Joint Review of
Eye Bank Standards of India
2013

We are thankful to the following people for their time and effort in making this a joint review document on Indian Eye Banking Standards.

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Part 1 – Introduction and Purpose

1.1 Scope

These standards are intended to apply to any and all of the eye bank functions, to include:

1. Donor screening and eligibility determination
2. Recovery
3. Processing
4. Storage
5. Tissue evaluation
6. Distribution

These standards shall be reviewed at least annually and revised as necessary to incorporate current research findings and improved clinical practice.
Part 2 - Staff and Training

2.1 General

Eye Bank Training Centers, Eye Banks and Eye Donation Centers should have at least the following personnel. Government eye banks should also set up a team within their administrative framework and designate the responsibilities as per the requirements and at the discretion of the head of the hospital or institute as applicable.

<table>
<thead>
<tr>
<th>Man Power (Staffs)</th>
<th>EBTC</th>
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<tbody>
<tr>
<td>Board of Directors</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Medical Director/Back Up Medical Director</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>Executive Director/Eye Bank Manager/Equivalent Post</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>Eye Bank Technician</td>
<td>Yes (2-3)</td>
<td>Yes (1-2)</td>
<td>Yes</td>
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<tr>
<td>Eye Donation Counsellor</td>
<td>Yes (2-4)</td>
<td>Yes (2-4)</td>
<td>Yes</td>
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</table>

An Eye Bank can designate and Delegate multiple responsibilities to a person as appropriate if necessary

HR Policy

The eye bank training center, eye bank and eye donation center should have a HR policy for regular appraisal of performance, in house skill upgrading & training programs, recruitment policies, and incentives for performance and counseling of all personnel.

2.2 Board of Directors

All EBs and EBTCs need to have a board of directors or equivalent committee composed of medical professionals and other professionals who could contribute to the smooth functioning of the organization. In the case of Eye Banks & Eye Bank Training Centres attached to Government hospitals, Director of Eye Hospital, Main Hospital with administrators from Health Department of the State to serve as board of directors

2.3 Executive Director/Eye Bank Manager

The Executive Director/Eye Bank Manager or designated equivalent will be responsible for managing the entire operations of the eye bank. It is the responsibility of the Executive Director to follow the policies of the Board or committee and wherever necessary shall consult the Medical Director/Eye Bank in-charge or other specialists for discharging the responsibilities. This person will be responsible for the day to day functioning of the eye bank and ensure compliance with the set standards. Non-compliance should be noted and brought to the attention of the MD.

2.4 Medical Director

The Medical Director (MD) must be an Ophthalmologist who has completed a corneal fellowship or who has demonstrated expertise in external eye disease, corneal surgery, research or teaching in
cornea and/or external disease or has an experience in corneal transplantation. If the eye bank does not have such a person it should have a consulting relationship with an ophthalmologist who satisfies the above criteria.

All policies and procedures of each eye bank shall be under the supervision of the MD.

The MD shall provide all staff members with adequate information to perform their duties safely and completely.

The MD shall oversee and provide advice on all medical aspects of Eye Bank operations. These include but are not limited to: Formulation, approval, and implementation of medical policies and procedures. Participation in training and oversight of technical staff with regard to tissue procurement, preservation, and evaluation. The MD shall also participate in the establishment and operation of a quality assurance programme.

The MD may delegate responsibility for tissue procurement, preservation, and tissue evaluation to qualified eye bank personnel; however, the MD shall ensure that the eye bank operates in compliance with the “Existing Medical Standards”. Ultimate responsibility of determining the suitability of donor tissue for transplantation is the transplant eye surgeon.

The Medical Director shall undergo regular continuing education in Eye Banking and related issue. The eye bank shall provide written documentation of such attendance at the time of the eye bank site inspection.

2.5 Technical and Non-Technical Staff

Eye Bank Technicians

Shall be responsible for the entire activities of eye banking such as retrieval, processing, evaluation, documentation, distribution of tissue and maintenance of the laboratory, instruments and equipment. He / She shall be Higher Secondary qualified with Science or Higher Secondary education with experience in a diagnostic or similar lab or experience in operation theatre procedures. He / she shall undergo training and qualify from designated training centers for Eye Bank Technicians

Eye Donation Counselor or Designate

Shall be responsible for counseling families at Hospitals and coordinate with eye bank and hospital for retrieval of cornea. Shall also be responsible for awareness campaigns both within the hospital and outside the hospital. Trained Eye Bank Technicians trained in counselling can also perform these duties if the situation warrants.

2.6 Training and Human Resource Development

It is essential that eye bank personnel are abreast of the latest developments in eye banking and corneal transplantation. Each eye bank shall ensure that their personnel are adequately trained and their skills are constantly upgraded.

Eye Bank Technician shall undergo a refresher training module at an eye bank at least once a year.
The Executive Director and / or Eye Bank Manager shall undergo a refresher training module at least once a year.

To attend Annual CME: By rotation, each staff will attend a CME on Eye Banking – once in 3 years to update his/her knowledge.

**Training Period for initial recruitment:**

**EB Technician:** Training period - 4-8 weeks depending upon the Eye Bank’s volume. Each technician should able to perform – 15 Enucleations and Lab excisions and/or 15 in-situ excisions within the time frame.

**Eye Donation Counsellor:** Training period – 1 month in local language. This training period would include both in-house (1 week) and in the field (3 weeks) training components.

### 2.7 Technician Annual Competency

The Eye Bank shall institute and document a competency assessment program for all technical staff performing eye bank functions. The Medical Director or their designated staff trainer is responsible for performing these competency reviews. This program should also include any action to be taken if expected competence was not achieved.
Part 3 - Facilities and Equipment

3.1 General
The Eye Bank or eye donation center should have adequate space, equipment, and supplies to perform the required laboratory services with accuracy, efficiency, asepsis, timeliness and safety.

Documented procedures should be established to maintain all equipment that may affect the safety and/or quality of tissue or reagents (critical equipment).

Each eye bank must have the following equipment and facilities to perform the volume of laboratory services with optimal accuracy, efficiency, sterility, timelines, and safety.

3.2 Eye Bank Laboratory
The laboratory(s) shall be a separate area(s) with limited access in which activities directly related to eye tissue processing are carried out. The laboratory shall have a sink with a drain and running water and a dedicated hand-washing sink. There shall be adequate counter space for processing of donor material. The room including walls, floor and sink must be kept clean. Appropriate documentation of regular laboratory cleaning schedules shall be retained for a minimum of three years.

The Eye Bank laboratory shall have an adequate stable electrical source and a sufficient number of grounded outlets for operating laboratory equipment.

3.3 Equipment, Maintenance and Cleaning
The Eye Bank shall:

a. Identify all critical equipment that may affect tissue safety and/or quality to include a tissue storage refrigerator with a continuous temperature monitoring device, laminar flow hood, recovery instruments, slit lamp, and specular microscope. Optional equipment may include a centrifuge and an autoclave depending on the individual eye banks operations. Eye Donation Centers which only perform tissue recovery need only equipment that is relevant for tissue recovery and shipping to a fully-equipped eye bank.

b. Specify details of the equipment type, unique identification, location, and frequency of checks, check method, acceptance criteria, and the action to be taken when results are unsatisfactory.

c. Specify cleaning and routine maintenance schedules and procedures for each piece of critical equipment in the appropriate Standard Operating Procedure (SOP).

d. Maintain appropriate maintenance, certification, monitoring, sterilization, and cleaning records on each piece of critical equipment. These records shall show dates of inspection, performance evaluations and any maintenance procedures or repairs performed. These records shall be kept for a minimum of three years.

e. Identify the calibration status of critical measuring equipment, and ensure that calibration is performed against a traceable standard.

f. Ensure that the handling and maintenance of critical equipment is such that the accuracy and fitness for use are maintained.
3.4 Refrigerator

Each eye bank laboratory shall have a refrigerator with a device, internal or external for continuously recording temperature. Current temperature shall be monitored and recorded daily and remain within the range appropriate to that stored item. This range shall be specified in the Eye Bank’s Standard Operating Procedures (SOP) Manual. The continuous temperature device shall be calibrated against a reference thermometer as defined by the appropriate regulatory agency at least once a year.

Eye Banks shall detail required cleaning intervals and documentation in their Standard Operating Procedures Manual.

In the event of a power failure or malfunction, there shall be provision for immediate notification and action to be taken or an emergency power supply to maintain essential storage temperatures within the range specified.

The refrigerator should be maintained exclusively for use by the eye bank. It must contain clearly defined and labeled areas for all tissues stored, i.e. surgical tissue awaiting distribution, quarantined tissue, tissue for research, and defined areas for non-tissue items (e.g. reagents).

3.5 Laminar Airflow Hood

A HEPA-filtered biohazard safety cabinet used for the processing of eye tissue in the laboratory shall be cleaned before and after each use and at regularly scheduled intervals to prevent cross-contamination. The laminar air flow hood must meet ISO Class 5 standards or documented annually to have less than 25 colony forming units per 90 mm settle plate per one hour exposure. Calibration, including settle-plate air culturing, must be performed annually.

Tissue must be processed in such a way as to prevent cross-contamination and labeling mix-ups (e.g., tissue from different donors may not be processed simultaneously).

3.6 Recovery Instruments

Adequate sterile instruments must be available to provide for aseptic retrieval of whole eye and corneas.

Instruments must be inspected frequently enough to assure that they function properly, and shall be suitably decontaminated and cleaned prior to sterilization and re-use.

All sterilized instruments, supplies and reagents, such as corneal preservation medium, must contain sterilization dates and expiry dates that are current at all times.

3.7 Slit Lamp

Each eye bank must have routine access to a functioning Slit Lamp with the ability to accurately and adequately evaluate donor corneas. The Slit Lamp shall have variable features including
magnification, light-beam width and length, and light intensity. Maintenance, calibration, and cleaning should be as per the manufacturer’s recommendations.

3.8 Specular Microscope
Each eye bank laboratory shall have a specular microscope to capture an image of donor cornea endothelium and calculating endothelial cell density. Maintenance, calibration, and cleaning should be as per the manufacturer’s recommendations.

3.9 Standard Operating Procedures (SOP) Manual
Each eye bank shall maintain its own procedures manual (SOP) that details all aspects of its specific retrieval, processing, testing, storage, distribution and quality assurance practices. Each procedure must be initially approved signed and dated by the Medical director or Officer-in-charge of the eye bank. An annual review of each eye bank’s procedures manual with signing and dating by the Medical director or Officer-in-charge is required. Each eye bank must maintain copies of each procedure it uses and the length of time the procedure was in use. The current standards of eye banking document can be used as the procedures manual with a document detailing any deviations or modifications with justification as required.

3.10 Bio-hazardous Waste Disposal
Human tissue and waste items shall be disposed of in such a manner as to minimize any hazard to eye bank personnel and the environment and comply with applicable regulations. Dignified and proper disposal procedures shall be used to obviate recognizable human remains.

3.11 Infection Control and Personnel Safety
Care must be taken that eye bank resources are utilized optimally and eye bank personnel are not exposed to any health hazards. The following guidelines ensure that resources are put to optimum use and that eye bank personnel are not exposed to any health hazards.

All eye bank personnel must operate under the universal precautions for health care workers. These written procedures must be included in the eye bank’s procedure manual. All technical personnel should receive Hepatitis B vaccination and any other recommended vaccination that may be announced from time to time.
Part 4 – Consent, Donor Screening and Contraindications

4.1 General

Eye tissues for transplant are almost invariably derived from cadaveric donors; therefore discussions regarding consent for donation are usually undertaken with the next of kin of a deceased person. Donation of eye tissue cannot proceed unless legal authority to remove tissue is established under the relevant Central and State legislation and regulations. Details of this authority shall be documented in the Standard Operating Procedures (SOP) Manual. In most instances, this authority is obtained by the receiving of informed consent from the potential donor, the donor’s next-of-kin (see definitions), or authorization of a Designated Officer or Coroner (when they are legally in possession of the body).

Obtaining of legal consent prior to eye tissue retrieval is essential.

4.2 Consent Documentation

Consent shall be obtained in writing (by a signed Consent Form), as determined by local or national legislation. In all cases, documentation of the consent shall be made and the consent retained as part of the donor records. A Consent Form shall be maintained in the donor’s medical records at the retrieving facility (if applicable to that facility), and a copy retained for inclusion in the donor record at the Eye Bank. Information contained on the Consent Form should follow the requirements of the local, State, or National health authority and shall be defined in the Standard Operating Procedures (SOP) Manual. The exact procedure for obtaining consent will also follow the legal requirement and should be defined in the SOP manual.

4.3 Donor Serologic Testing

This section specifies required serologic tests which must be performed on each donor from which tissue is designated for surgical use. Eye Banks must use a serology testing laboratory, or test kits approved for use by the appropriate authority.

A blood sample from the donor must be tested - this sample may be either:

1. a post-mortem sample drawn as soon as practicable after the time of death, or at the time of tissue recovery, or

2. a pre-mortem sample drawn within 7 days prior to death

A hard copy of serological results shall be received and assessed by the Eye Bank prior to release of tissue designated for surgical use. Eye tissue from the donor may be released for transplantation if the donor’s sample is nonreactive when tested for required infectious disease, and all other requirements are met. If the approved testing methodology is only approved for pre-mortem serology samples and no post mortem testing kits are approved for use, these pre-mortem test kits may be utilized for testing cadaveric samples.
Minimum Testing: Blood (serum or plasma) must test non-reactive to the following *required* infectious diseases:

1. Human Immunodeficiency Virus Types 1 and 2: anti-HIV-1, anti-HIV-2
2. Hepatitis C Virus (HCV): anti-HCV
3. Hepatitis B Virus (HBV): HBsAg
4. Syphilis

All tissue intended for transplantation shall be stored in quarantine until results of all serology testing are complete.

**Syphilis screening**

All eye banks must have operational syphilis screening programme using an approved test for all donors. If the screening test is positive, a negative confirmatory test must be documented before tissue is released.

4.3.1 Non-required Laboratory Results

If laboratory results of non-required test for infectious disease are available for tissue, for transplantation, they must be taken into account and/or acted upon by the MD. Any relevant information shall be provided to the transplanting surgeon.

If donor screening for HTLV-I and/or HTLV-II has been performed, a negative screening test must be documented prior to release of tissue for transplantation.

4.3.2 Non-surgical Donor Eye Tissue

If donor tissue is provided for purposes other than surgery, e.g., research, practice surgery, etc., that donor tissue should also have been screened for HIV and Hepatitis B and Hepatitis C. In case the donor has not been screened for some unavoidable reason and the tissue has to be sent for research or other purpose, then a label stating that screening for HIV-antibody, Hepatitis B or Hepatitis C has not been carried out or stating “Potentially hazardous biological material” or some other indication must be attached to the container used for the donor tissue storage and/or transport.

4.4 Plasma Dilution / Hemodilution

The testing of plasma or serum samples shall take into account any factors which may cause dilution sufficient to alter tests results. In particular, recognition shall be given to the transfusion of blood and other fluids within 48 hours of the sample being taken. In these instances, either:

1. A pre-transfusion/infusion sample shall be obtained and tested. It is recommended that testing be done on the most recent pre-transfusion/infusion specimen for which identity and quality can be ensured, or
2. The Eye Bank shall use an algorithm for calculating the effect of plasma dilution on the donor sample and demonstrate that it is less than the designated limit. This plasma dilution algorithm shall be defined by the eye banks SOP, and meet appropriate regulatory standard.
4.5 Donor Screening

The suitability of a specific individual for eye tissue donation shall be documented and shall be based on medical and social history, clinical status, physical assessment, testing and autopsy (if performed). All donors shall be identified by name. Each Eye Bank shall have a consistent policy for examination and documentation of the prospective donor’s available medical record and death investigation. Review of all available records on each donor shall be performed by an individual who is qualified by profession, education or training to do so, and who is familiar with the intended use of the tissue.

Useful sources for determining eligibility can be found on donor screening forms and/or copies of medical charts, medical and social histories, coroner review and initial autopsy reports as well as adequate donor evaluation which include:

1. Serologic testing
2. Physical assessment of the donor
3. Eye tissue evaluation

Prior to distribution of tissue for transplantation, the MD or his/her designee shall review and document the medical and laboratory information in accordance with medical standards.

4.6 Contraindications

Tissue from donors with the following are potentially health threatening and also affects the success of the surgery and shall not be offered for surgical purposes. In conditions considered absolute contraindications for transplantation, donor family should be informed clearly and made fully aware of this fact. Eyes should not be harvested unless the donor family is fully aware of this and still wishes to donate.

Tissue from donors with the following is potentially hazardous to eye bank personnel and harvesting eyes should be strictly avoided.

1. Active Viral Hepatitis
2. Acquired immunodeficiency syndrome (AIDS) of HIV
3. Active viral encephalitis or encephalitis of unknown origin
4. Creutzfeldt-Jakob disease
5. Suspected rabies and persons who, within the past six months, were bitten by an animal suspected to be infected with rabies

Contraindications for transplantation:

Conditions with potential risk of transmission of local or systemic communicable disease from donor to recipient

1. Death of unknown cause and likelihood of exclusionary criteria as outlined in this list
2. Death with progressive neurodegenerative disease of unknown etiology, including but not limited to the following:
   a. Chronic idiopathic demyelinating polyneuropathy
   b. Amyotrophic lateral sclerosis
   c. Multiple sclerosis
   d. Huntington’s chorea
   e. Alzheimer’s disease
   f. Dementia (exceptions include dementia due to CVA, brain tumor, head trauma, or medication or drug-induced)
   g. Myasthenia gravis
   h. Parkinson’s syndrome
   i. Parkinson’s like disease
   j. Creutzfeldt-Jakob disease

3. Active meningitis (viremia, bacteremia, tubercular)

4. Active viral encephalitis of unknown origin or progressive encephalopathy (including but not limited to subacute sclerosing panencephalitis, and progressive multifocal leukoencephalopathy)

5. Active septicemia at the time of death
   a. Septicemia at any time prior to death – i.e. hospital admission – which is shown through clinical evidence to not be present just prior to or at the time of death, may be acceptable for transplantation.
   b. Clinical evidence of sepsis (including, but not limited to, bacteremia, viremia, fungemia, septicemia, sepsis syndrome, systemic infection, systemic inflammatory response syndrome (SIRS), or septic shock):
   c. Clinical evidence of infection; and
   d. Two or more of the following systemic responses to infection if unexplained by other disease processes:
      i. Temperature of $> 38^\circ$ C (100.4$^\circ$ F);
      ii. Heart rate $>$90 beats/min;
      iii. Respiratory rate $>$20 breaths/min or PaCO2 $<$32; or
      iv. WBC $>$12,000 cells/mm3, $<$4,000 cells/mm3, or $>$10% immature (band) forms.
   e. More severe signs of sepsis include unexplained hypoxemia, elevated lactate, oliguria, altered mentation, and hypotension.
   f. Positive (pre-mortem) blood cultures might be associated with the above signs.

6. The following are examples of specific exclusions for systemic viral disease (viremia) which is active at the time of death: Active Chikungunia, Active H1N1 Influenza, Active Dengue Fever

7. Active viral hepatitis
8. Congenital rubella
9. Reye’s syndrome
10. Suspected rabies and persons who, within the past six months, were bitten by an animal suspected to be infected with rabies
11. Active miliary tuberculosis
12. Hepatitis B surface antigen positive donors
13. HTLV-I or HTLV-II infection
14. Hepatitis C seropositive donors
15. HIV seropositive donors
16. Active syphilis or seropositive for syphilis. It is acceptable to transplant an “RPR reactive” donor tissue only if a subsequent FTA confirmatory test on the same blood sample results “FTA negative.” In this case, the donor is considered seronegative for Syphilis.
17. Leprosy

**Conditions with potential risk of transmission of non-communicable disease from donor to recipient**

1. Intrinsic eye disease:
   a. Active ocular or intraocular inflammation conjunctivitis, scleritis, iritis, uveitis, vitreitis choroiditis, keratitis, and retinitis (at the time of death).
   b. Retinoblastoma.
   c. Malignant tumours of the anterior ocular segment.
   d. Known adenocarcinoma in the eye of primary or metastatic origin.

2. Snake bites specific for neurotoxins

**Conditions that will affect graft outcome**

Congenital or acquired disorders of the eye that would preclude a successful outcome for the intended use

1. **NOT suitable for PKP or ALK:**
   i. superficial disorders of the conjunctiva or corneal surface involving the central optical area of the corneal button
   ii. Prior surgery which compromises the corneal stroma
   iii. Local eye disease, disorder, or pathology affecting the anterior stroma

2. **NOT suitable for PKP or EK:**
   i. Local eye disease, disorder, or pathology affecting the posterior stroma or corneal endothelium
   ii. Endothelial density below 2000 cells per square millimeter

3. **Therapeutic / Tectonic Tissue**

   Tissue not suitable for optical use may be used for therapeutic or tectonic use. All other medical exclusionary criteria apply also to therapeutic tissue

4. **Sclera tissue for transplantation:**
   i. Medical exclusionary criteria are the same, except that tissue with local eye disease, disorder, or pathology affecting only the cornea (listed above) is acceptable for use.
   ii. Structural defects will not be acceptable for use
Behavioral / History, Laboratory and Medical Exclusion Criteria.

1. HIV or high risk for HIV corneas from: persons meeting any of the following criteria should not be offered for transplantation
2. Men who have had sex with other men in the preceding 5 years (homosexual behavior)
3. Persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years (IV drug abuse)
4. Persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrate
5. Men and women who have engaged in sex for money or drugs in the preceding 5 years (commercial sex workers)
6. Persons who have had sex in the preceding 12 months with any person described in item 26-29 above or with a person known or suspected to have HIV infection
7. Persons who have been exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, or mucous membrane
8. Children meeting any of the exclusionary criteria listed above for adults should not be accepted as donors
9. Children born to mother with HIV infection or mothers who meet the behavioral or laboratory exclusionary criteria for adult donors regardless of their HIV status should not be accepted as donors unless HIV infection and be definitely excluded in the child as follows:
   a. children >18 months of age who are born to mothers with or at risk for HIV infection, who have not been breast fed within the last 12 months and whose HIV antibody tests, physical examination, and review of medical records to not indicate evidence of HIV infection can be accepted as donors
   b. Children <18 months of age who are born to mothers with or at risk for HIV infection or children of mothers with or at risk of HIV infection who have been breast fed within the past 12 months should not be accepted as donors regardless of their HIV test results
10. Persons who cannot be tested for HIV infection because of refusal, inadequate blood samples (e.g. haemodilution that could result in false-negative tests), or any other reasons
11. Persons with a repeatedly reactive screening assay for HIV-1 or HIV-2 antibody regardless of the results of supplemental assays
12. Persons whose history, physical examination, medical records, or autopsy reports reveal other evidence of HIV infection or high-risk behavior, such as diagnosis of AIDS, unexplained mucous membranes hemorrhages kaposi’s sarcoma, unexplained lymphadenopathy lasting >1 month, unexplained temperature > 100.5F (38.6 C) or >10 days, unexplained persistent diarrhea, male-to-male sexual contact, sexually transmitted diseases, or needle tracks or other signs of parenteral drug abuse
13. Physical evidence of recent tattooing, ear piercing, or body piercing. Persons who have undergone tattooing, ear piercing, or body piercing in the preceding 12 months, in which sterile procedures were not used (e.g., contaminated instruments and or/ink were used), or instruments that had not been sterilized between uses were used

4.7 Donor Age

Donor age criteria are determined individually by each eye bank. The criteria must be written in the eye bank’s SOP.
4.8 Interval between death, enucleation, excision, and preservation

Death-to-Preservation time varies according to circumstances of death, storage of the body after death, and storage of tissue between enucleation and preservation in media.

- If ambient temperature is hot (e.g. summer weather), then eyes must be preserved or refrigerated within six (6) hours of death
- If ambient temperature is not hot (e.g. winter weather), then eyes must be preserved or cooled within eight (8) hours of death
- If ocular area including eyes, or the entire body, or enucleated eyes are continuously cooled within the above constraints of 6 or 8 hours, respectively, then tissue can be preserved no later than 24 hours from time of death

With documentation, the above time requirements may be waived on a case-by-case basis if tissue is continuously refrigerated and deemed medically suitable by the medical director. Factors to consider include mortuary cleanliness and documentation of cooling / temperature log.
Part 5 – Recovery, Processing and Preservation

5.1 Recovery Procedures

Retrieval procedure could be either enucleation of the whole globe or Corneal scleral rim excision. The retrieval procedures should be documented in detail in each eye bank in their Standard Operative procedure manual. The Medical and Executive director / Eye Bank manager are responsible to ensure that all eye bank staffs as well as those of related eye collection centers are well trained in the SOP.

The donor should be identified either by verifying the tabs attached or by a relative / hospital / mortuary staff. After obtaining appropriate consent, details about time and cause of death, availability of death certificate should be confirmed. Donor’s personal and medical history or medical records if available should be collected. A detailed gross physical examination to rule out possible contraindications should be carried out. Tissue retrieval either as whole globe enucleation or in-situ corneoscleral rim excision should be done under strict aseptic conditions as per guidelines. Gross examination of the eye should be done and documented in case of in-situ corneoscleral excision. The corneo-scleral rim excision later can be done in a laminar flow hood cabinet or in an operating room.

5.2 In Situ, Enucleation and Laboratory Excision

Someone authorized as per current THOA legislation trained in enucleation / excision from an Eye Bank is only allowed to retrieve eyes/corneas from the donor. In absence of death certificate, a Medical Practitioner must satisfy self that life is extinct prior to recovery.

Individuals specifically trained for in situ retrieval and/or laboratory removal of the corneal scleral segment shall perform removal of the corneal scleral rim using sterile technique. If the procedure is done in a laboratory the removal must be performed in a laminar flow hood, cabinet or in an operation room. For corneal scleral removal, the eye shall be examined with the use of a penlight preferably and a slit lamp prior to excision.
Part 6 – Tissue Evaluation

6.1 General
The ultimate responsibility for determining the suitability of the tissue for transplantation rests with the transplanting surgeon.

6.2 Gross Examination
The corneal-scleral segment shall be initially examined grossly for clarity, epithelial defects, foreign objects and contamination and scleral color, e.g., jaundice. Refer Section III, H8.800 for details.

6.3 Slit Lamp Examination
The cornea shall be examined for epithelia and stromal pathology and in particular endothelial disease.

Enucleated globes shall be examined in the laboratory prior to distribution and/or corneal excision. If in situ corneal excision is performed, examination of the donor eye anterior segment with a penlight or a portable slit lamp is required. After corneal excision, the corneal-scleral rim shall be evaluated by slit lamp biomicroscopy, even if the donor eye has been examined with the slit lamp prior to excision of the corneal-scleral rim, to ensure that damage to the corneal endothelium or surgical detachment of Descemet’s membrane did not occur.

6.4 Specular Examination
Determination of endothelial cell density via specular microscopy shall be a standard method of corneal tissue evaluation for all Eye Banks. When it is impossible to obtain an endothelial cell count this requirement may be waived on a case-by-case basis by the MD.
Part 7 – Storage, Packaging and Shipping

7.1 Storage of Tissue

All surgical tissue shall be stored in quarantine until results of HIV, HbsAg, HCV, Syphilis and any other relevant donor screening tests have been recorded as non-reactive. All tissue shall be stored aseptically at a temperature appropriate to the method of preservation used. Eye banks must precisely document their procedures for storage of corneal tissue, whether it is in the form of the whole eye or the cornea only in an appropriate medium.

Eye Bank shall use approved corneal storage medium (such as MK, Optisol GS, EUSOL, etc) from a reliable source. The medium shall be used and stored according to the manufacturer’s recommendations for temperature, date and other factors. The manufactured medium purchased and shipped to the eye bank shall be inspected for damage upon arrival and the lot number of medium used for each cornea shall be recorded on the tissue tracking and recall.

Long term preservation

Some eye banks employ long-term preservation of corneal tissue, such as glycerine preservation or organ culturing. An eye bank that uses long-term preservation shall carefully document the procedure in their procedure manual, and adhere to rigid aseptic technique.

Whole globe preservation

Eye Banks that store whole eyes shall employ aseptic practice. The selected preservation method must be documented in the eye bank’s own procedures manual.

Sclera preservation

Eye banks shall preserve scleral tissue aseptically. The selected preservation method must be documented in the eye bank’s own procedure manual. A preservation date for scleral tissue shall be indicated.
Part 8 - Distribution

8.1 General
Eye Banks shall establish and document a system of eye tissue distribution that is applicable to their service area that follows all relevant Central and State legislation and regulations, local rules or guidelines, and that is just, equitable and fair to all surgeons and recipients served by the Eye Bank.

All tissue distributed shall comply with these Standards, and those required by applicable regulatory agencies. Tissue for transplantation shall be only distributed to registered medical practitioners, and to other Eye Banks. Ultimate responsibility for the suitability of each tissue for transplantation rests with the transplanting surgeon. Access to tissue shall be provided without regard to recipient sex, age, religion, race, creed, color or national origin. Documentation of distribution of tissue shall be available for inspection by applicable regulatory agencies.

Eye Banks shall require receipt of specific recipient identification details for all tissues transplanted, and retain these as part of the records to enable traceability from a named donor to a named recipient. Requests for eye tissue shall be taken only for a specific named potential recipient. However, if in the event of unforeseen medical reasons the surgeon is not able to perform the transplant on this named recipient and the tissue may be transplanted into another individual, the Eye Bank shall require the surgeon to notify them of this information. The Eye Bank shall request that each unit of tissue distributed shall be only transplanted into a single patient. If a unit is used for more than one recipient, then the eye bank shall request recipient information for all pieces used.

The Eye Bank shall ensure anonymity of the donor to any individual or institution receiving tissue for surgical use, and that any details which may identify the donor are not provided. If tissue is transferred to another Eye Bank for distribution (e.g. excess to requirements, for emergency surgery), the Eye Bank sending the tissue (the source Eye Bank) shall provide all donor screening and testing information as required by the receiving Eye Bank (the distributing Eye Bank) to ensure they are satisfied as to the adequacy of the processes performed by the source Eye Bank.

8.2 Recipient Follow-Up Information
The distributing Eye Bank shall request from the transplanting surgeon post-operative outcome and recipient follow-up information concerning possible adverse reactions on all eye tissue used for transplantation. Eye Banks may request that provision of this, and any additional follow-up information required, is mandatory for the supply of tissue.

This information shall include the following (as a minimum):

1. Recipient’s name
2. Date of birth (or year of birth if a precise date of birth is unknown) or Age
3. Diagnosis i.e. indication for transplant
4. Name of surgeon receiving/transplanting tissue
5. Date of surgery
6. Location of surgery

8.3 Adverse Reactions

The Eye Bank shall establish and document a procedure in their SOP Manual for the receiving surgeon to notify the Eye Bank of any adverse reactions arising from the transplantation of eye tissue.

The Eye Bank shall establish a procedure for investigating, documenting and reporting on all adverse reaction notifications. The Medical Director shall receive and review such reports on each adverse reaction and authorise a response to the transplanting surgeon. As part of this process, the Medical Director shall also determine if any corrective/preventative actions are required. These shall be documented and reviewed as part of regular quality management review processes as required by the Eye Bank’s Quality System and regulatory agencies (if applicable).

8.4 Tissue Processing Charges

There should be no commercial dealing or profiteering in the supply of donated human tissues. Service fees may be levied by the Eye Bank to recover costs related to tissue retrieval, processing, storage and distribution.

8.5 Tissue Returned to Eye Banks

For transplant tissue returned and redistributed, tissue transportation and storage information must be documented and made available to the transplanting surgeon.
Part 9 – Records, Labeling and Traceability

9.1 Labeling
Each corneal or scleral tissue container shall be clearly and indelibly labeled to include at least the information below:

- Name of source eye bank
- Tissue identification number. There must be unique identification number for each ocular tissue or fraction thereof that is distributed for surgical use.
- Type of tissue
- Date and time of donor’s death
- Date and time of Cornea/scleral preservation
- Preservation date for scleral tissue and long-term preserved tissue
- A statement that the tissue is intended for single patient application only and that it is not to be considered sterile and culturing or re-culturing is recommended.
- Type of preservation medium

9.2 Length of Record Storage
All records shall be kept for a minimum of ten years (or comply with appropriate laws) from the date of transplantation/implantation.

9.3 Confidentiality
All eye bank records and communications between the eye bank and its donors and recipients shall be regarded as confidential and privileged.
Part 10 – Quality Assurance

10.1 General

The Eye Bank shall have a formally established quality assurance program (hereafter called Quality System) that defines and documents a series of systematic processes that shall be followed by all those working in the organization. These processes shall be designed to ensure that quality is evident in every part of the organization and to effect continuous quality improvement. A major objective is to avoid errors, however, if an error does happen, the cause should be identified, a risk assessment performed, and the process amended if necessary so that the error is not repeated.

The Eye Bank shall define and document how the requirements for quality will be met. The Medical Director of the Eye Bank (as defined in part 2.4) shall have overall responsibility for the Quality System. The Quality System shall include ongoing monitoring and evaluation of activities, identification of problems, and implementation of plans for corrective actions. The aim of using a Quality System in Eye Banks is to maximize the safety and quality of the eye tissues and services provided. The Standards defined in this document shall provide the basis for the development of the Quality System. A Quality System is based on adherence to effective and adequate documentation. The Eye Bank shall establish and maintain relevant documents relating to all aspects and stages of the Eye Bank’s work practices and services.

10.2 Quality Control

The MD shall prescribe tests and procedures for measuring, assaying or monitoring properties of tissues essential to the evaluation of their safety for transplantation, e.g., hepatitis B surface antigen and human immunodeficiency virus (HIV) antibody, and conform to legal and regulatory requirements. Results of all such tests or procedures, together with evaluations based on these findings, shall become part of the permanent record of all tissue processed.

Testing

If an eye bank performs its own microbiologic or serologic testing it must meet applicable accreditation requirements.

Microbiologic Culturing

Culturing of Eye Bank donor eyes is advised despite the recognition by many that bacteriologic contamination of donor eyes does not necessarily lead to infection and that pre-surgical or surgical cultures may not correlate with postoperative infection if it should occur. Cultures may be performed either before and/or at the time of surgery.

A. Pre-surgical cultures (Optional)

Eye Banks may elect to perform corneal-scleral rim cultures at the time of corneal preservation in tissue culture medium. Positive culture reports shall be reported to the receiving surgeon or recipient eye bank.
B. Surgical culturing

Each eye bank shall recommend culturing of the corneal scleral rim for corneal transplantation, or a piece of sclera for scleral implantation at the time of surgery. Positive results in cases of postoperative infection shall be reported to the eye bank/eye donation centre that procured the tissue as well as to the eye bank that distributed the tissue.

10.3 Approval, Review and Audit

Procedures, documents and forms shall be reviewed and approved by the Quality Manager or other authorized person before they are issued. Current documents shall be readily identifiable to ensure that invalid or obsolete documents are not used. The Quality System shall be reviewed at appropriate regular intervals by the Quality Manager in conjunction with Eye Bank management to ensure its suitability and effectiveness. The Eye Bank shall establish and document a procedure for the scope and frequency of routine and/or focused internal Quality Assurance audits of at least the critical Eye Bank functions and records. These should be performed at least annually, and by a person familiar with, but not directly responsible for, the processes being audited.

10.4 Control of Materials

There shall be a system of defining and documenting the requirements for critical materials such as reagents used in the processing and storage of eye tissues. There shall be a record of receipt of all critical materials, and methods for inspection to determine conformity with specifications and fitness for use. Critical materials shall be stored and used according to the manufacturer’s instructions, or if materials are produced within the Eye Bank, that they are stored and used according to validated procedures. Critical supplies not in current use shall be clearly distinguishable from those in current use. Critical supplies shall be stored in a manner that ensures package integrity is maintained. These critical supplies shall not be used if expired.

10.5 Process Controls and Changes

Eye Banks shall document in their Standard Operating Procedures (SOP) Manual details of all critical processes that affect safety and quality of tissues and ensure that they are carried out under controlled conditions, as appropriate to the particular process being performed. Processing, preservation and storage procedures shall be validated, to assure that they shall not render the tissues harmful or clinically ineffective to the recipient. This validation shall be based on demonstration of one or more of the following:

a. performance of specific tests, trials or procedures

b. risk assessment for potential effect on safety and quality

c. previously published studies

d. retrospective evaluation of the Eye Bank’s own data

Modifications to a critical process should be evaluated for their potential effect on safety and quality of tissue (risk assessment). Modifications considered significant to critical processes shall be validated as to ensure no significant detrimental effect on safety and quality of tissues. Deviations to
a procedure that are necessary or unavoidable shall be assessed for risk to quality and safety of the tissue and be documented. Any non-conformance shall have a risk assessment performed and an appropriate response implemented and documented that is relative to the assessed risk. Tissue(s) from more than one donor shall be processed separately through all stages of retrieval, testing, sampling and evaluation to avoid errors or cross-contamination. Separate instruments, supplies and reagents shall be used on tissues from different donors.

**10.6 Tissue Recall**

Eye banks must have a policy and procedure for potential recall of tissue. Positive test results or information about behavioral risks or medical history, received after release of tissue, that indicate a risk for transmission of a communicable disease must be reported to the:

1. Eye bank’s medical director
2. Consignee (i.e. the transplanting surgeon, processor or distributing eye bank), within 45 days.
Part 11 – Standards for Non-Technical Activities of Eye Banks

11.1 General

For an efficient eye banking system, a three tier organization structure has been recommended. At the top of the pyramid is the Eye Bank Training Center followed by Eye Banks and at the base of the pyramid is the eye donation center. Activities, responsibilities, manpower required for each of the above viz., Eye Bank Training Center (EBTC), Eye Bank (EB) and Eye Donation Center (EDC) has been dealt in detail under section A1.100 to section A1.300

11.2 Eye Banking System

Objective

The objective of this section is to standardize all non-technical activities of eye banking like administration, awareness and Human Resource development so that management becomes simple. This section also clearly defines the ideal and preferred eye banking system and lays down specific responsibilities and scope of each of the component of the eye banking system.

11.2.1. Eye Banking System

For efficient functioning of eye banking system a three tier structure has been developed. At the top are Eye Bank Training Centers numbering five, one each for the five zones in the country, followed by 45 eye banks. These 50 eye banks and eye bank training centers are networked with 2000 eye donation centers.

In developing countries such as India, one has to develop a system that is effective, efficient and financially relevant. A 3-tier structure encompassing all activities of eye banking will address this issue rather well and the determinants will be the infrastructure and manpower available with a profile of functions covered.

11.2.1.1. Eye Donation Center (EDC)

Eye Donation Center is affiliated to a registered eye bank, which should provide

(1) public and professional awareness about eye donation

(2) co-ordinate with donor families and hospitals to motivate eye donation

(3) to harvest corneal tissue and collect blood for serology
(4) to ensure safe transportation of tissue to the parent eye bank.

11.2.1.2. Eye Bank (EB) is an institution that should

Provide a round-the-clock public response system over the telephone and conduct public awareness programmes on eye donation.

Co-ordinate with donor families and hospitals to motivate eye donation Hospital Cornea Retrieval Programme – (HCRP)

To harvest corneal tissue

To process, preserve and evaluate the collected tissue

To distribute tissue in an equitable manner for Keratoplasty

To ensure safe transportation of tissue.

11.2.1.3. Eye Bank Training Centre (EBTC)

All of the eye bank functions plus training for all levels of personnel in eye banking and research.

11.2.2 Awareness

The main activity of an eye donation center, eye bank or eye bank training center is to create awareness about eye donation and also educate public about the need for eye donation. In the present scenario awareness campaigns have to be planned in such a way that the overall objective is achieved. Awareness campaigns can be General awareness campaigns and Focused awareness campaigns.

11.2.2.1. General Awareness

In general awareness various media like Print, Electronic and Movie are used and the message about eye donation is spread among the general public. This form of awareness though does not yield immediate results, helps in changing the mindset of the people gradually. EBTC, EB and EDCs in all their awareness programs and campaigns should ensure that:

1. Public are educated about magnitude of corneal blindness, cure for corneal blindness and the need for eye donation.
2. Only published statistics of NPCB or EBAI should be quoted so that there is consistency.
3. Education for formalities related to eye donations. Public is educated about precautions to be taken after death and after decision for eye donation is made, till the eye bank team reaches the spot.
4. Public are educated that eyes cannot be removed in certain medical contraindications.
5. Families are educated about the need to arrange for death certificate etc before the eye bank team arrives.

11.2.2.2. Focussed Awareness Campaigns

Voluntary eye donation is a result of realization of ones social responsibility towards the corneal blind. However, in moments of grief this realization may not materialize into actual eye donation. Eye donation counselling or grief counselling is a motivational approach whereby the family members of the deceased are directly motivated for an eye donation. This process provides direct access to the family members of the deceased to attempt counselling. Moreover, several advantages follow tissue retrieval from hospitals. Availability of medical history, availability of tissues from younger individuals, reduction in the time interval between death and enucleation / corneal excision and cost effectiveness are some of these. The program also allows the EDCs to get to know of potential eye donors within the hospital.

Only Eye Banks shall have the Hospital Cornea Retrieval Program. In cases where the hospital is far from the eye bank and is closer to an eye donation center, the eye donation center shall offer all necessary assistance like retrieve eyes and transport to the eye bank but nevertheless the Eye Donation Counselor shall be under direct control of the eye bank.

11.2.2.3. Choice of hospitals

An important step in the initiation of HCRP is identification of the hospitals to be included in the program. Ideally the hospitals to be chosen are Large multispeciality hospitals with a high mortality rate (3 to 4 per day or more) >3000/year. Medium multispeciality hospitals with moderate mortality rate (of 1 to 2 per day or more)> 2000/year.

11.2.2.4. Link between the hospital and the eye bank

Role of the Director of the Eye Bank or equivalent designee

The Director of the Eye Bank shall initially meet the Hospital management and sign a memorandum of understanding. The eye bank Directors or equivalent committee members shall meet the hospital authorities (Administrators, Public Relations Officer, Medical Officer and Nurses) and educate them on the basics of eye banking and the HCRP.

They shall seek permission for the display of publicity materials and posters about eye donation in the wards and patient lounges in the hospitals.

The administrative and medical staff of the hospital shall be requested to cooperate well with the eye donation counsellor (EDC), and provide information regarding the potential eye donor.
The eye bank Directors shall periodically meet the hospital authorities to make enquiries about the progress / problems encountered during counselling and to strengthen the bond between the eye bank and the hospital.

The eye bank Management to make arrangements for training the eye donation counsellor on grief counselling techniques.

The eye bank Directors shall periodically verify the records of EDCs and advise the counsellor on improving the counselling techniques.

11.2.2.5. Attributes of an Eye Donation Counsellor (EDC)

The EDC shall be initially told and taught the concept of eye banking through classes comprising of both theory and demonstration. He/She shall also be instructed about the dress codes while on duty.

A candidate selected to the post of eye donation counsellor shall be committed to the cause of eye donation.

The EDC shall have good communication skill and shall be well conversant with the regional language.

The EDC shall be dressed professionally.

The EDC shall wear a white apron and an identity card.

The EDC shall attend the following classes (theory and demonstration) (On job training of at least 1 month).

Ocular anatomy (Theory & demonstration).

Corneal anatomy and physiology (Theory & demonstration)

Corneal blindness (Theory).

Corneal transplantation (Theory & Video demonstration).

Eye bank and its level of operation (Theory).

Corneal excision (Theory & demonstration).

Grief counselling (Theory).

The EDC shall initially be posted in the Eye Bank for one week in order to acquaint himself/herself with all aspects of eye bank functioning.
11.2.2.6. Grief counselling techniques

The EDC shall approach the family members of the deceased at an appropriate time. The EDC shall not present the matter in a hurry to the family member. He/she shall wait until the family members are found mentally relaxed. The EDC shall initially introduce himself/herself by name and the eye bank he/she belongs to.

The EDC shall talk to limited family members in an ideal surrounding.

The EDC shall only talk to those who are found supportive to the cause.

The EDC shall provide comfort, moral support and sympathy to the family members while attempting to motivate them for an eye donation.

The EDC shall respect the feelings of the family members.

The EDC shall listen to the bereaved family members patiently.

The EDC shall address the fears and queries raised by the family members (Frequently Asked Questions – Appendix – 14).

The EDC shall have adequate knowledge about the myths and facts about eye donation (Facts & Myths About Eye Donation – Appendix - 15).

The EDC shall be aware of the procedure to be followed in Medico-legal cases. It is important that the EDC gets written approval from the police personnel before alerting the eye bank.

The EDC shall assure the family members that there will be no delay caused in making funeral arrangements.

The EDC shall give adequate time for the family members to discuss and decide about eye donation.

The EDC shall only suggest eye donation to the family members and not force them to make an eye donation.

The EDC shall express his/her gratitude to the family member upon obtaining consent. The EDC shall express gratitude to the family members of the deceased even in the absence of obtaining consent for eye donation.

11.2.2.7. Alerting the eye bank team

The EDC shall alert the eye bank soon after obtaining consent for eye donation. He/She shall inform the eye bank team where exactly the body is placed so as to enable the team to reach the site without delay. The EDC shall keep a copy of the death certificate ready before the eye bank team reaches the site as it is mandatory to have a death certificate prior to proceeding for corneal excision.
11.2.2.8. Expression of gratitude

The EDC shall express gratitude to the family members of the deceased after obtaining the consent for eye donation as well as after performing corneal excision.

11.2.2.9. Documentation of case reports

On a daily basis, the EDC shall document relevant details of every case approached and motivated during the work period in the form designed for the purpose (HCRP Daily Report – Appendix – 16). The daily reports will be analyzed at the closure of every month and recorded (HCRP Monthly Report – Appendix – 17.)
Part 12 – Registration and Accreditation

12.1 General
Each eye bank unit, should be registered under Transplantation of Human Organs Act and also should undergo the Accreditation appraisal.

12.2 Registration
Eye Bank Training Centers, Eye Banks and Eye Donation Centers should apply to their respective state government health authorities and get registered under Transplantation of Human Organs Act 1994. They should perform their activities as prescribed in the applicable law like Transplantation of Human Organs Act until the registration is completed.

12.3 Accreditation
After registration the eye bank units should offer themselves for appraisal by an Accreditation Authority (AA) within one year to obtain valid accreditation documents before they are declared as fully operational to the public.

Accreditation will include evaluation of the following:

- Demonstrate compliance with Medical Standards
- Demonstrate compliance of all requirements during site inspection.
- Demonstrate proficiency in all aspects of eye banking viz. procuring, processing and distributing corneal tissue. The eye bank should collect at least 25 surgical grade tissues (i.e. tissues for optical keratoplasty) annually and provide documentation of their performance.
- Certify compliance with applicable laws and regulation. Once accredited, an eye bank must be inspected and reaccredited at a frequency as defined by the accreditation authority.
- In cases of non compliance a reasonable time period will be given to rectify deficiencies and satisfy accreditation requirements.
- If the eye bank does not meet the standards within the deadline it may not receive accreditation as an eye bank and may be re-designated as an eye collection center. The State Registration Authority shall be informed about failure to meet accreditation requirements and to cancel registration under Transplantation of Human Organs Act.

12.4 Accreditation Authority
Shall be a body comprising of nominees by Government of India, State Government, any other nominated by NPCB and EBAI.

12.5 Eye Bank Inspection
The Accreditation Committee shall be responsible for inspecting each Eye Bank as outlined in the written procedures of the EBAI and the Government of India.
Accreditation and reaccreditation site inspections shall be scheduled following written notification of the impending inspection. Unannounced inspections may be conducted in case of receipt of any allegation of violation of “Medical Standards” by any eye bank. Failure to permit an inspection will result in suspension or revocation of an eye bank’s accreditation and registration under Transplantation of Human Organs Act.

12.6 Procurement of Eye Bank Essentials

The Eye Bank should have a policy and procedure for maintaining sufficient stocks of essential eye bank supplies and also a procedure for procuring eye bank supplies. Procurement procedure has to be documented and produced at the time of site inspection.
Part 13 – References


3. Technical Guidelines for Ocular Tissue, European Eye Bank Association (EEBA), May, 2008


7. GUIDANCE DOCUMENT FOR CELL, TISSUE AND ORGAN ESTABLISHMENTS, Safety of Human Cells, Tissues and Organs for Transplantation, Health Canada, Published by authority of the Minister of Health, 6/18/2013