this either a fresh unused open vial of medium or drop a sterile chamber onto sterile field.
5. If transferring to different medium, also drop sterile forceps onto sterile field.
6. Don mask and cap to cover hair, scrub and don sterile gloves.

Rationale

3. To set up a sterile field.

7. Using forceps, carefully and gently grasp the cornea by the scleral rim and transfer to fresh vial containing medium. Culture the tissue and/or old medium if this is your eye bank's policy. Or, gently pour in a single motion, the tissue and medium from existing vial to sterile corneal storage viewing chamber (CSVC). Be sure to keep the endothelial side up.
8. Record the transfer date, time, technician's initials and type of medium transferring from and to on your eye bank's form as indicated.
9. Wipe down the work surface of the hood or cabinet with a disinfectant solution immediately after use and allow it to air dry. Document these cleaning procedures according to your eye bank's Policies and Procedures.

7. Avoid contamination of tissue or damage to the corneal endothelium during this step.
8. This is particularly important if transferring from Optisol to MK, etc., which is essential information for tissue used for refractive keratoplasty (epikeratoplasty.)

F1.000 Tissue Evaluation

F1.100 Gross Examination In Vivo

Purpose:

To describe the technique of gross examination of ocular tissue prior to removal from the donor.

Materials needed:

Sterile ophthalmic irrigating solution such as normal saline
Non-sterile gloves
Personal protective equipment
Pen
Pen light
Portable slit lamp (optional)
Donor information form

Procedure	Rationale
1. Don Personal Protective Equipment.	1. Adhere to Universal Precautions and protect tissue from contamination.
2. Irrigate each eye with sterile ophthalmic solution.	2. Irrigation will wash away any particulate matter on epithelial surface.
3. Illuminate each eye obliquely with a pen light prior to prepping donor.	3. Many corneal defects can be observed upon gross examination with proper lighting at the right angle.
4. Examine the face, eyelids, cornea, sclera and conjunctiva.	
5. Note any abrasions, infiltrates, foreign bodies, opacities, scars, epithelial defects, presence of intra ocular lens, prior surgeries or other defects. Note any sclera discoloration, i.e. jaundice (icterus), or defects; eyelid or conjunctival abnormalities such as edema, trauma or foreign bodies; abnormal pupil or iris shape or color. Examine eye for symmetry, shape, curvature or other abnormalities.	5. Presence of extensive defects may determine whether the corneal tissue should be removed, particularly if it is not suitable for surgical or other use.
6. Record information on the appropriate form.	

F1.200 Slit Lamp Examination In Vitro

Purpose

To delineate the procedure for slit lamp biomicroscopy of corneal tissue in the laboratory.

Definition of terms:

Arcus senilis: An opaque, grayish ring at the periphery of the cornea caused by deposits of lipids

Bowman's membrane: The anterior elastic or limiting membrane of the cornea

Condition of anterior chamber: Formed, shallow, flat, or evidence of blood

Cornea: Clear transparent anterior portion of the outer coat of eyeball forming front of aqueous chamber

Corneal edema: Haziness caused by excessive hydration of the cornea

Keratic Precipitates: Inflammatory cells found on the endothelium

Descemet's membrane: An elastic basement membrane produced by the delicate layer of endothelial cells that line the inner cornea

Endothelium: A flat, monolayer of cells lining the inner surface of the cornea

Epithelium: The outermost anterior multi-cell layer of the cornea

Epithelial defects: Breaks or disruption of the epithelial surface caused by drying, erosion, sloughing, tears or abrasion

Folds: Striations due to wrinkling of Descemet's membrane from excessive hydration, an extended period from time of death to time of procurement, or traumatic stretching of the cornea during removal

Guttata: Dark, drop-shaped changes appearing on the corneal endothelium

Polymegathism: Variations in endothelial cell size with some cells appearing larger than normal

Pleomorphism (or polymorphic): Having multiple (two or more) forms or shapes of endothelial cells

Slit lamp biomicroscope: A binocular microscope with varying magnification settings attached to a light source with varying intensity settings

Stretch striae: Evidence of corneal endothelial stretching that appears as a streak or a line in a linear fashion

Stromal infiltrates: Abnormal accumulation of cells and fluid in the corneal stroma

Specular microscope: A monocular microscope with an illumination of light directed through a series of prisms or mirrors through the optical lens onto the corneal endothelium

Materials needed:

Slit lamp biomicroscope

Utility clamp or other appropriate device to hold the ocular tissue

Sterile Cotton-tipped applicators

Sterile ophthalmic irrigating solution

Sterile gloves

Alcohol prep pads

Mask and cap

Rating scale

Forms for documentation

Tissue in containers

Procedure

1. Allow the eye or cornea to reach normal room temperature. Avoid multiple repeated warming/cooling cycles.
2. Don mask, cap, sterile gloves, protective clothing and protective eye wear when examining the whole eye.

Rationale

1. In order to obtain an accurate evaluation of the corneal endothelium.

3. Remove eye jar lid and place it so that the inside of the cap is facing up in a clean area such as the hood or biosafety cabinet.
4. Remove any excess liquid from eye jar.
5. Insert eye jar, vial, or corneal storage viewing chamber into utility clamp or other appropriate device.
6. Using sterile cotton-tipped applicators, gently manipulate eye cage, if one is used, to bring cornea within viewing range of slit lamp. Sterile forceps or hemostats can also be used instead of cotton-tipped applicators.
7. For whole globe evaluation, moisten the eye with sterile ophthalmic irrigating solution as necessary.

For a preserved corneal evaluation DO NOT OPEN the storage container.

8. Perform a low power examination first at 10 X magnification when evaluating an eye/cornea for the first time.
9. Diffuse illumination of the cornea is done with a wide slit of light directed on the cornea at approximately a 15° to 20° angle of incidence and then moved to scan the entire cornea.
10. Next perform direct focal illumination using high power examination to perform an in-depth evaluation of the cornea. Adjust the width of the beam; a narrower slit beam will allow more in-depth examination and detail. With specular reflection you can observe the endothelium, cell morphology, dark areas, and areas where the cells are absent.
11. Make notations on the donor information form regarding the evaluation and what was observed during initial evaluation.
12. Record and diagram any abnormalities present regarding epithelium, stroma, and endothelium. Bowman's layer and Descemet's membrane are not necessarily visible with slit lamp examination.
13. Evaluate and record the minimum information below:

A. Corneal clarity, noting any scars, edema, or significant arcus that would reduce the optical clear zone needed by the transplanting surgeon

3. Prevents contamination of ocular tissue when lid is returned to eye jar.
4. Minimizes leakage on slit lamp biomicroscope and work area while evaluating.
5. This secures the ocular tissue while performing the evaluation.
6. The contents of the eye jar are assumed to be sterile. Using sterile instruments during examination will ensure sterility is maintained.

7. This prevents excessive drying and possible contamination of corneal epithelium.

Prevents contamination of cornea in media.

8. This gives orientation and location and entire view of cornea and eye simultaneously.
9. To properly evaluate and see endothelium, the angles indicated must be observed.
10. Corneal endothelium is a good indicator of the quality of ocular tissue. Anything other than normal hexagonal shaped cells should be noted and documented.

11. After preserving ocular tissue, the initial evaluation may differ from final evaluation.

12. It is important to record quality of ocular tissue when determining whether it is suitable for surgery.

- B. Folds or striae, noting severity.
 - C. Presence or absence of epithelial defects, and amount
 - D. Presence or absence of guttata change and amount
 - E. Presence or absence of stretch striae
 - F. Presence or absence of polymegathism or pleomorphism and amount
 - G. Evidence of any technical problems in removal
 - H. Presence of any infiltrates or foreign bodies
14. Assign a rating to the ocular tissue, such as excellent, very good, etc., according to your eye bank's policy and rating scale. The classification used in the rating scale should be defined in the eye bank's procedure manual.
15. Repeat the evaluation of the cornea following the lab excision. May also repeat slit lamp evaluation prior to tissue distribution.

14. Slit lamp evaluation of the cornea following removal from the eye and placement into tissue culture medium is mandatory and must be performed and recorded. See EBAA Medical Standards section F1.200.
15. Document both pre- and post-excision slit lamp examinations of tissue intended for transplant.

F1.300 Specular Microscopy

Purpose:

To describe the examination of donor corneas using specular microscopy, if performed.

Definition of terms:

Folds: Striations due to wrinkling of Descemet's membrane from excessive hydration or traumatic stretching of the cornea during removal.

Guttata: Dark, drop-shaped areas or excrescences on the surface of the corneal endothelium

Keratic precipitates: Cells that appear in response to an inflammatory condition, and which appear as small particulate matter on endothelial surface

Polymegathism: Variations in endothelial cell size with some cells appearing larger than normal

Pleomorphism (or polymorphic): Having multiple (two or more) forms or shapes of endothelial cells

Specular microscopy: A technique by which illumination of light is directed through a series of prisms or mirrors through the optical lens into the donor cornea. The light that is reflected from the endothelium is used to visualize the corneal endothelium.

Endothelial cell density: The average calculated number of endothelial cells per square millimeter.

Endothelial Striae: Evidence of endothelial stretching that appears as a streak or a line on the endothelium.

Materials needed:

Specular microscope configured for eye banking with image capturing capability, such as a camera with film or a video cassette recorder or computer with adequate backup.

TV monitor

Polaroid 600 film and camera with filter

Labeled corneal tissue in storage viewing chamber containing medium with intact shrink seal

Option: Computer-based specular microscopy system with adequate backup.

Set up:

The labeled viewing chamber or medical vial containing the medium and cornea with intact shrink seal is placed in the holding well of the specular microscope. The light source is turned on. Ensure that the image recording system is ready for use. Follow the manufacturer's recommended procedures for set-up, maintenance, calibration and operation for the particular specular microscope system in use. Document initial setup of system and keep a log of calibrations, cleanings and repairs.

Procedure

1. Allow cornea to reach normal room temperature. The most optimal evaluation and cell count may be obtained as soon as possible following excision of the cornea.
2. Position chamber in holding well of microscope. With the adjustment knob of the microscope, lower the magnifying lens until it *almost* touches viewing chamber. **Caution:** Do not allow lens to touch surface of viewing chamber; this may scratch the lens.
3. Begin slowly raising the magnifying lens with knob until cells come into focus; scan areas of the cornea for the brightest reflection of light.

Rationale

1. This will allow an accurate evaluation of the endothelium and a clear picture of cell membranes.
2. Basic laboratory technique should be observed at all times when using any type of microscope.
3. If cells are not visible at first, scanning for bright lights can put you in a better position for illumination of cells.

4. Once cells come into focus, a cell count is obtained and measured by cells/square mm. (It is up to the individual eye bank's medical director to determine acceptable cell densities.)
5. Include pertinent donor data, such as age, sex, eye bank tissue number, cause of death, time of death, time of preservation, and cell density.
6. After obtaining specular micrographs, the ocular tissue should immediately be returned to the refrigerator.
7. Record the specular microscopic evaluation according to your eye bank's policy on the ocular tissue information form.

4. Cell density for transplantable corneas may be established by the individual eye bank's medical director.
5. A specular photograph can help assure the surgeon of the ocular tissue's quality.
6. Ocular tissue preserved in corneal storage medium and maintained at optimal temperature will enhance cell viability.

G1.000 Quality Assurance

Purpose:

To outline the steps for an eye bank's quality assurance plan and required EBAA quality control measures in order to provide uniformly safe, high quality eye tissue for surgical use.

Definition of terms:

Review: An indicator may measure a result or outcome that is desirable or undesirable.

Indicators: A flag that identifies or directs attention to specific performance issues that need more intense review.

Quality Assurance: A continual process for monitoring and evaluating activities, the identification of problems, development and implementation of corrective actions, and specific procedures or practices which prevent recurrence of errors or accidents.

Materials needed:

Your eye bank's policy and procedure on quality assurance
Quality control forms for monitoring and record keeping

Procedure	Rationale
1. Assign responsibility for your eye bank's quality assurance program to a responsible individual within your organization. Medical directors and/or executive directors are responsible overall, while another technical staff member(s) will be assigned specific monitoring and follow-up activities.	1. Eye bank medical directors and executive directors are ultimately responsible for all delegated quality assurance activities.
2. Define the scope of service for your eye bank. This will depend on the missions of your organization and other factors such as whether you procure bone and other tissue, provide professional education programs, etc. Scope of service for an eye bank may include the following:	2. These are meant to serve as examples and are not all-inclusive.
A. Suitable eye donors will be identified and ocular tissue recovered according to established criteria and protocol.	
B. Ocular tissue will be distributed to surgeons, dentists, and institutions requesting tissue according to EBAA Medical Standards.	
C. Eye bank technical staff will routinely offer the opportunity for eye donation to next-of-kin, according to eye bank policy and procedure.	
D. The eye bank will provide public and professional education according to its written policy.	

3. The executive director, medical director, and other designated individual responsible for quality assurance must identify those aspects of the eye bank's operation or service that are particularly critical to the overall functioning of the bank, that are important to avoid a potential adverse outcome, or are high-volume activities. For example, laboratory maintenance and cleaning procedures and refrigerator temperature monitoring are important for functioning of the laboratory and EBAA certification. Contaminated ocular tissue that results in a serious postoperative infection is a serious adverse outcome. Completion of donor and recipient records is another critical high volume activity.

4. Next, identify appropriate indicators that will flag or direct attention to specific areas requiring more intense review and follow-up.

A rate-based indicator measures the frequency of an event that may require further review if the rate exceeds predetermined thresholds. Indicators may measure outcome (what happens as a result of an action taken), or the process involved in arriving at an outcome, and may be a desirable or undesirable endpoint. An adverse reaction would be an undesirable outcome indicator.

5. Rates or thresholds must be determined for each identified indicator. These are based on EBAA Medical Standards and findings reported in the medical and eye banking literature. For example, EBAA Medical Standards requires that all donor tissue for surgical use be tested and found non-reactive for HIV 1/2-antibody prior to distribution. Using completion of eye bank records as another example, you may determine that records should be fully completed 100% of the time. A retrospective review of all records for one month would provide data on how frequently records are found incomplete. The rate of occurrence may be determined by the following formula:

Number of records that were incomplete "divided by" total number of records reviewed x 100 = the percent or occurrence of incomplete records.

6. The executive director and technical supervisor or other designated individuals must decide how to collect and organize the data from quality assurance activities, e.g. a checklist of information required in a donor's packet. This checklist should be the coversheet of the packet.

3. Regulatory standards, such as the EBAA Medical Standards establish minimum expectations.

4. For example, a sentinel indicator, such as a reported adverse reaction which is an EBAA Medical Standards requirement, measures a serious, undesirable, often unavoidable outcome. Adverse reaction events are usually infrequent, but are of a sufficiently serious nature that a thorough investigation must be conducted for each and every occurrence.

5. EBAA Medical Standards require a 100% compliance rate or threshold.

The rate of occurrence is compared against the predetermined threshold. If the rate of record completion is found to be 80%, and it was determined that the threshold for compliance should actually be 100% then this would signal a problem requiring corrective action.

7. The collected data must be periodically reviewed and evaluated by the executive director, medical director, technical director, or other appropriate individual.
8. Any corrective action taken based on data analysis and evaluation must be documented, per EBAA Medical Standards. Actions taken may include:
 - A. Revision of an eye bank's policy and procedure in the identified problem area.
 - B. Provision of education programs to staff, when deficiencies are identified.
 - C. Disciplinary action for the staff members involved.
9. Assess corrective action taken and document whether or not it was effective in correcting a problem or deficiency, and preventing its recurrence.

Documentation of this action should be retained as an occurrence in an incident log.

10. The information gathered and any corrective action taken should be communicated to all staff and medical director(s).
11. The entire quality assurance program for your eye bank must be documented in your eye bank procedures manual. This documentation should be specific as to indicators, thresholds, and procedures for corrective action.
12. EBAA required quality control procedures are detailed below.

Quality Control Procedures required according to EBAA Medical Standards include but are not limited to the following:

- | | |
|---|-------------------|
| A. Laboratory and equipment cleaning | C3.100 and C3.200 |
| B. Equipment maintenance | C3.200 |
| C. Instrument cleaning and maintenance | C3.300 |
| D. Refrigerator temperature monitoring | C3.200 |
| E. Technical staff performance review, i.e., records of staff meetings and in-services provided | C2.000 |
| F. Tissue monitoring | |

7. This information serves as the basis for identifying the need for corrective action.
8. These are only a few examples of corrective action.

See EBAA Medical Standards sections as listed below:

- | |
|-------------------|
| C3.100 and C3.200 |
| C3.200 |
| C3.300 |
| C3.200 |
| C2.000 |

- | | |
|---|---------------|
| 1) Adverse reaction reporting | G1.000 |
| 2) Serologic testing | G1.220-G1.290 |
| 3) Microbiologic culturing | G1.210 |
| 4) Recipient follow-up | M1.500 |
| G. Infection control and safety procedures | C3.600 |
| H. Donor screening procedures | D1.000 |
| I. Ocular tissue distribution procedures and review of donor medical history. | K1.100, |
13. Documentation of the eye bank's quality assurance program must be maintained for a minimum of 10 years. This includes any corrective or remedial action taken for detected deficiencies. This includes deficiencies discovered by accrediting or regulatory agencies.
14. The above documentation must be made available for review at the time of an accreditation inspection.

G1.100 Quality Control

Purpose:

To establish a policy and procedure for measuring, assaying, or monitoring properties of tissue.

Procedure

1. The director will be responsible for ensuring that tests and procedures are in place for measuring, assessing, or monitoring essential properties of tissues to ensure their safety for transplantation.
2. These tests and procedures must be performed, documented and reviewed prior to release of tissue for transplant.
3. Results of all such tests or procedures shall become part of the permanent record of all tissues processed.

Rationale

1. To ensure that the facility is following its policies and procedures.

G1.200 Testing

Purpose:

To ensure that facilities that are performing their own microbiologic and/or serologic testing conform to state and federal regulations.

Procedure

Microbiologic

1. The director will be responsible for ensuring that the eye bank meets all applicable accreditation requirements established under the Clinical Improvement Act (CLIA), as well as any state regulations.
2. Documentation of accreditation, verification of satisfactory compliance with a College of American Pathologists (CAP) Proficiency Testing Program, or other proficiency-testing program approved by CLIA, shall be available at time of site inspection.

Serologic

1. The Director will be responsible for ensuring that the eye bank meets all applicable accreditation requirements established under the Clinical Laboratories Improvement Act (CLIA), as well as any state regulations.
2. Documentation of accreditation, verification of College of American Pathologists (CAP) Proficiency Testing Program, or other proficiency program approved by CLIA, shall be available at the time of site inspection.
3. Copies of the test kit manufacturer's guidelines must be kept on file.

Rationale

Microbiologic

1. To ensure compliance with CLIA.

Serologic

1. To ensure compliance with CLIA.

G1.210 Microbiologic Culturing

Purpose:

To describe techniques for culturing donor ocular tissue prior to surgical use.

Definition of terms:

Aerobes: Microorganisms that require the presence of oxygen for survival.

Anaerobes: Microorganisms that thrive or grow in the absence of oxygen.

Spores: Inactive forms of microorganisms. They are resistant to destructive methods, and may become active under favorable conditions.

Materials needed:

Your eye bank's policy and procedure on culturing ocular tissue

Culturette tubes

Sterile cotton-tipped applicators

Aerobic medium, e.g., blood agar plates

Anaerobic medium, e.g., thioglycolate broth tubes or trypticase soy broth

Incubator

Requisition forms

Procedure

1. The eye bank's policy and procedure manual must include one of the following options regarding culturing of donor ocular tissue.
 - A. No ocular tissue cultures are performed by the eye bank.
 - B. Corneoscleral rim cultures are performed using aerobic and anaerobic culturette tubes which are then submitted to a College of American Pathologists (CAP) approved laboratory for bacterial identification and antimicrobial susceptibility testing.
 - C. Corneoscleral rim cultures are performed using aerobic agar plates or broth and anaerobic broth tubes which are then incubated to permit growth.
2. Include a statement recommending culturing at the time of surgical use on the ocular tissue label, package insert form, or other form that accompanies the ocular tissue sent to the surgeon.
3. If an eye bank elects to perform cultures of the donor ocular tissue, refer to your eye bank's protocol.

Rationale

1. See EBAA Medical Standard G1.210. This applies to sclera as well as corneal tissue.
 - C. Eye banks which perform bacterial identification and antimicrobial susceptibility testing must participate in a CAP approved bacteriology proficiency testing program and be capable of reviewing gram stain slide preparations to assure the consistent reporting of accurate results.
2. See EBAA Medical Standards section G1.210. This statement is required regardless of whether the eye bank performs the cultures.

4. Use culturette tubes or swabs to collect swab cultures.
5. Complete necessary information on requisition form to be submitted with the specimen. Request both anaerobic and aerobic cultures according to your eye bank's policy.
6. Set up sterile field and begin corneoscleral rim excision as usual.
7. Take swab cultures before antibiotic drops are instilled.
8. Take cultures at the time of corneal excision, whether in situ or laboratory. Cultures of the conjunctival sac are not recommended, since previously reported studies have shown that almost all donor eyes will be culture positive.
9. Take cultures of the incision site prior to separation, or of the aqueous or sclera at the limbus. Or a piece of sclera may be removed and placed in trypticase soy broth.
10. Using aseptic technique, swab the incision site. If the culturette option is used, the swab should then be inserted into the culturette tube. If the cotton-tipped applicator option is used, one applicator may then be smeared on an agar plate followed by insertion into an aerobic broth tube and another inserted into an anaerobic broth tube. These steps should be performed on both eyes.
11. Label the specimen tubes with unique donor identification number, date and time.
12. Submit specimen to a laboratory or incubate in the eye bank's incubator to observe for presence or absence of growth. If growth is observed, submit to a laboratory for identification of organism.
13. Record results in donor case record. Attach hard copy to the donor record.
14. If results are positive, notify the receiving surgeon immediately. Antibiotic susceptibility testing may be useful information to the surgeon. Record this notification.
15. Request that all surgeons who receive ocular tissue report any cases of postoperative infection with a positive corneoscleral rim culture.

8. See reference list.

12. See step 1-B above.

14. See EBAA Medical Standard G1.210.A.

15. See EBAA Medical Standard G1.210.B.

G1.220 Serologic Testing

Purpose:

To outline the serologic tests required by the EBAA before ocular tissue can be released for surgical use.

Materials Needed:

Sample of the donor's blood appropriately labeled
Completed requisition form with donor identification number and request for specific tests
College of American Pathologists' approved and CLIA certified laboratory

Procedure

1. Verify the IV infusion/transfusion status of the donor to determine if a preinfusion sample is necessary.
2. Label tube with donor identification number, date, time of draw and any other required information
3. Draw the donor's blood. Avoid hemolysis as indicated in procedure E1.700.
4. Complete requisition form to accompany the blood sample to the laboratory.
5. Submit sample to a laboratory for testing. If the eye bank perform its own tests, it must provide documentation of satisfactory compliance with a CAP proficiency-testing program.
6. The EBAA requires that all ocular tissue for surgical use be tested and found non-reactive, using an FDA approved test methodology, for the following:
 - A. HIV-1 antibody
 - B. HIV-2 antibody
 - C. Hepatitis B surface antigen
 - D. Hepatitis C antibody
7. Screening for HTLV-I or II and syphilis is not required. If lab results of non-required tests for infectious disease are reported to the eye bank they must be taken into account and/or acted upon by the medical director.
8. For screening tests where a supplemental test may be run, the eye bank must have a written policy regarding the circumstances under which

Rationale

1. See EBAA Medical Standards section G1.220.
6. See EBAA Medical Standards section listed below:
 - A. Section G1.230
 - B. Section G1.230
 - C. Section G1.240
 - D. Section G1.250
7. See EBAA Medical Standards section G1.260-G1.290
8. If non-reactive supplemental test results such as RIBA for HCV-antibody are used to release tissue for transplantation, the eye bank must

ocular tissue will be released for surgical use.

9. Negative screening test results shall be reviewed and documented as negative prior to release of tissue for transplantation.
10. The eye bank must retain a copy of the laboratory's official serologic report. File the hard copy results with the donor record.

G1.230 HIV Screening

Purpose:

To establish requirements for HIV serologic screening.

Procedure

1. The eye bank will complete HIV serologic screening using and FDA approved test kit for HIV 1 & 2 on all donors of surgically designated tissue.
2. The sample tested must be an adequate sample.
3. The testing must be performed by an accredited lab, e.g. CLIA.
4. A negative screening test must be documented, and a hard copy received at the eye bank, prior to tissue release.
5. If the screening test is repeatedly reactive, the tissue cannot be used for transplant even if neutralization or confirmatory tests are negative.

G1.240 Hepatitis B Screening

Purpose:

To establish requirements for Hepatitis B Surface Antigen serologic screening

Procedure

1. The eye bank will complete Hepatitis B Surface Antigen serologic screening using and FDA approved test kit on all donors of surgically designated tissue.
2. The sample tested must be an adequate sample.
3. The testing must be performed by an accredited lab, e.g., CLIA.

have a specific written policy for this.

9. To ensure that the ocular tissue will not inadvertently be transplanted prior to receipt of non-reactive serology.

Rationale

1. To perform required serologic screening.

Rationale

1. To perform required serologic screening.

4. A negative screening test must be documented, and a hard copy received at the eye bank, prior to tissue release.
5. If the screening test is repeat reactive, the tissue cannot be used for transplant even if neutralization or confirmatory tests are negative.

G1.250 Hepatitis C Screening

Purpose:

To establish requirements for Hepatitis C serologic screening.

Procedure	Rationale
1. The eye bank will complete Hepatitis C serologic screening using an FDA approved test kit on all donors of surgically designated tissue.	1. To perform required serologic screening.
2. The sample tested must be an adequate sample.	
3. The testing must be performed by an accredited lab, e.g., CLIA.	
4. A negative screening test must be documented, and a hard copy received at the eye bank, prior to tissue release.	
5. If the screening test is repeatedly reactive, the tissue cannot be used for transplant even if neutralization or confirmatory tests are negative.	

G1.280 Non-Required Laboratory Results

Purpose:

To establish requirements on non-required laboratory results.

Procedure	Rationale
1. The eye bank's Medical Director will be responsible for taking into account and/or acting upon non-required test results on tissue for transplantation.	1. Other tissue donation and/or state regulation may require serologic testing that is not required by the EBAA.

G1.290 Conflicting Serology Tests

Policy:

Conflicting serologic and positive non-required test results that may be indicative of risk for HIV or hepatitis will be reported to the EBAA, Medical Director and to any recipient surgeons for further follow up. Report must be made to EBAA within sixty days of receipt of discordant or positive test results. Additionally, positive serological results would be reported back to other associated agencies.

Procedure	Rationale
1. Positive serologic results on any eye donors will be copied and sent to affiliated organizations such as OPOs or tissue bank if involved with the same donor.	1. Refer to EBAA Medical Standard G1.290.
2. Eye banks sharing donors with affiliated organizations should establish a protocol to receive positive serology results from those affiliated organizations.	
Discordant serology results will be reported to the EBAA.	
3. Any tissue that has been transplanted from donors with conflicting and/or positive serology [HIV 1/2 or Hepatitis] results will necessitate notifying the transplanting surgeon of the conflicting and/or positive serology results, as well as any findings from the quality assurance review process, which may help to identify confounding factors or data associated with sample collection, handling, storage, and testing.	
4. Follow up with specific recipients will be at the discretion of the transplanting surgeon.	
5. If possible, confirmatory tests will be run if any tissue has been transplanted.	
6. Any tissue in stock from donors with conflicting serology results will be quarantined and discarded.	
7. A completed Donor Discordant Serologic Test Report will be sent to the EBAA within sixty days of the receipt of the results.	

H1.000 Non-Surgical Donor Tissue

Purpose:

To outline the procedure for handling donor eye tissue distributed for non-surgical purposes.

Definition of terms:

Screening or Screening Tests: Laboratory tests, licensed by the FDA, which rule out the presence of infectious disease such as AIDS and hepatitis B and C.

Procedure	Rationale
1. Label the ocular tissue in the usual manner with source eye bank, donor identification number, etc.	1. See procedure J1.000.
2. HIV 1/2, hepatitis B and C screening are not required by EBAA for non-surgical donor eye tissue.	2. See EBAA Medical Standards section H1.000.
3. If HIV 1/2, hepatitis B and C screening are not performed, the donor tissue must be labeled with a red or orange biohazardous symbol and statements indicating the tissue has not been tested and the tissue is potentially hazardous biological material, or some other designation acceptable by CDC guidelines	3. The label will alert the person receiving the ocular tissue to exercise infectious disease precautions.
4. Attach the label to the container, i.e., jar, vial, or viewing chamber in a prominent place. The label should be bright orange or red.	4. The label will alert the person receiving the ocular tissue to exercise infectious disease precautions.
5. The ocular tissue should be appropriately stored according to its method of preservation.	5. Consult your eye bank's policy for storage of non-surgical tissue.
6. Distribute the ocular tissue according to your eye bank's policy and procedure.	
7. Distribution records should be kept and a donor ocular tissue information form should accompany the tissue.	

11.000 Storage

Purpose:

To delineate the conditions under which donor eye tissue is to be maintained and stored.

Definition of terms:

Asepsis: To keep free from bacterial contamination.

Potentially hazardous biological material: Any donor tissue that has not been screened for infectious disease.

Quarantine: To isolate tissue until infectious disease screening is completed.

Screening or Screening Tests: Laboratory tests, approved by the FDA, which rule out disease such as AIDS, hepatitis B and hepatitis C.

Materials needed:

Sterile container, e.g., vial or jar

Preservation or storage solutions for the particular type of tissue

Refrigerator with temperature recording device, backup power supply or alarm system.

Procedure

1. Surgical eye tissue (whole globe, corneas or sclera) is preserved in a manner appropriate for use of the ocular tissue. Research tissue should be maintained according to your eye bank's protocol.
2. Maintain the temperature of the eye tissue according to EBAA requirements. The ocular tissue must be stored in a refrigerator with a continuous temperature-recording device and visible without opening the refrigerator. Refer to section C3.200 of this manual.
3. Store all ocular tissue aseptically in separate vials or jars. Asepsis is to be maintained throughout the storage of the donor eye tissue.
4. Quarantine all ocular tissue until the results of HIV 1/2, HBsAg, and HCV testing have been reported as non-reactive and a hard copy of the results have been received and recorded. If any other screening tests are performed, they must also be considered before any ocular tissue can be released from quarantine.
5. Ocular tissue is to be quarantined by designating an area within the refrigerator that is labeled "Quarantined".
6. A second area is to be designated for ocular tissue for which all serologic testing is non-reactive and where all donor screening has been completed (for example Medical/Social History

Rationale

1. To maximize the potential for a successful surgical procedure by preserving the integrity of the ocular tissue.
2. The temperature must be maintained within stipulated limits in order to ensure optimal viability of the ocular tissue.
3. Asepsis must be maintained to prevent contamination of the ocular tissue.
4. Quarantine assures that "potentially hazardous material" is not released for surgical use.
5. A designated "quarantine area" ensures that ocular tissue is not distributed until all testing is completed and suitable determination has been made.
6. This designated "transplant tissue" area further ensures complete separation of transplantable and quarantine tissue to minimize the likelihood of accidental distribution of quarantine tissue that

screening, obtaining gross autopsy results). This area may be termed "Transplant Tissue" or "Non-Reactive Serology". Tissue in this area must have documentation completed in the donor record to indicate that the Medical Director or designee has released the tissue for transplant.

7. Move surgical ocular tissue for which the blood screening had been completed and the results are non-reactive to the transplant area only after a hard copy or results of serology have been received and all other required screening procedures have also been completed. The donor record must be reviewed and tissue "released" for transplant must be noted prior to placing tissue in the "Transplantable" area. Only ocular tissue that has been removed from quarantine can be distributed for surgical use.
8. Ocular tissue for which the serologic testing has been completed and has been reported as "reactive" or positive is to remain in quarantine until repeat testing is completed according to the individual eye bank's policy.
9. Ocular tissue that is repeatedly positive or reactive for any one of the serologic tests performed is to be removed from the refrigerator and discarded according to section C2.400 of this manual and the policy of the individual eye bank.
10. Research ocular tissue, whether tested or untested, should be stored in your eye bank's refrigerator in an area labeled "Research Tissue". Untested research tissue must have an additional biohazardous legend label affixed.

has not been released for surgical use.

7. Assures that the ocular tissue is safe to release for surgery. Preliminary hard copy results may be faxed to the eye bank by the laboratory.
8. To prevent the release of "potentially hazardous" ocular tissue for surgery.
9. Biohazardous material must be disposed of quickly and safely.
10. See procedure H1.000.

J1.000 Labeling

Purpose:

To delineate the EBAA procedure for labeling of ocular tissue from time of procurement through time of distribution for surgical use, research, and teaching.

Definition of terms:

Intermediate or temporary label: A temporary label applied at time of procurement to identify the ocular tissue until a permanent label can be affixed.

Permanent label: The final label for all ocular tissue distributed by an eye bank.

Materials needed:

Temporary or intermediate label: Masking tape, sterilization indicator tape or other tape on which you can write.

Pen

Permanent label: Your eye bank's label with preprinted information

Pen, typewriter, or word processor

Procedure

1. Each ocular tissue must be in a labeled container with a unique identification at all times.
2. Write the donor's identification number, name, or other unique identifier with the date and time of procurement and whether right or left eye on a piece of masking tape or other adhesive backed plain paper. Also include the name of the technician or enucleator.
3. Once the ocular tissue has been transported back to the laboratory for final processing and disposition, determine the type of final or permanent label that the ocular tissue will require. This will depend on whether the ocular tissue will be used for corneal transplantation, sclera for surgical use, whole globes for lamellar keratoplasty, research or teaching, or whether the ocular tissue will be disposed of.
4. All ocular tissue for surgical use, including corneas, sclera, and whole eyes, shall have a permanent label that conforms to EBAA Medical Standards. Preprinted labels are recommended, but not required. These labels shall include the following:
 - A. Name of source eye bank
 - B. Ocular tissue identification number unique to each tissue or fraction thereof.
 - C. Type of tissue.

Rationale

2. Intermediate or temporary labeling provides identification of the ocular tissue prior to final processing and application of a permanent label.
4. See EBAA Medical Standards section J1.000

- D. Date and time of donor's death
 - E. Date and time of ocular tissue preservation, e.g., cornea, sclera, or other.
 - F. Preservation date for scleral tissue and long-term preserved tissue.
 - G. The statement that the ocular tissue is intended for single application only. Also a statement that the ocular tissue is not considered sterile and reculturing is recommended.
 - H. A statement that the ocular tissue was tested and was non-reactive for HIV-1/2 antibody, hepatitis B surface antigen and hepatitis C antibody.
 - I. Type of preservation medium
5. If ocular tissue is provided for research and serologic screening is not performed, then a biohazardous legend label must be applied.
5. See EBAA Medical Standards section H1.000, which requires a statement alerting the receiver of this ocular tissue that this tissue is potentially hazardous biological material.

K1.000 Distribution of Tissue

Purpose:

To provide consistent criteria for the distribution of ocular tissue as a foundation for an individual eye bank's defined system of distribution and to ensure compliance with EBAA Medical Standards and with applicable state and federal regulations.

Definition of terms:

Distribution of ocular tissue: The allocation of ocular tissue to patients through surgeons or dentists.

Eye Bank: Individual EBAA certified eye bank carrying out distribution of eye tissue.

Tissue distribution system: The policies and procedures followed by an individual eye bank in distributing/allocating human donor eye tissue.

Materials needed:

Completed donor record that includes:

- Donor screening form
- Medical history, reviewed by medical director or designee
- Ocular tissue evaluation/rating
- Serology results
- Autopsy results (if performed)
- Culture results (if available)
- Any other relevant information
- Computer terminal or PC

Procedure for distribution as defined by each eye bank

List of professionals/institutions approved by the eye bank to receive ocular tissue

Eye bank forms to record distribution

Procedure	Rationale
1. Review distribution procedures established by your eye bank, as needed.	1. EBAA Medical Standards section K1.300 states that "Eye banks must establish and document a system of distribution". Ensures consistency in distribution practice.
2. Assemble needed materials and information as listed above.	2. Availability of materials facilitates efficient communication of needed information and minimizes potential errors.
3. Verify that the Medical Director or designee has reviewed the medical history and ocular evaluation. Document that the medical and laboratory information is in accordance with EBAA Medical Standards and state and federal regulations for each ocular tissue to be distributed.	3. EBAA Medical Standards section K1.100 states that "Medical director or his/her designee must review and document that the medical and laboratory information is in accordance with medical standards prior to the distribution of ocular tissue for transplantation". Standard D1.120 identifies contraindications for surgical use of ocular tissue. EBAA Medical Standards section F1.000 identifies methods for ocular tissue evaluation.
4. Identify potential receivers of ocular tissue according to eye bank procedures.	4. EBAA Medical Standards section K1.200 states that "tissue may be distributed to physicians,

5. Distribute ocular tissue, using the procedure established by the eye bank, which may be patient-based or surgeon-based.

6. The recommended order of priority is a) emergency request, b) eye bank service area, c) EBAA eye banks within region according to tissue sharing protocol, d) other EBAA eye banks, e) eye banks in other countries.

7. Offer ocular tissue to potential receiver, providing information to assist him/her to determine acceptability of the ocular tissue being offered, according to EBAA Medical Standards and individual eye bank procedures.

Record each offer of ocular tissue and outcome of offer.

8. Continue to offer ocular tissue for surgical use, according to eye bank procedure, until tissue has been placed or until time limits established by the eye bank for surgical use have expired.

9. If ocular tissue cannot be distributed for its original intended use, e.g., surgical use, follow eye bank procedure for distribution for alternative utilization, e.g., research or disposal.

dentists, institutions and other eye banks". Eye bank should maintain a list of persons and/or institutions eligible to receive ocular tissue from the individual eye bank.

5. EBAA Medical Standards section K1.300 states that "eye banks shall establish and document a system of distribution which is just, equitable and fair to all patients served by the eye bank. Access to ocular tissue shall be made without regard to recipient gender, age, religion, race, creed, color or national origin."

6. Bona fide emergency cases take precedence over scheduled elective or waiting list cases. Emergencies include corneal perforations or lacerations, acute corneal infections, and corneal/scleral "melts".

7. Sufficient information on donor medical history (e.g., age, time, cause of death, ventilator time, relevant health conditions, lab results), tissue characteristics (e.g., tissue evaluation, cultures done and results, if available) and procurement information (e.g., procedure, death to preservation time, tissue culture medium) to enable the receiving surgeon to make an informed decision about accepting the tissue.

EBAA Medical Standards section F1.000 states that "the ultimate responsibility for determining the suitability of the tissue for transplantation rests with the transplanting surgeon".

8. Consideration should be given to how long it takes the ocular tissue to reach its destination and whether it would still be suitable for its original intended use. Long distances or prolonged travel times may increase the time interval beyond acceptance limits between death of the donor and preservation of the ocular tissue, to the time of grafting.

9. Each eye bank should establish and document a system for distribution of ocular tissue for research and training needs that meets EBAA Medical Standards for fairness, equity, and safety. (EBAA Medical Standards sections K1.000, H1.000)

Research Tissue: Requests for research tissue are filled in relation to specific research needs and protocols within the eye bank service area. Eye banks may communicate with agencies such as the Foundation for Glaucoma Research, Retinitis Pigmentosa Foundation, and National Disease Research Interchange (NDRI) to fulfill requests for ocular tissue for researchers

10. Record distribution according to eye bank procedure.

working in specialized areas.

Practice/Teaching Tissue: Requests are filled on an as needed basis from either fresh donor eye tissue or stored frozen specimens.

In some situations, research tissue may be released prior to obtaining a complete medical history due to the necessity of some biochemical studies being performed with 2 to 3 hours maximum of death. This ocular tissue should be distributed with a label indicating that is a potential biohazard, in accordance with section H1.000 of the EBAA Medical Standards.

10. EBAA Medical Standards section K1.300 specifies that documentation shall include: a) time and date of request for eye tissue, b) time and date of offers of eye tissue, and c) time and date of delivery of eye tissue.

Documentation of distribution shall be available for inspection by the EBAA Medical Standards Committee.

K1.400 Returned Tissue

Purpose

To outline the minimum information necessary to document the return of a cornea distributed for transplant.

Materials Needed:

Eye bank form to record storage and return information

Procedure	Rationale
1. Assemble the eye bank forms needed to document a return when a receiver of tissue notifies the eye bank of the need to return a cornea.	1. Documentation at the time of notification is an efficient method for obtaining the necessary information from a source that is familiar with the circumstances.
2. Record the method of transportation used to return the cornea to the eye bank including the method and condition of storage while the cornea was outside the eye bank.	2. EBAA Medical Standards section K1.400 states that "For corneas returned and redistributed, tissue transportation and storage information must be documented and made available to the eye bank and transplanting surgeon." Provides the eye bank with storage information critical to determining if the cornea is suitable for redistribution.
3. Examine tissue storage container's tamper evident seal and the condition of the tissue.	3. Check seal integrity to determine if tissue was opened prior to being returned. Additionally, evaluating the condition of the tissue after transportation is advised to determine tissue suitability.
4. Provide storage and transportation information to the potential receiver of ocular tissue if the cornea is offered for transplant again. The storage and transportation information must be retained in the eye bank records also.	4. Allows transplanting surgeon to have all the information to determine the suitability of the cornea for the intended patient.

K1.500 Tissue Recall

Purpose

To outline a procedure for issuing a tissue recall

Materials Needed:

Eye bank distribution Record
Eye bank donor record
Eye bank recall form

Procedure	Rationale
<ol style="list-style-type: none">1. When a tissue has been released for transplant and new information disqualifying the donor under the FDA Final Rule Human Tissue Intended for Transplantation 21 CFR Parts 16 and 1270, EBAA Medical Standards section D1.120, or the eye bank's policy and procedures becomes available, that tissue is considered unsuitable and some action must be taken for proper disposition.2. Review recall procedures established by your eye bank, as needed.3. Assemble needed materials and information as listed above.4. Further distribution of any remaining tissue from the disqualified donor should cease immediately. Destroy any remaining tissue or place in quarantine until such time as the recall can be lifted through correction.5. Review the eye bank records for the disposition of each tissue from the disqualified donor.6. Notify all parties who received tissue from the disqualified donor immediately. If the transplant has not occurred, cancel the surgery and make arrangements to have the tissue returned to the eye bank for destruction or quarantine.7. If the tissue has been used for transplant consult your Medical Director to develop a recall strategy.8. Notify the receiver or transplanting surgeon of the new information documenting the conversation in the eye bank donor records.	<ol style="list-style-type: none">1. Medical Standards section K1.500 states "Eye banks must have a policy and procedure for potential recall of tissue." FDA Recall Policies and Procedures 21 CFR Part 7 describes the guidelines for initiating a voluntary recall.

9. Send written notification of the recall to the receiver of ocular tissue. Written notification should be brief and to the point, clearly identify the tissue in question, as well as explain the reason for the recall and any potential hazards involved. Make a copy of the notification letter for the eye bank donor record.
10. The transplanting surgeon is responsible for determining patient therapy and course but may request consultation with the eye bank's Medical Director.
11. FDA requests eye banks notify their district office of any voluntary recall.

L1.000 Documentation to Accompany Donor Tissue

Purpose:

To describe the minimum information and forms which must accompany each piece of ocular tissue at the time of distribution.

Procedure

1. Identify the method used to enclose forms with your eye bank's tissue, at time of shipment, according to your eye bank's policy and procedure. This may be in an envelope placed within the transport container or in a plastic sleeve taped to the outside of the transport container. The method used should maintain confidentiality for the donor information.
2. A minimum of two types of information must accompany the properly labeled ocular tissue. These are the ocular tissue report form and the package insert form. A re-hydration procedure must be included as a package insert for all sclera preserved in alcohol.
3. Complete the forms fully and accurately prior to enclosure with the tissue.
4. Retain a copy of the ocular tissue report form for your eye bank's records. Be sure that you have retained a copy of the slit lamp and/or specular microscopic evaluation of the donor tissue.
5. Consult your eye bank's policy and procedure for any other forms that must be included with the shipment including packing list, recipient information form, blank adverse reaction form, purchase order, bill of lading, or invoice.

Rationale

2. See EBAA Medical Standards section L1.000 for information that must be included on the ocular tissue report and package insert forms.
4. See EBAA Medical Standards section M1.400 for information that must be retained by the eye bank.

L2.000 Packaging, Sealing and Packing for Transport

Purpose:

To outline the minimum requirements and procedures for packaging, sealing, and packing ocular tissue for transport to a hospital, surgeon, or eye bank.

Materials needed:

Ocular tissue for shipment in a labeled container
Tamper-evident shrink wrap or seal
Sealing device
Shipping container
Frozen water beginning to melt sealed in plastic Ziplock bag
Packing material, e.g., cardboard or foam insert to cradle ocular tissue vials inside shipping canister
Forms to accompany ocular tissue
Tape
Labels for outside of shipping container

Procedure	Rationale
1. Seal each ocular tissue (cornea, whole eye, sclera) in a container with a tamper-evident shrink seal. The seal shall not interfere with visual inspection of the ocular tissue for integrity and suitability for use.	1. To alert the receiver if any tampering of donor tissue occurred prior to receipt. See EBAA Medical Standards section L2.000.
2. Wrap each ocular tissue in a waterproof bag or sealable pouch prior to local distribution or shipment to another eye bank.	2. To prevent melted water from ice or coolant from wetting labels on ocular tissue container.
3. Absorbent material must surround each tissue so that if the storage container is broken, potentially biohazardous liquid/material will not leak from the shipping container.	3. To comply with federal standards for shipping known or potentially biohazardous materials.
4. Place cornea, whole eye, or research tissue in an appropriate transport case with coolant and cradled in a foam block for local distribution/delivery.	4. To maintain ocular tissue at proper temperature, cushion it to prevent breakage of ocular tissue container, and maintain container in an upright orientation.
5. For export to another eye bank or corneal surgeon via airline, bus, etc., place the ocular tissue in a waterproof bag/pouch in an appropriately insulated shipping container, and cushion with a foam block or other method. (Foam blocks may have custom-cut holes to firmly hold the tissue container.) The ocular tissue, container, and foam block shall be placed in an inner plastic bag with an appropriate coolant (wet ice is best). The plastic bag is sealed and placed in an eye bank shipping container. The shipping container is then closed and taped shut.	5. To maximize the vapor barrier function of the entire container assembly in order to maintain proper temperature and prevent leakage of melt water during shipment.

The use of "wet" or water ice should be distinguished from frozen ice or block ice that can decrease the temperature in the transport container to 0° C or lower, resulting in frozen ocular tissue.

6. Attach appropriate labels to the shipping container identifying the contents as "**Human Eye Tissue**", and listing the addressee/destination and source eye bank, including telephone numbers to be contacted if there is a delay or problem in transit.
 7. Attach on the outside or include on the inside package insert information. If placed inside, it must be sealed in a waterproof bag or pouch.
 8. Donor tissue for research with a known infectious agent, such as HIV, shall be packaged and labeled in accordance with Federal regulations for the shipment of biohazardous materials (see Appendix).
 9. Use a shipping container that will maintain donor tissue at a temperature between 2° to 6°C for a minimum of 24 hours for domestic shipment, and a minimum of 48 hours for international shipment.
 10. Each eye bank shall have a written procedure for packaging ocular tissue.
 11. Ocular tissue preserved in ethanol or glycerin, or fixed in formalin for histopathological study does not have to be refrigerated during shipment. (Glutaraldehyde fixatives do require refrigeration.)
7. See EBAA Medical Standards section L1.200.
 8. See EBAA Medical Standards section H1.000.

M1.050 Eye Bank Record Entry and Entry Correction

Purpose:

To describe recommended practice in recording eye donor information and a legally correct method of altering or changing an eye bank medical record entry.

Materials needed:

Black or blue pen
Record to be altered

Note: **White out must never be used**

Procedure

1. Use standard good practice when recording eye donor information.
 - A. Write neatly and legibly
 - B. Use proper spelling and grammar
 - C. Use black or blue pen
 - D. Use military time (24 hour clock)
 - E. Use authorized abbreviations only
 - F. Record information promptly
 - G. Do not leave blanks on forms
2. Use the following procedure to correct a mistaken entry:
 - A. Draw a single line through the incorrect entry using black or blue ink. Be sure the original entry is readable.
 - B. Write "mistaken entry" or "error" above or beside the original entry.
 - C. Place the date and the eye bank technician's initials next to the words "mistaken entry." Use "ME" as an abbreviation, if desired. Add this to your list of approved abbreviations.
 - D. Write in the appropriate information. Complete mistaken entry corrections as soon as possible after they are detected.
 - E. Chart in clear, concise, unambiguous terms.
3. Do not tamper with any existing eye bank record. Tampering includes:
 - A. Adding to an existing record by filling in the blanks.

Rationale

1. To avoid inaccurate or erroneous assumptions based on illegible record entries; to avoid confusion and misunderstanding. Black and blue ink shows up best when a record is photocopied.
2. Never attempt to cover up an error with white out or correction tape. This serves as a red flag in medical-legal situations should eye bank records be reviewed by an attorney.
 - A. Trying to recall details long after the fact is prone to inaccuracy due to memory lapses.

B. Rewriting a record. Never discard original notes and rewrite an entire record. Always retain the original page if you must rewrite notes. Indicate this on the rewritten pages.

C. Adding to another person's notes.

4. Eliminate bias from recorded entries. Avoid descriptive terms such as bad, good, etc. Chart objectively by describing specific observations, e.g., instead of saying tissue was rated as bad for transplantation, describe appearance in terms used in your corneal rating system.
5. Record all information you report to the medical director and his or her decision. Date and time this information.

B. Rewriting notes because of coffee stains for example may be interpreted to mean information was destroyed because it was damaging.

M1.550 Adverse Reaction Reporting

Purpose:

To outline the process for investigating and reporting an adverse reaction:

A reportable adverse reaction is any communicable or other disease transmissible by, and attributable to, transplantation of donor eye tissue, including infection (as manifested by endophthalmitis, keratitis, or systemic viral disease) and biologic dysfunction (such as immediate donor endothelial failure or donor corneal dystrophy).

Materials Needed:

Adverse Reaction Form

Procedure

1. Eye banks must have a mechanism in place for surgeons to report an adverse reaction following transplantation of ocular tissue. Postoperative adverse reactions must be reported immediately. Eye banks must seek recipient follow-up information concerning possible adverse reactions on all tissues distributed between three and twelve months postoperatively. A mailing to the transplanting surgeon requesting outcome data for a tissue referenced by its unique identification number is an appropriate mechanism. Diligent pursuit of information may be required.
2. An adverse reaction report will be completed by the distributing eye bank. The Eye Bank Association of America has created an appropriate reporting form for this use. The transplanting surgeon is asked to provide information about the recipient, type of adverse reaction, and microbiology cultures if performed. The eye bank must provide information concerning the donor tissue. The eye bank Medical Director is asked to make an assessment whether the adverse reaction probably was or was not due to donor tissue. Diligent pursuit of information may be necessary in order to collect data from multiple sources.
3. The completed Adverse Reaction Report will be copied and distributed to:
 - A. The procuring eye bank
 - B. The distributing eye bank, if different than the procuring eye bank
 - C. The EBAA.
 - D. Other parties affected, e.g., infectious

Rationale

1. Early referral of post-surgical complications allows remaining tissue from the donor to be scrutinized or recalled. Patients may develop an adverse reaction at some time other than the immediate postoperative period. These occurrences are thought to be under reported. A follow-up interaction requesting outcome data helps ensure industry trends are being tracked. See Medical Standard M1.500.
2. The form summarizes information allowing the EBAA to look for trends in practice that may a problem. Some information requested may be difficult to collect. Surgeons should be assured patient identification information will be treated anonymously.
3. Distribution of the Adverse Reaction Report to the affected parties allows for information to be gathered in the interest of patient safety, quality assurance, and infection control. The EBAA will analyze reports for trends that may impact eye banking practice. Eye banks operating within universities, hospitals or other institutions may need to report these reports to an infectious disease office. Some states may require their health departments be informed of certain adverse reactions. Maintaining and adverse

disease offices, state health departments, regulatory agencies or the surgeon reporting the adverse reaction. Adverse reaction records shall be available for EBAA site inspections. Adverse reaction records shall be kept for at least ten years.

reaction file for inspection helps ensure eye banks are seeking outcome data on distributed donor eye tissue.

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